tissue reinforcement in both medically necessary and cosmetic breast procedures: GalaFLEX scaffold offers a unique combination of properties that are optimal for soft mastectomy. GalaFLEX scaffold may also be used in cosmetic breast procedures. Breast surgery procedures. Examples of medically necessary procedures include reduction mammoplasty to remove excessive breast tissue and breast revision surgery to correct a medical condition. GalaFLEX scaffold may also be used in cosmetic breast procedures where the existing soft tissue is deficient to support the surgical repair. Examples of such breast surgery applications include reduction mammoplasty where the existing soft tissue is deficient to support the surgical repair. GalaFLEX scaffold is designed to be used in patients undergoing soft tissue repair and reinforcement in medically necessary breast surgery procedures.

Important Safety Considerations

Possible complications include recurrence of the soft tissue defect, infection, seroma, pain, scaffold migration, wound dehiscence, hemor- rhage, and breast revision surgery to correct a medical condition. GalaFLEX scaffold may also be used in cosmetic breast procedures. GalaFLEX scaffold is intended for use, as an adjunct to sutures, for the reinforcement and repair of soft tissue where weakness exists and where the addition of a reinforcing material is needed to obtain the desired surgical result in patients undergoing breast surgery. The GalaFLEX scaffold is designed to be used in patients undergoing soft tissue repair and reinforcement in medically necessary breast surgery procedures. Examples of medically necessary procedures include reduction mammoplasty to remove excessive breast tissue and breast revision surgery to correct a medical condition. GalaFLEX scaffold may also be used in cosmetic breast procedures.

GalaFLEX scaffold offers a unique combination of properties that are optimal for soft tissue reinforcement in both medically necessary and cosmetic breast procedures:

- Biologically Derived: Produced by a safe and biological fermentation process, standard in pharmaceutical production
- Monofilament: Designed to minimize risk of infection and encourage a healing response
- Strong: Provides a lattice for new tissue ingrowth and regeneration resulting in tissue 3-5x stronger than native tissue
- Bioresorbable: Naturally broken down to CO2 and H2O, with full biosorption by 18-24 months

Important Safety Considerations

Possible complications include recurrence of the soft tissue defect, infection, seroma, pain, scaffold migration, wound dehiscence, hemorrhage, additional safety and risk information is located on the back cover, and at www.galateasurgical.com
Experience the Difference of Strength and Beauty

**Biologically Derived**

GalaFLEX® biologically derived P4HB construction

- Proprietary fermentation process designed and optimized to provide a safe, biologically friendly product that when combined with all other features encourages the patient's natural healing response.
- P4HB devices have been tested in pre-clinical and clinical studies to evaluate safety and efficacy.
- More than 1 million patients worldwide have GalaFLEX devices implanted, and results indicate a strong safety profile.

**Monofilament**

GalaFLEX macroporous, monofilament scaffold design

- Designed with an open pore knit pattern to encourage rapid tissue ingrowth throughout the macropores of the monofilament scaffold, such that the newly formed tissue is well integrated with the scaffold, such that the newly formed tissue is well integrated with the scaffold.
- The scaffold is embedded within mature fibrous and richly vascularized connective tissue (rich network of CD31, SMA, and Collagen III-positive blood vessels).
- By 6 Weeks, organized collagen to build and healthy blood vessels to form.
- Type I Collagen spans the entire length of the new tissue and is integrated with the scaffold.

**Strong**

GalaFLEX strength retention

- Designed specifically for strength retention throughout critical wound healing.
- Rapid tissue regeneration resulting in tissue 5-5 times the strength of the native tissue as demonstrated in pre-clinical studies.
- GalaFLEX encourages new tissue ingrowth and regeneration

- Provides a scaffold for new tissue ingrowth.
- Maintains ~70% of its strength at 12 weeks in vivo.
- As the scaffold bioresors, mechanical load is transferred to the new tissue, providing strength to the repair site.
- By 25-52 weeks, the tissue from the scaffold repair site is 1.05 mm thick and most of the repair strength is coming from new tissue.

**Long-Term Repair Strength in a Preclinical Model**

<table>
<thead>
<tr>
<th>Duration (Weeks)</th>
<th>Scaffold Strength (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>300</td>
</tr>
<tr>
<td>6</td>
<td>250</td>
</tr>
<tr>
<td>12</td>
<td>200</td>
</tr>
<tr>
<td>18</td>
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<tr>
<td>48</td>
<td>0</td>
</tr>
<tr>
<td>52</td>
<td>0</td>
</tr>
</tbody>
</table>

**Factors that can negatively impact the strength of the scaffold**

- Host Tissue Contribution
- P4HB Contribution

**Important Safety Considerations**

- Possible complications include recurrence of the soft tissue defect, infection, seroma, pain, scaffold migration, wound dehiscence, adhesions, hematoma, inflammation and extrusion.
- Additional safety and risk information is located on the back cover.

**Bioresorbable**

GalaFLEX fully bioresorbable polymer

- Naturally “turns off” after completing its function, providing a strong, healthy matrix to support the surgical outcome.
- Gradually and predictably bioresorbs over the course of 10-24 months.
- Eliminated from the body as carbon dioxide and water primarily by the process of hydrolysis.
- No polymer metabolites remain after the degredation process is complete.

**History of P4HB Products**

- **1980s**
  - Researchers at MIT developed a recombinant bacteria (Bacillus polyhydroxyalkanoates (PHAs) in microbial cultures.

- **1990s**
  - Researchers at Molecular Genetics developed fermentation systems for P4HB in 1998.
  - Tepha, Inc. was incorporated in 1998 to pursue the medical applications of P4HB.

- **2007 / 2008**
  - The first P4HB medical device: TephaFlex® Suture was FDA cleared for clinical use.
  - TephaFlex® Suture was used clinically for the first time.

- **2009 / 2010**
  - Tepha partnered with S. Isour Medical to receive the CE Mark for the P4HB device: MenoMat® Suture.
  - MenoMat® Suture was the first commercial launch of a P4HB device in Europe (2009) and in the US (2010).

- **2011**
  - GalaFLEX® Scaffold received FDA clearance for use in a wide range of surgical fields.
  - GalaFLEX® Scaffold received CE Mark for use in Europe.

- **2012 / 2013**
  - Tepha partnered with Bard/Davol® to commercially launch the P4HB device: Phasix® mesh for hernia repair.

- **2014 / 2015**
  - Tepha P4HB devices achieved international clearing for treating patients globally, with over 1,000 aesthetic plastic surgery patients.
  - GalaFlex L explanted polyhydroxyalkanoate (P4HB) scaffolds received CE Mark for use in cardiovascular tissue engineering.

- **2016 / 2017**
  - GalaFLEX® scaffold encourages cells to migrate into its pores, allowing stronger, organized collagen to build and healthy blood vessels to form.