



# Sustainable Hospitals Project

A Project of the Lowell Center for Sustainable Production, University of Massachusetts Lowell

## Use MedWatch to Report Sharps Injuries

### Q. What is MedWatch?

**A.** MedWatch is a voluntary program of the United States Food and Drug Administration (FDA) for healthcare professionals and consumers to report serious adverse events and serious problems with drugs and medical devices they prescribe, dispense or use.

### Q. How does it relate to me?

**A.** If you receive an injury or blood exposure from needles or other sharps, MedWatch is a good avenue for recording your injury. MedWatch should also be considered for reporting other medical device related problems such as allergic reactions to latex or glove additives, glove failures (e.g. finding blood inside a glove with no visible holes), and surgical adhesions and granulomas caused by glove powder. MedWatch is **confidential** and the FDA does not notify the health care provider's employer that a MedWatch report was filed.

### Q. Why report to MedWatch?

**A.** Your report, combined with others, provides a driving force for change:

- **Get counted!** Reporting failures and problems provides an accounting of product shortcomings and provides a driving force for safer products. It also provides data that justifies the need for better-engineered safety needles and sharps.
- Since FDA governs medical devices, they are in a key position for **influencing development of better products**. Feedback about injuries from healthcare professionals can be a prompt for taking action.
- Healthcare professionals who work in a healthcare facility and have a device-related illness or injury are considered "patients" of that facility. **Healthcare workers' experiences are reportable** just as if it had happened to a patient in that facility.

### Q. The FDA says that MedWatch is for reporting "SERIOUS adverse events". What if the FDA doesn't consider my injury or exposure serious enough?

**A.** According to the FDA, "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 other words, even if your injury or exposure turns out to be non-life threatening (or you're not yet sure of long term health effects), you still have the right to report. It is important to report, because the next person to be injured may not be so lucky.

### Q. How do I use MedWatch for a sharps or needle injury or blood exposure?

**A.** Report your injury to MedWatch by phone, online, or by submitting the MedWatch 3500 form by mail or fax.

When you fill out your report, **be very specific about the device** – manufacturer, model, type, size, and any other information available. If you don't know the specifics about the device, provide as much information as you can. Sketches, measurements, component colors, and the like can all be helpful information.

Forms and instructions for using MedWatch are available by calling the FDA at 800-FDA-1088 or online at:

- ♦ MedWatch home page of general information - <http://www.fda.gov/medwatch/index.html>
- ♦ MedWatch FDA Form 3500 - <http://www.fda.gov/medwatch/safety/3500.pdf> (*this is a postage paid MedWatch Form*)
- ♦ Instructions for Completing MedWatch FDA Form 3500 – <http://www.fda.gov/medwatch/report/consumer/instruct.htm>

References:

- “Improving Patient Care by Reporting Problems with Medical Devices” (September, 1997), a MedWatch Continuing Education Article provided by the Uniformed Services University of the Health Sciences, Bethesda, MD, and the Food and Drug Administration, Rockville, MD
- “Instructions for Completing MedWatch FDA Form 3500”, (April, 2000), U.S. Food and Drug Administration, Rockville, MD
- “MedWatch FDA Form 3500”, U.S. Food and Drug Administration, Rockville, MD
- “MedWatch: The FDA Desk Guide for Adverse Event and Product Problem Reporting”, online at <http://www.fda.gov/medwatch/report/DESK/TPCFINAL.HTM>

### MedWatch Program Summary

<b>Reporting is:</b>	Voluntary
<b>Who reports:</b>	Individual health professionals or consumers
<b>What prompts a report:</b>	<p>Observation of a serious adverse event associated with any medical product, including any patient* outcome that results in:</p> <ul style="list-style-type: none"> <li>• Death</li> <li>• a life-threatening event</li> <li>• hospitalization</li> <li>• disability</li> <li>• congenital anomaly</li> <li>• the need for medical or surgical intervention to prevent permanent damage or impairment, <b>or</b></li> <li>• 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</li> </ul> <p>FDA is also interested in product problems, including:</p> <ul style="list-style-type: none"> <li>• inaccurate or unreadable labeling</li> <li>• packaging or product mix-up</li> <li>• suspected contamination</li> <li>• questionable stability</li> <li>• defective devices</li> <li>• therapeutic failures</li> <li>• product confusion (caused by name, labeling, design or packaging).</li> </ul> <p>*Healthcare professionals who work in user facilities and sustain a device-related illness/injury (or death) are considered “patients” of that user facility.</p>
<b>Does one have to establish causality?</b>	Health professionals do not need to prove causality; a suspected possible association between a product and an adverse outcome is sufficient reason to report.

# MEDWATCH

## The FDA Safety Information and Adverse Event Reporting Program

FDA Use Only

Triage unit sequence #

Page \_\_\_\_ of \_\_\_\_

### A. Patient information

1. Patient identifier	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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In confidence

### 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 _____ (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

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.)

### C. Suspect medication(s)

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)

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

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

10. Concomitant medical products and therapy dates (exclude treatment of event)

### D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: \_\_\_\_\_

5. Expiration date (mo/day/yr)

6. model # \_\_\_\_\_

catalog # \_\_\_\_\_

serial # \_\_\_\_\_

lot # \_\_\_\_\_

other # \_\_\_\_\_

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes  no  returned to manufacturer on \_\_\_\_\_ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

### E. Reporter (see confidentiality section on back)

1. Name & address

phone # \_\_\_\_\_

2. Health professional?  yes  no

3. Occupation

4. Also reported to

manufacturer

user facility

distributor

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

# 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 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

## 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.

## 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:

<https://www.accessdata.fda.gov/scripts/medwatch/>

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 this 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:

DHHS Reports Clearance Office  
Paperwork Reduction Project (0910-0291)  
Hubert H. Humphrey Building, Room 531-H  
200 Independence Avenue, S.W.  
Washington, DC 20201

Please **DO NOT**  
**RETURN** this form  
to this address.

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

FDA Form 3500-back

**Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

## Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

### Official Business

Penalty for Private Use \$300

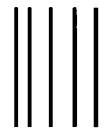
## BUSINESS REPLY MAIL

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



NO POSTAGE  
NECESSARY  
IF MAILED  
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