

FROM THE MARKET LEADERS AND PIONEERS IN ADM TECHNOLOGY

# ARTIA<sup>™</sup> RTM

Our next advancement in porcine-derived ADM<sup>1</sup>

## POSITIVE BIOLOGIC RESPONSE<sup>2,\*</sup> - CONSISTENCY<sup>3,4,†</sup> - PLIABILITY<sup>5,†</sup>

\*Correlation of these results to results in humans has not been established. \*Clinical significance is unknown.

ADM=acellular dermal matrix; RTM=reconstructive tissue matrix.

### **INDICATIONS**

ARTIA<sup>™</sup> Reconstructive Tissue Matrix (ARTIA<sup>™</sup> RTM) is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes which require the use of reinforcing or bridging material to obtain the desired surgical outcome. The implant is intended for reinforcement of soft tissue in plastic and reconstructive surgery. ARTIA<sup>™</sup> RTM is supplied sterile and is intended for single patient, one time use only.

### **IMPORTANT SAFETY INFORMATION**

### CONTRAINDICATIONS

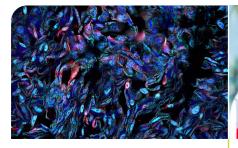
This product should not be used in patients with a known sensitivity to porcine material and/or Polysorbate 20.

Please see additional Important Safety Information throughout this brochure.

# From the market leaders in ADM—ARTIA<sup>™</sup>

- ARTIA<sup>™</sup> is intended for use to reinforce soft tissue where weakness exists during plastic and reconstructive surgery<sup>1</sup>
- Porcine dermis processed and designed to incorporate into the recipient tissue with associated cellular and microvascular ingrowth<sup>1,2</sup>

## Since 1994, Allergan Aesthetics has been a pioneer in ADMs<sup>6</sup>



### HISTORY

Pioneer in regenerative tissue matrices harnessing over 30 years of expertise



## RESEARCH

Dedicated R&D team solely focused on providing Regenerative Medicine options

### PARTNERSHIP A legacy of innovation and surgeon collaboration

and surgeon collaboration to help improve surgical outcomes and patient care



Harnessing 30 years of experience and knowledge of dermal tissue, ARTIA<sup>™</sup> is a porcine matrix that offers similar handling characteristics and biologic response to human tissue, while offering consistency in thickness and stretch.<sup>2-6,\*,†</sup>

\*Correlation of these results to results in humans has not been established. \*Clinical significance is unknown.

## IMPORTANT SAFETY INFORMATION (continued) WARNINGS

**Do not resterilize.** Discard all open and unused portions of this device. **Do not use** if the package is opened or damaged. **Do not use** if seal is broken or compromised. **Do not use** if the temperature monitoring device does not display "OK." After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations. ARTIA<sup>™</sup> Tissue Matrix **cannot be reused** once it has been removed from the packaging and/or is in contact with a patient without increased risk of patient-to-patient contamination and subsequent infection. The user should be aware of high recurrence rates when using a surgical mesh for bridging repair in load-bearing applications (eg, hernia repair).

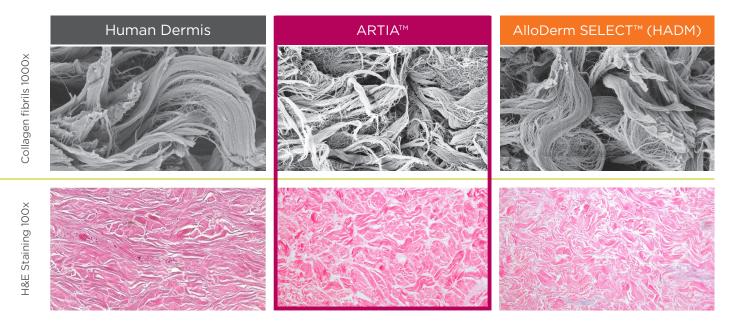
Please see additional Important Safety Information throughout this brochure.

# ARTIA<sup>™</sup> has desired characteristics of both allografts and xenografts<sup>7</sup>

ALLOGRAFT CHARACTERISTICS Biologic Response<sup>2,\*</sup> Drape Characteristics<sup>5</sup> Extensive Experience<sup>6</sup>

# Our processing maintain positive recognition

ARTIA<sup>™</sup> demonstrated a similar histological microstructure to both human dermis and AlloDerm<sup>™</sup> RTM after processing<sup>®</sup>



Ultrastructural out-of-package morphology of surgical scaffolds as compared with native human dermis (1000x scanning electron micrographs). Hematoxylin and Eosin (H&E) staining at 100x magnification. HADM=human acellular dermal matrix.

Our proprietary LifeCell Tissue Processing is designed to preserve the structure and strength of the matrix, reduce inflammatory response, and support regeneration.<sup>9,10,\*</sup>

erience<sup>6</sup>

Product Consistency<sup>3,†</sup> Stretch Characteristics<sup>4,†</sup> No Source Limitations<sup>1</sup> Platform for Innovation

XENOGRAFT CHARACTERISTICS

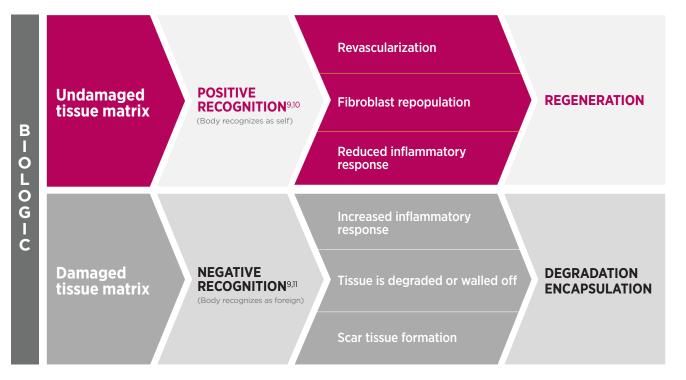
## Our processing maintains an intact tissue matrix to support



## Not all ADMs are the same— **Regeneration is key**

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.<sup>9,0</sup>

## An ADM is recognized either positively or negatively\*



ARTIA<sup>™</sup> is an undamaged, intact ADM that enables positive recognition and is designed to support regeneration, as demonstrated in preclinical models.<sup>2,9,10,\*</sup>

\*Correlation of these results to results in humans has not been established.

### **IMPORTANT SAFETY INFORMATION (continued)** PRECAUTIONS

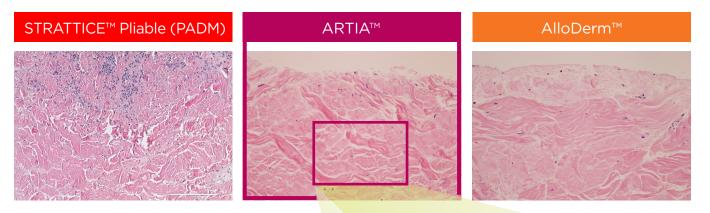
Use of the product in breast reconstruction has not been studied in a prospective clinical trial.

Discard product if handling has caused possible damage or contamination, or the product is past the expiration date. Ensure the surgical mesh is soaked in room temperature sterile saline or room temperature sterile lactated Ringer's solution for a **minimum of 2 minutes** prior to implantation in the body. Place the product in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling. The surgical mesh should be hydrated and moist when the package is opened. If the product is dry, do not use. If a tissue punch-out piece is visible, remove using aseptic technique before implantation.

#### Please see additional Important Safety Information throughout this brochure.

## **ARTIA<sup>™</sup>** demonstrated a positive biologic response

Demonstrated rapid revascularization, cellular repopulation, and minimal inflammatory response in a primate model<sup>2,\*</sup>



### ARTIA<sup>™</sup> had minimal inflammation with widespread fibroblast and blood vessel formation

All implant samples are the same study taken from 2-week primate subcutaneous model. H&E staining shown 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.<sup>2</sup>

PADM = porcine acellular dermal matrix.

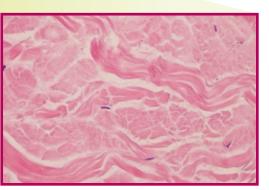
Harnessing over 30 years of experience in tissue processing, the steps to remove antigens in xenografts have been optimized for ARTIA<sup>™</sup>, improving its biologic response.<sup>26,\*</sup>

Both ARTIA<sup>™</sup> and AlloDerm<sup>™</sup> explants at 2 weeks, evaluated per histology, supported regeneration in a primate model.<sup>2,\*</sup>

### **Positive Biologic Response**

Preclinical Response in a Primate Model\*





275x magnification of selected portion of H&E stain.



## **ARTIA™**—Backed by the market leaders in ADM



The ARTIA<sup>™</sup> RTM Guarantee Program offers facility customers a replacement of any piece of ARTIA<sup>™</sup> 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 Aesthetics Customer Service at 1.800.367.5737

# **ARTIA<sup>™</sup>** provides thickness consistency<sup>\*</sup>

Derived from a controlled source material<sup>1</sup>



Has an average thickness of 1.49 mm (SD, 0.23 mm)<sup>4</sup>



SD = standard deviation. \*Clinical significance is unknown.

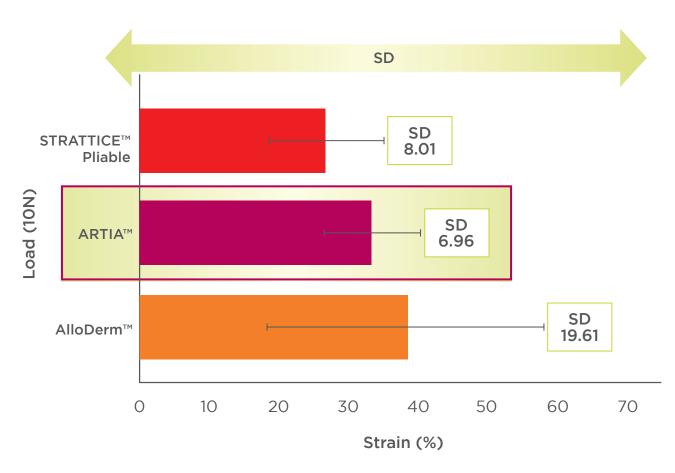
### **IMPORTANT SAFETY INFORMATION (continued) PRECAUTIONS** (continued)

Certain considerations should be used when performing surgical procedures using a surgical mesh product. Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation.

### Please see additional Important Safety Information throughout this brochure.

## **ARTIA<sup>™</sup> demonstrates consistency** in stretch\*

AlloDerm<sup>™</sup> and STRATTICE<sup>™</sup> Pliable<sup>₄</sup>



Loads represented are per 2-cm-width samples, and the error bars represent one SD from the mean.<sup>4</sup>

# ARTIA<sup>™</sup> delivers consistency and stretch between

## ARTIA<sup>™</sup> demonstrated less stretch with **3x less** variation than AlloDerm<sup>™,4</sup>



# ARTIA<sup>™</sup> provides desirable pliability and handling

ARTIA<sup>™</sup> is designed to have similar drapability to AlloDerm<sup>™ 5,\*</sup>



Quantification of drape showed similar characteristics for ARTIA<sup>™</sup> and AlloDerm<sup>™.5,\*</sup>

\*Clinical significance is unknown.

### IMPORTANT SAFETY INFORMATION (continued) PRECAUTIONS (continued)

Bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh.

### **ARTIA<sup>™</sup> RTM** is available by prescription only.

For more information, please see the Instructions for Use (IFU) for ARTIA<sup>™</sup> RTM available at www.rxabbvie.com/pdf/artia\_ifu.pdf or call 1.800.678.1605.

For product complaints and potential adverse events, please contact your local Sales Representative, or 1.800.433.8871.

Please see additional Important Safety Information throughout this brochure.

# ARTIA<sup>™</sup> offers an extensive portfolio that aligns with your clinical needs





Ready to use out of the package following a 2-minute soak<sup>1</sup>

# ARTIA<sup>™</sup> is available in a variety of sizes, shapes, and textures

oduct Description	Piece Size	Coverage	Product Code
Contour Perforated	X-Large - 11.8 cm x 23.7 cm	200 cm <sup>2</sup>	CXL1097P
	Large - 10.7 cm x 21.5 cm	164 cm <sup>2</sup>	CL1097P
	Medium - 9.6 cm x 19.3 cm	132 cm <sup>2</sup>	CM1097P
	Small - 7.3 cm x 14.7 cm	77 cm <sup>2</sup>	CS1097P
Contour	X-Large - 11.8 cm x 23.7 cm	200 cm <sup>2</sup>	CXL1097
	Large - 10.7 cm x 21.5 cm	164 cm <sup>2</sup>	CL1097
	Medium - 9.6 cm x 19.3 cm	132 cm <sup>2</sup>	CM1097
	Small - 7.3 cm x 14.7 cm	77 cm <sup>2</sup>	CS1097
Perforated	16 cm x 20 cm	320 cm <sup>2</sup>	16201097P
Nonperforated	16 cm x 20 cm	320 cm <sup>2</sup>	16201097
	8 cm x 20 cm	160 cm <sup>2</sup>	08201097
	10 cm x 16 cm	160 cm <sup>2</sup>	10161097
	8 cm x 16 cm	128 cm <sup>2</sup>	08161097
	6 cm x 16 cm	96 cm <sup>2</sup>	06161097

Does not require refrigeration—can be stored at room temperature<sup>7</sup>



# **AlloDerm<sup>™</sup> Important Safety Information**

### INDICATIONS

ALLODERM SELECT<sup>™</sup> Regenerative Tissue Matrix (ALLODERM SELECT<sup>™</sup> RTM refers to both ALLODERM SELECT<sup>™</sup> RTM and ALLODERM SELECT RESTORE<sup>™</sup> 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.

### 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<sup>™</sup> 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<sup>™</sup> RTM.

**DO NOT** re-sterilize ALLODERM SELECT<sup>™</sup> 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.

### 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<sup>™</sup> 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.

ALLODERM SELECT<sup>™</sup> 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.

ALLODERM SELECT<sup>™</sup> 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 (e.g., 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<sup>™</sup> RTM.

### **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.

**ALLODERM SELECT<sup>™</sup> RTM is available by prescription only.** 

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.

# **STRATTICE<sup>™</sup> Important Safety Information**

#### INDICATIONS

STRATTICE™ Reconstructive Tissue Matrix (RTM). STRATTICE™ RTM Perforated. STRATTICE™ RTM Extra Thick. and STRATTICE™ RTM Laparoscopic are intended for use as soft tissue patches to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use of these products include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. STRATTICE™ RTM Laparoscopic is indicated for such uses in open or laparoscopic procedures. These products are supplied sterile and are intended for single patient one-time use only.

### **IMPORTANT SAFETY INFORMATION** CONTRAINDICATIONS

These products should not be used in patients with a known sensitivity to porcine material and/or Polysorbate 20.

#### WARNINGS

Do not resterilize. Discard all open and unused portions of these devices. Do not use if the package is opened or damaged. Do not use if seal is broken or compromised. After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

**Do not reuse** once the surgical mesh has been removed from the packaging and/or is in contact with a patient. This increases risk of patient-to-patient contamination and subsequent infection.

For STRATTICE<sup>™</sup> RTM Extra Thick, **do not use** if the temperature monitoring device does not display "OK."

### PRECAUTIONS

Discard these products if mishandling has caused possible damage or contamination, or the products are past their expiration date. Ensure these products are placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation in the body. Place these products in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling. These products should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.

Certain considerations should be used when performing surgical procedures using a surgical mesh product. Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation. Bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh. In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.

implantation.

For STRATTICE<sup>™</sup> RTM Laparoscopic, refrain from using excessive force if inserting the mesh through the trocar.

### STRATTICE™ RTM, STRATTICE™ RTM Perforated, STRATTICE™ RTM Extra Thick, and STRATTICE™ RTM Laparoscopic are available by prescription only.

For more information, please see the Instructions for Use (IFU) for all STRATTICE™ RTM products available at www.allergan.com/STRATTICEIFU or call 1.800.678.1605.

### To report an adverse reaction, please call Allergan at 1.800.367.5737.

References: 1. Allergan Inc. Artia™ Reconstructive Tissue Matrix Instructions for Use, 2018. 2. Data on file, Allergan; Study Report LRD-2014-01-002. 3. Data on file, Allergan; Study Report LRD-2017-06-009. 4. Data on file, Allergan; Study Report LRD-2015-12-002. 5. Data on file, Allergan; Study Report LRD-2016-08-005. 6. LifeCell Corporation (1994, August 3). LifeCell Corporation reports second quarter results: announces formation of AlloDerm® advisory board. [Press release]. 7. Data on file, Allergan; Study Report DTM-LDC-14-02. 8. Data on file, Allergan; Study Report LRD-2016-02-011. 9. Harper JR, McQuillan DJ. Extracellular wound matrices: a novel regenerative tissue matrix (RTM) technology for connective tissue reconstruction. Wounds. 2007;19(6):163-168. 10. Xu H, Wan H, Sandor M, et al. Host response to human acellular dermal matrix transplantation in a primate model of abdominal wall repair. Tissue Eng Part A. 2008;14(12):2009-2019. 11. Sandor M. Xu H. Connor J. et al. Host response to implanted porcine-derived biologic materials in a primate model of abdominal wall repair. Tissue Eng Part A. 2008;14(12):2021-2031.

For STRATTICE<sup>™</sup> RTM Perforated, if a tissue punch-out piece is visible, remove using aseptic technique before



FROM THE MARKET LEADERS AND PIONEERS IN ADM TECHNOLOGY

# ARTIA<sup>™</sup> RTM Our next advancement in porcine-derived ADM<sup>1</sup>



## POSITIVE BIOLOGIC RESPONSE<sup>2,\*</sup> - CONSISTENCY<sup>3,4,†</sup> - PLIABILITY<sup>5,†</sup>

\*Correlation of these results to results in humans has not been established. \*Clinical significance is unknown.

ADM=acellular dermal matrix; RTM=regenerative tissue matrix.

# **Contact Us**



For more information, visit us at ARTIATISSUEMATRIX.com or call Allergan Aesthetics Customer Service at 1.800.367.5737



### **INDICATIONS**

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### CONTRAINDICATIONS

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