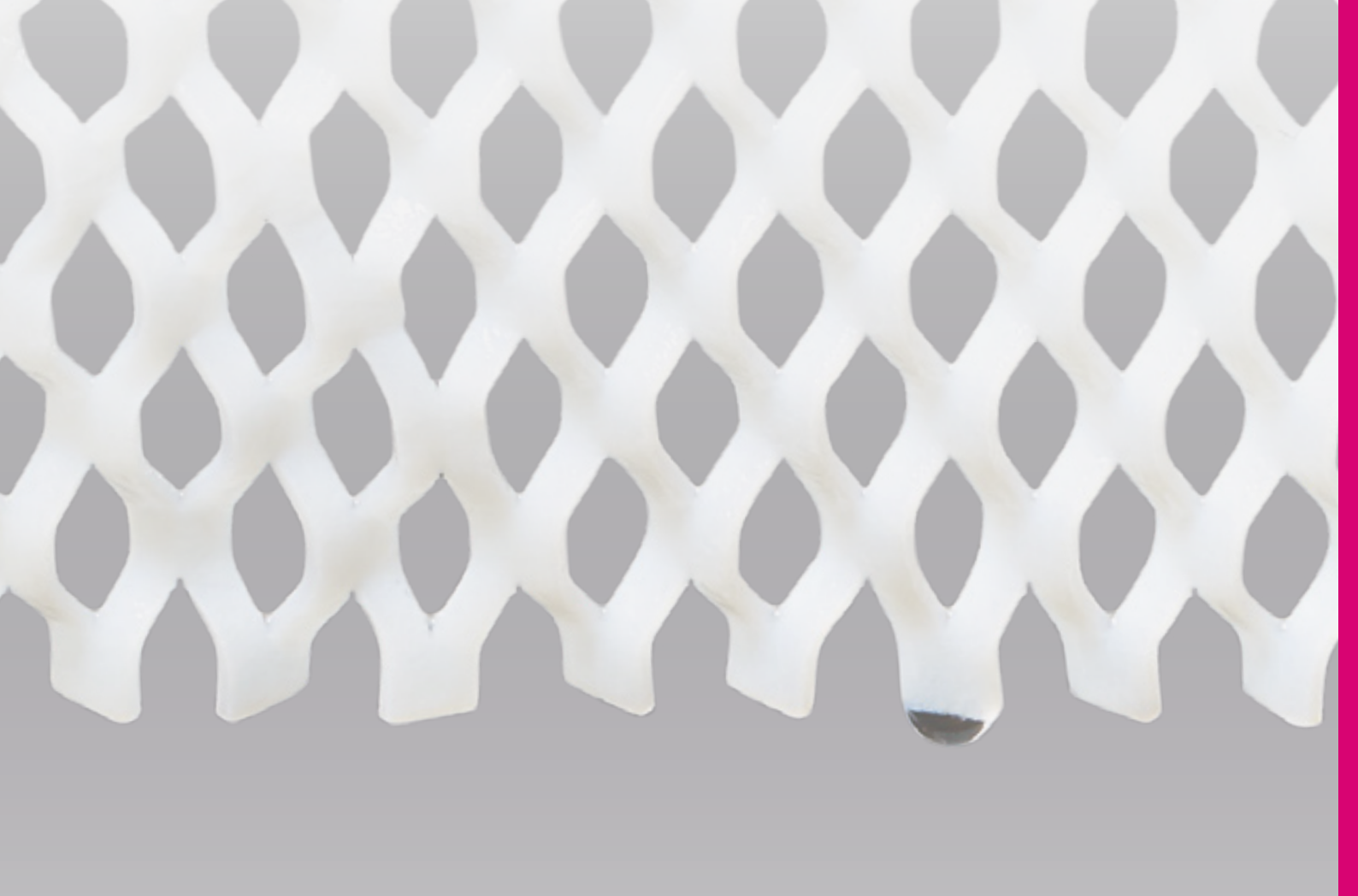




# **SurgiMend® PRS Meshed**

in pre-pectoral direct to implant  
immediate breast reconstruction

**PROCEDURAL GUIDE**  
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Mr. Gui was awarded the Master of Surgery degree from the University of London and is a Teacher and Examiner for the University of London. He is also Honorary Senior Lecturer at the Institute of Cancer Research, London.

**SurgiMend® PRS Meshed in pre-pectoral direct to implant immediate breast reconstruction**

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# Introduction

Biological acellular dermal matrices have become an established adjunct to implant based immediate breast reconstruction. With regenerative capacity to form a healthy pocket around an implant, the ability to create a stable reconstruction has led to a rise in popularity of direct to implant breast reconstruction. Although termed one-stage in concept, breast reconstruction is best considered a process of care where secondary procedures to optimise breast form and symmetry are offered. With implant breast reconstruction, there is also a likely need for maintenance surgery over time. Two-stage tissue expansion surgery, where patients are committed to implant exchange at a second surgical procedure, can now be reserved for at risk patients where the soft-tissue environment may be suboptimal and gentler to the skin and the healing surgical incision. Recent developments in implant reconstruction have focused on pre-pectoral techniques of implant placement. This technique reduces the surgical trauma created by raising the pectoralis major off the lower rib cage, thus contributing to an easier post-operative recovery with less pain, preservation of shoulder function and muscle power,

with significant reduction of animation deformity. The quest for pre-pectoral implant placement has been revolutionised by SurgiMend® Meshed biological matrix. This is available in 20x10cm sheets that when rehydrated and stretched increase to approximately 18x22cm and can easily provide full implant cover of full projection implants in standard use. It is a very versatile product that is simple to use. The SurgiMend® Meshed spaces allow for easy tissue ingrowth for rapid integration whilst maintaining high tensile strength required for implant support. With increasing acceptance of nipple sparing mastectomies in the appropriate oncologic context, SurgiMend® Meshed offers excellent implant cover as a biological meshed matrix when remote incisions off the breast mound are used, such as in the inframammary crease or lateral approach from the breast periphery. The dominant nipple blood supply through the breast gland is disrupted by mastectomy, and nipple viability depends on the blood supply through the skin, derived mainly through intercostal perforators, which should be consciously maintained during surgery, and through the subdermal plexus.

| Patient Selection Criteria                                                                                                                                                                                                                                                                                                                                                                    | Risk Factors                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Applicable to most patients with early breast cancer.<br>Risk-reducing mastectomy.                                                                                                                                                                                                                                                                                                            | Poor quality thin skin with compromise to mastectomy flap blood supply, such as extensive exposure of dermis and disruption of subdermal plexus. |
| Suitable for implant based reconstruction after immediate breast reconstruction.                                                                                                                                                                                                                                                                                                              | Previous or planned radiotherapy.                                                                                                                |
| Well performed mastectomy is essential.                                                                                                                                                                                                                                                                                                                                                       | Co-morbid risk factors: e.g. diabetes, connective tissue disorders.                                                                              |
| Careful surgical attention must be paid to the soft tissues of the mastectomy flap to: <ul style="list-style-type: none"><li>• Preserve vascularity to maximise restorative capacity of Acellular Dermal Matrix interface between flap and implant.</li><li>• Edges of skin incision for uncomplicated wound healing.</li><li>• Good quality skin- flap in a stable implant pocket.</li></ul> | Patient factors: e.g. smokers.                                                                                                                   |

## Step 1

### Pocket preparation



After the mastectomy is complete, haemostasis is secured and the surgical pocket is prepared for implant placement. A wash with sterile water or normal saline whilst normotension is maintained by the anaesthetist allows checks for bleeding points and the security of diathermied points or suture ligations to be made. Irrigation of the pocket with sterile water or normal saline mixed with betadine 50:50 by volume helps to maintain sterility (Figure 1).



Neat BETADINE® is used to re-prepare the skin (Figure 2). New surgical drapes may be applied or reinforced as appropriate. A single drain is placed into the pre-pectoral pocket.

## Step 2

### Rehydration of SurgiMend® PRS Meshed

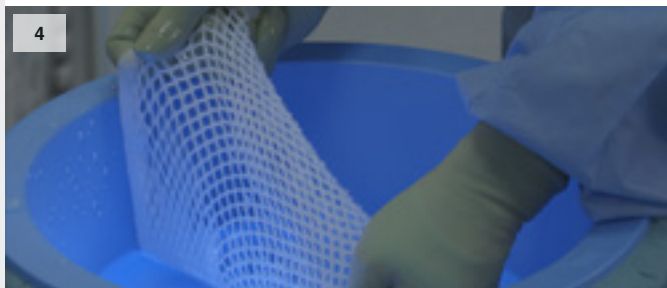


SurgiMend® Meshed is prepared on a surgical trolley set-up immediately prior to use, to include containers for receiving implant and sizers, as well as the working surface to trim the matrix to size. When the team is ready, the SurgiMend® Meshed packaging is opened and placed into the sterile bath set up at room temperature (Figure 3).

SurgiMend® Meshed rehydrates fully within 30 seconds and is then ready for use. Personnel movement through theatres should be restricted, especially at the time of matrix preparation.

### Step 3

#### Stretching the SurgiMend® PRS Meshed



SurgiMend® Meshed stretches in one direction. The matrix should be pulled firmly and deliberately three times to achieve maximal length across the entire width of the biological matrix (Figure 4).

The elasticity in this stretched axis is best used to orientate in the cranio-caudal plane of the breast reconstruction, to mimic the intended direction and tension in the upright position and to best reproduce the natural hang and pseudoptosis of the breast.

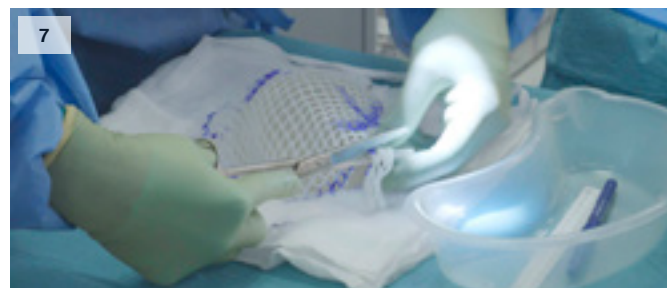
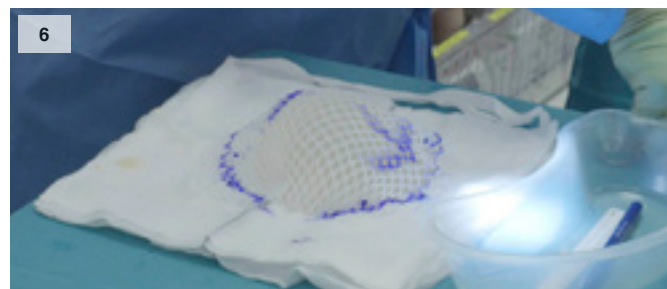
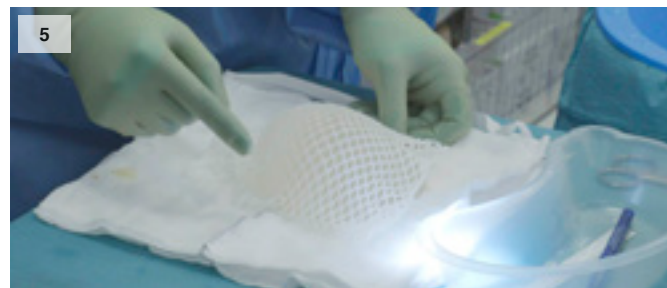
## Step 4

### Preparation of SurgiMend® PRS Meshed

The stretched SurgiMend® Meshed is draped over the sizer on the sterile preparation table, carefully marked and trimmed to size (Figure 5).

The biological matrix can be used either to fit comfortably over the implant, or designed to allow excess biological matrix to be tucked around and under the implant (Figure 6). Unless the implant chosen is very small, SurgiMend® Meshed is unlikely to cover both the anterior and posterior surfaces.

Tucking the SurgiMend® Meshed over the inferior pole of the implant allows the lower pole of the implant to rest in a hammock to create pseudoptosis. Whichever method is chosen, SurgiMend® Meshed is trimmed on the preparation table to suit the surgical design. An orientation arrow in the meridian of the trimmed SurgiMend® Meshed allows for accurate placement when the biological matrix is subsequently sited in the surgical pocket (Figure 7).

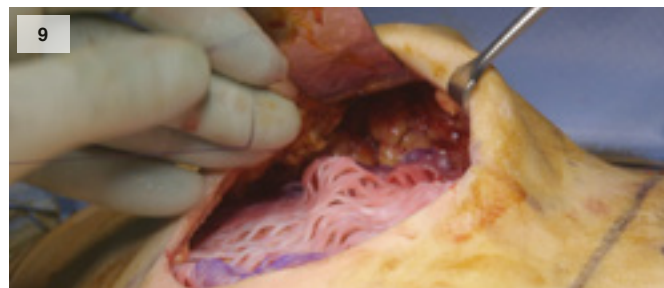


## Step 5

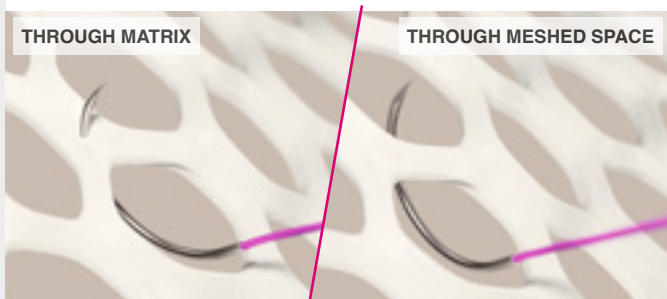
### Placing and suturing SurgiMend® PRS Meshed



When the pre-prepared surgical site is ready, an extra BETADINE® soaked gauze can be used to protect the biological matrix from direct skin contact at the time of placement. The biological matrix should be placed and orientated once (with the help of the marked arrows), to avoid unnecessary manipulation to avoid contamination (Figure 8).



The matrix can be displaced and result in exposure of the implant to the anterior skin flap, or become bunched up and creased, disrupting effective integration of matrix at the biological interface. Either could result in unevenness of the mastectomy surface and cause unwanted tethering. As the suturing technique is easy, there is ready access to the breast periphery even with nipple-sparing mastectomy through an inframammary skin crease incision (Figure 9).

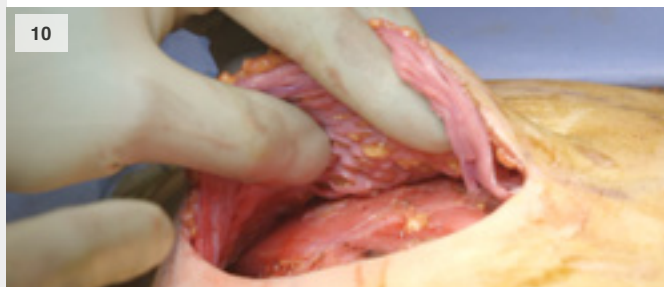


The matrix is sutured to the periphery of the desired implant footprint using an absorbable monofilament such as 3/0 PDS sutures. The suture can be positioned through the matrix itself, or through the meshed space.

## **Step 6**

### **Avoiding displacement of SurgiMend® PRS Meshed**

Commonly, 2-3 sutures are placed at each of the superior, inferior and medial borders of the biological matrix. For an inframammary crease incision, with these sutures in place, holding the free inferior edge to the mastectomy skin flap whilst placing the implant avoids matrix displacement (Figures 10 & 11).



## **Step 7**

### **Checking implant position, draping & slope of cleavage**

With the implant placed and before the inferior sutures are placed, the implant position is checked, ensuring adequate draping of the soft tissues including SurgiMend® Meshed, over the implant. The external surface markings are checked for the desired implant position.



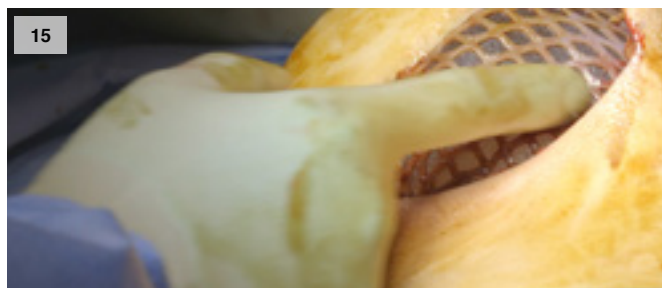
The position and slope of the cleavage surface is checked, recognising that this is controlled not only by the medial position of the implant but also by lateral pocket closure and therefore the position of the sutures at the lateral matrix border (Figure 12).

## Step 8

### Final positioning of SurgiMend® PRS Meshed & suturing

If the inframammary crease has not been opened at the time of mastectomy, implant dislocation in the caudal direction is unlikely. If the inframammary crease has been opened, the inframammary crease needs to be repaired, with or separately from the reinforcing sutures of the matrix inferiorly. SurgiMend®. SurgiMend® PRS Meshed should sit comfortably around the implant before the sutures to close the inferior pocket are placed (Figure 13).

The inferior sutures are placed either to fit the footprint of the implant to match the inframammary crease (Figure 14), or to cradle the implant in a hammock with the sutures placed posteriorly on the chest wall (Figure 15).



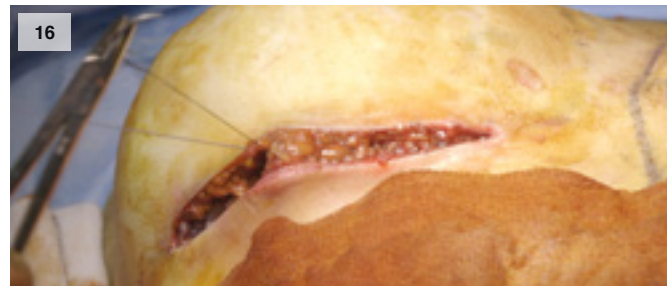
## Step 9

### Closure and dressing

It is important that three layer closure of the mastectomy incision is achieved such that the surgical pocket containing the biological matrix and pre-pectoral implant is airtight and water-tight at the end of the operation.

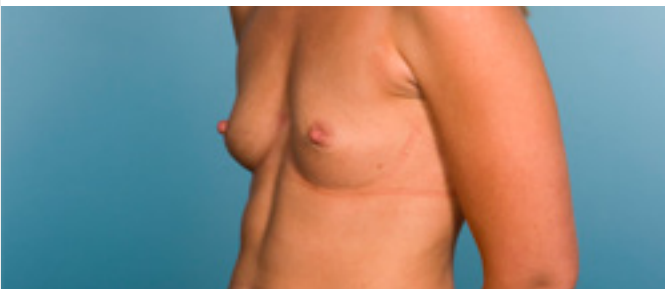
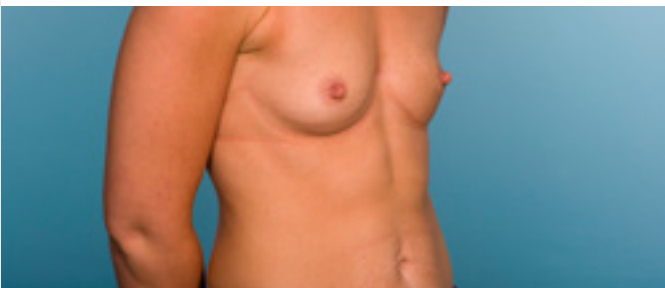
Figure 16 shows closure of the deepest layer incorporating fascia, not just fat. The final result is checked with the patient sitting and dressings are applied (Figure 17).

Surgical drains are typically removed when volumes are less than 30ml per day.



## Bilateral risk reducing mastectomies with implants and SurgiMend® Meshed in a BRCA-1 carrier

Pre-operative views



Post-operative views



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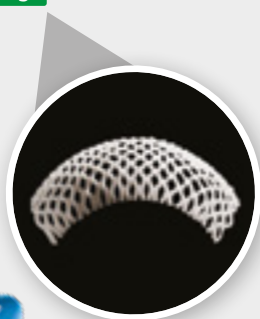
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**SurgiMend® PRS Meshed** is a 2:1 expandable acellular collagen matrix for pre-pectoral breast reconstruction without detrimental inflammation that may lead to rapid degradation or encapsulation.

SurgiMend PRS Meshed is an expandable matrix that provides up to twice the out-of-the-box area once hydrated and fully expanded. It features a meshed design which allows for:

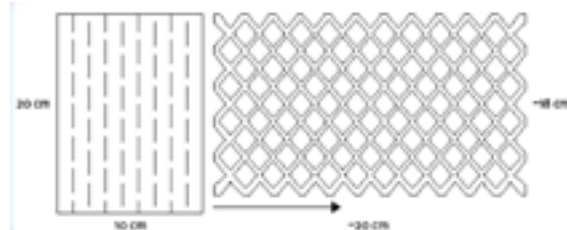
- **Improved implant conformity**

- Vascular ingrowth
- Fluid drainage



All SurgiMend PRS products are derived from fetal bovine dermis which is rich in Type III collagen<sup>1</sup>. Type III collagen has shown to mediate tissue healing and regrowth while inhibiting scarring.<sup>2,3</sup>

SurgiMend PRS is without preservatives, denatured proteins, artificial chemical crosslinks, cells, lipids, carbohydrates or other constituents, all of which can induce inflammation. As a result, SurgiMend PRS does not elicit a detrimental inflammatory response upon implantation.<sup>4,5</sup>



**2:1 meshed design  
allows unique adjustment**

SurgiMend PRS Meshed provides up to **400cm<sup>2</sup>** of coverage when hydrated and fully expanded.<sup>6</sup>

*Post-Hydrated Meshed*

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5. Data on file, internal testing PDR 252.

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# SurgiMend® PRS Meshed in pre-pectoral direct to implant immediate breast reconstruction

Gerald Gui, Consultant Oncoplastic Surgeon, Royal Marsden NHS Trust

## Indications

SurgiMend PRS / SurgiMend PRS Meshed is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. SurgiMend PRS / SurgiMend PRS Meshed is specifically indicated for plastic and reconstructive surgery, including breast reconstruction.

## Contraindications

- SurgiMend should not be used for patients with a known history of hypersensitivity to collagen or bovine products.

## Warnings and Precautions

- Excessive heat can damage collagen. Do not hydrate in 0.9% saline warmed above room temperature. If, when hydrated, the product shrinks in size, DO NOT use the device.
- The device should be used with caution in regions where infection exists or is suspected. Treat any existing infection appropriately. If used in contaminated or infected wounds, collagen-based implants can weaken or break down.
- The device is for single patient use only.
- Do not use the device if the foil seal is broken.
- Discard all opened and unused portion(s) of the device.
- Do not re-sterilize the device.
- The device has not been evaluated for use in pregnant women.
- The patient's medical condition may adversely impact healing of the deficient tissue. These conditions may include, but are not limited to: obesity, smoking, diabetes, insufficient blood supply at the implant site, and exposure of the implant site to radiotherapy and chemotherapy.
- Do not use the device past the expiration date.
- Do not mesh or fenestrate the device.



As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- WARNING: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

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