



## Innovations Series Presents: Scoping New Technologies November 2006

By Joyce Laird, Contributing Writer

Minimally invasive procedures offer tremendous advantages over more traditional techniques. As a result, medical device manufacturers have continually improved endoscopic instruments and tools to enable these types of procedures. This article explores the latest advances that are available in endoscopic technologies and examines the benefits they provide.

*By Joyce Laird, Contributing Writer*

### AT A GLANCE

- Finished devices
- Advanced technologies
- Enhancements and benefits
- What's ahead

What began as a tube with a simple vision apparatus now covers a huge range of devices: endoscopes, arthroscopes, neuroendoscopes, laparoscopes, and thoroscopes. A recent Frost & Sullivan U.S.

Endoscopes Market report states that this industry totaled \$449.96 million in 2005 and estimates it will grow to \$513.46 million by 2012. This article will delve into how some key players in this field are supporting this growth.

### Devices, Materials, and Systems

Devices, materials, and systems all enhance the full spectrum of innovative endoscopic technology.



**On the cover:** Smith & Nephew's Condor System functions as a command center for the Digital OR. It offers voice-activated control.  
*(Photo: Smith & Nephew)*



**The InScope Multi-Clip Applier** is a sterile, single patient use, disposable instrument capable of attaching clips to the mucosal lining of the gastrointestinal tract. *(Photo: Ethicon Endo-Surgery)*

Ethicon Endo-Surgery Inc. (EESUS), a Johnson & Johnson company, recently introduced two products that expand the efficiency of endoscopic surgery. Joanne Hull, product director at EESUS Global, says, "Our InScope Multi-Clip Applier is used in upper GI endoscopy and colonoscopy to stop bleeding and close defects. It is the first and only multiple clip applier for flexible endoscopes."

The device is a sterile, single patient use, disposable instrument capable of attaching clips to the mucosal lining of the gastrointestinal (GI) tract. The distal portion of the applier works with a flexible endoscope. Two opposing jaws grasp tissue via a manually activated lever on a proximal handle. Once latched, a manually activated firing mechanism deploys a titanium clip. What makes this product different from existing devices is that the tool comes preloaded with four clips, can be rotated and repositioned, and fires up to four clips without removing the device.

The second product is EESUS's Echelon™ 60 Endopath Stapler, which is also a sterile, single patient use instrument. It is used for laparoscopic weight loss,

colorectal, and thoracic procedures.

"It's about a foot and a half long and unlike earlier devices, it has a very rigid, heavy duty shaft," Fred Shelton, Product Design Engineer explains. "This is the next generation in laparoscopic staplers. It can handle thicker tissue such as encountered in gastric bypass surgery. It places six rows of staples and cuts in the middle, so the surgeon has 3 rows on either side of the cut. It can be reloaded 7 times for a total of 8 firings."

Smith & Nephew Inc. Endoscopy Division has focused one division on developing a product not part of an endoscope, but used with it: the Calaxo Osteoconductive Interference Screw.

Sally Maher, VP of research and development says, "The Calaxo screw is used in Arthroscopic knee surgery to repair a ruptured anterior cruciate ligament. The screw holds a graft in place until it re-approximates to the bone. The Calaxo material is designed for complete bone regrowth within a year. The source is a breakthrough material called poly lactide carbonate which, is akin to 'milk for bones.' It enables the screw to replace itself with healthy bone. Most existing devices today either do not go away at all or have a very long re-absorption time, leaving a hole that requires repair."



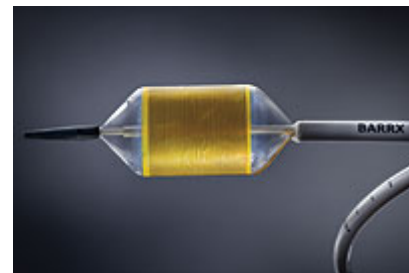
Development of new materials has an impact on the design and durability of end products. W. L. Gore & Associates is a key provider of endoscopic components for the flexible endoscope market, with a focus on the development of new autoclavable materials that extend product life. Jason Davis, product manager for Gore's Endoscope Component Business, says, "By using Gore Sil-Kore material sets, we are able to produce endoscope components that can withstand a greater number of sterilization cycles compared to standard industry options."

**Gore Sil-Kore** Coherent and Illumination Fiber Bundle Sleeving easily slides over image or illumination fiber bundles contained within an endoscope. (Photo: W.L. Gore)

Examples include Gore Sil-Kore Bending Sheaths which are used as an elastic jacket material on the distal tip of endoscope devices and Gore Sil-Kore Coherent and Illumination Fiber Bundle Sleeving, which easily slides over image or illumination fiber bundles contained within an endoscope. Davis notes that Gore's thin-walled, low friction fluoropolymer coatings are also an excellent choice for coating the articulation wires inside flexible endoscopes. The toughened

fluoropolymer coating enables consistent articulation performance with minimal degradation over time.

Barrx Medical is dedicated to a system solution for a single condition. Greg Barrett, president and CEO, explains, "We focus on Barrett's Esophagus, which is a precancerous condition affecting the lining of the esophagus that leads to esophageal adenocarcinoma—currently the most rapidly rising type of cancer in the United States."

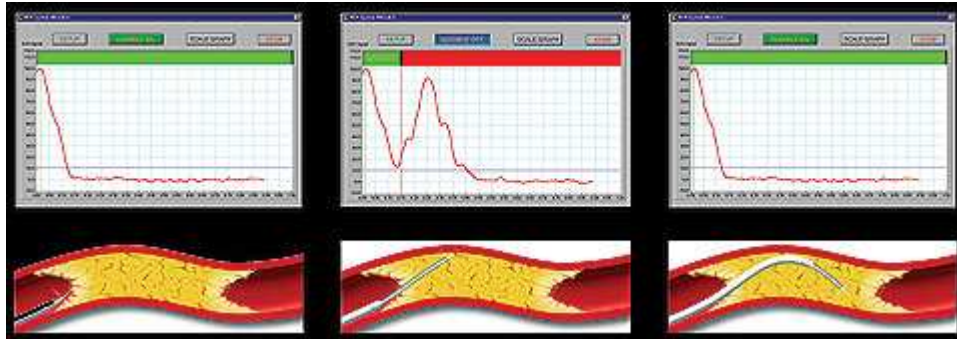


The Barrx Halo 360 System uses radio frequency (RF) for precise ablation of the esophagus to eliminate this condition. It consists of 60 individual bands that are tightly spaced over an expanding balloon-catheter device. Current travels from one band to the other and energy is controlled at a very efficient level so the depth is very uniform.

**The Halo 360** consists of 60 individual bands that are tightly spaced. The current travels from one band to the other as opposed to going deep down into the tissue. (Photo: Barrx)

"The Halo 360 works under direct visualization," Barrett explains. "The catheter does not go through the scope. The scope follows behind the balloon. It's very innovative. It displays the esophagus diameter in millimeters and also makes a recommendation for what size of ablation catheter to use."

Another company using an RF ablation system for minimally invasive treatment of a life threatening condition is Kensey-Nash Corp. Their Safe-Cross System for removal of coronary blockage received FDA marketing clearance in 2004 and is in the process of entering its next product generation.



**The Safe-Cross system** enters the femoral artery using OCR technology to detect the difference between the occlusion and the artery wall. It removes the occlusion using RF energy. (Photo: Kensey Nash)

It is designed to safely remove chronic total occlusions using optical coherence reflectometry technology and radio frequency," Rodney Bosley, director of business development states. "It does this by traveling through the femoral artery into affected coronary vessels where it removes the occlusion using RF energy. Our system often offers a successful alternative to coronary bypass surgery."

### Vision and Control Systems

Today, high definition (HD) is the buzz in endoscopic surgery as much as in home entertainment—but for a better reason. A surgeon can't operate on what can't be seen. Incorporating video-chip technology within the distal end of a scope provides endoscopic surgeons details of structures not possible to see unaided.

Stryker Endoscopy is a leading medical technology company providing innovative HD tools. The Endoscopy division of Stryker Corp. recently launched its second-generation high-definition visualization platform for minimally invasive surgery. Built on the clarity of their 1188 HD 3-Chip Camera, X8000 Lightsource and Vision Elect HD flat-panel monitor, this second-generation visualization platform infuses the operating room with the latest advancements in HD technology.

Adam Heaps, marketing manager, video accessories for Stryker says, "The challenge was to develop a high definition platform that was state of the art and affordable at the same time. Our system can capture still pictures and moving video in high definition and can export these images to CDs, DVDs, and other external media devices. It has the interface to be able to send the information across networks. It records the entire intra-operative procedure in the operating room in HD for archive purposes."

Creating endosurgery arenas that address all OR requirements with single, seamless,

centralized control is another growing area.

Smith and Nephew recently launched their High Definition 660HD Image Management System, which digitally captures, edits, exports, and prints endoscopic surgical images and patient information. It enables medical practitioners to select the most significant and useful images captured during any type of surgical procedure. OR staff can export images to DVD, CD, or USB, and integrate them into the hospital's information technology architecture where they can be stored with the patient's electronic medical records.

Added to this is their new control system, Condor. Together they create a Digital Operating Room suite.

"This product suite turns any OR into a digital OR without the expense or the need for renovation," explains Sal Chiovari, VP and general manager of Digital OR and Condor Control System for Digital OR. "ORs can be video conferenced and transmission of endoscopic images can move across the room so nurses are well aware of where they're at in the OR process. Condor can optionally respond to voice command so the surgeon can control all the aspects hands-free. We even added things like, 'Condor, Compliment the Nurse.' Condor will say, 'You are a wonderful and very effective nurse.' So we also help with morale," adds Chiovari.

Pentax Medical Company is another that specializes in complete OR solutions.

The University of Texas Medical Branch (UTMB) at Galveston recently opened a newly expanded gastrointestinal (GI) medical suite that includes 12 examination and research rooms, equipped with Pentax GI and ultrasound endoscopes and video processors. It also includes Pentax Motion Picture Studio data and imaging software which enables endoscopists to capture full motion video endoscopic data in real-time for subsequent editing and review on a high-speed network. In addition to the GI suite, Pentax provided state-of-the-art endoscopy and imaging equipment on long-term loan to UTMB's research facility.

The innovations provided by all of these companies allow hospitals to offer patients endoscopic diagnostic and surgical capabilities that are truly leading edge.

#### Robotics

Visual depth perception and hand-eye-instrument coordination have traditionally limited endoscopic surgery. Advances in HD vision are helping in the first area, but classic endoinstruments still only function in five degrees of freedom. Also, the surgeons hand and tip of the instrument move in fulcrum, not natural motion. This has made it difficult to penetrate delicate areas such as coronary, spinal, and neurosurgery. Robotics may be the solution.



Intuitive Surgical Inc. is a ground breaker in this area. Their DaVinci Surgical System was the first to perform successful endoscopic cardiac surgery, bringing minimally invasive surgical procedures into a new realm.

Alexs Cukic, VP business development and strategic planning, says, "Our system basically translates open surgery techniques into endosurgery techniques."

Using the DaVinci system, the surgeon is seated at a console away from the actual patient. Looking at a 3D binocular display of the operative field, the surgeon manipulates instrument controllers positioned under the display. The robotic arms exactly reproduce the motion of the surgeon's hands with full seven degrees of freedom. The computer system eliminates occasional tremor.

**The DaVinci mechanical wrist** of the instruments has seven degrees of freedom. Tip articulations mimic the up/down ("pitch") and the side-to-side ("yaw") flexibility of the human wrist. *(Photo: Intuitive Surgical)*

The robotic side cart supports three interactive mechanical arms. One is used to position a 3D endoscope and the two others hold the removable articulated instruments. The visualization system is made up of two 3-chip cameras mounted on a custom 3D endoscope with two separate optical channels. Independently acquired images are transmitted to a high-resolution binocular display of the operative field. The operative image

magnification may be up to 10 times actual size.

"Our goal is to continue to move surgery beyond the limits of the human hand," explains Cukic. "Regardless of the surgeons skill, all hands have a certain size; they are limited. Human eyes also have limitations. If we can magnify things to put them in better perspective and then reduce hands, wrists, and fingers in size, we take surgery to a completely different level." There are approximately 467 DaVinci systems installed worldwide. Per Cukic, 43 hospitals now own more than one DaVinci.

#### Future-Tech

Endoscopic surgery in all its variety is the surgical future. Systems, devices, and materials that allow this technology to advance into the most intricate of surgical arenas will lead the way, offering more options for surgeons and patients. Surgical robotics are a growing segment that is pushing the envelope for endoscopic procedures.

Companies like those mentioned here and their dedication to continual R&D in all areas of endoscopic surgery will bring about systems that will streamline surgery, reduce patient recovery time, and extend survival rates. When it comes down to the bottom line, isn't that what it's all really about?

## ONLINE

For additional information on the technologies and products discussed in this article, see the following websites:

- [www.barrx.com](http://www.barrx.com)
- [www.ethiconendo.com](http://www.ethiconendo.com)
- [www.intuitivesurgical.com](http://www.intuitivesurgical.com)
- [www.kenseynash.com](http://www.kenseynash.com)
- [www.pentaxmedical.com](http://www.pentaxmedical.com)
- [www.endo.smith-nephew.com](http://www.endo.smith-nephew.com)
- [www.stryker.com](http://www.stryker.com)
- [www.gore.com](http://www.gore.com)