



TELA Bio® Announces Publication of Case Series Evaluating OviTex® in Hiatal and Inguinal Hernia Repair

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Two papers report no hernia recurrences during postoperative period, highlight advantages in repair reinforcement and pain management.

MALVERN, Pa., Sept. 11, 2018 /PRNewswire/ -- TELA Bio®, Inc., a surgical reconstruction company leading the development and commercialization of OviTex® Reinforced BioScaffolds (RBSs) for soft tissue repair, today announced that two papers have been published reporting on recent clinical results with the use of OviTex RBSs in a series of patients treated for hiatal and inguinal hernias. OviTex RBSs are a distinct class of surgical implants that integrate biologic and synthetic materials in a unique embroidered construction that allows movement of fluid and cells through the construct.

"As we continue to work to expand patient access and provide OviTex RBSs to hospital networks across the U.S., we also remain focused on collecting important feedback and real-world insights from surgeons who now have extensive experience with nearly 3,000 hernia repair procedures completed to date," said Maarten Persenaire, chief medical officer of TELA Bio. "We are pleased to announce the publication of two new papers that evaluate OviTex RBSs performance in hiatal and inguinal hernia repair surgeries. The results demonstrate clinical outcomes we have always hoped to achieve, reinforcing the repairs while also providing benefits in pain management."

A paper published in the *Journal of the Society of Laparoscopic Surgeons* is the first reported series on the use of OviTex RBSs in hiatal hernia repairs. A retrospective chart review was conducted for 25 consecutive patients undergoing laparoscopic or open hiatal hernia repairs with OviTex RBSs. There were no reported hiatal hernia recurrences. Reinforcement of the crural repair was accomplished in all cases, and fundoplication was constructed in all but one patient. Good to excellent symptom control or resolution was achieved for heartburn (95%), dysphagia (94.7%), regurgitation (100%), nausea and vomiting (100%), dyspnea (100%), and chest pain or discomfort (85.7%).

"As the first biological repair material that is reinforced with resorbable or permanent suture, OviTex RBSs represent a new paradigm in hernia repair," said Michael Sawyer, MD, FACS, general surgeon at Comanche County Memorial Hospital and author of the paper. "The use of OviTex RBSs has been associated with excellent early patient outcomes in hiatal hernia repairs, and we look forward to conducting long-term follow up and additional studies to confirm these results."

A separate paper published in the *International Journal of Surgery Open* evaluated the role of OviTex RBSs in inguinal hernia repair to help reduce the incidence of chronic postoperative pain. Data from 31 consecutive patients who had an inguinal hernia repaired using an open Lichtenstein technique with OviTex RBSs was collected. There were no reported recurrences during the postoperative period. There were also no complications that required surgical intervention and no reported surgical site infections for 30 days postoperatively. No patients reported chronic postoperative inguinal pain, and no OviTex RBSs required explantation for infection, chronic pain, meshoma or any other reason.

"Chronic postoperative inguinal pain represents one of the most frequent and dreaded causes of inguinal hernia complications," said Stephen Ferzoco, MD, Boston-based hernia surgeon and author of the paper. "It is encouraging to find that no patients reported any postoperative pain that was disabling or lasted beyond three months when OviTex RBSs were used in the repair, which suggests the novel surgical mesh may minimize the inflammatory response seen in many synthetic hernia mesh patients. Importantly, none of these patients required a narcotic pain medications refill."

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 TELA Bio plans to launch OviTex RBSs in the European Union. 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 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.

Media contact

Kelly Wakelee
Berry & Company Public Relations
212-253-8881
kwakelee@berrypr.com

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