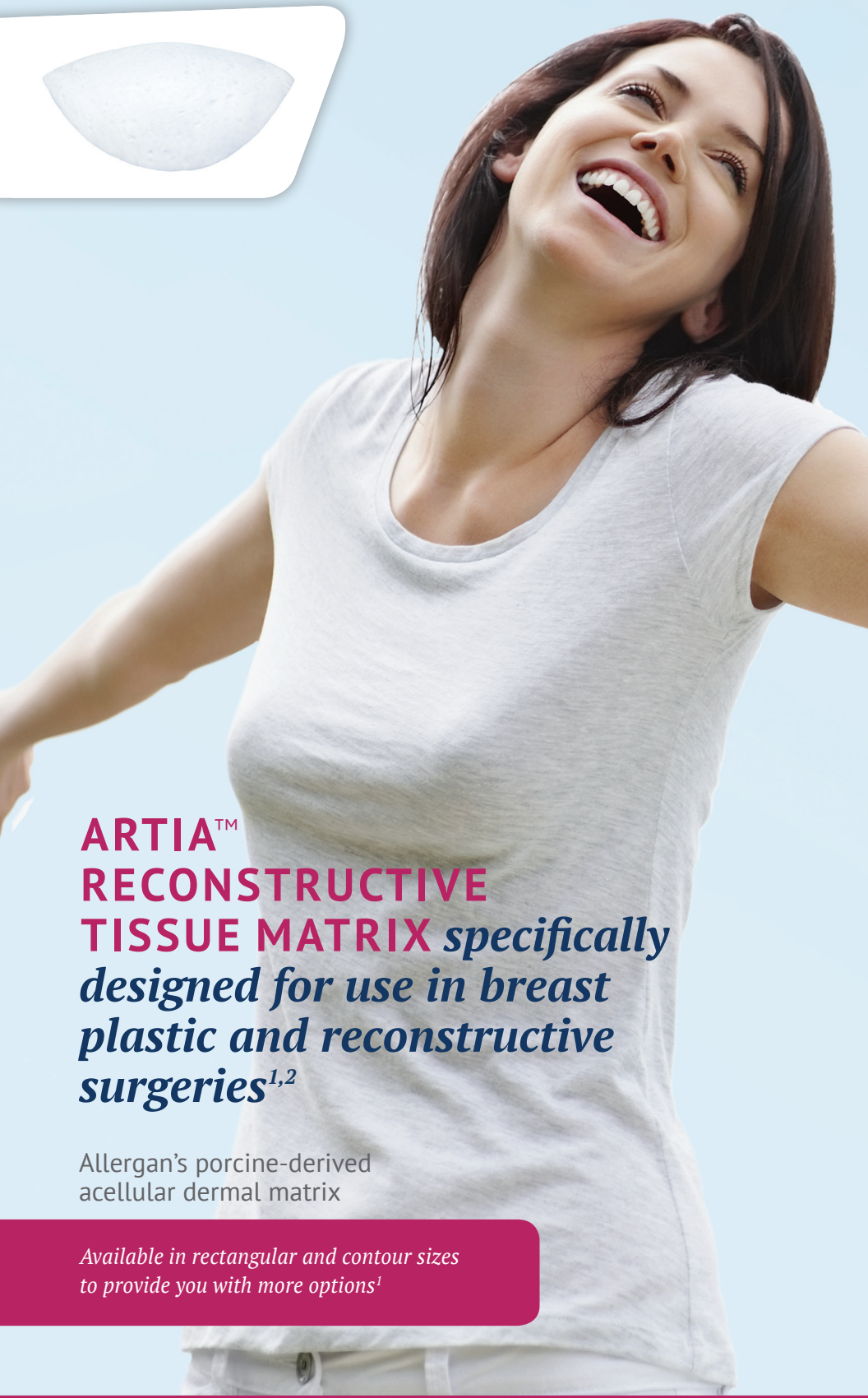

# ARTIA™ RECONSTRUCTIVE TISSUE MATRIX *specifically designed for use in breast plastic and reconstructive surgeries*[1,2]

Allergan's porcine-derived acellular dermal matrix

*Available in rectangular and contour sizes to provide you with more options*[1]

Allergan

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ARTIA

## WHAT IS ARTIA™
## Reconstructive Tissue Matrix?

- A **sterilized, surgical mesh that is derived from porcine skin**, and is processed and preserved in a patented aqueous phosphate-buffered solution containing matrix stabilizers[2]
- A **tissue patch designed to reinforce soft tissue** where weakness exists, and for the surgical repair of damaged or ruptured soft tissue membranes[2]
- Provides for a **strong and biocompatible implant** that will incorporate into the patient's tissue with associated cell and microvascular ingrowth[2]

### *Product characteristics[2]*

- Pre-sterilized[2]
- Does not require refrigeration—can be stored from -8°C–30°C[2]
- Ready-to-use out of the package following a 2-minute soak in sterile saline or lactated Ringer's solution[2]
- Once opened and retained in sterile solution, must be used within 4 hours[2]

### *Perforated options designed to:[1]*

- Allow fluid to flow through matrix[1]
- Support tissue ingrowth[1,3*]
- Incorporate a 1.2 cm space around the perimeter of the perforation pattern in each piece to avoid suturing interference[1]

### *Contoured shape options specifically designed for breast reconstruction, and designed to:[1]*

- Reduce time for product trimming[1]
- Make intraoperative placement easier and more predictable[1]

Consider Artia™ to **reconstruct, recontour and reform** human soft connective tissue[2]

* As demonstrated in a non-human primate abdominal wall model

## HOW DOES ARTIA™ COMPARE
## to other acellular dermal matrices (ADMs)?

Artia™ enables the surgical repair of damaged or ruptured soft tissue membranes in breast plastic and reconstructive applications[2]

### *Material performance*

### Drape
(ratio of draped area over undraped area)

- Artia™ demonstrated **superior drapability** than Strattice™ Pliable[4]
- Artia™ demonstrated statistically similar drapability to AlloDerm™[4]

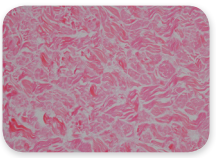
### Variability in tissue stretch
(standard variability in strain)

- Artia™ demonstrated **3x less variation in stretch** than AlloDerm™[5]
- Artia™ demonstrated a **higher average strain than Strattice™ Pliable**[5]
- In terms of stretch, Artia™ behaved in a **more predictable** way than AlloDerm™ RTU[6]

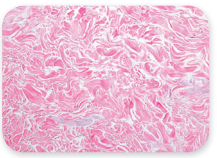
### Thickness uniformity
(standard deviation in thickness)

- Artia™ demonstrated a **more uniform thickness from piece to piece** than AlloDerm™[7]
- Compared to AlloDerm™, Artia™ demonstrated similar **thickness consistency within pieces**[7]

### Out-of-the-package histology[8]
[hematoxylin and eosin (H&E) staining]



H&E staining of Artia™
Image courtesy of Allergan



H&E staining of AlloDerm™
Image courtesy of Allergan

- Artia™ demonstrated **similar histological microstructure to AlloDerm™**, both of which are structurally **similar to human tissue**[8]

Artia™ offered equal or better handling, drapability, and ease of suturing through compared to Strattice™ Pliable and SurgiMend®[9]*

* Based on qualitative evaluation by European surgeons (n=10).

## HOW DOES ARTIA™ COMPARE
## to other acellular dermal matrices (ADMs)?

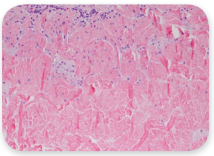
### *Preclinical results*

Artia™ demonstrated superior biologic response to Strattice™ Pliable in the immune-competent-rat-subcutaneous-implant model at both 2 and 4 weeks[10]

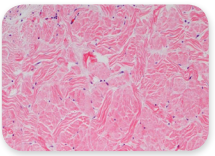
### Inflammatory response
(Monocyte activation)

- **Human monocytes did not activate** in presence of Artia™ in vitro, similar to AlloDerm™[11]
- Artia™ demonstrated a **minimized immunological response** in vitro[11]

### Subcutaneous in vivo testing
(Immune-competent rodent, H&E staining)



Strattice™ at 4 weeks
(10x magnification)[12]
Image courtesy of Allergan



Artia™ at 2 weeks
(10x magnification)[12]
Image courtesy of Allergan

- Artia™ demonstrated **less inflammatory cell infiltration and greater and more consistent cell repopulation** (fibroblasts) compared to Strattice™[12]

### Subcutaneous in vivo testing
(non-human primate model)

- The overall **biologic response** of Artia™ was found to be **superior to Strattice™ Pliable**[13]
- The overall **biologic response** of Artia™ was found to be **equivalent to AlloDerm™**[13]

Artia™ is the latest addition to the ADM family and offers better biologic response compared to Strattice™ Pliable, as demonstrated in a primate model[13]

## HOW DOES ARTIA™ COMPARE
## to other acellular dermal matrices (ADMs)?

### *Clinical results*

In a short-term safety profile evaluating the outcomes following the use of Artia™ in consecutive immediate implant-based breast reconstruction in 17 patients,[14]

- There were **no implant losses** (mean follow up of 177 days), compared with over 9% identified in an audit for the Implant Breast Reconstruction evAluation (IBRA) study[14]
- Artia™ appeared to provide an **effective, functional, reconstructive matrix with a generally good safety profile** when utilised for either therapeutic or prophylactic mastectomy with implant reconstruction[14]
- Investigators stated they associated Artia™ with **minimal post-operative complications** and **good patient satisfaction**[14]

Outcome data in patients who had received Artia™-assisted breast reconstruction was compared to patients recipient of other ADMs such as Strattice™ or Surgimend™[15]

- Artia™ was **used in 31 patients** undergoing 51 implant-based breast reconstructions between July 2016 and August 2017[15]
- The **overall complication rate was 9.8%** with reports of complications in 5 breasts from 4 patients (mean follow-up of 171 days)[15]
    - Minor complications: 3 cases of seromas which were drained in the post-operative clinic appointment[15]
    - Major complications: 1 patient suffered bilateral implant losses following infection and skin necrosis[15]
- **No delays to adjuvant treatment** in therapeutic cases[15]
- **Complication rates compared with those of well-established ADMs** such as Strattice™, Surgimend™ and AlloDerm™ from literature[15]

Artia™ has been demonstrated in breast reconstruction patients to be effective, with a generally good safety profile, and with minimal post-operative complications.[14,15]

## ORDERING INFORMATION

### *Artia™ RTM*

Allergan's porcine-derived acellular dermal matrix for breast reconstruction

### *Artia™ RTM*[1]

| Product Code | | Product Size | Coverage |
|---|---|---|---|
| 06161097EU | 06161097 | 6 x 16 cm | 96 $cm^2$ |
| 08161097EU | 08161097 | 8 x 16 cm | 128 $cm^2$ |
| 10161097EU | 10161097 | 10 x 16 cm | 160 $cm^2$ |
| 08201097EU | 08201097 | 8 x 20 cm | 160 $cm^2$ |

## ORDERING INFORMATION

### *Artia™ Contour*

Specifically designed for breast reconstruction[1]

### *Artia™ Contour*[1]

| Product Code | | Product Size | Coverage |
|---|---|---|---|
| CS1097EU | CS1097 | Contour Small<br>14,7 x 7,3 | 77 $cm^2$ |
| CM1097EU | CM1097 | Contour Medium<br>9.6 x 19.3 cm | 132 $cm^2$ |
| CL1097EU | CL1097 | Contour Large<br>10.7 x 21.5 cm | 164 $cm^2$ |
| | CXL1097 | Contour X-Large<br>23,7 x 11,8 | 200 $cm^2$ |

## ADDITIONAL INFORMATION

### *Ordering:*

To place an order, please call **GD Medical at 040 - 3031090**, contact your account manager or visit **gdmedical.nl**.

Please refer to the package insert supplied with each device for indications, contraindications, warnings, instructions for use, limited warranty, and patient, physician, and manufacturer information.

### *Adverse events and reporting:*

Potential adverse events are those typically associated with the surgical mesh materials and/or their implantation procedures including, but not limited to, infection, foreign body response, failure to integrate, hematoma, seroma formation, lack of tissue perfusion, wound dehiscence, recurrence of tissue defect, and inflammation. If an unanticipated event occurs, alteration of surgical plan may be necessary at the surgeon's discretion.[2]


**References:**

**1.** Allergan Inc. Unpublished Data: LifeCell Portfolio—Product Options, INT/0218/2018. **2.** Allergan Inc. Artia™ Reconstructive Tissue Matrix Instructions for Use, 2018. **3.** Allergan Inc. Data on File: Evaluation of Immune/Inflammatory Response, Collagen Deposition, and Myofibroblast Prescence in Perforated Porcine Acellular Dermal Matrix (pADM), INT/0260/2018. **4.** Allergan Inc. Data on File: Artia™ In-Vivo testing – Draping, INT/0768/2017(1). **5.** Allergan Inc. Data on File: Artia™ – Mechanical testing, INT/0770/2017. **6.** Allergan Inc. Data on File: Artia™ tissue stretch, INT/0204/2018. **7.** Allergan Inc. Data on Fie: Comparative Testing of ADMs - Thickness, INT/0225/2018. **8.** Allergan Inc. Data on File: Artia™ In-Vitro Testing, out of package histology, INT/0779/2017. **9.** Allergan Inc. Data on File: Artia™ Hands-on assessment, INT/0261/2018. **10.** Allergan Inc. Data on File: Artia™ & Strattice™, 4 week histology, INT/0767/2017. **11.** Allergan Inc. Data on File: Artia™, measure monocyte activation by flow cytometry, INT/0764/2017a. **12.** Allergan Inc. Data on File: Artia™ vs. Strattice™ in an immune competent rodent - LRD2014-05-003, INT/1022/2017. **13.** Allergan Inc. Data on File: Artia™ Results from non-human primate subcutaneous model, INT/0769/2017. **14.** Wood B, Tait C, Linforth R. The short-term safety profile of Artia™ ADM implant based immediate breast reconstruction. Poster session presented at: Oncoplastic and Reconstructive Breast Surgery International Scientific Meeting; 2017 Sept 25-27; Nottingham UK. 2017. **15.** Fakim B, Highton L, Murphy L. Breast reconstruction with Artia™. Poster session presented at: Oncoplastic and Reconstructive Breast Surgery International Scientific Meeting; 2017 Sept 25-27; Nottingham UK. 2017.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