Xenform™

Soft Tissue Repair Matrix

Boston Scientific

Conformity meets Functionality

Xenform™ Soft Tissue Repair Matrix

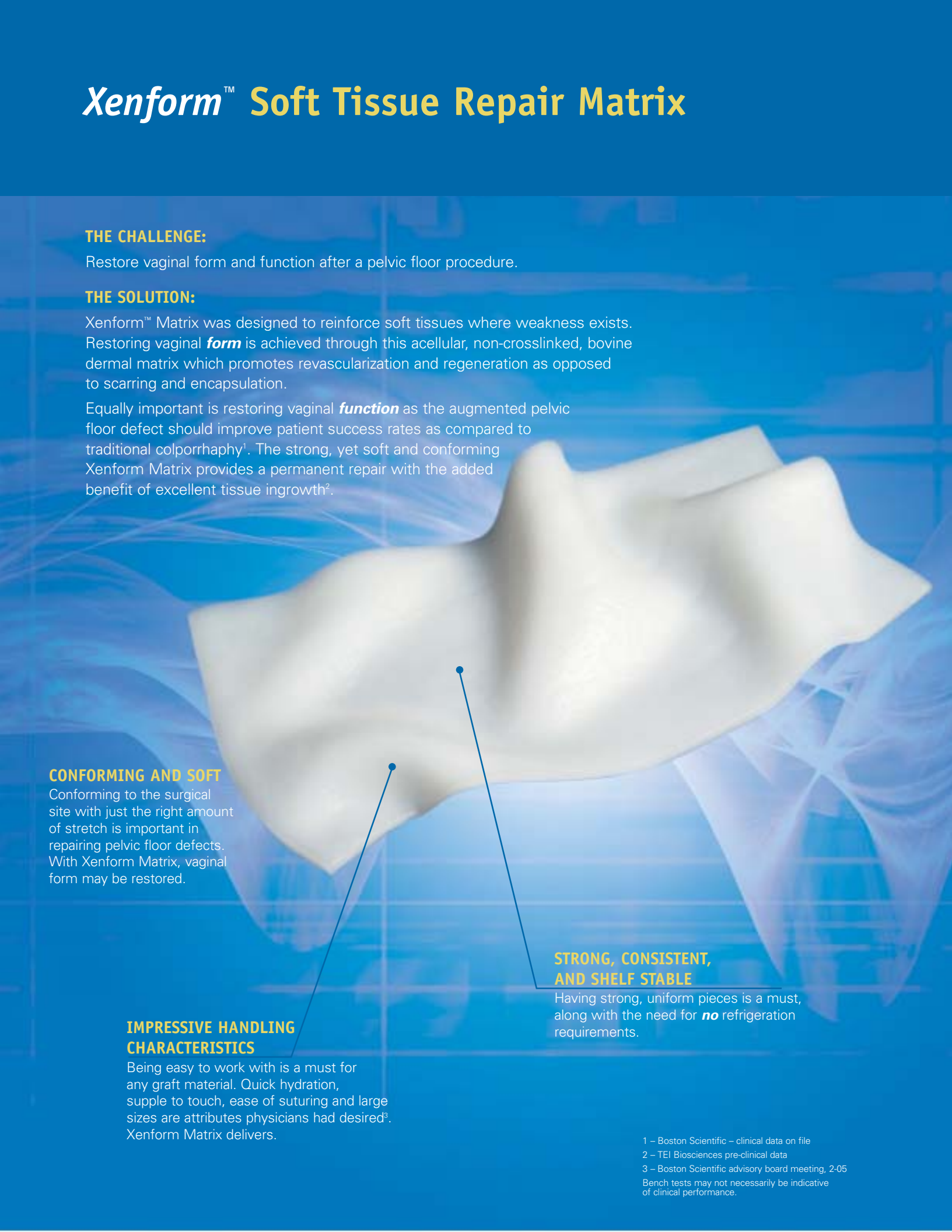
THE CHALLENGE:

Restore vaginal form and function after a pelvic floor procedure.

THE SOLUTION:

Xenform™ Matrix was designed to reinforce soft tissues where weakness exists. Restoring vaginal ***form*** is achieved through this acellular, non-crosslinked, bovine dermal matrix which promotes revascularization and regeneration as opposed to scarring and encapsulation.

Equally important is restoring vaginal ***function*** as the augmented pelvic floor defect should improve patient success rates as compared to traditional colporrhaphy[1]. The strong, yet soft and conforming Xenform Matrix provides a permanent repair with the added benefit of excellent tissue ingrowth[2].



CONFORMING AND SOFT

Conforming to the surgical site with just the right amount of stretch is important in repairing pelvic floor defects. With Xenform Matrix, vaginal form may be restored.

STRONG, CONSISTENT, AND SHELF STABLE

Having strong, uniform pieces is a must, along with the need for ***no*** refrigeration requirements.

IMPRESSIVE HANDLING CHARACTERISTICS

Being easy to work with is a must for any graft material. Quick hydration, supple to touch, ease of suturing and large sizes are attributes physicians had desired[3]. Xenform Matrix delivers.

1 – Boston Scientific – clinical data on file

2 – TEI Biosciences pre-clinical data

3 – Boston Scientific advisory board meeting, 2-05

Bench tests may not necessarily be indicative of clinical performance.

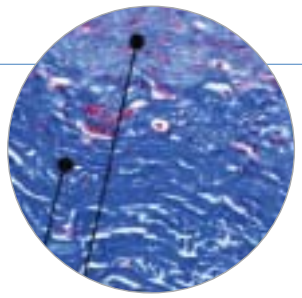
CONFORMITY MEETS FUNCTIONALITY

SUPPLE • CONSISTENT • REVASCULARIZATION

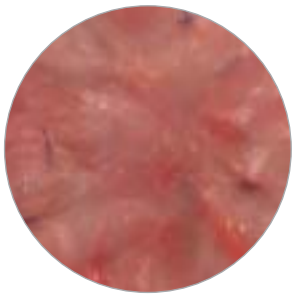
PRODUCT COMPARISON

LEADING XENOGRAFT IMPLANT	XENFORM™ MATRIX
Xenograft	√
Consistent thickness	√
Good handling characteristics	√
No refrigeration necessary	√
Hydrates quickly	√
Rigid, non-conforming	Softer and more pliable
Can become encapsulated	Allows for cellular ingrowth
Material is chemically crosslinked	No chemical crosslinking required
Material "shelf" palpable on patient follow-up	Vaginal form and function restored
Wound dehiscence	Rapid revascularization and healing

Explanted Xenform Matrix at 3 weeks. The implant was evident and there was no evidence of inflammation or a foreign body reaction.



Xenform Matrix at 3 weeks revealed incorporation of the implant. The matrix had been populated with host cells and blood vessels (bottom point). New tissue was seen overgrowing the implant (top point).



Explanted Xenform Matrix at 9 months. Implant has been remodeled and replaced by robust, host connective tissue. The soft tissue defect was effectively reinforced and repaired.

1 – TEI Biosciences – Pre-clinical data on file - Bench test results may not be indicative of clinical performance

PRE-CLINICAL REVIEW

XENFORM SOFT TISSUE REPAIR MATRIX[1]:

- Was successful in an acute (3 weeks) and long term (9 and 15 months) evaluation in a rodent soft tissue repair model
- At 15 months, demonstrated biocompatibility with:
  - **no** evidence of eliciting a foreign body response
  - **no** surgical adhesions
  - **no** herniation
- Was repopulated by host cells and blood vessels as early as 3 weeks
- Was remodeled at 9 and 15 months into strong, robust connective tissue that effectively repaired the surgically created soft tissue defect

Xenform™

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[2]
- 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 (transmissable spongiform encephalopathy) infectious prions have been identified in fetal tissues[2]
- Xenform Matrix has passed the rigorous criteria for certification by the EDQM (European Directive for the Quality of Medicine)[3]

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	***Skin***, connective tissues, ***fetal tissues***, 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.

Boston Scientific

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Ordering Information
1.888.272.1001

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