Media Contact:
Meg Farina
mfarina@its.jnj.com
+1 610-724-1079

Investor Contact:
Sarah Wood
swood15@its.jnj.com
+1 732-524-2617

ETHICON'S ECHELON CIRCULAR POWERED STAPLER ASSOCIATED WITH MAJOR REDUCTION IN SERIOUS COMPLICATIONS FOLLOWING COLORECTAL SURGERY

New Real-World Study Shows 74% Decrease in Anastomotic Leaks Compared to Manual Staplers, Reinforcing Findings from Previous Clinical Studies

Cinncinnati, OH – Aug. 11, 2021 – Ethicon*, part of the Johnson & Johnson Medical Devices Companies**, today announced the results of a new real-world study that shows its ECHELON CIRCULAR Powered Stapler was associated with a 74% reduction in anastomotic leak rates (1.8% vs. 6.9%)[1] and a 44% reduction in 30-day inpatient hospital readmission rates (6.1% vs.10.8%) after colorectal surgery compared with manual circular staplers.[2]



The study, published in *Surgical Endoscopy*, shows the groundbreaking device is just as effective in reducing life-threatening and costly surgical complications in real-world surgical practice as demonstrated in recent clinical studies, where the leak rate was 1.7% for the ECHELON CIRCULAR and as high as 11.8% for manual staplers.[3]

For the real-world study, investigators drew from data in the ECHELON CIRCULAR clinical trial (165 patients) and the Premier Healthcare database (1,348 manual circular patients) for a matching adjusted indirect comparison of patients who underwent left-sided colorectal resection.

“The data is very positive in terms of postoperative complications and intraoperative events and ease of use, specifically related to the deployment of the circular powered stapler,” said study co-author Patricia Sylla, MD***, a colorectal surgeon and Associate Professor of Surgery at Mount Sinai Hospital in New York. “While anastomotic leaks are a complex problem with various contributing factors, the results of this study highlight the important role that the surgical stapler can play to reduce the potential for complications in colorectal surgery.”

Each year, more than 600,000 colorectal surgical procedures are performed in the United States[4] and despite advances in surgical technique, the incidence of anastomotic leaks remains high, occurring in nearly 12% of colorectal procedures.[5]

“The reductions in anastomotic leaks associated with the ECHELON CIRCULAR are so profound, not only in this study, but in previous ones, a closer look at stapler selection for colorectal surgery is warranted. It could lead to a change in standard surgical practice and improved patient outcomes,” said Ron Landmann, MD,*** FASCRS, Section Chief of Colon and Rectal Surgery at Baptist MD Anderson Cancer Center in Jacksonville, FL, who was not involved in the study.

An anastomosis is a critical part of colorectal surgery in which two ends of the colon are connected with staples after part of the organ has been resected or removed due to damage or disease. If this connection is faulty or weak, an anastomotic leak may occur, which can lead to lengthier hospitalization, increased healthcare costs, and/or death.[6,7] Studies show the mortality rate associated with anastomotic leaks can range from 10% to 15%.[8] The risk of death can be 3- to 15-times greater if an anastomotic leak is present.[9,10,11,12]

The ECHELON CIRCULAR combines two innovative and proprietary technologies -- 3D Stapling Technology that evenly distributes compression[13] and Gripping Surface Technology (GST) for gentler handling that reduces compressive forces on tissues.[14] ECHELON CIRCULAR significantly reduced leaks at the staple line without compromising perfusion.[15]

“The results of this study well exceeded our expectations and deserve strong consideration by the surgical community,” said Sanjoy Roy, Senior Director, Global Health Economics and Market Access, Ethicon, Inc. and a co-author of the latest real-world study. “The evidence, along with the innovation in design and performance, supports the possibility of this device raising the standard of care in the hands of surgeons.”

ECHELON CIRCULAR is the latest addition to a clinical and real-world evidence program that includes the publication of nine peer-reviewed studies in seven countries spanning more than 60 authors and more than 46,000 patients. ECHELON Powered Staplers are the only brand of staplers back by large-scale real-world evidence in bariatric, colorectal and thoracic surgery. Click here to learn more about ECHELON CIRCULAR.

About Ethicon
Ethicon, part of Johnson & Johnson Medical Devices Companies, has made significant contributions to surgery for more than 100 years from creating the first sutures, to revolutionizing surgery with minimally invasive procedures. Our continuing dedication to Shape the Future of Surgery is built on our commitment to help address the world's most pressing health care issues and improve and save more lives. Through Ethicon's surgical technologies and solutions including sutures, staplers, energy devices, trocars and hemostats and our

commitment to treat serious medical conditions like obesity worldwide, we deliver innovation to make a life-changing impact. For more information, visit www.ethicon.com.

About Johnson & Johnson Medical Devices Companies

At Johnson & Johnson Medical Devices Companies, we are helping people live their best lives. Building on more than a century of expertise, we tackle pressing healthcare challenges, and take bold steps that lead to new standards of care while improving people's healthcare experiences. In surgery, orthopaedics, vision and interventional solutions, we are helping to save lives and paving the way to a healthier future for everyone, everywhere.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the ECHELON CIRCULAR Powered Stapler. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Ethicon, Inc. any of the other Johnson & Johnson Medical Devices Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of regulatory approvals; uncertainty of commercial success; challenges to patents; competition, including technological advances, new products and patents attained by competitors; manufacturing difficulties and delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; changes in behavior and spending patterns of purchasers of health care products and services; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Ethicon Inc., the Johnson & Johnson Medical Devices Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

###

*Ethicon represents the products and services of Ethicon, Inc., Ethicon Endo-Surgery, LLC and certain of their affiliates. All other trademarks are the property of their respective owners.

**The Johnson & Johnson Medical Devices Companies comprise the surgery, orthopaedics, vision and interventional solutions businesses within Johnson & Johnson's Medical Devices segment.

***Consultant to Ethicon

---

[1] A retrospective matched analysis of 165 Echelon Circular cases from clinical study, and 1,348 manual circular stapler cases from Premier Healthcare Database [ECHELON CIRCULAR 1.8% (3/165) vs. manual circular 6.9% (93/1348), p<0.001]

[2] A retrospective matched analysis of 165 Echelon Circular cases from clinical study, and 1,348 manual circular stapler cases from Premier Healthcare Database [ECHELON CIRCULAR 6.1% (10/165) vs. manual circular 10.8% (146/1348), p=0.019]

[3] Pla-Martí, V., Martín Arévalo, J., Moro-Valdezate, D. et al. Impact of the novel powered circular stapler on risk of anastomotic leakage in colorectal anastomosis: a propensity score matched study. Tech Coloproctol (2020). https://doi.org/10.1007/s10151-020-02338-y

[4] https://www.sages.org/publications/patient-information/patient-information-for-laparoscopic-colon-resection-from-sages/

[5] Truven Commercial and Medicare, USA Colorectal Complication Rates 2010-2015

[6] Trencheva K, Morrissey K, Wells M, et al. Identifying Important Predictors for Anastomotic Leak After Colon and Rectal Resection. Annals of Surgery. 2013; 257: 108.

[7] Schiff A, Brady BL, Ghosh SK, et al. Estimated Rate of Post-Operative Anastomotic Leak Following Colorectal Resection Surgery: A Systematic Review. Journal of Surgery and Surgical Research. 2016;2(1): 060-067.

[8] Hyman, Neil MD; Manchester, Thomas L. MD; Osler, Turner MD; Burns, Betsy NP; Cataldo, Peter A. MD; Annals of Surgery: February 2007 - Volume 245 - Issue 2 - p 254-258 doi: 10.1097/01.sla.0000225083.27182.85

[9] Ribeiro et al. 2019 (Brazil) – The largest impact of AL was on the mortality rate, which was found to be 13.49 times higher in AL patients than in patients without AL in the analysis adjusted for age, gender, cancer diagnosis, and timing of surgery (p < 0 001).

[10] Gessler et al. 2017 (Sweden) - Thirty day mortality was 5% in the leakage group compared to 0.6% in the none leakage group (p 0.015). Similarly, the 90-day mortality was higher, 8.3 vs. 2% (p 0.004).
[11] Popescu et al. 2017 (Romania) – The mortality rate in patients with AL was significantly higher compared to the no leak group 28.6% vs. 1.9% (p<0.0001).
[12] Turrentine et al. 2015 (US) – Unadjusted analyses revealed significant differences between patients who had anastomotic leaks develop and those who did not: morbidity (98.0% vs. 28.4%; p < 0.0001), length of stay (13 vs. 5 days; p ≤ 0.0001), 30-day mortality (8.4% vs. 2.5%; p < 0.0001), long-term mortality (36.4% vs. 20.0%; p ≤ 0.0001), and hospital costs (chi-square [2] = 359.8; p < 0.0001).https://pubmed.ncbi.nlm.nih.gov/25592468/
[13]Staple line analysis in benchtop testing, comparing Ethicon CDH25P to Medtronic EEA2535.
[14]Benchtop testing on porcine colon, comparing Ethicon CDH29P to Medtronic EEA2835, p<0.001.
[15] Benchtop testing in porcine tissue ≤30mmHg (26mmHg average pressure experienced during intra-operative leak test), comparing Ethicon CDH29P to Medtronic EEA2835 (p<0.001) and preclinical perfusion model, in which perfusion was not significantly different between devices.

© 2021 Ethicon Inc. All Rights Reserved. 153751-200922