Conformity meets Functionality
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 colporrhaphy¹. The strong, yet soft and conforming Xenform Matrix provides a permanent repair with the added benefit of excellent tissue ingrowth².

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.

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 desired³. Xenform Matrix delivers.

STRONG, CONSISTENT, AND SHELF STABLE
Having strong, uniform pieces is a must, along with the need for no refrigeration requirements.

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

<table>
<thead>
<tr>
<th>LEADING XENOGRaFT IMPLANT</th>
<th>XENFORM™ MATRIX</th>
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<tbody>
<tr>
<td>Xenograft</td>
<td>√</td>
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<tr>
<td>Consistent thickness</td>
<td>√</td>
</tr>
<tr>
<td>Good handling characteristics</td>
<td>√</td>
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<tr>
<td>No refrigeration necessary</td>
<td>√</td>
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<tr>
<td>Hydrates quickly</td>
<td>√</td>
</tr>
<tr>
<td>Rigid, non-conforming</td>
<td>Softer and more pliable</td>
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<tr>
<td>Can become encapsulated</td>
<td>Allows for cellular ingrowth</td>
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<tr>
<td>Material is chemically crosslinked</td>
<td>No chemical crosslinking required</td>
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<tr>
<td>Material “shelf” palpable on patient follow-up</td>
<td>Vaginal form and function restored</td>
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<tr>
<td>Wound dehiscence</td>
<td>Rapid revascularization and healing</td>
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</table>

PRE-CLINICAL REVIEW

XENFORM SOFT TISSUE REPAIR MATRIX:

- 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

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

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.
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.

• 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.

• Xenform Matrix has passed the rigorous criteria for certification by the EDQM (European Directive for the Quality of Medicine).

WHO CATEGORIES OF INFECTIVITY IN BOVINE TISSUES AND BODY FLUID

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>DESIGNATION</th>
<th>TISSUES</th>
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</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><strong>Skin</strong>, connective tissues, fetal tissues, striated muscle, milk, serum, feces, and saliva</td>
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</tbody>
</table>


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