DERMAPURE® SIGNALS A NEW DIRECTION IN SOFT TISSUE REGENERATION

A next-generation decellularized dermal allograft

DERMA [PURE]
dCELL® technology

NOT ALL SURGICAL GRAFTS ARE CREATED EQUAL

All soft tissue surgical grafts have a purpose and function for surgeons, but not every graft can deliver on multiple procedural needs.

SURGICAL GRAFT GOALS

Repair & Replace OR **Reconstruct & Structurally Support**

What if there was a graft that could meet multiple needs of the surgeon, regardless of procedure?

- **GRAFT TAKE**
- **GRAFT INTEGRATION**
- **GRAFT HANDLING**

Choose DermaPure® for a surgical graft without compromise.
Add the allograft designed to meet your needs and signal a confident outcome.

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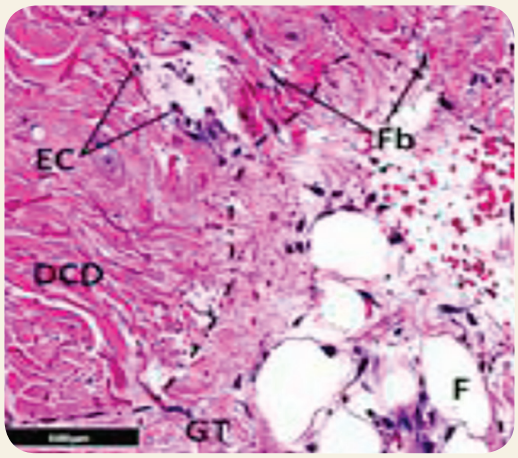
DERMAPURE® ENABLES GRAFT TAKE

After application, DermaPure® impacts soft tissue revascularization at the surgical site by signaling cellular migration and proliferation.

DermaPure® is an intact extracellular matrix with vascular-like channels necessary for revascularization.

DermaPure® retains collagens, proteoglycans, glycosaminoglycans, and other extracellular matrix proteins.



DermaPure® provides an access point for proliferation of native cells, including endothelial cells and fibroblasts.

x20 magnification

- **DCD** – DermaPure®
- **EC** – Endothelial Cells
- **Fb** – Fibroblast
- **F** – Subcutaneous fat
- **GT** – Granulation Tissue
- **Black dotted line** – border between DermaPure® and host tissue

DermaPure® facilitates the re-establishment of vascular channels, providing an access point to signal cellular activity enabling successful graft take in just seven days.[1]

DERMAPURE® PROMOTES GRAFT INTEGRATION

Skin substitutes differ in many ways: tissue source, processing methodologies, patient response — and surgeon use.

Xenografts

- Enhanced biomechanical strength, but less organized. Non-human matrix provides less infiltration for vascular integration
- Cross-linking of xenograft tissue can inhibit cell migration and proliferation
- Disorganized granulation tissue vessels are rapidly replaced by fibrotic tissue[1]

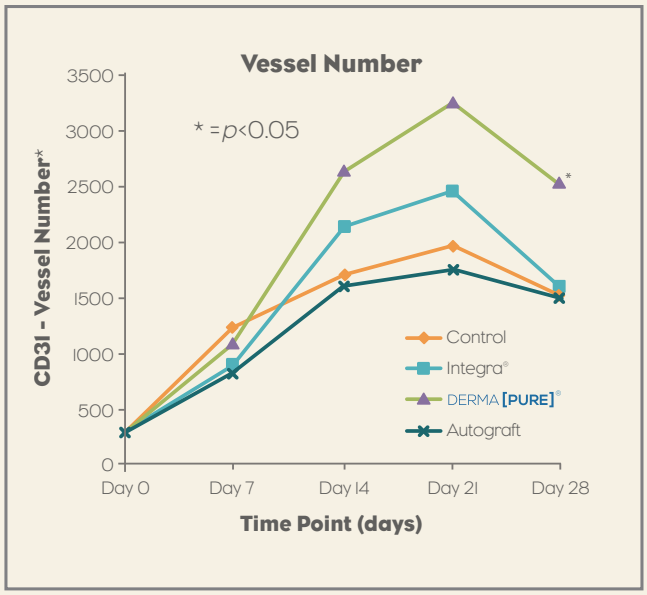
Autografts

- Prolonged operating room time with tissue harvesting and implantation
- Native tissue procured for target procedure may be insufficient and require follow-up procedure
- Patient comorbidities can affect the quality of tissue harvested and associated integration

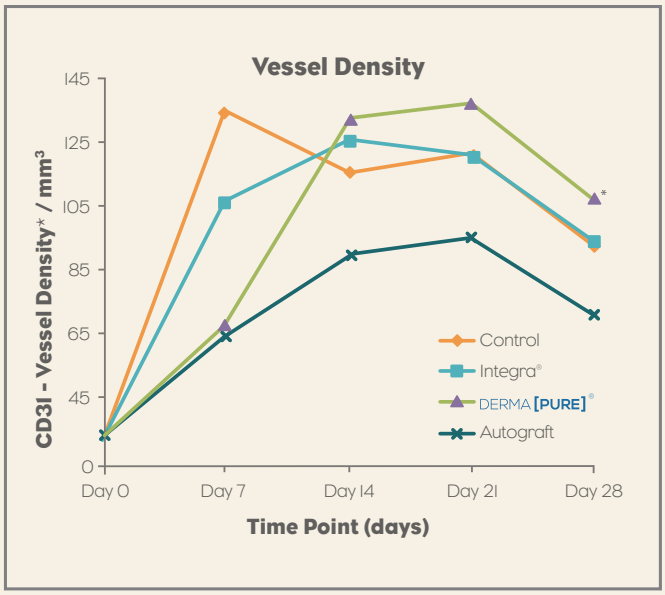
DermaPure® is a human-derived acellular matrix that has been demonstrated to provide **higher pro-angiogenic response during integration** with reduced fibrosis compared to Integra™ (xenograft) and control (secondary intention).[1]

REVASCULARIZATION:

Higher Quantity with DermaPure®



Higher Quality with DermaPure®

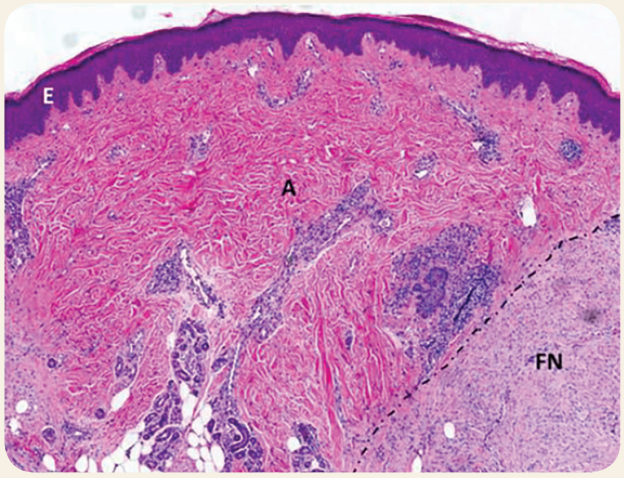


DermaPure® integrates with and closely approximates the structure and function of native tissue.[2]

Autograft

Displays retention of normal ECM architecture and minimal fibrosis

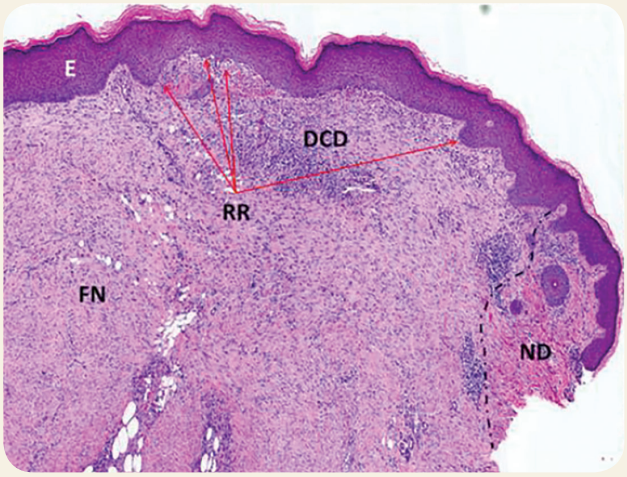
- **A** – Autograft
- **FN** – Fibrotic Neodermis.
- **E** – Epidermis

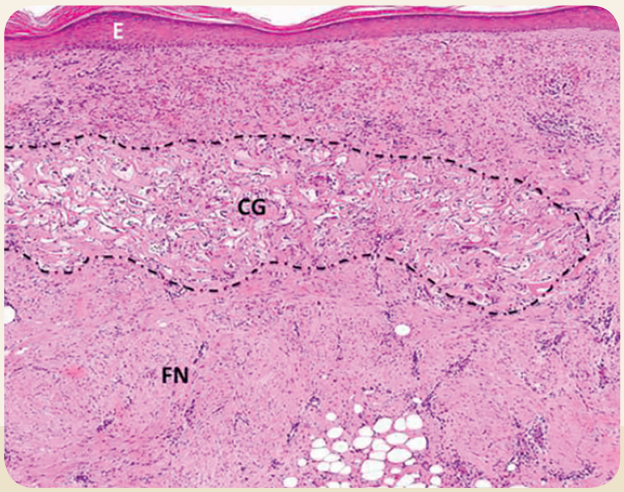


DermaPure®

Illustrates dense cellular infiltration, partial rete ridge reformation, uniform fibrosis, and **could not be distinguished from native dermis** once infiltrated by host cells.

- **DCD** – DermaPure®
- **ND** – Native Dermis
- **RR** – Rete Ridges
- **FN** – Fibrotic Neodermis
- **E** – Epidermis





Integra (Xenograft)

- Displays a dense, thick band of fibrosis and remains visibly present.
- Structural differences with xenograft group influences the distribution and organization of the vascular network required for integration.

- **CG** – Integra
- **FN** – Fibrotic Neodermis
- **E** – Epidermis

DERMAPURE® OPTIMIZES GRAFT HANDLING

DermaPure® is a thin, decellularized dermal allograft with enhanced handling and suturability that doesn't trade off strong biomechanical properties.

DERMAPURE® BIOMECHANICAL PERFORMANCE[3]

Biomechanical Test*	Thickness**	Ultimate Tensile Strength	Tensile Maximum Load	Tensile Elastic Modulus	Tensile Stiffness	Burst Maximum Load	Burst Maximum Pressure	Suture Peak Load
Metric	mm	MPa	N	MPa	N/mm	N	N/cm²	N
DermaPure®	**1.06 - 1.16**	**22.7**	**132.0**	**69.6**	**18.7**	**364.3**	**1,022.4**	**50.0**
Market Leader 1.0 mm	1.00 - 1.18	**16.4**	**81.3**	**52.8**	**10.8**	368.4	1,033.8	47.7
Market Leader 1.5 mm	1.34 - 1.76	**12.3**	**89.4**	**40.7**	12.8	361.7	1,015.2	47.7
Market Leader 2.0 mm	1.80 - 2.00	22.6	214.6	62.5	24.6	682.5	1,915.6	84.5

Values statistically significantly lower than DermaPure®
No statistically significant difference from DermaPure®
Competitor values statistically significantly higher than DermaPure®

*Tissue Regenix data on file; all results are mean values
**Mean thickness range of samples measured prior to biomechanical testing

Biomechanical Test Definitions

Ultimate Tensile Strength (UTS) – Maximum resistance to failure and load carried by one square unit area (stress).
Tensile Maximum Load – Maximum load used to calculate UTS; this result is dependent on the size & thickness of test specimen.
Tensile Elastic Modulus – The measure of a material's resistance to being deformed elastically (i.e. non-permanently) when a stress is applied to it.
Tensile Stiffness – The measure of a material's resistance to being deformed when a load is applied to it.
Burst Maximum Load & Pressure – Measure of force and pressure required to rupture or puncture specimen.
Suture Peak Load – Maximum force that can be applied before a suture pulls through the specimen.

dCELL® TECHNOLOGY IS THE DIFFERENCE

Not all tissue processing is the same: each process utilizes different methods.

Unlike alternative tissue processes, dCELL® Technology is a unique, proprietary, and patented process that produces high-quality, decellularized donor tissue with nearly no structural disruption and promotes regeneration.

	dCELL® Technology	Alternative Processes*
Remove Donor Cells and Cellular Debris	Uses extremely low concentration of single anionic detergent (SDS-0.01%) to remove donor cells and cellular debris	• Anionic detergents (NLS, SDS) can damage structural and mechanical properties of tissue[4] • Tissue integrity can be affected by number of anionic detergents used, concentration, and duration used during processing • Intact cells still present in donor tissue[5]
Remove DNA	Utilizes a nuclease treatment that results in >99% DNA removal[3]	• Lack of nuclease treatment results in incomplete DNA removal • Residual DNA may trigger immunogenic response that could lead to failure or complications
Preserve Tissue Structure	Use of protease inhibitors helps preserve native tissue structure and biomechanical properties[6]	• Tissue structure and biomechanical properties may be altered when protease inhibitors are not utilized • Limits potential to promote regeneration
Neutralize Pathogens and Microbial Sterility	• Terminally irradiated to provide a sterility assurance level (SAL) of 10^{-6} for neutralization, essentially eliminating all pathogens • Reduces risk of further contamination and disease transmission[7] • Provides microbial sterility	• Aseptically processed tissue yields an SAL of 10^{-3} • May not eliminate the inherent microbial bioburden in tissue[7]

*Based on review of patents and scientific literature

dCELL® Technology delivers on each of the fundamentals of Tissue Decellularization that sets it apart from other biologic options.

- **Low concentration of SDS** to remove donor cells and cellular debris, while preserving tissue integrity
- **Nuclease treatment** for near complete DNA removal
- **Protease inhibitors** to preserve tissue structure, tissue integrity, and biomechanical properties
- **Terminally irradiated** to neutralize and eliminate pathogens to provide microbial sterility

DERMAPURE® SIGNALS A NEW DIRECTION IN SOFT TISSUE REGENERATION

- Minimally manipulated to preserve tissue structure
- Signals cell migration and proliferation
- Increases angiogenesis and reduces fibrosis
- Optimal handling and biomechanical strength in a thin profile biologic

DermaPure® is available in the following sizes:

SKU	Size
010200HD	1 cm x 2 cm
020200HD	2 cm x 2 cm
020300HD	2 cm x 3 cm
030400HD	3 cm x 4 cm
040600HD	4 cm x 6 cm
071000HD	7 cm x 10 cm
0071000HDN	7 cm x 10 cm (Non-Oriented)
07100HDMESH	7 cm x 10 cm (Unstretched)
091200HD	9 cm x 12 cm

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1. Greaves NS, Iqbal SA, Morris J, et al. Acute cutaneous wounds treated with human decellularised dermis show enhanced angiogenesis during healing. PLoS ONE. 2015;10(1):e0113209. **2.** Greaves NS, Bayat A (2015). Skin Substitute-Assisted Repair Shows Reduced Dermal Fibrosis in Acute Human Wounds Validated Simultaneously by Histology and Optical Tomography. Wound Rep Reg (2015) 23 483-494 **3.** Data on file at Tissue Regenix **4.** Srokowski EM, Woodhouse KA. Decellularized scaffolds. In: Ducheyne P, ed. Comprehensive Biomaterials. New York, NY: Elsevier; 2011:369-386. **5.** Carruthers CA, Dearth CL, Reing JE, et al. Histologic characterization of acellular dermal matrices in a porcine model of tissue expander breast reconstruction. Tissue Engineering Part A. 2014;21(1-2):35-44. **6.** Booth, C, et al. Tissue engineering of cardiac valve prostheses I: development and histological characterization of an acellular porcine scaffold. J Heart Valve Dis. 2002;11(4):457-462. **7.** Singh R, Singh D, Singh A. Radiation sterilization of tissue allografts: a review. World J Radiol. 2016;8(4):355-369. doi:10.4329/wjr.v8.i4.355.

TR017rev03

TRX BioSurgery