

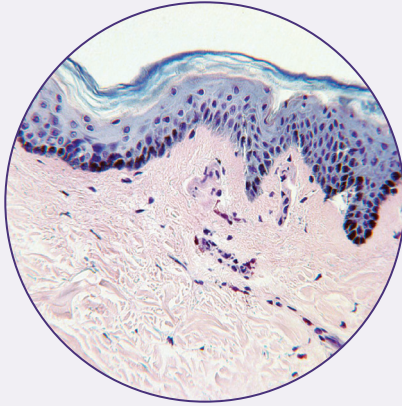
ParaDerm[®]

DERMAL MATRIX

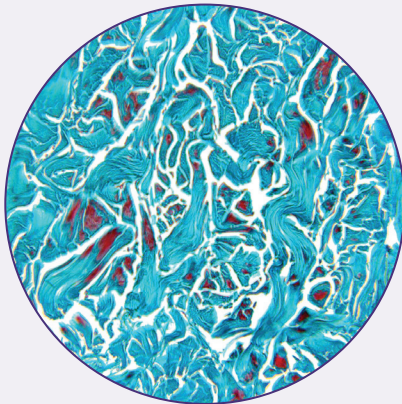
ParaDerm[®] Dermal Matrix



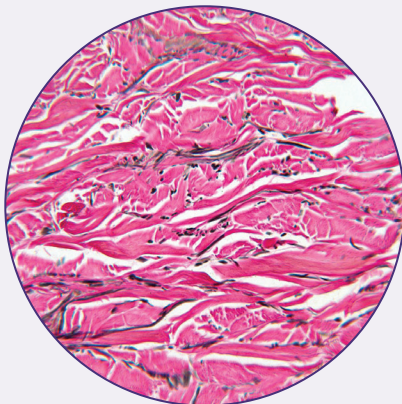
ParaDerm™ is a minimally manipulated and acellular dermal matrix allograft that allows for supplemental support, protection, reinforcement, or covering of a tendon or soft tissue.



Normal Skin



Collagen Fiber Stain



Elastin Fiber Stain

PARADERM® FEATURES AND BENEFITS¹

- ▶ Applied as reinforcement to help provide protection and extracellular matrix (ECM)/collagen framework while retaining intact vascular channels
- ▶ Versatile and flexible scaffold that can hold a suture
- ▶ Biocompatibility study demonstrated attachment and proliferation of:
 - Fibroblast cells
 - Marrow-isolated adult multilineage inducible cells
 - Primary chondrocytes
- ▶ Variety of sizes and thicknesses

PARADERM® PREPARATION

ParaDerm's unique processing reduces DNA and cellular material while preserving the inherent properties of dermal matrices, maintaining key extracellular matrix molecules, including collagen and elastin.¹ The extracellular matrix supports cellular infiltration, attachment, and proliferation.

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

NORMAL SKIN

The outer covering of the epidermis rests on the basement membrane, which is penetrated by epidermal appendages. Below the basement membrane is the dermis, a layer of dense collagenous fibroconnective tissue intermixed with elastic fibers. The dermis is penetrated by blood and lymphatic vessels, nerve endings, and epidermal appendages, such as sweat glands, hair follicles, and sebaceous glands. The dermis also contains mast cells, lymphocytes, and macrophages important to the immune system. Elastic and collagen fibers in the dermis are essential for maintaining the biomechanical properties of the skin.

DERMAL ALLOGRAFT INTERACTION WITH WOUNDED SKIN²

During the first 24–48 hours after a dermal allograft is placed, it is separated from the damaged tissue by a thin film of fibrin and plasma until a vascular supply is re-established. In the next phase, a fine vascular network begins to form within the fibrin layer and allows for the transfer of some nutrients and oxygen. Over the next few days, the interface between the allograft and the damaged tissue transitions into revascularization with new blood vessels directly invading the dermal allograft. In total, these phases may take up to 5 days to incorporate the allograft.



POTENTIAL APPLICATIONS FOR PARADERM[®]

Dermal allografts have been reported useful in many surgical and topical applications that include:

- ▶ Burns
- ▶ Full thickness skin defects
- ▶ Deep voids
- ▶ Amputations
- ▶ Wound dehiscence
- ▶ Surgical repairs
- ▶ Dermal augmentation
- ▶ Tendon augmentation
- ▶ Tunneling wounds



INDICATION FOR USE & STORAGE

- ▶ ParaDerm[®] is intended for support, protection, reinforcement, and/or covering during applications
- ▶ Can hydrate in site or in saline prior to use
- ▶ 5-year shelf life at ambient temperature storage



ALLOGRAFT ORIENTATION

Correct



Basement membrane facing up and out,
Reticular side facing the host tissue

ORDERING INFORMATION

PART #	DESCRIPTION
P01-PDM-1044	ParaDerm® 4x4 cm Dermal Matrix, Non-Fenestrated (0.4 mm–0.8 mm Thick)
P01-PDM-2044	ParaDerm® 4x4 cm Dermal Matrix, Non-Fenestrated (1 mm–2.5 mm Thick)
P01-PDM-1048	ParaDerm® 4x8 cm Dermal Matrix, Non-Fenestrated (0.4 mm–0.8 mm Thick)
P01-PDM-2048	ParaDerm® 4x8 cm Dermal Matrix, Non-Fenestrated (1 mm–2.5 mm Thick)
PDMW-4X4	ParaDerm® 4x4cm Dermal Matrix, Fenestrated (0.4 mm–0.8 mm Thick)
PDMW-4X8	ParaDerm® 4x8 cm Dermal Matrix, Fenestrated (0.4 mm–0.8 mm Thick)


References:

1. Data on file at Vivex Biologics, Inc.
2. Brunicaudi FC et al. Schwartz's Principles of Surgery 9th ed., Chapter 45, Plastic and Reconstructive Surgery

Paragon28 has used reasonable efforts to provide accurate and complete information herein, but this information should not be construed as providing clinical advice, dictating reimbursement policy, or as a substitute for the judgment of a health care provider. It is the health care provider's responsibility to determine the appropriate treatment, codes, charges for services, and use of modifiers for services rendered and to submit coverage or reimbursement-related documentation.

Manufactured for Paragon 28®

PD-001-Rev E
2024-06-19

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Exclusively foot & ankle ²⁸
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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>