

MEDWATCH

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

The FDA Safety Information and Adverse Event Reporting Program

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Mfr Report #
UF/Importer Report #
FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier <small>In confidence</small>	2. Age at time of event, or Date of Birth:	3. Sex <input type="checkbox"/> F <input type="checkbox"/> M	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg
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B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Product Switch (see instructions)

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

Death: _____ (mm/dd/yyyy) Disability or Permanent Damage
 Life-threatening Congenital Anomaly/Birth Defect
 Hospitalization - Initial or Prolonged Required Intervention to Prevent Permanent Impairment/Damage
 Important Medical Events Not Serious No Harm

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

5. Describe Event, Problem or Product Use Error

Product Used During Pregnancy? Yes
Product Used During Breast Feeding? Yes

SAMPLE

6. Relevant Tests/Laboratory Data, Including Dates

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

C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? (Do not send product to FDA)

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

D. SUSPECT PRODUCT(S)

1. Name, strength, manufacturer (from product label)

#1 _____
#2 _____

2. Dose or Amount	Frequency	Route
#1 _____	_____	_____
#2 _____	_____	_____

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

#1 _____
#2 _____

4. Diagnosis or Reason for Use (Indication)

#1 _____
#2 _____

5. Event Abated After Use Stopped or Dose Reduced?
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply

6. Lot #	7. Expiration Date
#1 _____	#1 _____
#2 _____	#2 _____

8. Event Reappeared After Reintroduction?

#1 Yes No Doesn't Apply
#2 Yes No Doesn't Apply

9. NDC # or Unique ID

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Type of Device

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device <input type="checkbox"/> Health Professional <input type="checkbox"/> Lay User/Patient <input type="checkbox"/> Other: _____
Catalog #	Expiration Date (mm/dd/yyyy)	
Serial #	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

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

G. INITIAL REPORTER

1. Name and Address Phone #

2. Health Professional? 3. Occupation 4. Initial Reporter Also Sent Report to FDA

Yes No Yes No Yes No Unk.

PLEASE TYPE OR USE BLACK INK

Medication and Device Experience Report

(Continued)

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.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

FDA USE ONLY

Refer to guidelines for specific instructions.

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H. 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			
SAMPLE			
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"/> Non-Clinical Setting <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		

J. DEVICE MANUFACTURERS	
1. Type of Reportable Event <input type="checkbox"/> Death <input type="checkbox"/> Serious Injury <input type="checkbox"/> Malfunction <input 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"/> 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. Indicated for Single Use? <input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Evaluation Codes (Refer to coding manual) 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	

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

The public reporting burden for this collection of information has been estimated to average one hour 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
MedWatch; HFD-410
5600 Fishers Lane
Rockville, MD 20857

OMB Statement:
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."