Frequent Asked Questions

What measures are taken to ensure against “Mad Cow Disease”?
When making the TissueMend® patch, TEI Biosciences has adopted a series of five effective methods known to the World Health Organization (WHO), the Food and Drug Administration (FDA) and the Commission of the European Communities to minimize the risk of Bovine Spongiform Encephalopathy (BSE):
1. All source materials are traceable to herds having no known incidents of BSE
2. All source materials are from animals certified fit for human consumption
3. All source materials are derived from bovine dermis, which is a category IV WHO designated tissue indicating no detectable BSE infectivity
4. All source material are of fetal origin; per the WHO, infectious BSE agents have not been identified in any fetal bovine tissues
5. All source materials are treated with sodium hydroxide (NaOH), a recognized prion inactivant

Can TissueMend® be Over-hydrated?
Within the confines of typical surgical protocol, it is not possible to over-hydrate the TissueMend® collagen matrix. However, if the collagen matrix were to be left in a saline solution for a period of a day or more, it would begin to degrade as a result of over-hydration.

What type of needle should be used when implanting TissueMend®?
Although the answer to this question ultimately depends upon the preference of each individual surgeon, clinical feedback has identified that a majority of surgeons prefer a taper needle.

How much tension should be put on the sutures?
The tension of the sutures should be enough to insure that the implant will be under some degree of continual stress. Just as Wolfe's Law specifies median levels of tension required for remodeling of bone, there is also a median range of tension that must be placed on collagen to stimulate its remodeling.

Why does the TissueMend® patch seem to be stronger than other available collagen implants?
If you were to compare literature for the various collagen implants, you would find that each product lists its implant's generic “strength” somewhere in a range of 20-30 MPa (MegaPascals). Technically speaking, this statement is true, for the generic “strength” of collagen is relatively uniform across all collagen types. Although technically true, this statement is somewhat deceiving, for a MegaPascal is a measurement of force (N) divided by area^2 (mm). When one takes into account the thickness of the TissueMend® product, the comparative area or our product is substantially greater than many competitive implants. Accordingly, the force that is necessary to compromise the product's integrity is also considerably greater, which contributes to the overall strength of the implant.

What are some of the physical differences between bovine and porcine collagen?
Aside from the obvious origin of the source, fundamental differences do exist between collagen that is derived from different sources. First and foremost, bovine collagen is typically derived from the skin, whereas porcine collagen is typically taken from the small intestine. Naturally, collagen that is derived from the inner lining of the small intestine is substantially thinner than that taken from the skin. To enhance the strength of the SIS collagen, the fibers can be either layered or crosslinked. Secondly, the physical structure of the fibers present in porcine and bovine collagen is markedly different, for porcine fibers tend to be less dense and more concentrated, further limiting strength and vascularity.
What is chemical crosslinking and how does it affect a collagen implant?

Crosslinking is a process that subjects a biologic material to a chemical agent, in an attempt to make the material stronger. Crosslinking is commonly done with a chemical called gluteraldehyde, which, in addition to adding strength, also changes a material from something cells can interact with to something that is recognized as a foreign body. Consequently, instead of allowing native cells to repopulate, grow and mature, scientists have found that crosslinked materials evoke foreign body reactions and wound contraction. Thus, although crosslinking does enhance the strength of collagen, it compromises its nativity and stimulates inflammatory response.

In the future, will the TissueMend® patch be available in additional sizes?

Although multiple sizes would be optimal for the dynamic needs of your surgeons, our current focus is designing a product that will meet the most immediate needs of your respective physicians. After launching this product to a national audience, we will evaluate the wants and needs of both patients and surgeons and adjust our focus accordingly. Until that time comes, TissueMend® will only be available in its current 5 cm x 6 cm size.

What should I tell a surgeon who does not feel comfortable using a product derived from a fetus?

First and foremost, you should tell your surgeon that fetal skins are used only because they are an unfortunate byproduct of the normal slaughtering process. You see, when adult cows are slaughtered for their meat, a certain percentage of the animals are pregnant when they are killed. There is essentially nothing that the farmers can do to prevent this from occurring, for the discovery of the fetus can come only after the cow has been killed. That being said, until the advent of the TissueMend® product, fetal material was almost exclusively used to produce kip skins, which is an extremely expensive form of leather commonly used in the making of parchment. If the material used in the making of these kip skins was not of a certain age, it would literally be thrown away, for no other use had been identified for the material. Thankfully, the tissue engineers at TEI Biosciences were intelligent enough to recognize the value of this material, transforming what would otherwise be waste into a valuable medical device.

What are the TissueMend® indications for use?

TissueMend® is intended for surgical implantation to reinforce soft tissue where weakness exists and for the repair of damaged or ruptured soft tissue membranes. In addition, the device is intended to reinforce soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff surgery.

Where can I get clinical papers that support the use of the TissueMend® product?

Clinical papers are currently under development and, following the national launch, a number of white papers will be made available to the entire sales force. Until that time comes, clinical papers are not available for the TissueMend® product.

References:
1 Data on file, TEI Biosciences, 2002
2 www.jointreplacement.com
3 www.arthrotek.com