



TELA Bio® Announces 510(k) Clearance for Restella™ Reconstructive BioScaffolds for Reconstructive Surgery

April 18, 2019

Innovative product portfolio based on TELA Bio's proven technology platform advances the design of biologic-based materials for reconstructive surgery.

MALVERN, Pa., April 18, 2019 /PRNewswire/ -- TELA Bio®, Inc., a regenerative medicine company leading the development of advanced medical devices for soft tissue reconstruction, announced today that the company's Restella™ Reconstructive BioScaffolds have been awarded 510(k) clearance from the U.S. Food and Drug Administration for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive procedures.

"We are excited to bring Restella Reconstructive BioScaffolds to U.S. surgeons and patients. These products were purposefully engineered to allow for rapid tissue integration and revascularization and biomechanical control," said Antony Koblisch, president and chief executive officer of TELA Bio. "Specifically designed for use in reconstructive surgery, Restella products leverage the strong clinical experience of our OviTex® Reinforced BioScaffolds that have now been implanted in more than 4,500 patients."

The TELA Bio technology platform is based on interwoven polymer through layers of biologic tissue in a patented "lockstitch" pattern that creates a unique embroidered construction. The biologic material, derived from ovine rumen, is optimized to reduce foreign body response, minimize inflammation, and enable functional tissue remodeling. The interwoven polymer helps provide support along with improved handling and load-sharing capability.

While biologic materials are often used for soft tissue reinforcement in reconstructive surgery, many surgeons report that currently available materials are costly and may stretch over time leading to patient dissatisfaction. Restella Reconstructive BioScaffolds are tailored to be highly permeable with controlled stretch to support a variety of surgical techniques and procedures. TELA Bio plans to offer resorbable and permanent polymer versions in the Restella Reconstructive BioScaffolds portfolio that will include a range of sizes and shapes.

"Our success in applying the advantages of our technology platform to develop Restella Reconstructive BioScaffolds is another example of TELA Bio's unique ability to bring innovation and cost savings to address a wide range of needs in surgery," said Mr. Koblisch, adding, "By expanding our platform to more surgeons and patients, we are bringing the same level of innovation and cost savings to the reconstructive surgery market that we have delivered with OviTex Reinforced BioScaffolds in hernia repair procedures."

About Restella Reconstructive BioScaffolds

Restella Reconstructive BioScaffolds are intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

Bench and animal testing may not be indicative of clinical performance.

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

About TELA Bio, Inc.

TELA Bio, Inc. is a disruptive regenerative medicine company focused on making advanced medical devices accessible to patients requiring soft tissue reconstruction. The company's products are designed to improve on shortcomings of existing biologics and minimize long-term exposure to permanent synthetic material. TELA Bio's portfolio is supported by high-quality, data-driven science and extensive pre-clinical research that has consistently demonstrated advantages over commercially available products. The company's OviTex Reinforced BioScaffolds for hernia repairs and abdominal wall reconstructions are commercially available in the U.S. and in Europe, and Restella Reconstructive BioScaffolds for reconstructive surgery are commercially available in the U.S. The company is collaborating with leading surgeons to drive rapid product development and establish TELA Bio as a leader in soft tissue reconstruction. To learn more about TELA Bio visit <http://www.telabio.com>.

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