



Asensus Surgical Announces FDA Clearance in General Surgery

March 3, 2021

Indications Expand to Include New Procedures in Large General Surgery Market

RESEARCH TRIANGLE PARK, N.C.--(BUSINESS WIRE)--Mar. 3, 2021-- [Asensus Surgical](#), Inc. (formerly TransEnterix, Inc.) (NYSE American: TRXC), a medical device company that is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery™, today announced the Company has received an additional FDA clearance for the Senhance Surgical System which allows for indication expansion in general surgery in the United States.

Asensus Surgical's technology platform, Senhance® Surgical System, is the first of its kind digital laparoscopic platform that leverages augmented intelligence to provide unmatched performance and patient outcomes through machine learning. Senhance goes beyond the typical surgical robotic systems, providing surgical assurance through haptic feedback, eye-tracking camera control, and 3D visualization, and is the first platform to offer 3 mm instruments (the smallest instrument available in the world on a robotic surgical platform).

"The expansion into general surgery for the Senhance Surgical System is a major milestone for the growth and clinical applicability of our technology," said Anthony Fernando, Asensus Surgical President and CEO. "General surgery is, by far, the largest area of manual laparoscopy which can benefit from the precision and insight of Performance-Guided Surgery. The indication expansion allows Senhance to be used in many high-value, complex reconstructive surgeries such as those used to treat reflux and obesity. Including previous indications granted, the Senhance Surgical System can now be utilized in over 2.7 million general surgical procedures performed in the US annually."

"Many of the procedures we perform in general surgery require complex reconstruction throughout a wide surgical field," said Dr. Sabino Zani, Assistant Professor of Surgery at Duke University and an investigator in the clinical studies submitted for indication expansion. "Senhance can now be seen as a widely applicable tool for general surgeons across the broad range of procedures that may be performed from deep in the pelvis to the upper abdomen."

Senhance US Indication for Use

The Senhance Surgical System is intended to assist in the accurate control of laparoscopic instruments for visualization and endoscopic manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, mobilization, and retraction. The Senhance Surgical System is intended for use in general laparoscopic surgical procedures and laparoscopic gynecological surgery. The system is indicated for adult use. It is intended for use by trained physicians in an operating room environment in accordance with the instructions for use.

About Asensus Surgical, Inc.

Asensus Surgical, Inc. is digitizing the interface between the surgeon and patient to pioneer a new era of Performance-Guided Surgery by unlocking the Clinical Intelligence to enable consistently superior outcomes and a new standard of surgery. This builds upon the foundation of Digital Laparoscopy with the Senhance® Surgical System powered by the Intelligent Surgical Unit™ (ISU™) to increase surgeon control and reduce surgical variability. With the addition of machine vision, augmented intelligence, and deep learning capabilities throughout the surgical experience, we intend to holistically address the current clinical, cognitive and economic shortcomings that drive surgical outcomes and value-based healthcare. Learn more about Performance-Guided Surgery and Digital Laparoscopy with the Senhance Surgical System here: www.senhance.com. Now available for sale in the US, EU, Japan, Russia, and select other countries. For a complete list of indications for use, visit: www.senhance.com/indications. For more information, visit www.asensus.com.

Forward-Looking Statements

This press release includes statements relating to the Senhance Surgical System and the FDA clearance to allow for a US indication in general surgery. These statements and other statements regarding our future plans and goals constitute "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, and are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that are often difficult to predict, are beyond our control and which may cause results to differ materially from expectations and include whether the expansion into general surgery for the Senhance Surgical System will be a major milestone for the growth and clinical applicability of the Company's technology. For a discussion of the risks and uncertainties associated with the Company's business, please review our filings with the Securities and Exchange Commission (SEC), including our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020 and our other filings we make with the SEC. You are cautioned not to place undue reliance on these forward looking statements, which are based on our expectations as of the date of this press release and speak only as of the origination date of this press release. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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