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Olympus obtains clearance for 3-D Laparoscopic surgical video system

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Olympus (Center Valley, Pennsylvania) reported that it has received 510(k) clearance from the FDA for its Articulating HD 3-D Laparoscopic Surgical Video System.

The company said the device delivers value to surgeons and patients by reducing surgical errors and improving the speed, accuracy and precision of surgical tasks such as dissection, grasping and suturing when compared with traditional 2-D surgical systems, based on internal testing conducted using a simulated surgical model. The company said that this is accomplished by restoring natural 3-D vision and depth perception when performing laparoscopic procedures and the benefits are independent of a surgeon's skill level.

The firm is now prepping for a full launch of the device.

"We'll do a full launch," David Colvin, executive director of marketing for Olympus, told *Medical Device Daily*. "The first public showing of the product will be at **Society of American Gastrointestinal and Endoscopic Surgeons** (SAGES; Los Angeles) annual meeting in Baltimore (on April 17th). "Immediately after that our entire Sales Force will be trained and we'll go on the show circuit. Our demo inventory is here and [the device] will be available for sale immediately."

The company pointed out that a significant advantage of the new Olympus HD 3-D video platform is its availability as a module that can be easily added to an existing Olympus EVIS EXERA III Universal Imaging System. The modular design reduces the investment necessary to add 3-D capability, and allows the surgeon to choose either 2-D or 3-D visualization from the surgical field. This helps to reduce capital investments and simplify asset management and training.

"The Olympus HD 3-D System brings value to those surgeons that need the precision, resolution, and depth perception of 3-D without the substantial capital investment and annual maintenance expenses associated with alternatives such as robotic technology," said Luke Calcraft, president of the medical systems group at Olympus. "We are leading the way with new innovations to help our customers realize the clinical efficacy and cost effectiveness required under Accountable Care."

Surgeons have been demanding endoscopic imaging tools that give a three dimensional look at the body. Colvin said that he feels that the Olympus HD 3-D system could be an answer to those demands.

"Here's some things that have been pointed out to us by surgeons," he said. "The comments that we've been hearing are that they want really super high resolution with a great depth of field so that you can see [specific areas] in the body very clearly in 3-D. The areas are deep into the pelvic floor . . . and the other area is opposite the torso in the fore gut area."

"The Olympus HD 3-D system is ideal for suturing, accurately identifying tissue planes and other precision surgical tasks that are required in my laparoscopic surgical cases," said Marcos Michellotti, MD, assistant professor of surgery at **Loma Linda University Health System** (Loma Linda, California). "In addition, the articulating design enables me to obtain the critical view of anatomical structures in HD 3-D without losing the important visual horizon. This is not possible with traditional fixed angle laparoscopes."

The device has the potential to be compatible with older and newer imaging technology, Colvin said.

"Olympus is a little different in the surgical endoscopy world because we believe in a broader platform product and our technological development cycle is longer than our competitors," Colvin told *MDD*. "What that allows us to do is have a platform that's both backward and forward compatible. Our platform will work with previous generation rigid scopes as well as future generation scopes." ■