Medtronic News

Covidien Receives U.S. FDA 510(k) Clearance for Reinforced Stapling Reload Technology

Endo GIA™ Reinforced Reload with Tri-Staple™ technology integrates tissue reinforcement buttressing capability with surgical stapling device

DUBLIN, Ireland--(BUSINESS WIRE)--Feb. 6, 2014-- Covidien plc. (NYSE:COV) announced that the U.S. Food and Drug Administration has granted 510(k) clearance for the company's Endo GIA™ Reinforced Reload with Tri-Staple™ technology. This clearance extends Covidien's industry-leading portfolio of advanced surgical staplers and represents a return by the company to the U.S. market for surgical staplers that integrate buttress material for additional tissue support.

The Endo GIA Reinforced Reload -- the only endoscopic stapler featuring pre-loaded tissue reinforcement -- combines the benefits of Tri-Staple technology with a pre-attached synthetic, porous buttress material that provides additional support to fragile tissue that is being stapled and resected. All Covidien Endo GIA reloads with Tri-Staple technology are designed to work in harmony with the natural properties of tissue to optimize performance during stapling.

"Covidien is committed to developing specialized solutions for our customers that enable better patient outcomes," said Michael Tarnoff, M.D., chief medical officer, Covidien. "This unique technology provides improved ease of use and reduced time in the operating room by eliminating extra steps, reducing procedure time and providing surgeons with an integrated, clinically validated buttress material for added security at the staple line."

The advanced polymer buttressing material is a version of NEOVEIL® felt, developed by GUNZE Ltd., which has been in clinical use in the Japanese market for more than 20 years.

"Our Tri-Staple platform of stapling products represents the most successful product line in Covidien's history," said Chris Barry, president, Advanced Surgical, Covidien. "This all-in-one solution advances our leadership in surgical stapling and meets an important customer need."

In January, Covidien received Shonin approval from the Japanese Ministry of Health, Labor and Welfare for the Endo GIA Reinforced Reload with Tri-Staple technology. Covidien expects to offer the new product in the U.S. and Japanese markets in the coming months.

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 develops, manufactures and sells a diverse range of industry-leading medical device and supply products. With 2013 revenue of $10.2 billion, Covidien has more than 38,000 employees worldwide in more than 70 countries, and its products are sold in over 150 countries. Please visit www.covidien.com to learn more about our business.

Source: Covidien plc

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