

Covidien Announces Interim Data Showing Parietex ProGrip(TM) Self-Fixating Mesh Significantly Reduces Early Pain Following Inguinal Hernia Repair

Covidien

Interim results of a nine-site prospective clinical study presented at Hernia Repair 2011

NORTH HAVEN, Conn., Mar 21, 2011 (BUSINESS WIRE) --

Covidien (NYSE: COV), a leading global provider of healthcare products, announced interim results of its multicenter, international, prospective study comparing use of its Parietex ProGrip(TM) self-fixating mesh to the traditional Lichtenstein repair, the gold-standard technique for inguinal hernia repair. The data were presented during a podium presentation at Hernia Repair 2011, the 14th Annual Meeting & Scientific Program of the American Hernia Society.

The interim data demonstrate that patients who received Parietex ProGrip self-fixating mesh during inguinal hernia repair experienced significantly less early pain compared to those whose hernias were repaired using the standard Lichtenstein method.¹ Investigators measured pain at discharge and at day seven. Results of the study also show that use of Parietex ProGrip mesh significantly shortened the surgery duration.¹

"By eliminating the need for abdominal wall sutures, Parietex ProGrip self-fixating mesh simplifies hernia repair, allowing for faster operating time and less pain in the week following surgery compared to the gold-standard Lichtenstein repair method," said principal investigator Prof. Andrew N. Kingsnorth, Professor of Surgery at Derriford Hospital, Plymouth, U.K. "We look forward to seeing additional data, including the final results of the study, to confirm these promising outcomes."

At the time of this interim data analysis, 390 patients had been randomized and followed for three months at nine international centers. Ultimately, 600 patients will be enrolled into the study and followed for a year.

To perform the Lichtenstein method, surgeons suture a mesh patch over the hernial opening to reduce weakness in the abdominal wall. This technique is associated with a 4% hernia recurrence rate after five years², and 6% of patients continue to experience severe chronic pain three years after the procedure.³ Parietex ProGrip self-fixating mesh has small, absorbable, polylactic acid grips on one side to secure immediate fixation to the abdominal wall, eliminating the need to suture the mesh into place.

The study protocol allowed surgeons to position the Parietex ProGrip self-fixating

mesh with one stitch of absorbable suture. Of the 193 patients who received Parietex ProGrip self-fixating mesh, 69% had it placed without a suture. When compared to the baseline, the pain was significantly reduced at one and three months for the patients without fixation compared to patients receiving the single stitch.

"These results underscore Covidien's commitment to providing clinicians with the evidence they need to confidently adopt our products to improve patient outcomes," said Michael Tarnoff, M.D., Chief Medical Officer, Covidien. "We always strive to deliver innovative products that respond to unmet needs for both surgeons and patients."

Separately at the meeting, surgeons presented new data supporting the adoption of:

- Parietex ProGrip self-fixating mesh in incisional hernia procedures.
- AbsorbaTack(TM) absorbable mesh fixation system in laparoscopic inguinal hernia repair.
- Permacol(TM) surgical implant in open incisional hernia repair.

Covidien highlighted products at Hernia Repair 2011 include:

[Parietex Optimized Composite Mesh \(PCO Optimized\)](#) [1] -- 510(k) clearance pending. Designed to deliver optimal strength, optimal handling and optimal outcomes.

[AbsorbaTack Fixation Device](#) [2]--A sterile, single-use device designed for fixation of prosthetic material, such as hernia mesh, to soft tissues in laparoscopic abdominal wall surgeries and open hernia repair. The tack is constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid.

[Parietex ProGrip Self-fixating Mesh](#) [3] -- Designed for ease of use, resorbable polylactic acid (PLA) microgrips enable surgeons to position and securely place the mesh in under 60 seconds without the use of additional fixation. Tension is evenly distributed for patient comfort.

[Permacol Surgical Implant](#) [4] -- The processing of this porcine dermal collagen implant gently removes cells, cell debris, DNA and RNA without damaging the 3D collagen matrix. The resulting acellular collagen matrix is then cross-linked for enhanced durability throughout the wound healing process in complex abdominal wall and hernia repairs.

About Inguinal Hernia

An estimated 600,000 inguinal hernia repair procedures are performed in the U.S. each year.⁴ An inguinal hernia is a condition in which intra-abdominal fat or part of

the small intestine, also called the small bowel, bulges through a weak area in the lower abdominal muscles. This type of hernia is designated inguinal because fat tissue or part of the intestine protrudes through a weak area at the inguinal ring at the opening to the inguinal canal, a passage in the front abdominal wall. An inguinal hernia appears as a bulge on one or both sides of the groin and can occur any time from infancy to adulthood. Inguinal hernias are much more common in males than females and tend to become larger over time.⁵

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 approximately 42,000 employees worldwide in more than 65 countries, and its products are sold in over 140 countries. Please visit www.covidien.com [5] to learn more about our business.

¹ Kingsnorth, A., Preliminary Results of a Comparative Randomized Study: Benefit Of Self-Gripping Parietex ProGrip(TM) Mesh In Open Inguinal Hernia Repair, Hernia 2011, the 14th Annual Meeting & Scientific program of the American Hernia Society, March 16, 2011, San Francisco, Calif., Data on file. Study sponsored by Covidien.

² Bisgaard T, Bay-Nielsen M, Christensen IJ, Kehlet H. [Risk of recurrence 5 years or more after primary Lichtenstein mesh and sutured inguinal hernia repair](#) [6], *Br J Surg.* 2007;94(8): 1038-1040.

³ Fr  nneby U, Sandblom G, Nordin P, Nystr  m O, Gunnarsson U. [Risk factors for long-term pain after hernia surgery](#) [7], *Ann Surg.* 2006;244(2): 212-9.

⁴ Malangoni MA, Gagliardi RJ. Hernias. In: Townsend C, Beachamp R, Evers B, Mattox K, eds. *Sabiston Textbook of Surgery*. 17th ed. Philadelphia: Elsevier Saunders Publishers; 2004: 1199-1218.

⁵ National Digestive Diseases Information Clearinghouse (NDDIC) Web site. <http://digestive.niddk.nih.gov/ddiseases/pubs/inguinalhernia/> [8]. Updated December 2008. Accessed March 9, 2011.

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