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Tensive reports pivotal 12-month clinical trial data confirming REGENERA™ delivers natural breast reconstruction after lumpectomy

- **Good-to-excellent cosmetic outcomes**
- **30 of 94 patients enrolled have now reached 24 months of follow-up**
- **High surgeon satisfaction sustained through study to date**
- **Improvements in patient-reported breast satisfaction and cancer worry were statistically significant and durable to date**
- **Five-year data from separate first-in-human study shows persistent volume replacement, device resorption leaving natural tissue, no capsule formation**
- **First EU regulatory approval, anticipated in early 2027**

Milan, Italy – July 28, 2026 – Tensive S.r.l., a clinical-stage advanced biomaterials medical device company, and the developer of REGENERA™/SOFTAG™ bioresorbable scaffolds for breast reconstruction and tissue marking, today reported positive interim 12-month follow-up data from its ongoing pivotal trial (NCT05941299) evaluating the REGENERA™ implant in patients undergoing lumpectomy. One year after implantation, the device continued to demonstrate a favorable safety profile, high surgeon satisfaction and durable, good-to-excellent cosmetic outcomes, with sustained improvements in patient-reported quality of life and no interference with oncologic follow-up.

“These twelve-month data reinforce what we have seen consistently across our clinical program: REGENERA™ is safe, it integrates naturally, and the benefit to patients endures,” said **Sanjay Kakkar, MD, Chief Executive Officer of Tensive**. “A year after implantation, cosmetic outcomes remain excellent, surgeons remain highly satisfied, and patients report lasting improvements in how they feel about the affected breast and less anxiety about cancer. This was all achieved without interfering with imaging. As we advance toward commercialization, with CE Mark as soon as early 2027, these results bring us closer to offering millions of women who today have no viable option for reconstruction after lumpectomy a natural, permanent solution.”

Tensive’s innovative polymeric bioresorbable scaffolds allow a natural, non-invasive, permanent and safe solution for breast reconstruction during lumpectomy. Positive interim six-month results from Tensive’s ongoing pivotal trial were published in April 2026 in the peer-reviewed journal *Updates in Surgery*.

Key results from the 12-month follow up data

The 12-month follow-up data covers all 94 patients enrolled in the trial, of whom 87 have exceeded twelve months and 30 have now completed 24 months (two years) of follow-up. One procedure-related adverse event — post-radiotherapy redness and wound retraction that did not regress over time — was reported. Even with this finding, the percentage of potentially related events remains well below the pre-specified 5% safety threshold. Mean investigator's satisfaction, measured on a 0–10 visual analogue scale, was 8.4 at implantation, 9.0 at six months, and 8.6 at twelve months, with a device usability score of 58 (scale 12–60).

Good-to-excellent cosmetic outcomes were recorded in 94.5% of evaluable cases at implantation, 96.5% at six months and 94.2% at twelve months. Patient-reported outcomes (BREAST-Q®) improved significantly versus baseline at both six and twelve months in the Satisfaction with Breast and Cancer Worry domains ($p<0.001$). REGENERA™ caused no interference with oncologic imaging on ultrasound, MRI or mammography. The full dataset from the pivotal trial will be the subject of a forthcoming peer-reviewed scientific publication.

These findings build on the six-month interim results published in *Updates in Surgery* in April 2026 [2] and on earlier first-in-human data [3,4], reinforcing a consistent picture of safety, biocompatibility and durable patient benefit as the pivotal trial matures toward its full read-out.

Five-year follow-up from first-in-human study

Separately, Tensive reported today that five-year follow-up from its first-in-human study continues to show excellent aesthetic outcomes, persistent volume replacement and vascularization of the implant site on ultrasound, with gradual resorption of the scaffold and no capsule formation — clear evidence suggesting that the natural reconstruction REGENERA™ is designed to deliver can be achieved.

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 increased 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; the sponge-like bioresorbable scaffold is placed during lumpectomy, fitting

seamlessly within surgical workflows. It is bioresorbable (gradually replaced by the patient's own natural tissue). Because REGENERA™ is a material similar in consistency to adipose tissue, it adapts to the surgical cavity without the need for any manual size adjustments and thereby offers surgeons 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™/SOFTAG™ 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 fast one-step, minimally invasive, easy-to-adopt procedure for surgeons. The patient's own healthy tissue regrows in the area initially filled by the biomaterial and gradually absorbs it. The result is breast restoration composed of the patient's own natural tissue while preserving the patient's original breast shape and feel from the time of surgery. Importantly, the implant is clearly differentiated from surrounding tissue on diagnostic imaging, facilitating precisely targeted delivery of radiotherapy and more accurate surveillance and follow-up.

References

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

[4] Mariniello et al. Breast Cancer 2025. https://doi.org/10.1007/s12282-025-01780-w

Tensive S.r.l. (www.tensive.com) is a clinical-stage advanced biomaterials medical device company developing bioresorbable, biomimetic polymeric scaffolds for breast reconstruction and tissue marking for patients recovering from lumpectomy or undergoing cosmetic procedures. Tensive's mission is to improve clinical outcomes and the quality of life for breast cancer patients 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