



Tensive appoints medical device veteran Bill Hunter Chairman as its bioresorbable scaffold for breast reconstruction after cancer approaches market

- **Has more than 30 years of experience bringing innovations to market, including one of the world's first drug-eluting coronary stents at Angiotech Pharma**
- **Appointment adds world-class capabilities to Tensive as the company approaches pivotal clinical trial milestones**
- **Pivotal trial may enable European and U.S. commercialization of Tensive's innovative bioresorbable REGENERA™ and SOFTAG™ devices for breast reconstruction and tissue marking**
- **Tensive published positive first impressions from pivotal trial in April, and from first-in-human trial in 2023**

Milan, Italy – August 5, 2025 – Tensive S.r.l, a clinical-stage advanced biomaterials medical device company, and the developer of REGENERA™ and SOFTAG™ bioresorbable scaffolds for breast reconstruction and tissue marking, has appointed Bill Hunter, MD, as Chairman of its Board of Directors. Dr. Hunter brings more than 30 years of leadership in the medical technology and life sciences sectors. His appointment reflects Tensive's focus on strengthening its governance and expanding its global network as it accelerates toward pivotal clinical milestones and commercialization in the U.S. and Europe.

Dr. Hunter is the founder and CEO of Canary Medical, a medical data company developing implantable sensor technology. Previously, he founded Angiotech Pharmaceuticals, where he led the development of one of the world's first drug-eluting coronary stents, a multi-billion-dollar innovation that transformed interventional cardiology.

"It's a great honor and validation of the medical potential of Tensive's advanced biomaterials that Bill has accepted to lead our board of directors. His track record of successfully guiding pioneering technologies from concept to commercialization is unmatched," said **Sanjay Kakkar, Chief Executive Officer of Tensive**. "Bill's strategic insights and industry perspectives will be crucial advantages as we complete registrational studies and advance our first device into regulatory processes for marketing approval and commercialization in the U.S. and Europe."



Tensive's innovative polymeric bioresorbable scaffolds allow a natural, non-invasive, permanent and safe solution for breast reconstruction during lumpectomy. In addition, they enable precision tissue marking, demarcating the affected area to direct more targeted radiotherapy and improve imaging accuracy during surveillance and follow-up.

"I am truly excited to join Tensive at such a pivotal moment in its journey," said **Bill Hunter, MD, Chairman of the Tensive Board of Directors**. "In addition to being impressed by the leadership, I became convinced that this was an exceptional opportunity after reviewing the recently published interim data from the ongoing pivotal study of REGENERA™, as well as the excellent long-term follow-up data from the first-in-human clinical trial. The enthusiasm expressed by the key opinion leaders involved with the clinical studies further confirmed my impression of the data. I look forward to supporting Sanjay and his experienced team at Tensive as they bring REGENERA™ and SOFTAG™ to the market."

REGENERA™ / SOFTAG™ advanced biomaterial is a bioresorbable implant designed to be placed during lumpectomy surgery. The bioresorbable medical device is gradually absorbed by the body and enables the patient's own tissue to regrow in the area it fills. The result is breast restoration composed of natural tissue that preserves the patient's original breast shape and feel, yet is clearly differentiated from surrounding tissues on imaging, supporting more targeted delivery of radiotherapy and more accurate monitoring for potential recurrence. The biomaterial used in REGENERA™ and SOFTAG™ resembles a sponge with a fine scaffold matrix; its placement during the lumpectomy surgery is a one-step, minimally invasive, rapid and easy-to-adopt procedure.

Currently, patients undergoing benign and malignant lumpectomy do not typically receive cosmetic intervention to prevent breast disfigurement, which can be psychologically devastating. Of the 2.1 million lumpectomies performed worldwide each year, 1.9 million are not reconstructed, constituting a sizeable unmet clinical need [1]. Despite the psychological impact of breast disfigurement following lumpectomy, more common cosmetic surgery options are rarely used, because they entail invasive and complex procedures that often fail to achieve the desired outcome.

Preliminary data from the first 16 patients in Tensive's ongoing multi-center pivotal trial in 94 patients undergoing malignant lumpectomy were published in *Updates in Surgery* in April 2025, with investigators writing: "In conclusion, we are convinced that REGENERA™ could represent a great innovation in breast oncological surgery, representing a possible alternative to volume replacement with faster operative time, faster recovery, less morbidity, and good patient satisfaction [2]."



These results followed the publication in *Breast Cancer* in 2023 of six-month follow-up data from five patients in a first-in-human trial that demonstrated positive outcomes in terms of both safety and performance, leading the clinical investigators who authored the paper to conclude that the data were “paving the way to an innovative approach with a potential remarkable impact on clinical application of tissue engineering [3].”

[1] Analysis based on estimates from the International Society of Aesthetic Plastic Surgery (ISAPS), Breast Cancer Research Foundation (BCRF), the American College of Surgeons (ACS), the World Health Organization (WHO) and Global Market Insights.

[2] A.V.E. Lisa et al. *Updates in Surgery* Apr 2025. <https://doi.org/10.1007/s13304-025-02212-2>

[3] Mariniello et al. *Breast Cancer* 2023. <https://doi.org/10.1007/s12282-023-01446-5>

Tensive S.r.l. (www.tensive.com) is a clinical-stage advanced biomaterials medical device company developing bioresorbable polymeric scaffolds for breast reconstruction and tissue marking. Its patented REGENERA™ biomimetic scaffold is designed to allow regeneration of a patient’s own breast tissue to create natural, safe, and lasting reconstruction for patients recovering from lumpectomy or undergoing cosmetic procedures, while its SOFTAG™ precision tissue marking device enables more targeted delivery of radiotherapy and increases the accuracy of surveillance and follow-up. Tensive’s mission is to improve clinical outcomes and the quality of life for women worldwide through accessible, innovative, and sustainable solutions.

For more information please contact:

Tensive Srl

media@tensivemed.com

info@tensivemed.com

Cohesion Bureau

Italian and international media & investors

Giovanni Ca’ Zorzi

tensive@cohesionbureau.com

+33 7 8467 0727