

Closer to Nature, Better Results.

A More Natural, More Intact Matrix.

TigoDerm™ is designed to maintain a more structurally intact extracellular matrix that is as close to nature as possible.

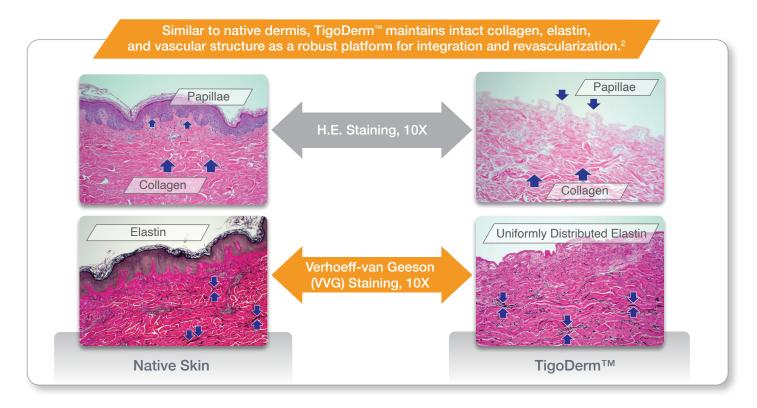
Tissue Engineering Expertise • Innovative Processing • Natural Restorative Solutions

Why TigoDerm™?

TigoDerm[™] is pre-hydrated human acellular dermal matrix that allows rapid integration, cellular repopulation, and rapid revascularization at the surgical site.

TigoDerm [™] Features¹
Proprietary and Patented Gentle Processing
Sterile: Sterility Assurance Level (SAL) 10-6
Ready to Use: Pre-hydrated without damage to matrix.

	TigoDerm [™] Advantages²
√	Closer to Human Dermis
√	Low Inflammatory Response
√	Rapid Integration
1	Enhanced Pliability





² Aziyo® Biologics data on file.





Customer Service and Ordering

office@tigonmedical.com

TigoDerm™ is an ambient product. **TigoDerm™** is available in a range of sizes. Storage must be maintained at room temperature, and must not exceed 25°C.

Thickness: 0.63 - 1.48 MM		
Order Code	Size	
TGD.060.0202	2cm x 2cm	
TGD.060.0204	2cm x 4cm	

Thickness: 2.00 - 3.50 MM		
Order Code	Size	
TGD.200.0407	4cm x 7cm	

INSTRUCTIONS FOR USE

DONATED HUMAN TISSUE FROM U.S. TISSUE BANKS. THE RECOVERY AND PROCESSING WAS PERFORMED USING ASEPTIC TECHNIQUES. THE ALLOGRAFT IS TERMINALLY STERILIZED TO A STERILITY ASSURANCE LEVEL OF 10-6 IN ITS FINAL PACKAGING.

Thickness: 2.80 - 3.50 MM		
Order Code	Size	
TGD.280.0407	4cm x 7cm	

DESCRIPTION

TigoDerm™ Hydrated Acellular Dermal Matrix (HADM) is a human skin allograft minimally processed to remove epidermal and dermal cells and then preserved in a gamma irradiation protection solution. The process utilizes a proprietary and patented technology to preserve the remaining bioactive components and extracellular matrix of the dermis. The resulting acellular matrix is pre-hydrated without damage to the matrix components and is designed to be rinsed quickly in a sterile isotonic solution. The resulting allograft functions as a framework to support cellular repopulation and revascularization at the surgical site.

INDICATIONS FOR USE

TigoDerm™ is used for the repair or replacement of damaged or insufficient integumental tissue or for other homologous uses of human integument.

TigoDermTM is to be used for the replacement of damaged or insufficient integumental tissue or for the repair, reinforcement, or supplemental support of soft tissue defects. Each package of $TigoDerm^{TM}$ is intended for use in one patient on a single occasion by a licensed physician.

CONTRAINDICATIONS

Use of TigoDerm $^{\text{TM}}$ in patients exhibiting autoimmune connective tissue disease is not recommended. TigoDerm $^{\text{TM}}$ should not be used in patients with sensitivities to processing agents (see WARNINGS).

Orientation: Has two (2) distinct sides: a basement membrane and a dermal side. The basement membrane appears dull and repels blood. The dermal side appears shiny and absorbs blood. When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. The allograft has a 2-5 mm slit that when oriented vertically in the upper right corner indicates that the basement membrane is facing upward.

WARNINGS

Potential adverse effects that may result from placement of TigoDerm™ include, but are not limited to wound or systemic infection; seroma; dehiscence; hypersensitivity; allergic or other immune response; sloughing or failure of the graft; and disease transmission.

- Trace amounts of processing agents include, but are not limited to: gentamicin.
- Do not re-sterilize or reuse.

Extensive medical screening procedures have been used in the selection of all tissue donors (see Donor Screening and Testing). Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material may transmit infectious agents or diseases.

MARKETED BY

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MANUFACTURED BY

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