



TELA Bio begins commercialization for Large Size OviTex® for Hernia Repair and Abdominal Wall Reconstruction after Aroa Biosurgery receives 510k clearance.

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MALVERN, Pa. and AUCKLAND, New Zealand, Jan. 10, 2019 /PRNewswire/ -- TELA Bio®, Inc. and Aroa Biosurgery, the joint developers of OviTex® Reinforced BioScaffolds (RBSs) for soft tissue repair, today announced 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market large sizes of OviTex RBS. The OviTex Permanent product line is now commercially available in United States from TELA Bio in sizes up to 25x40 cm (1,000 cm²), which is a 150% surface area increase over currently available devices.

"We are pleased to launch larger OviTex RBSs as we continue our mission to provide valuable solutions for a full range of hernia repairs and abdominal wall reconstructions, including the most complex cases," said Antony Koblisch, president and CEO of TELA Bio. "Traditionally, large abdominal wall hernias can present a technical challenge for some surgeons. Our devices are now positioned to ensure that patients who are most at need have access to the most advanced technology to assist with their hernia repair."

A distinct class of surgical mesh, OviTex RBSs are the only devices available that reinforce biologic materials with polymer fibers in a unique embroidered construction that allows for functional tissue remodeling, as well as improved strength and handling.

"The ability to cover a larger surface area could have many potential benefits for patients and surgeons in terms of securing the most complex hernia repairs properly and reducing the risk of recurrence," said Brian Ward, CEO of Aroa Biosurgery. "As a joint developer and the manufacturer of the OviTex technology, it is encouraging to see growing demand and the continued expansion of our product portfolio. We provide a robust and comprehensive suite of accessible and affordable options that address the current shortcomings in surgical hernia repair solutions."

About TELA Bio, Inc.

TELA Bio, Inc. is a privately-owned company focused on bringing innovative, cost-effective, surgical reconstruction solutions to surgeons, hospitals and patients. The company's OviTex Reinforced BioScaffolds (RBSs) products, designed for hernia repair and abdominal wall reconstruction procedures, integrate polymer and biologic materials in a uniquely embroidered construction using novel engineering design principles. The OviTex portfolio is supported by high-quality, data-driven science and extensive pre-clinical research that has consistently demonstrated the advantages of an RBS over commercially available products. OviTex RBSs are commercially available in the U.S. and in Europe. The company is collaborating with leading surgeons to drive rapid product development and establish TELA Bio as a leader in surgical reconstruction. To learn more about TELA Bio visit <http://www.telabio.com>.

About Aroa Biosurgery

Aroa is a private, venture funded soft-tissue repair company that develops and manufactures medical products to provide a head start in healing challenging wounds and injuries. Their products are developed from their *Endoform*® platform, a novel extracellular matrix biomaterial. Aroa strives to improve the speed and quality of healing while reducing cost. To learn more about Aroa visit <http://www.aroabio.com>.

About OviTex Reinforced BioScaffolds

OviTex Reinforced BioScaffolds (RBSs) are intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Do not use OviTex RBSs in patients known to be sensitive to materials of ovine (sheep) origin. For additional important safety information, please see the OviTex RBSs Instructions for Use.

The statements made or results achieved by TELA Bio customers described herein were achieved in their specific setting. Due to variations in clinical experience and technique, there is no guarantee that these results are typical. Bench testing may not be indicative of clinical performance.

Caution: Federal (US) law restricts this device to sale by or on order of a physician.

TELA Bio, Inc. owns or has applied for the following trademarks or service marks: OviTex, TELA Bio.

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