An innovation in breast reconstruction
**Strattice™ Reconstructive Tissue Matrix, an innovation in breast reconstruction**

A solution for the limitations of current TE/implant techniques

<table>
<thead>
<tr>
<th>Limitations</th>
<th>Benefits</th>
<th>Benefits</th>
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<tbody>
<tr>
<td>Inframammary fold (IMF) definition</td>
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<tr>
<td>Lateral mammary fold LMF definition</td>
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<tr>
<td>Natural ptosis</td>
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<td>☑</td>
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<tr>
<td>Decreased risk of serratus band contracture</td>
<td>☒</td>
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<tr>
<td>Decreased expansion time</td>
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**Benefits**

Reinforcement of pocket which may prevent:
- Bottoming out
- Lateral malposition
- Symmastia

Reinforcement of pocket which may prevent:
- Decreased risk of exposure
- Decreased risk of extrusion
- Decreased risk of TE/implant visibility
- Decreased risk of TE/implant palpability

Strattice™ TM delivers all of the benefits of FMC and PMC without the limitations of either.

*Courtesy of Ron Israeli, MD, FACS, Manhasset, New York, USA.
**Courtesy of Scot B. Glasberg, MD, New York, New York, USA.
***Courtesy of Andrew Salzberg, MD, Valhalla, New York, USA.
****Courtesy of Scott L. Spear, MD, FACS, Washington, DC, USA.
**Strattice™ Reconstructive Tissue Matrix, optimizing aesthetic outcomes and minimizing risk of some complications**

### Aesthetic challenges

<table>
<thead>
<tr>
<th>Strattice™ TM</th>
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<tbody>
<tr>
<td>Insufficient tissue coverage due to aggressive mastectomies where muscle is resected</td>
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<tr>
<td>Provide additional tissue for implant coverage where tissue has been aggressively resected</td>
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<tr>
<td>Implant visibility (wrinkling and rippling)</td>
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<tr>
<td>Provide an additional layer of tissue to existing thin tissue that may help hide implant visibility</td>
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<tr>
<td>Lack of breast ptosis</td>
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<tr>
<td>Provide reinforcement for existing tissue creating a hammock that allows for a more elastic breast pocket</td>
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<tr>
<td>Control of breast pocket positioning and definition of inframammary and lateral mammary folds</td>
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<tr>
<td>Strattice™ TM allows the surgeon to anchor the matrix where desired, which helps to support and define the inframammary and lateral mammary folds.</td>
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### Complication challenges

<table>
<thead>
<tr>
<th>Strattice™ TM</th>
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<tr>
<td>Bottoming out or extrusion of implant</td>
</tr>
<tr>
<td>Provide additional tissue reinforcement to support the tissue expander/implant</td>
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<tr>
<td>Thinning resulting from pressure on skin flap</td>
</tr>
<tr>
<td>Act as an &quot;internal bra&quot; which reinforces the skin flap; this reduces the pressure, which can help prevent thinning</td>
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<tr>
<td>Pectoralis major muscle retraction or animation</td>
</tr>
<tr>
<td>Anchor the inferior border of the pectoralis major muscle to chest wall which may prevent the muscle from retracting</td>
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<tr>
<td>Morbidity associated with serratus muscle elevation</td>
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<tr>
<td>Eliminate the need to elevate the serratus muscle</td>
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### Other challenges

<table>
<thead>
<tr>
<th>Strattice™ TM also</th>
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<tr>
<td>Numerous expansions required to reach final implant volume</td>
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<tr>
<td>May allow for immediate expansion and may reduce the total number of expansions necessary</td>
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<tr>
<td>Difficult single-stage reconstruction</td>
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<tr>
<td>Help enable direct-to-implant procedure by providing a larger implant pocket</td>
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Results above are with the use of Strattice™ TM.
Photos courtesy of Scott L. Spear, MD, Washington, DC, USA.
Strattice™ Reconstructive Tissue Matrix offers surgeons and patients unique clinical benefits

For tissue expander/implant breast reconstruction

Strattice™ TM is a reconstructive tissue matrix that supports tissue regeneration. It is derived from porcine dermis and undergoes a non-damaging proprietary process that removes cells that might elicit an antigenic response and significantly reduces the key component (1,3 alpha galactose epitope) believed to play a major role in the xenogeneic rejection response. Strattice™ TM is recommended for use in soft-tissue repair including tissue expander/implant breast reconstruction.

Clinical experience

4.5-month histology and gross observation

Gross appearance

- Blood vessel
- Blood vessel
- Strattice™ TM

Revascularization

- Presence of blood vessels within Strattice™ TM as further evidenced by brown staining of alpha smooth muscle actin within vessel walls.

Gross appearance of Strattice™ TM 4.5 months after placement at breast lower pole for expander coverage, showing tissue integration and revascularization as evidenced by the red building throughout the Strattice™ TM.

Repopulation

- Expander
- Lack of synovia-like metaplasia
- Cells
- Strattice™ TM

Maximization of inflammatory response

- H&E stain 200X. Robust cellular ingrowth within Strattice™ TM and lack of synovia-like metaplasia at expander/Strattice™ TM interface.
- H&E stain 100X. Strattice™ TM/capsule interface showing a sharp transition from synovia-like metaplasia within capsule indicative of a foreign body response, to a normal cell density with Strattice™ TM.

Intraoperative view: Strattice™ TM coverage and support of breast lower pole

Postoperative results: Strattice™ TM coverage and support of breast lower pole

- A: Preoperative stage. B: 4.5 months after initial surgery at the completion of expansion. C: 4 months after expander exchange. Photos courtesy of Scot B. Glasberg, MD, New York, New York, USA.

“Strattice™ helps create well-contoured, symmetrical breasts with excellent projection and ptosis.”

Scot B. Glasberg, MD, New York, New York, USA
Not all biologic tissue matrices perform the same. Soft-tissue repair materials that support regeneration may provide clinical benefit for breast reconstruction patients.*

**Immunologic response**
- **Positive Recognition**
- **Negative Recognition**

**Mechanism of action**
- **Regeneration**
- **Resorption**
- **Encapsulation**

**1-month histology and gross observation**
- **Strattice™ Reconstructive Tissue Matrix**

**6-month histology and gross observation**
- **Denatured porcine tissue**
- **Cross-linked porcine tissue**

**Tissue processing**
- **Extracellular matrix is preserved and intact**

**Clinical outcomes/ Biological performance**
- **Rapid revascularization and cell repopulation**
- **Converts into host tissue**
- **Reduces inflammatory response**

**Damaged matrix**
- **Foreign antigens**

**Negative**
- Increased risk of:
  - Visibility
  - Palpability
  - Skin flap wrinkling and rippling
  - Thinning
  - Malposition

**Similar to resorbable synthetic**
- Deposition of capsule tissue
- Increased risk of palpability

**Similar to permanent synthetic**

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*H&E stain 200x. Explant histology and gross observation of cross-sectional view of abdominal wall explant in primate model.

*Correlation of these results to results in humans is not established.**

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**Strattice™**

**Reconstructive Tissue Matrix**

**Blood vessel**

**Fibroblast**

**Inflammation**

**No cells or blood vessels**

**Avascular**

**Acellular**

**Graft perimeter inflammation**

**Inflammatory cells, no blood vessels**

**Positive Recognition**

**Regeneration**

**Resorption**

**Encapsulation**

**Inflammation**
Key opinion leaders* in breast reconstruction recommend the following technique considerations for optimizing outcomes

Expand-to-implant technique

**Strattice™ TM placement**
- Center over mid-arc.

**Anchoring Strattice™ TM**
- Suture inferior border to chest wall tissue, not to skin flap.
- Ensure that there are no gaps when suturing superior border of Strattice™ TM to pectoralis major muscle.

**Pectoralis major muscle placement**
- Bring muscle over prosthesis as far inferolaterally as possible without overstretching it.
- Position muscle below incision site, if possible.

**Prolonged use of drains**
- Maintain drains until <30cc drainage over 24-hour period.
- Commence postoperative expansion after two weeks or after skin incision has healed, even if drainage >30cc/day.
- Utilize closed drainage system to minimize risk of infection if seroma develops after drain removal.

**Extent of expansion**
- Expand intraoperatively as much as skin flap and Strattice™ TM repair will comfortably tolerate to minimize dead space (seroma accumulation) as much as possible.

Direct-to-implant technique

**Considerations, in addition, to those listed under the Expand-to-implant section**

**The ideal patient**
- Medium to small breasts with good symmetry
- Viable skin flaps with some subcutaneous fatty tissue
- No breast base footprint asymmetry or bony chest wall asymmetry/deformities
- No planned postoperative radio therapy

**Creating symmetry**
- Placing patient in a semi-upright position >45 degrees for entire procedure, or at least periodically for assessment, can facilitate visualization of effect of implant weight on soft-tissue envelope.
- In bilateral reconstructions, start with the most challenging breast first in case additional tissue resections or manipulations are required.
  - Examples: IMF violated or destroyed, poor skin envelope
- Re-establish the preoperative breast footprints after mastectomy by recreating the lateral mammary fold and inframammary fold positions.
- Placing arms at patient’s side before inserting the Strattice™ TM and implants can minimize tension on the pectoral muscle and help with achieving desired degree of ptosis.

*US and European key opinion leaders

**NOTE:** Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies. Please consult a physician and product instructions for use prior to application. This material is intended for healthcare professionals only.
### Ordering information

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<th>Product size</th>
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<td>8 x 20cm</td>
<td>0820001EU</td>
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**Stratticide™ Reconstructive Tissue Matrix Pliable**

**Revisions**

3 x 14cm 0314001EU
4 x 16cm 0416001EU
6 x 8cm 0608001EU
8 x 8cm 0808001EU

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### References

2. MLC1744-EU: Advanced technique discussion with Scott L. Spear, MD - Use of Stratticide™ Reconstructive Tissue Matrix for implant or expander coverage and support post-mastectomy.

Before use, physicians should review all risk information, which can be found in the *Instructions for Use* attached to the packaging of each LifeCell™ Tissue Matrix graft.