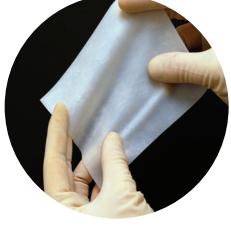
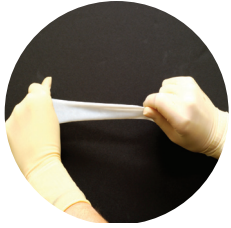


# SurgiMend<sup>®</sup>

*Collagen Matrix for Soft Tissue Reconstruction*



Sterility Assurance

Viral Safety

TSE Safety

Biocompatibility

Packaging & Shipping

Storage & Shelf Life

Hydration

Frequently Asked Questions

## SurgiMend Design

SurgiMend was designed by TEI Biosciences to satisfy the demand for a safe, consistent, high-quality biologic mesh for use in a broad range of surgical specialties including plastic and reconstructive surgery, trauma surgery, breast reconstruction, TRAM, and hernia repair.

SurgiMend is an acellular collagen matrix derived from the dermis of fetal calves, one of the purest sources of collagen available.

The product is manufactured using methods designed to remove cellular components and potentially infectious agents from the raw material while preserving the biological properties and structure of the native collagen.

Biocompatible, cell-friendly, and intrinsically strong with no artificial chemical crosslinking, the material acts as a scaffold that can be progressively integrated, remodeled, and ultimately replaced by functional host tissue.

## Sterility Assurance

SurgiMend is terminally sterilized via exposure to ethylene oxide gas. The cycle has been validated to provide a sterility assurance level of  $10^{-6}$  with undetectable levels ( $<0.01$  mg per device) of ethylene oxide chemical residuals. So long as the product package has not been damaged or opened, the contents are guaranteed sterile.

## Viral Safety

TEI Biosciences' SurgiMend manufacturing process includes a chemical viral inactivation step validated to ensure inactivation of potentially contaminating virus classes including:

- Enveloped RNA virus
- Non-enveloped RNA virus
- Enveloped DNA virus
- Non-enveloped DNA virus

## TSE Safety

SurgiMend has been specifically designed to safeguard against the possibility of transmitting prion-related Transmissible Spongiform Encephalopathy (TSE) diseases, including variant Creutzfeldt Jakob Disease (vCJD), the human form of Bovine Spongiform Encephalopathy (BSE), commonly known as Mad Cow Disease.

The product is derived from fetal bovine dermis which has been designated safe by the World Health Organization and EU scientific committees as no detectable levels of infectivity have been identified for this type of tissue.<sup>1</sup>

The source tissues for SurgiMend are selected and processed in accordance with strict US and European regulatory requirements. The products have passed the rigorous criteria for TSE safety certification by the European Directorate for the Quality of Medicines.<sup>2</sup>

## World Health Organization (WHO) Categories of Infectivity of Bovine Tissues and Body Fluid<sup>1</sup>

Category	Designation	Tissues
I	High infectivity	Brain, spinal cord, eye
II	Medium infectivity	Spleen, tonsil, lymph nodes, CSF, dura mater
III	Low infectivity	Peripheral nerves, nasal mucosa, thymus, bone marrow, liver, lung, pancreas
IV	No detectable infectivity	<b>Skin</b> , connective tissues, <b>fetal tissues</b> , striated muscle, milk, serum, feces, saliva

1 - Report of a WHO (World Health Organization) Consultation on Medicinal and Other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies — With the Participation of the Office International des Epizooties (OIE) — Geneva, Switzerland, 24-26 March (1997).

2 - EDQM Certificate No. RO-CEP 2004-116 Rev. 00 for Collagen Matrix, Strasbourg, 23 November 2004.

## SurgiMend Biocompatibility Summary<sup>3</sup>

Test Performed	Standard	Result
Cytotoxicity, MEM Elution	ISO 10993-5	No evidence of causing cell lysis or toxicity
Sensitization, Maximization	ISO 10993-10	No evidence of causing delayed dermal contact sensitization
Acute Intracutaneous Reactivity	ISO 10993-10	No evidence of significant irritation
Acute Systemic Toxicity	ISO 10993-11	No mortality or evidence of systemic toxicity
Genotoxicity, AMES Bacterial Reverse Mutation	ISO 10993-11	Nonmutagenic to <i>Salmonella typhimurium</i> test strains TA98, TA100, TA1535, TA1537, and <i>Escherichia coli</i> strain WP2uvrA
<i>In Vitro</i> Hemolysis, Modified ASTM Direct Contact Method	ISO 10993-3	Nonhemolytic
<i>In Vitro</i> Hemolysis, Modified ASTM Extraction Method	ISO 10993-4	Nonhemolytic
Surgical Muscle Implantation, 4 & 12 Weeks	ISO 10993-6	Macroscopically and microscopically classified as a nonirritant as compared to negative control plastic

3 - Data on file, TEI Biosciences Inc.

### Biocompatibility

The biocompatibility of SurgiMend has been evaluated by a third-party laboratory in accordance with ISO 10993, the internationally recognized standard for medical implants intended for long-term use. The results of these tests are summarized in the table above.

### Packaging & Shipping

Each SurgiMend unit is packaged dry within a Tyvek-laminate pouch that may be passed directly into the sterile field. The inner pouch is sealed within a foil pouch that acts as a light and moisture barrier, allowing for long-term storage.

The product is shipped via methods validated per ISTA 2A, the ship testing standard recognized by US and European regulatory authorities.

### Storage & Shelf Life

Upon receipt, SurgiMend should be stored at room temperature, away from direct heat sources; refrigeration is not necessary. The product has a three-year shelf. The expiration date is indicated on the device label.

### Hydration

Packaged dry, SurgiMend requires hydration for approximately one minute in room temperature, sterile 0.9% saline prior to use. The product must not be hydrated in solutions warmed above room temperature, as excessive heat may damage the collagen.

## Frequently Asked Questions

### What impact will hydration in hot saline have on SurgiMend?

*Heated saline solutions may damage the product, potentially eliciting an inflammatory response upon implantation. Always verify that the saline is at room temperature (15-30°C; 59-86°F) prior to hydration.*

### Can the hydration process be sped up in the operating room?

*Yes. As indicated in the Instructions for Use, you may speed hydration somewhat by applying light pressure with sterile-gloved fingers to squeeze out any bubbles trapped within the matrix.*

### Should the product be cut to size while dry, or following hydration?

*SurgiMend may be cut to size to meet the individual patient's needs in either its dry or its hydrated state. Note that the mesh may swell slightly upon hydration.*

### Can SurgiMend be stretched intraoperatively?

*Yes. Derived from a natural tissue, some degree of stretch is inherent to SurgiMend. The product may be stretched intraoperatively at the surgeon's discretion.*

### Does SurgiMend have to be implanted with a specific side up?

*No. There is no sidedness associated with SurgiMend. It may be placed in any orientation.*

### Is a bovine sensitivity skin test required prior to implantation of SurgiMend?

*No. This test is associated with other collagen preparations, e.g. injectable collagen, and is not required for SurgiMend.*

### Can SurgiMend be used in infected/contaminated surgical sites?

*SurgiMend should be used with caution in regions where infection exists. Collagen is susceptible to break-down in the presence of bacterial enzymes. Use of this product should be avoided when low pH solutions (i.e. stomach acid, bile) are present, as these substances can also rapidly degrade collagen. Please refer to the Indications for Use included with each device for complete warnings and contraindications.*

### Can SurgiMend be resterilized?

*No. The product is ethylene oxide sterilized for single-patient use only. Resterilization can damage SurgiMend.*



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PN 606-999-023 v01

