What is ptosis? Why would a patient need additional reinforcement for a procedure?

Ptosis is the drooping or sagging of the skin usually due to natural aging, excessive weight loss, sun exposure, pregnancy and many other reasons. As we grow older, our skin becomes thinner, and less durable due to a significant loss in collagen and elastin. Because of these various factors, skin may begin to show signs of sagging or skin may feel very loose and therefore not provide sufficient mechanical support to withstand the external or internal forces imposed upon it.

The Galatea collection of scaffolds can be used to provide soft tissue reinforcement. Because it is a bioresorbable product, a Galatea scaffold initially provides much of the strength of the repair. Over time, new tissue regenerates, growing into the Galatea scaffold and this new tissue provides the long-term support.

When used in the body during a surgery to correct ptosis, soft tissue reinforcement is designed to extend the life of your repair by providing extra support to the skin envelope and tissue.

Why might my doctor suggest soft tissue reinforcement?

Clinical studies show that within 3 years, anywhere from 15-40% of patients undergo another surgery to revise their result.[3] The most commonly cited reason for these re-operations is the re-occurrence of the sagging or drooping.

Physicians have integrated the use of a Galatea scaffold in procedures where patients have weakened tissue and require soft tissue support to achieve the desired surgical outcome. Galatea scaffolds aid in the support, repair, and elevation of weakened tissue and promote strong tissue ingrowth, providing mechanical support to the surgical site.

By providing internal support immediately after your surgery, soft tissue reinforcement can be used to help support newly lifted and tightened tissue and potentially prevent re-sagging.

Does a Galatea scaffold interfere with future diagnostic tests such as mammograms?

Clinical data show that there is no visibility of the Galatea scaffold at one year of follow up with ultrasound and mammogram. At that point, the scaffold has integrated well into the tissues and is typically not even detectable by the radiologist.[9]

Support the look you love.

Indications for Use

The Galatea collection of scaffolds is indicated for use as a bioresorbable scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery, and general soft tissue reconstruction. The Galatea collection of scaffolds is also indicated for the repair of fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Important Safety Considerations

Possible complications include infection, seroma, pain, scaffold migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion and recurrence of the soft tissue defect.

The safety and product use of a Galatea scaffold for patients with hypersensitivities to the antibiotics kanamycin sulfate and tetracycline hydrochloride is unknown. The safety and effectiveness of a Galatea scaffold in neural tissue and in cardiovascular tissue has not been established. The safety and effectiveness of a Galatea scaffold in pediatric use has not been established.

Consult the Galatea scaffold Instructions for Use for complete prescribing information; including its indications for use, warnings and precautions.

This information is not intended to replace a discussion with your doctor.

* as compared to multifilament design.

1. American Society of Plastic Surgeons. 2014 Plastic Surgery Procedures Statistical Report. *ASPS* www.plasticsurgery.org 2014.
2. Wolloscheck, T (2004) "Inguinal hernia: Measurement of the biomechanics of the lower abdominal wall and the inguinal canal" *Hernia* 8:233-41.
3. Galatea Surgical Physician Preference Study. Data on File. 2014.
4. Badylak, S.F. "Load transfer: mechanism of Phasix™ fully resorbable mesh degradation and tissue integration for a durable repair. A scientific, evidence-based theory of progressive load transfer." White paper. Bard Davol, 2015.
5. Deeken CR, Matthews BD. "Characterization of the Mechanical Strength, Resorption Properties, and Histologic Characteristics of a Fully Absorbable Material (Poly-4-hydroxybutyrate-PHASIX Mesh) in a Porcine Model of Hernia Repair." *ISRN Surg.* 2013; 2013:238067.
6. Martin DP, Badhwar A, Shah DV, et al. *J Surg Res.* Apr 2 2013. Martin, DP et al. (2013) "Characterization of poly-4-hydroxybutyrate mesh for hernia repair applications" *Journal of Surgical Research* 184:766-73.
7. S. Todros, P. G. Pavan, A. N. Natali. "Synthetic surgical meshes used in abdominal wall surgery: Part I materials and structural conformation." Society for Biomaterials. 9 June 2015.
8. Data on File.
9. Data as part of Galatea Surgical Post Market Study, 2016.

For more information about reinforcing your procedure with a Galatea scaffold, please contact us at **contact@galateasurgical.com**

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Surgical Scaffold for Soft Tissue Reinforcement

Galatea Scaffold Collection

Strength and Beauty.
Inside and Out.

Elevate
Support
Repair
Reinforce

GALATEA SURGICAL

If you or someone you know is considering aesthetic surgery, you are not alone.

In the United States, nearly 2 million aesthetic procedures are performed each year, including over:

- 280,000 breast surgeries
- 210,000 nose procedures
- 170,000 face and forehead lifts
- 154,000 body lifts*
- 120,000 breast reductions
- 90,000 breast lifts (mastopexy)
- 55,000 neck lifts[1]

* including tummy tucks, thigh lifts, arm lifts, and buttock lifts.

The overwhelming majority of each of these are performed on women 30-54 years of age.[1]

As we age, the make-up and appearance of our skin changes which may result in droopiness and wrinkles. More patients, both men & women, are now seeking to improve their appearance with aesthetic surgery.

What is a Galatea Scaffold?

In the same manner that a trellis works to support the growth of flowers in a garden, a Galatea scaffold encourages the regeneration and growth of a patient's own natural tissue after surgery.

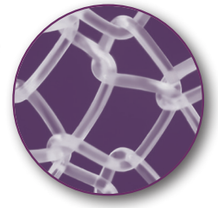
The Galatea scaffold is used to support soft tissue and to reinforce areas that may benefit from additional strength and support. The scaffold provides a porous framework or lattice for the patient's own tissue to grow into. Over time, the lattice bioresorbs, leaving the patient's tissue to provide support.

The Galatea scaffold is a knitted monofilament surgical scaffold made from a completely bioresorbable and biologically derived material called P4HB. P4HB products have been cleared for sale in the United States and Europe since 2007 and have been used in over a million patients worldwide. The Galatea collection of scaffolds is indicated for use by the FDA for soft tissue reinforcement in plastic and reconstructive surgery.

How does a Galatea scaffold work?

A Galatea scaffold is implanted during surgery to support soft tissue that would benefit from additional strength and reinforcement.

Immediately at work, the Galatea scaffold provides the initial mechanical support to the surgical area, but more importantly it serves as a foundation for tissue regeneration during the healing period. The Galatea scaffold encourages cells to migrate into its pores, allowing collagen to build, and healthy blood vessels to form. During this regeneration and healing process, the Galatea scaffold is naturally absorbed by your body, leaving behind only a strong, healthy tissue to support the primary surgical outcome. This tissue regeneration begins immediately and results in tissue that is 3-5 times stronger.[4]



The Galatea Scaffold Collection is Designed to Extend the Life of your Surgical Repair

3-Dimensional: The first and only contoured design that fits and uplifts the body's natural shape

Biologically Derived: Produced by a safe and natural biological fermentation process, standard to antibiotic and vaccine production, designed for biocompatibility and minimal inflammatory response

Monofilament: Knitted with an open-pore design to encourage tissue ingrowth and healing, reducing the risk of infection*[,2,5,6]

Strong: Provides a lattice for new tissue ingrowth with the resulting tissue 3-5x stronger than native tissue[5]

Bioresorbable: Over time, as new tissue is formed, the scaffold slowly resorbs over a period of 18-24 months, eventually leaving behind only the new, stronger tissue[8]

How long does it take for a Galatea scaffold to naturally absorb?

The Galatea scaffold degrades in the human body primarily through hydrolysis. Hydrolysis is a process by which the material is broken down by water. The scaffold loses all of its strength by about 12 months, and is fully absorbed in approximately 18-24 months. The resulting byproducts are carbon dioxide and water, which are natural to the body.

Is the Galatea scaffold a tissue?

Galatea scaffolds are a biological fiber, knitted into an implantable medical device. They are made from neither human nor animal tissue, but rather a bioresorbable polymer that is fully compatible with the body.

Is a Galatea scaffold reimbursable?

Depending on the type of surgery you are having, insurance coverage for the procedure and product may be available and offered through a patient's insurance provider. Please speak with your doctor or hospital to understand more.

We would like to hear from you!

We hope you choose a Galatea scaffold to support the look you love. At Galatea Surgical, we believe that our product will provide your body with the support it needs. Should you choose a Galatea scaffold for your aesthetic procedure, we would like to hear your feedback.

Please contact us at contact@galateasurgical.com