

GalaFLEX®

Everyone Needs a Lift Sometime

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

In the United States, the following procedures are performed annually:

- 90,000 breast lifts (mastopexy)
- 100,000 breast reductions
- 300,000 breast augmentations

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

Why the gain in popularity? As women age, the make-up and appearance of their skin change (see graphic inside) which may cause droopiness and wrinkles. More women are now seeking to fix this with cosmetic surgery. Your doctor may recommend the use of a soft tissue reinforcement, which is surgically implanted and acts as an internal support to elevate your weakened tissue.



Important Considerations

GalaFLEX scaffold is cleared for sale by the United States Food and Drug Administration (FDA) and is indicated for use as a transitory scaffold for soft tissue support and to repair, elevate and reinforce deficiencies where weakness or voids exist that require the addition of a material to obtain the desired surgical outcome. This includes reinforcement of soft tissue in plastic and reconstructive surgery and general soft tissue reconstruction. GalaFLEX mesh 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.

Because GalaFLEX is resorbable, it may potentially reduce risks traditionally associated with permanent implants. However, every surgical procedure is associated with risks and complications that you should consider. Many of the risks and side effects of using GalaFLEX are similar to those normally experienced in surgical procedures. These may include infection, hematoma, seroma, inflammation, wound problems, pain, and any other additional risks that may be described by your surgeon. The unique risks associated with using a surgical scaffold include palpability, pain, extrusion, migration, or a recurrence of your soft tissue defect, which may require removal of the product.

The safety and product use of GalaFLEX for patients with hypersensitivities to the antibiotics kanamycin sulfate and tetracycline hydrochloride is unknown. This information is not intended to replace a discussion with your doctor. It does not describe the potential risks and benefits associated with GalaFLEX.

1. American Society of Plastic Surgeons. 2013 Plastic Surgery Procedures Statistical Report. ASPS www.plasticsurgery.org 2014.
2. Martin DP, Badhwar A, Shah DV, et al. J Surg Res. Apr 2 2013.
3. Galatea Surgical Physician Preference Study. Data on File. 2014.
4. Quan, M. et al. Defining Pseudoptosis (Bottoming Out) 3 Years After Short-Scar Medial Pedicle Breast Reduction. Aesth Plast Surg (2011) 35:357-364

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For more information about GalaFLEX please contact us at info@galateasurgical.com

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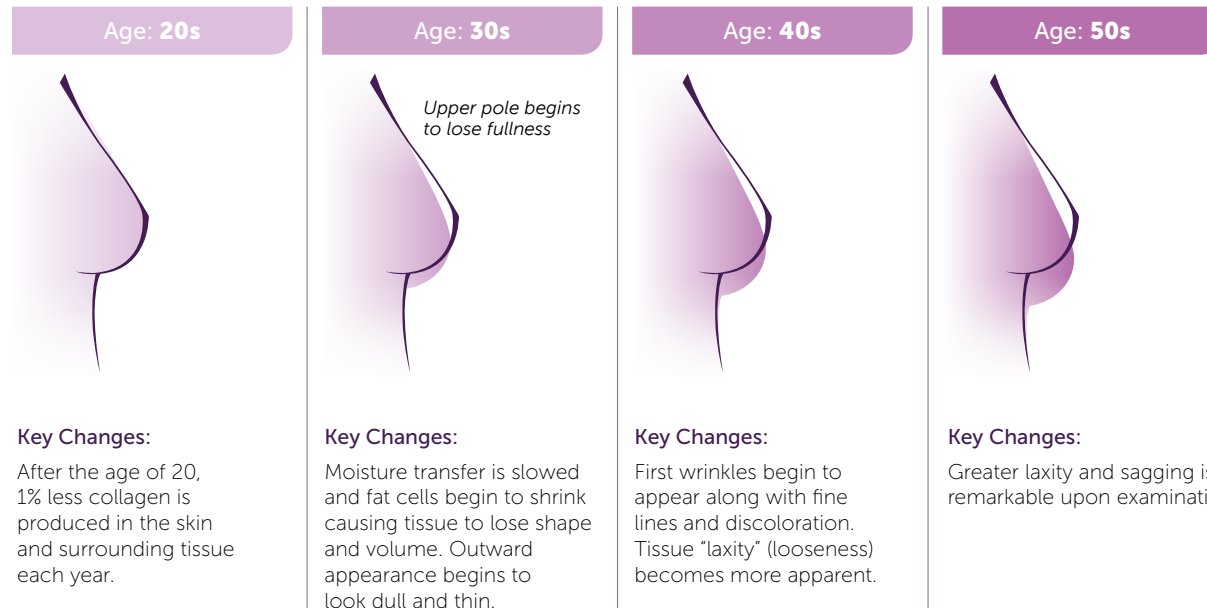
Do You Need a Lift?

GalaFLEX®

MONOFILAMENT
RESORBABLE
SUPERIOR STRENGTH

GALATEA

How Tissue Quality Changes As We Age



What are the different types of breast surgeries and why might my doctor suggest soft tissue reinforcement?

There are many different types of cosmetic breast surgeries including the lift (mastopexy), breast augmentation, and reduction.

- The mastopexy procedure can be used to correct ptosis (i.e., drooping) by lifting and shaping your breasts. Over the past few years, this procedure has become more popular with a 70% increase in procedures since 2000.¹
- Breast reduction reduces the size of your breasts, and may also lift and shape them.
- Breast augmentation increases the size of your breasts with implants. It is the most popular cosmetic surgery procedure; however, the implants place additional weight on the skin surrounding the breast, which can mean a faster rate of sagging after the surgery.

Clinical studies show that within 3 years, anywhere from 15-40% of breast augmentation patients undergo another surgery to revise their result. The most commonly cited reason for these re-operations? The re-sagging of the patients' breasts.

Soft tissue reinforcement can be used to help support newly lifted and tightened tissue and potentially prevent re-sagging. Much like undergarments lift, support and shape the body from the outside, soft tissue reinforcement provides internal support immediately after your surgery.

What is GalaFLEX®?

In the same manner that a trellis works to support the growth of a rose bush in a garden, GalaFLEX provides a strong and flexible scaffold that encourages the continuing growth of a patient's own natural tissue.

Over time, as new tissue is formed and developed around the scaffold, the scaffold is slowly resorbed over a period of 12-18 months, eventually leaving behind only the new, stronger tissue.²

GalaFLEX is a knitted monofilament surgical scaffold made from a completely resorbable and naturally derived material called P4HB. GalaFLEX is cleared for sale by the FDA for soft tissue reinforcement in plastic and reconstructive surgery. P4HB products have been cleared for sale in the United States and Europe since 2007 and have been used in nearly one million patients worldwide.

How does GalaFLEX perform?

Early GalaFLEX clinical results in patients undergoing a mastopexy procedure have demonstrated an average of a 10% change in their breast position from one month to one year.³ Compared to historical clinical literature, this is approximately half the drop in what is seen in patients without reinforcement.⁴ While these results cannot be guaranteed for patients, the data appears to be encouraging.

Is GalaFLEX a reimbursable product?

Depending on the type of surgery you are having, coverage and coding 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 GalaFLEX. We at Galatea Surgical believe that our product will provide your body with the support it needs. Should you choose GalaFLEX, we would like to hear your feedback.

Please contact us at
contact@galateasurgical.com