



## **Tensive publishes positive interim pivotal clinical data showing REGENERA™ supports natural breast reconstruction in *Updates in Surgery***

- **Advanced biomaterial device designed for use in lumpectomy surgeries**
- **Interim results from the first 25 of 94 patients at 6 months follow up**
- **Confirms REGENERA™ is safe and biocompatible as breast tissue replacement**
- **100% of patients completed adjuvant whole-breast radiotherapy**
- **No device-related complications**
- **No imaging interference reported (MRI/ultrasound)**
- **High and improving surgeon satisfaction (VAS 9.2 at 6 months)**
- **Good-to-excellent cosmetic outcomes in 88% of patients**
- **Statistically significant improvements in patients' breast satisfaction**
- **Statistically significant reduction in cancer-related distress at six months**
- **First regulatory approval expected in EU in early 2027**

**Milan, Italy – April 15, 2026** – Tensive S.r.l., a clinical-stage advanced biomaterials medical device company developing REGENERA™ bioresorbable scaffolds for breast reconstruction and tissue marking, today announced new data in a peer-reviewed article published in [\*Updates in Surgery \(UPIS\)\*](#). The paper reports preplanned interim results from the first 25 of 94 patients in Tensive's ongoing pivotal trial (NCT05941299), who completed six months follow-up after breast-conserving surgery (BCS) and adjuvant whole-breast radiotherapy. The company previously reported top-line results without providing the data published for the first time in UPIS.

In the new publication, REGENERA™ was safe, 100% biocompatible, and well-suited for volume replacement in all 25 patients, providing high satisfaction and excellent aesthetic outcomes without compromising radiotherapy delivery or follow-up imaging, underscoring REGENERA™'s potential as an off-the-shelf, natural, permanent, and safe solution:

“REGENERA™ could represent a potentially invaluable innovation in the oncoplastic surgery toolkit, offering a convenient, high success rate and reproducible solution for volume replacement after lumpectomy,” said **Dr. Matteo Ghilli, MD, Director of the Breast Unit, Breast Centre, Azienda Ospedaliero-Universitaria Pisana, Pisa, and lead author of the publication.** “Our results demonstrate, albeit from a short-term follow-up, that the scaffold



integrates well with host tissue, does not compromise follow-up imaging or radiotherapy delivery. Importantly, it also improved patient satisfaction and delivered excellent cosmetic outcomes. The safety profile and the absence of imaging interference are particularly meaningful in an oncologic setting, where accurate surveillance after surgery is essential. We look forward to the longer-term data that will be generated from the full cohort.”

“This publication marks another important step in building the clinical evidence base for REGENERA™,” said **Sanjay Kakkar, MD, Chief Executive Officer of Tensive**. “This advanced biomaterial device promises to make lumpectomy less burdensome for patients. We are grateful to the patients for their participation and to Dr. Ghilli, Prof. Roncella, Prof. Rietjens, Prof. Acea, and the entire investigator team for their rigorous work. We remain on track for CE mark submission in mid-2026 and our first regulatory approval in early 2027, bringing us closer to offering this solution to the millions of women who currently have no viable option for reconstruction after lumpectomy.”

### **Key results from the interim analysis**

Zero device-related adverse events were observed within 90 days, meeting the primary safety endpoint. All 25 patients completed whole-breast irradiation without permanent interruption; acute toxicity was exclusively grade 1–2 in 44% of patients, consistent with expected rates for whole-breast irradiation. Radiological scaffold integration was satisfactory on MRI and ultrasound with no interference with oncologic surveillance. Investigator satisfaction (VAS) rose from 8.4 at implantation to 9.2 at six months, with device usability scoring 57.3 out of 60. Patient-reported outcomes (BREAST-Q©) showed statistically significant improvements in breast satisfaction (+8.9 points,  $p=0.041$ ) and cancer-related distress (–10.3 points,  $p=0.006$ ) at six months. Good-to-excellent cosmetic outcomes were independently recorded in 88% of patients, assessed using the Harvard scale.

These results build upon previously published findings from this trial [3] and an earlier first-in-human study [4,5], reinforcing a consistent picture of safety, biocompatibility, and patient benefit across settings.

**Breast conserving surgery (BCS)** is the gold standard for early-stage breast cancer, yet cosmetic outcomes remain a significant clinical challenge: deformity risk is substantial when tumor-to-breast ratios are high or lesions are centrally located and is associated with poor psychosocial outcomes and fear of recurrence[1]. Conventional volume replacement options carry autologous tissue rejection risk, longer operative times, and significant technical demands, leaving an estimated 1.6 million women per year without viable options for reconstruction after lumpectomy[1,2]. REGENERA™ addresses this directly: a



bioresorbable scaffold placed during lumpectomy, fitting seamlessly within surgical workflows, and is bioresorbable, (gradually replaced by the patient's own natural tissue). Because REGENERA™ is a flexible sponge-like material, similar in consistency to adipose tissue, it adapts to the surgical cavity without the need for any manual adjustments and thereby offering a fast, convenient and low risk solution during the initial lumpectomy surgery. Furthermore, as it is bioresorbable, it eliminates the risks, costs and inconvenience of further surgical intervention to reconstruct the breast or remove the device.

**REGENERA™** advanced biomaterial is a bioresorbable implant designed to be inserted in place of the surgically removed tumor during a lumpectomy procedure. The biomaterial used in REGENERA™ resembles a sponge with a fine scaffold matrix; it can be rapidly placed during the lumpectomy surgery in a one-step, minimally invasive, fast and easy-to-adopt procedure for surgeons. The biomaterial enables the patient's own healthy tissue to regrow in the area it fills and is gradually absorbed by the body. The result is breast restoration composed of the patient's own natural tissue in the patient's original breast shape and feel. In addition, the implant is clearly differentiated from surrounding tissue on diagnostic imaging, supporting more targeted delivery of radiotherapy and more accurate monitoring for potential recurrence.

- [1] J.F. Waljee et al. *Plast Reconstr Surg* 2008. Analysis of unreconstructed lumpectomies based on estimates from ISAPS, BCRF, ACS, WHO and Global Market Insights.
- [2] M. Ghilli et al. Safety of the use of an absorbable implant in breast-conserving surgery followed by radiotherapy: preplanned interim results from a prospective study. *Updates in Surgery* 2026. <https://link.springer.com/article/10.1007/s13304-026-02629-3>
- [3] A.V.E. Lisa et al. *Updates in Surgery* 2025. <https://doi.org/10.1007/s13304-025-02212-2>
- [4] Mariniello et al. *Breast Cancer* 2023. <https://doi.org/10.1007/s12282-023-01446-5>
- [5] Mariniello et al. *Breast Cancer* 2025. <https://doi.org/10.1007/s12282-025-01780-w>

**Tensive S.r.l.** ([www.tensive.com](http://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 also supporting precision tissue marking to enable targeted delivery of radiotherapy and accurate surveillance and follow-up. Tensive's mission is to improve clinical outcomes and the quality of life for breast cancer patients worldwide through accessible, innovative, and sustainable solutions.



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**Important information**

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