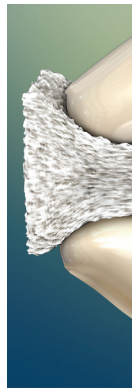
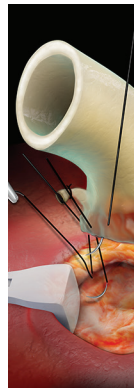
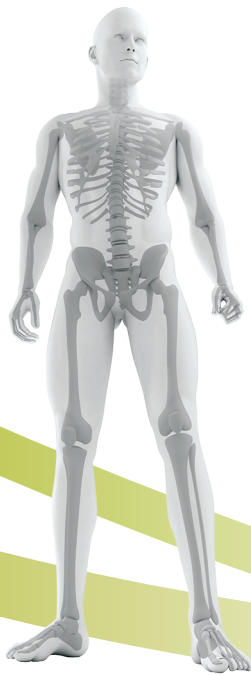
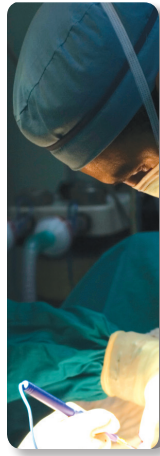


Representative Reports Using **ArthroFLEX**[®] in Sports Medicine Procedures





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LifeNet Health distributes more than 20,000 sports medicine allograft bio-implants annually. We understand the safety and quality of your allograft bio-implants are critical to you and your patients. We provide high-quality allograft bio-implants with the biomechanical specifications you need to perform successful sports medicine surgeries. LifeNet Health offers a variety of safe and clinically proven decellularized dermal matrix bio-implants, ArthroFlex, to provide soft tissue support and covering soft tissue repairs. The list of articles below demonstrates the efficacy of our ArthroFlex acellular dermal matrix bio-implants.

Clinical Reports Using **ArthroFLEX**

Gilot GJ, Alvarez AM, Barcksdale L, Westerdahl D, Krill M, Peck E. Outcome of Large to Massive Rotator Cuff Tears With and Without Extracellular Matrix Augmentation: A Prospective Comparative Study. *Arthroscopy*. 2015 Apr 17. pii: S0749-8063(15)00141-3.

- This prospective study compares the results of 35 large and massive rotator cuff repairs with and without augmentation using ArthroFlex at two years post-operative. The control group (non-augmented) had a 26% re-tear rate compared to only 10% in the augmented group. Researchers conclude that using ArthroFlex to augment “large to massive rotator cuff reduces the incidence of re-tears, improves patient outcome scores, and is a viable option during complicated cases in which a significant failure rate is anticipated.” [Click here for link](#). Reprint available upon request.

Mirzayan R, Conroy C, Sethi P. Distal Biceps Repair With Acellular Dermal Graft Augmentation. *Techniques in Shoulder & Elbow Surgery*. Sept 2015;16(3):89-92. [Click here for link](#).

- Authors describe a technique to repair a ruptured distal biceps tendon using an acellular dermal matrix to augment the repair.

Gilot GJ, Attia AK, Alvarez AM. “Arthroscopic Repair of Rotator Cuff Tears using Extra-Cellular Matrix (ECM) graft.” *Arthrosc Tech.*, 2014 Aug; 3(4):e487-9.

- This technique article demonstrates the use of ADM augmentation using ArthroFlex in the arthroscopic repair of large to massive rotator cuffs. Their results support the use of an ADM, such as ArthroFlex, for rotator cuff repairs. [Click here for link](#).

Levenda AC & Sanders NR. A Simplified Approach for Arthroscopic Repair of Rotator Cuff Tear with Dermal patch Augmentation. *Advances in Orthopedic Surgery*. 2015, Article ID 423949

- This article describes a surgical technique to arthroscopically augment a standard rotator cuff tear with ArthroFlex. Author also presents an informal case series of the technique used on 12 patients with 2-4 cm large tears. Patients have reported significantly less pain, as well improved strength and range of motion. Of the 12 patients, 2 patients suffered re-tears due to falls. However, upon second look during arthroplasty, the graft and repair were still intact. [Click here for link](#).

Representative Reports using **ArthroFLEX**[®] in Sports Medicine Procedures



Acevedo DC, Shore B, Mirzayan R. Orthopedic Applications of Acellular Human Dermal Allograft for Shoulder and Elbow Surgery. *Orthop Clin N Am*. 2015 Jul;46(3):377-388.

- Authors review the basic science, rationale for use, and surgical applications of human dermal allograft, such as ArthroFlex, in various shoulder and elbow injuries. [Click here for link](#).

Lee B, Acevedo D, Mirzayan R. Reconstruction of the Acromioclavicular Joint, its Superior Capsule, and Coracoclavicular Ligaments Using an Interpositional Acellular Dermal Matrix and Tibialis Tendon Allograft. *Techniques in Shoulder & Elbow Surgery*. 2014;15(3):79-86.

- This technique article describes a biologic and anatomic reconstruction for the coracoclavicular ligaments and AC joint using ArthroFlex and an anterior tibialis tendon. Senior author has performed 12 reconstructions with this technique. Only one as failed as a result of the patient attempting push-ups at two months post-operative. [Click here for link](#).

Atzei A & Bertasi G. “Repair of Distal Triceps Tendon Rupture with a Human Acellular Dermal Matrix (ADM)” 2013 White Paper (68-20-097)

- Case study describes the surgical technique and outcome for use of Dermacell in a successful distal triceps tendon repair.
- NOTE: Dermacell is another trade name for ArthroFlex. Available upon request.

Atzei A & Bertasi G. “Reconstruction of Finger Flexor Tendon and Pulley Repair with Human Acellular Dermal Matrix (ADM)” 2013 White Paper (68-20-098)

- Case study describes a successful outcome by using Dermacell to augment the flexor digitorum profundus tendon and pulley repair in a 16 year-old male.
- NOTE: Dermacell is another trade name for ArthroFlex. Available upon request.

Hirahara, A. SpeedBridge Rotator Cuff Repair Augmented with ArthroFlex Acellular dermal extracellular matrix. YouTube. 2013. [Click here for video](#).

Hirahara Biologics: <http://www.youtube.com/watch?v=XQv2XBW8Th0> OR <http://www.hiraharamd.com/orthopaedic-services/orthobiologics/ArthroFlex>

DeBerardino: http://www.aarthroscopia.com/sites/default/files/documentos/Webcast_AEA/archivos/2011/PDF/TI_P36.pdf

Animal and Non-Clinical Reports Using **ArthroFLEX**

Capito, A.E., Tholpady, S.S., Agrawal, H., Drake, D.B. & Katz, A.J. “Evaluation of Host Tissue Integration, Revascularization, and Cellular Infiltration Within Various Dermal Substrates.” *Annals of Plastic Surgery*. 2012 Oct; 68(5):495-500. doi: 10.1097/SAP.0b013e31823b6b01. Reprint available upon request.

- The purpose of this study is to determine and compare these properties of 4 different acellular dermal matrices (AlloDerm, Dermacell, DermaMatrix, and Integra) in an in vivo rat model. Tissue specimens were obtained at various time points. Histology and immunohistologic assays were used to quantify the extent of cellular infiltration and revascularization within the various matrices. A bimodal cellular response was observed in all products except for Dermacell. Cellular infiltration was highest in Dermacell and lowest in AlloDerm, and angiogenesis was evident by day 7. [Click here for link](#).
- NOTE: Dermacell is another trade name for ArthroFlex.



Rosines E, Qin X, and Chen S. "In Vivo Assessment of Bacteria Infection Clearance of an Acellular Dermal Matrix and a Synthetic Mesh." Poster Presentation at SAWC Spring 2014. Poster available upon request.

- Matracell treated dermis demonstrated resistance to infection in a rat model where a polymer mesh did not. Both types of grafts were seeded with *S. aureus* and implanted into the abdominal wall of a rat. After 28 days, the implants were removed and analyzed. The ADM was able to resist infection and showed better incorporation compared to the synthetic polyester mesh.

Agrawal H, Tholopady SS, Capito AE, Drake DB, Katz AJ. "Macrophage phenotypes correspond with remodeling outcomes of various acellular dermal matrices." *Journal of Regenerative Medicine*. 2012. Vol 1, No. 3, pp 51-59. [Click here for link.](#)

- Results of study demonstrate that ADM's, particularly Dermacell, with a higher ration of M2 to M1 were associated with a more constructive tissue remodeling outcome. Greater M2 activity promoted cell proliferation and tissue repair. ADM's with more M1 activity showed more inflammatory tissue remodeling, which inhibits cell proliferation and causes tissue damage.
- NOTE: Dermacell is another tradename for ArthroFlex.

Rosines, E. & Lin, Q. "Analysis of the Acellular Matrix, Growth Factors, and Cytokines Present in ArthroFlex[®]" 2012.

- Human skin is a complex tissue containing various extracellular matrix molecules, growth factors, and cytokines. The purpose of this study was to ensure that ArthroFlex, a minimally manipulated human skin product, retains the components of healthy human skin relevant to the structural support of damaged soft tissue. "Findings suggest that ArthroFlex retains a broad array of extracellular matrix components, matrikines, growth factors, and cytokines present in healthy human skin and provides structural ECM components that can help prevent re-tearing of surgically attached tendons." "ArthroFlex provides the collagens that supplement structural integrity and mechanical strength to surgically attached tendons, aiding in the prevention of a re-tear." Available upon request.

Moore, M.A. "Inactivation of enveloped and non-enveloped viruses on seeded human tissues by gamma irradiation." 2012. *Cell Tissue Bank*. 13(3):401-7. doi: 10.1007/s10561-011-9266-0. [Click here for link.](#)

- Author studied effect of low dose gamma irradiation on viruses seeded onto human tissue. "...Data presented here indicate that terminal sterilization using a low temperature, low dose gamma irradiation process inactivates both enveloped and non-enveloped viruses containing either DNA or RNA, thus providing additional assurance of safety from viral transmission."

LifeNet Health Research and Development "Analysis of DNA Residuals in ArthroFLEX Tissue" 2013 White Paper. Available upon request.

- Paper shows that "MatrACELL processing effectively removes DNA and cellular components from human dermis, potentially improving graft incorporation, healing, and biocompatibility by decreasing or eliminating cellular immune response."

Moore MA, Samsell B, Wallis G, Triplett, S, Chen S, Linthurst Jones A, Quiz X. "Decellularization of Human Dermis Using Non-Denaturing Anionic Detergent and Endonuclease: A Review." *Journal of Cell and Tissue Banking*. [Click here for link.](#)

- "MatrACELL process effectively removes cellular material, including DNA and immunogenic components, yielding an acellular dermis, which retains biomechanical strength and is biocompatible. Both preclinical and clinical results support the use of this allograft tissue in a myriad of clinical applications.



Biomechanical or Literature Reports Using **ArthroFLEX**

Beitzel, K., Chowanec, D.M., McCarthy, M.B., Cote, M.P., Russell, R.P., Obopilwe, E., Imhoff, A.B., Arciero, R.A, & Mazzocca, A.D. "Stability of double-row rotator cuff repair is not adversely affected by scaffold interposition between tendon and bone." *Am J Sports Med*. 2012 May;40(5):1148-54. [Click here for link.](#)

- Investigators used 25 cadaveric shoulders to evaluate strength of rotator cuff repairs without augmentation and augmentation using Viscogel, Mucograft, and ArthroFlex interpositionally, as well as augmentation with ArthroFlex on top of repair (5 groups). Authors conclude that ArthroFlex used on top of repair demonstrated an increased ultimate load to failure.

Van der Meijden, O.A., Wijdicks, C.A., Gaskill, T.R., Jansson, K.S., & Millett, P.J. "Biomechanical analysis of two tendon posterolateral rotator cuff tear repairs: extended linked repairs and augmented repairs." *Arthroscopy*. 2013 Jan;29(1):37-45. doi:10.1016/j.arthro.2012.07.012. [Click here for link.](#)

- Investigators compared single-row (SR), extended double-row (DR), and augmented, extended double row (aDR) in 20 cadaveric shoulders. ArthroFlex was used for the aDR group. Authors conclude that "augmentation with a collagen patch (aDR) did not influence biomechanical repair qualities in this model, but did result in less variability in failure load and more consistency in the mode of failure."

Ely E, Figueroa, N, Gilot G. "Biomechanical Analysis of Gap Formation and Ultimate Tensile Failure Loads of Rotator Cuff Repairs with Extracellular Matrix Graft Augmentation." *ORTHOPEDICS*. 2014;37(9):608-614. [Click here for link.](#)

- Biomechanical study demonstrates that cadaveric RCR's augmented with ArthroFlex had an increased ultimate load to failure by 29% compared to controls and decreased gap formation by 21% compared to controls.

Ehsan, A., Lee, D.G., Bakker, A.J., 7 Huang, J.I. "Scapholunate ligament reconstruction using an acellular dermal matrix: a mechanical study." *J Hand Surg Am*. 2012 Aug;37(8):1538-42. doi: 10.1016/j.jhas.2012.04.043. [Click here for link.](#)

- Investigators compared reconstructions of the scapholunate ligament using 1.0 mm-thick and 1.5 mm- thick ArthroFlex grafts to the intact native ligament in 15 cadaveric specimens. The authors conclude that "scapholunate ligament reconstruction using acellular dermal matrix demonstrates similar biomechanical properties to previously described techniques" and can be a potential treatment for chronic scapholunate instability.

Other Articles Using Acellular Dermal Matrices

Parks RM, Parks SM. Lateral Ankle Stabilization Using Acellular Dermal Allograft Augmentation. *J Am Podiatr Med Assoc*. 2015 May; 105(3):209-217. [Click here for link.](#)

- Authors used various ADM's to augment Brostrom-type procedures in 33 patients with satisfactory results and no recurrent instability.

Barber, F.A., Burns, J.P., Deutsch, A., Labbé, M.R., & Litchfield, R.B. "A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair." *Arthroscopy*. 2012 Jan;(1):8-15. doi: 10.1016/j.arthro.2011.06.038.

- Large rotator cuff repairs arthroscopically. Study included 42 patients, 22 of which were in the augmented group. Functional outcome scores were significantly better in the augmented group than the non-augmented group. Gadolinium-enhanced MRI films showed intact cuffs in 85% of the augmented group compared to only 40% in the non-augmented group. [Click here for link.](#)

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Barber, F.A., Herbert, M.A. & Boothby, M.H. "Ultimate tensile failure loads of a human dermal allograft rotator cuff augmentation." *Arthroscopy*. 2008 Jan;24(1):20-4. doi: 10.1016/j.arthro.2007.07.013. [Click here for link.](#)

- Investigators examined failure mode of supraspinatus tendon repairs with and without human dermal allograft augmentation in 10 matched pairs of human cadaveric supraspinatus muscles and tendons. Augmented tendons had greater ultimate failure load supporting the hypothesis that a human dermal allograft significantly increases the strength of a repaired tendon.

Kokkalis, Z.T. Zanaros, G., Weiser, R.W., & Sotereanos, D.G. "Trapezium resection with suspension and interposition arthroplasty using acellular dermal allograft for thumb carpometacarpal arthritis." *J Hand Surg Am*. 2009 Jul-Aug;34(6):1029-36. doi: 10.1016/j.jhsa.2009.03.001. [Click here for link.](#)

- Authors used an acellular dermal allograft in arthroplasty for thumb carpometacarpal arthritis in 89 patients (100 thumbs). Patients reported significantly reduced pain levels, increased grip strength and key pinch strength. They conclude that using an acellular dermal matrix is highly effective for the treatment of thumb carpometacarpal arthritis via trapeziectomy with suspension and interposition arthroplasty.

Lee, D.K. "A preliminary study on the effects of acellular tissue graft augmentation in acute Achilles tendon ruptures." *J Foot Ankle Surg*. 2008 Jan-Feb;47(1):8-12. [Click here for link.](#)

- Author evaluated the effectiveness of an acellular human dermal tissue matrix as an augmentation material in acute Achilles tendon repairs in 11 patients. At 20-month postoperative follow-up, there have been no cases of re-rupture or recurrent pain. Clinical results suggest "that with an acellular human dermal tissue matrix to augment acute Achilles tendon, primary repair offers a desirable return-to-activity time without any re-rupture or complications."

Yao CA, Ellis CV, Cohen MJ Kulber DA. Preserving the Posttrapeziectomy space with a Human Acellular Dermal Matrix Spacer: A Pilot Case Series of Patients with Thumb Carpometacarpal Joint Arthritis. *Plast Reconstr Surg Glob Open*. 2013 Oct; 1(7):e65.

- Authors used a Human ADM to fill space left by trapeziectomy in 16 patients with good outcomes. [Click here for link.](#)

Rao BM, Kamal TT, Vafaye J, Taylor L. Surgical repair of hip abductors. A new technique using Graft jacket allograft acellular human dermal matrix. [Click here for link.](#)

- Authors used a human ADM in 12 patients for repair of gluteus medius and minimus insertions with good outcomes.

Surgical Technique Guides Featuring **ArthroFLEX**

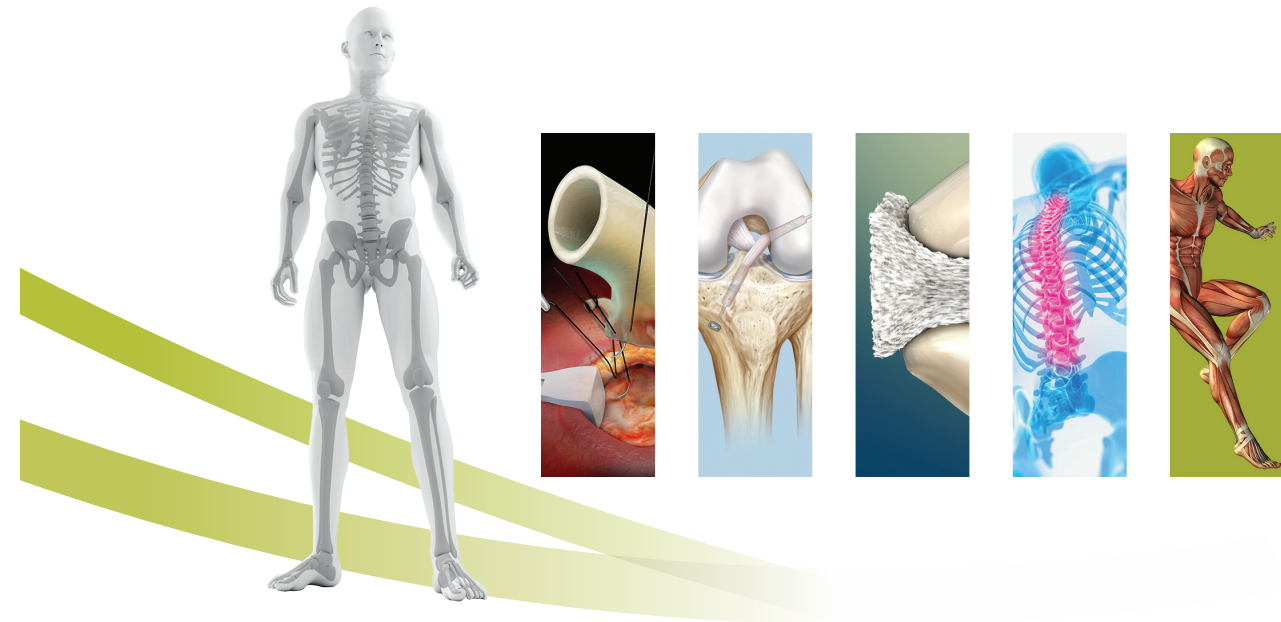
Arthrex. Massive Rotator Cuff Repair and Augmentation using the SpeedBridge™ and ArthroFlex® Dermal Matrix Surgical Technique. Document available upon request. [Click here for link.](#)

Arthrex. Achilles Tendon Reinforcement with ArthroFlex® Decellularized Dermis Surgical Technique. [Click here for link.](#)

Arthrex. SpeedBridge™ and SpeedFix™ Knotless Rotator Cuff Repair using the SwiveLock® C and FiberTape® Surgical Technique. [Click here for link.](#)

Arthrex videos and presentations featuring ArthroFlex. [Click here for link.](#)

Suture Retention Strength of ArthroFlex by Raffy Mirzayan. [Click here for video.](#)



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