

Beyond the “Yuck Factor”: Product Liability Implications of Medical Device Reprocessing

By Peter J. Goss



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Product liability litigation is a fact of life for medical technology manufacturers. But when a reprocessed version of a medical device or instrument fails, can the original manufacturer of the device be held liable for compensating a patient injured by the reused device?

Unfortunately for the original manufacturers of the equipment—and contrary to logic and fairness—the answer is yes.

The practice of medical device reprocessing, which involves the cleaning, repair and re-sterilization of used medical equipment, has rapidly grown into a \$125 million industry dominated by two

major reprocessing companies. Because reprocessed devices cost about half as much as new ones, hospitals are highly motivated to buy used—even devices clearly labeled by the original equipment manufacturer as “single use only” because they have not been proven safe for reprocessing.

Beyond the revulsion many patients may feel over the idea that instruments used in them have already been inside another person's body—the “yuck factor,” as one reprocessing industry leader called it—there has been much public debate over whether the potentially increased risks to patients outweigh the cost savings for hospitals.

But one important question lingers: when a reprocessed single-use device fails, how should judges, juries and policymakers approach the difficult task of assigning legal liability for injuries caused by reprocessed devices?

Liability Concerns for Device Manufacturers

Despite reprocessors' assurances that reprocessed devices are just as safe as (if not safer than) new ones, inevitably some number of reprocessed single-use devices will injure patients, just as brand-new devices sometimes do. It seems only fair, then, for reprocessors to accept full liability for placing used single-use devices back in the stream of commerce, against the clear contrary instruction of the manufacturer. After all, if devices were disposed of in accordance with the manufacturer's "single use only" instruction, they would never have the second opportunity to do harm.

reprocessors must now provide a "prominent and conspicuous mark" on reprocessed single-use devices, but that requirement only took effect on Aug. 1, 2006. Since then, millions of unmarked reprocessed devices have been used, and in all likelihood thousands more are still on hospital shelves awaiting reuse. If a reprocessed device has not been marked as such, the reprocessor is not likely to be named in a subsequent product liability lawsuit. Instead, the original equipment manufacturer—whose name, device model and serial number, and other identifying information will be found in the patient's or the hospital's records (if not on the device itself)—becomes the sole target. It is impossible to say for sure, but in all probability manufacturers have settled claims that involved reused devices, unbeknownst to them or the claimant.

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In this respect, the reprocessor is always the "but-for" cause of the patient's injuries, even in cases where the reprocessing itself cannot be shown to have weakened the device or caused it to fail.

However, there are several factors that could lead the original equipment manufacturer to get most, if not all of the blame:

1. **Lack of reprocessor identification.** It is impossible to tell just from looking at a device whether it has been reprocessed. With the passage in 2005 of the federal Medical Device User Fee and Stabilization Act,
2. **No disclosure to doctors and patients.** Physicians and surgeons typically do not know whether a device has been reprocessed. It is unlikely that patients ever know. Hospital administrators may know, but they will be reluctant to disclose a device's status out of concern for the hospital's own potential liability. This may explain why adverse events involving reused devices are rarely reported.
3. **Underreporting of adverse events.** Until very recently, the Food and Drug Administration's MedWatch adverse event report form did not specifically

call for a device's reprocessing status. Thus, the number of reports in the FDA database for any given device will almost certainly be understated for reused devices and overstated for new ones.

- 4. Lack of interest from the plaintiff's bar.** Although the reprocessing industry has achieved record growth in recent years, the major third-party reproprocessors are still smaller and less well-known than the original manufacturers whose products they sell. Plaintiffs' lawyers typically concentrate their efforts on the "deep pocket" defendant, which in most cases will be the original equipment manager, not the reproprocessor.
- 5. Reprocessors' best defense:** Blame the original manufacturer. If a reproprocessor is sued, it will very likely argue that the original device was defective prior to any reprocessing. This compounds liability exposure for the manufacturer, who now faces allegations of product defect not only from the plaintiff, but from the very company that reprocessed and resold its device. Reprocessors are already making such arguments now, outside of any pending litigation.

These are just a few of the reasons why device manufacturers face significant product liability exposure from reprocessed single-use devices—despite the fact that they do not endorse or condone reprocessing and explicitly warn against it through the "single use" instruction. Meanwhile, the reprocessing industry continues to fly under the plaintiffs' radar: To date, there are no reported verdicts or judicial opinions holding a reproprocessor liable for injuries caused by a reused single-use device.

Matching Risk to Reward

An original equipment manufacturer's single-use designation reflects that either

the device is not safe and effective when reused or the manufacturer has no test data to support the device's safety and efficacy when reused. The statutory and regulatory scheme specified by the 2002 Medical Device User Fee and Modernization Act requires reproprocessors to "fill the gap" by validating their techniques and proving the safety and efficacy of devices that undergo their processes. But validation testing alone will not lead to a fair and rational allocation of the liability risks involved with reprocessing. Reprocessors must accept liability—or original equipment manufacturers should be granted immunity—for claims involving products that, according to the manufacturer's express instruction, should have been thrown out instead of recycled.

Recognizing this imbalance and the potential for injustice, Utah has adopted legislation that protects original manufacturers from product liability claims involving reprocessed devices. Other states should consider following Utah's example. After all, product liability litigation is a fact of life for medical technology manufacturers, and reproprocessors—who are now deemed "manufacturers" under federal law—should not be exempt. If reprocessed devices are to be treated as equivalent to new ones, reproprocessors and original manufacturers should face the same risk of liability when the products they sell cause harm.

With domestic health care spending projected to reach a staggering \$4 trillion by 2015, the future promises a steady increase in the number of procedures performed with lower-cost, reprocessed equipment. Some of those devices will inevitably fail. The hope is that when that happens, the party that caused the harm—whether by putting a "single use" device through a second (or third or 30th) use or by damaging the device during reprocessing or both—will be the one assigned the liability.

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