Reprocessed Single-Use Devices

ABSTRACT: The reprocessing and reuse of single-use instruments has become increasingly common. Although there are limited data on reprocessed single-use devices, existing studies have found a significant rate of physical defects, performance issues, or improper decontamination. There are currently no data in the medical literature of studies evaluating the cost-effectiveness of reprocessed single-use devices in gynecologic surgery. The use of a reprocessed single-use device provides no direct benefit to an individual patient or her physician. It is the operating surgeon’s ethical responsibility to make a good faith effort to know whether reprocessed single-use devices are to be used, and to not use instruments if he or she has concerns about the quality or safety of the instrument(s). Studies on the safety, quality, and cost-effectiveness of reprocessed single-use devices in gynecologic surgery are needed. Physicians should be informed whether the instruments used in surgery are original or reprocessed, and adverse events should be reported to improve the safety information about reprocessed single-use devices.

Reprocessed Single-Use Devices

Because of the variety of single-use devices, from simple and inert to complex and electronic, it is challenging to critique the process. Single-use devices range from an external device designed to lie against the skin, such as the plastic boots used for venous thromboembolism prophylaxis (intermittent pneumatic compression), to more invasive and complex electrothermal equipment consisting of insulation, sharp blades, and crevices that may become filled with blood or human tissue.

Regulation

Current law requires that the institutions or companies that reprocess single-use devices for repeat use be held to the original manufacturing specifications for the single-use instrument. Testimony regarding the 1977 Compliance Policy Guide issued by the U.S. Food and Drug Administration (FDA) clarified that hospitals that reprocess single-use devices assume full liability and responsibility for their reprocessing actions (1). This policy did not provide for third-party reprocessors, so in 2000, the FDA issued a new guidance document that included descriptions of the regulations that the FDA would apply to third-party and hospital reprocessors of single-use devices (2). Under the Medical Device User Fee and Modernization Act of 2002, a reprocessed medical device is considered a product of the reprocessing company and no longer a product of the original manufacturer; the name of the manufacturer of the reprocessed device is required to be placed in the space identifying the person responsible for reprocessing (3). This 2002 congressional act established new statutory requirements for reprocessed single-use devices, including labeling to identify the devices as reprocessed, submission of validation data for many reprocessed single-use devices, and submission...
of premarket notification (510[k]) with validation data (3, 4).

Safety and Quality
In a 2008 report to the U.S. Congress, the Government Accountability Office (GAO) stated that despite increased use of reprocessed single-use devices, there appears to be no increased health risk (5). However, this report may not reflect the full spectrum of important safety issues because it refers to all categories of devices and relies only on voluntarily reported adverse events. The GAO also stated that because of the limited number of identified peer-reviewed studies related to reprocessing, there was insufficient evidence to support a comprehensive conclusion on the relative safety of reprocessed single-use devices compared with single-use devices on their initial use.

As with any surgical device, reprocessed or not, relying on voluntarily reported adverse events likely underrepresents associated health risks. In the case of reprocessed single-use devices, particularly in products used for invasive procedures such as hysterectomy, it is unlikely that a postoperative surgical site infection would ever be linked to, or reported as related to, the use of a reprocessed single-use device. Furthermore, if an adverse event were to be reported, it may be attributed erroneously to the original manufacturer of the product. (For more information, MedWatch, the FDA safety information and adverse event reporting program can be accessed at http://www.fda.gov/Safety/MedWatch/default.htm.)

Publications exist in the medical literature on orthopedics and laparoscopic surgery that report on the quality of reprocessed single-use devices, such as arthroscopic shavers and harmonic scalpels (6–10). These studies have largely been funded by the original device manufacturers, and limited independent studies are available. However, all studies found a significant rate of physical defects, performance issues, or improper decontamination of reprocessed single-use devices.

Cost-Effectiveness
There are currently no data in the medical literature of studies evaluating the cost-effectiveness of reprocessed single-use devices in gynecologic surgery. Each reprocessed device costs less to purchase than the original, but no information is available regarding any change in operative time or the need to use more than one device if malfunction occurs. Reprocessed devices result in cost savings for the hospital, but it is not apparent that there is any financial benefit to the patient or third-party payers.

Existing Guidelines
The Association of periOperative Registered Nurses has issued a guidance statement regarding reprocessed single-use devices (11). This group’s recommendations include that the sterility, integrity, and functionality of a reprocessed single-use device must be documented as safe for patient care and/or equal to the original device specifications.

Ethical Issues
The use of a reprocessed single-use device provides no direct benefit to an individual patient or her physician. Devices must be clearly labeled as manufactured by the reprocessor. Physicians should be informed that the instrument being used is a reprocessed single-use device. The right of the patient to be informed is also a consideration. It remains the operating surgeon’s ethical responsibility to make a good faith effort to know whether reprocessed single-use devices are to be used. If the surgeon has concerns about the quality or safety of the instrument(s), he or she has the ethical obligation to not use the instrument(s).

Conclusion
Studies on the safety, quality, and cost-effectiveness of reprocessed single-use devices in gynecologic surgery are needed. Physicians should be informed whether the instruments used in surgery are original or reprocessed. Adverse events should be reported to improve the safety information about reprocessed single-use devices.

References


