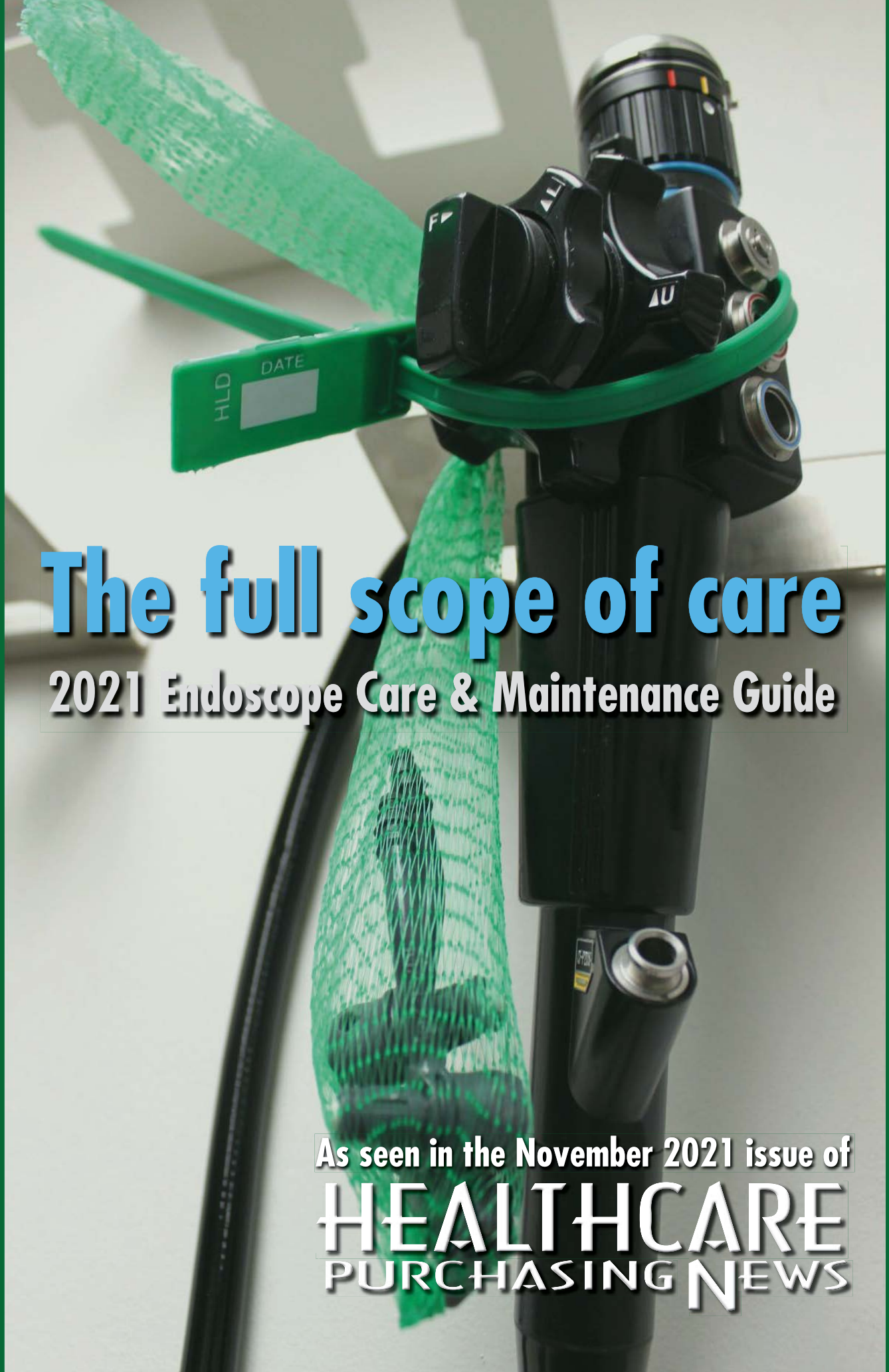

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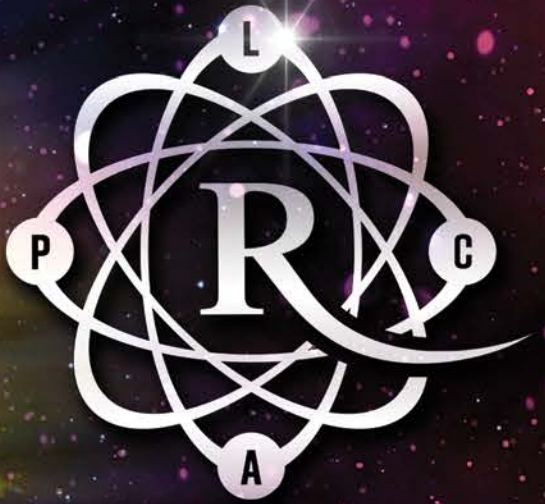

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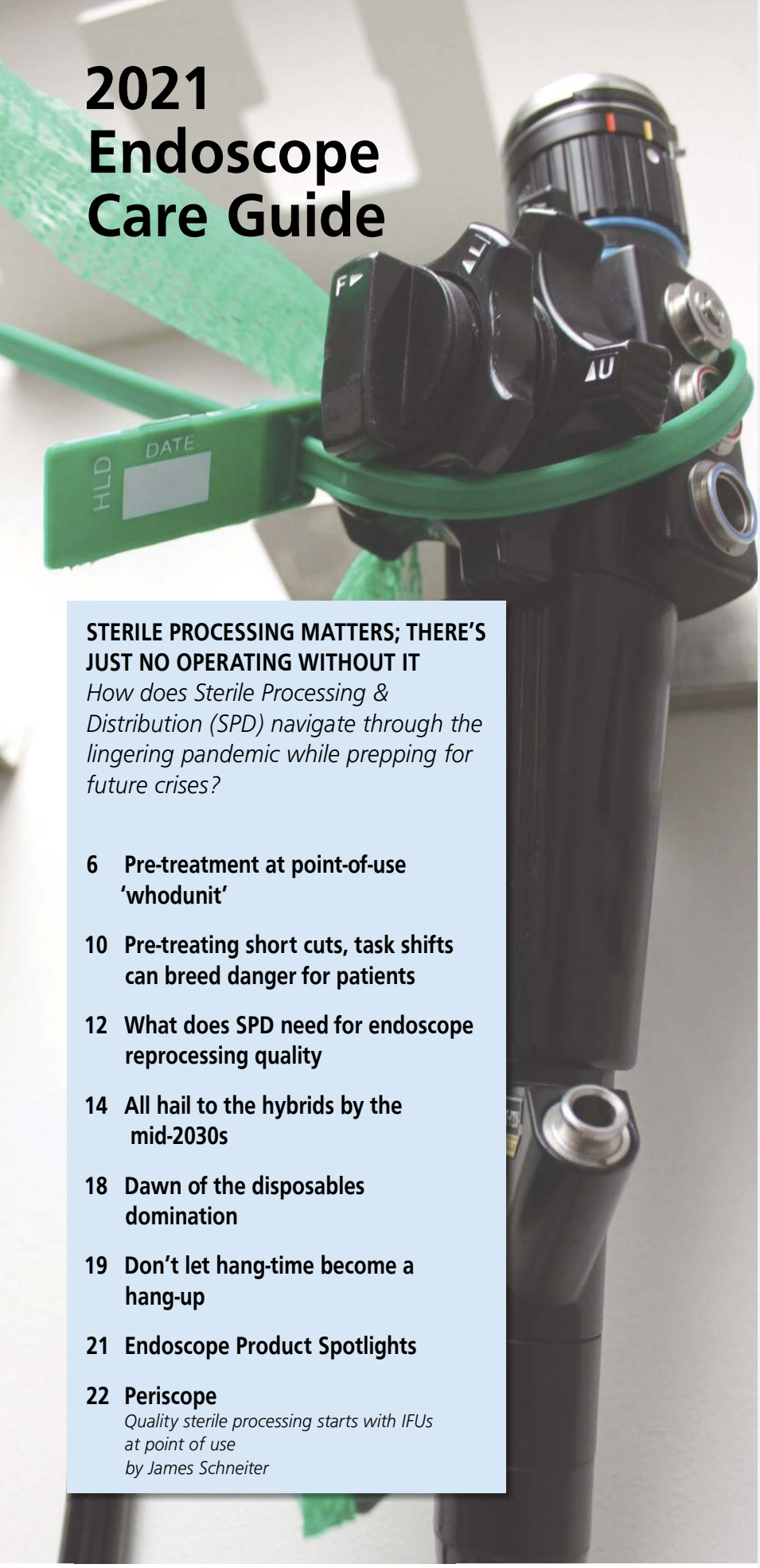

STERILE PROCESSING MATTERS; THERE'S JUST NO OPERATING WITHOUT IT

How does Sterile Processing & Distribution (SPD) navigate through the lingering pandemic while prepping for future crises?

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Sterile Processing *matters*, there's just no operating without it

by Rick Dana Barlow

The following refrain bears repeating … frequently: Sterile Processing is the engine of a hospital and ambulatory/outpatient surgery center, among other healthcare facilities.

How is that possible? Simple. What happens to a cruise ship or even the Starship Enterprise without crew members manning the engine room? That cruise ship becomes stranded in the Gulf of Mexico or the U.S.S. Enterprise in the outskirts of the Alpha Quadrant in space.

Without the engineering crew enabling these vessels to operate, they go nowhere. Floating land barges in the water; stationary but rotating space station in the final frontier.

Now imagine a healthcare facility – inpatient or outpatient – without the sterile processing crew. Before the relatively recent advent of disposable endoscopic devices, for example, surgeons relied exclusively on reusable models that require extensive cleaning (including pre-treating at the point of use, the new phrasing for the former "pre-cleaning" concept), disinfection – high-level or otherwise – and sterilization. After each use on each patient.

Without the Sterile Processing engine crew, who brings these expensive surgical tools back for acceptable and proper use on patients? The surgeons? The nurses?

Will complete adoption of disposable or single-use endoscopic devices solve the problem and even reduce the need for Sterile Processing's capable crew? Not really. You'll read why a few pages from here.

So how does Sterile Processing & Distribution (SPD) navigate through the lingering pandemic while prepping for future crises and remain relevant?

For Jean Sargent, veteran Supply Chain and SPD leader-turned-consultant who has served on the editorial advisory board of *Healthcare Purchasing News* faithfully for nearly 25 years, it requires three central tenets:

1. Support from senior leadership: "Through the pandemic, many sterile processing departments came into view at a higher level than their direct management," said Sargent, Principal, Sargent Healthcare Strategies. "It is time to take advantage of the newfound recognition by educating leadership, physicians and staff on the function of SPD, its importance, the guidelines that must be followed – walk a day in the shoes of an SPD tech."
2. Appropriate pay: "Now that the senior leaders have seen the functioning of the department, the knowledge required, and the certification(s) required – pay the staff at an appropriate level. Kudos to those who have met that need," she continued.
3. Recognition: "Recognize the department for their important contributions to patient care, patient safety and supporting the clinicians," she urged. "Bring physicians into the department and allow them to visualize the time and care taken to process each and every item/tray."

Sterile Processing matters. That's why *HPN* extensively has covered the profession and function since the 1970s. In fact, this Endoscope Care section represents the 17th consecutive year it has shared insights and prose from the pros on proper procedures within *HPN*'s 44 years in print.

In fact, last year, *HPN* editorially dissected the multistep process of reprocessing endoscopic devices in one of the most extensive education and training handbooks on the matter worth keeping. You can revisit that story, "Endoscope Care in 2020 and beyond" here: https://www.hpnonline.com/sterile-processing/article/21157237/endoscope-care-in-2020-and-beyond. You also can find additional useful information at *HPN* Online (www.hpnonline.com). Just use the search term "Endoscope Care."

Continue reading …

Whether in print, online or digital, *HPN* has SPD covered.

Photo courtesy: Healthmark Industries

Pre-treatment at point-of-use 'whodunit'

Follow expert clues to determine whether it's in OR or SPD

by Rick Dana Barlow

Ask any Sterile Processing & Distribution (SPD) technician, supervisor, manager, director or clinical educator about the most important first step in what they do for the operating room (OR) and if they don't recite from memory the refrain, "Cleaning, because if it's not clean, it cannot be disinfected or sterilized," then they might be from an alternate/parallel dimension.

But SPD professionals have long recognized how difficult and strenuous it is to clean post-procedure used devices and instruments – complex endoscopic models or otherwise – coming from the OR … particularly if those products have been enjoying a good soaking and instead are left in the open air for bioburden and organic material to gelatinize or harden into crusty scabs of tissue left behind.

Pre-treating at the point-of-use (formerly known as "pre-cleaning") begs the following questions whose responses should be standard operating procedure industry wide.

Who's responsible for pre-treating used devices and instruments and where? Circulating or surgical nurses in the OR? SPD techs?

How soon after a surgical procedure is completed before the used devices and instruments should undergo pre-treatment in a soak?

What materials should be used in this pre-treatment process?

Finally, who should take responsibility when these steps are not carried out?

Timing is everything

While this issue remains a sensitive one that has simmered seemingly for ages, SPD experts and leaders acknowledge that something should be done to promote safe and efficient practices and even see some headway being made.

"This is an age-old question," Shaun Sweeney, Vice President, Cygnus Medical, told *Healthcare Purchasing News*. "Logic dictates that it should be done immediately following the procedure for several reasons. Mainly the efficacy of the overall process but also for preventing stainless steel pitting caused by extended contact with blood. However, the OR turnover time often takes precedence. Seeing case carts lined up in the hallway untouched is a common sight.

"Many hospitals have SPD personnel working within the OR to take over these responsibilities," he continued. "This is a good step towards improving the process. Rinsing blood and other contaminants from the instrument as soon as possible is always the best option but is not always practical. Preventing pockets of biofilm from forming in cracks and crevices is a time-sensitive topic. It is more in the realm of minutes and hours than in days. The use of pretreating instruments with detergents is an option, but if the gel or detergent is left to dry it may create a soap film that can harbor microbes. This is an even worse outcome.

"Maintaining moisture in or around the instrument will keep the blood in a more rinsible state but water is also the one element biofilm needs to colonize. Not to mention the negative effects of stainless steel pitting and rusting still remain. In a perfect world rinsing and drying instruments after the procedure offers the greatest overall benefits," Sweeney added.

J. Hudson Garrett Jr., PhD, MSN, MPH, MBA, FNP-BC, CPHQ, PLNC, AS-BC, IP-BC, VA-BC, CFER, CPPS, CDONA, DICO-C, GDCN, NREMT, NCEE, FACDONA, TR-C, FAAPM, FNAP, FSHEA, Adjunct Assistant Professor, Division of Infectious Diseases, Department of Medicine, Center for Education and Training in Infection Prevention, University of Louisville School of Medicine, and an advocate for disposable/single-use only options, adds some context and depth to the discussion.

"First and foremost, the device should be handled and cleaned according to the manufacturer's instructions for use (IFU)," Garrett advised. "These instructions for use may dictate the timeframe for which the [pre-treatment] should take place. These instructions for use are part of the validated cleaning processes submitted by the device manufacturer to the Food and Drug Administration. Generally speaking, the sooner that [pre-treatment] and the removal of gross, organic soil can take place, the less likely the device is to form a dangerous biofilm, which can lead to patient contamination. As such, [pre-treating] at the bedside would typically be most prudent prior to transporting the device to another department."

J. Hudson Garrett Jr.

The paramount issue is timing, according to Ron Banach, Director of Clinical Education, Ruhof Inc.

"'Time is of the essence' is a critical requirement for point-of-use [pre-treating] whether Operating Room or SPD staff are assigned to the task," Banach insisted.

"Science has proven in laboratory studies that bioburden (e.g., blood, protein, fats, carbohydrates and starches) immediately starts to dry and create a biofilm shell made of polysaccharides over the micro-organisms left on the medical device," he noted. "In order to effectively perform the chemical treatment, it must be applied immediately after the procedure so it can solubilize the polysaccharide shell to allow the HLD or sterilization process to kill the micro-organisms."

David Willoughby, Vice President, Marketing & Business Development, Medtrica, stresses the criticality of timing.

David Willoughby

"We believe that [pre-treating] is critical at the point of use (POU) immediately after a procedure and prior to transport." Willoughy told *HPN*. "Once instruments leave the procedure room there are too many variables that can and will delay [pre-treating] so by not using an enzymatic based [pre-treating] agent at POU immediately after a procedure is, in our view, extremely problematic.

"Although POU [pre-treating] can at times be perceived as an inconvenience in terms of time, it is still an important and a critical first step in the cycle of instrument reprocessing," he noted. "By using [pre-treating] solutions in surgical theatres or other clinical areas conducting patient procedures, will greatly reduce the occurrence of bio-contaminants adhering to instrument surfaces. And, as simple as applying a POU [pre-treating] solution sounds – and is to do – unless this takes place at the POU the infection control chain can be broken causing the very outcomes [healthcare-associated infection] prevention polices were established to avoid and prevent."

Michelle Lemmons RN, PHN, CNOR, CCSVP: Clinical Educator – Operating Room, Key Surgical, a STERIS company, pinpoints the precise location for pre-treating used devices and instruments. And it's not in SPD or even the hallway outside the OR.

Michelle Lemmons

"Without any hesitation, the [pre-treating] step should be completed in the procedure room," she said. "It is well known that scopes can be a challenge to clean. In fact, in 2008 the HICPAC Guidelines for disinfection and sterilization in healthcare facilities states that 'contaminated endoscopes have been linked to more healthcare-associated infections than any other medical device.' Not starting the cleaning process at the point of use can make it more difficult to effectively clean/sterilize instruments. Shortening the time from use to cleaning will decrease the risk of biofilm formation and increase the ease of reprocessing."

Note the 'golden hour'

Lemmons' colleague, Jamie Zarembinski CCSVP, CER: Clinical Educator – Sterile Processing, Key Surgical, a STERIS company, offers the SPD perspective with some gilding.

"The goal is to reprocess the scope within the 'golden hour,'" she said. "Most often, this means that cleaning needs to begin at the bedside. To minimize the growth of microorganisms, the length of time between patient use and delivery to decontamination needs to be as short as possible, and this time varies between facilities. In addition to reducing the time between use and cleaning, facilities should standardize their [pre-treating] process. Standardizing the workflow can reduce endoscope turnover time, improve communication and training processes between OR and SPD, and can minimize the opportunity for errors."

Melinda Benedict

Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, affirms that pre-treating surgical devices and the timing of this step – the sooner the better – is widely accepted by professional

organizations, healthcare providers and suppliers alike.

"Medical device instructions for use (IFU) generally recommend pre-cleaning be performed at the end of the procedure, immediately after use, while still in the OR," she said. "Delays in reprocessing may require additional steps in making the device patient ready and safe. In that regard, OR staff are in the best position to carry out this critical step in reprocessing as they are most aware of the 'procedural stop time.'"

Benedict recommends this step as a standard inclusion of workflow.

"Wiping and flushing with water or detergent can easily become part of the workflow as a documented standard of care at the bedside," she said. "The purpose of the wipe or flush is to remove heavy debris from the instrument to avoid drying of residual bioburden. Highlighting the rationale for this activity can increase user knowledge as to why the step is important and facilitate understanding of why pre-cleaning should be carried out by the OR staff who have immediate access to a device following a procedure."

Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, Agiliti, understands the conundrum between OR clinicians or SPD techs handling pre-treatment.


Melissa Kubach

"Unfortunately, there is no simple answer to this question," she indicated. "There are pros and cons for both scenarios, but the smart move is to follow the option posing the least risk. [Pre-treating] should be completed every time at the point of use – as soon as possible – and should involve [those] already in the room since timeliness is important. Delaying [pre-treatment] or waiting for a courier before transporting to Sterile Processing invites potential delays and other logistical questions. How many case carts are in line to be cleaned? Which ones contain endoscopes? How many Sterile Processing departments have available staff to send post-case to the Operating Room? Sterile Processing departments across the country are already struggling with personnel shortages."

The type of device also can complicate the process for SPD, according to Kubach.

"Large diameter gastrointestinal models require cleaning steps unable to be completed without their processor/light source, bottle, tubing set-ups, valves and active suction," she noted. "It is doubtful that a secondary tower and accessories would be housed in Sterile Processing due to cost alone."

Kubach acknowledges that Operating Rooms have long struggled with flexible endoscope [pre-treating] requirements and compliance.

"Critical steps are often partially completed or skipped entirely. While there are many reasons for this lack of compliance, the reality is that there are many natural barriers and competing priorities that lead to ineffective [pre-treating] in the Operating Room," she continued. "For example, a controlled sterile environment is not conducive to utilizing non-sterile liquids and detergents, especially while the patient is present. OR staff are naturally relucent to introduce the potential of a messy, contaminated process. Patient care and recovery rightfully must take priority after the procedure and post-case turnover activities may be rushed. These challenges are not easily solved for and should not be dismissed."

But she sees room for improvement and suggests some "quick-wins" through engaging and comprehensive education.

"OR staff rarely receive formal model- or manufacturer-specific training, and most have never seen or read [pre-treating] requirements in the endoscope manufacturer's IFU," she said. "The greater the number of personnel involved proportionately decreases the likelihood of effective 'hands-on' training, especially for models with [pre-treating] procedures that are quite complex. Additional underlying factors also contribute, such as a perception that cleaning should only take place in a reprocessing area or that [pre-treating] is not important since SPD will just be cleaning it again anyway."

POU POV

Jean Sargent, Principal, Sargent Healthcare Strategies, has extensive experience as a hospital Supply Chain and SPD leader and remains sacrosanct.


Jean Sargent

"This is a point of use function," she said. "The scopes are delicate, intricate and expensive. The scopes generally require a quick turnaround time. Delaying the start of the cleaning process by 15 minutes allows the bioburden to begin to harden. This extends the overall cleaning time, therefore turnaround-times, and can cause possible damage to the scope to the point of taking it out of service. All delays in patient care."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare, concurs with the location of pre-treatment and even specifies who should be responsible for doing it.

"[Pre-treatment] of surgical instruments should always be done in the OR," he asserted. "During the procedure, when instruments – including endoscopes – are traded off by the surgeon, the scrub nurse/tech should remove any gross debris. After the surgery, for rigid endoscopes, the scrub should carefully wipe off all gross debris using a clean towel or sponge soaked in water."


Gregg Agoston

For all endoscopes, the distal end should receive particular attention, according to Agoston.

"The distal end contains the optic window and light window and in the case of some flexible endoscopes channel openings and air water nozzles," he said. "It is very easy to run a sponge up and down the shaft of a rigid endoscope or the insertion tube of a flexible endoscope, however, the distal end is the most challenging to clean due to its small size and cervices formed by the juncture of the windows/channels."

Agoston insists that saline solution should never be used because the salt can cause harm to components.

"For flexible endoscopes it is essential for the scrub/surgeon to follow the manufacturer's IFU and suction water or enzymatic solution in sufficient quantities through the endoscope, and in addition, wipe down the insertion tube with water or enzymatic solution," he continued. "One of the key concepts is that the quantity of water/enzymatic solution must be sufficient per the IFU. Often, we see clients use smaller quantities of water/enzymatic solutions (e.g., 250ml for an adult colonoscope when 500ml should be used on this device) when a greater volume is required for thorough [pre-treating]."

Accessory instruments, such as cameras, light guides and instruments, should also be wiped off with a moist towel or sponge to remove gross debris, Agoston advises.

After pre-treating in the OR, the instruments must be transported to SPD.

"To prevent drying, a towel moistened with water can be placed over the instruments and/or the instruments can be sprayed with enzymatic solution/foam designed for [pre-treating]," Agoston recommended. "As a prerequisite to using a sprayed enzymatic solution/foam, the instrument should be cleaned of all gross debris. In addition, it is very important that the enzymatic solution/foam cover the entire instrument and lumens if indicated.

Agoston urges that transport and cleaning of the instruments should occur as quickly as possible following the surgical procedure for a very logical reason:

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"Certain instruments require an extended processing cycle if too much time passes between the procedure and the start of the cleaning process. IFUs should always be followed," he warned.

"In cases where it is known that processing will be delayed, there are foam products that are designed for extended hold times," he said. "These products are specifically designed to encapsulate the flexible endoscope, keeping it moist and working to prevent the formation of biofilms for extended periods of time. When using these products, it is extremely important to follow the IFU regarding filling all channels with the product. Covering only the exterior of the endoscope is not sufficient to prevent biofilm formation in the channels." HPN

Editor's Note: Due to a recent industry lexicon change, all references to "pre-cleaning" have been changed to "pre-treating" or "pre-treatment."

Pre-treating short cuts, task shifts can breed danger for patients

by Rick Dana Barlow

Delaying or even skipping out on the pre-treatment of used surgical devices and instruments – endoscopic or otherwise – creates serious problems for Sterile Processing & Distribution professionals and can lead to dangerous problems for patient outcomes.

"When pre-cleaning is not performed, the likelihood for biofilm formation increases due to the prolonged time afforded for bacteria to adhere to the device itself," said J. Hudson Garrett Jr., PhD, MSN, MPH, MBA, FNP-BC, CPHQ, PLNC, AS-BC, IP-BC, VA-BC, CFER, CPPS, CDONA, DICO-C, GDCN, NREMT, NCEE, FACDONA, TR-C, FAAPM, FNAP, FSHEA, Adjunct Assistant Professor, Division of Infectious Diseases, Department of Medicine, Center for Education and Training in Infection Prevention, University of Louisville School of Medicine. "Skipping this step altogether can tremendously endanger the overall efficacy of high-level disinfection of the device."

Ron Banach, Director of Clinical Education, Ruhof Inc., is more direct: "Once the biofilm process has started, the ability to attain high-level disinfection or sterilization will fail."

If there are any questions about pre-treatment or the delay or lack thereof, Jamie Zarembinski CCSVP, CER, Clinical Educator – Sterile Processing, Key Surgical, a STERIS company, synopsizes the inevitable outcome. "Patient harm. There is no way around it. An improperly reprocessed scope is a hazard for the patient," she warned. "Taking shortcuts, skipping steps in the reprocessing cycle, and not following the instructions for use (IFU) ultimately leads to patient harm. There is significant pressure in this role to get things done quickly. This pressure is often coupled with inadequate training and insufficient continuing education opportunities. Endoscopes are incredibly complex and should be reprocessed with great care and attention to detail. These devices are required to come with detailed IFUs for the manufacturer to obtain 510(k) clearance. The IFU must contain reprocessing instructions. By referencing the IFU for each device, providing adequate training and continuing education, and keeping IFUs accessible, facilities can reduce errors and the risk of patient harm related to neglecting steps in the reprocessing cycle."

Zarembinski's colleague on the OR side agrees wholeheartedly.

"It is vital to remember that the patient on the operating room table is all our patient, and we are dealing with their life," indicated Michelle Lemmons RN, PHN, CNOR, CCSVP, Clinical Educator – Operating Room, Key Surgical, a STERIS company. "There is no shortcut that is worth putting a person's well-being and life at risk. The 'do more, with less, in less time' cycle can be challenging to overcome. However, keeping the patient front of mind is the solution to breaking this cycle. As Jamie stated, endoscope reprocessing is complex and attention to detail is imperative. The scope reprocessing role should be considered as specialty, and the training and preparation for this role should reflect that. Remember that the 2008 HICPAC Guidelines stated, "contaminated endoscopes have been linked to more healthcare-associated infections than any other medical device." Prioritizing this specialty through training and education is a great investment for any facility."

Cornerstone of quality

[Pre-treating] is critical to ensure subsequent reprocessing steps, including high-level disinfection or sterilization, can be effective, according to Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas.

"When performed correctly and with knowledge as to why the process is critical, [pre-treating] is a cornerstone in high quality safe patient care," she noted. "[Pre-treating] requires minimal time to complete and provides the foundation for effective and efficient reprocessing of medical devices."

The absence of pre-treatment at the point of use, interrupts the linear progression of the entire process, according to David Willoughby, Vice President, Marketing & Business Development, Medtrica.

"Simply put, failure to conduct [pre-treating] on post-procedure instruments can significantly complicate the manual cleaning/decontamination process, which in turn increases the risk of patient morbidity and patient cross-contamination," Willoughby said. "It is well understood that the longer bio-contaminants are left on instruments the harder they are to remove. Microbes can easily damage instruments if they remain on instrumentation surfaces (internal and external) for prolonged periods of time, making the removal of these encrustations and biofilms extremely challenging, if not impossible, to address through standard cleaning procedures. This in turn creates a cascade of problems and circumvents the very procedures so rigidly adhered to by SPD.

"So, in essence, POU [pre-treating] really comes down to effectively adhering to and applying pre-transport protocols with the most effective enzymatic and detergent-based [pre-treating] and wetting agents (formulations) available in order to not only prevent instrument damage and or malfunction but also (and more importantly) to mitigate the risk of surgical site infection," he added.

John Whelan, RN, Clinical Education Specialist, Healthmark Industries, cautions that OR and SPD professionals should not short-change pre-treatment but also should recognize additional necessary steps in that early process. This includes disconnecting accessories, preparing handoff communication, and preparation for soiled transport, he added.

Where and when this occurs matters for six key reasons, according to Whelan.

- "It's in endoscope manufacturer's IFUs to perform point-of-use treatment as soon as the procedure is complete. IFUs always need to be followed.

- "It's consistently found in national standards and guidelines – endoscopes need to undergo [pre-treating] at point of use. Standards and guidelines direct best practices.
- "For certain brand, generation and type of endoscopes, there are steps that can only occur at the point of use – while the scope is still hooked up to the processor. For example, certain GI endoscopes require flushing the air water channel with the air water channel cleaning adapter. This can only happen while the scope is connected to the airflow regulator in the procedure room – so it can't be done in the reprocessing room.
- "The rationale here is critical to understand the significance. The sooner the better to remove residual bioburden and limit biofilm development. It only takes minutes for biofilm to form and proliferate.
- "Each step of processing done correctly and completely allows the steps that follow to be more successful.
- "Each step performed correctly and completely serves to limit chances for patient injury/infection."

Simple math

OR and SPD professionals merely need to equate the pre-treatment process as a mathematical equation, according to Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, Agiliti.

"Each flexible endoscope cleaning step serves a purpose necessary for achieving the desired outcome – a patient-safe device," Kubach said. "[Pre-treating] is the first step in an extensive line of steps. Skipping any one step places all subsequent cleaning actions at a disadvantage.

"Mathematically speaking, each stage of cleaning equates to reducing bacteria," she continued. "Every stage, from [pre-treating] to scrubbing to flushing to rinsing, is only able to achieve a certain level of logarithmic bacteria reduction. Even with repetitious cleaning, there will be a point for which no additional benefit will be realized. This is even more concerning when employing high-level disinfection; a method that does not remove or kill all living microorganisms.

"Delayed cleaning allows bacteria to multiply at exponential rates. Consequently, as bioburden is allowed to increase, the proportionate ability to produce a thoroughly clean final product has decreased. Additionally, biofilms can form as bacteria adhere to internal channels, making removal increasingly difficult or even impossible - and which places patients at even greater risk of infection," Kubach noted.

Shaun Sweeney, Vice President, Cygnus Medical, encourages the OR and SPD to set priorities.

"Unfortunately, unlike with flexible endoscopes many ORs have not prioritized [pre-treating] as a critical step," he observed. "The more intricate the instrument the more chances of gross contamination drying in crevices and not being properly removed in the wash cycle. Like eggs on a plate, they are easily removed with water immediately after the case. With added time they are proportionately harder to remove. The quality of patient care for the next patient and the overall condition of the instrument inventory are at risk."

Because flexible endoscopes represent some of the most complex instruments to clean, processing errors have resulted in serious patient harm and death, which has been well-document in media reports and professional studies, according to Gregg Agoston, M.B.A., Vice President, Business Development, SPD Transformation Services, SpecialtyCare.

"The American College of Surgeons identified two risk factors for [surgical site infections] that specifically pertain to Sterile Processing," Agoston said. "First, the longer a patient is exposed to the OR the greater the risk of SSI. Second, the instruments must be sterile or high-level disinfected. The level of processing is dependent upon the IFU/Spalding Classification. Instrument processors can impact the length of OR exposure if the instrument is not available or if an instrument is delivered to the OR that is not in good working condition. In addition, if an instrument is not clean it cannot be considered sterile and could lead to an SSI. While there are many risk factors that contribute to an SSI – some intrinsic to the patient (e.g., smoking, diabetes, etc.) and other extrinsic (e.g., patient preps, sterile technique, use of antibiotics etc.), instrument processing does play a significant role in the prevention of SSI by ensuring that products they are responsible for do not extend patient exposure in the OR and by ensuring that instruments are in fact sterile or high-level disinfected."

Jean Sargent, Principal, Sargent Healthcare Strategies, has extensive experience as a hospital Supply Chain and SPD leader, and highlights the butterfly effect.

"The delay in completing the complex cleaning process of over 100 steps will likely create delays in turnaround-times, and possibly cause damage, further delaying the time to have the scope ready for the next patient. Delay in patient treatment or cancellation of treatment is an issue in the satisfaction scores," she said. **HPN**

Editor's Note: Due to a recent industry lexicon change, all references to "pre-cleaning" have been changed to "pre-treating" or "pre-treatment."

What does SPD need for endoscope reprocessing quality performance?

As much of the Sterile Processing & Distribution profession buzz swirls around the emergence of disposable/single-use-only endoscopic devices, SPD leaders want to ensure those on the front lines remain grounded in the fundamentals.

They quickly point out that the media coverage surrounding healthcare-associated infections likely stemming from improper reprocessing may not be blamed totally on the devices and technological complexity, even as they acknowledge that endoscopes include numerous nooks, crannies and areas that can be hard to clean, which makes them hard to disinfect and sterilize.

But the disposable/single-use-only endoscopes don't represent the silver bullet that some might hope will solve the quality issues bedeviling SPD operations. In short, this represents less of a device issue and more of a communication, education and training issue that must be checked and solved regardless of the device or technology being upgraded or redesigned. It's akin to the old adage, if a device isn't clean, it can't be sterilized.

For the fourth consecutive year, *Healthcare Purchasing News* surveyed a small group of sterile processing subject matter experts on seven potential – but likely scenarios – that may direct and redirect how SPD navigates the 2020s from a quality standpoint. *HPN* asked the executives from device manufacturers and reprocessing product companies to rank the seven strategies (1 being the most important or influential; 7 being the least important or influential).

To show the trends year over year, *HPN* publishes the aggregate respondent data from 2020, 2019 and 2018 as well. What's noteworthy is that the results seem consistent. In fact, the top two strategies this year are the same as the top two last year, which had represented a transposition of the top two the year before that. Essentially, the top two strategies – fundamental in their own right – have remained consistent for three consecutive years. Curiously, the proverbial Bullwhip moves up a notch to No. 3 and Big Brother jumps three spots to No. 4 – both of them above the relatively new disposable/single-use tech breakouts.

1. **Thoroughly educating, training, vetting and certifying SPD staffers on proper and effective cleaning techniques**
   2021 average score: 1.7
   2020 average score: 2.43
   2019 average score: 2.5
   2018 average score: 1.5
2. **Demanding, receiving and following validated instructions for use (IFUs)**
   2021 average score: 2.6
   2020 average score: 2.64
   2019 average score: 1.9
   2018 average score: 2.5
3. **Holding staffers accountable/responsible for endoscope cleaning "violations"**
   2021 average score: 4.0
   2020 average score: 4.23
   2019 average score: 4.8
   2018 average score: 2.8
4. **Comprehensively monitoring and tracking all steps in the process with sensors and video technology**
   2021 average score: 4.5
   2020 average score: 4.85
   2019 average score: 4.7
   2018 average score: 3.4
5. **Switching to endoscopes that contain disposable/single-use-only components that can be discarded or swapped out after use**
   2021 average score: 4.8
   2020 average score: 3.62
   2019 average score: 4.1
   2018 average score: n/a
6. **Switching to disposable/single-use-only endoscopic devices for selected endoscopic procedures only (e.g., bronchoscopy, etc.)**
   2021 average score: 5.3
   2020 average score: 4.46
   2019 average score: 4.3
   2018 average score: n/a
7. **Switching to disposable/single-use-only endoscopic devices for all endoscopic procedures**
   2021 average score: 6.6
   2020 average score: 4.77
   2019 average score: 6.1
   2018 average score: 4.8

HPN invited respondents to explain their perspectives and even offer alternatives. Here's what they shared.

Shaun Sweeney, Vice President, **Cygnus Medical**, emphasizes that "thoroughly educating, training, vetting and certifying endoscopy staffers on proper and effective cleaning techniques" is essential. "Bedside cleaning still falls within the realm of the endoscopy unit and is the most important step in the process," he added.

Although she ranked No. 6 a little higher, Melinda "Mindy" Benedict, CIC, CFER, Global Senior Manager, Infection Prevention, **Olympus Corporation of the Americas**, qualifies the option from a regulatory perspective. "Single use for certain patients and procedures is recommended by the FDA, whose guidance is of utmost importance," she said.

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, **SpecialtyCare**, remains squarely in the camp of the top 4 rankings (with the bottom two in that group transposed). He points to staff quality as paramount.

"For the processing of flexible endoscopes used in a GI clinic, most hospitals and clinics have dedicated staff whose only job is to assist with the endoscopes and process them," Agoston noted. "Having a dedicated team, who are highly trained to follow all steps outlined in the [instructions for use] is critical to the successful cleaning and processing of the devices. For flexible endoscopes used in the OR, many hospitals

process these in SPD often with much lower rates of confidence that all processes in the IFU have been followed. This is partially due to the competency of the technician who performed the cleaning. It is also due to the common practice in most SPDs where everyone takes a turn at all functions (including decontamination, assembly, sterilization, case carts etc.).

"By not designating qualified staff to the important function of cleaning flexible endoscopes, significant variation is created in quality," Agoston continued. "With some flexible endoscopes IFUs containing over 100 pages of instruction for processing, if the hospital does not designate highly trained specialists to clean flexible endoscopes there is a significant chance that the instruments will not be properly prepared for sterilization or high-level disinfection."

Agoston points to cross-training and multitasking as the culprit even though some feel it's more efficient.

"When we look at the root cause of processing failure, it usually boils down to not having qualified staff perform the processes, lack of proper equipment/supplies for the process and the lack of standard work developed as the process," he indicated. "Allowing everyone to take a turn in decontamination to clean complex instruments results in significant errors."

Switching fully to disposable/single-use devices poses its own challenges, according to Agoston.

With over 50 million GI procedures and another 25 million surgical procedures performed with flexible endoscopes (e.g., ureteroscopy, cystoscopy, ENT, etc.), if we switched to disposable flexible endoscopes, the mountains of surgical waste would be enormous," he said. "In addition, while flexible endoscopes are complex instruments, they certainly are not the only complex instrument that we ask SPD to process. If we are calling for disposable or 'semi-reusable' flexible endoscopes because we are not confident in SPD to process them, then we should be calling for disposables for Da Vinci instruments, and most of the other complex instruments used in minimally invasive orthopedic, spine, ENT, etc."

Agoston traces the roots to quality concerns in SPD to roughly 80 years ago.

"The cause of all of this is found in the origin of SPD back in the 1940s when the American College of Surgeons called for a centralization of the sterilization process," he recalled. "At the time the instruments were very simple by today's standards, but the sterilization process was complex due to not having automation for the sterilization process or record keeping of the sterilization parameters. At the time, you could move staff over from dietary or [environmental services] and with good supervision, [they could] clean and sterilize the stainless steel instruments used in open surgical procedures that were being done at that time.

"Fast forward to the advent of [minimally invasive surgery] and advanced surgical procedures where the majority of the devices are complex," he continued. "Thinking that you can bring in 'lay-people' and expect them to know every IFU, work process, piece of equipment in the department, how to disassemble, clean, reassemble, test, package and sterilize for every instrument in a hospital is not attainable, particularly given the very high rate of turnover in SPD staff.

"The solution is in allowing for specialization in SPD where there [are] staff who are more highly trained to process complex instruments," he recommended. "We do this in orthopedics with the help of the vendor reps, and we do it in GI endoscopy clinics. For the vast amount of other complex instruments for MIS, everyone in SPD takes a turn. Recall that there are many small diameter flexible endoscopes that are processed by SPD. This variation in staff competency results in significant variation in quality."

Automation plays a key role, too, according to Agoston.

"Automation of processes is very important because no matter what is done, humans will vary in their processes," he noted. "Machines do not unless they are malfunctioning. With machines we get consistent times, chemical exposure, rinsing and disinfection. Most rigid endoscopes can be processed through automated washers if they have the proper container, but most hospitals do not do this, resulting in variation in cleanliness. All facilities processing flexible endoscopes should have the latest equipment for cleaning and processing the devices. This can also be said for DaVinci instruments where we see hospitals that do not have the appropriate ultrasonic equipment to clean the devices. The list goes on.

Supervision also must be addressed. "Without a knowledgeable supervisor and documented competency, process variation again will enter," he said. "Variation is the enemy of quality." **HPN**

All hail to the hybrids by the mid-2030s

New model excitement eventually will settle into balance in motion

by Rick Dana Barlow

As the billowing smoke clears from the roiling emergence of disposable/single-use-only endoscopes, Sterile Processing & Distribution executives and leaders are beginning to see some clarity on endoscopic product market shifts as the future comes into focus.

From an armchair investor standpoint, their advice seems to line up this way:

1. Don't invest in reusable endoscope growth, but don't totally dump all your stock in it.
2. Don't bet your entire fortune on disposable/single-use-only domination just yet, but certainly bolster your portfolio.
3. Look for the future to be somewhere in between the previous two extremes as the market and SDP behaviors will find balance between moving back and forth rather slowly.

Healthcare Purchasing News continues to explore the emergence of disposable/single-use-only endoscopic devices that currently are making some headway in terms of generating interest and gaining customers. Just a few years ago, the Surgical Services and SPD market segments had disposable/single-use endoscopic devices on their wish lists as the products remained in development. They're here now.

And rather than keeping these new products at arm's length, SPD executives and leaders fully acknowledge they're here to stay, but SPD likely shouldn't be concerned that their future in reprocessing reusable devices is in jeopardy.

HPN reached out to a small group of executives at manufacturers of endoscope devices and related reprocessing supplies and equipment about their changing forecast of any market shifts during the next 10 to 14 years through 2035. They were able to choose from among five different potential market scenarios and to share their reasoning.

1. **Fully reusable endoscopes will remain.** Healthcare organizations will continue to rely on fully reusable flexible and rigid endoscopes for the majority of minimally invasive surgical (MIS) procedures
2. **Hybrid models will become a minority segment.** Healthcare organizations will increasingly shift toward using hybrid flexible and rigid endoscopes that incorporate disposable components that can be discarded after use, but the hybrid models WILL NOT surpass the use of fully reusable models
3. **Hybrid models will become the majority.** Healthcare organizations will increasingly shift toward using hybrid flexible and rigid endoscopes that incorporate disposable components that can be discarded after use, and the hybrid models WILL surpass the use of fully reusable models
4. **Disposable/single-use only models will become a minority segment.** Healthcare organizations will increasingly shift toward using fully disposable flexible and rigid endoscopes, but the disposable models WILL NOT surpass the use of fully reusable models
5. **Disposable/single-use only models will become the majority.** Healthcare organizations will increasingly shift toward using fully disposable flexible and rigid endoscopes, and the disposable models WILL surpass the use of fully reusable models

Move to the middle

Experts remain steadfast and unmovable in their opinions that the two "fringe" elements – Nos. 1 and 5 – likely will not happen. They believe the market will not sustain the use of only reusable endoscopes for surgical procedures. At the same time, they also argue the market will not shift totally to disposable/single-use models either, nor will these models surpass or overwhelm the use of reusables.

Several, however, anticipate a growing shift toward use of disposable/single-use endoscopes for an increasing number of surgical procedures but they will not surpass the use of fully reusable models.

"Continuing outbreaks associated with all flexible and rigid endoscopes dictate that there is a device-related contamination issue that transcends medical disciplines," concluded J. Hudson Garrett Jr. PhD, MSN, MPH, MBA, FNP-BC, CPHQ, PLNC, AS-BC, IP-BC, VA-BC, CFER, CPPS, CDONA, DICO-C, GDCN, NREMT, NCEE, FACDONA, TR-C, FAAPM, FNAP, FSHEA, Adjunct Assistant Professor, Division of Infectious Diseases, Department of Medicine, Center for Education and Training in Infection Prevention, University of Louisville School of Medicine. "As such, there must be a shift from using the exact devices that the data shows cause infection outbreaks and move to a more suitable platform of sterile, single-use endoscopes that completely eliminate the need for reprocessing. Eliminating

this risky process is the highest possible level of infection control intervention."

Melinda "Mindy" Benedict, CIC, CFER, Global Senior Manager, Infection Prevention, **Olympus Corporation of the Americas**, concurs to an extent and with caveats.

"Single-use endoscopes will surpass reusables in some specialty areas, but adoption will be different for different patient populations, different physician preferences and different facilities," she said. "The medical waste and cost challenges will need to be addressed."

Hybrids stake shallow claim

The majority of sterile processing subject matter experts remain solidly behind so-called hybrid model endoscopes, which are reusable devices that incorporate disposable/single-use components that can be discarded after use. And while this group foresees hybrids gaining in popularity, they are split right down the middle on whether they will overtake the use of fully reusable devices.

"I do not see disposable rigid endoscopes taking over their reusable counterparts," said Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, **Agiliti**. "Disposable rigids have been tried in the past, but adoption was minimal due to problems with image and lighting quality, and those devices ended up being cost prohibitive. Without addressing those issues, I believe the industry will stay with the current rigid equipment.

"Incorporation of hybrid flexible endoscopes with disposable components will increase," she observed, "especially for procedures with elevated risk. This is further supported by the current [Centers for Disease Control and Prevention] recommendations."

Kubach predicts fully disposable models to be reserved for specialized functions.

"Employing fully disposable flexible endoscopes has and will continue to increase for certain procedures and specialties such as airway management, including some bronchoscopy," she noted. "Currently, this has been highly based on emergency use or convenience, such as after-hour or weekend use, when cleaning staff are not readily available. Disposable 'back-up' inventories have also increased for high-volume Anesthesia departments. Another area benefiting from disposable-use based on need is Urology. Fast-paced patient turnover and the delicate nature specific to small diameter flexible ureteroscopes has created a niche."

Kubach sees certain endoscope types not yet fully ready for disposable prime time.

"Standard large diameter flexible endoscopes will be slow to jump the disposable threshold," she indicated. "Reimbursement, or the lack thereof, is key. Further speed-bumps are related to current reusable high-definition image quality and the 'feel' of the endoscope itself. Physicians will be slow to relinquish high resolution and technological features such as anatomical positioning and enhancements from narrow band lighting, spectral imaging or blue and white light features."

Weighing the pros and cons of using primarily reusable models indicates that the rise of hybrid models seems inevitable, according to Shaun Sweeney, Vice President, **Cygnus Medical**.

"The current reusable scope image quality and construction clearly offer the doctor greater control, which leads to greater patient care," Sweeney said. "The industry is constantly improving cleaning techniques at each of the cleaning stages, but there are some challenges that remain. Focusing on the problem areas, such as using disposable components of ERCP elevator mechanisms, has already begun. Disposable valves have been very successful in making this transition.

"The infection control benefits of a 100% disposable scope does not outweigh the benefits of the performance quality of current reusable scopes," he continued. "Having had an 8-track player in my first car, I have come to realize how hard it is to see how dramatically things can change overnight. Likely, 20 years from now, there will be an exponential technology shift that has not even raised its head in today's market. I think the best strategy today is to constantly be looking for incremental improvements until that time comes."

John Whelan, RN, Clinical Education Specialist, **Healthmark Industries**, casts his impressions in context of the previously unforeseen circumstances from the COVID-19 pandemic.

"Who could have foreseen the global semiconductor shortage that has crippled availability for new vehicles?" he asked. "Also using the automobile analogy, the cost of hybrid and fully alternative (for endoscopes, read as fully disposable) technology is prohibitive for many facilities to consider. I believe even 15 to 20 years out, purchase/lease decisions [for] flexible endoscopes will still be considerably influenced by purchase/supply costs, and less so by sustainability (i.e., recycling) considerations."

Because healthcare institutions are layered organizations, change happens slowly, according to Whelan. "Until or unless governmental direction is even more prescriptive, and/or full facility reimbursement for single-use endoscopes is guaranteed across-the-board, reusable endoscopes will still be in use," he said. "What I do believe will change more over the next several years is technological advances in the automated cleaning, disinfection and sterilization for reusable devices – including flexible endoscopes. Research and development continue underway to bring such changes to the market, and with a goal of affordable implementation."

Gregg Agoston, Vice President, Business Development, SPD Transformation Services, **SpecialtyCare**, expects the market will shift to help solve current problems.

"To this end, hybrid products will play a role and to the end that the product changes provide economic and safety benefits that outweigh current products, they will be accepted," Agoston indicated. "Often with flexible endoscopes, they are the singular product used in the procedure, thus it is relatively easy to identify the endoscope as the cause of an infection when this occurs.

"In the majority of other [surgical site infections] it is not so easy," he continued. "Was it the rigid endoscope, the shaver, the [minimally invasive surgery] hand instrument, the failure of the nurse to properly prep the patient, or the patient intrinsic factors that lead to the infection? My point being that if we are moving to more costly or waste-producing products because we are fearful that the SPD staff cannot properly clean them, then we should do this for all surgical procedures that use complex instruments because all can cause infection.

"We know that the SSI rates as of the last report were the only category of [healthcare-associated infections] that did not show a decrease," he said. "We also know that SSI are only tracked for a certain few procedure types, thus the true number of SSI is much higher than reported. At a recent meeting for OR business managers I asked the audience how many had had or had a close relative or friend acquire an SSI and three-fourths of the audience raised their hand. The solution should be focused on product improvements to make them easier to process, process improvements to automate as much as possible and staffing improvements recognizing the importance of a well-trained, stable staff of professionals whose role it is to process complex instruments."

Hybrids go deep

Some may not believe hybrids will progress so far as to be used by the majority, but others certainly do.

"The most important things that will be considered are budget, Infection rates, and material quality," said Jamie Zarembinski CCSVP, CER, Clinical Educator – Sterile Processing, **Key Surgical**, a STERIS company. "If the cost of a hybrid or disposable scope is comparable to the cost of reprocessing a reusable scope, it will increase their use. Further, if hybrid/disposables decrease infection risk, the industry trend will undoubtedly support the transition to hybrid/disposables. Finally, the material quality and complex video components in each type of scope will influence choice.

"One of the current hot topics causing hesitation to transition to hybrid/disposable scopes is image quality," she said. "If surgeons are unable to properly visualize, diagnose and treat related to scope image issues, the industry is going to stick with reusables. There is a lot of pressure on manufacturers of all types of scopes to optimize outcomes in all three of these areas – budget, infection rate reduction, and quality, but this pressure will ultimately lead to greater patient outcomes."

For Ron Banach, Director of Clinical Education, **Ruhof Inc.**, economics and image quality will drive migration.

"The cost of the disposables will limit the full integration of disposable flexible and rigid endoscopes unless the insurance companies adjust their procedure reimbursement rates to include the additional cost for the disposables devices, and the manufacturers can equal or exceed the physicians demands for diagnostic quality," he said.

Sterile Processing technicians have had to endure the cleaning challenges with complex reusable medical devices like flexible, semi-rigid, and rigid endoscopes, according to Cheron Rojo, CHL, CIS, CER, CFER, CRCST, Clinical Education Specialist, **Healthmark Industries**.

"With the implementation in recent years of a disposable tip for some of the vendors of duodenoscopes the change has made a positive difference for sterile processing professionals regarding cleaning, but there is still room to expand without altering the feel or function of the medical device for the surgeon or proceduralist," Rojo said.

"Hybrid [models] with both reusable and disposable sections save money and the environment instead of a full disposable medical device that can be costly to the patient and add to the landfill, especially in states with clean initiatives like California, Hawaii, etc.," he said. 'Further development still needs to take place to think outside the box to provide hybrids in semi-rigid and rigid endoscopes that meet surgeon, sterile processing and healthcare facility's needs; and most of all, provide a functional, clean, and safe medical device for patients."

Jean Sargent, Principal, **Sargent Healthcare Strategies**, and a former Supply Chain and SPD director, offers a curious perspective that hearkens to the bottom line.

"For me personally, I am hoping hybrid models will be a back up to reusables," she said. "However, in dealing with requests from physicians for disposable or hybrid scopes for convenience, we are overlooking the root cause. Is the root cause staffing? Proximity to processing facilities? Not enough reusable scopes? Once a root cause analysis is completed, determine what needs to be done to address the need. It may be reusable/hybrids or it may be staff or updated processes. Each and every organization is different and should look at the need from all three viewpoints when determining a strategic direction for these products." HPN

ENDOSCOPE CARE 2021

Dawn of the disposables domination

Or maybe that dream is single-use only vs. sustainable?

Sterile Processing & Distribution (SPD) executives and leaders with special expertise in endoscopic devices may envision a future flush with hybrid products that represent the optimal answer to the reusable vs. disposable debate.

But do they *ever* anticipate disposable/single-use rigid and/or flexible endoscopes emerging as the preference used by the majority of surgeons and healthcare organizations? Maybe. Maybe not.

"In the long term, I think this is very much a possible reality to reduce the risk to patients and to improve clinical through-put of clinical procedures. There are two critical determining factors that will likely drive this transition: Clinical device performance and functionality and price. The single-use devices must perform the same or better as reusable devices and the single-use devices must be economically priced to encourage use. In addition, additional single-use device reimbursement will help healthcare facilities in making the transition away from reusable devices."

J. Hudson Garrett Jr., University of Louisville School of Medicine

"At this point, I do not see fully disposable endoscopes gaining an overall 100% acceptance rate. Widespread, fully disposable rigid use will remain minimal. Small diameter flexible disposables use will continue to grow in areas of non-therapeutic procedural need. Duodenoscopes used for ERCP procedures will continue to move towards partially or fully disposable aspects. The remaining reusable flexible models will continue to be the norm until issues such as image quality, features, cost-effectiveness and waste concerns are sufficiently addressed."

Melissa Kubach, Agiliti

"It depends on the facility's focus on sustainability, cost and staffing levels. The impact on the environment to manufacture disposables must be taken into consideration. The cost of disposables could possibly pay for another staff member. What happens to all the scopes that are in good working condition? I liken this to disposable laryngoscope blades and handles – so much waste and stacks of reusables in drawers. That is not caring for the environment."

Jean Sargent, Sargent Healthcare Strategies

"Single-use endoscopes are going to be a great option depending on facilities' volume of cases and their infection rate. For a low-volume, high infection rate facility, it's a clear choice: Go single-use. Similar to instruments in the operating

room, surgeon preference and case-mix are going to be drivers in making these decisions. According to the American Gastroenterological Association, gastroenterologists suffer from overuse injuries such as pain in their fingers, wrists, forearms and back. It would be great to see the considerations between single-use and reusable create some positive ergonomic changes to scope design and further optimize the user experience in addition to improving safety and quality of these devices."

Michelle Lemmons, Key Surgical, a STERIS company

"Clinics where there are specialized staff dedicated to the processing of flexible endoscopes, given that they have the proper training, supervision, equipment specifically designed and automated as much as possible, should not need to rely on single-use endoscopes.

"Hospitals where they require the SPD to process GI scopes and small diameter flexible endoscopes, often without proper training, supervision, and equipment specifically designed for these devices, run the serious risk of the instruments not being properly processed. This concept applies not only to flexible endoscopes but also to all complex instruments. I believe that the answer is in solving the root cause of the problem, which in some cases is the design of the endoscopes, but in most cases is in providing a dedicated highly trained staff that is properly incented to perform high quality work, and [with] the tools to do so – these being supervision, automated equipment, proper supplies and standard work through documented processes and procedures."

Gregg Agoston, SpecialtyCare

Don't let hang-time become a hang-up

Aeration, drying and storage represent integral finishing steps for patient safety

Photo courtesy: Healthmark Industries

From pre-treatment at the point of use to visual inspections and leak testing to cleaning to high-level disinfection and rinsing to sterilization, the process to reprocess endoscope devices and instruments can be as complex as the products themselves.

But the final step in the reprocessing process – aeration, drying and storage – before handling/transportation to the point of use and ongoing maintenance and repair – represents the last and perhaps most important quality checkpoint before those endoscopic devices and instruments exit Sterile Processing & Distribution (SPD) on the route back to Surgical Services.

Because that closing step remains so essential for patient safety, *Healthcare Purchasing News* recruited a small group of SPD experts to share useful tips and tricks to ensure ready-to-use endoscopic devices and instruments. Here's what they recommend.

Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, **Olympus Corporation of the Americas**, emphasizes that endoscope drying and storage play a key role in endoscope reprocessing as it is important to stress that preventing the introduction of contaminants after disinfection is pivotal to patient safety. Benedict's tips on drying and storing reprocessed endoscopic devices:

1. "The quality of compressed air used to dry endoscopes is important. Inadequately filtered air could introduce contaminants to a clean endoscope. Societies are moving toward the use of instrument-quality air. The AORN guidelines state, "The exterior surfaces of the endoscope should be dried with a soft, lint-free cloth or sponge and all channels purged with instrument air."[1] GNA indicates that step No. 8 in endoscope reprocessing is drying, "which requires an alcohol flush, followed by forced-air drying with instrument-quality compressed air."[2]
2. "Heathcare facilities may want to consider avoiding the use of oil-based compressors for drying endoscopes.
3. "When drying endoscope channels, be sure the maximum air pressure introduced does not exceed manufacturer IFU requirements. The latest Multisociety Guidelines recommend, "Endoscopes should be completely dried after reprocessing and before use."[3]
4. "Whenever possible, store the endoscope in a drying cabinet. If a drying cabinet is not available, dry the endoscope (exterior and lumens) and hang it in a well-ventilated HEPA cabinet that provides positive pressure.
5. "Once disinfected, endoscopes should be dried and stored in a way that will protect them from external contaminants. Hang the endoscope in a vertical position

to enable drying and maintain scope integrity. Remove caps, valves, and other detachable parts per IFU instructions."

Ron Banach, Director of Clinical Education, **Ruhof Inc.**, urges SPD pros to look intricately for moist and dark lumens.

"Once the endoscope [high-level disinfection] process has been completed, studies have reported that bacteria growth can occur in a moist and dark lumen. There are scope drying devices or endoscope storage cabinets with a HEPA-filtered air flow pump that use connector tubing attached to the endoscopes lumens/channels while it hangs in the storage cabinet."

Melissa Kubach, Clinical Education and Training Manager, National Solutions Team, **Agiliti** recommends following the proper order of things.

"Proper drying of flexible endoscopes has taken priority over hangtime. Fully dried endoscopes are essential for discouraging conditions that facilitate bacterial growth. There are many methods and products currently available for completing effective drying.

"Drying principals are simple, but often misunderstood. The air must be HEPA-filtered at minimum to avoid blowing contaminants and particulates into the channels. It is necessary to control temperature and humidity conditions, as well as utilize multiple filters, including ULPA and oil filtration, when employing traditional mechanical air compressors. Storage areas and cabinet conditions should be monitored for humidity and temperature as well.

"Many users associate drying with air pressure (PSI), which is not the correct correlation for highly effective drying. Instead, the emphasis should be on airflow, which facilitates thorough and timely drying through air circulating over the drying surface, which is measured in cubic feet per minute (CFM).

"Drying time should be ample to address the hard-to-dry internal channels. Keep in mind, lengthy small diameter channels are the most difficult to dry, especially without automated drying. If drying takes place prior to storage, then cabinet conditions should encourage maintaining the 'dry' status. This may include circulated or positive air pressure and/or continuous air feed within the channels."

Shaun Sweeney, Vice President, **Cygnus Medical**, cautions that gravity doesn't solve everything.

"The past five years have introduced several eye-opening studies that have shown the amount of water remaining in the channels after [high-level disinfection] reprocessing. For years the common practice and assumptions, were that by hanging a scope long enough gravity would remove any droplets from the channel. A good portion of the water is removed this way. However, trails of tiny micro droplets are left behind in the process, and sometimes large droplets. At their level of atomic mass, the surface tension of water is stronger than the forces of gravity leaving the droplets there indefinitely. With no natural air exchange there is no mechanism for evaporation, so the droplets remain.

"Also in question is the role of an IPA alcohol purge. We have found in our studies that although there is a benefit the effect and results have been grossly overstated. The most effective process is evaporation through a continuous air flow. We have found the same results whether scopes are dried vertically or horizontally and with or without an alcohol purge."

John Whelan, RN, Clinical Education Specialist, **Healthmark Industries**, suggests surpassing well beyond the urge to purge.

"The drying that occurs in an automated endoscope reprocessor (AER) is a purge, not an intentional drying cycle. Anyone who has removed an endoscope from an AER knows it is still wet on the outside, and water drips from the channels. Scopes need to be purposely dried at the end of processing, even when an AER is used. Clinical investigations and research have shown that fluid remains in endoscope channels for days after placed in storage. This provides an ideal environment for microbial contamination and biofilm growth.

"Current expectations from standards and guidelines call for:

- Active HEPA-filtered forced air drying prior to storage, or the use of HEPA-filtered forced air-drying cabinets (where endoscope channels are connected to continuous airflow); and
- Active drying post-processing – regardless of whether the scope is headed to another procedure or into storage.

"The good news is that multiple options for drying are already on the market, and more are coming. These include drying cabinets as well as table-top dryers. As with any automated process though, it will be important to periodically perform quality control testing. This is where drying verification tests come in. These are very easy and quick ways to corroborate channel drying adequacy.

"Reprocessed items post high-level disinfection are not packaged like sterilized items that are in peel pouches or trays, so you can't tell just by looking at the device that it's been through processing. A scope after processing can look the same as a scope pre-AER. This calls for visual cues on the individual endoscope – before leaving the processing area. This means a label or tag attached to the scope that includes:

- the processing date
- the name(s) of the person(s) who performed the processing
- expiration ('hang time') date, based on the facility's established risk assessment.

"Multiple options exist for endoscope tags and labels, including various colors, blank or pre-printed, hang tag and zip tie options."

David Willoughby, Vice President, Marketing & Business Development, **Medtrica**, stresses keeping each device separated and secure.

- "Hang in containers or cabinets with unrestricted clean airflow so that gravity and clean air movement can effectively help with aeration and drying.
- "Do not allow instruments to make contact with another instrument or itself during storage.
- "Use a disposable and breathable cover to act as a physical barrier between the instrument itself, other instruments and the environment during both storage and pre-procedural transport
- "Use a disposable and breathable paper-based cover on the insertion tube during storage to wick away any remaining moisture after reprocessing.
- "Use a sterile cover to protect the distal end of an instrument during storage and transport, one that is not only disposable and breathable, but also one that is constructed with non-porous/non-absorbent materials."

Gregg Agoston, M.B.A., Vice President, Business Development, SPD Transformation Services, **SpecialtyCare**, reminds SPD pros not to proceed to the aeration/drying/storage step if prior steps have not been satisfied.

"If a flexible scope fails leak testing upon the return of the instrument to the processing area, this failure means that the instrument technically was not sterile or high-level disinfected during the procedure unless it can be documented that the cause of the leak test failure happened post-case. No one would ever allow a flexible endoscope to be used in a procedure if it was known to have a leak." HPN

References

1 Association of periOperative Registered Nurses. Guideline for Processing Flexible Endoscopes. Revised February 2016 for publication in Guidelines for Perioperative Practice, 2016 edition

2 Society of Gastroenterology Nurses and Associates. Standard of Infection Prevention in the Gastroenterology Setting. 2016.

3 Multisociety Task Force Article. Guideline on reprocessing flexible GI endoscopes and accessories. 2021.

ENDOSCOPE PRODUCT SPOTLIGHTS

HEALTHMARK

The new FIS-007 borescope is designed to visually inspect internal channels of potentially soiled or damaged items with enhanced light, vision, and magnification. This new addition to the ProSys Optical Inspection line features a modular design with interchangeable flexible inspection scope attachments available in multiple diameters. These scopes have a working length of 110cm and attach to a control box which allows for light level adjustments, image capture, and video recording.

Visit www.ksrleads.com/?111hp-052

CYGNUS MEDICAL

The Airtime Instrument Channel Dryer:

- Uses .01 micron HEPA filtered air to dry endoscope air/water, suction, and auxiliary water channels after automated reprocessing.
- A scope removed from the AER can be dried quickly, so it will not be stored or put into immediate use with wet channels.
- Uses two independent pumps and timers that will dry two scopes simultaneously.
- Line pressure channel sensors will immediately shut off the pump and alert the user of a potentially clogged channel.

Visit www.ksrleads.com/?111hp-051

RUHOF

Elementum AW is a multi-tiered enzymatic detergent that has been optimized for the automatic, ultrasonic, and manual cleaning of surgical instruments. Elementum AW is synergistically blended to produce the most powerful detergent for use on clinically used medical devices. This best-in-class solution has superior soil penetration and suspension, rapidly breaks down tough-to-clean medical soils, including the multi-layers of bioburden, and prevents redeposition.

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RUHOF

The **ScopeValet TipGuard** is an endoscopic distal tip protector which provides a simple, safe, and highly effective method of protecting the delicate optics of an endoscope, while allowing the tip to aerate, decreasing the likelihood of microbiological growth. This product fits onto a wide variety of scopes (diameters ranging from 2.5mm to 14mm), is individually packaged for one-time-use, and ensures guideline compliance.

Visit www.ksrleads.com/?111hp-054

HR PHARMACEUTICALS

Surgilube Sterile Surgical Lubricant provides premium lubrication for endoscopes while reducing tissue trauma easing patient discomfort. Sterile and bacteriostatic for infection control and prevention, water-soluble for effective reprocessing. The 31g foilpac is specifically designed for endoscopy use, providing sufficient lubrication and reducing waste. Request a free sample today.

Visit www.ksrleads.com/?111hp-056

KEY SURGICAL

Solve the issue of sticking tissue.

Electrosurgery has unique challenges; such as sticking tissue and instrument charring. Key Surgical presents a solution with a new product called Electro Lube. This patented product coats the instrument tip, providing a protective barrier and helping improve the cutting or cauterization process. Visit keysurgical.com to learn more.

Visit www.ksrleads.com/?111hp-053

AMBU

The Ambu aView 2 Advance is a high-quality, portable, full-HD monitor for use with Ambu's entire line of single-use endoscopes. Its excellent imaging, intuitive operation, and simple setup keeps the focus on patients. A streamlined solution with integrated EMR and DICOM connectivity, the innovative design keeps you connected and updated for your documentation needs.

Visit www.ksrleads.com/?111hp-057

MEDTRICA

Endoscope Lens Tip Protectors: Expandable mesh protects lens from front and side impact. Allows moisture to escape, eliminating potential bacteria growth that occurs with most foam or solid protectors. Sterile/Non-Sterile.

EndoSock Flexible Scope Sleeve protects and wicks moisture away from insertion tube. Scope cleaning information labels can be placed directly on sleeve, then can be easily removed to patient's chart. No need to tape to endoscope boot.

Visit www.ksrleads.com/?111hp-058

Quality sterile processing starts with IFUs at point of use

by James Schneiter

Protecting patients from the risk of infection is the chief responsibility of those involved in the sterile processing of reusable medical devices. The stakes are high; returning a contaminated instrument to surgery could be catastrophic.

The work begins with pre-cleaning a device at the point-of-use and involves all personnel involved in decontamination, cleaning and sterilization processes. The manufacturer of a device has an equal responsibility in protecting patients from harm. Validating the cleaning and sterilization Instructions for Use (IFU) promises that only clean, sterile, moisture-free devices will result from every processing cycle.

Unfortunately, many people mistakenly believe that if a device has been sterilized, even though it remains contaminated with organic debris after cleaning, it is safe to use on a patient. Nothing could be further from the truth. Any device that remains contaminated with residual organic debris is not safe to use, even after complete and thorough sterilization.

1 The first step in quality sterile processing begins with treating the device at the point of use.

The process starts by placing the contaminated device into sterile water or an approved enzymatic detergent. This initial step in the cleaning process is vital because if soiled organic materials dry or bake onto the device, the removal process becomes much more difficult. Even worse, it can render the disinfection or sterilization process less effective, or even ineffective.[2] Reusable medical devices must be presoaked or rinsed in neutral pH water or in a detergent solution immediately after use to prevent blood from drying. A spray detergent may be used in place of water or a detergent solution to keep the devices moist during transport. Once the devices have been treated at the point of use they are ready for transport to the decontamination area.

The Association of periOperative Registered Nurses (AORN) also recommends pre-cleaning at point of use.[3] Finally, point-of-use treatment is recommended and covered in sections 6.3 thru 6.4 in AAMI ST79 (2017).

2 The next step in quality sterile processing involves the decontamination and cleaning of the device. Manual cleaning is required in those areas that do not have mechanical cleaning units (e.g., ultrasonic cleaners or washer disinfectors). Manual cleaning is also required for fragile or difficult-to-clean instruments (e.g., Kerrison Rongeurs, laparoscopic instruments, etc.).

The most common types of mechanical or automatic cleaners are ultrasonic cleaners, washer decontaminators, washer-disinfectors and washer-sterilizers. The use of a washer-disinfector requires additional care when loading surgical instruments into the unit. All modular/take-apart instruments should be disassembled as per the manufacturer's IFU.[4]

Sterile Processing can ensure that devices are completely clean after processing and prior to the sterilization cycle. Conduct a verification test to help ensure that the device is clean and ready for further processing. These tests include protein tests, adenosine triphosphate (ATP) bioluminescence tests, both of which test for residual soils. Other options include reagent tests that test for protein and hemoglobin, and another 3-in-1 test for lumen devices that test for blood, protein and carbohydrates, all at the same time.[5]

Also consider using devices that have had their cleaning and sterilization IFUs validated by an independent testing laboratory using "worst case" cleaning validation protocols as established by the Association for the Advancement of Medical Instrumentation (AAMI) and the Food and Drug Administration (FDA). Without a validated IFU, sterile processing personnel can be doing everything right, according to the manufacturer's non-validated IFU, and still not have the assurance of sending clean, sterile, moisture-free devices back to surgery.

In order to ensure quality sterile processing in your facility — and the patient safety that lies at the heart of these efforts -- you must demand that device manufacturers provide a copy of their validated IFU. When asking a device manufacturer for a copy of the validated IFU, you need to be sure the manufacturer understands you are asking for more than just cleaning and sterilization instructions. The manufacturer must provide you with the independent laboratory validation test report that proves their IFUs actually work for cleaning and sterilizing the device. If a device manufacturer can't – or won't – provide you with cleaning and sterilization IFUs that have been independently validated using AAMI and FDA testing protocols, then you need to look for another device manufacturer who can and will.

If you would like to learn more about this subject, please visit #IFUcan via social media. The online resource was created by a small group of independent veteran healthcare executives, advocates and specialists in the subjects of sterile processing and distribution (SPD). The site explores the use of validated IFUs to improve sterile processing quality and reduce the risk of patient harm. Visit https://www.linkedin.com/showcase/68681202/admin/ for more details. **HPN**

Full version available:
https://hpnonline.com/21241528

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2. Ibid, "CDC"
3. https://aornguidelines.org/tool/content?gbosid=396870
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5. Ibid, "CDC"

Prior to his semi-retirement in December 2018, James Schneiter was founder, owner and president of America's MedSource Inc., which designed, developed, licensed and marketed implantable vascular devices, laparoscopic devices and neurosurgical instruments. Schneiter has nearly five decades of experience in medical device design and production, and is a recognized expert in instructions for use (IFU) and independent laboratory IFU validation studies. He is a co-founder and the principal author of #IFUcan. Schneiter can be reached at jas.schneiter@talloaks2014.com.