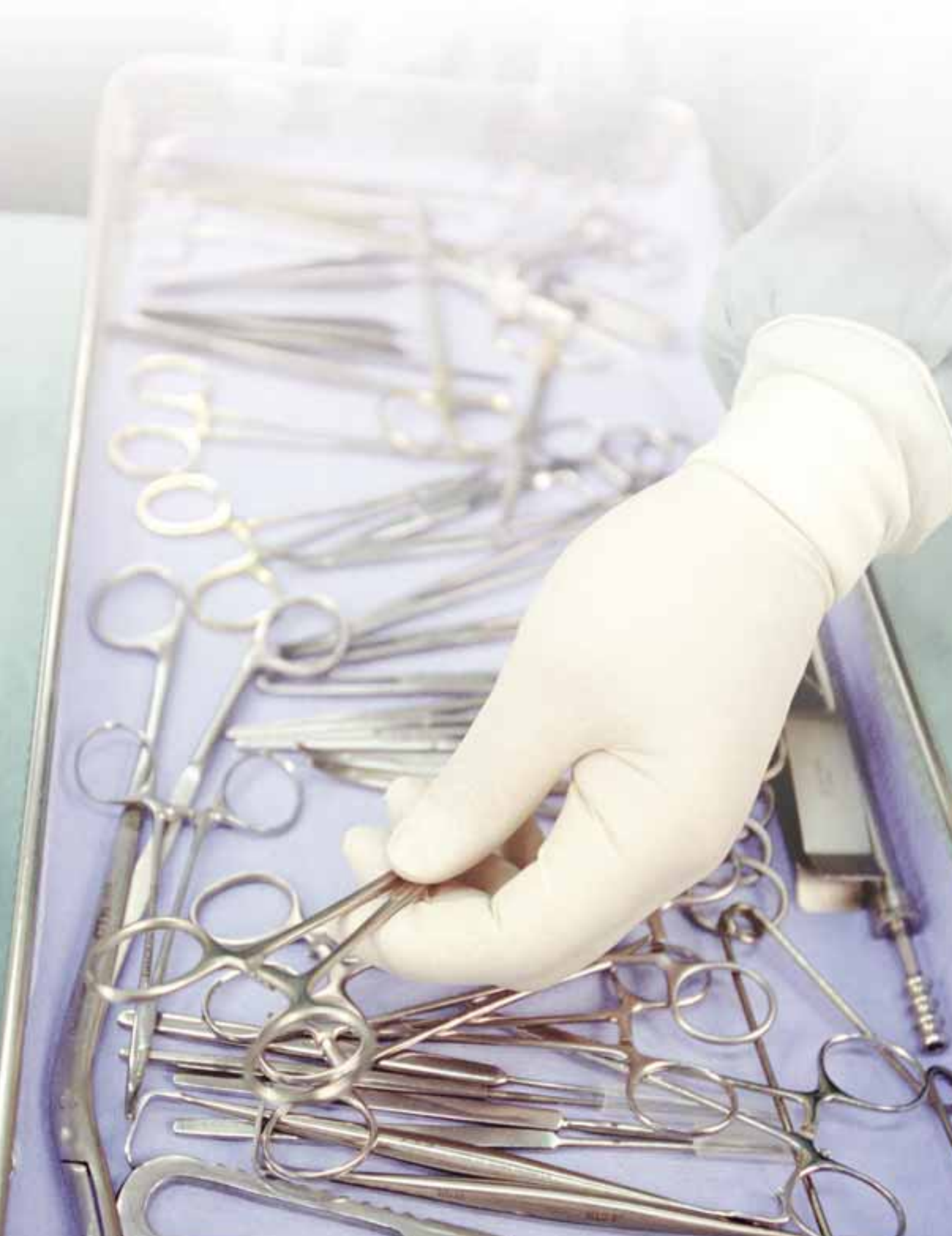

THIRD-PARTY REPROCESSING OF SINGLE-USE DEVICES IN THE OPERATING ROOM: A MANAGERIAL PERSPECTIVE

Jeffrey J Cortese, CST

Health care costs continue to soar, while providers struggle to keep costs low. The operating room is no exception. The average charge for use of the operating room itself is in the range of $30-$35 a minute. This charge, combined with anesthesia, personnel, X-rays, and supply charges, can represent an enormous debt for a patient without insurance and for the hospital to tolerate. One way to combat these costs is to reprocess single-use devices (SUDs).

Not a new concept, the reprocessing of single-use devices can save the facility thousands of dollars in supplies, while maintaining a high standard of care for the surgical patient. In these days of lower reimbursements, escalating costs of supplies, and shortages of staff, reprocessing seems to be a very sensible way of saving money in the operating room.

With the emergence of third-party reprocessors, the Food and Drug Administration (FDA) has become more involved in the regulation of reprocessed single-use devices. Guidelines for reprocessing and regulatory requirements have been spelled out for these companies as well as for hospitals.

When an institution first considers implementing single-use device reprocessing, there will be opposition to the idea. However, instruments and other devices are reprocessed on a daily basis without an increased risk to the patient. Therefore, the reprocessing of devices labeled as "single use" can be utilized in the health care setting.

Editor's Note: In an effort to keep our members informed of issues in the operating room, AST is providing two perspectives on the controversial topic of reprocessing. The use of single-use devices is just one of the topics that the AST Standards of Practice Subpanel will address in their work.

To express your opinion or relate your experience with reprocessing or single-use devices, please log onto the AST Discussion Server at www.ast.org/forum. First time participants will need to register before posting. Registration is free.

Review of literature

Belkin reported on the reuse of single-use devices as a matter of economics. According to the General Accounting Office, 30% of hospitals included in a survey are reusing single-use devices.[1] The benefits of reprocessing single-use devices are several. The cost of reprocessing is less than that of purchasing a new item. Belkin proposes that the transition from the era of single-use devices to those that are reusable might be one of the elements of change that will emerge during the US reform of the health care system.[1]

An article surveyed in *Hospital Materials Management* showed that more institutions are deciding to hire third-party companies to reprocess single-use devices.[5] The article described a study in which the FDA surveyed hospitals with 250 or more beds on their particular reprocessing protocols. The survey showed that 45% of the hospitals reprocess single-use devices, and 84% of those hospitals employ an out-of-house reprocessing company.[5] Of all of the Veterans Hospitals in Texas, members saved a total of $25 million during the first year of implementing a reprocessing program.[5] Another health care system in Norfolk, Virginia, which is comprised of six hospitals, saved a total of $505,000 by reprocessing.[5] During the first year of utilizing a third-party reprocessing company, $90,000 was saved in Concord, Massachusetts, by utilizing a third-party reprocessor located in the state.[5]

In an article assessed in *Same-Day Surgery,* the FDA reported that 25% of all hospitals in the United States reuse single-use devices.[6] Of these devices, sequential compression devices comprised 15.8% of the items that are reprocessed. Drill bits, saw blades, burrs, biopsy forceps, and snares were some of the other items that were reprocessed.[6]

In an article published in *Biomedical Safety & Standards,* the FDA published the results of a survey regarding the reuse of single-use devices.[2] The article pointed out that hospitals with 100 beds or fewer (60% of the hospitals surveyed) tend to reprocess single-use devices in-house.[2] The survey also reported that 24.2% of all the US hospitals surveyed reuse single-use devices on other patients.[2]

Interestingly, *Healthcare Risk Management* published an article on what health care professionals thought about the reprocessing of single-use devices.[3] Out of the surgeons surveyed, three out of four believed that the reprocessing of single-use devices posed a threat to the surgical patient.[3] Seventy-nine percent of the nurses interviewed thought that the use of reprocessed single-use devices should be discontinued.[3] Out of the 82 nurses interviewed, 71% state that they would feel uncomfortable if a reprocessed single-use device was used on them or one of their family members.[3] Finally, the article pointed out that the patient population would expect to be informed about the practice of using reprocessed single-use devices at a ratio of two to one.[3]

In 2000, Janet Heinrich, associate director, Health Financing and Public Health Issues, Health Education, and Human Services Division, testified before the United States General Accounting Office on the reprocessing of single-use devices.[4] Her testimony focused on the extent of single-use device reprocessing, the health risks associated with the reprocessing, and the cost savings of reprocessing single-use devices. She pointed out that, after various surveys were conducted, 20% to 30% of American hospitals reuse at least one type of single use device.[4] One-third of the hospitals that took part in this survey employ third-party companies to reprocess the devices.[4]

Heinrich reported that the reprocessing of some devices could be 10% less than the same item purchased new from the company.[4] Her testimony identified only 13 third-party reprocessing companies in the United States. For these companies, $20 million per company was received annually for their services.[4]

Experts at the Centers for Disease Control (CDC) have proven that reprocessing of single-use devices poses a minimal health risk to the public. Of the hospitals that were surveyed, none received any claims of patient injuries resulting from the use of reprocessed single-use devices. Although the reprocessing of single-use devices is relatively safe, there have been a few incidents. A manufacturer in 1999 told the FDA that six

reprocessed biopsy forceps used in gastrointestinal endoscopies were not sterile upon retrieval from one Florida hospital.[4]

William B Stoermer Jr published an article in *Medical Device & Diagnostic Industry* magazine on the debate of reprocessing single-use devices. Stoermer explained that reprocessing is a standard practice in the United States today.[7] As Stoermer explained, "Certain reusable instruments are often provided to the hospital on loan from a manufacturer. Although such devices sometimes arrive at the hospital packaged and sterilized, more often than not these manufacturer-provided instruments are delivered nonsterile by the company representative in the trunk of his or her car—just in time for the hospital to sterilize them for use in the surgical procedure for which they have been requested. Very seldom are biological indicators (BIs) run to assure the sterility of such loaner instrument trays, even though the bioburden level is totally unknown. Is this practice considered safe? If the answer is 'Yes,' then why not reprocess and sterilize the single-use saw blade or drill bit as well?"[7]

Stoermer posed the question, "Should all single-use devices be reprocessed?" He stated that there are usually no distinctions drawn concerning the risk of reuse of various devices.[7] When choosing what items can be reprocessed, keep this in mind: if the item cannot be cleaned effectively, then the item cannot be sterilized. The emergence of third-party reprocessors has raised the standards of what items are reprocessed and the manner in which they are processed.[7]

With regard to third party reprocessing versus in-hospital reprocessing, Stoermer pointed out major differences between the two.[7] These third-party reprocessors operate on a different level than the hospitals. These corporations are regulated by the FDA, while the hospitals are regulated by the Occupational Safety and Health Administration (OSHA). For all practical purposes, the FDA is more stringent on regulation than OSHA. However, the FDA's policy concerning third party reprocessing is still an unclear one, leaving some loopholes in the system. It states that the reprocessing of sin-

Definitions of Terms

Bioburden: The number and types of viable microorganisms that contaminate an article.

Clean: Removal of visible contaminants and environmental debris (eg, microscopic particles of tissue, body fluids, dust, body waste, dirt).

Opened but unused: Disposable devices for which sterility has been breached or compromised or the sterile package had been opened but not placed on the surgical field.

Opened but unused and contaminated: Devices placed on the surgical field that were not used during the procedure and are free from visible contamination (eg, tissue, blood, body fluids).

Reprocessing: Disassembling, decontaminating, cleaning, inspecting, testing, packaging, relabeling, and sterilizing single-use devices (SUDs) after they have been used on a patient for their intended purpose. Reprocessing also is performed on SUDs that had been removed from the package but not used on a patient or whose expiration date had passed.

Resterilization: The repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level. This process is performed on devices with an expiration date that has passed or that have been opened and may or may not have been used on a patient.

Single-use device (SUD): A disposable device, usually labeled as such by the original manufacturer, manufactured for single use and not intended to be reprocessed or reused.

Sterilization: Act or process that completely eliminates or destroys all forms of life, particularly microorganisms.

Third-party reprocessor: A business establishment, separate from the original equipment manufacturer and the user facility, whose primary business is to reprocess single-use devices.

gle-use devices is lawful as long as the company abides by all regulatory requirements enforced on them.[7]

Finally, Stoermer explained some of the benefits of reprocessing single-use devices. With the ever-present rise in health care costs, changes in reimbursement, and downsizing of staff, hospitals are forced to finds ways of increasing revenue without raising the price of the care.[7] One way of increasing revenue is by reprocessing disposable devices. After effective cleaning, testing, repackaging, and sterilization, these items can be used safely to help the patient.[7]

Discussion

Single-use devices in surgery are as common as suture material. Surgical drapes, gloves, gowns, sponges, and even some instrumentation are just a few examples of single-use devices in the operating room. Surgical drapes and gowns have always been reprocessed for multiple uses. Sponges and gloves, although reusable many decades ago, are now truly disposable items.

The majority of surgical instrumentation used in the operating room setting is reusable. For the item to be of single-use caliber, the quality has to be exceptional and the cost high enough to justify reprocessing. Reprocessing some items could save a department as much as half the replacement cost of purchasing a new item. For example, the average cost of a surgical saw blade used in open-heart surgery (sternotomy blade) is about $50. This disposable, high quality item is used once to make a cut into the sternum and then discarded. If an institution performs 300 open-heart surgeries a year, the cost for new saw blades from the manufacturer would total $15,000. Keep in mind, this cost is for one item that is used in one type of surgery and doesn't take into account the other types of surgeries that require the use of saw blades. Compared to the cost of reprocessing this blade, the cost for purchasing it new can be excessive.

Now consider the use of a reprocessed blade. The process begins in the operating room itself. The surgical technologist separates the items for reprocessing into special containers provided by the third-party reprocessor. These items are then sent to the central sterile department for cleaning. For example, used items may be cleaned by immersion in an ultrasonic bath. After the cleaning process, the items are packaged to be shipped out for reprocessing.

Upon arrival at the reprocessing facility, the items are bar coded, labeled and logged into the reprocessor's tracking system. This identifies the item's health care facility, departmental ownership, job number, and reprocessing history. After sorting, the items are manually and ultrasonically decontaminated. All processing data is saved in a database for future reference. For saw blades, the company uses computer-controlled methods that sharpen to the half micron. This method can also be applied to orthopedic devices, such as burrs and drill bits.

After the final inspection, the items are packaged for final sterilization. The labels on the package retain the printed barcode so the facility can trace the exact history of the item within. The items are then sterilized in ethylene oxide and shipped back to the correct department of the originating facility.

The turn-around time for a blade to be reprocessed is about two weeks. Once a facility builds an inventory of reprocessed items, the turnaround time will seem shorter because they will have an ample number of reprocessed items on the shelf. The cost of reprocessing each saw blade is $25. For this one item, used in one type of surgery, the overall annual savings would total $7,500.

Saw blades and orthopedic items are not the only single-use items that can be reprocessed. The most commonly reprocessed items are sequential compression devices. These sleeves, made of either plastic or fabric, are placed around the legs of patients who are nonambulatory. These sleeves inflate and deflate to massage the legs, thus decreasing the chance of a deep vein thrombosis or blood clot. Every patient scheduled in the operating room for more than one hour receives these sleeves. A majority of the time, these sleeves are discarded once the patient is discharged from the recovery room.

The amount of money saved by using a reprocessed sleeve, in comparison to purchasing a new sleeve, is very impressive. Institutions across the country are saving anywhere from $90,000 for a single hospital to $25 million for a state-wide health network. This savings can be applied to other areas of the department in need of upgrade or repair or can be used to purchase new technology or instrumentation. The possibility of saving money, while maintaining a high standard of care for the patient, is not an unrealistic one.

The FDA has become the driving force behind the third-party reprocessing companies in the United States. They have improved regulatory requirements placed on the third-party reprocessors, as well as hospitals that are reprocessing their own single-use devices. This major involvement has given the backing that the third-party reprocessors, which represent 85% of the reprocessing market, need since there are many institutions that frown upon reprocessing.

With regard to the acceptance of reprocessing of single-use devices, the numbers speak for themselves. After reviewing the money saved with reprocessing, along with education for the staff, it is easy to surmise that reprocessing single-use devices saves dollars. One must have an open mind when looking at the potential benefits of using reprocessed devices, since the quality of the processing is strictly regulated.

Conclusion

The current cost for a minor surgery to be performed would stagger most people who are not in the health care field. Combine this with the ever rising costs of equipment and supplies, lowered reimbursements and staffing reductions, one can easily deduce why a surgical services department would consider reprocessing single-use devices for multiple patient use.

Hospitals with an operating room in their facility process hundreds of surgical instrumentation on a daily basis. The majority of these instruments are of a solid metal design, such as a hemostat or scissors. However, many hospitals reprocess instruments and other devices made of other materials, such as plastic and cloth.

It is common for manufacturers to label products for single use. This action is mostly economically driven. Products have to meet certain FDA standards before they are made available for purchase. Those standards are the same for any product, regardless of whether that product is intended for single or multiple use. Therefore, the manufacturers are able to benefit economically by selling more products as single use items, than selling a product of the same quality labeled as a reusable item.

On a daily basis, instrumentation is reprocessed for multiple patient uses. Instrumentation with complex inner workings are effectively cleaned, checked, and sterilized to be used on the next surgical patient. A common example is the reprocessing of laparoscopic equipment. These instruments have several working parts, housed in a tube which allows passage into the body via small ports placed in the abdominal wall. These instruments have the capability of being broken down into a few parts. These parts are cleaned, rinsed, and reassembled for sterilization and, eventually, for use on the next surgical patient. Therefore, why cannot other items with the same characteristics as these instruments, be handled in a similar fashion? With the correct protocol in place for cleaning, disinfection, packaging and sterilization, items that were once considered disposable are being reused safely and at a substantially lower cost to the hospital.

To date, there are approximately 15 third-party companies that specialize in the reprocessing of single-use devices. These companies are strictly regulated by the FDA to ensure that the highest quality is adhered to during reprocessing. With the employment of a third-party reprocessor, a health care facility can save hundreds of thousands of dollars a year in supplies, as well as reduce the amount of biohazard waste in our already diseased planet. These savings could be put to more beneficial uses, such as the purchases of new equipment, research, or community programs.

The outsourcing of nonclinical areas of the hospital is becoming a national trend. Companies that specialize in one area of the health

care facility tend to be more productive, while maintaining or exceeding the existing quality of work. These companies assume all liability for the function, safety, and quality of the items they reprocess. The most obvious benefit of reprocessing is the potential for saving money.

To determine the potential savings of a reuse program, estimate the maximum number of times a device can be reused before it is discarded. A conservative approach is to divide that number by a reasonable safety factor of two. The maximum number of reuses, therefore, is reduced by one-half. Again, most of the savings associated with reuse are achieved in the first reuse cycle, with successive reprocessing yielding progressively decreasing savings. The potential risks associated with reusing SUDs provide sound rationale for minimizing the number of reuses, because the more reuse cycles performed, the greater the risk of adverse events occurring.

The most significant issue in evaluating a reuse program is patient safety. Before designing or implementing a reprocessing program, health care facilities must perform careful cost analyses to ensure that cost savings are realized. The steps involved in reprocessing (cleaning and inspecting, packaging, sterilizing, tracking, testing, validating) are numerous and complex. This process cannot be implemented casually. It must be controlled and vigorously monitored to ensure clean and sterilized reprocessed items are used.

Patient safety is paramount in all phases of reprocessing. Any item that cannot be guaranteed to be free from blood, fluid, body tissues, bioburden, or other contaminants should not be included in a reprocessing program. Policies and procedures should be established in measurable, objective terms to support each phase of reprocessing, and this process should be supported by senior management. Facilities are responsible for demonstrating that reprocessed devices continue to be safe, effective, and of high quality.

About the author

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Additional resources

Janet Heinrich's testimony before the Committee on Health, Education, Labor and Pensions, US Senate on Medical Devices: Reprocessing and Reuse of Devices Labeled Single-Use is available online at ***www.amdr.org/documents/he00143tTestimony.pdf***.

Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals published by the Food and Drug Administration, the US Department of Heath and Human Services, and the Center for Devices and Radiological Health is available online at ***www.fda.gov/cdrh/comp/guidance/1168.pdf***.

REPROCESSING OF SINGLE USE DEVICES IS RISKY BUSINESS

TERI JUNGE, CST, CFA

Is reprocessing single-use devices (SUDs) a risky business? Yes! Why? To answer this question, three main issues must be taken into consideration.

First, cross contamination must be considered. Single-use items are not designed to allow disassembly for proper cleaning, decontamination, and sterilization. According to Eucomed, recent studies show blood residue and dirt may be retained due to the difficulty/impossibility of cleaning single-use devices. Additionally, contamination from infectious particles, such as the prion that causes Creutzfeldt Jacob Disease (CJD) that are resistant to conventional methods of sterilization, may be present. The presence of pathogens puts both the health-care worker and the patient at risk.

Second, performance issues must be considered. Items intended to be disposable are manufactured to be assembled only one time and may not be capable of withstanding the conditions of disassembly, cleaning, reassembly, repackaging, resterilization, and reuse without compromise. Compromise—such as corrosion, distortion, a change in the pliability of the item, and other physical alterations, such as chipping and cracking—may occur when an item is exposed to various sterilization processes. The item's strength may not be sufficient to withstand multiple uses. This may cause the patient to suffer a poor, postoperative result, due to impaired performance, or experience a retained foreign body, due to breakage. Additionally, certain components of a disposable device may retain toxic residue from various resterilization processes. For example, an item originally sterilized utilizing ionizing radiation may be subsequently sterilized with ethylene oxide, which may cause toxic residue to be retained in/on the item. Reprocessing a single-use device will most likely void the manufacturer's warranty.

Third, legal/ethical issues must be considered. Do patients have the right to know that items intended for single use are being reused for their procedures? Should informed consent be obtained prior to use of such an item? What type of records should be kept on these items? Who will assume liability if a problem should occur?

The name alone, "single-use device," should offer the first indication that the devices are intended to be used just once. Several national/international organizations, including the International Association of Healthcare Central Service Materiel Management, AORN, and the British Society of Gastroenterology, have raised concerns in opposition to reprocessing of single use items. In Australia, an outbreak of hepatitis C virus, with a possible link to the reuse of single-use medical devices, caused 22 facilities to ban the reuse of reprocessed items completely. Further study and strict regulation of reprocessing protocol must be in place for this practice to be widely adopted.

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CE Exam

252 FEBRUARY 2005 2 CE CREDITS IN CATEGORY 1

Third party reprocessing of single use devices

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1. The primary factor driving the trend toward reprocessing SUDs is:
a. cost savings
b. safety
c. time savings
d. staff shortages

2. Which group is the most involved in the regulation of reprocessed single-use devices?
a. AHA
b. FDA
c. OSHA
d. CDC

3. According to at *Healthcare Risk Management* article, ____ believed the reprocessing of SUDs posed a treat to surgical patients.
a. 70% of nurses
b. three of four surgeons
c. 60% of hospitals
d. none oppose reprocessing

4. Third party reprocessors are regulated by ____; hospitals are regulated by ____.
a. OSHA; AHA
b. FDA; AHA
c. CDC; OSHA
d. FDA; OSHA

5. For an item to be considered for reprocessing, it must be:
a. of high quality
b. costly enough to justify the expense
c. capable of being cleaned and sterilized
d. all of the above

6. Bar codes on reprocessed items do not track:
a. hospital name
b. reprocessing history
c. patients' names
d. department within the hospital

7. The most common SUD reprocessed is:
a. sternotomy blades
b. sequential compression devices
c. burrs and drill bits
d. gloves

8. A benefit of a reprocessing program is:
a. biohazard waste reduction
b. cost savings
c. funding for new initiatives (equipment, etc)
d. all are benefits

9. The most significant issue in evaluating a reuse program is:
a. patient safety
b. cost savings
c. hospital efficiency
d. funding for new initiatives (equipment, etc)

10. ____ is an important consideration proposed by opponents to SUD reprocessing.
a. cross contamination
b. performance issues
c. legal/ethical issues
d. all of the above

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Third party reprocessing of single use devices

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2	❑	❑	❑	❑	7	❑	❑	❑	❑
3	❑	❑	❑	❑	8	❑	❑	❑	❑
4	❑	❑	❑	❑	9	❑	❑	❑	❑
5	❑	❑	❑	❑	10	❑	❑	❑	❑

Mark one box next to each number. Only one correct or best answer can be selected for each question.