



An innovative technique
for breast reconstruction

A solution for the limitations of current TE/implant techniques

Over the last several decades, surgical techniques have evolved from full muscle coverage to partial muscle coverage to attain the aesthetic goals surgeons performing breast reconstruction procedures are trying to achieve. Full muscle coverage has a number of benefits associated with it, but also has numerous limitations as well. Over time, surgeons have migrated to partial muscle coverage for many of their patients because it provides a number of benefits that directly answer the limitations of full muscle coverage. However, although partial muscle coverage provides many new benefits, it comes with a whole new list of limitations of its own.

Today, supporting the lower part of the breast using Strattice® provides the benefits of both full muscle coverage and partial muscle coverage without the limitations of either. This technique, which makes use of biological surgical implants, is helping surgeons attain optimum aesthetic outcomes without an increased risk of complications.

Clinical goals

Inframammary fold (IMF) definition

Lateral mammary fold (LMF) definition

Good projection

Natural ptosis

Less morbidity

Less pain and bleeding

Decreased risk of serratus band contracture

Decreased expansion time

Decreased risk of high-riding breast implant

Control of pocket helps prevent:

- Bottoming out
- Lateral malposition
- Synmastia

Muscle under incision provides:

- Good blood supply to skin flaps/incision site

Decreased risk of exposure

Decreased risk of extrusion

Decreased risk of TE/implant visibility

Decreased risk of TE/implant palpability



| Poor projection/ptosis*



| Serratus band contracture**

*Courtesy of Ron Israeli, MD, FACS, North Shore Hospital, Manhasset, NY, USA.

**Courtesy of Scot B. Glasberg, MD, Lenox Hill Hospital, New York, NY, USA.

***Courtesy of Scott L. Spear, MD, FACS, Georgetown University School of Medicine, Washington, DC, USA.

Late 1970s.....Today

Full muscle coverage	Partial muscle coverage	The Strattice technique
Limitations	Benefits	Benefits
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
X	✓	✓
Benefits	Limitations	
✓	X	✓
✓	X	✓
✓	X	✓
✓	X	✓
✓	X	✓
✓	X	✓
✓	X	✓
✓	X	✓
✓	X	✓

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



| Bottoming out*



| Lateral malposition*



| Synmastia*



| High-riding breast***

Optimising aesthetic outcomes and minimising risk of some complications

For years there have been many challenges associated with tissue expander/implant breast reconstruction. An increasing number of surgeons are now overcoming these issues with novel techniques involving tissue matrices that support regeneration. The range of breast reconstruction aesthetic challenges and complications, along with the benefits of using LifeCell tissue matrices, are outlined in the table below.

Aesthetic challenges	LifeCell tissue matrices
Insufficient tissue coverage due to aggressive mastectomies where muscle is resected	Provide additional tissue for implant coverage where tissue has been aggressively resected
Implant visibility (wrinkling and rippling)	Provide an additional layer of tissue that may help hide implant visibility
Lack of breast ptosis	Provide additional tissue creating a hammock that allows for a more ptotic breast
Control of implant position and definition of inframammary and lateral mammary folds	Allow the surgeon to anchor the tissue where desired. This gives the surgeon control of implant location and the ability to define the inframammary and lateral mammary folds

Preoperative



1-month



6-months

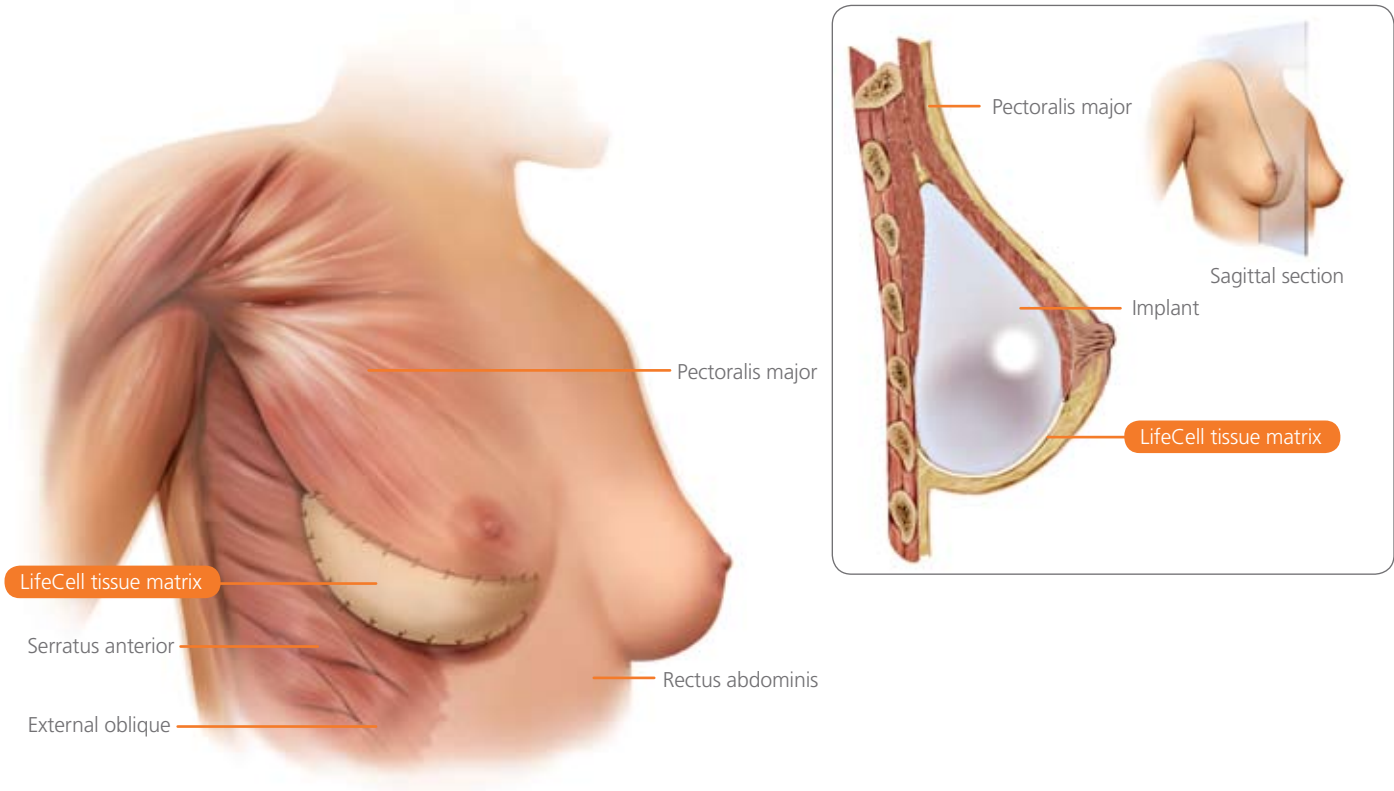


18-months



Results above are with the use of AlloDerm®.
Photos courtesy of Scott Spear MD, Georgetown University School of Medicine, Washington, DC, USA.

Complication challenges	LifeCell tissue matrices
Unnatural feel of implant (palpability)	Offer an additional layer of tissue that may help mask implant palpability
Bottoming out or extrusion of implant	Support the tissue expander/implant
Thinning resulting from pressure on skin flap	Act as an “internal bra” which reinforces the skin flap; this reduces the pressure, which can help prevent thinning
Pectoralis major muscle retraction or animation	Anchor the inferior border of the pectoralis major muscle to chest wall, which may prevent the muscle from retracting
Morbidity associated with serratus muscle elevation	Eliminate the need to elevate the serratus muscle



Other challenges	LifeCell tissue matrices also
Numerous expansions required to reach final implant volume	May allow for immediate expansion and may reduce the total number of expansions necessary
Difficult single-stage reconstruction	Help enable direct-to-implant procedure by providing a larger implant pocket

Not all biologics perform the same. Soft-tissue repair materials that support regeneration may provide clinical benefit for breast reconstruction patients

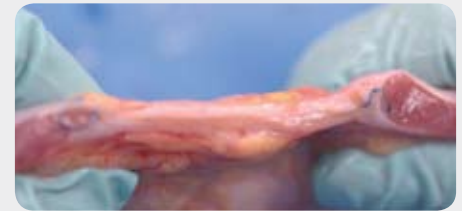
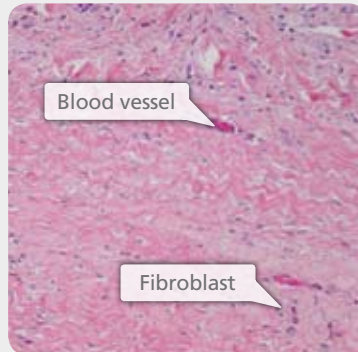
Mechanism of action¹

Regeneration

Body accepts and integrates the intact tissue matrix as part of the host through rapid revascularisation, white cell migration and cell repopulation.

1-month histology and gross observation

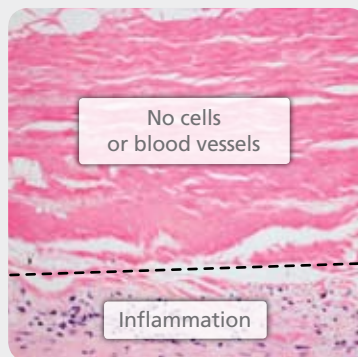
Strattice® Reconstructive Tissue Matrix



Resorption

Body attacks the damaged tissue to break it down and eliminate it.

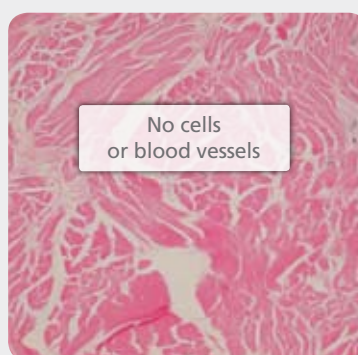
Denatured porcine tissue



Encapsulation

Body attacks the cross-linked tissue to extrude or wall it off from the host.

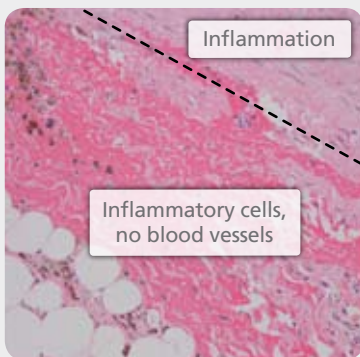
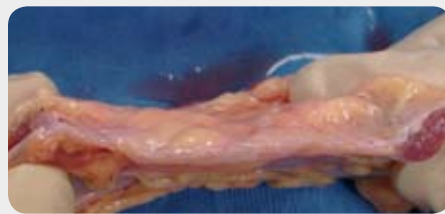
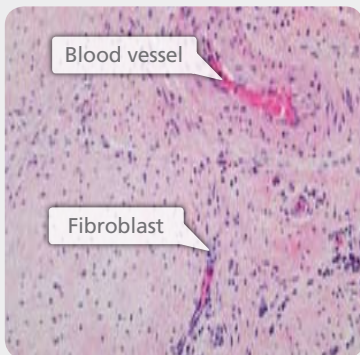
Cross-linked porcine tissue



H&E stain 20x. Explant histology and gross observation of cross-sectional view of abdominal wall explant in primate model.*

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

6-month histology and gross observation



Clinical outcomes

Rapid revascularisation and cell repopulation

- Skin flaps are already vascularly compromised

Reduced inflammatory response*

- May minimise the deposition of capsule/scar tissue*

Converts into host tissue

- May help prevent skin flap thinning over time ("internal bra")
- Provides extra layer of tissue which may:
 - mask implant visibility and palpability
 - decrease risk of implant extrusion

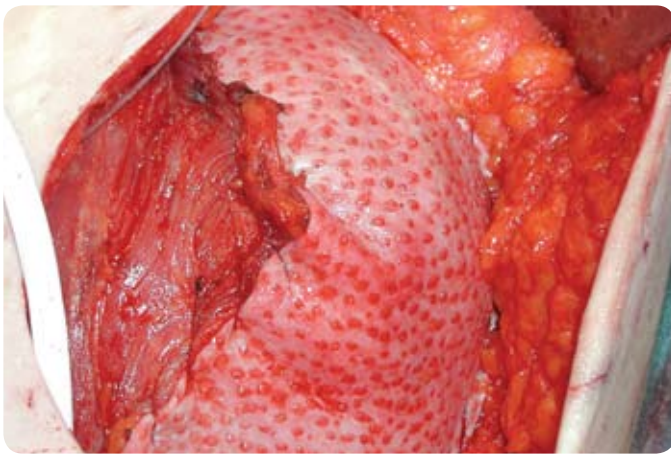
- Similar to resorbable synthetic
- Deposition of capsule tissue
- Increased risk of:
 - visibility
 - palpability
 - skin flap wrinkling & rippling
 - thinning
 - malposition

- Similar to permanent synthetic
- Deposition of capsule tissue
- Increased risk of palpability

For tissue expander/implant breast reconstruction

Strattice® 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 is recommended for use in soft-tissue repair including tissue expander/implant breast reconstruction.

Intra-operative view: Strattice coverage and support of breast lower pole



Photos courtesy of Scot Glasberg, MD, New York, NY, USA.

Post-operative results: Strattice coverage and support of breast lower pole



Outcome of breast reconstruction. A: Pre-operative stage. B: Well contoured, symmetrical breasts at the completion of expansion. C: Excellent breast projection, ptosis and symmetry, 4 months after expander exchange.

Clinical experience

4.5-month histology and gross observation

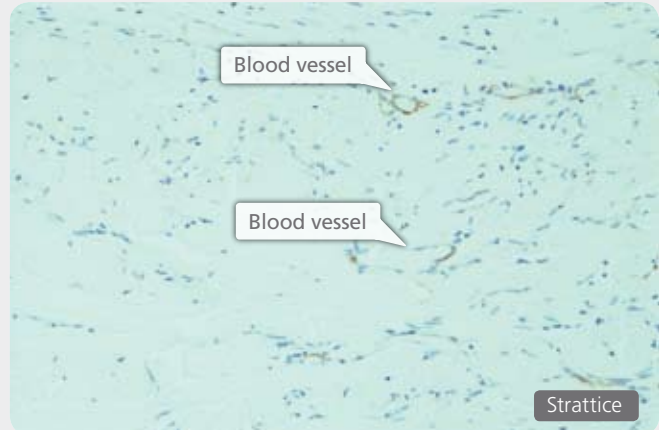
Gross appearance



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

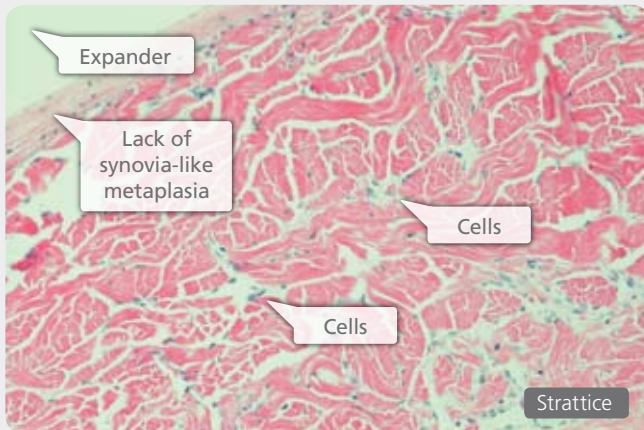
4.5-month histology and gross observation

Revascularisation



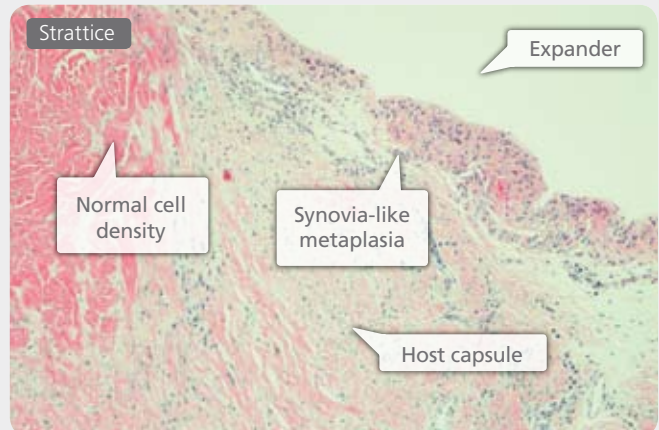
I Presence of blood vessels within Strattice matrix as further evidenced by brown staining of alpha smooth muscle actin within vessel walls, magnification: 200X.

Repopulation



I Robust cellular ingrowth within Strattice matrix and lack of synovia-like metaplasia at expander/Strattice interface. H&E staining, magnification: 200X.

Minimisation of inflammatory response



I Strattice/capsule interface showing a sharp transition from synovia-like metaplasia within the capsule, indicative of a foreign body response, to a normal cell density within Strattice. H&E staining, magnification: 100X.

I Courtesy of Scot B. Glasberg, MD, Lenox Hill Hospital, New York, NY, USA.

Using Strattice[®]

Strattice technique considerations

Key opinion leaders recommend the following considerations for optimising outcomes:

Strattice placement

- Centre over mid-arc.

Anchoring Strattice

- Suture inferior border to chest wall tissue, not to skin flap.
- Ensure no gaps when suturing superior border of Strattice 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 post-operative expansion after two weeks or after skin incision has healed, even if drainage >30cc/day.
- Utilise closed drainage system to minimise risk of infection if seroma develops after drain removal.

Extent of expansion

- Expand intraoperatively as much as skin flap and Strattice repair will comfortably tolerate to minimise dead space (seroma accumulation) as much as possible.



Ordering information

	Product size	Product code
Strattice Pliable	5x16cm	0516001EU
	8x16cm	0816001EU

References:

1. Harper JR, McQuillan DJ. A novel regenerative tissue matrix (RTM) technology for connective tissue reconstruction. *Wounds*. 2007;19(6):163-168.

Before use, surgeons should review all risk information, which can be found in the "Instructions for Use" attached to the packaging of each Strattice Reconstructive Tissue Matrix.

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