SurgiMend® Design

SurgiMend was designed to satisfy the demand for a safe, consistent, high-quality biologic mesh for use in a broad range of surgical specialties. It has become the product of choice for general, trauma, plastic & reconstructive, and head & neck surgeons.

SurgiMend is an acellular collagen matrix derived from fetal and neonatal bovine dermis, two 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, SurgiMend acts as a supportive, reinforcing scaffold in soft tissue reconstruction.

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

SurgiMend’s manufacturing process includes a chemical viral inactivation step validated to ensure inactivation of potentially contaminating virus classes including:
- Enveloped & non-enveloped RNA virus
- Enveloped & non-enveloped DNA virus

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 on the following page.

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 and neonatal 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.¹

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.²

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 using validated packaging.

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 shelf life of up to five years. 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.
## SurgiMend® Biocompatibility Summary

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

### 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 breakdown 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 Instructions 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.
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. 

- Always refer to the appropriate instructions for use for complete clinical instructions.
- 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.