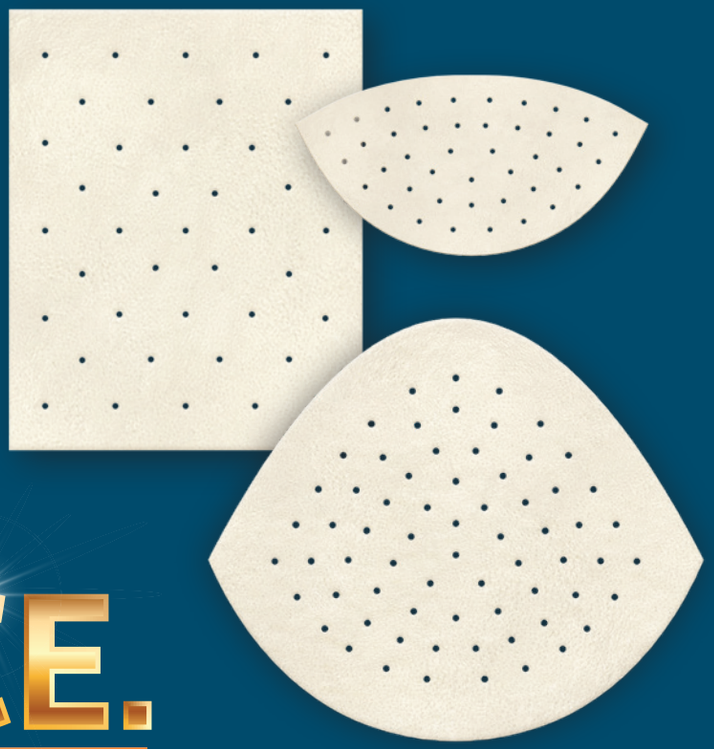
AlloDerm™
Regenerative Tissue Matrix



TRUST.

4M+ implantations[1]

EVIDENCE.

> 1,000 publications[2]

EXPERIENCE.

30 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. ALLODERM SELECT™ RTM is intended for use in post-mastectomy breast reconstruction surgical procedures where the use of the acellular dermal matrix (ADM) is considered homologous, such as managing a potential skin defect created from harvesting tissue for use in autologous tissue reconstruction. Examples of uses in post-mastectomy breast reconstruction not considered homologous include use of an ADM to form an extension of the submuscular pocket for placement of a breast implant or tissue expander, and use to prevent expander or implant extrusion, or to constrain the expander or implant in the correct position. This product is intended for use in one patient, on a single occasion. 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.

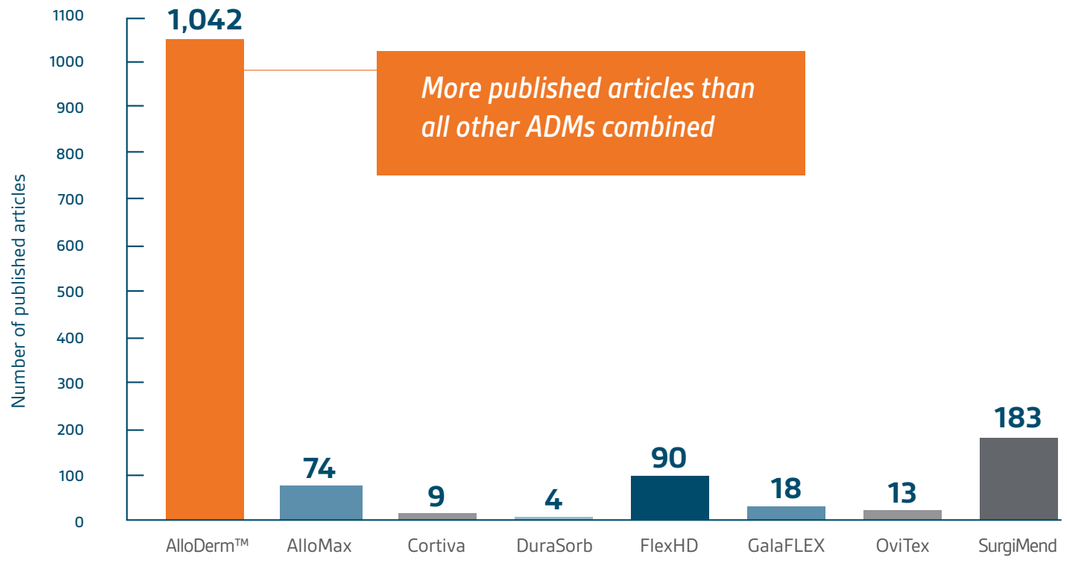
Please see additional Important Safety Information throughout this brochure.

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 4 million implantations*[1]
Extensive coding, coverage, and reimbursement[7]	*Comprehensive portfolio with ongoing innovation*

Most-studied ADM, with over 1,000 scientific‡ and clinical articles[2§]



*According to surgeon survey data (n = 75), July 2023.
†Correlation of these results, based on animal studies, to results in humans has not been established.
‡iData MedSKU Hospital Purchasing, data ending January 2023.
§Based on multiple database searches from May 2024.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS

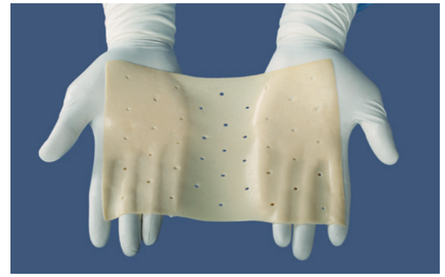
Processing of the tissue, laboratory testing, and careful donor screening minimize the risk of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, ALLODERM SELECT™ RTM is not guaranteed to be free of all pathogens. No long-term studies have been conducted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

Please see additional Important Safety Information throughout this brochure.

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 4 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

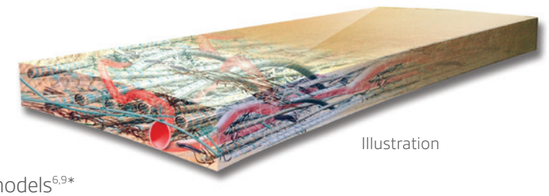
Allergan Aesthetics tests tissue from every donor prior to release to ensure that it is an intact ADM designed to regenerate and strengthen weak tissues

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]



Illustration

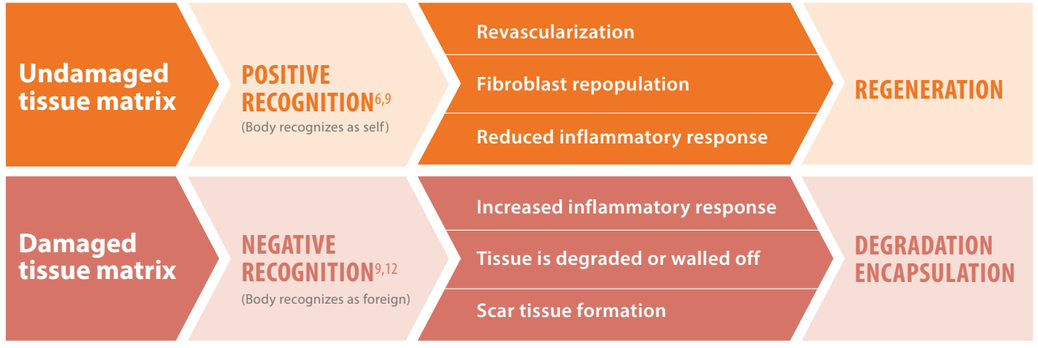
*Correlation of these results, based on animal studies, to results in humans has not been established.

When it comes to ADM processing,

TISSUE INTEGRITY MATTERS

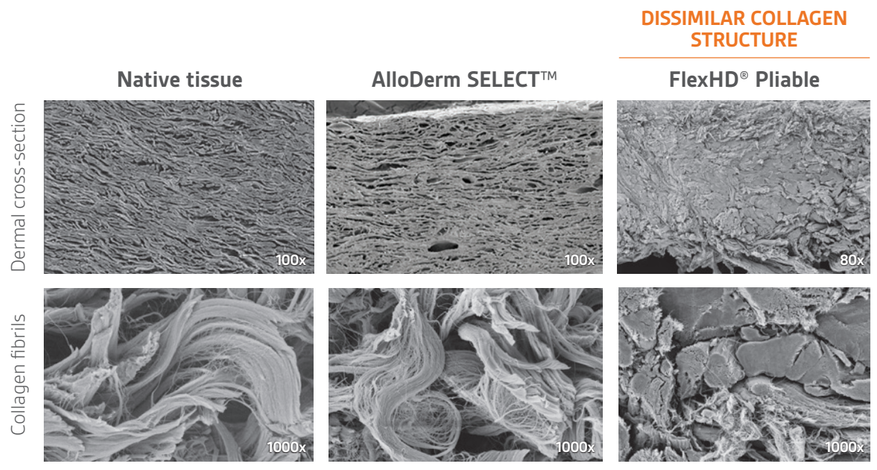
*An ADM is recognized either positively or negatively**

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.



AlloDerm™ RTM has a similar structure to native dermis[13]

AlloDerm™ RTM is minimally manipulated and gently processed to ensure it retains components critical to maintaining the biochemical and biomechanical integrity of the native tissue[9]



Ultrastructural out-of-package morphology of surgical scaffolds as compared with native human dermis revealed that AlloDerm SELECT™ RTM had a similar structure to native dermis.

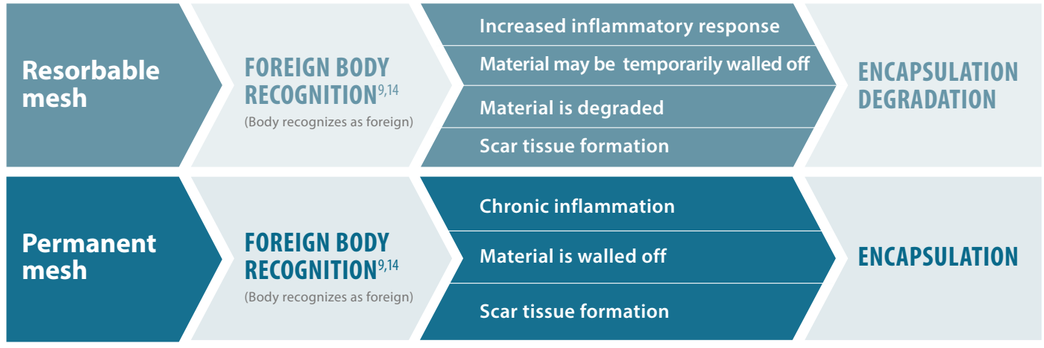
*Correlation of these results, based on animal studies, to results in humans has not been established.

As shown in preclinical animal studies,

NOT ALL SCAFFOLDS ARE THE SAME

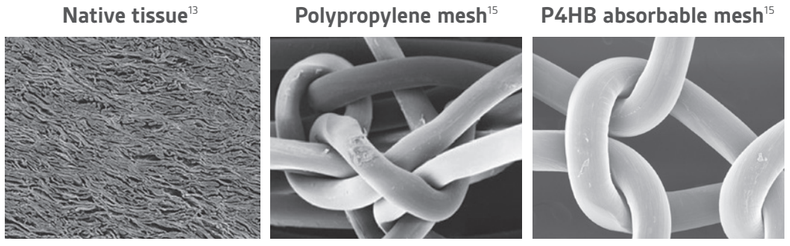
*A synthetic surgical scaffold can be recognized negatively**

If the body recognizes an implant as foreign, it will begin a reparative process, not a regenerative one. This can lead to encapsulation, degradation, and scar formation.[9,14]



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

Compare out-of-package morphologies



Ultrastructural out-of-package morphology of surgical scaffolds as compared with native dermis.[13]*

Ultrastructural out-of-package morphology of P4HB mesh has a similar structure to polypropylene synthetic mesh.[15]*

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

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS (continued)

DO NOT re-sterilize ALLODERM SELECT™ RTM. **DO NOT** reuse once the tissue graft has been removed from the packaging and/or is in contact with a patient. Discard all open and unused portions of the product in accordance with standard medical practice and institutional protocols for disposal of human tissue. Once a package or container seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded. **DO NOT** use if the foil pouch is opened or damaged. **DO NOT** use if the seal is broken or compromised. **DO NOT** use if the temperature monitoring device does not display "OK". **DO NOT** use after the expiration date noted on the label. Transfer ALLODERM SELECT™ RTM from the foil pouch aseptically. **DO NOT** place the foil pouch in the sterile field.

Please see additional Important Safety Information throughout this brochure.

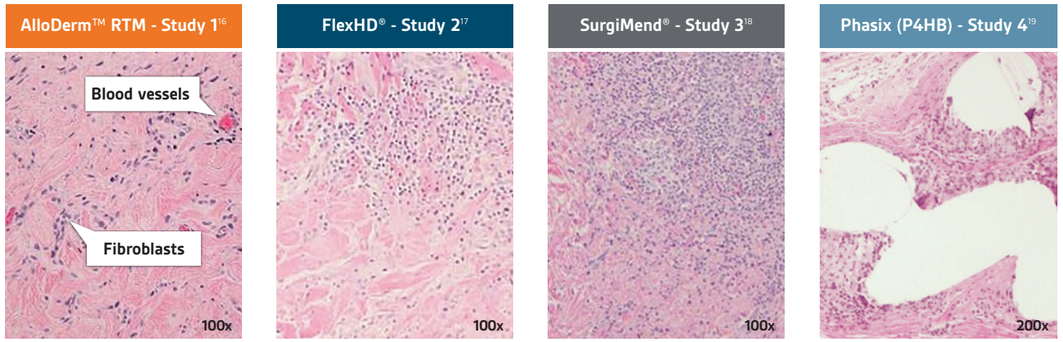
As shown in preclinical animal studies,

NOT ALL SCAFFOLDS ARE THE SAME...

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

Damaged matrices and synthetic meshes experience delayed revascularization, which impedes white blood cell migration and fibroblast formation.[6,9,12*]

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. Images for AlloDerm™ RTM, FlexHD®, and SurgiMend® are shown stained with Hematoxylin & Eosin (H&E) at 200x magnification. The Phasix (P4HB) image is shown stained at 100x 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.[20]

Resists infection

Formation of intact vascular channels allows white blood cells to migrate to the site of an infection to minimize risk.[21]

Prevents necrosis

Cellularized tissue matrices that do not revascularize will necrose.[22]

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.

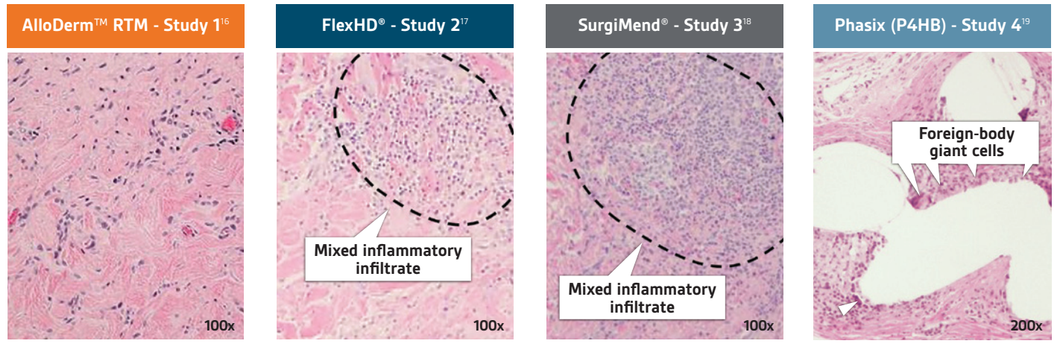
Please see additional Important Safety Information throughout this brochure.

...REGENERATION IS KEY

AlloDerm™ RTM demonstrated minimal inflammation in a preclinical model

Damaged matrices and synthetic meshes are viewed by the body as foreign and trigger a chronic inflammatory response that leads to matrix degradation or encapsulation, which may impede regeneration (noted by dashed circle).[6,9,12*]

Minimal inflammatory response



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

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.[23,24]

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.[25,26]

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

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.

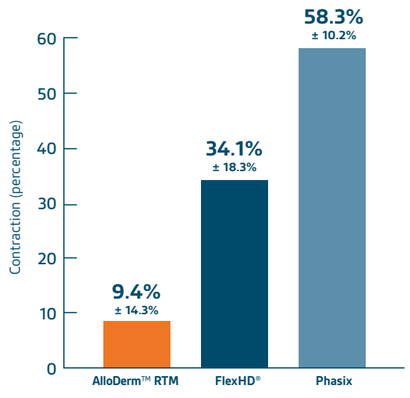
Please see additional Important Safety Information throughout this brochure.

POSITIVE RECOGNITION LEADS TO REGENERATION

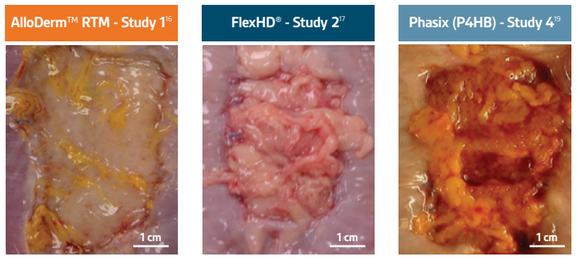
AlloDerm™ RTM did not demonstrate resorption in a preclinical model

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.[6,9,12,13,16]*

Graft contraction at 1 month[16,17,19]



Baseline at time of placement
3 cm x 7 cm[16,17,19]



9.4% ± 14.3% | 34.1% ± 18.3% | 58.3% ± 10.2%

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 scaffolds were fixated to the edges of a 3 x 7 cm full-thickness defect in the abdominal wall of an 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.[12]

Loss of support

Damaged ADMs have demonstrated decreased biomechanical healing strength and diminished graft integrity.[27]

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.[6,12,28]

IMPORTANT SAFETY INFORMATION (continued)

PRECAUTIONS (continued)

ALLODERM SELECT™ RTM should be hydrated and moist when the package is opened. **DO NOT** use if this product is dry. Use of this product is limited to specific health professionals (eg, physicians, dentists, and/or podiatrists). Certain considerations should be made to reduce the risk of adverse events when performing surgical procedures using a tissue graft. Please see the Instructions for Use (IFU) for more information on patient/product selection and surgical procedures involving tissue implantation before using ALLODERM SELECT™ RTM.

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NEGATIVE RECOGNITION LEADS TO SCARRING

Scar tissue formation is a suboptimal response

When the body sees the implant as a foreign material, it triggers an excessive inflammatory response that can lead to degradation and resorption or encapsulation. Each of these may result in scar tissue.[9]

Compared with native tissue, scar tissue:

- **Is weaker**[9,29]
- **Has less stretch**[23]
- **Contracts**[23]
- **Has poor vascularity**[9]
- **Is painful**[23]
- **Causes visual deformities**[23]

If it is not regeneration, it is scar tissue formation

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

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

IMPORTANT SAFETY INFORMATION

ADVERSE EVENTS

Potential adverse events which may result from surgical procedures 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.

ALLODERM SELECT™ RTM is available by prescription only.

For more information, please see the Instructions for Use (IFU) for ALLODERM SELECT™ RTM available at https://hcp.alloderm.com/ or call 1.800.678.1605.

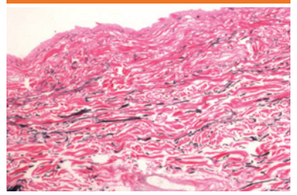
To report an adverse reaction, please call Allergan Aesthetics at 1.800.433.8871.

Please see additional Important Safety Information throughout this brochure.

SEE THE ALLODERM™ RTM DIFFERENCE

AlloDerm™ RTM offers desired pliability and handling[4,30]

AlloDerm™

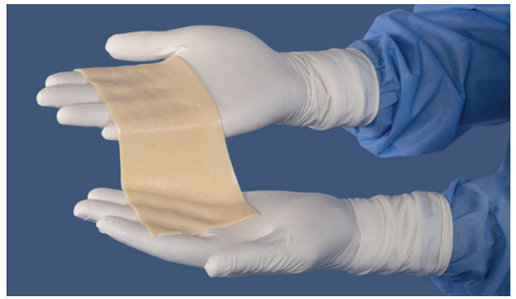


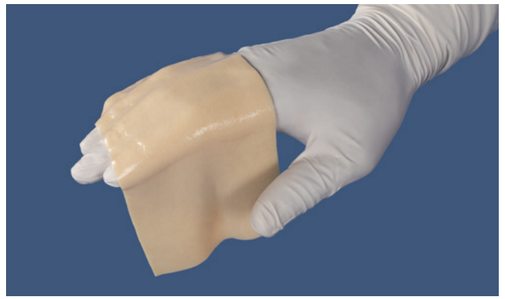
Out-of-package Verhoeff-Van Gieson staining for elastin, 100x. Elastin stains black.

AlloDerm™ RTM retains elastin, which functions with collagen, helping to provide elasticity and shape retention[6,9,31]

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.[9,13]*

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





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.[13,32]

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.[8,13]

IMPORTANT SAFETY INFORMATION

INDICATIONS

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Please see additional Important Safety Information throughout this brochure.

COMPREHENSIVE SERVICES AND SUPPORT

behind every piece of AlloDerm™ RTM

Reimbursement for AlloDerm™ RTM

Q4116 AlloDerm™ RTM has its own product-specific HCPCS code: **Q4116**

Extensive commercial insurance coverage

AlloDerm™ RTM may qualify for incremental reimbursement to the facility for outpatient cases

Reimbursement support includes:

- Appeals assistance
- Coding (physician, facility)
- Coverage and payment assistance
- Reimbursement
- Education and health policy
- Prior authorization
- Processing support

Contact your local reimbursement representative today or access our Reimbursement Hotline

1.888.543.3656
Monday to Friday 8:30 AM - 6:00 PM ET
(Closed on major observed holidays)

1.877.499.2986

AllerganPRM@thepinnaclehealthgroup.com

Medical Support Team

Medical Information

Medical Affairs

If you have any medically related product inquiries, please call us at 1.800.678.1605, option 2, or visit https://www.abbviemedinfo.com/ for help from our medical support team.

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)

CONTRAINDICATIONS

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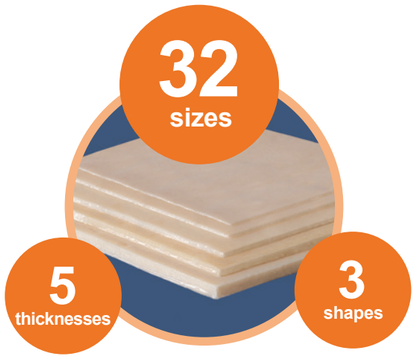
AlloDerm™ RTM offers

A WIDE RANGE OF PRODUCTS...

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

- **Sterile**[8]
- ***Ready to use* with a minimum 2-minute soak**[8]
- **Zero documented disease transmissions**[10]
- **Able to be stored without refrigeration**[8]



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

*Perforated options facilitate regeneration**

FLUID COMMUNICATION
- Designed to allow fluid to move through the matrix at time of implantation[34*]

INTEGRATION
- Perforations designed to facilitate tissue ingrowth[34*]

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[35]

AlloDerm™ 16 x 20

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

...TO MEET YOUR NEEDS

Shapes designed to facilitate placement

AVAILABLE IN 3 DISTINCT SHAPES
- May help reduce time required for product trimming
- May make intraoperative placement easier

PERFORATIONS AVAILABLE
- All AlloDerm™ shapes and sizes are available perforated and nonperforated

AlloDerm™ RESTORE

LARGE DESIGN
- Offers 327 cm^2 of coverage
- 20.1 x 23.6 cm^2

2-CM RIM
- Allows for fixation and trimming without impacting the perforation pattern

AlloDerm™ 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)

WARNINGS
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TRUST. EVIDENCE. EXPERIENCE.

It's what AlloDerm™ is made of.

AlloDerm™ Regenerative Tissue Matrix

For more information, call Allergan Aesthetics Customer Service at **1.800.367.5737**

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VISIT US ON YouTube

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS (continued)

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PRECAUTIONS

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ALLODERM SELECT™ RTM should be hydrated and moist when the package is opened. **DO NOT** use if this product is dry. Use of this product is limited to specific health professionals (eg, physicians, dentists, and/or podiatrists). Certain considerations should be made to reduce the risk of adverse events when performing surgical procedures using a tissue graft. Please see the Instructions for Use (IFU) for more information on patient/product selection and surgical procedures involving tissue implantation before using ALLODERM SELECT™ RTM.

ADVERSE EVENTS

Potential adverse events which may result from surgical procedures 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.

ALLODERM SELECT™ RTM is available by prescription only.

For more information, please see the Instructions for Use (IFU) for ALLODERM SELECT™ RTM available at https://hcp.alloderm.com/ or call 1.800.678.1605.

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

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