SUMMARY

The Xenform Matrix is made from collagen, the material that makes up the majority of all human and animal tissues. The collagen used in these and many other collagen medical devices is derived from cows. As such, there is a theoretical possibility that these collagen devices could transmit viruses or variant Creutzfeldt-Jakob disease (vCJD), the human form of mad cow disease, a transmissible spongiform encephalopathy (TSE).

Per regulatory requirements, the manufacturing process for The Xenform Matrix has been rigorously validated to help assure product sterility and inactivation of any potentially contaminating viruses. Additionally, the product has been specifically designed to safeguard against the possibility of transmitting vCJD as it is derived from fetal bovine skin. Fetal bovine tissue, designated safe by the World Health Organization (WHO), US and EU Scientific Committees, has no detectable levels of TSE.¹

STERILITY²

The Xenform Matrix 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 harmful ethylene oxide chemical residuals.

VIRAL INACTIVATION²

The Xenform Matrix manufacturing process includes a chemical viral inactivation step validated to ensure inactivation of potentially contaminating virus classes:

- Enveloped RNA virus
- Enveloped DNA virus
- Non-enveloped RNA virus
- Non-enveloped DNA virus
**TSE SAFETY**

- The Xenform Matrix is derived from **dermal** bovine tissue, which, per WHO designation, has no known detectable TSE infectivity.\(^1\)

- The Xenform Matrix is derived from **fetal** bovine tissue which is designated safe by the World Health Organization (WHO), US and EU Scientific Committees, has no detectable levels of TSE.\(^1\)

- The source tissues for The Xenform Matrix are selected and processed in accordance with strict US and European regulatory requirements; tissue is obtained only from animals certified as fit for human consumption.\(^2\)

- The Xenform Matrix has passed the rigorous criteria for TSE safety certification by the European Directorate for the Quality of Medicines.\(^3\)

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**WORLD HEALTH ORGANIZATION (WHO) CATEGORIES OF INFECTIVITY IN BOVINE TISSUES AND BODY FLUID**\(^1\)

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DESIGNATION</th>
<th>TISSUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>High Infectivity</td>
<td>Brain, spinal cord, eye</td>
</tr>
<tr>
<td>II</td>
<td>Medium Infectivity</td>
<td>Spleen, tonsil, lymph nodes, CSF, dura mater</td>
</tr>
<tr>
<td>III</td>
<td>Low Infectivity</td>
<td>Peripheral nerve, nasal mucosa, thymus, bone marrow, liver, lung, pancreas</td>
</tr>
<tr>
<td>IV</td>
<td>No Detectable Infectivity</td>
<td>Skin, connective tissues, <strong>fetal tissues</strong>, striated muscle, milk, serum, feces, and saliva</td>
</tr>
</tbody>
</table>

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2. Data on file, TEI Biosciences Inc.

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**XENFORM SOFT TISSUE REPAIR MATRIX**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Size (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0068302410</td>
<td>Xenform Soft Tissue Repair Matrix</td>
<td>2 x 7</td>
</tr>
<tr>
<td>M0068302430</td>
<td>Xenform Soft Tissue Repair Matrix</td>
<td>4 x 7</td>
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<tr>
<td>M0068302450</td>
<td>Xenform Soft Tissue Repair Matrix</td>
<td>6 x 10</td>
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<tr>
<td>M0068302470</td>
<td>Xenform Soft Tissue Repair Matrix</td>
<td>8 x 12</td>
</tr>
</tbody>
</table>

Packaged one (1) per box.

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Xenform Soft Tissue Repair Matrix is manufactured by TEI Biosciences Inc. and distributed by Boston Scientific.

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

Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.