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U.S. Food and Drug Administration  
Center for Devices and Radiological Health

(b) (6)

10903 New Hampshire Ave.  
Silver Spring, MD 20903

(b) (6)

**RE: Postmarket Surveillance (PS) Study: PS160001/R005  
30-Month Study Report**

Trade Name: Essure® System for Permanent Birth Control  
Reference PMA: P020014

March 01, 2019

(b) (6)

921 Parker Street  
Berkeley, CA 94710  
Phone: (b) (6)

Dear (b) (6):

Reference is made to FDA's letter dated February 29, 2016 regarding order to conduct a postmarket surveillance study for Essure under Section 522 of the Federal Food, Drug and Cosmetic Act. Reference is also made to FDA's approval of the Essure 522 study plan on September 2, 2016. Additionally, FDA's approval letter for PS160001 S004 requested the submission of the next study report due on March 4, 2019.

Bayer is herewith submitting the 30-month Interim Postmarket Surveillance Report (see **Attachment 1**).

The information contained in this submission is considered confidential, and Bayer therefore requests protection of this information in accordance with 18 USC 1905, 21 USC 331 (1), 5 USC 522.

This submission is provided in accordance with the eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff (October 10, 2013).

Bayer HealthCare Pharmaceuticals certifies that this submission has been scanned for viruses and is virus free using TREND MICRO™ Office Scan™, Program Version Office Scan™, Program Version 10.6 or higher. For any questions regarding eCopy technical aspects of this electronic submission, please contact

(b) (6)

Bayer looks forward to closely working with the FDA on this post market surveillance study. Should you require additional information, please feel free to contact (b) (6) or by email at (b) (6).

Respectfully,

(b) (6)

**ATTACHMENT 1: 30-Month Interim Postmarket Surveillance Report**

cc: (b) (6)



## **30-Month Interim Postmarket Surveillance Report**

An open-label, non-randomized, prospective observational cohort study to assess post-procedural outcomes in two cohorts of women who chose to undergo either hysteroscopic sterilization (Essure®) or laparoscopic tubal sterilization

Bayer Study (b)(4)

Postmarket Surveillance  
Application #PS160001

Date of Report: 01 MAR 2019

Data Current to:

04 JAN 2019



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## List of abbreviations

AE	Adverse event
FAS	Full analysis set
HSG	Hysterosalpingogram
LTS	Laparoscopic tubal sterilization
MedDRA	Medical Dictionary for Regulatory Activities
(b)(4)	
PSV	Pre-selection visit
SAE	Serious adverse event
SOC	System organ class
TEAE	Treatment-emergent adverse event
TVU	Transvaginal ultrasound



## 1. General Information

Postmarket Surveillance Application Number: PS160001

### 1.1 Sponsor Information

Name: Bayer Healthcare LLC  
Address: 100 Bayer Blvd.  
P.O. Box 915  
Whippany, NJ 07981 USA

Contact Person: (b) (6)  
Telephone: (b) (6)

Email Address: (b) (6)

### 1.2 Product Information

Device trade name and model number: Essure<sup>®</sup> System (ESS305)

Date of the 522 order: 29 FEB 2016

Date of postmarket surveillance plan approval: 02 SEP 2016

## 2. Report Information

Date of report: 01 MAR 2019

Data included in this report: clinical study

Type of submission: interim Postmarket Surveillance Report

## 3. Postmarket Surveillance Information

### 3.1 Study Purpose

#### 3.1.1 Goals

Study (b)(4) is an open-label, non-randomized, continuous enrollment, prospective observational, postmarket surveillance study of two cohorts of subjects who chose to undergo:



- hysteroscopic sterilization (Essure System), or
- laparoscopic tubal sterilization.

### 3.1.2 Objectives

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### 3.1.3 Study Endpoints

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### 3.2 Study Population

The planned study population includes subjects of reproductive age, at least 21 years of age, who have not been pregnant within the past 6 weeks.

The Essure study population group includes subjects who chose to undergo hysteroscopic sterilization and who meet the criteria as outlined in the most current approved version of the Essure Instructions for Use.

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Subjects will be followed for a total of 60 months post-procedure. [Table 1](#) provides the subject follow-up visit schedule.

**Table 1 Subject Follow-up Visit Schedule**

Time of Visit	Office Visit	Telephone Contact or Office Visit
(b)(4)		

### 3.3 Report Dates

The postmarket surveillance plan was approved by the Food and Drug Administration on 02 SEP 2016.

The data extract used for the tabulations provided in this report includes all data entered into the database as of 04 JAN 2019. Data are preliminary and will be updated with ongoing monitoring efforts.

### 3.4 Summary of Study/Surveillance Progress Milestones/Timeline Elements

#### 3.4.1 Site and Subject Recruitment Status

The site and subject enrollment progress as of 04 JAN 2019 is shown below. A subject is considered to be enrolled after signing informed consent.

- number of sites contacted: approximately 8774
- number completing Questionnaire #1 (Interest): 421 (341: Yes; 50: Maybe; 30: No)
- number completing Questionnaire #2 (Feasibility): 359
- number identified for pre-selection visit (PSV): 133
- number of PSVs completed: 104
- number of sites approved for participation: 90
- number of Institutional Review Board approvals: 74
- number of clinical sites activated (approved to begin screening): 67
  - type of facilities (note: additional categories have been added to this section to reflect the verbatim response provided by sites for type of facility):
    - University Hospital: 12
    - Public/Private Hospital: 4
    - Research Center: 3
    - Private Practice: 30
    - Private Practice/Research Center: 11
    - Public/Private Hospital/Private Practice/Research Center: 2
    - Public/Private Hospital/University Hospital: 1
    - Public/Private Hospital/Private Practice: 1
    - University Hospital/Research Center: 1
    - University Hospital/Private Practice: 1
    - Integrated Care System: 1
- number of sites with subjects enrolled: 60
- subject accrual start date: 03 MAY 2017





- subject accrual completion date: target = to be determined
- number of subjects enrolled (signed informed consent): 807 (Essure: 296; LTS: 511)
- percentage of subjects reaching each designated study phase: see Section [3.4.2](#).

On 20 JUL 2018, Bayer announced a business decision to discontinue sales of the Essure device effective 31 DEC 2018. Per FDA request, in order to better assess how study enrollment rates change over time with changing device sales, the monthly enrollment from July through December 2018 as a percentage of Essure sales was evaluated ([Table 2](#)).

**Table 2 Subject Enrollment as a Percentage of Essure Sales**

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### 3.4.2 Subject Disposition and Accounting

The disposition of subjects enrolled (signed informed consent) as of the 04 JAN 2019 data extract is shown in [Table 3](#). Of the 296 subjects in the Essure group and 511 subjects in the LTS group who signed informed consent and entered the screening phase, (b)(4) and (b)(4) subjects, respectively, attended the procedure visit and of these, (b)(4) and (b)(4) subjects, respectively, had the procedure attempted. (b)(4)

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A full accounting of subjects by treatment group and study phase is in [Table 4](#).



**Table 3 Disposition – Overview (All Enrolled Subjects)**

Disposition	Essure	Laparoscopic Tubal Sterilization	Total
Number (%) of subjects enrolled	296	511	807
Screening Failures	(b)(4)		
Primary Reason			
Pregnancy			
Inclusion/exclusion Criteria not met			
Lost to follow-up			
Withdrawal by Subject			
Other			
Entered Procedure Phase			
No Procedure Attempted			
Procedure Attempted			
Told to Rely <sup>1</sup>			
Completed the End of Study visit	(b)(4)		
Discontinued from the Study			
Primary Reason			
Pregnancy			
Protocol deviation			
Lost to follow-up			
Withdrawal by Subject			
Other <sup>2</sup>			

(b)(4)



**Table 4 Subject Accountability by Treatment Group (Full Analysis Set)**

**Treatment Group: Essure**

	Procedure	1 Week	3 Months	12 Months	24 Months
Eligible for visit	(b)(4)				
Active					
Visit performed					
Missed visit					
Discontinued					
Lost to follow-up					

**Treatment group: Laparoscopic Tubal Sterilization**

	Procedure	1 Week	3 Months	12 Months	24 Months
Eligible for visit	(b)(4)				
Active					
Visit performed					
Missed visit					
Discontinued					
Lost to follow-up					

(b)(4)

**3.5 Subject Demographics, Baseline Characteristics, and Medical History**

(b)(4)



**Table 5 Demographics, Baseline Characteristics, and Medical History (Full Analysis Set)**

	Essure (b)(4)	Laparoscopic Tubal Sterilization (b)(4)	Total (b)(4)
(b)(4)			



**Table 5 Demographics, Baseline Characteristics, and Medical History (Full Analysis Set) (continued; 2 of 3)**

	Essure (b)(4)	Laparoscopic Tubal Sterilization (b)(4)	Total (b)(4)
(b)(4)			



**Table 5 Demographics, Baseline Characteristics, and Medical History (Full Analysis Set) (continued; 3 of 3)**

	Essure (b)(4)	Laparoscopic Tubal Sterilization (b)(4)	Total (b)(4)
(b)(4)			

**3.6 Procedure-Related Findings**

(b)(4)





(b)(4)



**Table 6      Essure Insert Placement Status (Full Analysis Set)**

Essure  
(b)(4)

(b)(4)





### 3.7 Interim Safety Results

(b)(4)





**Table 7 Overall Summary of Adverse Events (Full Analysis Set)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 7 Overall Summary of Adverse Events (Full Analysis Set) (continued; 2 of 4)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 7 Overall Summary of Adverse Events (Full Analysis Set) (continued; 3 of 4)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 7 Overall Summary of Adverse Events (Full Analysis Set) (continued; 4 of 4)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 2 of 14)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)





**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 3 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 4 of 14)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 5 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number	Number of	Number	Number of	Number	Number of
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 6 of 14)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)		(b)(4)		(b)(4)		(b)(4)



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 7 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 8 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 9 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 10 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						





**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 11 of 14)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number	(b)(4) Number of	Number	(b)(4) Number of	Number	(b)(4) Number of
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 12 of 14)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 13 of 14)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)



**Table 8 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 14 of 14)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						



### **3.7.2 Events of Special Interest**

#### **3.7.2.1 Chronic Lower Abdominal/Pelvic Pain**

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**Table 9 Subject Incidence of Treatment Emergent Chronic Lower Abdominal and/or Pelvic Pain by SOC and Preferred Term (Full Analysis Set)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)	(b)(4)		(b)(4)		(b)(4)	



### 3.7.2.2 Abnormal Uterine Bleeding Events

(b)(4)





**Table 10 Subject Incidence of Treatment Emergent Abnormal Uterine Bleeding Events by SOC and Preferred Term (Full Analysis Set)**

	Essure (b)(4)		Laparoscopic Tubal Sterilization (b)(4)		Total (b)(4)	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)						





### 3.7.2.3 Invasive gynecologic surgery

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**Table 11 Subject Incidence of Invasive Gynecologic Surgery Post Sterilization Procedure (Full Analysis Set)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)	Number of AEs	Number of Subjects (%)
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)



### 3.7.2.4 Device Events

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**Table 12 Number of Subjects with Device Events by Primary System Organ Class and Preferred Term (Full Analysis Set)**

	Essure		Laparoscopic Tubal Sterilization		Total	
	Number of Events	Number of Subjects (%)	Number of Events	Number of Subjects (%)	Number of Events	Number of Subjects (%)
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)

01 MAR 2019

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### **3.7.2.5 Adjudicated Allergic/Hypersensitivity Reactions and Autoimmune Disorders**

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#### 4. Summary

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## 5. Appendix



### 5.1 Adverse Events – Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Footnotes please refer to the last page.

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b)(4)											

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BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b)(4)											

Footnotes please refer to the last page.

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Treatment Group (b)(4)

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Treatment Group (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day) End Date (Day) Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)	(b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

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Unique Subject Identifier/	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b)(4)											

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

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Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day/ End Date (Day/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Serious /Reason	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Treatment Group: (b)(4)

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Treatment Group (b)(4)

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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Treatment Group: (b)(4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

Unique Subject Identifier/ Age/Race	Attended Steril-ization Procedure/ Attempted Steril-ization/ Rely on Steril-ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce-dures	Treatment of AE	Outcome	Comment
(b)(4)											

Footnotes please refer to the last page.

Postmarket Surveillance Report

BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Footnotes please refer to the last page.

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BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b)(4)

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BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Footnotes please refer to the last page.



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BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b)(4)

Unique Subject Identifier/ Age/Race	Attended Sterilization Procedure/ Attempted Sterilization/ Rely on Sterilization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Footnotes please refer to the last page.

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BAY (b)(4)



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BAY (b)(4)



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Postmarket Surveillance Report

BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Postmarket Surveillance Report

BAY (b)(4)



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BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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BAY (b)(4)



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Postmarket Surveillance Report

BAY (b)(4)



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Protocol No: BAY (b)(4)

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Postmarket Surveillance Report

BAY (b)(4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

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Footnotes:

Race is identified as: A = Asian, B = Black, W = White, AI = American Indian or Alaska Native, NH = Native Hawaiian or Other Pacific Islander, NR = Not Reported, MUL = Multiple.

The unit of 'Age' is years.

'(Day)' is the day relative to the index event date.

Y=Yes, N=No

AEOSI = adverse event of special interest

---

(b) (6)

**From:** (b) (6)  
**Sent:** Tuesday, March 5, 2019 5:04 PM  
**To:** (b) (6)  
**Cc:** (b) (6)  
**Subject:** PS160001/R5 - Bayer Healthcare, LLC - email receipt

Trade Name: Essure System for Permanent Birth Control  
Document Number: PS160001/R5  
Dated: March 1, 2019  
Received: March 4, 2019

Dear (b) (6) :

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your section 522 postmarket surveillance (PS) 30 month report. Within 60 days of the receipt date, FDA will notify you in writing of the decision.

Please be sure that future correspondence regarding your 522 PS study is sent to the attention of (b) (6) . If you have any procedural or policy questions concerning postmarket surveillance requirements, please contact (b) (6)

**Thank you,**

(b) (6)



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(b)(4)

(b) (6)

**From:** (b) (6)  
**Sent:** Wednesday, May 15, 2019 10:42 AM  
**To:** (b) (6)  
**Cc:** (b) (6)  
**Subject:** FDA Decision - Bayer Healthcare, LLC - PS160001/R5

Dear (b) (6) :

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your section 522 postmarket surveillance (PS) study report PS160001/R5. This report is for the Postmarket Surveillance Study.

We have determined that you have sufficiently met the reporting expectations for the above report.

Please be advised that your study status will be marked as “Progress Adequate” on the Section 522 Postmarket Surveillance Studies webpage ([www.fda.gov/522studies](http://www.fda.gov/522studies)). Please also consider the following advisories concerning your study report and progress:

(b)(4)



Your next scheduled report is due September 3, 2019.

**Thank you,**

(b) (6)



(b) (6)



*Excellent Customer Service is important to us. Please take a moment to provide feedback regarding the customer service you have received.*

(b)(4)

MEMORANDUM

Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002

Date: April 19, 2019

From: (b) (6)

Subject: [PS160001](#)  
Essure System for Permanent Birth Control, Bayer Pharma AG  
522 Study Requirement Name: Postmarket Surveillance Study  
Epidemiologic Review of Postmarket Surveillance (PS) Study Interim Report

PS Order: Date of PS Order: February 29, 2016  
ODE/OIR Document(s) on which the PS order was issued: P020014

To: The Record

Through: (b) (6)

**Conclusion/Recommendation:**

Choose One: The interim report can be accepted

522 Requirement Progress Status: Progress Adequate

**Purpose:**

The purpose of this memorandum is to present the epidemiologic review for the 30-month 522 Postmarket Surveillance (PS) Study Interim Report for the Essure System for Permanent Birth Control submitted by Bayer Pharma AG. This memo includes:

- background information
- PS study protocol overview
- the review and assessment of the interim study results
- PS study tracking information
- overall conclusions and recommendations
- any applicable deficiencies

## **Background:**

### ***Device Description***

#### A. Essure System Components

The Essure System is comprised of the Essure micro-insert, a disposable delivery system, and a disposable split introducer.

##### Essure Micro-Insert

The Essure micro-insert is a spring-like device that consists of a stainless steel inner coil, a nickel titanium (Nitinol) expanding outer coil, and polyethylene terephthalate (PET) fibers. The PET fibers are wound in and around the inner coil. The micro-insert is 4 cm in length and 0.8 mm in diameter in its wound down configuration. When released from the delivery system, the outer coil expands to 1.5 to 2.0 mm in diameter to anchor the micro-insert in the varied diameters and shapes of the fallopian tube. The spring-like device is intended to provide the necessary anchoring forces during the acute phase of device implantation (3 months post-micro-insert placement), during which time the PET fibers are eliciting tissue in-growth into the coils of the Essure micro-insert and around the PET fibers.

The Essure Micro-insert is provided attached to the delivery wire, in a wound-down configuration. The delivery wire is composed of a nitinol core wire, which is ground at the distal end to result in a flexible, tapered profile. The device is constrained by the release catheter, which is sheathed by a flexible delivery catheter. A black positioning marker on the delivery catheter aids in proper placement of the device in the fallopian tube.

The delivery handle controls the device delivery and release mechanism. The thumbwheel on the delivery handle retracts both the delivery catheter and the release catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to retracting the release catheter. The delivery wire is detached from the micro-insert by rotating the system.

##### Split Introducer

The split introducer is placed into the sealing cap of the working channel of the hysteroscope, and is intended to help protect the Essure Micro-insert as it is being passed through the sealing cap of the hysteroscope working channel.

#### B. Mechanism of Action

##### 1. Placement at Utero-Tubal Junction

The Essure Micro-insert is intended for placement into the fallopian tube with the implant portion of the device spanning the utero-tubal junction (UTJ). For purposes of micro-insert placement, the UTJ is defined as the portion of the fallopian tube, just as it enters the uterus. Placement at the UTJ is expected to aid in anchoring since it most consistently represents the narrowest portion of the fallopian tube. Expulsion of the Essure Micro-insert has occurred when micro-insert placement was too proximal. If the

device is placed without any trailing portion of the device in the uterus, then direct visualization of device location is not possible.

## 2. Tissue In-Growth

The effectiveness of the Essure Micro-insert in preventing pregnancy is believed to be due to a combination of the space-filling design of the device and a local, occlusive, benign tissue response to the PET fibers. The tissue response is the result of a chronic inflammatory and fibrotic response to the PET fibers. It is believed that the tissue ingrowth into the device caused by the PET fibers results in both device retention and pregnancy prevention.

## 3. Permanency of Tubal Occlusion (and Sterilization)

The long-term nature of the tissue response to the Essure micro-insert is not known. The majority of the clinical data regarding PET in the fallopian tube is based on 12-24 months of implantation, with little data at 36 months. Therefore, beyond 24 months, the nature of the cellular fibrotic response and the ability of the response and the device to maintain occlusion are not known.

### ***Indication for Use***

The Essure System is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

### ***Regulatory History***

On September 24, 2015, FDA convened a [meeting](#) of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee (see [transcript](#)), and the panel recommended additional data collection via postmarket surveillance. On February 29, 2016, FDA issued a [522 order](#) for the Essure Permanent Birth Control System.

In July 2018, Bayer notified FDA that they would be discontinuing sales of Essure devices for business reasons. Bayer noted that they would continue to sell Essure through December 31, 2018. (b) (5)

(b) (5)

Due to the discontinuation of sales, the company would be unable to enroll the originally planned number of subjects in the 522 protocol. Therefore, the company submitted a supplement to modify the 522 protocol on (b) (4). The supplement was reviewed by (b) (6). FDA approved the changes in the protocol, which included the following major modifications:

(b) (4)

(b) (4)



**PS Study Protocol Overview:**

(b)(4)





(b)(4)



Study Element	Description
Real-World Evidence (RWE)	N/A
Study Design	Open-label, non-randomized, prospective observational cohort study of two cohorts of subjects who chose to undergo either hysteroscopic sterilization (Essure) or laparoscopic tubal sterilization.
Study Hypothesis	There is no hypothesis testing.
Study Population	The study population will include subjects who are at least 21 years of age who have not been pregnant within the past 6 weeks.  The study population will include women who chose to undergo hysteroscopic sterilization (Essure) and who meet the criteria as outlined in the Essure Instructions for Use (IFU).  Women seeking laparoscopic tubal sterilization must be considered appropriate surgical candidates by the investigator.
Sample Size	878 women from up to 90 sites (292 women in the Essure arm and 574 women in the LTS arm for a 2:1 ratio)
Study Endpoints	Follow-up measures will include adverse event assessment, medical history including gynecological procedures, patient reported outcome (PRO) measures for chronic pelvic pain and abnormal uterine bleeding, bloodwork for women with certain adverse events, and analysis of removed Essure devices. Key Endpoints: Pain: The proportion of subjects reporting AEs of chronic lower abdominal and/or pelvic pain after insertion of Essure System (ESS305) (b)(4)  Bleeding: The proportion of subjects reporting AEs of abnormal uterine bleeding after insertion of Essure System (b)(4)

Study Element	Description
<p><b>Length of Follow-up and Frequency of Follow-up Assessments</b></p>	<p>(b)(4)</p> <p>Total incidence of new onset or worsening abnormal bleeding events will be based on AE reporting.</p> <p>Hypersensitivity/allergy/autoimmune disorders: The proportion of subjects with adjudicated new onset or (b)(4) allergic/hypersensitivity reactions (b)(4)</p> <p>(b)(4)</p> <p>Proportion of subjects undergoing invasive gynecologic surgery (b)(4) ; including Essure insert removal (b)(4)</p> <p>(b)(4)</p> <p>Additional endpoints:</p> <ul style="list-style-type: none"> <li>• Patient reported outcome measures (b)(4)</li> <li>• Rates of AEs (b)(4)</li> </ul> <p>60 months.</p>
<p><b>Enrollment Plan and Follow-up Measures</b></p>	<p>(b)(4)</p>
<p><b>Statistical Plan</b></p>	<p>(b)(4)</p>

Study Element	Description
	(b)(4)

*Timeline for Study Implementation*

The latest study timeline showing below was approved during the review of study protocol change (b) (4) on December 20, 2018.

Milestone	Proposed Timing
Expected date of study initiation <sup>a</sup>	(b) (4)
Expected monthly number of study sites with IRB approvals	No criterion; aim for 90 sites total
Expected date of initiation of subject enrollment	May 2017
Expected number of subjects enrolled per site per month	No criterion; enrollment of subjects will continue as long as Essure is available for implantation. Expected total patient number by July 2019 is 292 in the Essure arm, with no expected enrollment through December 31, 2019.
Expected date of enrollment completion	December 2019
Expected date of study follow-up completion	December 2024
Expected date of Final Report submission	April 2025

**PS Study Interim Status/Results and Assessments:**

This report covers the time period of September 2, 2016 through January 4, 2019.

**Study Elements**

**Number of IRB Approvals/sites enrolled**

---

Description: IRB approvals

- As of January 4, 2019: 74 approvals
- As of April 1, 2019 (interactive review): 76 approvals

Description: Sites Enrolled

- As of January 4, 2019: 67 sites activated
- As of April 1, 2019 (interactive review): 67 activated

Assessment

- Since the last interim report (PS160001/R004, data cutoff July 2, 2018), the number of IRB approvals and sites enrolled has remained at the same level.
- **Progress Adequate.**

**Number of subjects enrolled**

Description

- Enrollment began on May 3, 2017
- As of January 4, 2019: total enrollment of 807 (296 Essure, 511 LTS; LTS to Essure ratio 1.7)

- (b)(4)

- As of April 1, 2019 (interactive review): total enrollment of 891 (307 Essure, 584 LTS; LTS to Essure ratio 1.9)

Assessment

- (b)(4)

In addition, it is expected that enrollment continue as long as Essure is being implanted.

- (b)(4) In addition, patients continue to be enrolled after the discontinuation of Essure sales.
- The ratio of LTS to Essure patients is expected to be 2:1. Currently, the ratio is 1.9, which is on target.

- (b)(4)

- **Progress Adequate.**

**Follow-up rate**

Description

(b)(4)



(b)(4)



(b)(4)



(b) (4)

#### Summary of Interim Study Results for the 522 Webpage

Study Elements	Description
Number of study sites enrolled	As of April 1, 2019, 891 patients have been enrolled (307 in the Essure arm and 584 in the laparoscopic tubal ligation arm).
Number of subjects enrolled	As of April 1, 2019, 67 sites have been enrolled. 62 sites are open for enrollment

#### **PS Study Tracking Information:**

1. What is the Overall Study Status? Check only one.

<input type="checkbox"/>	Plan Pending	FDA has not approved the study protocol, and it has been less than 6 months since issuance of the order.
<input type="checkbox"/>	Plan Overdue	FDA has not approved the study protocol, and it has been 6 months or more since issuance of the order.
<input type="checkbox"/>	Study Pending	The protocol has been approved, but no subjects have been enrolled.
<input checked="" type="checkbox"/>	Progress Adequate	The study has begun, and the study progress is consistent with the protocol (e.g., meeting enrollment schedule, follow-up rates, endpoints evaluated).
<input type="checkbox"/>	Progress Inadequate	The study has begun, but the study progress is inconsistent with the protocol (e.g., not meeting enrollment schedule, missing timepoint evaluations, poor follow-up rates, not all endpoints evaluated).

<input type="checkbox"/>	Completed	The sponsor has fulfilled the condition of approval, and FDA has closed the study. This is a final study status
<input type="checkbox"/>	Terminated	The sponsor has not fulfilled or cannot fulfill the condition of approval (e.g., study questions are no longer relevant, sponsor withdraws PMA, data cannot answer 522 question), and, after all appropriate efforts to fulfill the condition of approval have been exhausted, FDA has terminated the study. This is a final study status.
<input type="checkbox"/>	Other	Used when the study status does not fit another category (e.g., not marketing the device and have no plans to market the device, change in ownership underway, redesigning device and need PMA approval prior to use in a PAS, pending separate study being used to address condition of approval). This is an interim study status.

**Deficiency List:**

None.

**Advisory**

Please be advised that your study status will be marked as “Progress Adequate” on the Section 522 Postmarket Surveillance Studies webpage ([www.fda.gov/522studies](http://www.fda.gov/522studies)). Please also consider the following advisories concerning your study report and progress:

(b)(4)



(b) (6)





(b) (6)

cc: (b) (6)

**Document History:**

Date	Activity	Initials
4/19/19	Drafted	(b) (6)
4/19/19	Reviewed with comments	(b) (6)
4/22/19	Reviewed and cleared	(b) (6)
4/22/19	Finalized	(b) (6)

This template last updated – March 23, 2016

(b) (6) Revised to add interim data elements January 9, 2017

(b) (6) Revised for upload to CDRH Docs, Apr 20, 2017

Reviewer's Sign-Off	(b) (6)
Branch Chief Sign-Off	

**Appendix 1: Interactive review emails April 5, 2019, April 10, 2019 and April 17, 2019**

April 17, 2019 – Email 1

Dear (b) (6)

(b)(4)

Thank you,

(b) (6)

Freundliche Grüße / Best regards,

(b) (6)

////////////////////

Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710  
United States

(b) (6)

Web: <http://www.bayer.us>

**From:** (b) (6)

**Sent:** Friday, April 12, 2019 7:53 AM

**To:** (b) (6)

**Subject:** Additional request - PS160001 Essure 522 Interim Report

Hello (b) (6)

We had one additional request for information concerning your report. Please address the following, and provide your response ASAP, but no later than Monday, April 15, 2019. If you have any questions, please reach out to me. Thank you,

(b) (6)

Information request:

(b)(4)

(b)(4)

(b) (6)

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
TEL: (b) (6)



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---

April 17, 2019 – Email 2

Dear (b) (6),  
(b) (4)

Thank you,  
(b) (6)

Freundliche Grüße / Best regards,

(b) (6)



Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710

United (b) (6)  
Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6)  
Web: <http://www.bayer.us>

**From:** (b) (6)  
**Sent:** Wednesday, April 10, 2019 11:50 AM  
**To:** (b) (6)  
**Subject:** RE: PS160001 Essure 522 Interim Report

Hi (b) (6)

(b) (4)

(b) (6)

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
TEL: (b) (6)



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April 10, 2019

Dear (b) (6)

Below please find the table requested.

(b)(4)



Thank you,

(b)(4)

Freundliche Grüße / Best regards,

(b)(4)



Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710  
United States  
Tel: (b) (6)  
Mobile: [redacted]  
E-mail: [redacted]  
Web: <http://www.bayer.us>

**From:** (b) (6)

**Sent:** Monday, April 08, 2019 7:21 AM

**To:** (b)(4)

**Subject:** RE: PS160001 Essure 522 Interim Report

H (b)(4) ,

Thank you! I have one additional request. (b) (4)



(b) (4)

information as soon as possible, that would be great. Thank you,

If you could provide this

(b) (6)

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
TEL: (b) (6)



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April 5, 2019

H (b) (6)

Sorry about that.

- Number of subjects enrolled (by arm): Essure – 307; LTS – 584

Freundliche Grüße / Best regards,

(b) (6)



Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710  
United States  
Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6)  
Web: <http://www.bayer.us>

**From:** (b) (6)  
**Sent:** Friday, April 05, 2019 10:57 AM  
**To:** (b) (6)  
**Subject:** RE: PS160001 Essure 522 Interim Report

Hi (b) (6),

I think some of your message got clipped. Could you add in the enrollment info? Thanks!

(b)(4)

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
TEL: (b)(4)



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**From:** (b) (6) >  
**Sent:** Friday, April 05, 2019 1:47 PM  
**To:** (b) (6)  
**Subject:** RE: PS160001 Essure 522 Interim Report

Dear (b) (6),  
Please find the enrollment update as of April 1, 2019 below.

- Number of sites approved for participation: 90
- Number of IRB approvals: 76
- Number of clinical sites activated and open for enrollment: 67 activated, 62 open for enrollment (b) (4)
- Number of sites with subjects enrolled: 60
- Number of subjects enrolled (by arm): Essure

Thank you,  
(b) (6)

Freundliche Grüße / Best regards,

(b) (6)



Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710  
United States  
Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6)  
Web: <http://www.bayer.us>

**From:** (b) (6)  
**Sent:** Thursday, April 04, 2019 5:17 AM  
**To:** (b) (6)  
**Subject:** PS160001 Essure 522 Interim Report

Hello (b) (6),

I am reviewing your report, and wanted to ask if you would be able to provide an update to the 522 study enrollment numbers for subjects and sites through April 1, 2019. I realize the reporting period is through January 4, 2019, but I would like to understand the enrollment following discontinuation of sales. If you could provide this information by the end of the week, that would be great. Thank you,

(b) (6)

Silver Spring, MD 20993  
TEL: (b) (6)



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**Appendix 2: Interactions with** (b) (6)

*April 17, 2019 Email*

(b) (5)

**From:** (b) (6)  
**Sent:** Wednesday, April 17, 2019 9:22 AM  
**To:** (b) (6)  
**Subject:** FW: PS160001 Essure 522 Interim Report

(b) (6)

(b) (5)

(b) (6)

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
TEL: (b) (6)



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: Click [here](#) for survey link

**From:** (b) (6)  
**Sent:** Tuesday, April 16, 2019 7:53 AM  
**To:** (b) (6) >  
**Subject:** RE: PS160001 Essure 522 Interim Report

Dear (b) (6),  
(b)(4)

Thank you,  
(b) (6)

Freundliche Grüße / Best regards,

(b) (6)

////////////////////

Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710  
United States  
Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6)  
Web: <http://www.bayer.us>

April 17, 2019 Email 2:

(b) (5)

**From:** (b) (6)  
**Sent:** Wednesday, April 17, 2019 9:20 AM  
**To:** (b) (6)  
**Subject:** FW: Additional request - PS160001 Essure 522 Interim Report

See below regarding the (b) (4) What do you think?

(b) (6)

10903 New Hampshire Avenue  
Silver Spring, MD 20993  
TEL: (b) (6)



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: Click [here](#) for survey link

**From:** (b) (6) >  
**Sent:** Tuesday, April 16, 2019 4:00 PM  
**To:** (b) (6)  
**Subject:** RE: Additional request - PS160001 Essure 522 Interim Report

Dear (b) (6),

(b)(4)

Thank you,  
(b) (6)

Freundliche Grüße / Best regards,

(b) (6)


////////////////////

Bayer U.S. LLC  
Development, Pharmaceuticals  
Essure & Devices  
921 Parker Street  
Berkeley CA 94710  
United States  
Tel: (b) (6)  
Mobile: (b) (6)  
E-mail: (b) (6)  
Web: <http://www.bayer.us>

April 11, 2019

(b) (4), (b) (5)

(b) (4), (b) (5)



**From:** (b) (6)

**Sent:** Tuesday, April 09, 2019 9:14 AM

**To:** (b) (6)

**Subject:** Essure 30-month report

Hi (b) (6) ,

(b) (5)




(b) (6)

**Appendix 3: Informal consult email dated April 1, 2019**

(b) (6),

(b) (4), (b) (5)



Thanks,

(b) (6)



(b) (6)

Silver Spring, MD 20993

Phone (b) (6)



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received (b)(4)