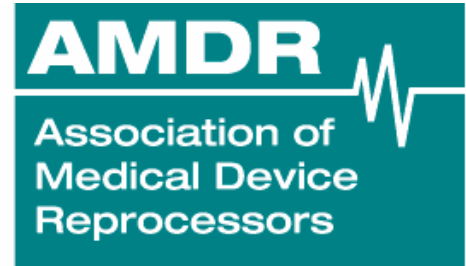


AMDR Position Paper
Unique Device Identification (UDI)



The Association of Medical Device Reprocessors (AMDR) supports efforts to trace all medical devices. All reprocessed medical devices are already 100 percent traceable. While the technology AMDR-member reprocessors use varies from device to device (bar codes, laser etching, engraving, ink marking, etc.), reprocessors have a means of tracing all our devices. Our tracing mechanisms allow us to know which medical facility the devices we receive came from, how many times they have been reprocessed, and how many times (turns) the devices have left.

Congress recently passed, and the President signed into law, the Food and Drug Administration Amendments Act of 2007 (FDAAA).¹ This act requires the U.S. Food and Drug Administration (FDA) to implement a Unique Device Identification (UDI) System. FDA anticipates that this new system, when implemented, will require:

- the label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices
- the unique identifier to be able to identify the device through distribution and use
- the unique identifier to include the lot or serial number if specified by FDA²

The Association of Medical Device Reprocessors (AMDR) strongly supports this initiative.

Currently, medical device manufacturers are NOT required to trace or mark their devices in any way. Once the packaging from a device is removed, if an adverse event should occur (such as a saw blade breaking), the hospital may not know whether they have just used a Smith & Nephew® saw blade, a Stryker® saw blade, or any other brand. In contrast, if there is a problem with a reprocessed device, hospitals can easily identify its source.

Federal law already requires that all reprocessors prominently and conspicuously place their company's name, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer (reprocessor) on the device, or on an attachment thereto.³ Additionally, all packaging for reprocessed devices must clearly state: Reprocessed device for single use. Reprocessed by [name of the reprocessor]."⁴

In the interest of accuracy and transparency, AMDR supports a universal mechanism to trace all medical devices.

¹ The Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85.

² See FDA's Unique Device Identification web-site at: <http://www.fda.gov/cdrh/ocd/udi/>

³ Medical Device User Fee Stabilization Act of 2005, Pub. L. No. 109-43, 119 Stat. 439 (codified as amended in 21 U.S.C. 352(u).

⁴ Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, 116 Stat. 1588 (codified as amended in scattered sections of 21 U.S.C).