AlloDerm™
Regenerative Tissue Matrix

TRUST.

3M+ implantations[1]

EVIDENCE.

~900 publications[2]

EXPERIENCE.

Over 25 years[3]

It's what AlloDerm™ is made of.

PRODUCT PORTFOLIO BROCHURE

INDICATIONS

ALLODERM SELECT™ Regenerative Tissue Matrix (ALLODERM SELECT™ RTM refers to both ALLODERM SELECT™ RTM and ALLODERM SELECT RESTORE™ RTM products) is intended to be used for repair or replacement of damaged or inadequate integumental tissue or for other homologous uses of human integument. This product is intended for single patient one-time use only. ALLODERM SELECT™ RTM is not indicated for use as a dural substitute or intended for use in veterinary applications.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

ALLODERM SELECT™ RTM should not be used in patients with a known sensitivity to any of the antibiotics listed on the package and/or Polysorbate 20.

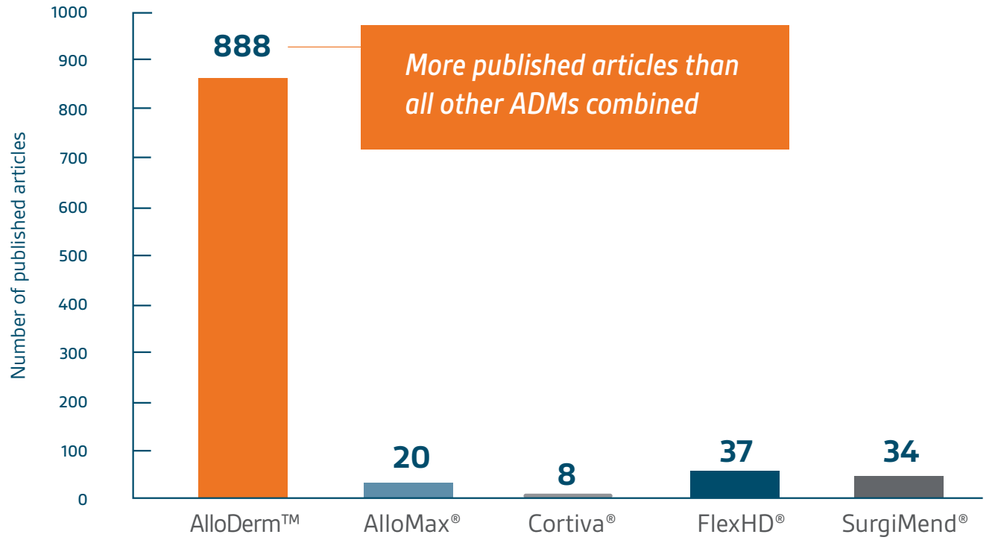
Please see additional Important Safety Information throughout this brochure.

Trusted by plastic surgeons,[4*]

ALLODERM™ RTM IS THE LEADING ADM[1-3,5]

Proprietary tissue processing	*Proven tissue regeneration*[6†]
Most-used ADM[5]	*Over 3 million implantations*[1]
Extensive coding, coverage, and reimbursement[7]	*Comprehensive portfolio with ongoing innovation*

Most-studied ADM, with nearly 900 scientific† and clinical articles[2]



*According to surgeon survey data, May 2022.

†Correlation of these results, based on animal studies, to results in humans has not been established.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS

Processing of the tissue, laboratory testing, and careful donor screening minimize the risk of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, ALLODERM SELECT™ RTM is not guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of ALLODERM SELECT™ RTM.

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Committed to providing the

HIGHEST-QUALITY SCAFFOLDS

At Allergan Aesthetics, our strict donor-screening protocols, proprietary tissue processing, and comprehensive release-testing requirements meet the highest industry standards to give you a safe, intact acellular dermal matrix (ADM) of high quality.[6,8,9] **Over 3 million implants have been used overall, with no documented disease transmissions.**[1,10]

The LifeCell Tissue Process 3-phase approach

Phase 1

DONOR SCREENING AND TESTING

- All tests required by the FDA regulations and American Association of Tissue Banks (AATB) standards[8]
- Final transfer vetted by 3-tiered review system consisting of specialists, nurses, and physicians

Phase 2

TISSUE PROCESSING

- Skin recovery and temperature verification performed
- Aseptically processed in environmentally controlled and monitored areas
- Rigorous controls and thorough documentation[8]
- Cells removed while preserving the integrity of the tissue matrix[8]
- Final quality control inspection

Phase 3

PRODUCT-RELEASE TESTING

Allergan Aesthetics tests tissue from every donor prior to release to ensure that it is an intact ADM designed to regenerate and strengthen weak tissues

Hematoxylin & Eosin (H&E) testing
- Successful removal of epidermis
- Intact papillary to reticular transition
- Intact collagen structure

Immunohistochemistry staining
- Intact basement membrane
- Successful removal of cells and cellular membrane
- Preserved structural integrity

The end result: AlloDerm™ RTM

- Undamaged, intact, and decellularized tissue matrix[6,9]
- Critical biochemical components are preserved[8]
- Designed to support a positive immunologic response and regeneration, as seen in primate models[6,9*]
- No evidence of microbial pathogens detected[8,11]

*Correlation of these results, based on animal studies, to results in humans has not been established.

When it comes to ADM processing,

TISSUE INTEGRITY MATTERS

Components of an undamaged matrix

PROTEOGLYCANS[12]
Guide revascularization and cell repopulation and regulate extracellular matrix structure through assembly and construction

FIBRONECTIN[13]
Mediates a variety of cellular interactions; modulates cell adhesion, migration, growth, and differentiation

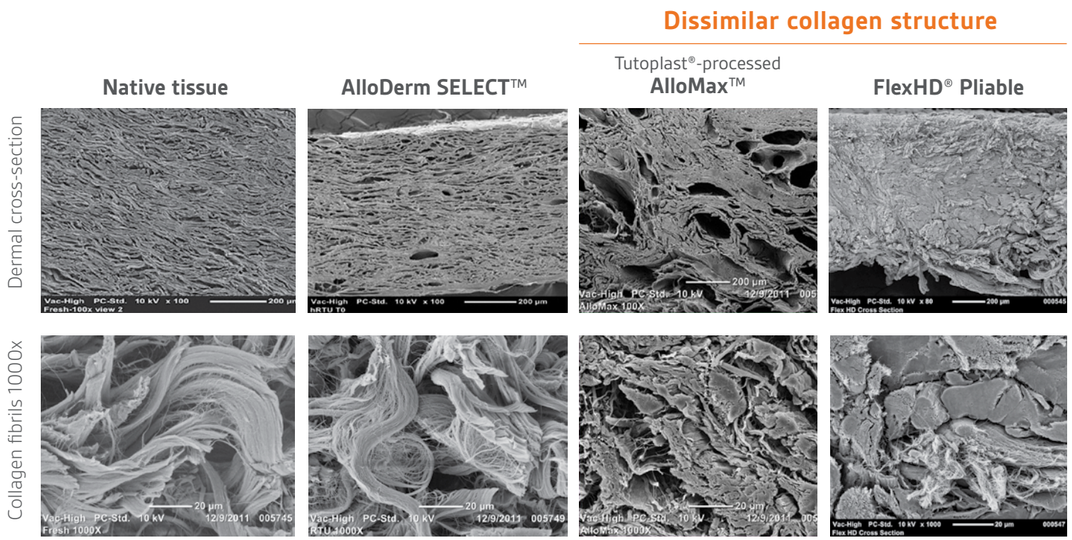
FIBRILLAR COLLAGENS[14]
Provide structure and tensile strength

VASCULAR CHANNELS[8]
Provide blood flow throughout the matrix, enabling initial revascularization

ELASTIN[14]
Functions with collagen to provide elasticity and recoil

HYALURONAN[15]
Controls tissue hydration and maintains the elastoviscosity of connective tissues throughout the body

AlloDerm™ RTM has a similar structure to native dermis[16]



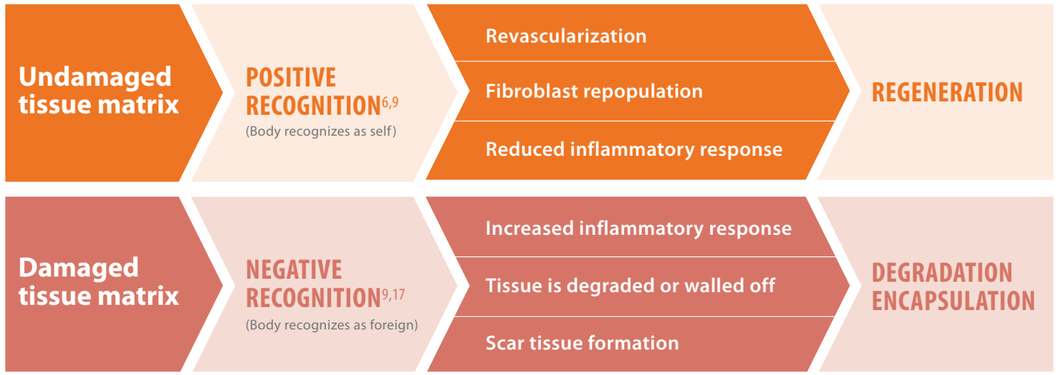
Ultrastructural out-of-package morphology of surgical scaffolds as compared with native human dermis (1000x scanning electron micrographs) revealed that AlloDerm SELECT™ RTM had a similar structure to native dermis.

As shown in preclinical animal studies,

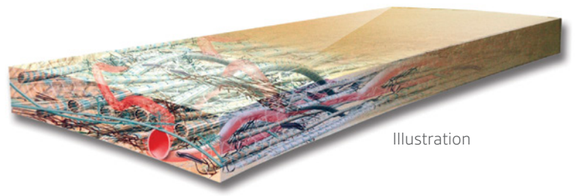
NOT ALL ADMS ARE THE SAME

An ADM is recognized either positively or negatively

Harnessing the body's natural processes is essential to restoring and maintaining the structure, function, and physiology of tissue. Upon tissue injury, the body will begin the repair or regeneration process, based on its recognition of the material used. An intact extracellular tissue matrix contains the ideal scaffold, with critical cellular and biochemical components to support the regenerative process.[6,9]



AlloDerm™ RTM is an undamaged, intact acellular dermal matrix that enables positive recognition and supports regeneration, as demonstrated in preclinical models[6,8,9]*



Illustration

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IMPORTANT SAFETY INFORMATION (continued)

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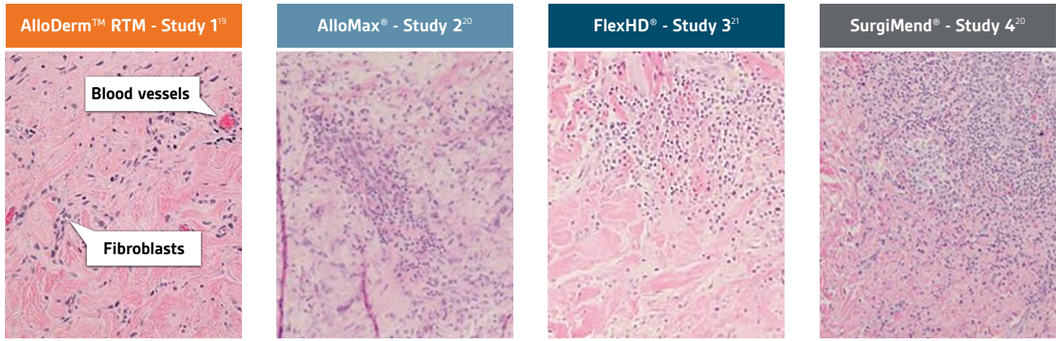
As shown in preclinical animal studies,

NOT ALL ADMS ARE THE SAME...

AlloDerm™ RTM supported rapid revascularization, fibroblast repopulation, and remodeling in a preclinical model

Damaged matrices experience delayed revascularization, which impedes white blood cell migration and fibroblast formation.[6,9,17,18]*

Widespread fibroblast & blood vessel formation



All samples are from 1-month implantation in nonhuman primate abdominal wall repair (NHP-AWR) models in 4 different studies. These studies followed the same protocol and were performed at the same institution at different times. Each image is shown stained with Hematoxylin & Eosin (H&E) at 200x magnification. H&E stains collagen fibers pink and cell nuclei blue-purple. Nuclei of lymphocytes are round, fibroblasts are elongated, and macrophages are round and diffuse.

*Correlation of these results, based on animal studies, to results in humans has not been established.

The importance of cell repopulation and revascularization

Supports remodeling

Without vascular supply, there is no pathway for cells to remodel the tissue.[22]

Resists infection

Formation of intact vascular channels allows white blood cells to migrate to the site of an infection to minimize risk.[23]

Prevents necrosis

Cellularized tissue matrices that do not revascularize will necrose.[24]

IMPORTANT SAFETY INFORMATION (continued)

PRECAUTIONS

Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implanting ALLODERM SELECT™ RTM as such conditions may compromise successful clinical outcome. Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.

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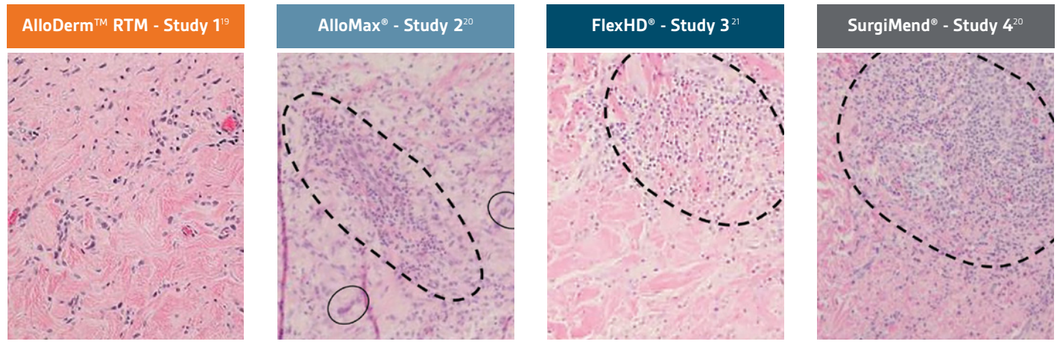
...REGENERATION IS KEY

AlloDerm™ RTM demonstrated minimal inflammation in a preclinical model

Damaged matrices are viewed by the body as foreign and trigger a chronic inflammatory response that leads to matrix degradation or encapsulation, which may impede regeneration.[6,9,17]*

Minimal inflammatory response



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The negative effects of chronic inflammation

Prevents remodeling

The body perceives a damaged tissue matrix as foreign, which may cause inflammation that impedes regeneration.[6,9]*

Provokes scar formation

Chronic inflammation results in the formation of scar tissue. As inflammation increases, the rate of scar tissue formation is exacerbated.[25,26]

Inhibits the ability to fight infection

Chronic inflammation may delay revascularization, which may impede fibroblast integration, blood vessel formation, and the ability to fight infection.[27,28]

IMPORTANT SAFETY INFORMATION (continued)

PRECAUTIONS (continued)

ALLODERM SELECT™ RTM has a distinct basement membrane (upper) and dermal surface (lower). When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue. Soak the tissue for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the tissue. If any hair is visible, remove using aseptic technique before implantation.

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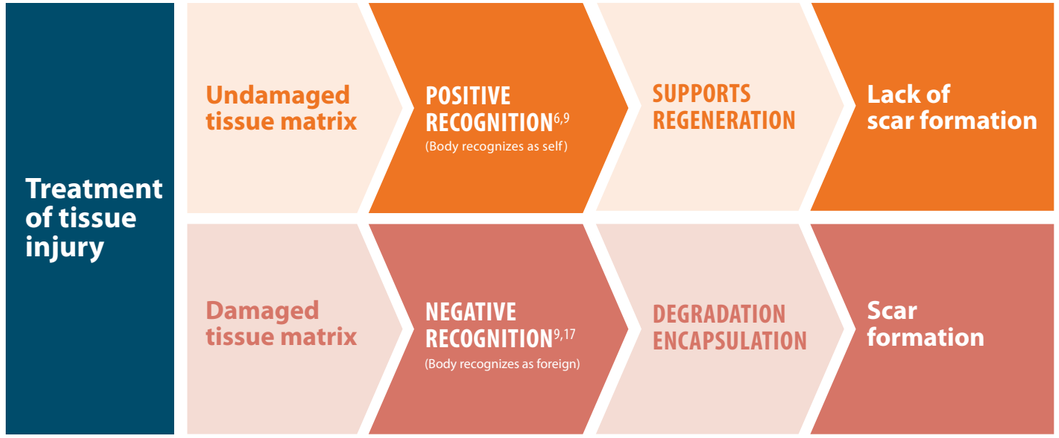
As shown in preclinical animal studies,

NOT ALL ADMS ARE THE SAME...

Positive recognition of AlloDerm™ RTM supports a regenerative rather than fibrotic response, as shown in preclinical models

The body recognizes and responds to implanted materials either positively or negatively. Negative recognition causes excessive or prolonged inflammation and often promotes scar formation, while positive recognition causes minimal inflammation and supports regeneration.[8,29*]



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The negative effects of scar formation

Weak

Scar tissue has suboptimal functional, biomechanical, and physiological characteristics. It is weaker than normal fascia.[25,26]

Contractile

A damaged tissue matrix is more likely to result in greater levels of scar and subsequent contracture. In a primate model, AlloDerm™ RTM demonstrated minimal contraction.[17,19]

Causes visual deformities

Graft contraction can cause a visual deformity (loss of domain) and reduce function and mobility of the tissue.[25]

IMPORTANT SAFETY INFORMATION (continued)

PRECAUTIONS (continued)

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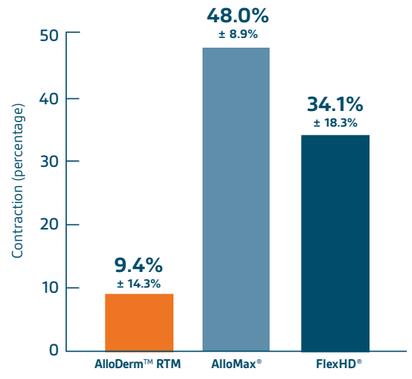
...REGENERATION IS KEY

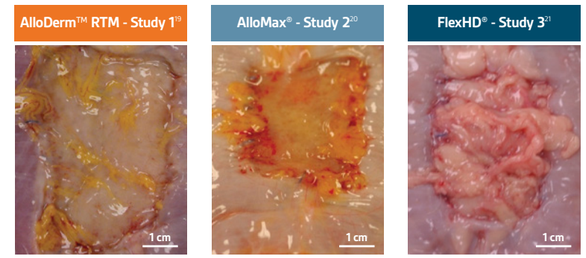
AlloDerm™ RTM did not demonstrate resorption in a preclinical model

AlloDerm™ RTM showed minimal change in size 1 month after implantation, with no resorption and minimal contracture of surrounding tissue. Damaged matrices have altered structure and therefore are viewed by the body as foreign, which leads to contraction and resorption of the graft.[6,9,16,19*]

Graft contraction at 1 month[19-21]



Baseline at time of placement 3 cm x 7 cm[19-21]



9.4% ± 14.3% | 48.0% ± 8.9% | 34.1% ± 18.3%

Representative gross photographs of tissue matrices evaluated following 1-month implantation in NHP-AWR models. Samples are taken from 3 different studies that followed the same protocol and were performed at the same institution at different times. All tissue matrices were fixated to the edges of a 3 x 7 cm full-thickness defect in the abdominal wall of NHP in an interpositional bridging configuration.

*Correlation of these results, based on animal studies, to results in humans has not been established.

The consequences of resorption

Loss of strength

Damaged ADMs demonstrated a loss of graft strength due to resorption.[17]

Loss of support

Damaged ADMs have demonstrated decreased biomechanical healing strength and diminished graft integrity.[29]

Replaced with scar

A damaged tissue matrix may lead to degradation, resulting in partial or complete resorption and replacement of collagen matrix fibers with scar tissue.[6,17,30]

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE EVENTS

The most commonly reported adverse events associated with the implant of a tissue graft include, but are not limited to the following: wound or systemic infection; seroma; dehiscence; hypersensitive, allergic or other immune response; and sloughing or failure of the graft.

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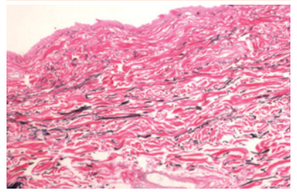
SEE THE ALLODERM™ RTM DIFFERENCE

AlloDerm™ RTM offers desired pliability and handling[4,31]

AlloDerm™



Out-of-package Verhoeff Van Gieson staining for elastin, 100x. Elastin stains black.

AlloDerm™ RTM retains elastin, which functions with collagen, helping to provide elasticity and shape retention[6,9,14]

By maintaining graft integrity, including intact elastin microfibrils and collagen fibers, AlloDerm™ RTM provides appropriate mechanical properties, including tensile strength and elasticity, both out-of-package and following implantation.[9,16]*

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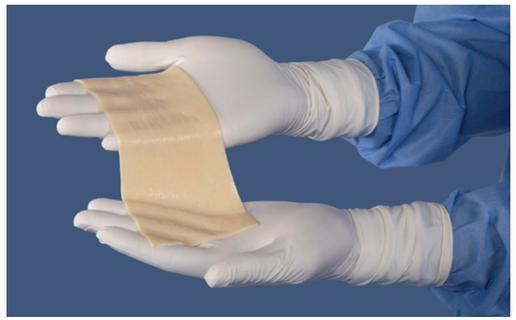

The importance of pliability

Conforms to defect

An undamaged tissue matrix retains characteristics of native tissue and is pliable and able to conform to a defect.[16,32]

Tissue apposition

Tissue needs to conform to the defect to have appropriate apposition to the vascular surface to revascularize.[33]

Ideal handling

Tissue processed using certain damaging reagents can affect tissue characteristics and collagen structure.[8,16]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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EXTENSIVE INSURANCE COVERAGE

from major payors in the US[7]

AlloDerm™ RTM meets the highest standards of medical necessity to be specifically named and covered by major payors in the US[7]

Commercial insurance company[7]	AlloDerm™ RTM **Q4116**[34]
UnitedHealthcare®	✓
Anthem®	
Aetna®	
Cigna®	
Kaiser Permanente®	
Blue Cross and Blue Shield of Illinois	
Blue Cross and Blue Shield of Texas	
Blue Cross Blue Shield of Michigan	
Blue Shield of California	
Florida Blue	

Top 10 insurers covering AlloDerm™ RTM in the US

Reimbursement Hotline support is just a call, click, or fax away

Contact us:

Monday to Friday 8:30 AM - 6:00 PM ET
(Closed on major observed holidays)

AllerganPRM@thepinnaclehealthgroup.com

1.888.543.3656

1.877.499.2986

Backed by a 100% Guarantee

The AlloDerm™ RTM Guarantee Program offers facility customers a replacement of any piece of AlloDerm™ RTM that is explanted

- To be eligible for the guarantee, facilities must comply with all terms and conditions
- For more information, contact your local Allergan Aesthetics representative today, or call Allergan Customer Service at 1.800.367.5737

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS

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AlloDerm™ RTM offers

A WIDE RANGE OF PRODUCTS...

AlloDerm™ RTM offers an extensive portfolio that aligns with the evolving clinical needs of surgeons and their patients

Sterile[7]

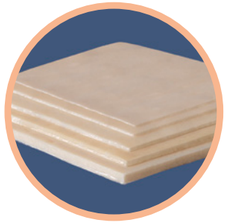
***Ready to use* with a minimum 2-minute soak**[8]

Zero documented disease transmissions[10]

Able to be stored without refrigeration[8]

32 SIZES • 5 THICKNESSES • 4 TEXTURES • 3 SHAPES

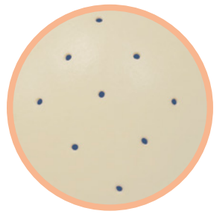
Thickness offerings for different applications



X-Thin: 0.55 ± 0.25 mm
Thin: 1.0 ± 0.2 mm
Medium: 1.6 ± 0.4 mm
Thick: 2.4 ± 0.4 mm
X-Thick: 3.4 ± 0.6 mm

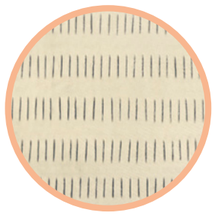
Textured to suit your needs

NON-TEXTURED



PERFORATED

FENESTRATED



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IMPORTANT SAFETY INFORMATION (continued)

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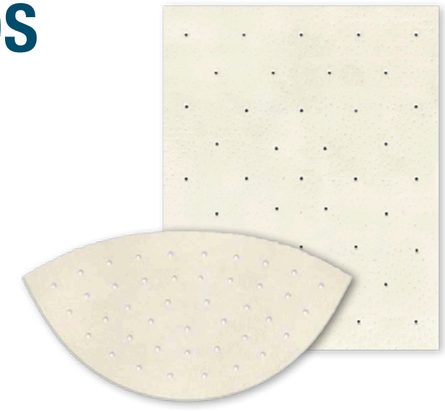
...TO MEET YOUR NEEDS

Perforated options facilitate regeneration



FLUID COMMUNICATION
Designed to allow fluid to move through the matrix at time of implantation[35]

INTEGRATION
Perforations designed to facilitate tissue ingrowth[35]

STRENGTH
Perforation pattern designed to maintain similar strength to nonperforated AlloDerm SELECT™ RTM

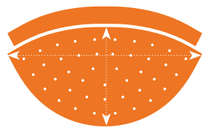
PROPRIETARY DESIGN
3 mm in diameter, covers <3% of matrix. Tissue perimeter designed to accommodate suturing[36]

Shapes designed to facilitate placement

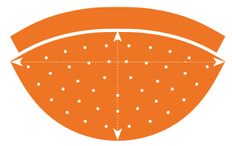
- May help reduce time required for product trimming
- May make intraoperative placement easier and more predictable
- Available in perforated and nonperforated

Contour

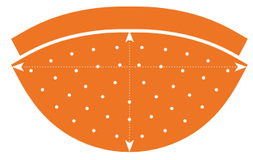
CONTOUR SMALL
7.3 x 14.7 cm
Coverage: 77 cm^2



CONTOUR MEDIUM
9.6 x 19.3 cm
Coverage: 132 cm^2



CONTOUR LARGE
10.7 x 21.5 cm
Coverage: 164 cm^2



CONTOUR X-LARGE
11.8 x 23.7 cm
Coverage: 200 cm^2

IMPORTANT SAFETY INFORMATION (continued)

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TRUST. EVIDENCE. EXPERIENCE.

It's what AlloDerm™ is made of.

AlloDerm™ Regenerative Tissue Matrix

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VISIT US AT ALLODERM.COM

FOLLOW @ ALLODERMHCP

VISIT US ON YouTube

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For more information, please see the Instructions for Use (IFU) for ALLODERM SELECT™ RTM available at www.allergan.com/AlloDermIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.433.8871.

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