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February Cover Story

Maintaining instrument maintenance programs

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February 2016

CS Connection

Maintaining instrument maintenance programs

by Kara Nadeau

Properly maintaining and repairing surgical instruments has far reaching implications beyond the instruments themselves, from the financial pressures to protect a hospital's

Instrumental News

FDA Communication: FUJIFILM validates revised reprocessing instructions

FUJIFILM Medical Systems, U.S.A., Inc. (Fuji) issued revised, validated manual reprocessing instructions for the ED-530XT duodenoscope to replace those provided in the original device labeling. The FDA reviewed the revised reprocessing instructions and the validation data and determined they meet the Agency's expectations.

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equipment investment, to the ability to serve the operating room (OR) with properly functioning instruments when needed, to protecting patients from healthcare acquired infections (HAIs) and other harm that can result from improper maintenance and repairs.

At the same time, the ability for a hospital to maintain the quality of its surgical instrumentation hinges on many different factors, including staff education and training, communication between OR and central sterile/sterile processing department (CS/SPD) staff, adherence to manufacturers' instructions for use (IFUs) and the competency and availability of outside resources (OEMs and third-party repair services).

In this month's article, we present insights from CS/SPD professionals, instrument manufacturers, repair service providers and others in the industry on the latest trends in instrument maintenance and tips for establishing processes and selecting services that are right for your organization.

How instrument maintenance is evolving

As surgical instruments evolve to meet the more complex and demanding needs of the OR, maintenance of these items must advance as well. Maintenance programs must take into account the broader range of instrumentation used in today's surgical procedures and manufacturers' requirements for care and handling as defined in their IFUs.

"Overall the industry is making great strides to raise awareness regarding instrument maintenance," said Marcus Super, Director of InstruSafe Sales and Marketing at Summit Medical. "I believe part of this is being driven by the complexity of 21st-century surgical instrumentation and adverse events that have been popping up in the news lately."

While surgical procedures are growing in both volume and scope, healthcare facilities are feeling the pressure to cut costs and operate more efficiently. One way they can do this is to proactively maintain their surgical instrument inventory, which represents a significant

FDA recommends that facilities using Fuji's ED-530XT duodenoscope train staff on the new instructions and implement them as soon as possible.

As noted in FDA's February 2015 Safety Communication, the complex design of duodenoscopes may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. The FDA has been working with duodenoscope manufacturers as they modify and validate their reprocessing instructions to further enhance the safety margin of their devices and show with a high degree of assurance that their reprocessing instructions, when followed correctly, effectively clean and disinfect the duodenoscopes.

In May 2015, Fuji initiated testing to validate the revised reprocessing instructions and provided the cleaning validation reports to FDA in July 2015. Between July and October 2015, the Agency continued to work with Fuji to clarify and ultimately confirm that their cleaning and high-level disinfection instructions met the Agency's expectations. In October 2015, the FDA notified Fuji that the validation data for the ED-530XT duodenoscope were acceptable and worked with the company as they developed revised instructions for use.

The revised instructions include a more rigorous protocol for pre-cleaning, manual cleaning and high-level disinfection procedures. They also incorporate the use of an additional disposable brush (Model WB1318DE) to manually clean the distal end of the scope. The agency reviewed the validation data and believes that when followed, the revised, validated reprocessing instructions demonstrate consistent and reliable cleaning and

capital investment for most institutions. Proper instrument maintenance also contributes to better and safer patient care by ensuring surgeons have the highest quality equipment in their hands for every procedure.

Marcus Super

"The financial challenges of providing healthcare along with the overriding goal of keeping patients safe when having surgery have encouraged a greater focus on preserving resources and ensuring that instruments used in surgery are functioning as they should," said Cynthia Spry, MA, MS, RN, CNOR(E), CSPDT, an independent CS/SPD consultant. "One of the best ways to preserve resources and provide properly functioning instruments to the surgical team is through preventive maintenance. Although many facilities are paying more attention to preventive maintenance there are still many facilities where the focus is on repair rather than prevention of damage."

Tyler M. Shelbert

Tyler M. Shelbert, Senior Brand Manager for Zimmer Biomet-Surgical, has witnessed a trend in healthcare facilities prolonging manufacturer recommended maintenance. But he points out that increased regulatory scrutiny surrounding maintenance from the Joint Commission is now forcing healthcare facilities to better align with device manufacturers' recommendations for maintenance, inspection and testing activities.

"The most important maintenance strategy for a healthcare facility is partnering with its medical device manufacturer to ensure certified repairs and preventative maintenance (PM) checks are performed on a regular basis," said Shelbert.

Noreen Cioffi

While putting off instrument maintenance may save a healthcare facility some money in the short term, a proactive maintenance and repair program can generate significant savings over time, as Noreen Cioffi, Marketing Manager for Aesculap Technical Services, points out:

"Our data shows that facilities with quality repair and maintenance programs have the lowest rates of unrepairable instruments, with cost savings of over 20 percent over a four year period.1 This can translate into a $20,000 to $60,000 decrease in annual expenses; it's a small initiative with a huge impact. Proper repairs and maintenance extend the life of instruments and saves on disposal and repurchasing costs."

Purchasing decisions

Facing greater financial pressures, a growing number of healthcare facilities are factoring instrument maintenance

high-level disinfection of the Fuji ED-530XT duodenoscope.

While formal validation testing with the revised reprocessing instructions is ongoing for Fuji's 250 and 450 duodenoscope models, FDA encourages healthcare facilities to apply the revised reprocessing instructions for the ED-530XT duodenoscope to reprocess the 250 and 450 duodenoscope models. FDA believes that the revised reprocessing instructions for the ED-530XT duodenoscope are more robust because of additional pre-cleaning, cleaning and high-level disinfection steps and, for that reason, should increase the safety margin of the 250 and 450 duodenoscope models.

See the FDA Safety Communication for details at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm478949.htm.

Alisandra Rizzolo

and repair into their purchasing decisions, explains Alisandra Rizzolo, Vice President and General Manager of Customer Care, Stryker Instruments Division.

"Analyzing total cost of ownership factors such as the expected lifespan, potential repair costs, training needs and projected technology upgrades, helps facilities provide more accurate spend forecasts to better manage costs," said Rizzolo. "With the added complexity of evaluating instrument purchases at this level, our hospital partners are looking to us to support their analysis in order to optimize the purchasing process and improve the longevity of their assets."

Kristina Cabel

"One thing we've noticed is that our customers want to 'do more with less,'" said Kristina Cabel, Senior Director of Marketing for Microline Surgical. "Among other things, this means maintaining equipment uptime, as well as finding ways to save on equipment and capital spend. Other strategies customers have implemented are careful selection of suppliers to focus on surgeon preference and hospital business needs, and implementing programs to rest assured that the right product will be in the OR."

Cabel explains how Microline Surgical has "reposable technology;" a reusable handpiece that may be fitted with a number of interchangeable disposable tips for laparoscopic surgery. According to Cabel, this "multi-tool" approach simplifies tray setup and central sterile workflow. The only product that needs maintenance is the handpiece. The company then offers extended warranty programs to protect the hospital's investment and ensure years of device usage. The program also offers fast turnaround in case of a damaged handpiece enabling operational efficiency and maximizing uptime.

Microline Surgical's reposable instruments feature a reusable handle with disposable tips

Healthmark Industries

HealthTrust Purchasing Group

Key Surgical

Maquet Medical Systems USA

MHI

Microline Surgical

Mobile Instrument Service

Olympus America Preowned

Olympus America 4K

One Source

Parker Labs Inc.

PartsSource

PDI

ROi

Ruhof at AORN

Ruhof Corporation

Sandel Medical

Subway

Another approach healthcare facilities are taking to factor maintenance into their instrument purchasing decisions is to involve CS/SPD staff in the decision-making process, says Spry.

"Input from sterile processing personnel is vital to ensuring the facility has the capability to process the device being considered for purchase," said Spry. "If a facility does not have the resources to process a device in strict accordance with the device manufacturer's IFUs the life of the device may be shortened and patient safety jeopardized."

Going back to the source: OEM

Steve Kovach

Healthmark Director of Education Steve Kovach has witnessed a growing trend in healthcare facilities sending instruments back to the original equipment manufacturers (OEMs) for repairs. He explains how this allows the facilities to save money by taking advantage of the original factory warranties.

"CS/SPDs are segregating their surgical instruments according to company for repairs and sending them back to the original manufacturer," said Kovach. "They are still using third-party repair services but combining that onsite service and instant repair feature."

"Purchasing preventative maintenance and warranty services at the point of sale minimizes downtime and allows for the hospital to plan around their maintenance requirements," said Shelbert. "In addition, scheduling regular in-servicing for all hospital staff reinforces proper device handling, increasing equipment durability and safety."

Zimmer Biomet is now offering a customer service, technical assistance and repair program called CSTAR. The CSTAR program features three comprehensive service solutions: preventative maintenance, extended warranty and premium warranty. Each service solution gives the customer access to the CSTAR program's mobile-friendly service portal where they can manage everything from scheduling service, monitoring equipment maintenance status, accessing training videos and educational downloads.

Maintenance schedules

Another trend is the transition from time-based to usage-based maintenance schedules. David Anbari, Vice President of National Sales and Operations for Mobile Instrument Service & Repair, explains how this approach enables healthcare facilities to maximize their maintenance and repair spend.

"This helps better align scheduled maintenance of instruments to their actual usage patterns," said Anbari.

"For some instruments, this means they get more frequent service as they are used more regularly and for others it means less service. Spend is better aligned with equipment that needs it and equipment readiness in the OR is improved."

David Anbari

Genti Koci

Genti Koci, BA, CRCST, Sterile Processing Professional, Medical Staffing Options, Ohio State University Hospital East, describes how an instrument tracking system helps facilitate usage-based maintenance.

"Usage-based maintenance prevents unnecessary sharpening of instruments, which can prolong the life of those instruments," said Koci. "Having a good tracking system in place can help facilitate this and cuts down on unnecessary labor. For example, the CS/SPD can identify which trays need to be sharpened before they are sterilized."

Spry suggests that CS/SPD professionals use manufacturers' IFUs to determine usage-based maintenance schedules. Using an IFU, technicians can determine what maintenance is required for a specific instrument, calculate instrument usage and then set preventive maintenance schedules accordingly.

"Instruments or devices with the highest utilization rates may require more frequent preventive maintenance whereas a longer interval between preventive maintenance may be appropriate for those instruments or devices that are used infrequently," notes Spry. "Although it is not usually possible to track use of individual instruments it is possible to track the number of times a particular set has been processed within a determined time frame. This information can be useful in setting up preventive maintenance schedules."

Censis Technologies' Censitrac solution is a highly advanced, web-based instrument management software system, focused on maximizing OR

Censis Technologies' Censitrac solution

throughput and regulatory compliance. Included, as a standard feature in the Censitrac solution, is the repair and maintenance module, which offers users the ability to manage their inventory at varying levels of detail, in order to maximize the effectiveness by keeping instrumentation and equipment in optimal working condition at the lowest possible cost. The system provides numerous automated methods for monitoring the need for repair/maintenance in order to provide the greatest level of flexibility and accuracy.

Tips for proper maintenance and patient safety

Today there are many factors that must be considered when establishing instrument maintenance and repair processes, and a variety of services and products that can assist the CS/SPD in these efforts. Below are some tips from the experts.

Determine what's right for you

Anbari recommends a comprehensive assessment of equipment management processes to identify deficiencies that are specific to a facility's operating environment and building a comprehensive work plan to optimize equipment handling. This can include the usual educational efforts, but also introduction of the right tools for cleaning and inspection and tracking systems to better manage the process.

"There are quite a few strategies that are available including usage-based preventive maintenance, self-testing instruments in SPD, rebuilding instruments in lieu of replacing them, ensuring cleanliness as well as sharpness and alignment, etc.," said Anbari. "But knowing which strategies will pay off is the harder task."

Because there are numerous instrument repair companies in the marketplace, CS/SPD managers must advocate for the company that is right for their

department, said Koci.

"Not all the repair companies are the same," he said. "It is very important to choose a company that will restore instruments to standards and make sure they meet OEM requirements. It is also vital to select that company that can help with loaners as it takes longer to repair more complex instruments. I would suggest that managers visit the repair facilities and get familiar with their capacities."

Forest Health Medical Center, a 68-bed multi-specialty surgical hospital in Ypsilanti, Mich., relies on a third-party mobile repair company to handle its instrument maintenance and repairs. Ann Marie Trybus, CSPDT, CRCST, CHL, Certified Sterile Processing Technician for Forest Health Medical Center, describes how this works for her smaller healthcare facility.

Ann Marie Trybus

"We put aside items in need of repair and when the bin gets a little cluttered, we call a repair company. They pull up a work van in the lot and repair on-site. It works out wonderfully," she said. "When we do a larger overhaul like scissor sharpening, they come out in a team of two employees and sharpen all of the scissors we own. We schedule this four to six months apart. It's very important to keep those scissors extremely sharp and burr-free because we don't want any damage to our patient's delicate veins, skin, etc. Bad scissors can lead to an untimely nick and unnecessary blood loss."

Inspect and test your instruments

Instrument inspections and testing, such as evaluating the sharpness of scissors, helps reduce the possibility of an improper functioning instrument being placed into use, says Kovach. He explains how enhanced visual inspection has become the standard of care for surgical instruments.

"As I think back to even 10 years ago the majority of workstations in the sterile processing area did not have a lighted magnifier at each station, now it is the norm," said Kovach. "With the advances in the quality and functionality of inspection scopes, sterile processing staff can now look into areas they could not visually inspect before. One of the really great innovations is the use of flexible borescopes designed to look inside the internal channels of devices, including arthroscopic

Healthmark's Flexible Inspection Scope

shavers and flexible endoscopes. With this technology, staff is able to do a better job of ensuring a medical device is really clean. Seeing is believing and being able to inspect with a flexible borescope provides a new level of assurance that a device has been effectively cleaned."

Healthmark offers a Flexible Inspection Scope that has a camera chip on the tip of a long, flexible shaft unlike traditional fiberoptic-based inspection scopes. According to Kovach, the advantage of such a design is that it is far more robust and delivers vastly superior image quality in a remarkably flexible design.

"Conduct routine maintenance and equipment checks to identify potential issues early on and to limit the potential for more costly repairs down the road," said Rizzolo. "This includes opening equipment up to check for proper lubrication, blade sharpness, damage to parts, and outdated technology that could result in costly downtime."

Adhere to manufacturer IFUs

According to Shelbert, abiding by manufacturers' preventative maintenance recommendations per their IFUs may increase device life and reliability.

Spry points out how some facilities have made it a requirement that processing personnel be aware of preventive maintenance requirements identified in the IFU and make this a competency requirement, as well as part of the performance appraisal.

"Because of the Joint Commission focus on ensuring that device manufacturers' IFUs are followed, facilities are paying more attention to the information in the instructions that relate to preventive maintenance," said Spry. "Being able to manage IFUs electronically through programs such as the one provided by

oneSOURCE makes it is easier to locate preventive maintenance guidelines within IFUs."

Through oneSOURCE, it is possible to retrieve information about which IFUs are accessed most often. A facility may choose to place this information in the cloud along with information about recommended preventive maintenance. According to oneSOURCE, some customers have found it helpful to place an electronic version of AAMI ST79 in the cloud thereby providing staff with easy access to the standards that drive their practice.

Consider instrument transport

Shawn Flynn, Senior Vice President of Customer Operations/Co-Founder of Restore Medical Solutions, explains that the logistics behind transporting instruments to the CS/SPD and back into surgery can include many "embedded pitfalls" that can shorten the life of instruments. For example, instruments contaminated with bioburden can sit for extended periods of time before they reach decontamination, which makes them harder to clean and can prematurely erode the protective passivation layer. This layer is key in preventing rust to develop, which may in turn contaminate other instruments in the tray.

Decades old technique and technology vs. Restore's new technique and technology.

The Restore Medical Solutions Restore IQ sterilization tray has been shown to reduce decontamination /assembly time by 70 percent, labor handling costs for decontamination/assembly by 67 percent, increase tray production by a minimum of 29 percent, and reduce bioburden on surgical instruments by 99.999 percent.2 That translates into a 106 log reduction after manual/mechanical cleaning utilizing Restore's system and point of use decontamination methods.3 Basically that means it has been demonstrated to clean down to the bacterial level prior to sterilization.

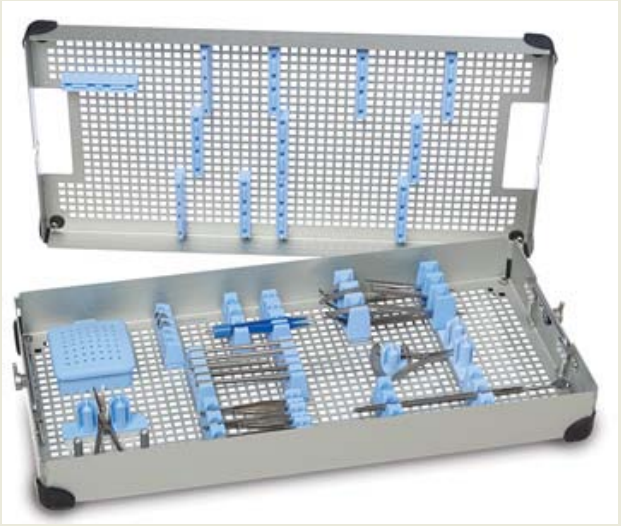
"Hospitals are looking at solutions that can maximize the life of instruments, cut costs and reduce the amount of replacements due to loss," said Flynn. "Worst case scenario is you get a patient in the room and that instrument doesn't work and/or is contaminated from another patient's surgery."

Super points out how understanding the root cause of surgical instrument damage and maintenance is an effective way to establish corrective action. He

notes that a combination of educated technicians trained to handle instruments and trays designed to properly organize and protect them during their use cycle is a lower cost alternative to maintenance.

"Maintenance starts with a tray or container designed to properly protect surgical instrumentation," said Super. "If you don't invest in this there becomes an exponential chance for damage to occur during decontamination, sterilization and transportation. If you pair this with an educated staff dedicated to the concept of instrument care and maintenance the results could be enough to drastically reduce your repair budget and eliminate the need for on-site repair services."

InstruSafe instrument trays by Summit Medical are designed by former sterile processing and OR professionals to properly organize and protect surgical instrumentation.



Summit Medical's Customized InstruSafe Tray for Ophthalmology instrument set

Appearances matter

Anbari explains that instrument appearance is not just a matter of aesthetics but also critical to proper function and endurance. He says poor cleaning practices can compromise the surface integrity of an instrument, which can ultimately cause surface pitting and lead to premature replacement of the instrument.

"If your instruments are stained badly, it can promote pitting and in some cases provide a surface for foreign matter to remain on the instrument through reprocessing," said Anbari. "It is vital that repair providers do their part to deep clean instruments and ensure the finish is restored to original condition to preserve the longevity of the instrument."

Mobile Instrument Service & Repair has seen an increased demand for comprehensive instrument restoration services. Facilities have engaged the company to refurbish all of their instruments, which has resulted in as many as eight of its service labs and technicians working around-the-clock to restore every instrument.

"We are called in because facilities need rapid improvement in instrument quality. Refurbishing 10 to 20 sets a day is inadequate and in fact confuses the

refurbishing effort. The business-as-usual approach takes months so we knew a different and better resourced task force was necessary," said Anbari.

Invest in CS/SPD education and training

CS/SPD professionals are a first line of defense when it comes to ensuring only properly functioning surgical instruments reach the hands of surgeons. But in order for CS/SPD professionals to perform these tasks properly they must have adequate training. Trybus advocates that all CS/SPD technicians be certified, stating:

"We handle the instruments that are to be placed into the surgeon's hands before they are placed in the patient's body. It is of huge importance that the technologists care a great deal and are highly knowledgeable about what they do. Also, it is time for hospitals to care about the sterile technician. We do a very important service but I, and others in my field, feel like we do not get the recognition we deserve."

According to Koci, CS/SPD professionals need not only appropriate training but also the necessary tools to perform tasks related to instrument maintenance.

"I suggest managers equip their techs with the knowledge and the tools for 'soft maintenance,'" said Koci. "SPD techs should know what to look for when inspecting instruments and how to do it. It is unacceptable that rongeurs have loose screws, or gelpis do not hold. Instrument maintenance starts at the assembly table, which requires the right education and tools."

Kovach agrees that CS/SPD departments must invest both in staff training and tools for instrument maintenance. He has seen a growing number of facilities make these investments, as evidenced by inspection worktables that are stocked with the proper material to test scissors and other surgical tools.

"CS/SPD technicians need inspection tools, such as flexible inspection scopes, and communication tools, including repair tags and other labeling products, to help identify devices that need further cleaning or repair," said Kovach.

To support CS/SPD education around instrument care and maintenance, Healthmark offers sample policy and procedures and education backed by continuing education credits (CEUs). The company's online CEU Games at Crazy4Clean.com educate CS/SPD staff on properly managing medical devices throughout their lifecycles.

Cioffi also stresses the need to have a "repair partner" versus a repair vendor, meaning a company that not only repairs instruments but also provides education and training. She notes that facilities also want more access to the vendor and technician network.

"At Aesculap we have been at the forefront of this movement, providing CEU credits and personalized preventative maintenance programs so we can be that resource and share our time-tested best practices," said Cioffi. "Our technicians and national repair network provide the reliability and consistent, high quality

repairs facilities demand. Our technicians are also trained to the use of OEM-sourced parts; it's a promise few non-OEM vendors can provide."

Aesculap has a new CEU Function Testing and Repairs program that walks CS/SPD professionals through the same checks its own technicians use. The company also offers webinars tailored to its customers through which it shares its instrument maintenance expertise.

"Hospitals are increasingly looking for partners to help find solutions to reduce costs and streamline processes," said Cabel. "We have fully trained sales professionals that can offer product inspections to protect our customers and patients from use of damaged product — that, coupled with our extended warranty programs helps us add value to our customers."

Collaboration with the OR and other stakeholders

Kisha Miller

Properly caring for and handling instruments to help reduce HAIs and surgical site infections (SSIs) requires collaboration among CS/SPD, OR and infection control staff, according to Kisha Miller, Director of Collaborative Education for Circle of Care. Her organization brings all of these stakeholders together in one arena to encourage education and collaboration to improve team based care for the benefit of the patient.

"There are so many different disciplines that have a hand in the care of surgical patients but yet we still operate in silos and seek out our education in silos," said Miller. "In surgery we love to point the finger at SPD and make statements like, they aren't educated enough or don't get our world. We make all of these claims yet the majority of the issues effecting the useful life of the instruments begin in the OR."

"For instance, "AORN, AAMI and AST all recommend wiping instruments down during and after a procedure, however, you would be surprised at how many clinicians within the OR don't understand that the decontamination process is supposed to begin at the point of use," she adds. "In many cases the root cause of improper care and handling is due to the OR returning instruments back to SPD after a procedure full of blood, protein and other bio burden which sticks like glue to the instrument making cleaning extremely difficult and time consuming, which impacts turnaround time and causes strife between the two departments."

Miller encourages the OR and CS/SPD to mutually reach out to each other to open up the lines of communication between the departments. She believes breaking down existing silos so that CS/SPD and OR staff better understand each other's roles and responsibilities when it comes to instrument handling and care is the only way to end this perpetual cycle that has been accepted as the norm.

"Interprofessional education and collaboration is the key to facilitating teamwork, trust and a shared vision that will lead to transformational patient outcomes. We are not going to achieve our goals until we work together as the team we are meant to be — one team, one goal," said Miller. **HPN**

1. Aesculap data on file.

2. Restore CBA/Trial from "Top 100" rated Academic 900 Bed University Medical Center located on the East Coast. Ranking established by http://health.usnews.com/best-hospitals/area%20Top%20100%20Hospitals.

3. Restore Independent 3rd Party Validation Cleaning Study, Restore GLP Cleaning Validation Report #688719.