

# SurgiMend<sup>®</sup> MP

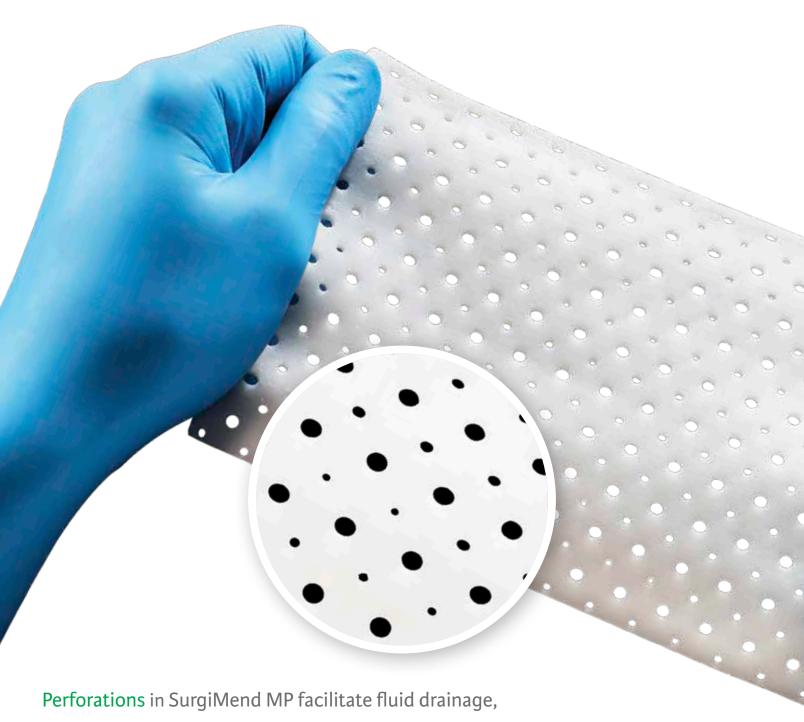
**Collagen Matrix for Soft Tissue Reconstruction** 





# **PERFORATIONS**

**SurgiMend® MP** is a 2mm thick **acellular collagen matrix** featuring a macroporous design that facilitates fluid drainage. SurgiMend MP provides the strength and structural support for complex hernia repair.



playing an important role in hernia repair.



### **TISSUE INTEGRATION**

Why settle for resorption or encapsulation when you can have tissue integration?



Histological image of SurgiMend MP in a small animal intra-muscular

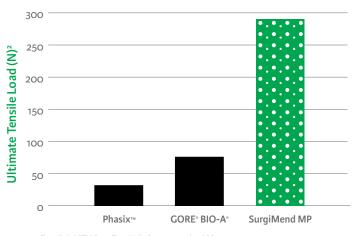
Above is a trichrome stained histological section of perforated SurgiMend (dark blue) implanted in a muscle (red). The perforation is filled with cells, blood vessels, and newly deposited host collagen.

implant model at 2 weeks.1



Surgimend MP strikes the right balance of biologic properties and strength.

In tensile strength testing, SurgiMend MP has been shown to be more than **3X stronger** than Phasix™ and GORE® BIO-A® and is not made of synthetic polymers.²





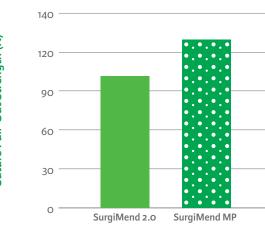


Even with numerous perforations, SurgiMend MP has comparable ultimate tensile strength to non-perforated porcine dermal matrices because of the inherent advantages in choosing bovine dermis as a source material.<sup>2</sup>

### SurgiMend MP

✓ Even greater suture pull out strength than non-perforated SurgiMend, when stitched through a hole at least 5mm from the edge.²







# PRODUCT DETAILS

### **At-a-Glance**

Native, bovine dermal tissue
Bovine dermis
Flat, perforated, dry sheet of uniform thickness and color
2 mm*
Room temperature storage
None
Approximately 60 seconds in room temperature saline <sup>^</sup>
Can be trimmed to size (wet or dry) and placed in any orientation, with either side up
Manufacturing process includes validated viral-inactivation steps
TSE safety certification by European Directorate for the Quality of Medicines; source tissue selected and processed in accordance with strict US and International regulatory requirements
Via exposure to ethylene oxide gas; sterility assurance level of $10^{-6}$ with undetectable ethylene oxide residuals

\*dry product

### **Ordering Information**

Reference	Description	Thickness*
606-206-001	10 cm x 15 cm perforated	2 mm
606-206-004	16 cm x 20 cm perforated	2 mm
606-206-003	13 cm x 25 cm perforated	2 mm
606-206-002	20 cm x 20 cm perforated	2 mm
606-206-005	20 cm x 25 cm perforated	2 mm
606-206-006	20 cm x 30 cm perforated	2 mm
606-206-007	25 cm x 40 cm perforated	2 mm
*Nominal		





<sup>^</sup>SurgiMend MP is specified to hydrate in ≤ 3 minutes; typically, it hydrates in ~60 seconds.

#### **Indications**

SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue membranes.

#### SurgiMend is specifically indicated for:

- Plastic and reconstructive surgery
- Muscle flap reinforcement
- · Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias

#### **Contraindications**

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

#### **Warnings and Precautions**

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

- Fluid flows through the fenestrated and perforated product faster than through solid product.
- Meshing of fenestrated or perforated product is not recommended.
- Do not expose to chemicals or substances other than sterile, room temperature 0.9% saline.
- 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 product as it may be damaged.
- SurgiMend 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.
- SurgiMend should be used with caution in surgical locations where the product may be exposed to stomach and/or intestinal contents. Collagen-based implants can be susceptible to degradation by digestive enzymes and conditions of acidic (low) pH.
- SurgiMend is for single patient use only; do not resterilize as this may damage SurgiMend.
- SurgiMend 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: smoking, diabetes, insufficient blood supply at the implant site, and exposure of the implant site to radiotherapy.

#### References

- 1. Data on file, Internal testing PDR 198
- 2. Data on file, internal testing PDR 231

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.

#### For more information or to place an order, please contact:

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