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Why use The Xenform™ Matrix?

A: The Xenform Matrix is made from undamaged, native collagen that naturally possesses biomechanical properties that are desirable for soft tissue repair. The Xenform Matrix's natural strength renders chemical cross-linking unnecessary. Because this natural material is supple when hydrated, it tends to conform to the surgical site. Over time, the patient's cells and blood vessels tend to penetrate the graft and replace it with new collagen. This regeneration process can reduce scarring, decrease the likelihood of wound separation over time, and provide a more lasting defect repair.

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Is The Xenform Matrix Safe?

A: The Xenform Matrix has been thoroughly tested to help ensure its safety and was cleared by the U.S. Food and Drug Association for use as a soft tissue repair matrix in June 2003. The manufacturing process for the device was designed to remove cellular components from the tissue and eliminate the potential for viral contamination.¹ The Xenform Matrix is also screened against the possibility of transmitting infectious BSE (Bovine Spongiform Encephalopathy, or "Mad Cow Disease").

¹ Data on file, TEI Biosciences Inc.

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.

Boston Scientific

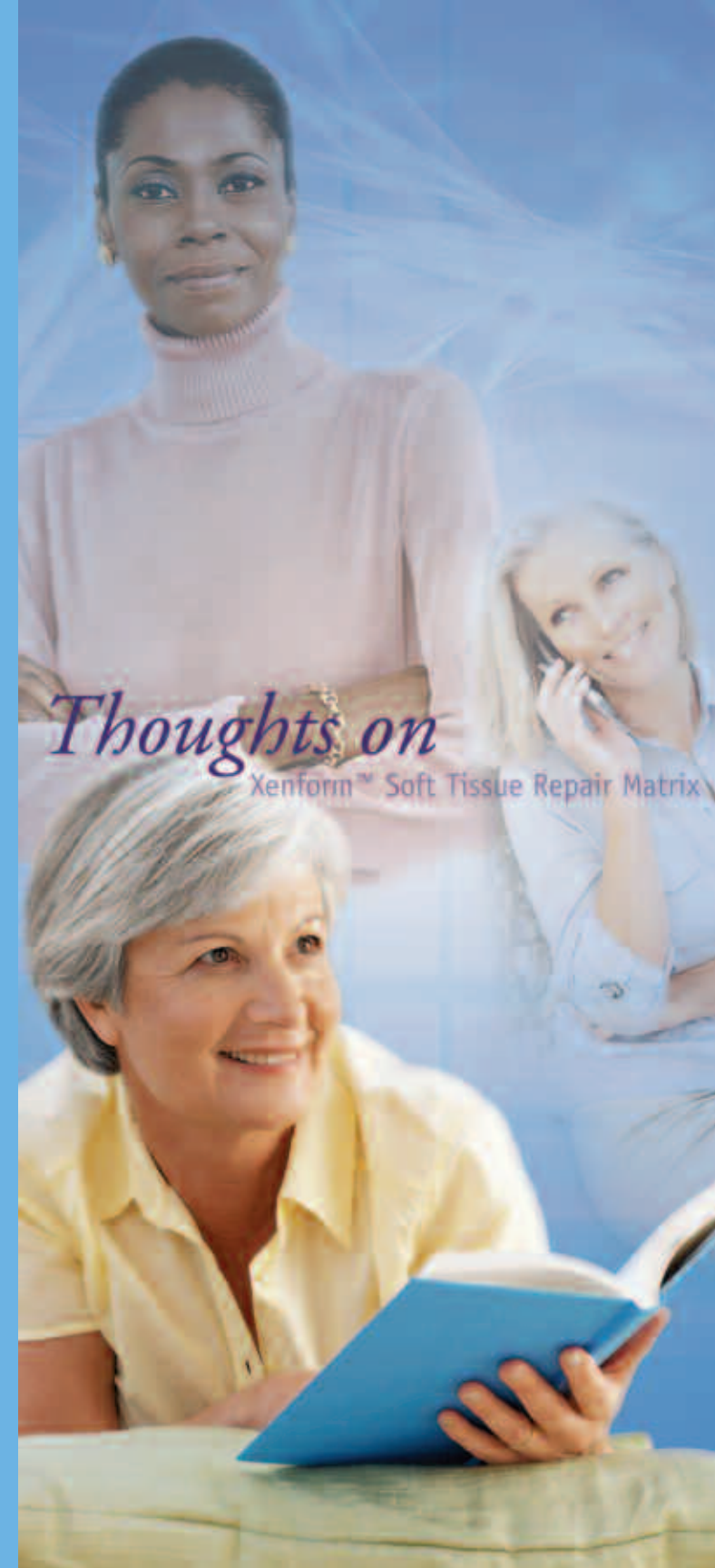
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Thoughts on
Xenform™ Soft Tissue Repair Matrix

What is The Xenform™ Matrix?

A: Xenform Soft Tissue Repair Matrix is a natural, collagen mesh designed to repair damaged or weakened soft tissues.

How is it made?

A: The Xenform Matrix is derived from the skins of fetal calves – one of the purest sources of collagen available. The skins are thoroughly cleaned and treated to remove cellular components as well as viruses present in the tissue. They are then sorted by thickness, freeze-dried, cut into convenient sizes and sterilized.

What are the advantages of collagen grafts as opposed to synthetic meshes?

A: While synthetic meshes have been used for decades for pelvic floor reconstruction, they have been associated with an increased risk of infection and erosion of the material into the lower urinary tract or vagina, which can result in voiding difficulty or sexual complications.

Collagen grafts, however, are designed to mimic the body's natural tissues. These scaffolds possess biologic properties that encourage cell and blood vessel penetration, allowing for remodeling of the graft into new tissue, providing natural, more lasting repair of soft tissue defects.

What other types of collagen grafts are available?

Collagen grafts are sometimes harvested from elsewhere on the patient's own body. Of course this is advantageous in terms of biologic acceptance of the autologous tissue; however, it may increase surgery and recovery time, predispose patients to incisional hernias, and leave undesirable cosmetic results.

Another approach is to use allograft tissue from human cadavers. These tissues are screened for viruses, treated with antibiotic solutions, freeze-dried and sterilized. While human allograft tissues have been shown to be effective for many applications, there are supply limitations, and the mechanical strength of the tissue can vary substantially from donor to donor, potentially leaving the patient at a higher risk of surgical failure of the graft.

To help overcome the limitations described above, clinicians have turned to xenograft materials (those derived from animal tissues) to satisfy their soft tissue repair needs. Not only is the source material readily available, it is generally more predictable and controlled than cadaveric source materials, helping to assure product uniformity while avoiding the ethical implications associated with human tissue usage.

