

# DermACELL<sup>®</sup>

Advanced Decellularized Dermis

---

## Breast Reconstruction



A sterile, ready to use acellular dermal matrix (ADM) that provides a biohospitable framework to support and promote healing.

**FOR INTERNATIONAL USE ONLY**



Dermacell is a human acellular dermal matrix (ADM) that serves as a scaffold to reinforce damaged or inadequate soft tissue at the surgical site. Using LifeNet Health's proprietary and validated Matracell® decellularization technology, epidermal and dermal cells are removed, while preserving the remaining components in the extracellular matrix (ECM) that aid and are vital in the healing cascade.

## Dermacell (ADM) provides an advanced and ideal healing solution through:

### Biohospitality

Matracell technology enables Dermacell to provide an intact framework and structural integrity to damaged skin, while native growth factors such as collagen and elastin are retained. This supports and promotes rapid cell infiltration, cell proliferation, and neo-vascularization.

### Biomechanical Integrity

The graft maintains its natural biomechanical profile after decellularization. The strong suture retention and ultimate load is not impacted by disinfection, decellularization, or preservation processes.

### Safety

Dermacell is sterilized to a Sterility Assurance Level (SAL) of  $10^{-6}$ , or a 1 in 1 million chance of the presence of a single viable microorganism on the graft. In fact, Matracell is robust enough to inactivate DNA, RNA, enveloped and non-enveloped viruses.

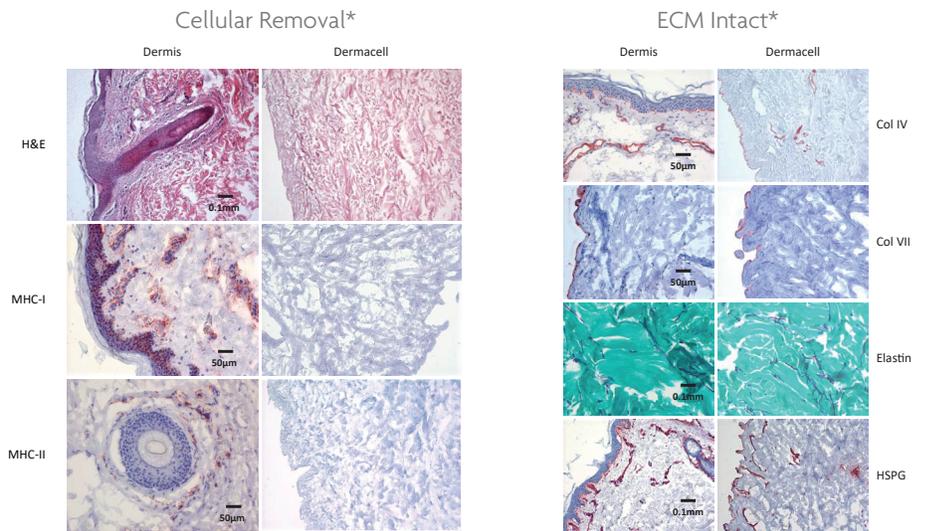
### Convenience

LifeNet Health's proprietary and validated technology allows for room temperature storage without the need for rehydration, leaving a product that is ready to use out of the package.

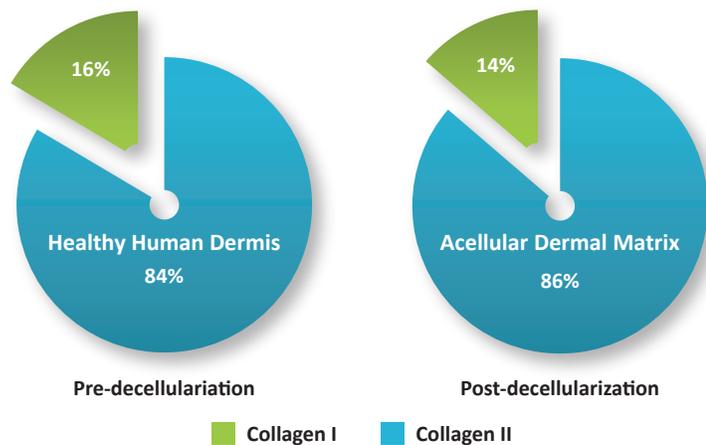
## Intact ECM Framework Supports Rapid Cell Infiltration, Proliferation and Neo-vascularization

Dermacell retains ECM components, matrikines, growth factors and cytokines consistent with healthy living skin and relevant to the natural repair of damaged skin. Additionally, ECM proteins that regulate growth factor activity are preserved in the processing of Dermacell. Native growth factors such as collagen and elastin are retained while providing structural support for cells.

- The H&E staining shows removal of epidermis and dermal fibroblasts (cell nuclei: blue; ECM: pink).
- The MHC-I and MHC-II staining (brick red) shows the efficient removal of potentially immunogenic cell surface antigens.
- Collagen type IV (brick red) is an essential component of basement membrane and collagen type VII (brick red) functions as an anchoring fibril between dermis and epidermis.
- Elastin is essential for skin elasticity (dark purple).
- Heprin sulfate proteoglycan (HSPG) (brick red) are integral components of the basement membrane in dermis. HSPG can modulate growth factor activities and influence cell growth and differentiation.
- The Matracell process maintains Collagen I and III (brick red), as well as the collagen ratio of I:III seen in healthy human dermis.



\*Data on File at LifeNet Health, NPR 05-013



\*Data on File at LifeNet Health, 68-20-064.01

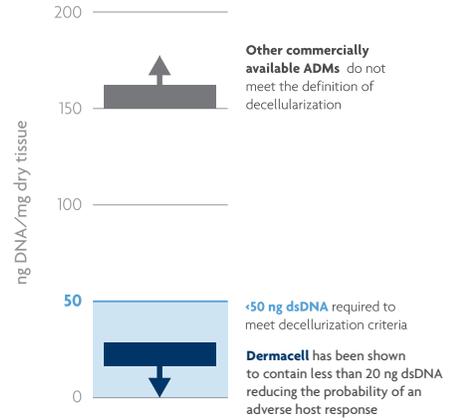
## Less Pro-Inflammatory than Other Leading ADMs<sup>1-3</sup>

Effective removal of cellular components from dermis can prevent an inflammatory or immunogenic response. Proprietary and validated Matracell technology has been shown to decellularize dermis, resulting in ≥97 donor DNA removal.

Evidence suggests that <50ng dsDNA per mg ECM dry weight of residual DNA satisfies the intent of decellularization;<sup>1</sup> Dermacell meets this criteria.

<sup>1</sup>Crapo PM, Gilbert TW & Badylak SF. An overview of tissue and whole organ decellularization processes. *Biomaterials*. 2011.  
<sup>2</sup>Choe JM, Bell T (2001) Genetic material is present in cadaveric dermis and cadaveric fascia lata. *J Urol* 166:122–124.  
<sup>3</sup>Derwin KA, Baker AR, Spragg RK, Leigh DR, Ianotti JP. Biomechanical, Biochemical, and Cellular Properties Commercial Extracellular Matrix Scaffolds for Rotator Cuff Tendon Repair. *J Bone Joint Surg Am*. 2006;88:2665–2672.

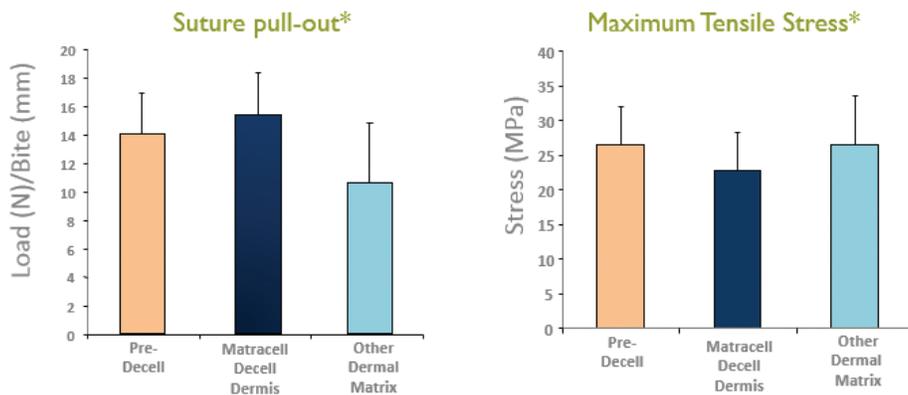
**Dermacell has been shown to contain less than 10 ng DNA/mg dry tissue**



## Biomechanical Integrity

### Retains Biomechanical Properties Similar to Autograft

The Matracell process allows the dermis to maintain its biomechanical integrity. In both suture pull-out and tensile strength testing, Matracell-processed acellular products exhibited no significant difference from fresh dermis. The Matracell Process, low-dose gamma irradiation at ultra-low temperature, and room temperature storage have no negative impact on suture pull out strength or maximum tensile stress.



\*Data on File at LifeNet Health, TR019- TR-0148

**DermACELL**® • Acellular Dermal Matrix

FOR INTERNATIONAL USE ONLY

## Virtually Eliminating the Threat of Disease Transmission

Not only is Dermacell sterilized to an SAL of  $10^{-6}$ , but the process has also been designed to degrade viral genetic material and dissolve its protective envelope. Viral remnant fragments are then removed with the donor cells. In fact, the Matracell process is designed to inactivate DNA, RNA, enveloped and non-enveloped viruses.



## Convenience

### Ready-to-Use

Dermacell is preserved with LifeNet Health's proprietary Preservon® technology, a solution comprised of USP glycerol and USP saline. This allows the decellularized dermis to be stored at room temperature and ready-to-use out of the package. Freeze-dried or frozen allografts can require lengthy thawing or rehydration steps. Using this patented technology, the need to thaw and rehydrate dermal allografts is eliminated, reducing allograft prep time to as little as 30 seconds and saving valuable operating room time without compromising product integrity.



Dermacell is available in many size configurations, thicknesses, perforations and even pre-shaped to fit virtually any surgical need.

## Pre-Clinical Data

- Dermacell demonstrated double the vessel formation at day 7 compared to other skin substitutes.<sup>1</sup>
- Dermacell has the highest depth of cellular infiltration/migration – 184% more than AlloDerm.<sup>1</sup>
- Dermacell had a higher M2 to M1 response, possibly indicating a greater propensity for cell proliferation and constructive tissue repair.<sup>2</sup>
- Dermacell outperformed ADM leader in histological and biomechanical testing.<sup>3</sup>

## Published Clinical Data

- Lower incidence of red breast syndrome.<sup>4</sup>
- Lower number of days to drain removal.<sup>4</sup>
- Lower number of seroma and infection.<sup>4,5,6</sup>
- Improved clinical outcome in breast reconstruction.<sup>3</sup>
- Lower capsular contracture.<sup>7</sup>



## References:

1. Capito, A.E., Tholpady, S.S., Agrawal, H., Drake, D.B. & Katz, A.J. "Evaluation of Host Tissue Integration, Revascularization, and Cellular Infiltration Within Various Dermal Substrates." *Annals of Plastic Surgery*. 2012 Oct; 68(5):495-500.
2. H. Agrawal et al. / *Open Journal of Regenerative Medicine* 1 (2012) 51-59 56
3. Sun-Young Nam 1, Dayoung Youn 1, Gyeong Hoe Kim 2, Ji Hwa Chai 3, Hyang Ran Lim 3, Hong Hee Jung 3 and Chan Yeong Heo. "In Vitro Characterization of a Novel Human Acellular Dermal Matrix (BellaCellHD) for Breast Reconstruction" *Bioengineering* 2020, 7, 39; doi:10.3390/bioengineering7020039
4. Pittman TA, Fan KL, Knapp A, Frantz S, Spear S. Comparison of different acellular dermal matrices in breast reconstruction: The 50/50 study. *Plast Reconstr Surg*. 2017;139(3):521-8.
5. Mowlds, D. S., A. A. Salibian, T. Scholz, K. Z. Paydar, and G. A. Wirth. "Capsular Contracture in Implant-Based Breast Reconstruction: Examining the Role of Acellular Dermal Matrix Fenestrations." *Plastic and reconstructive surgery*. U.S. National Library of Medicine, Oct. 2015. Web. 09 June 2017.
6. Chang E, Liu J. Prospective unbiased experience with three acellular dermal matrices in breast reconstruction. *J Surg Oncol*. 2017.
7. Ortiz, JA. Clinical outcomes in breast reconstruction patients using a sterile acellular dermal matrix allograft. *Aesth Plast Surg*. 2017;41(3):542-550.

**DERMACELL "THIN"**

ORDER CODE	SIZE (L x W) cm	Thickness (mm)	Area (CM2)	Shelf Life	Storage Temperature
DCELL200	4 x 12 cm	0.75 to 1.50 mm	48	4 years	15° to 30° C
DCELL201	6 x 12 cm	0.75 to 1.50 mm	72	4 years	15° to 30° C
DCELL202	4 x 16 cm	0.75 to 1.50 mm	64	4 years	15° to 30° C
DCELL203	5 x 16 cm	0.75 to 1.50 mm	80	4 years	15° to 30° C
DCELL204	6 x 16 cm	0.75 to 1.50 mm	96	4 years	15° to 30° C
DCELL205	8 x 16 cm	0.75 to 1.50 mm	128	4 years	15° to 30° C
DCELL206	8 x 20 cm	0.75 to 1.50 mm	160	4 years	15° to 30° C
DCELL207	16 x 20 cm	0.75 to 1.50 mm	320	4 years	15° to 30° C
DCELL208	20 x 20 cm	0.75 to 1.50 mm	400	4 years	15° to 30° C

**DERMACELL "THICK"**

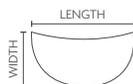
ORDER CODE	SIZE (L x W) cm	Thickness (mm)	Area (CM2)	Shelf Life	Storage Temperature
DCELL250	4 x 12 cm	1.25 to 2.00 mm	48	4 years	15° to 30° C
DCELL251	6 x 12 cm	1.25 to 2.00 mm	72	4 years	15° to 30° C
DCELL252	4 x 16 cm	1.25 to 2.00 mm	64	4 years	15° to 30° C
DCELL253	5 x 16 cm	1.25 to 2.00 mm	80	4 years	15° to 30° C
DCELL254	6 x 16 cm	1.25 to 2.00 mm	96	4 years	15° to 30° C
DCELL255	8 x 16 cm	1.25 to 2.00 mm	128	4 years	15° to 30° C
DCELL256	8 x 20 cm	1.25 to 2.00 mm	160	4 years	15° to 30° C
DCELL257	16 x 20 cm	1.25 to 2.00 mm	320	4 years	15° to 30° C
DCELL258	20 x 20 cm	1.25 to 2.00 mm	400	4 years	15° to 30° C

**DERMACELL "EXTRA THIN"**

ORDER CODE	SIZE (L x W) cm	Thickness (mm)	Area (CM2)	Shelf Life	Storage Temperature
DCELL214	6 x 16 cm	0.60 to 1.05 mm	96	4 years	15° to 30° C
DCELL215	8 x 16 cm	0.60 to 1.05 mm	128	4 years	15° to 30° C
DCELL216	8 x 20 cm	0.60 to 1.05 mm	160	4 years	15° to 30° C

**DERMACELL "EXTRA THIN" - MICRO-PERFORATED**

ORDER CODE	SIZE (L x W) cm	Thickness (mm)	Area (CM2)	Shelf Life	Storage Temperature
DCELL214M	6 x 16 cm	0.60 to 1.05 mm	96	4 years	15° to 30° C
DCELL215M	8 x 16 cm	0.60 to 1.05 mm	128	4 years	15° to 30° C
DCELL216M	8 x 20 cm	0.60 to 1.05 mm	160	4 years	15° to 30° C
DCELL217M	16 x 20 cm	0.60 to 1.05 mm	320	4 years	15° to 30° C



**DERMACELL "EXTRA THIN" - PRE-SHAPED**

ORDER CODE	SIZE (L x W) cm	Thickness (mm)	Area (CM2)	Shelf Life	Storage Temperature
DCELL231M	7 x 13 cm	0.60 to 1.05 mm	67	4 years	15° to 30° C
DCELL232M	10 x 18 cm	0.60 to 1.05 mm	134	4 years	15° to 30° C

Notes: Excursions up to 37°C for 3 months or less during transport or storage is allowed. Excursions down to -100°C for 30 days or less during transport or storage is allowed

**FOR INTERNATIONAL USE ONLY**



## Summary Of LifeNet Health Accreditations/Certifications

- ✓ AATB ACCREDITATION
- ✓ FDA REGISTERED TISSUE BANK
- ✓ UNOS MEMBER
- ✓ AOPO MEMBER
- ✓ ISO 13485 CERTIFIED
- ✓ CLIA CERTIFIED
- ✓ LICENSED IN REQUIRED COUNTRIES
- ✓ HEALTH CANADA CTO 10038



**LifeNetHealth.org**  
**LifenetHealth.eu**

LifeNet Health, the LifeNet Health logo, Dermacell, Matracell, and Preservon are a registered trademarks of LifeNet Health.

©2020 LifeNet Health, Virginia Beach, VA. All rights reserved.

68-00-046.01