



RECEIVED
3-3-17

PS 160001/R1

(b) (6)

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

(b) (6)

10903 New Hampshire Ave.
WO66-3211

**RE: Postmarket Surveillance (PS) Study: PS160001
6-Month Interim Postmarket Surveillance Report**
Trade Name: Essure System for Permanent Birth Control
Reference PMA: P020014

March 02, 2017

Bayer HealthCare
Pharmaceuticals Inc.
100 Bayer Boulevard
P.O. Box 0915
Whippany, NJ 07981-
0915 (b) (6)
Phone: (b) (6)
Fax: (b) (4)

Dear Ms. (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.

Bayer is herewith submitting the 6-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.

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)

Respectfully,

(b) (6)

ATTACHMENT 1: 6-Month Interim Postmarket Surveillance Report

cc: (b) (6)

Company Confidential

Postmarket Surveillance Report
BAY (b)(4)



02 Mar 2017

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6-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: 02 MAR 2017

Data Current to: 17 FEB 2017

Postmarket Surveillance Report
BAY (b)(4)



02 Mar 2017

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Postmarket Surveillance Report
BAY (b)(4)



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List of abbreviations

AE Adverse event
(b)(4)

DMC Data monitoring committee

FDA Food and Drug Administration
(b)(4)

IFU Instruction for Use

IRB Institutional review board

LTS Laparoscopic Tubal Sterilization

MedDRA Medical Dictionary for Medical Activities

MOS Medical Outcomes Study
(b)(4)

PSV Pre-selection visit

SAE Serious adverse event

Postmarket Surveillance Report

BAY (b)(4)

02 MAR 2017

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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)

Email Address:

1.2 Product Information

Device trade name and model number: Essure[®] 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: 02 MAR 2017

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 2 cohorts of subjects who chose to undergo:

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

Postmarket Surveillance Report
BAY (b)(4)

02 MAR 2017

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3.1.2 Objectives

(b) (4)



3.1.3 Study Endpoints

(b) (4)



Postmarket Surveillance Report
BAY (b)(4)

02 MAR 2017

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(b) (4)



3.2 Study Population

The planned study population includes subjects of reproductive age, between 21 and 45 years of age, who have not been pregnant within the past 6 weeks.

The Essure study population group will include 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 (IFU).

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A sample size of 1400 subjects in each treatment group is planned.

Subjects will be followed for a total of 36 months post-procedure. [Table 1](#) provides the subject follow-up visit schedule.

Postmarket Surveillance Report
 BAY (b)(4)

02 MAR 2017

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Table 1: Subject Follow-up Visit Schedule

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

3.3 Report Dates

The postmarket surveillance plan was approved by FDA 02 SEP 2016. This 6-month postmarket surveillance report covers the period from 02 SEP 2016 through 17 FEB 2017. The information included in this report is current through 17 FEB 2017.

3.4 Summary of Study/Surveillance Progress Milestones/Timeline Elements

- date of approval of the plan: 02 SEP 2016
- number of IRB approvals: none
- number of clinical sites enrolled: none
- number of clinical sites at which the study was initiated: none
- completion date for enrollment of clinical sites: MAY 2018
- number of subjects enrolled: none
- subject accrual start date: MAY 2017
- subject accrual completion date: not applicable
- percentage of subjects reaching each designated study phase: not applicable
- comparison of target versus actual enrollment and follow-up: not applicable
- anticipated study /surveillance completion date: MAY 2023

3.4.1 Site Recruitment Status

A total of 75 sites is planned. The expected completion date for site enrollment is May 2018. The site enrollment progress as of 17 FEB 2017 is as follows:

- number of sites contacted: approximately 670
- number completing Questionnaire #1 (Interest): 183 (140:Yes; 18:Maybe; 25:No)
- number completing Questionnaire #2 (Feasibility): 117
- number identified for pre-selection visit (PSV): 70
- number of PSVs completed: 45
- number of sites approved for participation: 32

Postmarket Surveillance Report

BAY (b)(4)

02 MAR 2017

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3.5 Interim Safety and Effectiveness Results

No subjects were enrolled as of 17 FEB 2017.

4. Summary

Study activities related to site and subject enrollment are on track to achieve first subject first visit by 29 MAY 2017.

(b) (6)

From: (b) (6)
Sent: Monday, May 01, 2017 3:18 PM
To: (b) (6)
Cc: (b) (6)
Subject: FDA Decision - Bayer Healthcare, LLC - PS160001/R1

Dear Ms. (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/R1. This report is for the Postmarket Surveillance Study (PSS).

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

Advisories

1. 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).
2. As you are aware, the study is expected to commence surveillance by May 29, 2017, which marks fifteen months since the date of the 522 order. Please submit another enrollment update during the week of May 22, 2017, so that FDA may assess ongoing study progress. Please send the update via email to Dr. (b) (6) no formal submission is required.

Your next scheduled report is due September 2, 2017.

Thank you,

(b) (6)
Division of Epidemiology
OSB/CDRH
(b) (6)
10903 New Hampshire Ave
Silver Spring, MD 20903-0002
(b) (6)



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(b) (6)

From: (b) (6)
Sent: Friday, March 03, 2017 2:13 PM
To: (b) (6)
Cc: (b) (6)
Subject: PS160001/R1 - Bayer Healthcare, Llc - email receipt

Trade Name: Essure System for Permanent Birth Control
Document Number: PS160001/R1
Dated: March 2, 2017
Received: March 3, 2017

Dear Ms. (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) 6 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) (b) (6), in DEPI/OSB. If you have any procedural or policy questions concerning postmarket surveillance requirements, please contact (b) (6)

Thank you,

(b) (6)

Division of Epidemiology
OSB/CDRH
(b) (6)
10903 New Hampshire Ave
Silver Spring, MD 20903-0002

(b) (6)



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MEMORANDUM

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

Date: May 1, 2017 [amended July 6, 2017]

From: (b) (6)
Office of Surveillance and Biometrics (OSB)/Division of Epidemiology
(DEPI)/Epidemiologic Evaluation & Research Branch (EERB) 3

Subject: [PS160001/R001](#)
Essure System for Permanent Birth Control, Bayer Pharma AG
522 Study Requirement Name: Postmarket Surveillance Study (PSS)
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: (b) (6), OSB/DEPI

Through: (b) (6), OSB/DEPI/EERB 3

Purpose:

The purpose of this memorandum is to present the epidemiologic review for the six-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

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 0.8mm

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 (UTJ)

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.

Indications for Use

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

PS Order

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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.

PS Study Protocol Overview ([PS160001/S001](#), approved January 23, 2017):

Postmarket Surveillance Study Question

The 522 order included the following questions:

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Study Design Description and Hypotheses

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. There is no hypothesis testing.

Study Population

The study population will include subjects of reproductive age, between 21 and 45 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).

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Sample Size (Patients and Sites)

2,800 women (1,400 per arm) enrolled at 50-75 sites.

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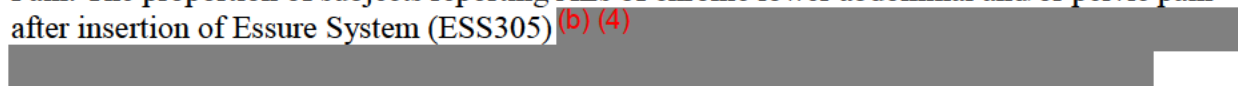


Data Collection (Endpoints)

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)



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Bleeding: The proportion of subjects reporting AEs of abnormal uterine bleeding after insertion of Essure System (b) (4)

Total incidence of new onset or worsening abnormal bleeding events will be based on AE reporting.

Hypersensitivity/allergy/autoimmune disorders: The proportion of subjects with adjudicated new onset (b) (4) allergic/hypersensitivity reactions (b) (4)

Proportion of subjects undergoing invasive gynecologic surgery (b) (4)

including Essure insert removal (b) (4)

Additional endpoints:

- Patient reported outcome measures (b) (4)

- Rates of AEs

Follow-up Visits and Length of Follow-up

(b)(4)

Enrollment Plan and Follow-up Measures

(b)(4)

Statistical Plan

(b)(4)

(b)(4)

Timeline for Study Implementation (approved on September 2, 2016; PS160001/A002)

Milestone:	Date:
Expected date of study initiation	September 2016
Expected monthly number of study sites with IRB approvals	Approximately 8 sites/month
Expected date of initiation of subject enrollment	May 2017
Expected number of subjects enrolled per month	Approximately 78 patients/month (when all sites activated)
Expected date of enrollment completion	May 2020
Expected date of study follow-up completion	May 2023
Expected date for final report submission	September 2023

Status of PS Study and Interim Study Results:

(b) (4)

Epidemiological Assessment of PS Study Status and Interim Study Results:

According to the current submission, no patients or sites had been enrolled as of February 17, 2017. In light of the high profile of this device and study, and given that per FDA's [guidance](#)

[document](#) the sponsor has 15 months to commence surveillance since the issuance of the 522 order (which would occur May 29, 2017), FDA requested a teleconference on April 26, 2017 in order to obtain an update regarding site and patient enrollment (see [Attachment 1](#) for meeting minutes). During the teleconference, the sponsor communicated the following progress:

(b) (4)

In addition, the sponsor has held an investigator meeting, posted the study to the <https://clinicaltrials.gov> website (Study Identifier NCT03127722), (b) (4)

Therefore, the sponsor has made acceptable progress toward commencing surveillance by the given deadline. The protocol specifies a target of 50 study sites, and the sponsor reports that 56 have been selected for participation, which exceeds the goal. The study progress is consistent with the approved study timeline. **The study status will be marked “Progress Adequate.”** The study status and interim enrollment information will be posted on the FDA’s 522 website (see [Attachment 2](#) for web elements).

FDA requested an additional update during the week of May 22, 2017, before the 15 month deadline, for the purposes of monitoring study progress and updating the 522 website. This request was communicated during the teleconference, and the sponsor agreed. **An advisory will be issued to request this update from the sponsor.**

AMENDMENT (JULY 6, 2017): *The decision letter was issued on May 1, 2017, including Advisory #2 below requesting an enrollment update. The sponsor communicated via email on May 3, 2017 that the FPFV (first patient first visit) had been achieved (see [Attachment 3](#)), and therefore the study has met the 15 month deadline to commence surveillance. The sponsor was informed via email that the update requested in Advisory #2 was considered complete and another update during the week of May 22, 2017 was no longer necessary. The FDA 522 website was updated with the May 3, 2017 enrollment data.*

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.

Conclusions and Recommendations:

No deficiencies were identified in the report; therefore, this interim report is considered complete.

Deficiency List:

None

Advisory

1. 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).
2. As you are aware, the study is expected to commence surveillance by May 29, 2017, which marks fifteen months since the date of the 522 order. Please submit another enrollment update during the week of May 22, 2017, so that FDA may assess ongoing study progress. Please send the update via email to Dr. (b) (6); no formal submission is required.

(b) (6)

CDRH/OSB/DEPI

cc: (b) (6)

Document History:

Date	Activity	Initials
------	----------	----------

4/26/17	Drafted	(b) (6)
4/28/17	Reviewed with comments	
5/1/17	Revised	
5/1/17	Reviewed/Cleared with edits	
5/1/17	Finalized	
7/6/17	Amended to include additional information	
7/6/17	Reviewed/Cleared	
7/6/17	Finalized	

This template last updated – March 23, 2016

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

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

Attachment List

[Attachment 1](#): Minutes of teleconference with sponsor (April 26, 2017)

[Attachment 2](#): Elements for Web, Study Interim or Final Data Summary

[Attachment 3](#): Additional information received via email on May 3-4, 2017

Attachment 1: Minutes of teleconference with sponsor (April 26, 2017)

FDA attendees:

(b) (6)

A large rectangular area of the document is redacted with a solid grey fill, covering the names of the FDA attendees.

Bayer attendees:

(b) (6)

A large rectangular area of the document is redacted with a solid grey fill, covering the names of the Bayer attendees.

Discussion:

(b) (4)

A very large rectangular area of the document is redacted with a solid grey fill, covering the entire discussion section.

(b) (4)



Attachment 3: Additional information received via email on May 3-4, 2017

From: (b) (6)
To:
Cc:
Subject: FW: FPFV achieved for Essure 522 study
Date: Thursday, May 04, 2017 9:24:56 AM

Dear (b) (6)

Please see below for an update to the site enrollment numbers. Have a great time off and please let me know if there is anything else you need.

Best regards,

(b) (6)

From: (b) (6)
Date: May 3, 2017 at 10:29:38 PM EDT
To: (b) (6)
Cc:
(b) (6)
Subject: RE: FPFV achieved for Essure 522 study

Hi (b) (6)

Thanks for letting me know! Since the R001 website update hasn't gone live yet, we still have time to incorporate this new information. Can you please check the language below, and let me know ASAP whether there is also an update to the site enrollment numbers? I'd like to change both to the May 3rd date for consistency.

Actual Number of Study Sites Enrolled

(b)(4)

Actual Number of Patients Enrolled

As of May 3, 2017, 1 patient has been enrolled.

I'll be out of the office tomorrow and Friday, but I'll be checking email in the evening.

The update we requested for the week of May 22 is no longer necessary.

Thank you!

(b) (6)

From: (b) (6)

Sent: Wednesday, May 03, 2017 4:21 PM
To: (b) (6)
Cc:
Subject: PPFV achieved for Essure 522 study

Dear (b) (6)

(b) (4)

Best regards,

(b) (6)

Bayer: Science For A Better Life

Bayer HealthCare Pharmaceuticals Inc.
BHP-BPH-TAGM-ME-ME-Reg, Regulatory Affairs GM
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