Ensuring Reusable Devices Are Safe for the Next Patient
Published in Medical Design Briefs, February 2019

Advances in manufacturing technologies are fostering an age of unprecedented innovation in the development of reusable medical devices and instruments. As designers develop smaller, more-complex, and increasingly intricate devices, however, manufacturers must not overlook the importance of ensuring that such products can be effectively cleaned and disinfected before being reused. In fact, appropriate cleaning processes must be validated by the manufacturer before a reusable product can be released into the marketplace. To find out more about the expertise required to establish safe processes for cleaning and disinfecting reusable medical devices, MDB recently spoke with Christopher Scott, Vice President of Eurofins Medical Device Testing (Lancaster, PA).

MDB: What characteristics define a ‘reusable’ medical device?

Scott: Technically, the term encompasses any device that is intended to be used more than once. Most attention, however, is paid to the products that must be cleaned or sterilized between uses. The most common examples are surgical instruments, which include a range of products from stainless steel retractors and forceps to endoscopes and cutting jigs for orthopedic implants.

MDB: Are such instruments typically cleaned by hospital staff between surgeries?

Scott: After use, instrument trays are typically sent to the hospital’s central supply department, where they are cleaned and resterilized. In recent years, however, there has been a growing trend toward outsourcing this activity to third-party reprocessors.

MDB: Are patients often unsettled by the thought that the instruments used on them could have been previously used on someone else?

Scott: Sometimes. But this is an everyday occurrence. And just as restaurant diners aren’t usually concerned about who last used their silverware, patients should be equally confident in the instruments used in their procedures, whether in an operating room or a dentist’s chair.

MDB: Hospital staff can’t perform sterility testing on every reusable device. How do they know that reprocessed instruments are actually clean and sterile before they are reused?

Scott: You’re right. Beyond the fact that completion of a sterility test takes 14 days, the very process of testing for sterility would render the product nonsterile. Instead, the reprocessing method must be validated in much the same way that a terminal sterilization method is validated for single-use items.

MDB: Is it the responsibility of the hospital to perform this validation?

Scott: No. It is the responsibility of the device manufacturer to provide a validated cleaning protocol to the hospital. Such protocols are typically included in the product’s instructions for use or provided in a standalone instruction manual. It then becomes the hospital’s responsibility to follow the instructions provided by the manufacturer.

MDB: Is that responsibility dictated by FDA regulations?

Scott: Yes. FDA’s guidance document on the topic explains the agency’s logic for applying its quality system regulation (21 CFR 820) to the validation of reprocessing methods for reusable devices. The guidance links instructions for cleaning instruments to the quality systems requirements for ensuring that a device conforms to defined user needs and intended uses — which naturally include preventing cross-contamination among patients.

MDB: How does a company go about validating a method for reprocessing its instruments?

Scott: Generally speaking, the process involves...
inoculating a device with an artificial contaminant, known as a ‘soil,’ and then testing the device for cleanliness after it has undergone a well-defined cleaning method. The choice of a particular soil is based on the application of the device, and is a synthetic formulation of proteins, acids, and lipids meant to simulate the environment where the device will be used, which may be blood-filled, mucosal, or gastric. Validation should be conducted under worst-case conditions, including inoculation of the device at a site identified as the most challenging location for cleaning.

MDB: Instruments used in orthopedic procedures can involve nearly a dozen different trays, each filled with a dozen or more instruments or trial implants. Does the manufacturer need to validate its reprocessing protocol for each part, or for the entire instrument set?

Scott: Every manufacturer needs to assess how its instruments are going to be used — including obvious or typical uses as well as less-likely scenarios — and ensure that its reprocessing protocols address each such application. Regulators will accept the bundling of products if a sufficient justification can be provided for treating items as a single family of products. In such a case, data for a worst-case example, or perhaps for a bracketed set of devices, can then be applied to an entire set of devices. A typical example might be a set of trial implants, or a set of reamers that vary only in diameter or length.

MDB: You mentioned that the validated cleaning method needs to be provided to the end-user in the device’s instructions for use. Do you have any insight into what those instructions should look like?

Scott: FDA expects that such instructions will advise users about how to thoroughly clean reusable devices in a way that is comprehensive and understandable, technically feasible, and reliant only on tools and cleaning solutions that are available in the marketplace, and that such labeling will reflect the intended use of the device.

MDB: In your view, why is it that the reprocessing of devices has lately become such a hot topic?

Scott: Advances in design and manufacturing technologies have resulted in devices with much greater complexity than those available a generation ago. The age of miniaturization and 3D printing has enabled engineers to develop products with tremendous functionality that would have been considered science fiction just 30 years ago. As such instruments have become smaller and incorporated more moving parts, however, they have also become more difficult to clean and reprocess. In recent years, unfortunately, there have been some cases in which patients died as a result of cross-contamination due to inadequate cleaning between surgeries.

MDB: It seems like reusability is something of a two-edged sword.

Scott: There is no doubt that the innovations we are seeing in surgical instrumentation offer tremendous benefits for patients. The rise of minimally invasive surgery, for instance, has revolutionized medical outcomes for millions of people, and that is a trend that needs to continue. However, as engineers are developing their next generation of innovative reusable products, it is important that they remain mindful that the cleanability of those instruments is a critical design requirement.

To find out more about Eurofins Medical Device Testing’s reprocessing validation services, visit here.