

**BEYOND THE “YUCK FACTOR”:
PRODUCT LIABILITY IMPLICATIONS OF
MEDICAL DEVICE REPROCESSING**

by
Peter J. Goss
Faegre & Benson LLP

Washington Legal Foundation
Critical Legal Issues
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BEYOND THE “YUCK FACTOR”: PRODUCT LIABILITY IMPLICATIONS OF MEDICAL DEVICE REPROCESSING

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INTRODUCTION

“The biggest single problem we have is the ‘yuck’ factor.”¹

- Dan Vukelich, Deputy Executive Director, Association of Medical Device Reprocessors

In recent years, medical device reprocessing – the cleaning, repair, and re-sterilization of used medical equipment – has gone from a diffuse practice carried out in-house at dozens of individual hospitals and care centers, to a rapidly growing and profitable industry concentrated in just two companies. The emergence of reprocessing as an industry coincided with the introduction of tighter regulations, which led most hospitals to discontinue their own reprocessing programs in favor of outsourcing to third-party reprocessing firms. But the main engine driving the expansion of reprocessing is cost: since reprocessed devices cost about half as much as new ones, hospitals are highly motivated to “buy used” – even, and perhaps especially, for devices labeled “Single Use Only.” With domestic health care spending projected to reach a staggering \$4 trillion by 2015,² we can expect a steady increase in the number of procedures involving “single-use devices” (“SUDs”) that have already

¹*Device Makers Fight Reuse of Surgical Tools*, THE BOSTON GLOBE (Oct. 19, 2005).

²National Coalition on Health Care, “Facts on Health Care Costs,” *available at* <http://www.nchc.org/facts/cost.shtml>.

been used at least once, if not many times.

Public discussion about reprocessing has centered mostly on whether the cost savings are outweighed by potentially increased risks to patients. Lately, the risks are getting more attention: a December 2005 series in the *Washington Post* reported on serious injuries involving reprocessed SUDs, and questioned the adequacy of current government oversight (noting that reprocessed devices are now bought and sold on E-Bay).³ In the wake of the *Post* series, the General Accounting Office announced plans to revisit its 2000 investigation of the reprocessing industry, which at that time found “little available evidence of harm.”⁴ Meanwhile, the reprocessing industry has stood by the safety of its practices, and has sharply criticized the *Post*’s reporting as “irresponsible,” “deliberately misleading,” and “unfairly disparag[ing to] an industry that is doing good for patients, hospitals, and the environment.”⁵

While the debate rages on, an important question lingers that has yet to attract much attention: When a reprocessed single-use device fails, who should be liable for compensating the injured patient? In other words, moving beyond the superficial “yuck factor” associated with reprocessing, how should judges, juries, and policymakers approach the difficult task of assigning legal liability for injuries caused

³*Hospitals Save Money, But Safety is Questioned*, WASH. POST (Dec. 11, 2005); *The Consequences of Cuts*, WASH. POST (Dec. 11, 2005); *Reused Devices Attract Entrepreneurs, Scrutiny*, WASH. POST (Dec. 12, 2005); *FDA Asked About Oversight of Reused Medical Devices*, WASH. POST (Dec. 17, 2005); *Used Medical Devices Being Sold on E-Bay*, WASH. POST (Dec. 22, 2005).

⁴*GAO To Examine Reuse of Single-Use Medical Devices*, Kaiser Daily Health Policy Report (Jan. 10, 2006); see also U.S. General Accounting Office, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* (June 2000) .

⁵*Nation’s Third-Party Medical Device Reprocessors: Washington Post Investigation of Reprocessed Devices Unable to Find Link Between the Safe FDA-Regulated Practice of Reprocessing and an Increase in Risk to Patients*, available at <http://www.amdr.org/news.html>.

by reprocessed devices?

If reprocessors and original equipment manufacturers (“OEMs”) agree about anything, it is that all medical devices carry some irreducible degree of risk, whether the device is being used for the first time or the fiftieth. Thus, even accepting the reprocessors’ assurances that reprocessed devices are just as safe as (if not safer than) new ones, inevitably some number of reprocessed SUDs will injure patients, just as brand-new devices sometimes do. Where OEMs and reprocessors part company, however, is on the question of assigning legal liability for injuries resulting from the failure of reprocessed devices.

The only fair policy is for reprocessors to accept full liability for placing used SUDs 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. 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.

Holding reprocessors accountable for injuries involving reused SUDs also makes sense from an economic standpoint. Reprocessors are the ones who profit from selling used devices; if risk truly follows reward, they should bear the liability risks attendant to the products they sell, and not the OEMs, who gain nothing – and stand to lose a lot – when their single-use devices are reused.

I. WHY DEVICE MANUFACTURERS FACE SIGNIFICANT LIABILITY EXPOSURE FROM REPROCESSED SINGLE-USE DEVICES

Although logic and fairness would impose liability squarely on the reprocessor when a reused device fails, there are several factors that could lead the OEM 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 Medical Device User Fee and Stabilization Act (“MDUFSA”), reprocessors must now provide a “prominent and conspicuous mark” on reprocessed single-use devices, but that requirement only took effect on August 1, 2006.⁶ Meanwhile, 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 OEM – 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’s impossible to say for sure, but in all probability OEMs have settled claims that involved reused devices, unbeknownst to them or the claimant.
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 FDA’s MedWatch adverse event report form did not specifically call for the 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. According to Lily Ng, former policy analyst in the Office of Surveillance and Biometrics at the FDA’s Center for Devices and Radiological Health, “We are aware that there could be under-reporting of adverse events because hospitals are not likely to report that they reused a

⁶See *Guidance for Industry and FDA Staff – Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices* (May 1, 2006) at 3.

device that was intended by the OEM for one-time.”⁷ This undermines any comfort one might take in the fact that reports of injuries involving reprocessed SUDs are relatively few.

4. ***Lack of Interest from the Plaintiff's Bar.*** If the paucity of reported verdicts and settlements is any indication, Reprocessors are not very attractive to plaintiffs' lawyers as targets for product liability litigation. Although the reprocessing industry has achieved record growth in recent years, the major third-party reprocessors are still smaller and less well-known than the OEMs whose products they sell. Plaintiffs' attorneys are more familiar with the OEMs from other tort litigation, and view the OEM as a better target for a larger number of cases. Most importantly, Plaintiffs' lawyers typically concentrate their efforts on the “deep pocket” defendant, which in most cases will be the OEM, not the reprocessor.
5. ***Reprocessors' Best Defense: Blame the OEM.*** If a reprocessor is sued, it will very likely argue that the original device was defective prior to any reprocessing. This compounds liability exposure for the OEM, 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.⁸ Similarly, reprocessors may also claim that the OEM had a duty to design the product to withstand repeated cleaning and reuse, and even to provide instructions on proper reprocessing, despite the fact that the device is labeled “single use only.”⁹ All of which leaves the OEM to ask, “Et tu, Brute?”

These are just a few of the reasons why device manufacturers face significant product liability exposure from reprocessed SUDs, despite the fact that they do not endorse or condone reprocessing, and explicitly warn against it through the “single

⁷Kelly M. Pyrek, *Reprocessing of Medical Devices: Government Intensifies its Scrutiny as Clinicians Debate Patient-Safety Issues*, TODAY'S SURGICENTER (Feb. 1, 2003).

⁸The website for the Association of Medical Device Reprocessors (“AMDR”) states that “if a reprocessed device injures a patient because of a design flaw in the original device, the fault lies with the original manufacturer and liability should remain with that manufacturer.” See <http://www.amdr.org/StateLegislation.html>. Similarly, AMDR's Deputy Executive Director Dan Vukelich has argued “[W]hat if it's an inherent design flaw? I'm not saying we shouldn't take responsibility, but we should take fair responsibility.” *Massachusetts Bill Considering Patient Consent Law for Reprocessed SUDs Fuels Further Debate*, INFECTION CONTROL TODAY (Feb. 1, 2006).

⁹Indeed, one of the major reprocessors has said: “If the manufacturer has knowledge that a high incidence of their devices are being reused, they have the responsibility for providing instruction for reuse according to pending FDA regulation.” *Information about Vanguard for Hospital Legal Counsel* (copy on file with Author).

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 reprocessor liable for injuries caused by a reused single-use device.

Recognizing this imbalance and the potential for injustice, Utah has adopted legislation that protects OEMs from product liability claims involving reprocessed devices.¹⁰ Other states should consider following Utah’s example. Product liability litigation is a fact of life for medical technology manufacturers, and reprocessors – who are now deemed “manufacturers” under federal law – should not be exempt. If reprocessed devices are to be treated as equivalent to new ones, reprocessors and original manufacturers should face the same risk of liability when the products they sell cause harm.

II. THE REPROCESSING CONUNDRUM: MORE DEVICE REUSE, FEWER REUSABLE DEVICES

The reprocessing industry has achieved impressive growth in a relatively short period, more than doubling its revenue from 2001-2004 and expanding to a \$125 million industry today.¹¹ The leading reprocessor of SUDs – Ascent Healthcare Solutions, formed in April 2006 through the merger of Alliance Medical Corp. and Vanguard Medical Concepts – has promised to save its customers \$92 million this

¹⁰See UTAH CODE ANN. § 78-11-28(2) (2005) (“A reprocessor who reconditions or reprocesses a critical single-use medical device assumes the liability: (a) of the original manufacturer of the critical single-use medical device; and (b) for the safety and effectiveness of the reconditioned or reprocessed critical single-use medical device”).

¹¹*Device Makers Fight Reuse of Surgical Tools*, BOSTON GLOBE (Oct. 19, 2005).

year alone.¹² All indicators point to continued growth in reprocessing; as providers' cost pressures intensify, we can expect that more devices, and more types of devices, will be reused.

Somewhat paradoxically, however, at the same time that reprocessing is expanding, new devices are becoming increasingly ill-suited to reuse. Today's medical technology is smaller, more multi-faceted, and less resilient to standard reprocessing techniques than in previous generations.¹³ As device engineering and manufacturing has become more sophisticated, even devices that appear simple – a loop of tubing, for example – can incorporate complex, microscopic features. The tubing used in many newer-generation products often has tiny surface modifications that allow for greater flexibility and enable the delivery of drugs and anesthetics. But the same small-scale features that enhance the device also create tiny voids that trap biomatter and are difficult, if not impossible, to clean without damaging the device or compromising its function. Lily Ng of CDRH remarks that “There may be no way to truly sterilize some of the complex devices to the level that healthcare workers are comfortable using them on another patient.”¹⁴ As device manufacturers continue to refine their products, we can expect those products to become harder to clean and less amenable to safe and effective reuse.

These two prevailing and opposite trends – more reprocessing, but fewer

¹²April 17, 2006 Press Release of Ascent Healthcare Solutions, *available at* <http://www.alliance-medical.com/News%20Release%20-%20Ascent%20FINAL4.3.06.pdf>.

¹³CDRH Director Daniel Schultz, M.D., has commented that “[d]evices are increasing in complexity ... and they are being miniaturized so that there's more technology in a tiny little device.” Linda Bren, *Ensuring the Safety of Medical Devices*, 40 FDA CONSUMER 11, 12 (May-June 2006).

¹⁴Pyrek, *supra* note 7.

devices that can be safely and effectively reprocessed – appear destined to collide, with potentially disastrous results for patients. Safety concerns are mitigated by the new FDA approval requirements for reprocessed SUDs. But FDA approval does not guarantee absolute safety in every instance. No medical device, new or used, is without risk, and the more reprocessed devices are used, the greater are the chances that someone will be hurt by one.

III. SAFETY VS. SAVINGS

Those concerned with the safety of SUD reprocessing cite mounting evidence that the practice is riskier than the available evidence would suggest. There is a small but growing literature showing residual contamination in some devices, and diminished performance in others.¹⁵ Also, the 2005 *Post* series raised a variety of safety concerns and reported on some patients and families who claim to have been harmed by reprocessed devices.¹⁶

Meanwhile, the reprocessing industry, citing studies supporting the safety of device reuse, emphasizes that the real issue is one of economics, not safety. While a surgical team – not to mention the patient – may be uncomfortable with the idea that a device was once used in another patient, reproprocessors claim that their rigorous

¹⁵See, e.g., Heeg P, et al., *Decontaminated single-use devices: an oxymoron that may be placing patients at risk for cross-contamination*, *Infect Control Hosp Epidemiol.* 2001 Sep;22(9):542-9; Lujt DS, et al., *Risk of infection by reprocessed and resterilized virus-contaminated catheters; an in-vitro study*, *Eur Heart J.* 2001 Mar;22(5):378-84; da Silva MV, et al., *Safety evaluation of single-use medical devices after submission to simulated reutilization cycles*, *J AOAC Int.* 2005 May-Jun;88(3):823-9.

¹⁶*Hospitals Save Money, But Safety is Questioned*, WASH. POST (Dec. 11, 2005; A01); *The Consequences of Cuts*, WASH. POST (Dec. 11, 2005; A07); *Reused Devices Attract Entrepreneurs, Scrutiny*, WASH. POST (Dec. 12, 2005; A01); *FDA Asked About Oversight of Reused Medical Devices*, WASH. POST (Dec. 17, 2005; D01); *Used Medical Devices Being Sold on E-Bay*, WASH. POST (Dec. 22, 2005; D01).

cleaning and quality control practices ensure that the reused device will be just as safe and effective the second (and third, and fourth) time around. In their view, there is no legitimate controversy over patient safety, there is only OEM propaganda – intended to scare patients, put reprocessors out of business, and deprive hospitals of savings that would otherwise go towards more nurses, new technology, and other improvements in patient care.

As with any polarized debate, the truth about reprocessing safety lies somewhere in the middle: some devices can be safely reprocessed, others cannot, and neither side will agree on which devices belong to which category. But what of the economic question? Accepting the reprocessing industry on its terms – that reprocessing is a matter of economics, not safety – are the risks and rewards of reprocessing allocated rationally and appropriately? The answer, unfortunately, is no.

IV. OEM LIABILITY FOR REUSED SUDS: A DEMONSTRATION

The following hypothetical illustrates how the liability issues could play out in an actual case:

A patient goes to her doctor for a biopsy of an intestinal growth seen on MRI. The surgeon is to perform the biopsy using a long, flexible device with a tiny scissor-like clamp at one end, which has already been removed from its packaging by the time the surgical team enters the operating room. During the procedure, the scissors stick open and one of the blades shatters as the surgeon attempts to retract the device. The patient suffers severe internal bleeding and is only stabilized after several additional hours of surgery. Fortunately, she makes a full recovery, although there is significant

scarring where the surgeon had to open her abdomen to remove the damaged device.

The hospital's investigation reveals that the device had been reprocessed, though no one in the operating room knew it at the time. The reprocessor had put its own name on the sterile packaging containing the reprocessed device, consistent with its obligations under the Medical Device User Fee and Stabilization Act of 2005 ("MDUFSA"),¹⁷ but the device itself carried no indication that it had been used before. Since the sterile packaging had been removed long before the surgical team entered the room, they had no reason to know that the device had been reprocessed.

The hospital cannot say how many times the device had been reused before the incident, since the hospital itself was not the original purchaser. The hospital has, however, used reprocessed biopsy devices like this one numerous times without incident. The hospital's investigation also reveals that "scissor-lock" and blade breakage has been reported to occur with new devices as well (though never at this hospital). Thus, after confirming with the reprocessor that the device met specifications when it left their facility, the hospital concludes that the reprocessing did not contribute to the device's failure, but rather involved a defect in the device itself.

The hospital submits a MEDWATCH report to the FDA notifying the Agency of the incident and that the device was the suspected cause of the injuries. Because the hospital has concluded that reprocessing did not compromise the device, and concerned about its own potential liability, it does not indicate in its report that the device had been reprocessed.

¹⁷See amended § 502(u) of the Food Drug & Cosmetic Act.

The FDA sends a copy of the report to the original manufacturer, who attempts to obtain more information from the hospital. Fearing litigation, the hospital refuses to release the device to the manufacturer for its own examination; thus, the manufacturer is unable to verify the cause behind the device's failure. Based on its own product testing, the company has estimated the risk of "scissor lock" at about .0004, or 4 failures per 10,000 devices. But the number of reports in the FDA's database, including this one, points to a much higher failure rate – as high as 4 failures per *thousand* devices. The company is very concerned about the higher rate, which it attributes to an increasing number of reprocessed devices on the market.

Six months later, the patient brings a lawsuit naming the hospital and the OEM as defendants. As discovery in the case proceeds, it is eventually discovered that the device had been reprocessed, and the plaintiff brings the reprocessor into the case as an additional defendant.

Discovery reveals that early in the development of the product, the OEM decided that it would not seek FDA approval to market it as reusable. This would have required expensive validation testing; moreover, the company's engineers doubted that the device could be cleaned and re-sterilized without compromising its performance. The OEM therefore labeled the device "SINGLE USE ONLY" and did no testing to evaluate the device's safety or effectiveness beyond the first use. The company also set a price lower than it would have for a reusable device, recognizing that customers would not pay as much for a disposable device.

It is further disclosed that not long after launching the product, the manufacturer learned that instead of throwing the scissors out after one use, hospitals

were sending them out for reprocessing. In the following months, sales of the device flattened and then declined, confirming that reprocessing had made significant inroads into the market. The manufacturer instructed its representatives to remind their accounts that the safety and effectiveness of the device has not been established beyond a single use. It also sends letters to the major reproprocessors with the same warning, and notifying them that it would seek indemnification from any personal injury lawsuits involving reprocessed devices. But nothing the manufacturer does seems to slow the steady increase in reprocessing of its product.

The manufacturer's product liability insurer – who, so far, has been paying for the defense of the case – based its coverage, and its premiums, on the understanding that each device would only be used once. When the insurer learns that the manufacturer was well aware that its devices were being reused, but failed to inform the insurer of that fact, the manufacturer's coverage is suddenly placed in jeopardy. The insurer sends the manufacturer a "reservation of rights" letter, conveying that it would continue paying for the manufacturer's defense, but reserved its right to recover those amounts and decline the claim.

The case goes to trial against the hospital, the reproprocessor, and the OEM. The hospital argues that its staff performed the operation within the standard of care; but for the failure of the device, there would not have been any injury. They also defend their use of reprocessed equipment, arguing that the reprocessing did not affect the device; that it failed due to an inherent design flaw; and that it could not afford to pay the manufacturer's exorbitant prices for new devices without sacrificing other important aspects of patient care.

In making its defense, the reprocessor emphasizes to the jury that it carefully follows the FDA's "Good Manufacturing Practices" regulations and has an excellent safety record. It touts the fact that there are only three unconfirmed reports of failure involving any of its reprocessed devices, among millions of devices sold. Like the hospital, the reprocessor argues that the device failed due to an inherent design flaw – which is evidenced by the greater-than-expected number of adverse events involving new devices.

In closing arguments, attorneys for the reprocessor and the hospital underscore the amount of money the hospital has saved through reprocessing, and the improvements those savings have allowed in other areas of patient care. They claim that the "single use" instruction has nothing to do with safety and is just a ploy to sell more new devices. Finally, they accuse the manufacturer of hypocrisy for questioning the safety of reprocessing, when their own data shows that their device can and sometimes does fail on its very first use.

The manufacturer's lawyer attempts to explain that the safety concerns are legitimate, but she lacks any concrete evidence to establish that reprocessing compromised the device (mainly because the hospital failed to preserve the device following the incident). At this point, the jury isn't listening much anyway. The plaintiff's lawyer leaves the defendants to fight amongst themselves on liability, and focuses instead on the plaintiff's overall damages – knowing that the finger-pointing among the defendants will only increase the potential for a major award.

The jury comes back with a sizeable plaintiff's verdict, apportioned 15% each to the hospital and reprocessor, and 70% to the OEM. The trial is now moving into the

punitive damages phase, and the OEM is left to wonder whether it will even have insurance coverage to protect against a potentially catastrophic loss.

CONCLUSION: MATCHING RISK TO REWARD

Obviously, not every product liability case involving a reprocessed SUD will follow the thread of the foregoing hypothetical. The results could be worse for the OEM, or they could be much better; a defense verdict could be a realistic and attainable goal in many cases. But no matter how well the OEM fares, the fundamental unfairness remains: the OEM is facing liability for a product it did not sell, and whose quality and characteristics after the first use are beyond its control. Worse, the party that made the sale – the reprocessor – is the OEM’s primary competitor, who steadily erodes new device sales while providing nothing in return to the OEM.

An OEM’s “single-use” designation reflects either (1) that the device is not safe and effective when reused, or (2) that the OEM 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 reproducers 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 OEMs should be granted immunity – for claims involving products that, according to the manufacturer’s express instruction, should have been thrown out instead of recycled.

So far, the reprocessing industry has refused to acknowledge any responsibility for product liability claims beyond errors in cleaning and re-sterilizing the device. Reprocessors cry foul over the lack of attention paid to failure rates for new devices as compared with reprocessed ones, and claim that reprocessed devices are actually less prone to fail due to the thorough testing they receive before being cleared for reuse. But this objection highlights a very important liability consideration: by putting used devices back on the shelf, reprocessing *increases* the statistical likelihood that the product will fail. Neither side denies that the future promises a steady increase in the number of procedures performed with reprocessed equipment, and that 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 thirtieth) use, or by damaging the device during reprocessing, or both – will be the one assigned the liability.