

Johnson & Johnson Announces CE Mark Approval for the New ETHICON™ 4000 Stapler

Designed to elevate the surgical experience and deliver reliable staple line integrity across a broad range of tissue thickness^{1} the ETHICON™ 4000 Surgical Stapler is certified for use in open and laparoscopic surgery across specialties in the European Union.*

- ETHICON™ 4000, the advanced surgical stapler, features ETHICON™ 3D Reloads with proprietary 3D Stapling Technology and enhanced Gripping Surface Technology to manage various tissues across specialties, including bariatric, colorectal and thoracic surgeries
- 3D stapling technology is designed to optimize compression not only underneath each staple but also across staples and multiple staple lines, including both stapled and unstapled regions of the tissue²
- New ETHICON™ advanced stapling technology to be harnessed for future use on the OTTAVA™ Robotic Surgical System

New Brunswick, N.J., April 22, 2026 – Johnson & Johnson today announced that it has received European CE Mark approval for its new ETHICON™ 4000 Stapler, an advanced surgical stapler designed to deliver reliable staple line integrity across a wide range of tissue thickness.^{1*}

With proprietary 3D Stapling Technology, a redesigned end-effector and streamlined reload options, the ETHICON™ 4000 and ETHICON™ 3D Reloads are certified for use in open and laparoscopic surgery across the European Union. The new advanced stapling technology and reloads are also planned for future use on the OTTAVA™ Robotic Surgical System.

“Surgical complications, including leaks and bleeding events, can impact surgical outcomes, causing distress to both patients and surgeons, and are associated with significant cost implications,” said François Gaudemet, President, Surgery EMEA, MedTech, Johnson & Johnson. “We are building on a long legacy of supporting surgeons and driving innovation for consistent and reliable experiences across open, minimally invasive and robotic surgery.”

Addressing surgical complications across specialties

Thick, fragile and inconsistent tissue present complex variables that can compromise staple line integrity and consequently, patient outcomes. As a result, surgeons are routinely intervening to mitigate complications, with one study finding that bariatric surgeons reinforced the staple line through oversew, buttress or a combination of both, in 77% of laparoscopic sleeve gastrectomy cases.³

^{*} Benchtop testing in porcine tissue for ETHICON™ 4000 Stapler with ETHICON™ 3D Reloads. Reliable staple line integrity defined as minimum 0.9 reliability at 90% confidence over the intended tissue thickness range for each reload. ETHICON™ 4000 Stapler with ETHICON™ 3D Reloads accommodates a tissue thickness range of 1.0mm to 4.0mm (measured at 8g/mm², tissue comfortably compressed to closed staple height during firing per IFU). Based on benchtop testing and clinical effect is unknown.

As well as affecting patient outcomes, complications such as leaks or bleeding events can be costly. In the UK, for example, prolonged air leaks were found to occur in 27% of patients undergoing thoracic surgery, at an average additional 90-days postoperative cost of €5,200 per patient.⁴ Another Swiss study found that bleeding events affected 8% of thoracic surgery cases, at an average additional cost of over €26,000.⁵

Surgical stapling technology backed by real-world evidence

Since 2017, the use of Johnson & Johnson's Surgical Stapling devices has been associated with improved clinical and economic outcomes — across tissue types, patient populations and countries — in bariatric, thoracic and colorectal procedures.^{6,7,8,9†}

The OTTAVA™ Robotic Surgical System is under development and is not authorized to be marketed or sold in any market. CE marking pending.

About Surgical Solutions from Johnson & Johnson MedTech

Across Johnson & Johnson, we are tackling the world's most complex and pervasive health challenges. For over 100 years, we have helped advance surgical care through our innovative portfolio across wound closure, adjunctive hemostats, surgical stapling and instruments, robotics and digital solutions. Together, with clinicians and healthcare experts around the world we are progressing what's next in surgery to better solve patient needs in metabolic and cardiovascular disease, cancer, and aesthetics and reconstruction.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more about our MedTech sector's global scale and deep expertise in cardiovascular, orthopaedics, surgery and vision solutions at jnjmedtech.com. Follow us at [@JNJMedTech](https://twitter.com/JNJMedTech) and on [LinkedIn](https://www.linkedin.com/company/jnjmedtech). Ethicon, Inc. is a Johnson & Johnson company.

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 ETHICON™ 4000 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 Johnson & Johnson. Risks and uncertainties include, but are not limited to:

[†] Compared with Johnson & Johnson and leading competitor manual and/or leading competitor powered staplers.

competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and global health care reforms 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 most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com, www.investor.jnj.com or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Important Information: Please refer to the latest Instructions for Use and/or Package Insert provided by the manufacturer of the device for the details such as indications, contraindications, side effects, warnings, and precautions.

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References

- ¹ Johnson & Johnson and its affiliates, Royal 60mm DV Staple Performance Sub Completion Report. August 2025. Windchill Document #501434442
- ² Rojatkari P, Nalagatla AK, Ricketts CD, Clymer JW, Yosh E. The Science of Stapling: Staple Form. *Surg Technol Int*. 2024 Jul 15;44:115-121. doi: 10.52198/24.STI.44.GS1773. Epub 2024 Mar 19. PMID: 38547410.
- ³ Zafar SN, Felton J, Miller K, Wise ES, Kligman M. Staple Line Treatment and Bleeding After Laparoscopic Sleeve Gastrectomy. *JSLs*. 2018 Oct-Dec;22(4):e2018.00056. doi: 10.4293/JSLs.2018.00056. PMID: 30607100; PMCID: PMC6305063.
- ⁴ Brunelli A, Chapman K, Pompili C, et al. Ninety-day hospital costs associated with prolonged air leak following lung resection. *Interact Cardiovasc Thorac Surg*. 2020;31(4):507-512. doi:10.1093/icvts/ivaa140
- ⁵ Schweizer N, Pinar MP, Trouiller J-B. RWD20 Assessing the clinical and economic burden of surgical bleeding in Switzerland. Poster presented at: ISPOR Europe 2025; November 9-12, 2025; Glasgow, Scotland. https://www.ispor.org/docs/default-source/cti-meeting-21305-documents/5fba3985-02b3-405b-b860-03145a744bb1.pdf?sfvrsn=cdb51f47_0. Accessed January 14, 2026
- ⁶ Roy S, Yoo A, Yadalam S, Fegelman EJ, Kalsekar I, Johnston SS. Comparison of economic and clinical outcomes between patients undergoing laparoscopic bariatric surgery with powered versus manual endoscopic surgical staplers. *J Med Econ*. 2017;20(4):423-433.
- ⁷ Gan C, Zeng F, Cong W, Tang T, Feng G. Powered stapling system with gripping surface technology for pulmonary resection of lung cancer: real-world clinical effectiveness. *Cost Eff Resour Alloc*. 2022;20(1):72. Published 2022 Dec 23.
- ⁸ Sylla P, Sagar P, Johnston SS, et al. Outcomes associated with the use of a new powered circular stapler for left-sided colorectal reconstructions: a propensity score matching-adjusted indirect comparison with manual circular staplers. *Surg Endosc*. 2022;36(4):2541-2553.

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⁹ Tsunetzuka Y, Tanaka N, Fujimori H. The Impact of Endoscopic Stapler Selection on Bleeding at the Vascular Stump in Pulmonary Artery Transection. Med Devices (Auckl). 2020;13:41-47. Published 2020 Feb 12