

## Medical Device Information Sources

The Food and Drug Administration (FDA) has released its most recent version of the Manufacturer and User Facility Device Experience Database (MAUDE), which lists reports of adverse events involving medical devices.

The data consist of all voluntary reports made since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996.

The FDA's Center for Devices and Radiological Health (CDRH) also has an online search capability that can produce information about devices that may have malfunctioned or caused a death or serious injury. To download the MAUDE files, visit [www.fda.gov/cdrh/maude.html](http://www.fda.gov/cdrh/maude.html) (Internet connection required). To search the CDRH database, visit [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM) (Internet connection required).

Another source of information for health care professionals can be found on the ECRI Web site. This nonprofit health services research agency provides an online database of reports based on ECRI investigations of medical device failures, and related injuries and deaths over several decades. Its goal is to provide information to help avoid "design and quality assurance problems and human factors limitations that increase the incidence of medical and user error," according to ECRI.

To access the database, visit [www.ecri.org](http://www.ecri.org), click on the "Professional Information" link, then the Medical Device Safety Reports case studies of medical device errors (Internet connection required).