U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

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

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mo/day/yr)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Disability
   - ☐ Congenital Anomaly
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage
   - ☐ Other: _____

3. **Date of Event** *(mo/day/year)*

4. **Date of This Report** *(mo/day/year)*

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.)*

1. **Name** *(Give labeled strength & mfr/labeler, if known)*
   #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 #** *(if known)*
   #1
   #2

7. **Exp. Date** *(if known)*
   #1
   #2

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC#** *(For product problems only)*
   – –

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

1. **Brand Name**

2. **Type of Device**

3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mo/day/yr)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. **If Implanted, Give Date** *(mo/day/yr)*

7. **If Explanted, Give Date** *(mo/day/yr)*

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: _____ *(mo/day/yr)*

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

1. **Name and Address**

Phone #

2. **Health Professional?**
   ☐ Yes ☐ No

3. **Occupation**

4. **Also Reported to:**
   - ☐ Manufacturer
   - ☐ User Facility
   - ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

Mail to: **MEDWATCH**
5600 Fishers Lane
Rockville, MD 20852-9787

-or-

FAX to:
1-800-FDA-0178

FORM FDA 3500 (12/03) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**