# Studies Show Potential Of Pure NOTES Surgery With Toolbox

CINCINNATI, June 3 /PRNewswire/ -- Ethicon Endo-Surgery, Inc. announce multiple studies at 2009 Digestive Disease Week (DDW) demonstrating the company's novel, investigational Toolbox enables natural orifice translumenal endoscopic surgery (NOTES) procedures without laparoscopic support in porcine models. One of the studies concluded that a new adaptable minimally-invasive surgical platform for NOTES and single-site laparoscopy (SSL) was successfully used to complete a variety of key surgical activities critical to pure natural orifice surgery and SSL.

The seven studies presented at DDW, which involved porcine models and a variety of NOTES procedures, follows 15 studies involving Ethicon Endo-Surgery devices presented in April at the 2009 Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Annual Meeting. In the coming months, the Ethicon Endo-Surgery Toolbox for natural orifice surgery will be evaluated in a human clinical trial under an investigational device exemption (IDE) from the U.S. Food and Drug Administration (FDA).

"To date, most NOTES procedures performed in humans have been with laparoscopic support. In our study, we found several of the devices in the Ethicon Endo-Surgery Toolbox could successfully be used to address some of the critical visibility and access obstacles present with a pure NOTES approach, warranting further investigation," said Klaus Thaler, M.D., Department of Surgery, University of Missouri Health System.

Investigators of the study entitled, "The Development and Testing of an Adaptable Minimally-Invasive Surgical Platform - The Hydra" found that this surgical platform addressed several challenges with NOTES, including visibility, platform stability and adaptability to be used in multiple interventions and procedures. The surgical platform was used both transgastrically and transvaginally completing multiple key surgical activities that included dissection, ligation, and specimen retrieval. The study, which is being presented as a poster at DDW, involved porcine models and was conducted by investigators from Sahlgrenska University Hospital in Gothenburg, Sweden and Imperial College, London.

"With the introduction of this adaptable minimally-invasive surgical platform, we believe we will be able to further address many of the issues experienced when NOTES or SSL procedures are performed with conventional surgical equipment designed for standard endoscopic or laparoscopic use," said Kenneth Sumner, Ph.D., Vice President, Clinical and Regulatory Affairs, Ethicon Endo-Surgery. "We plan to continue our research to investigate the existing contents of the Ethicon Endo-Surgery Toolbox for natural orifice surgery, as well as develop additional products for inclusion in it that may help fulfill the promise of this approach to minimally

invasive surgery."

Another poster presentation entitled "Hybrid Transgastric NOTES Cholecystectomy in a Porcine Model Using a Magnetically Anchored Cautery and Novel Instrumentation," conducted by the University of Texas, Southwestern Medical Center demonstrated preliminary feasibility for a particularly difficult NOTES procedure, transgastric cholecystectomy. Several devices specifically designed for natural orifice surgery were utilized in the study, including a live video manipulation (LVM) system and magnetically anchoring and guidance system (MAGS). Study investigators specifically cited the retraction abilities of the grasper and improved visibility of the provided by LVM, the latter which greatly reduced the workload on the surgical team.

The content of the investigational Ethicon Endo-Surgery Toolbox includes:

-- Tissue Apposition System -- Steerable Flex Trocar with Rotary Access Needle -- Flexible Bipolar Hemostasis Forceps -- Flexible Maryland Dissector -- Articulating Hook Knife -- Articulating Snare -- Articulating Needle Knife -- Articulating Graspers -- Articulating Biopsy Forceps

The devices listed above will be used within an IDE trial approved by the FDA. The Adaptable Minimally-Invasive Surgical Platform and MAGS are limited to non-clinical applications at this time.

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