

Inside the March Issue



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March Cover Story

[Value analysis is instrumental](#)

[2015 Surgical Instruments Guide](#)

HPN 2015
INDUSTRY GUIDE

[Self Study Series](#)

[White Papers](#)

[Special Reports](#)

[Purchasing Connection](#)

[Resources](#)

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Value analysis is instrumental

Experts reveal the tools for successful life cycle of surgical instrumentation

by Valerie J. Dimond

On the lookout once again for new technology and innovation in surgical instruments, accessories, services and procurement trends, *Healthcare Purchasing News* put out a widespread call to suppliers for their thoughts on what they think value analysis teams need to know. Here's what some of them said:

"Two areas where we see continuous innovation are in the increased interaction between instruments with software and advanced technologies and in the continuous advancement of minimally invasive instruments," says Jay Merkel, Director of Marketing and Product Management, [CareFusion](#), V. Mueller & Snowden-Pencer Minimally Invasive Surgical Instruments. "Whether it's through smaller instrumentation or robotics, minimally invasive surgery is on the forefront of innovation."



CareFusion's V. Mueller & Snowden-Pencer Minimally Invasive Surgical Instruments

Merkel said his company recently released a line of MicroLap instrumentation, giving surgeons miniature versions of traditional laparoscopic hand-held instruments. "These instruments are less than 3mm in diameter, resulting in even smaller incisions needed to perform laparoscopic surgery," he says. "We've improved the strength of these instruments from a previous generation of 3mm laparoscopic instrumentation so that moving from a 5mm instrument to a 3mm can be seamless from a user point of a view."

David Anbari, Vice President, [Mobile Instrument Service](#), also believes robotic systems are among the most current advancements in surgical treatment — but at what cost? "In virtually all cases, the experience and outcome for the patient is better so it is an easy argument to make," he says. "But there seems to be

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little investigation of the real costs and improved outcomes to justify the dollars pouring into new systems."

According to a February 2015 *Health Affairs* study, surgeons increasingly use robot-assisted minimally invasive surgery for a variety of medical conditions, also noting that "financial returns are not linked to any improvement in long-term patient outcomes in the current reimbursement environment." However, when looking at the value robot-assisted surgery provided for kidney cancer cases, they found the technology made partial nephrectomies much easier to perform (when appropriate), which, when compared to full kidney removal, significantly reduced mortality and renal failure. "The value of the benefits of robot-assisted minimally invasive surgery to patients, in terms of quality-adjusted life-years gained, outweighed the health care and surgical costs to patients and payers by a ratio of five to one," state the authors.

For thoracic surgery and critical vessel transections, [Ethicon](#) recently introduced its ECHELON FLEX Powered Vascular Stapler, which the company claims offers the narrowest anvil of any stapler on the market, an articulating shaft and advanced placement tip that may improve visibility, navigation and precise placement during procedures, including video-assisted thoracoscopic surgery for lung cancer. Compared to a similar product on the market, Ethicon says, "The ECHELON FLEX Powered Vascular Stapler has a curved, blunt anvil that is 26 percent narrower and a shaft that is 26 percent thinner, offering the greatest angle of reach in the tight intercostal space. The new powered stapler also provides 11 percent greater manual articulation in each direction, allowing more flexibility during final placement than the competitor device." The company also launched the ECHELON FLEX Gripping Surface Technology (GST) System, which provides superior grip and results in less tissue slippage. "This technology is being used more and more in bariatric procedures, particularly sleeve gastrectomy, which has emerged as the most popular procedure in the U.S., followed by laparoscopic gastric bypass," says Ethicon.



Ethicon's ECHELON FLEX Powered vascular Stapler

Another life-enhancing technology on the frontlines today is a product by [RF Surgical Systems](#) called RF Assure, which increases operating efficiencies and patient safety by reducing the incidence of retained surgical sponges (RSS). John Barnhill, the company's Vice President of Marketing and Business Development, explains how the technology works.

"The system consists of an antenna array body scanner that is placed under the patient during the procedure, allowing for a hands-free scan of RF-tagged sponges. Additionally, the patented Blair-Port Wand quickly scans the OR suite to identify the location of missing RF-tagged sponges in and around the sterile field," says Barnhill. "The only adjunct technology to focus on detection of surgical sponges to prevent retention, RF Assure uses a reliable, low-energy radio frequency signal specifically designed for the detection of misplaced surgical sponges through blood, dense tissue, and bone."



RF Assure Delivery System by RF Surgical Systems

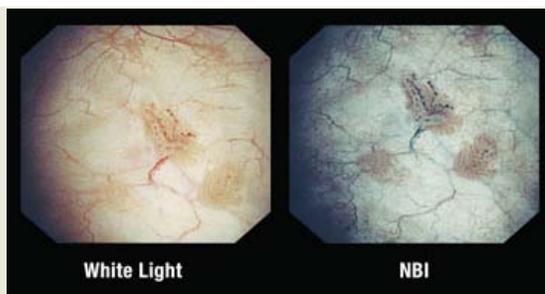
Barnhill points to a September 2014 study in the *Journal of the American College of Surgery* that shows using RF-tagged sponges and detection capability actually reduced the incidence of RSS by 93 percent and cut the average time per case by 16 minutes. He says 4,500 OR, trauma, and labor and delivery suites now use the RF Assure system.

Imaging technology is also making notable advancements. Narrow Band Imaging (NBI) developed by [Olympus Corporation of the Americas](#) just received FDA 510(k) clearance that will enable effective targeting of biopsies not seen under white light and improve visualization of tumor boundaries in non-muscle-invasive bladder cancer (NMIBC) patients.

"Cystoscopy is typically

- [Olympus America](#)
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- [PDI](#)
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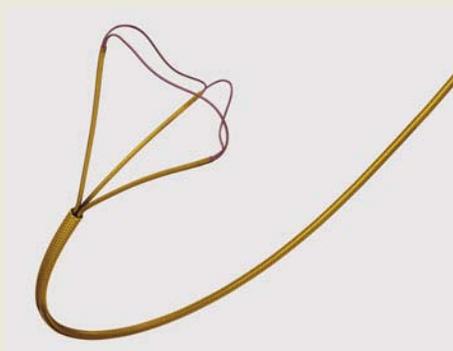
performed under white light, which uses the full color spectrum. NBI uses only blue and green light, which are strongly absorbed by blood, providing a greater contrast between capillaries, veins and the surrounding tissue to enhance visibility of vascular structures on the mucosal surface," explains Michael Levey, Director of Public Relations and Communications at Olympus.



Olympus's Narrow Band Imaging compared to white light imaging

"NBI is the only patented endoscopic light technology that enables effective targeting of biopsies not seen under white light without the use of dyes or drugs. Based on a weighted average, the aggregated FDA-reviewed studies show NBI has visualized NMIBC lesions in 17 percent additional patients when compared with white light, 24 percent additional tumors, and 28 percent additional carcinoma in situ (CIS or difficult-to-detect flat lesions)¹," Levey asserts. "This finding provides new treatment opportunities for urologists both in-office/clinic for cystoscopy (diagnosis) and in the OR or ambulatory surgical center for resection (tumor removal or Transurethral Resection of Bladder Tumor)."

David Reed, Vice President of Operations and Healthcare Business Solutions, [Cook Medical Inc.](#), believes customers also gain great service and value when companies stay focused on improving current products and services instead of racing to invent the latest gadget.



Cook Medical Inc. NGage Nitinol Stone Extractor

"Our foundation is in building simple devices that solve complex problems. A lot of our devices are improved through an iterative development process," explains Reed. "We've made smaller design improvements or added features that have, little by little, improved the overall surgical technique and patient outcomes. Sometimes, it's those baby steps that are important to improving healthcare continuously and not just the disruptive technologies that happen more rarely."

For example, "with the NGage Nitinol Stone Extractor you can catch and hold stones like a basket," Reed explains. "Or, you can extract and release stones like a grasper, with 50 percent greater retention strength than traditional graspers."²

Greening the OR

Sustainable surgical technology is also expanding — and interest in having it is growing steadily among both users and buyers, according to some major device manufacturers.



Johnson & Johnson Enseal G2 Articulating Tissue Sealer

"There's a notable increase of interest among healthcare professionals in

evaluating the importance of investing in sustainable medical products," says Keith Sutter, Director of Medical Devices and Diagnostics, Sustainability, [Johnson & Johnson](#). Sutter referred to a 2014 global study commissioned by his company that shows among 300 healthcare professionals surveyed, 54 percent said they now consider a product's sustainability when making purchasing decisions — good news for companies ahead of the green curve.

"It's exciting to see collaborative, innovative thinking among professionals to develop sustainable products with measurable outcomes," says Sutter. "We created the Earthwards approach and challenged ourselves to design more sustainable solutions that improve the impacts across a product's entire lifecycle — from formulation and manufacturing, to product use and end-of-life.

"One of our Earthwards recognized products, the ENSEAL G2 articulating tissue sealers, reduced the product weight by 13 percent as compared to the ENSEAL G2 Tissue Sealers resulting in a worldwide annual reduction of approximately three tons of red bag waste³ — that's the equivalent of nearly two mid-size cars or the daily waste of 1,533 people in the U.S. In addition, ENSEAL G2 has resulted in a worldwide annual reduction of five tons of packaging waste⁴ and five tons of PVC⁵."



*ZIMMER Pulsavac Plus AC
Wound Debridement System*

[Zimmer](#) is also turning out green surgical products, including its *Pulsavac Plus AC* Wound Debridement System, which they say has kept more than 5 million batteries and 400,000-plus pounds of waste out of landfills while reducing facility-costs since 2009.

"As the hospital supply chain matures, finding savings has become vital," says Candace L. Samudio, Manager, Clinical Excellence, Zimmer, Surgical Division. "Smart product evolution from the manufacturer's perspective should not only help hospitals meet their budget goals, but also synchronize with other valuable initiatives in the hospital."

Making instruments safer

Ralph Basile, Vice President, [Healthmark Industries](#), says its Flexible Inspection Scope (FIS) is designed to improve patient safety, allowing SPD staff to visually inspect the internal channels and lumens of reprocessed medical devices that were previously unobservable. "As devices have become more complex and more minute, they have also become a greater challenge to properly clean and to visually inspect for cleanliness," Basile says. "By combining a digital video camera, with integral LED lights at the end of a long, flexible shaft, the FIS now makes it possible to visually inspect these areas of surgical instruments with a tool that delivers remarkable clarity of image in a robust configuration. By taking advantage of the processing power and display technology of modern computer technology, sterile processing staff can easily and conveniently inspect, and document the condition of devices right at their work station."



*Healthmark Industries
Flexible Inspection Scope*

Other accessories can improve OR efficiencies. Laurie Clark, Senior Manager, Medical Sciences and Clinical Education, [Halyard Health](#), says the company made recent improvements to its sterilization wrap portfolio. The SMART-FOLD product is now 64 percent more durable and built to handle the heaviest trays and reduce tears and reprocessing costs — features that cut wrapping time and improve staff efficiency.

"Recently, Halyard became the first and only manufacturer to receive 510(k) clearance from the Food and Drug Administration for the

use of our sterilization wrap portfolio with all standard sterilization modalities, including Pre-vac and Gravity Steam, EO, V-Pro and STERRAD," says Clark. "This supports our ongoing mission to manufacture clinically superior solutions to help clinicians protect both themselves and their patients."



Source, manage, maintain

Outside of instrument quality and performance, how surgical tools are procured, managed and maintained is equally important.

Halyard Health Smart Fold Wrap

Should you lease or own, reprocess or discard, invest in new tracking software or modify your current inventory strategy? Those and other questions are worth considering.

"If maintaining access to the latest and greatest technology is important to your institution, then leasing is the right option," says Samudio. "With leasing it is also possible to include warranty and service cost as well, enhancing the value of the lease. Because the lease costs can be pulled from the operating budget, it is possible to preserve capital budget for other projects — preventing the uncomfortable tradeoffs that happen when capital budgets are limited."

Samudio notes also that sometimes purchasing certain instruments simply makes more sense. "Let's face it, some devices work well for a really long time. When that is the case, purchasing the equipment is the right move. Although capital budget is required, the value in keeping costs per case low is important, too."

Either way, Reed says when it comes to sourcing products there is no one size fits all in medicine — today or in the future — and that to be successful one must approach purchasing from a collaborative angle. "Supply chain is becoming a more integral piece of the equation, and we know that clinical teams and supply chain teams will have to work in close alignment moving forward. Ideally, if you're approaching the partnership between clinical and supply chain and provider and supplier correctly, then sourcing shouldn't be a major issue."

Merkel says it's also important to understand when it's best to choose single use or reusable surgical products.

"In certain cases, like the laparoscopic scissor which easily dulls after several uses, it might be more cost effective to use an option where a portion of the device (the handle) is reusable and the tips are disposable," suggests Merkel.

And if using a third party to reprocess disposable instruments, he says, "be sure to really get to know your re-processor. Once a single use instrument is reprocessed, the original equipment manufacturer (OEM) no longer holds the responsibility for the performance characteristics for that product. Make sure that the re-processor has adequate quality controls, validations and traceability in place to ensure that what you get back is the same quality as what you get from the OEM."

Ed Nuber, Group Product Director, Surgical Technologies, [Aesculap Inc.](#), believes hospitals understand that staying competitive today means driving better efficiencies, which requires improving communication and planning among the different departments involved.



Aesculap Inc. Surgical Instrumentation

"The focus has shifted over the last several years to breaking down barriers between the OR staff and the sterile processing department (SPD) staff to have a more team approach to product/service evaluations and the impact to both departments,"

says Nuber. "How is this new product or service going to help the OR and SPD improve efficiency and build a better working relationship? Efficiency is not just a lower price. The impact of the product or service must be evaluated based on its effect on overall processing flow within the healthcare delivery organization from procurement to sterile storage to aseptic presentation and patient benefit."

To help facilities improve clinical and financial outcomes and better manage their multi-million dollar surgical instrument fleets, Aesculap developed a Surgical Asset Management (SAM) program to analyze reprocessing practices and identify instrument and set standardization and optimization opportunities.

[Censis Technologies Inc.](#), an instrument management company, delivers end-to-end asset management using its Censitrac scalable surgical instrument tracking systems. Cheryl Heston, Director of Marketing, offers some advice on financing instrument management programs.

"I believe when looking at technology you are better off doing a subscription. With the speed that technology is changing this is the one area that you would truly benefit most from a subscription vs. an ownership," says Heston, adding that instrument tracking systems can substantially improve patient safety and efficiency. "There may be some fixes to bugs that you can download to try to keep your software up-to-date, but eventually you will need to buy the newer version because the one you purchased three years ago is now out of date. If subscription is not an option, then I would look at the lease option vs. owning when it comes to software. The thing to remember is that you own all your data."



Censitrac Surgical Instrument Management System

Mobile Instrument Service offers advisory and educational programs, new equipment and implant tracking software solutions and state-of-the-art in-house repair centers. "We find that hospital staff often has the revolutionary tools, they just need better awareness of how to care for them and a better process to manage them," Anbari says. "That is where tracking systems come in — they expose the data to better manage the operation."

Rob Mayer, Director of Product and Service Solutions, V. Mueller *IMPRESS*, says the technology and service needs within CS departments are evolving and that addressing those needs can make the OR run a lot smoother.

"The consistent need for CS Departments to deliver surgical instrumentation to the OR on a reliable basis has strained many department relationships and possibly placed some patients at risk if the surgeon did not have the appropriate instrument available to them during the procedure," asserts Mayer. "More hospitals are reaching out to vendors that provide instrument tracking solutions Like V. Mueller *IMPRESS* to help them keep track of where their instruments are, prioritizing which trays are built and measuring the productivity of their staff."

"In addition, facilities are beginning to kick off process improvement projects that may focus on reducing the number of tray configurations, reducing the number of IUSS [immediate use steam sterilization] events and improving tray throughput per tech," Mayer continues. "We see this as an opportunity to provide *IMPRESS* consultative services to those customers that are looking for an "outside view" into their operations and a means to drive sustainable change in their organizations."

Anbari offers a final piece of advice to buyers: Be crystal clear about what you really want and need.

"Make sure the things that matter most get the highest priority. Avoid being distracted when a vendor offers something new, when you may not need it anyway," he says. "We see so few buyers really take time to define what they need so it becomes impossible to assess their options." **HPN**

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3. Product weight reduction from .67 lbs (NSLG2S35) to .58 lbs (NSLG2S35A), with anticipated sales of over 74,000 per year.
4. Packaging weight reduction from .47 lbs (NSLG2S35) to .32 lbs (NSLG2S35A), with anticipated sales of over 74,000 per year.
5. Removed 2.4 ounces of PVC from ENSEAL G2 Articulating Tissue Sealer (NSLG2S35A) when compared to ENSEAL G2 Tissue Sealer (NSLG2S35), with anticipated sales of over 74,000 per year.

[Surgical Instrument Vendor Listings](#)

