News Release



September 21, 2021

Olympus Strengthens Surgical Portfolio with the Launch of POWERSEAL Advanced Bipolar Surgical Energy Devices

POWERSEAL Family of Devices Completes the Olympus Energy Portfolio, Offers Physicians Improved Performance and Ergonomics

Olympus Corporation (Representative Executive Officer, President and CEO: Yasuo Takeuchi) today announced the launch of the first devices in the new POWERSEAL™ family of advanced bipolar surgical energy products. The POWERSEAL 5mm Curved Jaw Tissue Sealer and Divider, Double-Action devices meet the highest standards of clinical performance for advanced bipolar surgical energy devices by delivering consistent sealing reliability in an ergonomic, multifunctional design that promotes procedural efficiency.

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With the release of the POWERSEAL devices, Olympus is introducing a line of versatile advanced bipolar surgical energy devices that augment an extensive and differentiated surgical energy portfolio, which features the unique THUNDERBEAT™ hybrid energy devices and SONICBEAT™ ultrasonic dissectors. The POWERSEAL devices position Olympus competitively within the growing global market for advanced bipolar surgical energy devices, currently estimated at over \$1.2B USD.ⁱⁱ

The POWERSEAL devices provide surgeons with state-of-the-art sealing, dissection, and grasping capabilities in laparoscopic or open surgery while greatly reducing the force required by the surgeon to close the jaws.ⁱⁱⁱ The POWERSEAL devices can be used in numerous forms of surgical intervention including general surgery and gynecological, colorectal, bariatric, urological, thoracic, and vascular surgical procedures.



The POWERSEAL 5mm Curved Jaw Tissue Sealer and Divider, Double-Action

The POWERSEAL devices are single-use devices designed to optimize patient outcomes, with features including:

- Strong and efficient sealing of vessels up to and including 7mm in less than 3 seconds, on average, with proven vessel burst pressure reliability of 3x systolic blood pressure (>99% confidence)ⁱ
- Reduced reach distances to device landmarks (jaw lever, cut trigger, shaft rotation wheel), when compared to the predicate device, and reduced squeeze force requirements for the jaw lever, which may reduce hand strain and make the devices easier to use, particularly for those with smaller handsⁱⁱⁱ
- Multifunctional capabilities such as dissection via the curved and tapered, doubleaction jaw, which are designed to reduce instrument exchanges during surgery
- Minimal thermal spread with fast cool-down times and low exterior jaw temperatures, which can reduce risk of damage to adjacent tissue and structures^{iv}

"Initial clinical experience has shown that the new 5mm POWERSEAL devices offer uniform tissue compression for consistently strong sealing," said Justin A. Maykel, MD, Chief of Colon and Rectal Surgery at UMass Memorial Health. "The product design makes the devices both intuitive and safe to use."

"We are thrilled to expand our surgical energy product portfolio with best-in-class advanced bipolar energy solutions that were designed with surgeons' needs and clinical outcomes as the primary drivers," said Phil Roy, Global Vice President and General Manager for Surgical Devices in the Therapeutic Solutions Division of Olympus Corporation. "These POWERSEAL devices were developed with a core requirement of zero compromise in meeting our goals of strength, efficiency and physician comfort. Testing showed we exceeded our goals across the key measures of surgical energy device performance such as sealing speed, reliability and thermal profile, all while delivering a superior user experience."

The Olympus Energy platform, made up of the ESG-400[™] and USG-400[™] electrosurgical generators, offers hospitals a complete energy solution for any operating room and powers the full range of Olympus Energy systems: monopolar, bipolar (HiQ[™], HICURA[™], PK[™] and Everest devices), ultrasonic (SONICBEAT devices), hybrid energy (THUNDERBEAT devices) and advanced bipolar (POWERSEAL devices). By operating from one energy platform, hospitals can reduce capital expenditures while meeting the other goals of the Quadruple aim, vi availing themselves of a range of surgical energy technologies that have been designed with both the patient and the physician in mind.

Advanced bipolar energy devices are distinguished from traditional bipolar energy devices through more efficient energy delivery, intuitive tissue monitoring, and uniform pressure applied to the tissue by the device jaws. These attributes enable Advanced Bipolar technologies to deliver more consistent and larger (7mm) vessel sealing than standard bipolar technology counterparts.ⁱ

The POWERSEAL devices are regulatory approved for sale in the U.S., Puerto Rico and Australia at this time, and are actively under review in numerous other global markets.

For more information about POWERSEAL, including usage and risks associated with use, visit medical.olympusamerica.com/products/powerseal or refer to the Instructions for Use.

The POWERSEAL devices are best-in-class advanced bipolar energy solutions providing consistent and strong tissue sealing, as well as dissection and grasping capabilities. With an ergonomic design, the POWERSEAL devices reduce the force needed to close the jaws and reduce the reach distances to the jaw lever, cut trigger, and shaft rotation wheel. The POWERSEAL devices can be used in laparoscopic or open surgery, including general surgery and gynecological, colorectal, bariatric, urological, thoracic, and vascular surgical procedures.

About Olympus

As a leading medical technology company, Olympus uses innovative capabilities in medical technology, therapeutic intervention, and precision manufacturing to help healthcare professionals deliver diagnostic, therapeutic, and minimally invasive procedures to improve clinical outcomes, reduce overall costs, and enhance the quality of life for patients. Olympus' Medical portfolio includes endoscopes, laparoscopes, and video imaging systems, as well as surgical energy devices, system integration solutions, medical services, and a wide range of EndoTherapy devices. For more information, visit www.medical.olympusamerica.com.

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ⁱ Internal test report DN0043135

ii Global Market Forecast, Advanced Energy, 2021 – 2025. 2020 DRG Global Market Model; latest MedTech 360 Laparoscopic and Open Market Reports: US, EU, Asia Pac & Japan

iii Internal test report DN0046457

^{iv} Based on internal tissue testing with Histology reports – DN0044287, DN0044290

^v Based on GLP Acute & Chronic animal studies reports – DN0044705, DN0044706

vi Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. *Ann Fam Med*. 2014;12(6):573-576. doi:10.1370/afm.1713