Careful attention must be given to the reprocessing of reusable medical devices. Technological advances in surgical techniques have continually evolved over the years and have required that surgical instrumentation and how instruments are processed keep pace. Today, there is a vast array of different instruments, in many sizes, designs, and complexity, which pose a tremendous challenge for the decontamination process in the healthcare setting. A decontamination process assessment must address how the device is to be used, the type of expected contamination and the potential risk to the patient of infectious pathogens.
Organic contaminants must be removed prior to processing. If these contaminants are not removed, they can neutralize the effect of sterilization or disinfection. Decontamination can be best standardized with a mechanical process. At times, manual cleaning is recommended for a device, i.e. endoscopes. Before decontamination, there are essential steps that must take place. These include keeping instruments moist after use to prevent encrustation and clogging of bioburden, as well as utilizing pre-soak cleaners at point of use to begin the breakdown of contaminants.

Mechanical action includes the use of special brushes for hard-to-clean areas such as hinges, joints and within lumened and cannulated devices. A thorough cleaning remains the most integral step in the decontamination process. The most important concept when dealing with reusable products is to sterilize such products between patients.

Deciding how to proceed depends on the type of item involved and its intended use. The Spaulding Classification was developed to give healthcare staff guidelines for determining the appropriate level of sterilization or disinfection for medical devices.

Items classified as critical devices by Spaulding, such as surgical instruments that enter vascular systems or sterile body tissues, pose the highest risk of infection transmission.

These devices require cleaning and sterilization prior to reuse. (See table on page 71.)

The importance of properly processing surgical instruments for the protection of patients cannot be overemphasized. People’s lives depend on it.

Microorganisms vary in resistance to disinfection and sterilization. Bacterial spores represent the greatest challenge. Processing surgical instruments is a risky business. Surgical instruments can be hazardous and could pose a serious risk to the patient if not adequately processed to provide a sterile product. As Bethta Litsky, Ph.D., a well-known microbiologist wrote: “An unsterile item used in surgery can be as dangerous as a loaded gun.”

All forms of sterilization are intended to kill microorganisms. Sterilizing an item involves three essential factors:
1. Conditions lethal to microorganisms must be present;
2. The amount of bioburden must be low enough to ensure the effectiveness of the sterilization process; and
3. There must be adequate contact of the sterilant for sufficient time on and within all surfaces of the item.

Disinfection is the destruction of pathogenic microbes by thermal or chemical processes. It is less lethal than sterilization. Even high-level disinfection can be ineffective against some bacterial spores.

When it comes to reprocessing surgical instruments in today’s ever-changing healthcare environment, a combination of three important factors—people, process and product—play a critical role in helping to ensure that surgical instruments will be adequately processed.

The combination of these factors contributes to safe patient outcome, in a cost-effective manner.

The People

Processing staff must be educated, trained, and demonstrate competency. The staff responsible for reprocessing surgical instruments requires specific knowledge and skills in the technical aspects of cleaning, packaging, sterilization and quality control of items to be reprocessed. The processing staff must be committed to develop the technical knowledge and skills needed through training, education, in-service and continuing education programs. In addition to on-the-job training for the processing staff, some healthcare facilities provide educational programs on-site, or encourage and support formal education of staff off-site, as well as certification.

Processing staff members must understand the principles of basic microbiology, infection control, instrument cleaning, inspection and assembly, packaging and sterilization. Technical aspects of the job requires the staff to be knowledgeable and currently informed about procedures and techniques, OSHA and JCAHO requirements, and AAMI recommended standards.

As surgical instrumentation changes, the processing staff must keep up with progress and respond to the current demands. Through continued learning opportunities offered at seminars, conferences, workshops and

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>LEVEL</th>
<th>RISK</th>
<th>OBJECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Sterilization</td>
<td>Very high</td>
<td>Touch bone or penetrate tissue; blood present</td>
</tr>
<tr>
<td>Semi-Critical</td>
<td>High level disinfection</td>
<td>Moderate</td>
<td>Touch mucous membrane but not penetrate; no blood</td>
</tr>
<tr>
<td>Non-Critical</td>
<td>Intermediate level</td>
<td>Low</td>
<td>Unbroken skin contact; no blood</td>
</tr>
</tbody>
</table>
The Basics of Reprocessing

- Always decontaminate devices prior to sterilization.
- Carefully follow manufacturer’s instructions for use.
- Treat used instruments as soon as possible.
- Rinse off gross soil.
- Open hinged instruments.
- Where possible, disassemble all components.
- Use only compatible products and accessories.
- Send through the complete process.
- Rinse with filtered or de-ionized water.
- Always dry thoroughly.

Evaluating Procedures

- Gravity flash to pre-vacuum flash sterilization
- Rinsing and flashing to fully decontaminating and flashing
- Time dating to event related practices
- Wrapping to use of sealed containers
- High-alkaline detergents to multi-enzymatic and pH neutral products
- The use of peel pouches in containers and wrapped packages to metal insert boxes

It is essential that the processing staffs receive specific training regarding their responsibilities and that written policies and procedures are readily available in the work area for reference by the staff. Staff should follow procedures consistently and strive to achieve the goal of 100% adherence.

The Process

Policies and procedures establish authority, responsibility, and accountability and help to control the outcome. They should be developed, implemented, reviewed periodically and revised as necessary. In the processing area, policies and procedures should address the major processing functions performed including cleaning, decontamination, inspection and assembly, packaging and sterilization.

Staff should follow procedures consistently and strive to achieve the goal of 100% adherence.
The authors recently conducted a survey of infection control and sterile processing practices that are being put out to pasture as well as new rituals that have been put into practice.

However, some new sacred cows need to be put out to pasture, and quickly. Examples include the assumption that peel pouches need no internal indicator, to use of germicides to wipe down sterilization containers as well as some surgical instruments without rinsing, to utilizing sterilization containers with valves that no one ever cleans to filters that never need to be changed, to flashing instruments in open pans, to placing wet instruments in flash pans and expecting a dry outcome, and using cleaning brushes with stainless steel bristles on instrument surfaces.

Another area requiring a thorough review is the issue of the three-minute gravity flash. It is important to note that the “minimum” exposure time is three minutes at 270°F. ANSI/AAMI ST37 refers to a “minimum” of three-minutes for non-porous items and Steris recommends a “minimum” of three minutes for a single flashed item in their systems. In fact, gravity displacement steam is an imperfect method, which is further challenged by the type of load processed, by the quality of the steam and the steam source, by the generation of the autoclave, by the size of the chamber, and whether the chamber is jacketed and the load pre-conditioned. Remember, overkill is required to reach 106 SAL.

**The Product**

New products offering technological improvements are constantly being developed and introduced in the marketplace. It is important for healthcare professionals to be aware and informed of the newest state-of-the-art products and latest innovative technology designed to meet ever-changing healthcare needs.

Products used for reprocessing surgical instruments should protect patients, staff, instruments and the bottom line. The same products must be environmentally safe.

“An unsterile item used in surgery can be as dangerous as a loaded gun.”

—Bethta Litsky, Ph.D.
Healthcare staffs have a choice of many products that can be used in reprocessing surgical instruments. The challenge is to make the right choice…the best choice. The staff needs to evaluate the options and weigh the variables. But the selection process can sometimes be overwhelming.

Healthcare staffs have a choice of many products that can be used in reprocessing surgical instruments. The challenge is to make the right choice…the best choice. The staff needs to evaluate the options and weigh the variables. But the selection process can sometimes be overwhelming.

General product evaluation criteria that have been used by healthcare staff to assist in establishing a basis for product selection include cost, quality, service, and comparison of similar products. Price, coupled with cost-effectiveness and value added services such as on-going education, support and service should make price the final consideration after all other criteria have been weighed.

Additionally, manufacturers can often provide specific criteria that can be used to assist in the evaluation of the product. Also, when evaluating products, it is essential that product claims be supported by pertinent written documentation such as technical reports, validation test results, and FDA 510k, if applicable. Be sure to get the facts, in writing.

An in-service should be conducted for all staff prior to the start of the evaluation. A written report by the participating staff at the conclusion of the evaluation period is crucial to assist the staff in making the decision to select the product that best meets their needs.

It is also essential that staff receive an in-service when any new product is going to be placed into use and that emphasis is placed on the need to always follow the manufacturer’s written instructions for use. Ongoing review and monitoring of products is necessary in order to determine if the products meet changing needs.

Conclusion
Take the time to look at your healthcare facility’s processing department and assess how decontamination is being done and review the results. Ask yourself the following questions:

- Is the staff performing the processing functions qualified and competent?
- Are proper procedures in place in the department and consistently followed?
- Are products that are currently in use safe, efficient and cost-effective?
Explore the possibilities for ways to improve what you are doing and also ways to save the healthcare facility money. Then, take the necessary action to meet the challenges impacting the reprocessing of reusable medical devices and find solutions to achieve the safest patient outcome, in a cost-effective way. Remember the age old saying, *You get what you pay for*. When it comes to reprocessing surgical devices, patients’ lives are in your hands.

Arlene Carlo, RN, BSN, FCSP, and Marcia Frieze, MS, have authored numerous articles relating to infection control, instrument processing, procedure tray organization as well as service excellence. Ms. Carlo, clinical specialist for Case Medical, is an experienced central service manager and educator. She was recently awarded the Leonard Leipus Award by the American Society for Healthcare Central Service Professionals (ASHCSP) for her contributions to the central service healthcare profession.

Ms. Frieze is CEO of Case Medical. She has been instrumental in developing the company’s synergistic line of SteriTite® sealed containers, MediTray® products and Case Solutions for safe and effective decontamination of medical devices. The SteriTite® system has been called the “benchmark for sealed container systems.”

The SteriTite® system can be used in traditional sterilization methods as well as in the newest processes, such as low-temperature gas plasma sterilization. Now, the same product with FlashTite® valve plate can be used to rapidly sterilize instrument sets in pre-vacuum flash and gravity displacement flash sterilization. Furthermore, the SteriTite® container comes with a full range of modular inserts that can be wrapped or serve as accessories to the device. Case Medical’s line of products also includes PentaPrep, a ready-to-use, multi-enzymatic presoak that is safe for surgical instruments and for sterilization containers. For more information about the company and its line of products, visit www.casemedical.com.