Covidien Announces U.S. 510(k) Clearance and European CE Mark Approval of Parietex(TM) Optimized Composite Mesh

Covidien

New product features optimized protection, integration and handling during laparoscopic ventral hernia repair

NORTH HAVEN, Conn., Jun 02, 2011 (BUSINESS WIRE) --

Covidien (NYSE: COV), a leading global provider of healthcare products, today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance and the European regulatory authorities have granted the CE Mark to Parietex(TM) Optimized Composite (PCOx) mesh.

Covidien launched PCOx during the recent European Hernia Society meeting in Ghent, Belgium and the product will be commercially available in the U.S. and Europe starting in June.

PCOx is the next-generation version of Covidien's Parietex(TM) Composite (PCO) mesh, engineered to better address surgeon and patient needs in open and laparoscopic ventral hernia repair. Compared to the original product, the new product design incorporates a more resistant barrier and a proprietary textile design with better visibility and increased strength.

"The original PCO is a very trusted product that has been backed by a robust body of supporting clinical data," said Brian P Jacob, MD FACS of the Laparoscopic Surgical Center of New York in New York City. "Based on PCO's characteristics, the new PCOx has been enhanced with a more resistant barrier and improved visibility through the mesh, creating an optimal mesh choice for a ventral hernia repair."

The original PCO mesh was introduced in 1999 as the first hernia mesh to offer a resorbable collagen barrier and has been evaluated in over 45 clinical and pre-clinical studies.

PCOx mesh is three times more resistant than its predecessor, to aid in insertion and placement. Additionally, the new, proprietary 3-D textile with x-stitch design is stronger and enables better visibility through the mesh. Importantly, PCOx has been shown in animals to promote rapid abdominal wall integration, minimize visceral attachments and facilitate strong tack fixation.

A version of PCOx with preplaced sutures that reduces the time needed for traditional suture placement is approved in Europe.

"I'm tremendously proud of our product team for the ingenuity and innovation they've demonstrated with the development of PCOx," said Michel Therin, Vice

President, Soft Tissue Repair & Biosurgery, Covidien. "It's an impressive accomplishment to improve upon a trusted product like PCO mesh by making it stronger and more resistant while simultaneously preserving the benefits that surgeons expect."

About Ventral Hernia

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) estimates that 90,000 ventral hernia repairs are performed each year in the United States. Ventral hernias typically occur in the abdominal wall where a previous surgical incision was made. The inner lining of the abdominal wall bulges through or tears the weakened abdominal wall muscles and forms a balloon-like sac. This can allow a loop of intestines or other abdominal contents to push into the sac. If the abdominal contents get stuck within the sac, they can become trapped or "incarcerated." This could lead to potentially serious problems that might require emergency surgery. Ventral hernias can also occur in the belly button (umbilicus) or any other area of the abdominal wall. SAGES warns that a hernia does not get better over time, nor will it go away by itself.

ABOUT COVIDIEN

Covidien is a leading global healthcare products company that creates innovative medical solutions for better patient outcomes and delivers value through clinical leadership and excellence. Covidien manufactures, distributes and services a diverse range of industry-leading product lines in three segments: Medical Devices, Pharmaceuticals and Medical Supplies. With 2010 revenue of $10.4 billion, Covidien has 41,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Please visit www.covidien.com [1] to learn more about our business.

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