

 **AlloDerm**[®]
REGENERATIVE TISSUE MATRIX

Ready To Use



Now ready when you are

Artist's rendering

 **LifeCell**[™]
An Acelity Company

AlloDerm® Regenerative Tissue Matrix (RTM) Ready To Use

Designed to have clinical and intraoperative performance similar to AlloDerm® RTM and is the alternative for surgeons who desire a ready to use sterile* matrix

Offers numerous intraoperative benefits:

- **Ready to use** with a minimum 2-minute soak
- **Sterile***
- Handling and pliability surgeons desire for breast reconstruction
- No refrigeration required

May help surgeons optimize outcomes:

- Provides additional reinforcement where tissue has been aggressively resected
- Provides an additional layer that helps reinforce thin tissue
- Allows the surgeon to anchor the matrix where desired, which helps to reinforce and define the inframammary and lateral mammary folds
- Eliminates the need to elevate the serratus and/or rectus abdominis muscles
- Provides for a larger and more elastic breast pocket
- Helps enable a single-stage procedure by reinforcing existing tissue
- Reinforces the skin flap
- Reinforces the tissue, allowing the surgeon to anchor the pectoralis major muscle (PMM) to the chest wall

*Terminally sterilized to a Sterility Assurance Level (SAL) of 10^{-3} . The inner foil pouch is also sterile and may be placed directly into the sterile field.

Preserves the structure and the integrity of the human dermal matrix

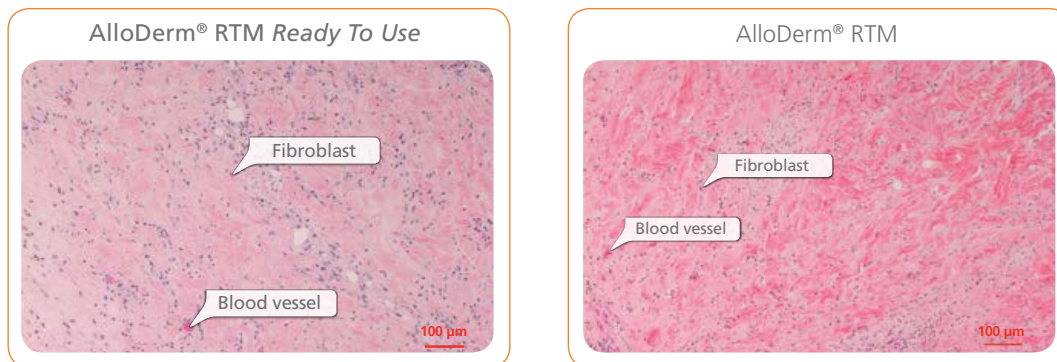
- The native collagen architecture, including basement membrane structure, is maintained through gentle processing in both AlloDerm® RTM and AlloDerm® RTM Ready To Use



H&E stain. Histology comparisons of human dermis to AlloDerm® RTM and AlloDerm® RTM Ready To Use. Data on file.

Demonstrates performance similar to AlloDerm® RTM in non-human primates†

- Non-human primate studies have shown that AlloDerm® RTM Ready To Use supports rapid revascularization, cell repopulation and white cell migration†



H&E stain. Histology of abdominal wall explants at one month in primate model. Data on file.

- No evidence of encapsulation, resorption or contracture

†Old World non-human primates are 92% genomically homologous to humans and thus an appropriate surrogate to model human immunologic response.^{1,2} Correlation of these results to results in humans is not established.

References:

1. Sibley CG, Ahlquist JE. DNA hybridization evidence of hominoid phylogeny: results from an expanded data set. *J Mol Evol.* 1987;26:99-121.
2. King FA, et al. Primates. *Science, New Series.* 1988;240(4858):1475-1482.

A solution for the limitations of traditional breast reconstruction techniques

Over the past several decades, in an effort to achieve better surgical results for their patients, surgeons have increasingly switched from full muscle coverage to partial muscle coverage techniques for breast reconstruction procedures. Full muscle coverage has a number of benefits, but it also has numerous limitations. Over time, some surgeons migrated to partial muscle coverage for many of their patients because it provided a number of benefits that directly answered the limitations of full muscle coverage. Although partial muscle coverage provided many new benefits, it came with a host of limitations all its own.

Today, soft tissue (skin flap) reinforcement using **AlloDerm® RTM Ready To Use** helps surgeons attain optimum surgical outcomes.

Clinical goals of reconstruction

Inframammary fold (IMF) definition

Lateral mammary fold (LMF) definition

Less morbidity

Easily expandable pocket

Lower pole strength and stability

Minimize risk of pectoralis major muscle (PMM) retraction

Stabilize the PMM beneath the incision site

Minimize the risks associated with tissue thinning

Late 1970s.....Today

Full muscle coverage	Partial muscle coverage	AlloDerm® RTM Ready To Use reinforcement technique may allow the surgeon to achieve
Limitations	Benefits	Advantages of soft tissue reinforcement
X	☐	☐
X	☐	☐
X	☐	☐
X	✓	✓
Benefits	Limitations	
☐	X	☐
☐	X	☐
☐	X	☐
☐	X	☐

Through tissue reinforcement, **AlloDerm® RTM Ready To Use** delivers many of the identified benefits of both full muscle coverage and partial muscle coverage without the identified limitations of either.

Not all biologic matrices perform the same

Non-human, primate studies have shown that **AlloDerm® RTM Ready To Use** supports regeneration and may provide clinical benefits for breast reconstruction patients.*

Immunologic response

Mechanism of action

1-month histology and gross observation

Positive Recognition¹

(Body recognizes as self)

Regeneration

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

AlloDerm® RTM Ready To Use



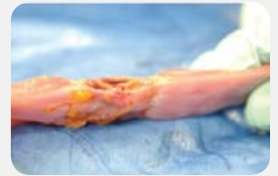
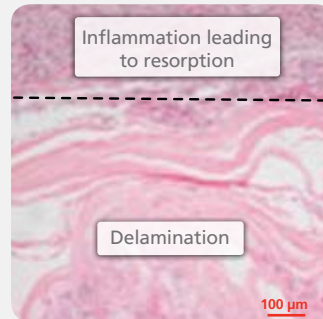
Negative Recognition²

(Body recognizes as foreign)

Resorption

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

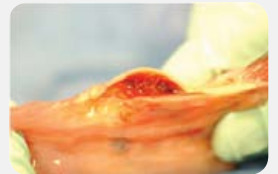
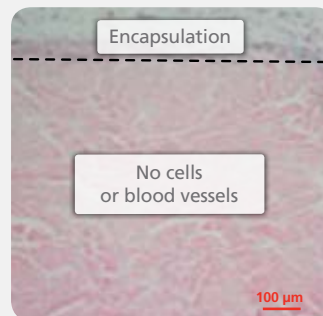
Denatured porcine tissue



Encapsulation

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

Cross-linked porcine tissue

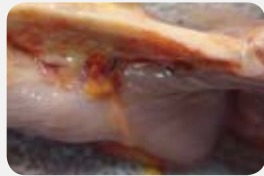


H&E stain. Explant histology and gross observation of cross-sectional view of abdominal wall explant in a non-human, primate model.

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

MLC 2457/12-2011

3-month histology and gross observation



Tissue processing

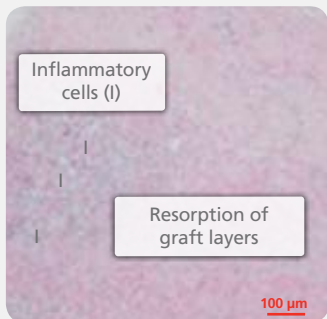
Extracellular matrix is preserved and intact

Potential clinical outcomes/ biological performance*

Rapid revascularization and cell repopulation

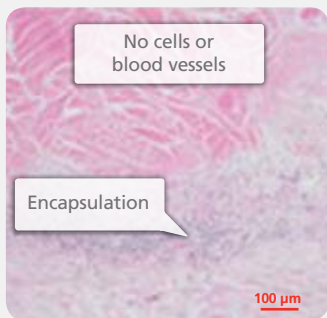
Reduced inflammatory response

Transitions into host tissue



Damaged matrix
Foreign antigens

Resorption
Replacement with scar tissue
Similar to resorbable synthetic



Chemically cross-linked

Encapsulation with scar tissue
Similar to permanent synthetic

References:

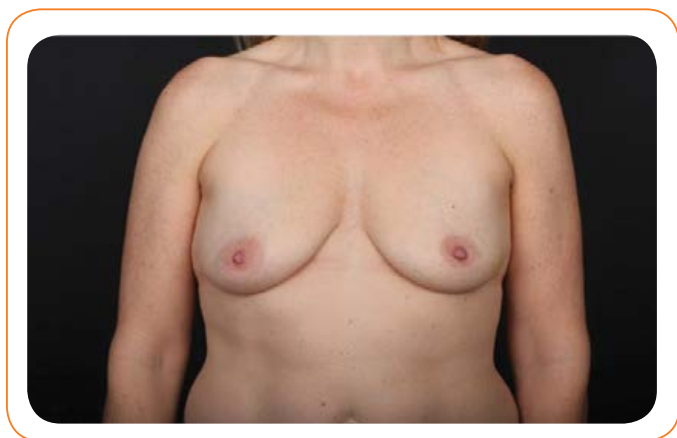
1. Xu H, Wan H, Sandor M, et al. Host response to human acellular dermal matrix transplantation in a primate model of abdominal wall repair. *Tissue Eng Part A*. 2008:14.
2. Sandor M, Xu H, Connor J, Lombardi J, Harper JR, Silverman RP, McQuillan DJ. Host response to implanted porcine-derived biologic materials in a primate model of abdominal wall repair. *Tissue Eng Part A*. 2008:14.

Clinical case experience: AlloDerm® RTM Ready To Use in breast reconstruction

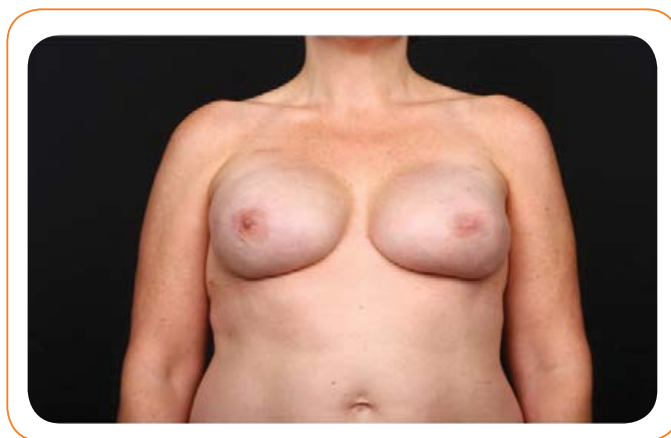
Based on clinical experience by Dr. Allen Gabriel,* Vancouver, WA

Patient 1: Breast reconstruction post chemotherapy

A 44-year-old woman with preoperative chemotherapy underwent an uneventful right nipple and left areolar sparing mastectomy with immediate placement of tissue expanders while using AlloDerm® RTM Ready To Use for soft tissue reinforcement. At 3-month exchange, robust cellular ingrowth and revascularization were observed.

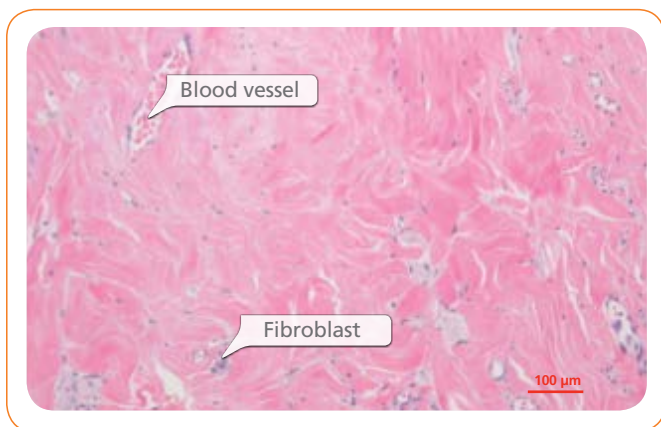


Preoperative.



Postoperative at 3 months.

3-month exchange



H&E stain at 3-month expander/implant exchange shows that AlloDerm® RTM Ready To Use integrated rapidly, with robust revascularization and cell repopulation.



Gross observation shows that AlloDerm® RTM Ready To Use was soft and supple, well adhered and well incorporated into the mastectomy skin flap.

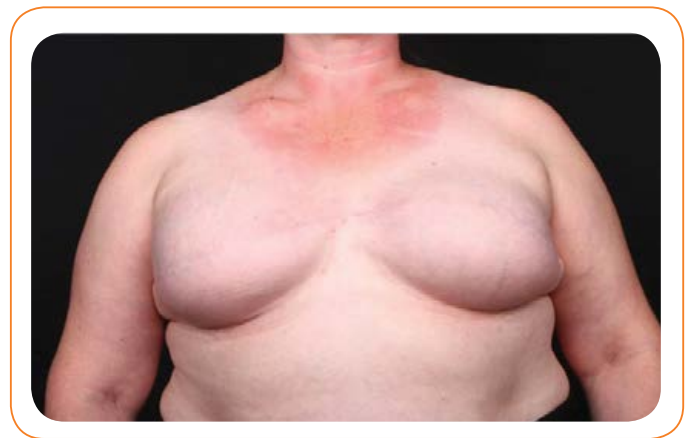
*Dr. Allen Gabriel is a consultant for LifeCell Corporation.

Patient 2: Breast reconstruction in morbidly obese patient

Five years after mastectomy that was followed by chemotherapy and radiotherapy, a 46-year-old morbidly obese woman (BMI of 45.2 kg/m²) underwent an uneventful delayed reconstruction with the placement of tissue expanders and **AlloDerm® RTM Ready To Use** for soft tissue reinforcement. Histology of **AlloDerm® RTM Ready To Use** at 3-month exchange transitioned into host tissue with fibroblast ingrowth and revascularization.

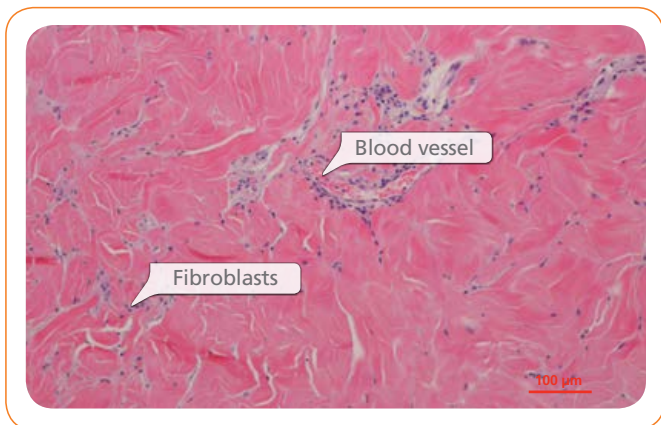


Preoperative.



Postoperative at 3 months.

3-month exchange



H&E stain at 3-month expander/implant exchange shows that **AlloDerm® RTM Ready To Use** integrated rapidly, with robust revascularization and cell repopulation.



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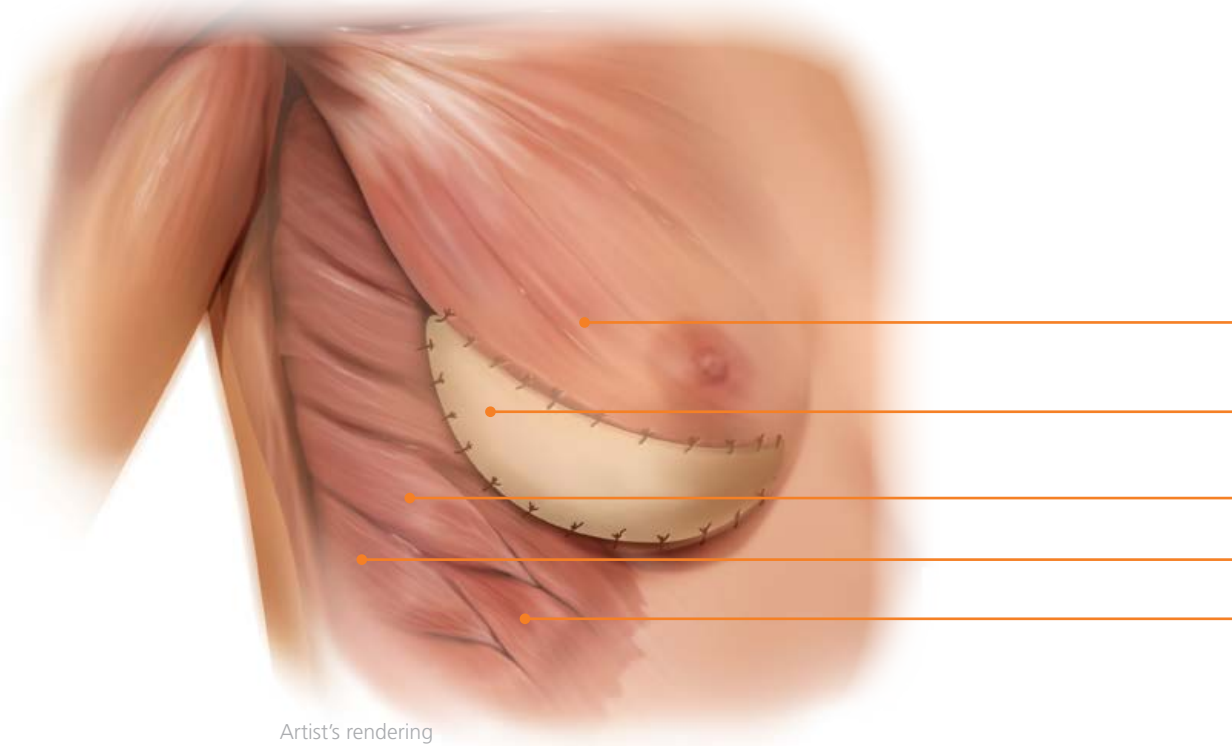
At LifeCell, we believe that regeneration, as evidenced by repopulation and revascularization, is critical to optimized patient outcomes.

AlloDerm® RTM Ready To Use has handling properties similar to AlloDerm® RTM

Surgeons presented with both products could not visually or tactilely distinguish between them

12 out of **12** surgeons surveyed found AlloDerm® RTM *Ready To Use* acceptably similar to AlloDerm® RTM in these key criteria*

- Thickness
- Pliability
- Cut/Trim
- Suturability



Artist's rendering

*Data on file.

Technique considerations for optimizing outcomes

Key opinion leaders recommend the following technique considerations for breast reconstruction with **AlloDerm® RTM Ready To Use** support

AlloDerm® RTM Ready To Use placement

- Center over mid-arc.

Anchoring AlloDerm® RTM Ready To Use

- Suture inferior border to chest wall tissue, either superficial fascia cuff or muscle fascia, not to skin flap.
- Ensure a smooth seam without gaps when suturing superior border 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 AlloDerm® RTM Ready To Use repair will comfortably tolerate to minimize dead space (seroma accumulation) as much as possible.

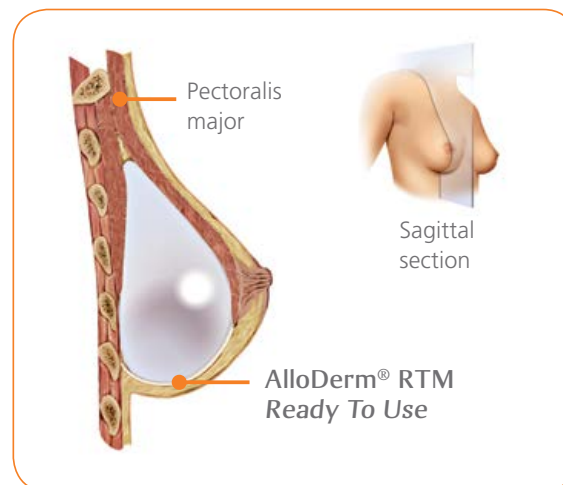
Pectoralis major

AlloDerm® RTM Ready To Use

Serratus anterior

External oblique

Rectus abdominis



The recommendations included in this brochure are not intended to be a comprehensive guide to the use of **AlloDerm® RTM Ready To Use**. Proper surgical procedure techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the techniques based on his or her own medical training and expertise.

Ordering Information

Product Code	Product Size (cm)	Product Thickness	Coverage (sq cm)
152048	4x12	Thick	48
152248	4x12	X-Thick	48
152072	6x12	Thick	72
152272	6x12	X-Thick	72
152096	8x12	Thick	96
152296	8x12	X-Thick	96
152064	4x16	Thick	64
152264	4x16	X-Thick	64
1520616	6x16	Thick	96
1522616	6x16	X-Thick	96
1520108	6x18	Thick	108
1522108	6x18	X-Thick	108
1520128	8x16	Thick	128
1522128	8x16	X-Thick	128
1520160	8x20	Thick	160
1522160	8x20	X-Thick	160
1520320	16x20	Thick	320
1522320	16x20	X-Thick	320

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.

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