DermaMatrix Acellular Dermis.
Human dermal collagen matrix.

- Rehydrates quickly
- Does not require refrigerated storage
- Bacterially inactivated
DermaMatrix Acellular Dermis is processed by the Musculoskeletal Transplant Foundation (MTF) and is available through Synthes CMF.

DermaMatrix tissue is an allograft derived from donated human skin. The epidermis and dermis are removed from the subcutaneous layer of the skin during the recovery procedure. The tissue is then processed using a sodium chloride solution and detergent to remove the epidermis and all viable dermal cells while maintaining the original dermal collagen matrix. The cells are removed to minimize inflammation or rejection at the surgical site.

DermaMatrix Acellular Dermis is then treated in a disinfection solution that combines detergents with acidic and antiseptic reagents to further clean the tissue so that it passes the United States Pharmacopeia Standard 71 (USP <71>) for sterility. Finally, it is freeze-dried, cut to size and packaged in a terminally sterilized double pouch and envelope.

When ready for use, DermaMatrix tissue should be rehydrated in at least 100 ml of sterile, room temperature saline or lactated Ringer’s solution. It will typically rehydrate in three minutes or less to a uniformly soft and pliable consistency. Additional rinsing to remove any residuals is not needed.

After DermaMatrix Acellular Dermis is transplanted into the patient, host cells begin to infiltrate the three-dimensional collagen matrix. The patient’s blood vessels revascularize the implant and fibroblasts are incorporated into the matrix.
Features

- Rehydrates quickly*
- Is aseptically processed and passes USP <71> for sterility. The tissue is bacterially inactivated by the disinfection process, which reduces the level of bacteria, spores, fungi, mold and yeast
- Does not require refrigeration—freeze-dried tissue can be stored under normal room temperature conditions
- Minimizes the amount of autograft needed
- Non-cross-linked
- Allows revascularization and cell repopulation in the three-dimensional collagen matrix for normal tissue remodeling**
- Minimizes inflammation or rejection at the surgical site, as a result of the tissue processing which removes viable cells and antigens
- Has a three-year shelf life
- Has 90% consistency of thickness across the length of the tissue

* Reconstitution time may vary with size and thickness of the tissue, temperature of saline or lactated Ringer's solution and/or donor's tissue property.
** Acellular Dermal Matrix. MTF internal report summarizing test results of Acellular Dermal Matrix on biomechanical properties, histological profile, structural analysis, preclinical evaluation and tissue safety.
DermaMatrix tissue is for homologous use only. Homologous use as defined by the FDA is: The replacement or supplementation of a recipient’s tissue with a tissue form that performs the same basic function or functions in the recipient as in the donor.

Clinical applications include, but are not limited to, the following:
- Parotidectomy
- Tympanoplasty
- Facial soft tissue defects
- Facial sling
- Lower eyelid reconstruction
- Nasal reconstruction
- Nasal septal perforation
- Cleft palate repair
- Oral resurfacing
- Vestibuloplasty
- Radial forearm free flap repair
- Breast reconstruction postmastectomy
- Abdominal wall repair

**Indications**
DermaMatrix tissue is processed to remove cells while maintaining the integrity of the matrix with the intent to address the issues of the specific and nonspecific inflammatory responses. It is used for the replacement of damaged or inadequate integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects.

**Contraindications**
Use of DermaMatrix tissue in patients exhibiting autoimmune connective tissue disease is not recommended.

- Specific or nonspecific immune response to some component of the graft

Please refer to the package insert for additional precautions and adverse effects.
**Biomechanical properties**

DermaMatrix tissue has been subjected to biomechanical testing to characterize its physical properties. Testing was conducted by MTF, in accordance with MTF established procedures and ASTM International standards, for mechanical strength and ability to hold suture. Test results were compared to the properties of a leading competitive dermal matrix material.

DermaMatrix Acellular Dermis demonstrates superior biomechanical properties in comparison with the leading competitor’s dermal matrix material. It exhibits an average tensile strength, an intrinsic property, of 14.6 N/mm² and can withstand an average maximum load of 63.2 N prior to yielding. The competitor’s material, when subjected to the same testing, exhibited an average tensile strength of 8.0 N/mm² and a maximum load before yield of 44.2 N.

The average elastic modulus, or ability of DermaMatrix tissue to resist deformation, is 8.8 MPa, compared to 5.8 MPa for the competitor’s matrix.

Suture retention testing showed that DermaMatrix tissue is equivalent to the competitor’s material.

These biomechanical properties are significant when considering applications, such as abdominal wall repair, where material strength and stiffness are required to promote healing and prevent additional failures at the wound repair site.

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**Tensile strength of acellular dermis**

![Tensile strength graph]

**Tensile modulus of acellular dermis**

![Tensile modulus graph]

**Suture retention strength of acellular dermis**

![Suture retention graph]
**Histological profile**

DermaMatrix Acellular Dermis has been processed to remove cells while maintaining histomorphological integrity. Standard histology and immunohistochemical methods have been used to assess the dermal matrix structure and its components. Hematoxylin and eosin staining of normal human skin and DermaMatrix tissue show that the matrix is preserved during processing and demonstrates an absence of the epidermis and cells in the resulting matrix.

Using immunohistochemical staining methods, Types I and III collagen and elastin were evaluated in DermaMatrix Acellular Dermis. The collagen components are not affected during processing, demonstrated by consistent staining throughout the matrix.

Elastin fibers also remain present after processing, as seen by darkly stained strands throughout the acellular dermal matrix. Elastin, in conjunction with collagen, contributes to the strength and structure of the dermal matrix scaffold.

Hematoxylin and eosin staining of normal skin (left) and DermaMatrix Acellular Dermis (right) from the same donor. Note absence of cells and preservation of matrix structure after processing.

Immunohistochemical staining shows Type I collagen in normal skin (left) and staining in DermaMatrix Acellular Dermis (right).

Immunohistochemical staining shows Type III collagen in normal skin (left) and staining in DermaMatrix Acellular Dermis (right).

Immunohistochemical staining shows elastin in normal skin (left) and in DermaMatrix Acellular Dermis (right).

All histology courtesy of Premier Laboratory, LLC.
Histological profile continued

Alcian blue staining reveals that hyaluronan, a major glycosaminoglycan, is present in the tissue. Glycosaminoglycans and glycoproteins, such as hyaluronan and vitronectin, are integral components of the extracellular matrix and play an important role in cell-cell and cell-matrix interactions.\(^1,2,3\) Hyaluronan is present in all living organisms and provides matrix structure and osmotic balance, and assists with cell migration and differentiation.\(^4,5\) Vitronectin, an adhesive glycoprotein, binds to collagen, and promotes cell attachment, proliferation, and differentiation.\(^6\)

Immunohistochemical evaluation of the acellular dermal matrix confirms that the major components of the extracellular matrix, including collagen, elastin, and major matrix components responsible for promoting cell attachment and growth, are preserved after processing. Cells are effectively removed, leaving the original dermal matrix architecture intact.

Immunohistochemical staining using Alcian Blue/PAS shows the presence of hyaluronan in normal skin (left) and in acellular dermal matrix (right) as indicated by indigo staining.

Immunohistochemical staining shows vitronectin in normal skin (left) and in acellular dermal matrix (right) as indicated by brown staining.

Structural analysis

Structural analysis of acellular dermis using high power transmission electron microscopy reveals that the collagen and elastin components of the extracellular matrix are preserved after processing. Collagen in normal skin is observed in the cross section while in the acellular dermis, the fibers are observed oriented in the transverse direction. Elastin appears as an amorphous structure in both sections. Higher magnification reveals normal periodicity of collagen fibrils in the specimens.

TEM analysis shows amorphous elastin and fibrous collagen structures in normal skin (left) and acellular dermis (right).

Higher magnification shows collagen fibrils in normal skin (left) and acellular dermis (right).

Microscopy courtesy of Structure Probe, Inc.
Musculoskeletal Transplant Foundation (MTF)
The Musculoskeletal Transplant Foundation (MTF) is a national consortium of medical schools, academic institutions and recovery organizations involved in the recovery, processing and distribution of bone and related soft tissue for use in transplant surgery. Its quality and safety standards have been developed by leading physicians, transplant surgeons, and specialists in the fields of science and medicine.

MTF’s quality and safety standards consistently meet or exceed the requirements of the American Association of Tissue Banks (AATB) and the current regulations published by the federal Food and Drug Administration (FDA). MTF is also in compliance with established Good Tissue Practices and the International Standards Organization.

MTF is AATB accredited and uses the most complete and technically advanced testing available, including Nucleic Acid Testing (NAT), for detection of transmittable diseases such as HIV and hepatitis, to assure the safety of every allograft they supply.

Since its inception in 1987, MTF has recovered and processed over 50,000 donors. It has distributed more than 3 million tissues and maintains an unrivaled safety record. MTF has been processing human dermis for 10 years for clinical use.

Donor selection
All potential donors must pass through an extensive process. Screening begins at the site of recovery, with a comprehensive medical and social history that includes the cause of death. Tissue and blood samples are tested for infectious diseases that include hepatitis, HIV and syphilis. MTF’s testing requirements exceed current AATB and FDA guidelines. A team of medical/technical specialists from the infectious disease and tissue banking fields evaluates all information, including test results.

Tissue safety
Every lot of DermaMatrix Acellular Dermis is tested for sterility per USP <71>, indicating that there is no microbial growth on a lot-to-lot basis for release.

MTF has successfully achieved a 5.7 log (almost a 1 million-fold) reduction in microbial levels with their disinfection process—validating the process to consistently reduce bacterial levels in DermaMatrix tissue. The microbial inactivation included the evaluation of a panel of the most common microorganisms found in the body or on the skin, which includes both aerobic and anaerobic species of bacteria, mold, yeast, and fungi: Candida albicans, Staphylococcus aureus, Staphylococcus epidermis, Pseudomonas aeruginosa, Clostridium sporogenes and Streptococcus pyogenes.

In addition to meeting United States Pharmacopeia sterility requirements and demonstrating effective inactivation of bacterial load, biocompatibility testing has been conducted in accordance with ISO 10993. This further establishes the safety of the tissue, and exceeds the minimum requirements for AATB compliance. DermaMatrix Acellular Dermis has been subjected to a panel of eight tests for biocompatibility and has been demonstrated to be noncytotoxic, nonhemolytic, and nonmutagenic, confirming that there are no adverse immunologic responses at the acute, subchronic, and chronic levels.

Information on product properties, donor selection and tissue safety has been prepared by the Musculoskeletal Transplant Foundation.
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Additional sizes may be available. Please contact Synthes sales consultants for details. To order, call Synthes Customer Service at (800) 522-9069 or fax to (877) 534-1560.