

PARADERM[®]

is a minimally manipulated, patent pending, biocompatible graft that supports cellular attachment and infiltration.



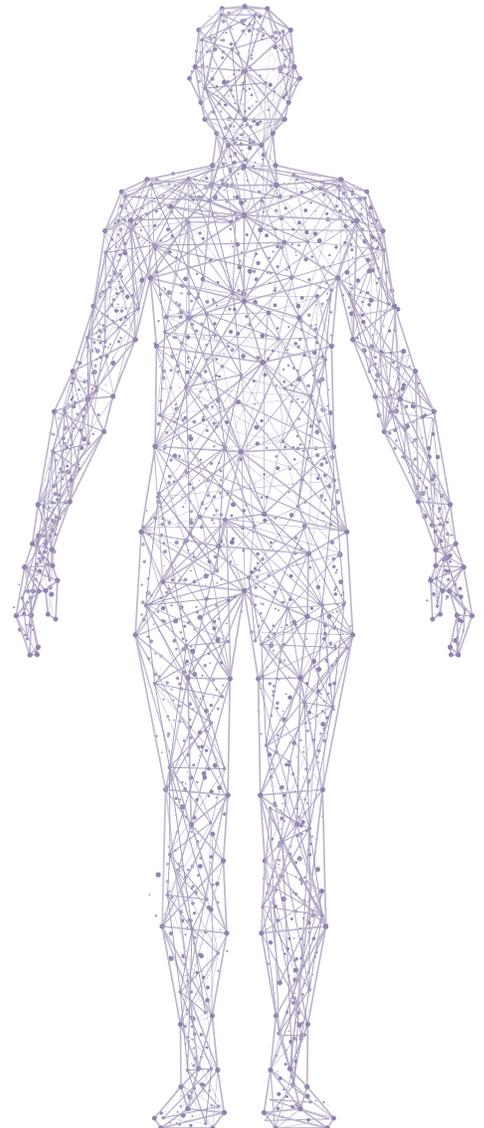
KEY FEATURES

- Retention of crucial extracellular matrix proteins¹
- Reduction or elimination of nucleic acids²
- Preservation of natural collagen matrix²
- Fenestrated and Nonfenestrated Offerings
- Preservation of native vascular channels¹
- Biocompatibility with multiple types of cells¹:
 - ▶ MSC's (MIAMI cells)
 - ▶ Fibroblasts
 - ▶ Chondrocytes

ParaDerm[®] is produced using a highly technical process that reduces native nucleic acids, cells, and other antigenic material while preserving the collagen matrix with vascular channels.² The extracellular matrix promotes cellular infiltration, attachment, and proliferation.²

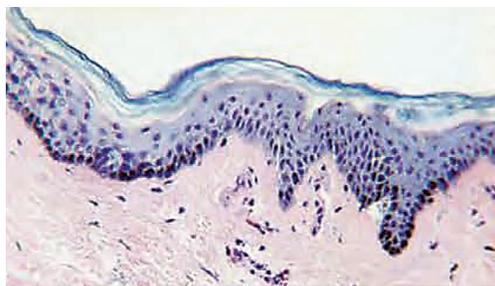
The unique processing technique preserves the collagen and elastin tissue fibers while maintaining the open channels through which mesenchymal cells can migrate, proliferate, and form new blood vessels.² This biologic process is crucial to the integration and remodeling of the allograft by host cells.

ParaDerm[®] is a biocompatible collagen matrix that promotes cellular infiltration and proliferation.²

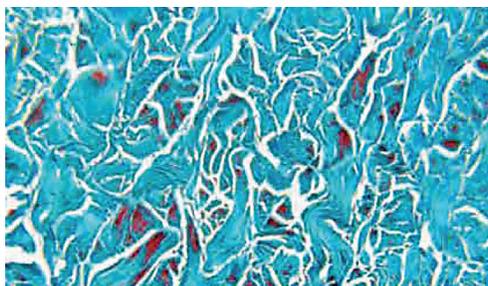


NORMAL SKIN

The outer covering of the epidermis is composed mainly of keratinocytes arranged in stratum corneum, stratum granulosum, and stratum spinosum. The epidermis rests on the basement membrane, which is penetrated by epidermal appendages. The inner surface of the epidermis is not smooth, but composed of epidermal papillae. Below the basement membrane is the dermis, a layer of dense collagenous fibroconnective tissue intermixed with elastin fibers. The dermis is penetrated by blood and lymphatic vessels and nerve endings. In addition to epidermal appendages (sweat glands, hair follicles, sebaceous glands), the dermis contains most cells, lymphocytes, and macrophages. Elastin fibers in the dermis are essential for maintaining the biomechanical properties of the skin.



Normal Skin. Romanowski-Giemsa stain x250.



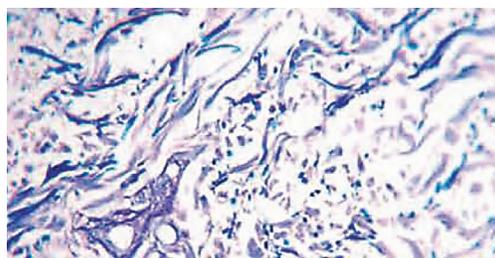
Dermis is composed primarily of collagen which stains blue with Masson trichrome stain x250.



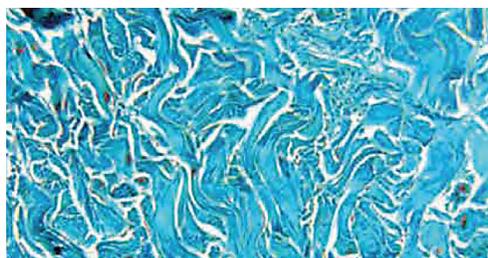
Elastin fibers (black) in normal dermis. Verhoeff's elastin tissue stain x250.

PARADERM® PREPARATION

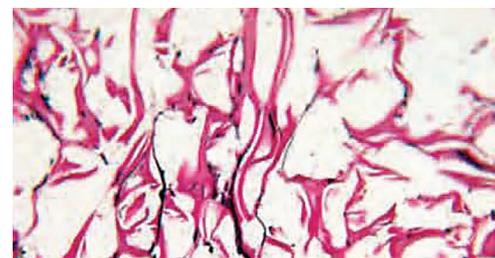
The epidermis from the skin surface as well as that from the skin appendages has been removed. Cellular elements have also been removed from the dermis. The dermal matrix is composed of collagen strands. The basement membrane and blood vessel channels are preserved, which allows for rapid revascularization. Multiple studies demonstrate that angiogenesis is critical in wound healing.³



ParaDerm preparation demonstrating retention of fibroconnective tissue fibers and blood vessel channels. Romanowski-Giemsa stain x250.



Collagen has been retained in ParaDerm preparations. Masson trichrome stain x250.



Elastin fibers are preserved in ParaDerm, assuring retention of the biomechanical properties of processed dermis. Verhoeff's elastin tissue stain x250.

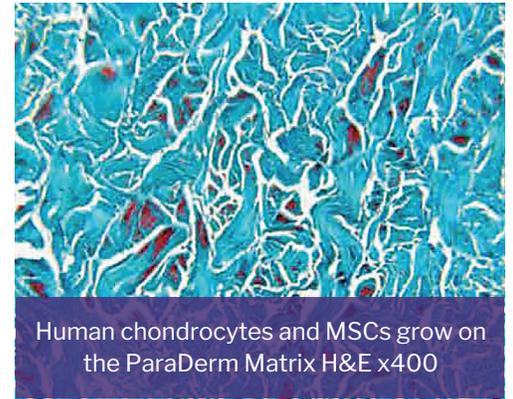
BIOCOMPATIBILITY

Cellular infiltration and attachment are important for demonstrating biologic potential for connective tissue host cell ingrowth into allograft matrices.

Fibrosarcoma L929 cells are a mouse fibrosarcoma cell line used for testing the biocompatibility of allograft matrices. Biocompatibility of these cells with an allograft matrix is an ISO requirement.



Fibroblasts in culture infiltrate and attach to the ParaDerm Matrix H & E x250.



Human chondrocytes and MSCs grow on the ParaDerm Matrix H&E x400

ParaDerm® preparations incubated in cell culture vessels with fibrosarcoma L929 cells showed these cells attaching to and infiltrating the ParaDerm® Matrix at day 5.¹

SAFETY & QUALITY



The University of Miami Tissue Bank was established in 1970 and has provided safe and effective musculoskeletal and skin allografts for transplantation without interruption or significant incident since its inception.

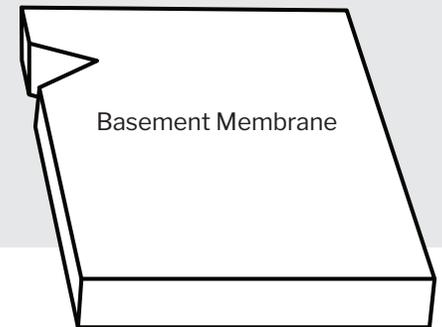
Extraordinary efforts are used to ensure aseptic procurement and processing to protect the biologic integrity of the graft

Allograft tissue is treated in such a way as to assure biocompatibility with the host, as well as their biomechanical integrity.

INDICATIONS FOR USE

1. Integumentary Augmentation

To orient the graft with the basement membrane facing up, the notch must be in the upper left hand corner of the graft (see figure to the right).



Product #	Description
P01-PDM-1044	Paraderm® 4x4cm Dermal Matrix, Non-Fenestrated (.4mm - .8mm Thick)
P01-PDM-2044	Paraderm® 4x4cm Dermal Matrix, Non-Fenestrated (1mm - 2mm Thick)
P01-PDM-3044	Paraderm® 4x4cm Dermal Matrix, Non-Fenestrated (2.2mm - 3.5mm)
P01-PDM-1048	Paraderm® 4x8cm Dermal Matrix, Non-Fenestrated (.4mm - .8mm Thick)
P01-PDM-2048	Paraderm® 4x8cm Dermal Matrix, Non-Fenestrated (1mm - 2mm Thick)
P01-PDM-3048	Paraderm® 4x8cm Dermal Matrix, Non-Fenestrated (2.2mm - 3.5mm)
PDMW-4X4	Paraderm® 4x4cm Dermal Matrix, Fenestrated (.4mm - .8mm Thick)
PDMW-4X8	Paraderm® 4x8cm Dermal Matrix, Fenestrated (.4mm - .8mm Thick)

ParaDerm[®]

DERMAL MATRIX

REFERENCES

1. Delcroix, GJ. et al. Decellularized human dermal matrix for wound healing. University of Miami Tissue Bank, Miami FL. ORS 2013 Annual Meeting. Poster No: 0440
2. Morris PR, Kast N, Temple TH, Wolfinbarger L, 2012, Regenerative tissue matrix, US20140341871A1
3. Angiogenesis in Wound Healing Journal of Investigative Dermatology Symposium Proceedings (2000) 5, 40-46; doi: 10.1046/j.1087-0024.2000.00014.x

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For the contraindications, potential complications and adverse reactions, warnings and precautions associated with this device, please refer to the device specific instructions for use at <http://www.paragon28.com/ifus>

Exclusively foot & ankle ²⁸
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