

Facts from the U.S. Food and Drug Administration

Reusing Disposable Medical Devices

(NAPSA)—Proper care can avoid double trouble when it comes to single-use medical devices. A single-use device, often called SUD for short, is a medical device to be used only on one patient for a single procedure. In recent years, however, hospitals have been cleaning, disinfecting or sterilizing SUDs and then reusing them. This practice lets hospitals cut down on disposable medical waste and save money.

The Food and Drug Administration (FDA), however, is concerned about the growing reuse trend. Today's medical devices are often complex. This can make the cleaning and re-sterilization process more difficult. FDA worries that this could lead to a potentially higher risk for infection and device failure. "Despite a lack of clear data that suggests that many injuries are occurring due to reprocessing practices," said David W. Feigal, M.D., director of FDA's Center for Devices and Radiological Health (CDRH), "FDA has concluded that the practice of reusing single-use devices needs additional attention and regulatory controls."

To prevent potential problems, FDA now requires hospitals and companies that reprocess SUDs to meet the same manufacturing standards used by the original manufacturer. In other words, they will have to ensure that the reprocessed SUD is as safe and as effective as it was when originally manufactured.

A recent report from the U.S. General Accounting Office (GAO), an auditing arm of the U.S. Con-



New government guidelines may protect patients from contaminated equipment.

gress, states that some SUDs could be safely reprocessed, if done properly. However, GAO recognizes that reprocessed SUDs can pose some health risks with certain devices. For this reason, FDA is increasing its oversight of SUD reprocessing.

The government agency also wants consumers to know that hospitals do reprocess and reuse SUDs. If you have any concerns about reused devices, you should speak to your doctor.

Examples of known reprocessed SUDs include:

- surgical drills,
 - biopsy forceps,
 - electrophysiology catheters,
- and
- laparoscopy scissors.

For the latest information on reuse of SUDs, go to FDA's reuse Web page www.fda.gov/cdrh/reuse/index.shtml.