



How To Complain About Medical Products and Get Heard

Every medical practitioner experiences problems with medical devices at one time or another – for example, medical gloves that leak, safety needles that won't activate, a flimsy device breaking during use. Often there doesn't seem to be a good way to complain unless a serious injury occurred.

Take heart - here is a way to speak up and be heard! The Food and Drug Administration (FDA) offers **MedWatch** for healthcare professionals and consumers to voluntarily report problems with medical products. Your feedback gets logged in to a database that is taken seriously by both the FDA and the device manufacturers.

Why report?

Even if you are only one voice, it's still important to report your experience to the FDA:

- MedWatch notifies manufacturers of product problems and compiles the reports into a searchable database. Reports of product problems that come in through MedWatch raise a flag for both the FDA and the manufacturers.
- FDA uses your reports for safety surveillance of FDA-regulated products. Your report may be the critical piece that prompts a modification in use or design of a product or leads to increased patient safety.
- You may think you're the only practitioner having a problem with a product (and a manufacturer's representative may tell you that you are), but your experience is probably happening elsewhere. MedWatch provides a credible forum for documenting a genuine problem and collating the experience of users nationwide.
- User feedback is a driving force for the development of safer, more user-friendly products. Manufacturers need to hear about infrequent problems as well as common ones to improve their products.
- The FDA's searchable database allows other practitioners to benefit from your experience during their selection and routine use of products.

How to Report?

FDA Form 3500 is used by healthcare professionals and consumers for voluntary reporting of adverse events related to medical products. You can fill out an online form, report by telephone, or download a form from the FDA website and fax or mail it in. Things to think about:

More information is available on the SHP Website:
www.sustainablehospitals.org

Sustainable Hospitals Project
Phone: 978-934-3386
Email: shp@uml.edu
Complain About Med Products.doc 091304

- When you read Form 3500 and its instructions, you may wonder whether your observation is serious enough to report. If it bothers you, it is!
- Give as much information as possible as you can – manufacturer, product name, size, lot number, how the product was being used, unusual conditions during use (e.g. low light, noisy environment, home care setting, et cetera). Seemingly unrelated factors can be relevant in troubleshooting problems, so it's important to paint the whole picture of how and when the product didn't perform satisfactorily.
- FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. If you do not want your identity released to the manufacturer, you can state that on the reporting form.

FDA MedWatch Web Address: <http://www.fda.gov/medwatch/>

FDA Phone Number: 1-800-FDA-1088

FDA Fax Number: 1-800-FDA-1078

How Can I find Out What Others Report to MedWatch?

FDA has a searchable database called MAUDE (Manufacturer and User Facility Device Experience Database). By typing in a search keyword (such as "glove", "needle", "mercury"), you can find adverse events provided to the FDA from voluntary reports, user facility reports, distributor reports, and manufacturer reports. MAUDE is a valuable tool for learning from and about other users' experiences.

MAUDE is online at: <http://www.fda.gov/cdrh/maude.html>

For more information visit the SHP website at <http://www.sustainablehospitals.org> or contact the SHP at 978-934-3386 or by email at shp@uml.edu.