Saving and/or retrieving your data can only be done with the full version of Adobe Acrobat and not with the free Adobe Reader.

U.S. Department of Health and Human Services | Save Data | Print | Next Page | Retrieve Data | Reset Form

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

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

General Instructions

Page ____ of ____

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION — Section A - Help

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

B. ADVERSE EVENT OR PRODUCT PROBLEM — Section B - Help

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**

(Continue on page 2)

6. **Relevant Tests/Laboratory Data, Including Dates**

(Continue on page 2)

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

(Continue on page 2)

C. SUSPECT MEDICATION(S) — Section C - Help

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)*

(Continue on page 2)

D. SUSPECT MEDICAL DEVICE — Section D - Help

1. **Brand Name**
2. **Type of Device**
3. **Manufacturer Name, City and State**
4. **Model #** | **Lot #**
   Catalog # | **Expiration Date** *(mo/day/yr)*
   Serial # | **Other #**
5. **Operator of Device**
   - ☐ Health Professional
   - ☐ Lay User/Patient
   - ☐ 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)*

(Continue on page 2)

E. REPORTER — *(Confidentiality statement)* — Section E - Help

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:** ☐

PLEASE TYPE OR USE BLACK INK

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.**

Save Data | Print | Previous Page | Retrieve Data | Reset Form

U.S. Department of Health and Human Services

(CONTINUATION PAGE)

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

5. **Describe Event or Problem** ***(continued)***

6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

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

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

Save Data | Print | Previous Page | Retrieve Data | Reset Form

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics
- Medication errors

Report product problems - quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening *(real risk of dying)*
- Hospitalization *(initial or prolonged)*
- Disability *(significant, persistent or permanent)*
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused the event
- You don't have all the details

-Fold Here-

How to report:

- Just fill in the sections that apply to your report
- Use section C for all products except medical devices
- Attach additional blank pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

-Fold Here-

Important numbers:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone or for more information
- 1-800-822-7967 -- For a VAERS form for vaccines

To Report via the Internet:

http://www.fda.gov/medwatch/report.htm

The public reporting burden for this collection of information has been estimated to average 30 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
MedWatch; HFD-410
5600 Fishers Lane
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

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."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

FORM FDA 3500 (12/03) (Back) **Please Use Address Provided Below -- Fold in Thirds, Tape and Mail**

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

Go Back to Form

General Instructions for Completing the MedWatch Form FDA 3500

For use by health professionals and consumers for voluntary reporting of adverse events and product problems with medications (drugs or biologics, **except vaccines**), medical devices (including in vitro diagnostics), special nutritional products (dietary supplements, infant formulas, medical foods) and other FDA-regulated medical products. Events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS) (http://www.fda.gov/cber/vaers/report.htm).

Note for consumers: If possible, please take the 3500 form to your health professional (e.g., doctor or pharmacist) so that information based on your medical record that can help in the evaluation of your report will be provided. If, for whatever reason, you do not wish to have your health professional fill out the form, you are welcome to do so yourself.

GENERAL INSTRUCTIONS

- Please make sure that all entries are either typed, printed in a font no smaller than 10 point, or written using black ink.
- Please complete all sections that apply to your report.
- To complete an item when information is not available, use the following as appropriate:
  - NA for not applicable
  - NI for no information at this time (but may become available later)
  - UNK for unknown
- Dates should be entered as month/day/year (e.g., June 3, 1998 = 06/03/1998).
  If exact dates are unknown, please provide the best estimate.
- For narrative entries, if the fields do not provide adequate space, attach an additional page(s) as needed.
- If the case report involves more than two (2) suspect medications or devices, please submit another copy of FDA Form 3500, with only **Section C** or **Section D** filled in as appropriate.
- **Section C** (Suspect medication(s)) may be used to report on special nutritional products such as dietary supplements as well as drugs or biologics.
- If your report involves a serious adverse event with a device and it occurred in a facility other than a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.
- Please incorporate the following specific information:
  - Identify all attached pages as Page __ of __
  - Indicate the appropriate section and block number next to the narrative continuation
  - Include the phrase continued at the end of each field that has additional information continued onto another page

If you have further questions about completing this form, call MedWatch at: 1-800-FDA-1088.

Go Back to Form

SECTION A: PATIENT INFORMATION

Complete a separate form for each patient, unless the report involves a medical device where multiple patients were adversely affected through the use of the same device. In that case, please indicate the number of patients in block B5 (Describe event or problem) and complete Section A and blocks B2, B5, B6, B7, and D11 for each patient. Enter the corresponding patient identifier in block A1 for each patient involved in the event.

When a newborn baby is found to have a congenital anomaly that the initial reporter considers possibly associated with a product administered to the mother during pregnancy, the patient is the newborn baby.

Parent-child/fetus report(s) are those cases in which either a fetus/suckling infant or the mother, or both, sustain an adverse event that the initial reporter considers possibly associated with a product administered to the mother during pregnancy. Several general principles are used for filing these reports:

- If there has been no event affecting the child/fetus, report only on the parent. For those cases describing fetal demise or spontaneous abortion, only a parent report is applicable
- When only the child/fetus has an adverse reaction/event (other than spontaneous abortion/ fetal demise), the information provided in section A applies to the child/fetus, and characteristics concerning the parent who was the source of exposure to the product is to be provided in section C
- If both the parent and the child/fetus sustain adverse events, two reports should be provided and linked using the narrative
- For devices, one form can be used in this circumstance

A1: Patient identifier

Please provide the patient's initials or some other type of identifier that will allow you, the reporter, to readily locate the case if you are contacted for more information. **Do not use the patient's name or social security number**.

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law.

If no patient was involved (such as may be the case with a product problem), enter none.

A2: Age at time of event or Date of birth

Provide the most precise information available. Enter the patient's birthdate, if known, or the patient's age at the time of event onset. For age, indicate time units used (e.g., years, months, days).

- If the patient is 3 years or older, use years (e.g., 4 years)
- If the patient is less than 3 years old, use months (e.g., 24 months)
- If the patient is less than 1 month old, use days (e.g., 5 days)
- Provide the best estimate if exact age is unknown

A3: Sex

Enter the patient's gender. If the adverse event is a congenital anomaly, report the sex of the child.

A4: Weight

Indicate whether the weight is in pounds (lbs) or kilograms (kgs). Make a best estimate if exact weight is unknown.

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM

B1: Adverse event *and/or* Product problem

Choose the appropriate box. Both boxes should be checked if a product problem may have caused or contributed to the adverse event.

Adverse event: Any incident where the use of a medication (drug or biologic), at any dose, a medical device (including *in vitro* diagnostics) or a special nutritional product (e.g., dietary supplement, infant formula or medical food) is suspected to have resulted in an adverse outcome in a patient.

To report, it is not necessary to be certain of a cause/effect relationship between the adverse event and the use of the medical product(s) in question. Suspicion of an association is sufficient reason to report. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Please limit your submissions to those events that are serious. An event is classified as serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability
- Congenital anomaly
- Required medical or surgical intervention to prevent permanent impairment or damage

Please see instructions for block **B2** for further information on each of these criteria.

While voluntary MedWatch reporting with Form 3500 is designed for serious reports only, you are welcome to report even if your case does not meet any of these specific criteria and you feel strongly that FDA should review the report. In that situation, you should check the other box and specify the reason for reporting, including patient outcome, in the space provided. The actual narrative of the event should be entered in block **B5**.

Product problem (e.g., defects/malfunctions): Any report regarding the quality, performance, or safety of any medication, medical device or special nutritional product. In addition, please select this category when reporting device malfunctions that could lead to a death or serious injury if the malfunction were to recur.

Product problems include, but are not limited to, such concerns as:

- Suspected contamination
- Questionable stability
- Defective components
- Therapeutic failures
- Product confusion (caused by name, labeling, design or packaging)
- Suspected super potent or subpotent medication
- Labeling problems caused by printing errors/ omissions

B2: Outcomes attributed to adverse event: Indicate all that apply to the reported event:

Death: Check only if you suspect that the death was an outcome of the adverse event, and include the date if known.

Do not check if:

- The patient happened to die while using a medical product, but there was no suspected association between the death and the use of the product
- A fetus is aborted because of a congenital anomaly, or is miscarried

Life-threatening: Check if suspected that:

- The patient was at substantial risk of dying at the time of the adverse event

  or

- Use or continued use of the device or other medical product might have resulted in the death of the patient

Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event.

Do not check if:

- A patient in the hospital received a medical product and subsequently developed an otherwise nonserious adverse event, unless the adverse event prolonged the hospital stay

Do check if:

- A patient is admitted to the hospital for one or more days, even if released on the same day
- An emergency room visit results in admission to the hospital
- Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage)

Disability: Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions. Such would be the case if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

Congenital anomaly: Check if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Required intervention to prevent permanent impairment or damage: Check if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.

(continued on next page)

SECTION B: ADVERSE EVENT OR PRODUCT PROBLEM *(continued)*

Drugs and Biologics: This box should be checked for important medical events that may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the other serious outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Other: Check only if the other categories are not applicable to the event. Briefly describe the patient outcome in the space provided. The actual narrative of the event will be entered in block **B5**.

B3: Date of event

Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.

When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child

When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated

If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block **B5**.

B4: Date of this report

The date the report is filled out.

B5: Describe event or problem

For an **adverse event**:

Describe the event in detail, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by your institution), please attach copies of these records with any confidential information deleted. **Do not identify any patient, physician, or institution by name. The reporter's identity should be provided in full in section E**.

Information as to any environmental conditions that may have influenced the event should be included, particularly when (but not exclusive to) reporting about a device.

- Results of relevant tests and laboratory data should be entered in block **B6**. (See instructions for **B6**).
- Preexisting medical conditions and other relevant history belong in block B7. Be as complete as possible, including time courses for preexisting diagnoses (see instructions for B7).

If it is determined that reuse of a medical device labeled for single use may have caused or contributed to an adverse patient outcome, please report in block **B5** the facts of the incident and the perceived contribution of reuse to the occurrence.

For a **product problem**:

Describe the problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood.

- If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section
- For a medication or special nutritional product problem, please indicate if you have retained a sample that would be available to FDA

B6: Relevant tests/laboratory data, including dates

Please provide all appropriate information, including relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/ assessment led to strong consideration of medical product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated.

Please include:

- Any relevant baseline laboratory data prior to the administration or use of the medical product
- All laboratory data used in diagnosing the event
- Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event

If available, please include:

- Any pre- and post-event medication levels and dates (if applicable)
- Synopses of any relevant autopsy, pathology, engineering, or lab reports

If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted. **Do not identify any patient, physician or institution by name.** The initial's reporter's identity should be provided in full in section E.

B7: Other relevant history, including preexisting medical conditions

If available, provide information on other known conditions in the patient (e.g. hypertension, diabetes mellitus, renal/hepatic dysfunction), significant history (e.g. allergies, pregnancy history, smoking, and alcohol use, drug abuse, etc.) and/or race and ethnicity.

Go Back to Form

SECTION C: SUSPECT MEDICATION(S)

For **adverse event reporting**:

A suspect medication is one that you suspect is associated with the adverse event. In block **C10** enter other concomitant medical products (drugs, biologics, medical devices, etc.) that the patient was using at the time of the event but which you do not think were involved in the event.

Up to two (2) suspect medications may be reported on one form (#1=first suspect product, #2=second suspect product). Attach an additional form if there were more than two suspect medications for the reported adverse event.

For **product problem reporting**:

A suspect medication is the product that is the subject of the report. A separate form should be submitted for each individual product problem report.

Identification of the labeler/distributor and pharmaceutical manufacturer (if known) and labeled strength of the product is important for prescription or non-prescription products.

This section may also be used to report on special nutritional products (e.g., dietary supplements, infant formula or medical foods) or other products regulated by FDA.

If reporting on a special nutritional or a drug product problem, please attach labeling/ packaging if available.

If reporting on a special nutritional only, please provide directions for use as listed on the product labeling.

C1: Name

Use the trade name as marketed. If unknown or if no trade name, use the generic name (with the manufacturer or labeler's name, if known). For quality problem reports, please include the manufacturer's name and the labeled strength for both prescription and non-prescription products.

C2: Dose, frequency & route used

Describe how the product was used by the patient (e.g., 500 mg QID orally or 10 mg every other day IV). For reports involving overdoses, the amount of product used in the overdose should be listed, not the prescribed amount.

See **APPENDIX I** for list of Routes of Administration

C3: Therapy dates

Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable (e.g., 2 years) or if therapy was less than one day, then duration is appropriate (e.g., 1 dose or 1 hour for an IV).

C4: Diagnosis for use

Provide the indication for which the product was prescribed or used in this particular patient.

C5: Event abated after use stopped or dose reduced

If available, this information is particularly useful in the evaluation of a suspected adverse event. In addition to checking the appropriate box, please provide supporting lab tests and dates, if available, in block **B6**.

C6: Lot #

If known, include the lot number(s) with all product problem reports, or any adverse event report with a biologic or medication.

C7: Expiration date

Please include if available.

C8: Event reappeared after reintroduction

If available, this information is particularly useful in the evaluation of a suspected adverse event. In addition to checking the appropriate box, please provide supporting lab tests and dates, if available, in block **B6**.

C9: NDC #

The national drug code is requested only when reporting a drug product problem. It can be found on the product label and/or packaging. Zeros and dashes should be included as they appear on the label.

C10: Concomitant medical products and therapy dates

Information on the use of concomitant medical products can frequently provide insight into previously unknown interactions between products, or provide an alternative explanation for the observed adverse event. Please list and provide therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that a patient was using at or around the time of the event. Do not include products used to treat the event.

Appendix I - ROUTES OF ADMINISTRATION

Auricular (otic) 001
Buccal 002
Cutaneous 003
Dental 004
Endocervical 005
Endosinusial 006
Endotracheal 007
Epidural 008
Extra-amniotic 009
Hemodialysis 010
Intra corpus cavernosum 011
Intra-amniotic 012
Intra-arterial 013
Intra-articular 014
Intra-uterine 015
Intracardiac 016
Intracavernous 017
Intracerebral 018
Intracervical 019
Intracisternal 020
Intracorneal 021
Intracoronary 022
Intradermal 023
Intradiscal (intraspinal) 024
Intrahepatic 025
Intralesional 026
Intralymphatic 027
Intramedullar (bone marrow) 028
Intrameningeal 029
Intramuscular 030
Intraocular 031
Intrapericardial 032
Intraperitoneal 033
Intrapleural 034
Intrasynovial 035
Intratumor 036
Intrathecal 037
Intrathoracic 038
Intratracheal 039
Intravenous bolus 040
Intravenous drip 041
Intravenous (not otherwise specified) 042
Intravesical 043
Iontophoresis 044
Occlusive dressing technique 045
Ophthalmic 046
Oral 047
Oropharingeal 048
Other 049
Parenteral 050
Periarticular 051
Perineural 052
Rectal 053
Respiratory (inhalation) 054
Retrobulbar 055
Sunconjunctival 056
Subcutaneous 057
Subdermal 058
Sublingual 059
Topical 060
Transdermal 061
Transmammary 062
Transplacental 063
Unknown 064
Urethral 065
Vaginal 066

Go Back to Form

SECTION D: SUSPECT MEDICAL DEVICE

The suspect medical device is 1) the device that may have caused or contributed to the adverse event or 2) the device that malfunctioned.

In block **D11**, report other concomitant medical products (drugs, biologics, medical devices, etc.) that the patient was using at the time of the event but which you do not think were involved in the event.

If more than one suspect medical device was involved in the event, complete all of section D for the first device and attach a separate completed section D for each additional device.

If the suspect medical device is a single use device that has been reprocessed, then the reprocessor is now the device manufacturer.

D1: Brand name

The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g., Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. Reprocessed single use devices may bear the Original Equipment Manufacturer (OEM) brand name. If the suspect device is a reprocessed single use device enter "NA".

D2: Type of device

The generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.). Please do not use broad generic terms such as "catheter", "valve", "screw", etc.

D3: Manufacturer name & address

If available, list the full name and mailing address of the manufacturer of the suspected medical device. If the answer is Block D8 is "yes", then enter the name and address of the reprocessor.

D4: Product identification number/expiration date

If available, provide any or all identification numbers associated with the suspect medical device exactly as they appear on the device or device labeling. This includes spaces, hyphens, etc.

Model #: The exact model number found on the device label or accompanying packaging.

Catalog #: The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging.

Serial #: This number can be found on the device label or accompanying packaging; it is assigned by the manufacturer, and should be specific to each device.

Lot #: This number can be found on the label or packaging material.

Expiration date (mo/day/yr): If available, this date can often be found on the device itself or printed on the accompanying packaging.

Other #: Any other applicable identification number (e.g., component number, product number, part bar-coded product ID, etc.)

D5: Operator of device

Indicate the type (not the name) of person operating or using the suspect medical device on the patient at the time of the event as follows:

Health professional = physician, nurse, respiratory therapist, etc.
Lay user/patient = person being treated, parent/ spouse/friend of the patient
Other = nurses aide, orderly, etc.

D6: If implanted, give date (mo/day/yr)

For medical devices that are implanted in the patient, provide the implant date or your best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D7: If explanted, give date (mo/day/yr)

If an implanted device was removed from the patient, provide the explant date or your best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D8: Is this a Single-use Device that was Reprocessed and Reused on a Patient?

Indicate "Yes" or "No".

D9: If Yes to Item No.8, Enter Name and Address of Reprocessor

Enter the name and address of the reprocessor of the single-use device. Anyone who reprocesses single-use devices for reuse in humans is the manufacturer of the reprocessed device.

D10: Device available for evaluation?

To evaluate a reported problem with a medical device, it is often critical for the manufacturer to be able to examine the suspect product. Thus, please indicate whether the device is available for evaluation.

Indicate if the device was returned to the manufacturer and, if so, the date of the return. Do not send the device to FDA.

D11: Concomitant medical products and therapy dates

Information on the use of concomitant medical products can frequently provide insight into previously unknown interactions between products, or provide an alternative explanation for the observed adverse event. Please list and provide product names and therapy dates for any other medical products (drugs, biologics, medical devices, etc.) that the patient was using at the time of the event. Do not include products used to treat the event.

Go Back to Form

SECTION E: INITIAL REPORTER

FDA recognizes that confidentiality is an important concern to health professionals in the context of adverse event reporting. The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. However, to allow for timely follow-up in serious cases, the reporter's identity may be shared with the manufacturer unless specifically requested otherwise in block E5. The FDA will not disclose the reporters identity in response to a request from the public, pursuant to the Freedom of Information Act.

E1: Name, address & phone #

Please provide the name, mailing address and phone number of the person who can be contacted to provide information on the event if follow-up is necessary. While optional, providing the contact's E-mail address and/or fax number, would be most helpful, if available. This person will also receive an acknowledgment letter from the MedWatch program.

This information is necessary for both adverse event and product problem reports.

E2: Health professional?

Please indicate whether you are a health professional (e.g., physician, pharmacist, nurse, etc.) or not. If you are not a health professional, please complete block **E3** by filling in NA.

E3: Occupation

Please indicate your occupation (particularly type of health professional), and include specialty, if appropriate.

E4: Also reported to

Please indicate whether you have also notified or submitted a copy of this report to the manufacturer and/or distributor of the product, or, in the case of medical device reports only, to the user facility (institution) in which the event occurred. This information helps to track duplicate reports in the FDA database.

E5: Release of reporter's identify to the manufacturer

In the case of a serious adverse event (see **B1**), the Agency may provide name, address and phone number of the reporter denoted in block **E1** to the manufacturer of the suspect product. If you do not want your identity released to the manufacturer, please put an X in this box.