

MEDWATCH
FDA eSubmitter Generated Form 3500A

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

Mfr Report #:
UF/Importer Report #: 1234567890-2023-00001
Form Code:
Exemption Number:

A. PATIENT INFORMATION

1. Patient Identifier (<i>In confidence</i>)	2. Age at Time of Event, Date of Birth	3a. Sex	3b. Gender	4. Weight
5. Ethnicity () Hispanic/Latino () Not Hispanic/Latino				
6. Race [] Asian [] White [] American Indian or Alaskan Native [] Native Hawaiian or Other Pacific Islander [] Black or African American				

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. [] Adverse Event and/or [] Product Problem (<i>e.g., defects/malfunctions</i>)	
2. Outcomes Attributed to Adverse Event (<i>Checked all that apply</i>) [] Death [] Disability or Permanent Damage [] Life-threatening [] Congenital Anomaly/Birth Defect [] Hospitalization (initial or prolonged) [] Other Serious or Important Medical Events [] Required Intervention to Prevent Permanent Impairment/Damage	
3. Date of Event (<i>dd-mmm-yyyy</i>)	4. Date of this Report (<i>dd-mmm-yyyy</i>)
5. Describe Event or Problem Additional event narrative.	
6. Relevant Tests/Laboratory Data, Including Dates	
7. Other Relevant History, Including Preexisting Medical Conditions (<i>e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.</i>)	

C. SUSPECT PRODUCT(S)

D. SUSPECT MEDICAL DEVICE

1. Brand Name	2. Common Device Name	
3. Manufacturer Name, City and State	4. Model #	Catalog #
	Serial #	Lot #
	Expiration Date (<i>dd-mmm-yyyy</i>)	
	Unique Identifier (UDI) #	
5. Operator of Device	6a. If Implanted, Give Date (<i>dd-mmm-yyyy</i>)	6b. If Explanted, Give Date (<i>dd-mmm-yyyy</i>)
7a. Is this a Single-Use Device that was reprocessed and Reused on a Patient? () Yes () No	7b. If yes, Enter Name and Address of Reprocessor	
8. Was this device serviced by a third party? () Yes () No () Unknown	9. Device Available for Evaluation? (<i>Do not send to FDA</i>) () Yes () No [] Returned to Manufacturer	

10. ConComitant Medical Products and Therapy Dates (*Excludes treatment of event*)

E. INITIAL REPORTER

1. Name and Address	2. Health Professional? () Yes () No
	3. Occupation

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4. Initial Reporter Also Sent Report to FDA? () Yes () No () Unk	

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)

1. User Facility or Importer () User Facility (•) Importer	2. User Facility/Importer Report Number 1234567890-2023-00001	
3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number	6. Date UF/Importer Became Aware of Event (dd-mmm-yyyy)	
	7. Type of Report () Initial (•) Follow-up #: 1	
	8. Date of This Report (dd-mmm-yyyy)	9. Approximate Age of Device
10. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code:	14. Manufacturer Name/Address	
11. Report Sent to FDA? () Yes () No		
12. Location Where Event Occurred		
13. Report Sent to Manufacturer? () Yes () No		

G. ALL MANUFACTURERS

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility	1. Contact Office - Manufacturing Site	
2. Report Source (Check all that apply) [] Foreign [] Health Professional [] Study [] User Facility [] Literature [] Company Representative [] Consumer [] Distributor/Importer [] Other	3. Date Received by Manufacturer (dd-mmm-yyyy)	
	4. Premarket Identification PMA/510(k): [] Combination Product Device BLA:	
	5. If IND/PreANDA, Give Protocol #	
6. Type of Report [] 5-day [] Periodic [] 7-day [] Initial [] 15-day [] Follow-up [] 30-day	7. Adverse Event Term(s)	8. Manufacturer Report Number

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event () Death () Serious Injury () Malfunction [] Summary Report No. of Events Summarized:	2. If Follow-up, What Type? [] Correction [] Additional Information [] Response to FDA Request [] Device Evaluation	3. Device Evaluated by Manufacturer? () Yes () No
4. Device Manufacture Date (dd-mmm-yyyy)	6. Adverse Event Problem (Refer to coding manual) Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code: Type of Investigation: Investigation Findings:	
5. Labeled for Single Use? () Yes () No		

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		Investigation Conclusions:
7. If Remedial Action initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Repair <input type="checkbox"/> Replace <input type="checkbox"/> Relabeling <input type="checkbox"/> Other	<input type="checkbox"/> Notification <input type="checkbox"/> Inspection <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Modification/Adjustment	8. Usage of Device <input type="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> Unknown
		9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number 10. Related Report Numbers:

11. Additional Manufacturer Narrative

File Attachments
No files attached.