



FDA Grants Ethicon Endo-Surgery Approval of its IDE Application to Commence Study of Notes Toolbox™

CINCINNATI - April 22, 2009 - Ethicon Endo-Surgery today announced that the U.S. Food and Drug Administration (FDA) granted approval of the company's Investigational Device Exemption (IDE) application to conduct the first study of devices designed for use in natural orifice transluminal endoscopic surgery (NOTES). The company is the first to receive an IDE to investigate devices specifically designed for natural orifice surgery. The feasibility trial will primarily evaluate the safety of the Ethicon Endo-Surgery NOTES Toolbox™, a comprehensive suite of devices specifically designed for this new approach to surgery. NOTES is a surgical procedure in which external incisions are eliminated.

The study will include up to 40 subjects undergoing either a cholecystectomy (gallbladder removal) or diagnostic peritoneoscopy (exploratory surgery to investigate chronic pelvic pain). Surgeons will use one of four different NOTES techniques supplemented with laparoscopic assistance. In addition to evaluating the safety of the Ethicon Endo-Surgery NOTES Toolbox™, the study is also designed to collect qualitative outcomes data and healthcare economic variables.

"This trial marks an important step in the continued effort to improve surgery for patients and reduce the overall trauma to the body," said Eric Hungness, MD, Northwestern University. "The contributions of the medical device industry are critical to advancing NOTES, and I applaud Ethicon Endo-Surgery for creating and studying the tools surgeons need to realize the potential benefits of this new and promising type of surgery."

During NOTES, an endoscope is passed through a natural orifice (e.g., mouth, vagina) then through an internal incision in the stomach, bladder, colon or uterus, thus avoiding any external incisions or scars.

"We are excited about the potential benefits of NOTES to patients and the overall healthcare industry," said Karen Licitra, Company Group Chairperson, Ethicon Endo-Surgery. "An integral piece to advancing NOTES surgery responsibly is ensuring surgeons have the proper technology at hand. This IDE represents an important step for Ethicon Endo-Surgery in fulfilling that need by pursuing a NOTES-specific indication for the NOTES Toolbox."

The four sites participating in the trial include Northwestern University Feinberg School of Medicine; University of California - San Diego Medical Center; The Ohio State University Center for Minimally Invasive Surgery; and the University of Missouri University Hospital. Each clinical trial site will investigate one of four methods: transgastric (through the mouth) and transvaginal (through the vagina) cholecystectomies and transgastric and transvaginal diagnostic peritoneoscopies.

About Ethicon Endo-Surgery

Ethicon Endo-Surgery, a Johnson & Johnson company, develops and markets advanced medical devices for minimally invasive and open surgical procedures, focusing on procedure-enabling devices for the interventional diagnosis and treatment of conditions in general and bariatric surgery, as well as gastrointestinal health, gynecology and surgical oncology.

Ethicon Endo-Surgery is actively leading the development of NOTES through research to determine the most appropriate tools and technologies that may enable safe and effective NOTES surgery. The Ethicon Endo-Surgery NOTES Toolbox devices are investigational devices that have not been approved for marketing in the U.S.

More information can be found at www.ethiconendo.com.