

EXERO MEDICAL'S SMART SENSOR GRANTED FDA BREAKTHROUGH DESIGNATION
Designation to Expedite Regulatory Clearance Process for Exero Medical's System, Providing Data on Internal Tissue Healing in the Gastrointestinal Tract for the First Time

Exero Medical, developer of a wireless system for early detection of anastomotic leaks (AL) following gastrointestinal (GI) surgery, announced that it has been granted FDA Breakthrough Designation – a status reserved for medical devices that provide more effective treatment or diagnosis of potentially life-threatening or irreversible conditions or diseases.

To achieve this status, Exero Medical demonstrated that its smart sensor for the early detection of potentially lethal AL following GI surgery, represents a breakthrough that may demonstrate substantial improvement over any available solution.

“In the realm of early detection of AL, there is currently no technology that offers clinicians insights on the state of a patient’s internal tissue healing following resection surgery in the GI,” explained Erez Shor, PhD., CEO of Exero Medical. “The time needed today to obtain definitive diagnosis of a leak often puts the patient in a critical state of health. Alternatively, some surgeons order invasive interventions as a precautionary step, putting patients through often-unnecessary additional procedures. Our system is designed to provide clinicians the needed data on tissue healing well before a patient reaches a catastrophic situation, enabling more precise and effective intervention, minimizing complications and potentially saving lives.”

To confirm that Exero’s smart sensor may provide effective early diagnosis of AL, the FDA scrutinized the company’s pre-clinical data from its animal studies as well as clinical data collected in the first in-human feasibility trial conducted at Rabin Medical Center.

“We are thrilled to work with the FDA to optimize our regulatory process. I expect the rapid interaction with FDA will reduce our time to market,” added Shor.”

“Erez and his team have developed a life-saving technology using a multi-disciplinary approach to medical device development that will have a significant impact on the GI surgical market,” said Shai Policker, CEO of MEDX Xelerator. “Achieving

the FDA’s Breakthrough Designation at this stage attests to the quality of their initial R&D and the urgent need for this technology to reach the hands of clinicians.”

Exero Medical is a portfolio company of MEDX Xelerator, a medical device and digital health focused incubator based in Israel, formed as a partnership between Boston Scientific, MEDX Ventures and Sheba Medical Center.

About Exero Medical

Founded in 2018 by the MEDX Xelerator, an Israeli Innovation Authority incubator, and Clalit HMO, the largest HMO in Israel. Exero Medical’s goal is to save lives through early detection of anastomotic leaks following gastrointestinal (GI) surgeries, addressing a \$2 billion market with its sensor technology. The company has created a patent-pending implantable biodegradable wireless sensor designed to continuously monitor the GI tract near the surgical site, alerting physicians to potential anastomotic leakage post-operation and also enabling early patient discharge by identifying proper tissue healing. Exero Medical is backed by seed investment from the MEDX Xelerator, Boston Scientific, MEDX Ventures and Intellectual Ventures.

For more information, visit:

<https://www.exeromedical.com/>

About MEDX Xelerator

MEDX Xelerator is a leading MedTech incubator formed as an initiative of MEDX Ventures Group together with Boston Scientific, Intellectual Ventures’ Invention Science Fund and Sheba Medical Center. Operating under the auspices of the Israel Innovation Authority, MEDX leverages the healthcare expertise and industry experience of its team with the industry leading insights of its partners to nurture its portfolio companies into successful medical ventures for the benefit of patients and health care professionals. MEDX’s current portfolio companies includes: EndoWays, Append Medical, Exero Medical, and PatenSee, Swift Duct and Dimoveo. Exero was formed as part of MEDX Xelerator’s early stage program, “XLab”.

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