Source: *Distalmotion*

October 28, 2024 05:00 ET

FDA Grants De Novo Marketing Authorization for the Distalmotion Dexter® Surgical Robot

Distalmotion's Dexter Surgical Robot opens an entirely new era for soft tissue robotics in the outpatient setting and ambulatory surgery centers that will have immediate benefit for patients.

Lausanne, Switzerland, Oct. 28, 2024 (GLOBE NEWSWIRE) -- Distalmotion has been granted De Novo approval by the U.S. Food and Drug Administration (FDA) to market the Dexter Surgical Robot for adult inguinal hernia repair. This significant milestone marks another step forward in Distalmotion's mission to empower robotic surgery excellence by expanding access and improving care with robotic assisted surgery in the hospital outpatient and ambulatory surgery centers (ASC's) where over 90 percent of inguinal hernia repairs are currently performed in the United States. [i] With more than 1,300 patients successfully treated in Europe, Distalmotion's extensive experience has paved the way for bringing this innovation to the U.S. market.

Distalmotion is focused on developing a robotic platform for high-volume procedures and bringing the benefits of robotic-assisted surgery to outpatient settings where demand for cost-effective and efficient solutions continue to grow (7 percent ASC market CAGR).[ii] Dexter's mobile design, combined with its small form factor, make it particularly well-suited to these environments, allowing hospitals and ASCs to optimize resources while still accessing the latest technologies and best-in-class surgical tools.

"We're excited to bring Dexter to the U.S. market and empower healthcare facilities with a robotic solution that addresses the barriers of cost, space, and workflow disruption," **commented Greg Roche, Distalmotion's CEO**. "Our goal is to enhance existing practices with robotics that support—not disrupt—the way surgical teams operate."

William Hope, MD, Associate Professor of Surgery, UNC Chapel Hill, General Surgery Residency Program Director, New Hanover Regional Medical Center (Novant Health) added, "Inguinal hernia repair is an excellent first indication for Dexter. Access to robots for these procedures has historically been a challenge. Dexter's design will undoubtedly enable more patients to benefit from robotic assisted surgery."

Dexter seamlessly integrates into existing operating workflows and is fully compatible with current operating room equipment, protecting hospitals' existing investments. Additionally, its single-use instruments remove the complexities of reprocessing, further enhancing workflow efficiency. Dexter's design enables direct and quick access to the patient from the sterile surgeon console, allowing surgeons the flexibility to choose the best technique for each step of the procedure. Dexter is designed to be the "surgeon's robot" that provides the physician complete control of the procedure to optimize patient outcomes.

Sharing his perspective, **Garth Jacobsen, MD, Professor of Surgery, Director of Hernia Surgery, UCSD commented,** "Dexter provides an open concept and the ability to transition from console to bedside seamlessly, resulting in a system that is more ergonomic and operatively efficient than current generation platforms. As a surgeon, I want the ability to use the tools and techniques that enable me to provide the best care to my patients. That's what Dexter delivers."

Echoing similar sentiments, **Ryan Broderick, MD, Associate Professor of Surgery, UCSD shared, "**Dexter delivers exceptional performance and without limitations. Its open platform allows flexibility, whether in terms of the surgeon console or the option to choose your preferred vision system, stapling, and advanced energy. We are seeing the continued shift of procedures moving to

the outpatient setting. The footprint and cost, both less than other solutions, enable Dexter to be the ideal robot for outpatient sites of care and those patients. Dexter is the solution for everyday surgeries and that's what the market needs."

ABOUT DEXTER

Dexter® is designed to deliver the benefits of robotics to more hospitals, hospital outpatient departments, and ambulatory surgical centers by being simple and straightforward to use, and more accessible as a modular, small format, and open system.

As an open system, Dexter is designed to work natively with third party 3D imaging systems, energy devices, vessel sealers and other laparoscopic devices.

It has a suite of fully wristed single use instruments providing the user with dexterity, precision of movement, reliable instrument performance, and lower reprocessing requirements.

ABOUT DISTALMOTION

Distalmotion is a medical device company founded and based in Lausanne, Switzerland. Our mission is to empower more hospitals, surgeons, and patients to benefit of robotic surgery. By removing the complexities of robotic surgery, our aim is to establish a new standard of care, where all patients in general, gynecologic, and urologic surgery have access to best-in-class minimally invasive care.

###

For further information visit: www.distalmotion.com/en-US and follow us on LinkedIn/Twitter: @Distalmotion.

---

[i] Internal data on file
[ii] Fortune Business Insights (2024). U.S. Ambulatory Surgical Centers Market. https://www.fortunebusinessinsights.com/u-s-ambulatory-surgical-centers-market-106323

Attachments

- About Dexter
- Dexter Surgical Robot