

U.S. Department of Health and Human Services  
Food and Drug Administration

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

Mfr Report #
UF/Importer Report #
FDA Use Only

**MEDWATCH**

FORM FDA 3500A (6/10)

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PLEASE TYPE OR USE BLACK INK

**A. PATIENT INFORMATION**

1. Patient Identifier  In confidence	2. Age at Time of Event: or _____ Date of Birth:	3. Sex <input type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight _____ lbs or _____ kgs
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**B. ADVERSE EVENT OR PRODUCT PROBLEM**

1.  Adverse Event and/or  Product Problem (e.g., defects/malfunctions)

2. Outcomes Attributed to Adverse Event (Check all that apply)

<input type="checkbox"/> Death: _____ (mm/dd/yyyy)	<input type="checkbox"/> Disability or Permanent Damage
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital Anomaly/Birth Defect
<input type="checkbox"/> Hospitalization - initial or prolonged	<input type="checkbox"/> Other Serious (Important Medical Events)
<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)	

3. Date of Event (mm/dd/yyyy)

4. Date of This Report (mm/dd/yyyy)

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

**C. SUSPECT PRODUCT(S)**

1. Name (Give labeled strength & mfr/labeler)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

2. Dose, Frequency & Route Used

#1 \_\_\_\_\_

#2 \_\_\_\_\_

3. Therapy Dates (If unknown, give duration) from/to (or best estimate)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

4. Diagnosis for Use (Indication)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

5. Event Abated After Use Stopped or Dose Reduced?

#1  Yes  No  Doesn't Apply

#2  Yes  No  Doesn't Apply

6. Lot #

#1 \_\_\_\_\_

#2 \_\_\_\_\_

7. Exp. Date

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8. Event Reappeared After Reintroduction?

#1  Yes  No  Doesn't Apply

#2  Yes  No  Doesn't Apply

9. NDC# or Unique ID

#1 \_\_\_\_\_

#2 \_\_\_\_\_

10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

**D. SUSPECT MEDICAL DEVICE**

1. Brand Name

2a. Common Device Name

2b. Procode

3. Manufacturer Name, City and State

4. Model #

Lot #

Catalog #

Expiration Date (mm/dd/yyyy)

Serial #

Unique Identifier (UDI) #

5. Operator of Device

Health Professional

Lay User/Patient

Other:

6. If Implanted, Give Date (mm/dd/yyyy)

7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

Yes  No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? (Do not send to FDA)

Yes  No  Returned to Manufacturer on: \_\_\_\_\_ (mm/dd/yyyy)

11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

**E. INITIAL REPORTER**

1. Name and Address

Phone #

Email Address

2. Health Professional?  Yes  No

3. Occupation

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

# MEDWATCH

FORM FDA 3500A (6/10) (continued)

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FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)		
1. Check One <input type="checkbox"/> User Facility <input type="checkbox"/> Importer		2. UF/Importer Report Number
3. User Facility or Importer Name/Address		
4. Contact Person		5. Phone Number
6. Date User Facility or Importer Became Aware of Event (mm/dd/yyyy)	7. Type of Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up # _____	8. Date of This Report (mm/dd/yyyy)
9. Approximate Age of Device	10. Event Problem Codes (Refer to coding manual) Patient Code: [ ] - [ ] - [ ] Device Code: [ ] - [ ] - [ ]	
11. Report Sent to FDA? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No	12. Location Where Event Occurred <input type="checkbox"/> Hospital <input type="checkbox"/> Outpatient Diagnostic Facility <input type="checkbox"/> Home <input type="checkbox"/> Ambulatory Surgical Facility <input type="checkbox"/> Nursing Home <input type="checkbox"/> Outpatient Treatment Facility <input type="checkbox"/> Other: _____ (Specify)	
13. Report Sent to Manufacturer? <input type="checkbox"/> Yes (mm/dd/yyyy) <input type="checkbox"/> No	14. Manufacturer Name/Address	

G. ALL MANUFACTURERS	
1. Contact Office - Name/Address (and Manufacturing Site for Devices)	
2. Phone Number	
3. Report Source (Check all that apply) <input type="checkbox"/> Foreign <input type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other: _____	
4. Date Received by Manufacturer (mm/dd/yyyy)	5. (A)NDA # _____ IND # _____ STN # _____ PMA/510(k) # _____ Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes
6. If IND, Give Protocol #	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input type="checkbox"/> 15-day <input type="checkbox"/> Follow-up # _____	
9. Manufacturer Report Number	8. Adverse Event Term(s)

H. DEVICE MANUFACTURERS ONLY	
1. Type of Reportable Event <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction <input checked="" type="checkbox"/> Other	2. If Follow-up, What Type? <input type="checkbox"/> Correction <input type="checkbox"/> Additional Information <input type="checkbox"/> Response to FDA Request <input type="checkbox"/> Device Evaluation
3. Device Evaluated by Manufacturer? <input type="checkbox"/> Not Returned to Manufacturer <input type="checkbox"/> Yes <input type="checkbox"/> Evaluation Summary Attached <input type="checkbox"/> No (Attach page to explain why not) or provide code:	4. Device Manufacture Date (mm/yyyy) 5. Labeled for Single Use? <input type="checkbox"/> Yes <input type="checkbox"/> No
6. Evaluation Codes (Refer to coding manual) Patient Code: [ ] - [ ] - [ ] Device Code: [ ] - [ ] - [ ] Method: [ ] - [ ] - [ ] - [ ] Results: [ ] - [ ] - [ ] - [ ] Conclusions: [ ] - [ ] - [ ] - [ ]	
7. If Remedial Action Initiated, Check Type <input type="checkbox"/> Recall <input type="checkbox"/> Notification <input type="checkbox"/> Repair <input type="checkbox"/> Inspection <input type="checkbox"/> Replace <input type="checkbox"/> Patient Monitoring <input type="checkbox"/> Relabeling <input type="checkbox"/> Modification/Adjustment <input type="checkbox"/> Other: _____	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. <input type="checkbox"/> Additional Manufacturer Narrative	and / or 11. <input type="checkbox"/> Corrected Data

The public reporting burden for this collection of information has been estimated to average 66 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850

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