

















## DEFINITIONS

	CONTENTS		OPEN HERE		DO NOT USE IF PACKAGE IS DAMAGED
	CORRECT SETTING		INCORRECT SETTING		MANUFACTURED BY
	ATTENTION, SEE INSTRUCTIONS FOR USE		STERILIZED USING IRRADIATION		DO NOT RE-STERILIZE
	FOR SINGLE USE ONLY		TEMPERATURE LIMITATIONS		USE BY DATE
	CATALOG NUMBER		LOT NUMBER	<b>Rx ONLY</b> CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.	
	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		PERFORATED		

## CUSTOMER SUPPORT

For product complaints and potential adverse events, please contact your local Sales Representative, or 1-800-433-8871.


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July 2017

 Manufactured by:  
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Branchburg, NJ 08876 USA



# ARTIA™ Reconstructive Tissue Matrix

## Surgical Mesh

### DEVICE DESCRIPTION

ARTIA™ Reconstructive Tissue Matrix (“ARTIA™ TM” or “the surgical mesh”) is a surgical mesh that is derived from porcine skin that is processed and preserved in a patented phosphate buffered aqueous solution containing matrix stabilizers. This device is designed to perform as a surgical mesh for soft tissue repair while presenting a scaffold for cellular and microvascular ingrowth. ARTIA™ Tissue Matrix consists of a terminally sterilized sheet of processed porcine dermal matrix provided in various geometric configurations and packaged in a plastic holder enclosed within a pouch.

Use of ARTIA™ Tissue Matrix provides for an implant that is strong and biocompatible for its intended use and which will incorporate into the recipient tissue with associated cellular and microvascular ingrowth.

### INDICATIONS FOR USE

ARTIA™ Tissue Matrix 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™ Tissue Matrix is intended for single patient, one time use only.

### CONTRAINDICATIONS

- ARTIA™ Tissue Matrix is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- Polysorbate 20 is a component of the phosphate buffered aqueous solution and therefore ARTIA™ Tissue Matrix should not be used in patients with a known sensitivity to this material.

**Rx ONLY** CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

### WARNINGS

- **Do not resterilize.** Discard all open and unused portions of the 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™ 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 (e.g., hernia repair).

## PRECAUTIONS

- The use of ARTIA™ Tissue Matrix in breast reconstruction has not been studied in a prospective clinical trial.
- Discard the surgical mesh if mishandling has caused possible damage or contamination, or the device is past its expiration date.
- Ensure that 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 surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell in-growth and tissue remodeling.
- The surgical mesh should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.
- If a tissue punch-out piece is visible, remove using aseptic technique before implantation.
- 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.
  - As standard practice, 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 to implantation of the surgical mesh.

## STORAGE

- ARTIA™ Tissue Matrix is a sterile medical device that should be stored in a clean, dry location at room temperature.
- Store in original packaging.
- Refer to the included temperature monitor to ensure that product has been stored within tolerance limits. Only use the product if the included temperature monitor displays "OK" on the screen. If screen displays anything other than "OK", do not use the product.
- The expiration date of the product is indicated as 4 digit year, 2 digit month, and 2 digit day (YYYY-MM-DD).

## STERILIZATION

- This product is sterilized by electron beam irradiation.

## INSTRUCTIONS FOR PREPARING ARTIA™ TISSUE MATRIX FOR SURGICAL USE

These instructions are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. Users should be familiar with surgical procedures and techniques involving surgical mesh before using ARTIA™ Tissue Matrix.

## REQUIRED MATERIALS

- Sterile forceps
- Soaking fluid: room temperature sterile saline or room temperature sterile lactated Ringer's solution
- One sterile basin per piece of surgical mesh.

## PREPARATION INSTRUCTIONS

1. Open the carton and remove the foil package.
2. Peel open the outer foil package and remove the plastic holder using aseptic technique. The plastic holder is sterile and may be placed directly into the sterile field.
3. Open the plastic holder carefully and aseptically remove the surgical mesh. Always use sterile gloved hands or forceps when handling the device.
4. Soak the surgical mesh for a **minimum of 2 minutes** using a sterile basin and sufficient room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the device.
5. Store the surgical mesh in the room temperature sterile solution until ready for implantation. Device can be stored in room temperature sterile solution for a maximum of 4 hours.

## IMPLANTATION INSTRUCTIONS

1. Prepare the surgical site using standard techniques. As with any surgical implant, careful aseptic technique should be practiced and contact of the mesh with the patient's skin should be minimized.
2. The surgical mesh may be folded, trimmed or cut as required to fit the surgical site using aseptic technique, ensuring allowance for overlap.
3. Transfer the surgical mesh to the surgical site using sterile gloved hands or forceps.
4. Secure the surgical mesh into place.
5. The surgical mesh should be placed in good approximation with healthy adjacent tissues without leaving potential spaces for fluid accumulation between the mesh and the adjacent tissues. Care should be taken to avoid placing the mesh adjacent to ischemic or poorly vascularized tissues whenever possible.
6. Complete the standard surgical procedure.
7. Discard any unused portions of the surgical mesh as per institutional procedures.

## POST-OPERATIVE CARE RECOMMENDATIONS

1. Proper post-operative care may include the use of appropriate drainage and negative pressure therapy.
2. As with any post-operative care, aseptic technique should be practiced when required to minimize contamination to the surgical wound.