



## Soft Tissue Repair Matrix

### SAFETY PROFILE

Xenform Matrix is screened against the possibility of infectious BSE (bovine spongiform encephalopathy) through the following measures:

- Xenform Matrix is derived from fetal **dermal** bovine tissues, which, per WHO and EU designation, has no known detectable prion infectivity<sup>2</sup>
- Xenform Matrix is derived from **fetal** bovine tissue which are designated safe by WHO, US, and EU scientific committees as no detectable levels of TSE (transmissible spongiform encephalopathy) infectious prions have been identified in fetal tissues<sup>2</sup>
- Xenform Matrix has passed the rigorous criteria for certification by the EDQM (European Directive for the Quality of Medicine)<sup>3</sup>

### WHO CATEGORIES OF INFECTIVITY IN BOVINE TISSUES AND BODY FLUID

CATEGORY	DESIGNATION	TISSUES
I	High Infectivity	Brain, spinal cord, eye
II	Medium Infectivity	Spleen, tonsil, lymph nodes, CSF, dura mater
III	Low Infectivity	Peripheral nerve, 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, and saliva

2 - Report of a WHO Consultation on Medical 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)  
 3 - EDQM Certificate No. R0-CEP 2004-116-Rev 00 for Collagen Matrix, Strasbourg, 23 November 2004

\* TEI Biosciences – Data on File  
 \* Bench test results may not be indicative of clinical performance

XENFORM SOFT TISSUE REPAIR MATRIX		
Order Number	Description	Size (cm)
M0068302410	Xenform Soft Tissue Repair Matrix	2 x 7
M0068302430	Xenform Soft Tissue Repair Matrix	4 x 7
M0068302450	Xenform Soft Tissue Repair Matrix	6 x 10
M0068302470	Xenform Soft Tissue Repair Matrix	8 x 12

Packaged one (1) per box.

Xenform Soft Tissue Repair Matrix is manufactured by TEI Bioscience 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.



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