DermaSpan™

Acellular Dermal Matrix

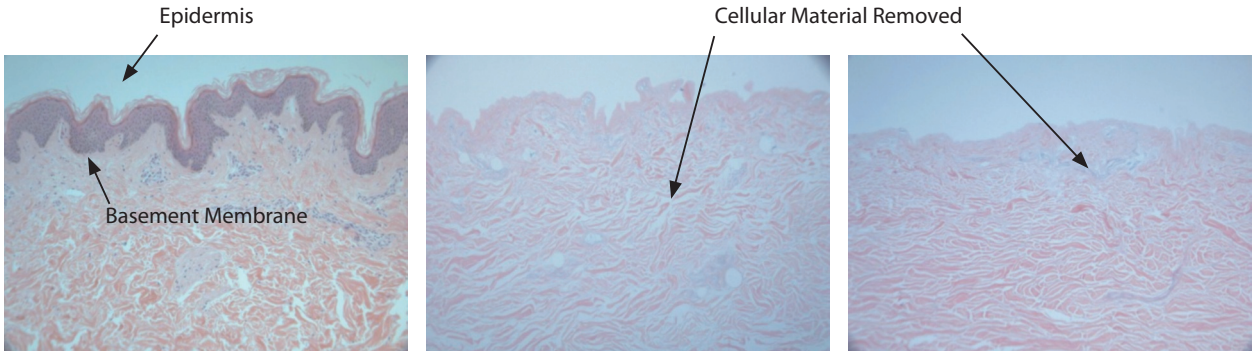
BIOMET® SPORTS MEDICINE

Sterilization has its advantages.

Through a unique, proprietary process DermaSpan™ Acellular Dermal Matrix is supplied sterile (SAL-10^{-6}). Histology studies have shown that Precision Dose Sterilization allows the graft to be sterilized while maintaining tissue integrity.[1]

Histology Studies[1]

These histology studies show no changes to the matrix, post sterilization:



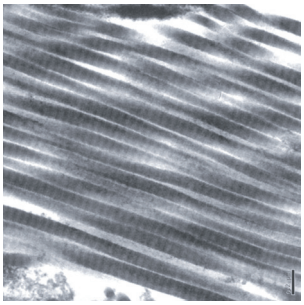
Normal Skin

ACD Pre-Gamma
Precision Dose Sterilization

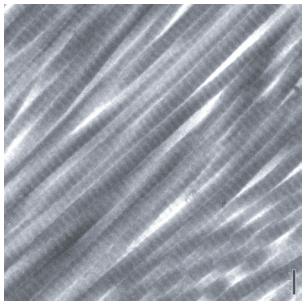
ACD Post-Gamma
Precision Dose Sterilization

Transmission Electron Micrographs (TEMs)[1]

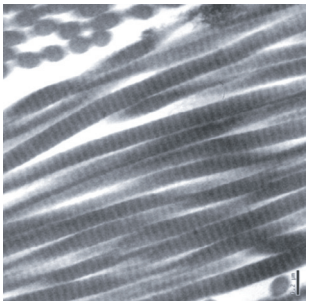
TEMs presented the same results. There is an similar collagen structure between normal dermis and dermis treated with the patented gamma precision sterilization process. Ultimately, DermaSpan Acellular Dermal Matrix is preserved through processing.



Non-Treated Dermis

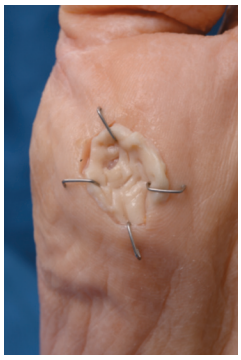


ACD Pre-treatment

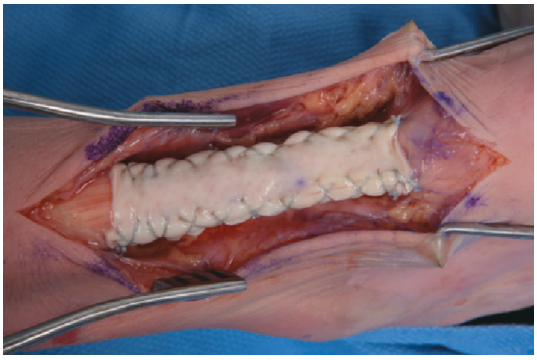


ACD Post-treatment

DermaSpan Acellular Dermal Matrix is derived from allograft skin. DermaSpan Acellular Dermal Matrix is very carefully processed to offer biocompatibility as well as biomechanical strength in tendon coverage or reinforcement and wound coverage procedures. DermaSpan Acellular Dermal Matrix has the added advantage of being supplied sterile…unlike many other dermal allograft products.



Wound Coverage

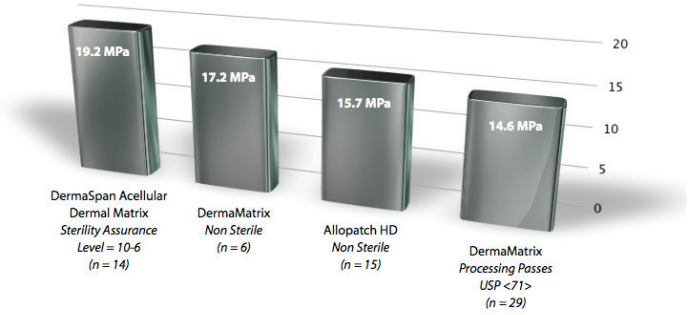


Achilles Tendon Coverage

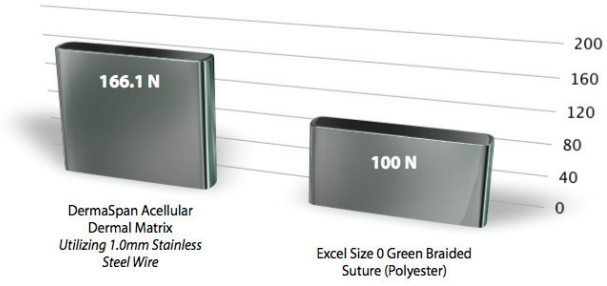
Feature	Benefit
Acellular dermal matrix	One lab study has shown acellular dermal matrix leads to reduced chance of inflammatory response.[2]
Allograft	Reduced risk of rejection as compared with xenograft.[3,4]
Infiltrated by host tissue	Effective graft procedures.
High suture pull-out strength	Enhances tissue reinforcement.
Provided sterile	Unique, proprietary process, provides the one of a few acellular dermal matrix products that is irradiated under validated sterilization process. Using sterile graft further reduces the risk of disease donor transmission.[5]
Convenient delivery sizes	Three sizes to address surgeon's needs.
No special handling or storage requirements	Does not need to be refrigerated.
Easily reconstituted in the O.R.	Simply hydrate in normal saline for 5–10 minutes.

Meets all FDA, AATB and state regulatory requirements for testing and donor screening

Ultimate Tensile Strength for Various Acellularized Dermis[6,7]



ACD Suture Pull-out Strength vs. Suture Break Strength[6,7]



Suture Pull-out Strength[6]

Suture pull-out strength is defined as the force required to separate the suture from the graft material.

- Suture failed before graft (Excel 0.0 Green Braided Suture)
- 166.1 Newtons pull-out with stainless steel wire

Tensile Strength[6]

Tensile strength is defined as the pulling force required to break a material standardized to its cross-sectional area.

- 19.2 MPa
- Exceeded tensile strength of competitor ACD graft

Ordering Information

DermaSpan Acellular Dermal Matrix	
92-1100505	5 x 5 cm (.8mm – 1.4mm thickness)
92-1100407	4 x 7 cm (.8mm – 1.4mm thickness)
92-1100510	5 x 10 cm (.8mm – 1.4mm thickness)

The DermaSpan™ Acellular Dermal Matrix is available in multiple sizes and thicknesses. Selection for the appropriate product size is the responsibility of the surgeon based on the individual patient needs. Graft thickness and strength should be considered based on application.

1. Tissue Banks International. Histological investigations of recellularization, revascularization, adhesions and other factors in three animal models of Tissue banks Internationals sterile human acellular dermal allograft. April 27, 2010. Animal studies are not necessarily indicative of clinical performance.
2. Richters, C. D., A. Pirayesh, H. Hoeksema, E. W. A. Kamperdijk, R. W. Kreis, R. P. Dutrieux, S. Monstrey, and M. J. Hoekstra. "Development of a Dermal Matrix from Glycerol Preserved Allogeneic Skin." *Cell and Tissue Banking* 9.4 (2008): 309-15. Print.
3. Jacobsen, Garth, and David Easter. "Allograft vs. Xenograft Practical Considerations for Biologic Scaffolds." *BellaDerm. MTF*. Web. 07 Feb. 2011. <http://www.belladerm.org/documents/AVX%20%20CME%20Monograph.pdf>.
4. Michael, Trice E. "Xenograft Risks: What You and Your Patients Need to Know." American Academy of Orthopaedic Surgeons - AAOS. June 2009. Web. 07 Feb. 2011. <http://www.aaos.org/news/aaosnow/jun09/research3.asp>.
5. McNickle, A.G., Wang, V.M., Shewman, E.F., Cole, B.J., and Williams, J.M.: "Performance of a Sterile Meniscal Allograft in an Ovine Model." 465(7):1868–1876, *Clinical Orthopaedics and Related Research*, July 2009.
6. Tissue Banks International. Mechanical testing of Tissue banks International's acellular dermis (ACD) allograft. May 18, 2010.
7. As reported by competitors.

*Bench test results are not necessarily indicative of clinical performance.

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