The objective of a hospital’s central sterile services department (CSSD) is to process medical devices so that they function exactly as they were designed and intended for use. Each time a device is reprocessed, numerous steps described in the manufacturer instructions for use (IFU) need to be followed. The CSSD processes a wide variety of medical devices, including simple hand-held stainless steel instruments, complex devices (such as flexible endoscopes with hard-to-reach channels), power equipment, rigid endoscopes, and futuristic robotic technology. Inspecting devices for functionality is a key step in reprocessing, and when a device is not functioning appropriately, it is removed from service and sent for repair.

Medical device repair involves three main considerations:
1. Healthcare facilities expect items to be repaired to their original condition, making them safe and effective for patient use
2. Repairs must be economical/fit within a facility’s budget
3. Repairs must be timely, as devices are essential to effective patient care.

Sending a device to the original equipment manufacturer (OEM) may be costly and time consuming. Some, but not all, OEMs provide good repair service at a reasonable cost. Third-party repair companies provide an alternative to OEMs; however, quality is a major consideration, and currently there is no oversight of third-party repairs. Concern exists that unqualified personnel may be used to perform service, maintenance, refurbishment, and alterations on medical devices and that the work performed may not be adequately documented. In addition, the parts used may not be the same as the original parts, placing the established reprocessing steps at risk.

To ensure the safety of medical devices, the repairs should be performed using replacement parts that are functionally equivalent or superior to those of the OEM. These parts must demonstrate compatibility with the cleaning processes and sterilization modality that were validated in the medical device’s IFU. Using parts or components with materials that were not submitted for 510(k) clearance could affect the cleaning and sterilization processes and therefore jeopardize patient safety. Some material(s) may be incompatible with the cleaning processes or cleaning chemistries, or with the disinfection or sterilization modality, possibly resulting in unsterile devices, chemical injuries, and device malfunction.

With healthcare facilities under pressure to reduce costs, high-quality third-party repair companies that employ competent, skilled, and well-trained repair professionals—and only use parts for repairs or replacement that are equivalent to those of the OEM—can offer healthcare facilities considerable savings, without sacrificing device quality and safety.

CSSDs process a wide range of medical devices, and proper training for CSSD staff is a key component to ensuring that items are processed correctly. The medical device manufacturer may provide training for the user of the medical device on how to use the device for patient care. Some, but not all, OEMs provide in-depth processing training for the CSSD staff. In some instances, training may not be provided to the staff processing the medical device or the training may be ineffective. Of note, some third-party repair companies provide this valuable service and even provide preventive maintenance training.