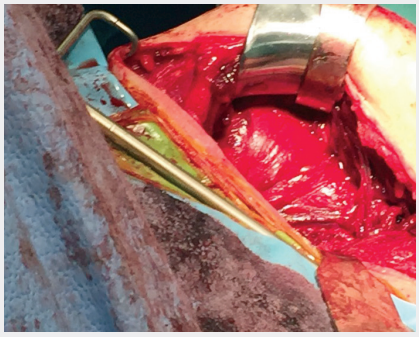
MIMEDX

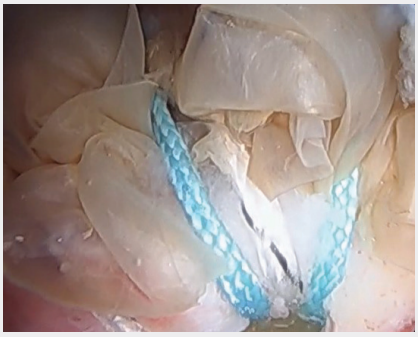
VOLUME 1 | EDITION 2

ADVANCED PLACENTAL-BASED ALLOGRAFTS

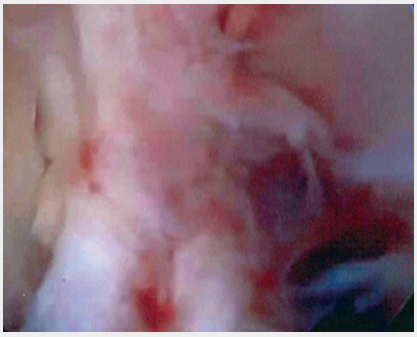
ORTHOPEDIC SURGERY CASEBOOK



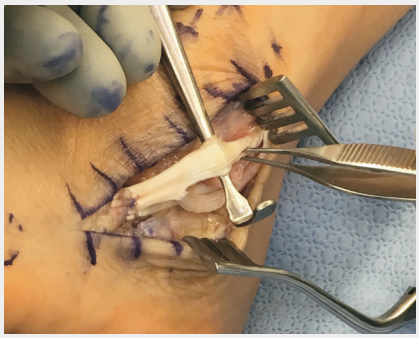
TOTAL SHOULDER REPAIR WITH AMNIOFIX®



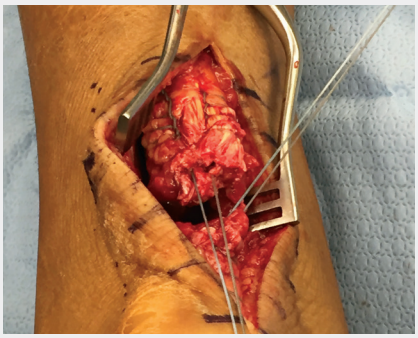
ARTHROSCOPIC ROTATOR CUFF REPAIR WITH AMNIOFIX FEATURING: LINK TO TECHNIQUE VIDEO



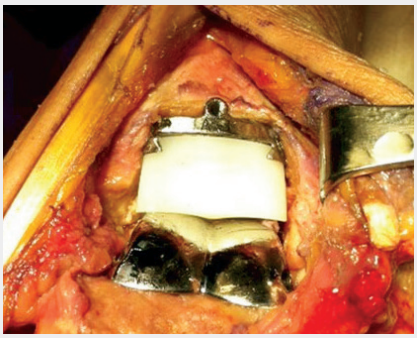
ACL RECONSTRUCTION & REPAIR OF PARTIAL PATELLAR TENDON TEAR WITH AMNIOFIX



REPAIR OF A PERONEAL TENDON TEAR WITH AMNIOCORD®



REPAIR OF RUPTURED ACHILLES TENDON WITH AMNIOCORD



TOTAL ANKLE REPLACEMENT WITH AMNIOCORD

US-ME-2100057 v3.0

Total Shoulder Repair With AMNIOFIX

Lonnie Paulos, MD | Orthopedic Surgery | Salt Lake City, Utah

Clinical History

A 43-year-old male with a history of traumatic injury to the shoulder developed chronic osteoarthritis (OA) of the glenohumeral joint due to an injury with six prior open or arthroscopic procedures to correct it. He subsequently developed chronic pain and shoulder instability. In addition to the severe OA noted, the patient had developed significant scarring and adhesions throughout the subcutaneous shoulder capsular tissues. His range of motion was significantly reduced.

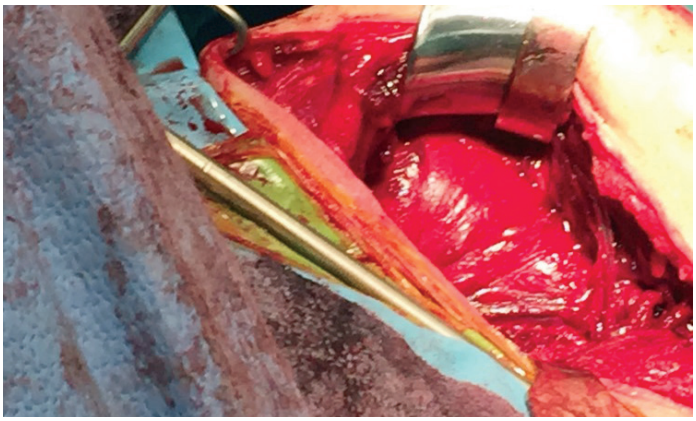
Surgical Intervention

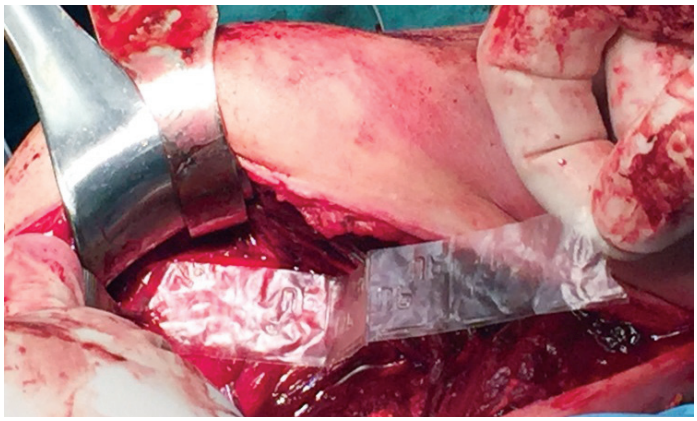
The patient's previously placed prosthesis was removed and replaced with a total shoulder system, and a capsular release was performed. The surgery included a pectoralis transfer to reconstruct the attenuated subscapularis muscle tendon. One 2 cm x 12 cm and two 2 cm x 3 cm AMNIOFIX grafts were placed under the deltoid (anteriorly, posteriorly, and laterally). Placement sites were on the superior aspect of the rotator cuff and at the proximal humerus, below the deltoid muscle. AMNIOFIX is a dehydrated human amnion/chorion membrane allograft. AMNIOFIX sheets provide a protective barrier and environment that supports the healing cascade. AMNIOFIX provides a human biocompatible extracellular matrix (ECM) and contains 300+ regulatory proteins.[1-3]

Follow-Up

On the first postoperative day, the patient's condition was substantially improved. He was seen as an outpatient on postoperative Day 4 and noted to have a good range of motion, using his arm in a very normal, functional manner. His range of motion progressed quickly, and he was able to discontinue physical therapy after three weeks.

At his one-year visit, the shoulder was stable and pain free. Shoulder range of motion was reduced somewhat, with 20 degrees full flexion, internal rotation performed to the level of the 3rd lumbar; external rotation was 150 degrees at 0 degree abduction, and 60 degrees at 90 degree abduction. However, a better than expected outcome was achieved.





2 cm x 12 cm AMNIOFIX placement

US-ME-2100057 v3.0

Arthroscopic Rotator Cuff Repair With AMNIOFIX

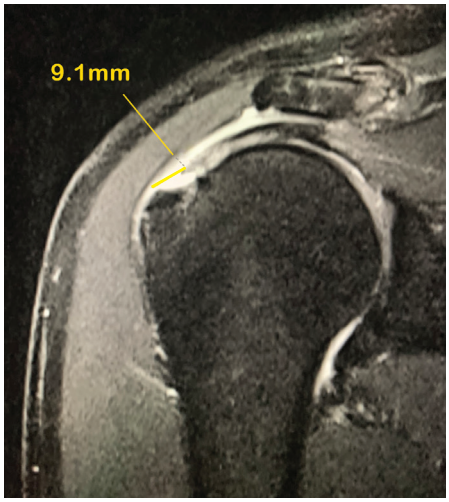
Brett Cascio, MD | Orthopedic Surgery and Sports Medicine | Lake Charles, LA

Clinical History

A 52-year-old male smoker with a right shoulder injury due to a minor fall onto his outstretched hand approximately one month prior to presentation. He reported immediate pain and popping in his right shoulder which he managed with over-the-counter medications. The pain had progressed to a level of 6 out of 10, which made it difficult to perform work activities and sleep.

Physical exam: Active forward flexion of the right shoulder was 150 degrees. Empty can test was positive. Impingement signs were positive. There was tenderness over the bicipital groove and acromioclavicular joint, and he had pain with cross-body adduction.

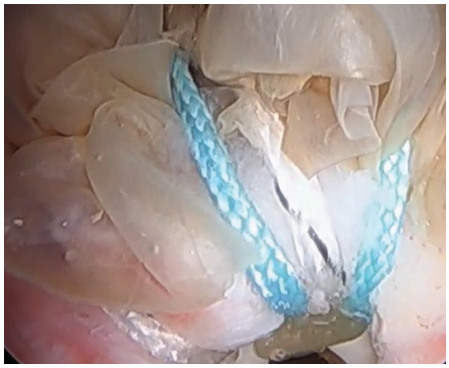
The patient underwent a steroid injection at his initial visit, and a course of physical therapy was ordered. Approximately two weeks after his steroid injection, the patient reported that the injection helped for a few days, but he continued to have pain and difficulty sleeping. An MRI demonstrated a focal full-thickness supraspinatus tear, long head of the biceps tendinopathy, osteoarthritis of the acromioclavicular joint, and a glenoid labrum tear.



Pre-MRI: A focal full-thickness supraspinatus tear, long head biceps tendinopathy, osteoarthritis of the acromioclavicular joint, and a glenoid labrum tear

Surgical Intervention

The patient underwent a right shoulder arthroscopy with rotator cuff repair and application of AMNIOFIX allograft. AMNIOFIX was selected due to concerns with the patient's poor healing potential.



AMNIOFIX allograft secured to the repair site

Follow-Up

At the 3 month follow-up visit, the patient's pain was minimal, function was excellent, and he returned to full work capacity, including overhead lifting and turning activities. Upon further follow up, the patient reported that his shoulder was doing well and declined a post-op MRI.

Technique Video: View by scanning code with camera on smartphone

Endoscopic ACL Reconstruction & Repair of Partial Patellar Tendon Tear With AMNIOFIX

Daniel Kharrazi, MD | Orthopedic Surgery | Los Angeles, CA

Clinical History

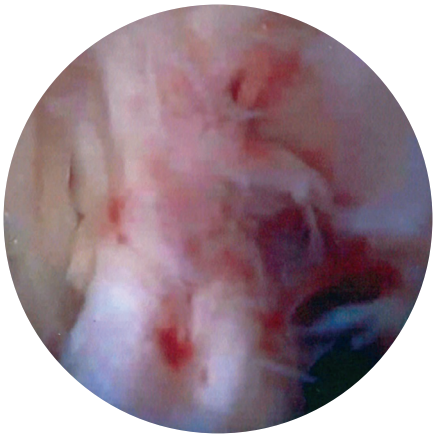
A 28-year-old female sustained a grade III ACL tear while skiing. Her examination confirmed positive Lachman, anterior drawer and pivot shift tests. She was also diagnosed with a concurrent tear of the lateral patellar tendon at its proximal attachment.

Surgical Intervention

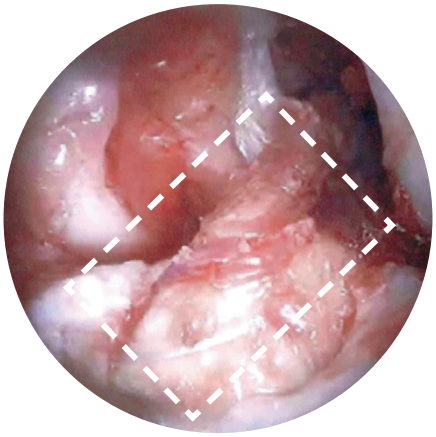
She underwent surgical reconstruction of the left knee three months after her injury, which included endoscopic reconstruction of the ACL utilizing Achilles tendon allograft with augmented repair of a partial tear of the lateral patellar tendon using AMNIOFIX. The ACL Achilles tendon allograft was wrapped with AMNIOFIX.

Follow-Up

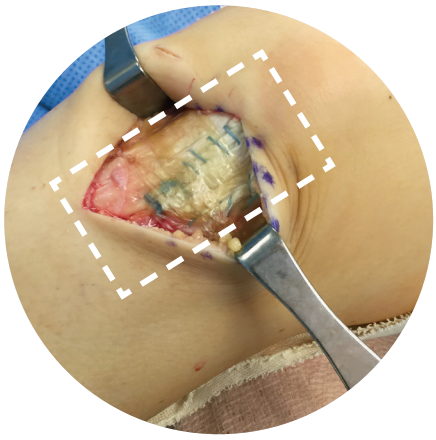
Initial outcomes were as expected, with rehabilitation based on an accelerated ACL protocol. A postoperative functional hinged brace was used for the first few weeks and switched to a functional ACL brace at two months. She was noted to have full extension with flexion of 130 degrees, with stable Lachman and anterior drawer tests with a negative pivot shift. She also had 5/5 strength in extension of her left knee. At four months postop, a light jogging program and swimming program was initiated. She was discharged from care at eight months, as she had excellent progress and recovery following ACL reconstruction, along with repair of partial tear of the lateral patellar tendon with AMNIOFIX augmentation.



ACL was completely ruptured from its femoral attachment



Anatomical ACL reconstruction using augmented allograft wrapped with AMNIOFIX



Repair of the partial tear of the lateral patellar tendon with AMNIOFIX augmentation

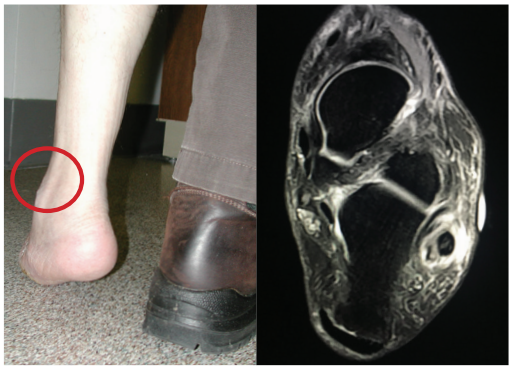
US-ME-2100057 v3.0

Repair of a Peroneal Tendon Tear With AMNIOCORD

Steven K. Neufeld, MD | Orthopedic Surgery | Falls Church, VA

Clinical History

A 58-year-old male presented with long-standing tenderness and swelling along his left peroneal tendons. Past medical history is significant for multiple ankle inversion injuries all treated conservatively. He experienced pain with resisted eversion. MRI showed a complex peroneal brevis tear with associated tenosynovitis.

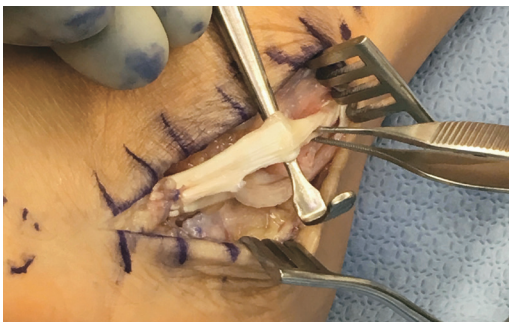


MRI

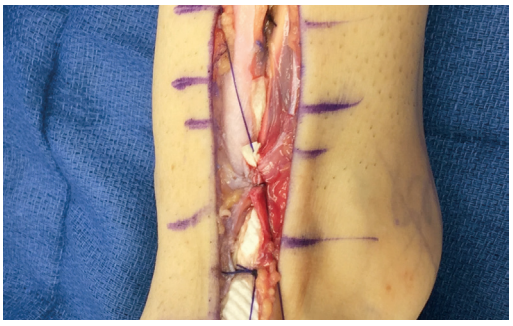
Surgical Intervention

A complex peroneal brevis tear involving greater than 50% of the tendon and associated degeneration, scarring and tenosynovitis was noted. The severely shredded peroneal brevis tendon was debrided and repaired by connecting the intact peroneal longus tendon to the torn peroneal brevis tendon. AMNIOCORD was applied over the repair and sutured around the connected tendons to act as a barrier. The superior peroneal retinaculum was also repaired and augmented with AMNIOCORD.

AMNIOCORD is a dehydrated human umbilical cord allograft that provides a protective environment to support the healing process. It protects the wound bed to aid in the development of granulation tissue. The product provides a human biocompatible extracellular matrix of hyaluronic acid and collagen and contains 250+ regulatory proteins.[3,4]



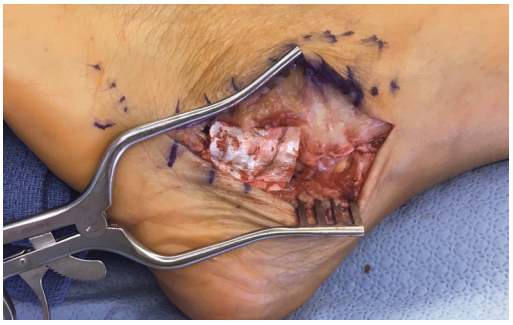
Lack of healthy tendon after removal of necrotic, torn tissue



Tenodesis of the peroneals

Follow-Up

The patient was placed in a splint postoperatively and told to remain non-weight-bearing on crutches. Postop Day 10, he was placed in a weight-bearing cast. The cast was removed four weeks postop. The patient began physical therapy, and good early range of motion was observed. He was able to return to his normal activities three months after the procedure with no discomfort.



AMNIOCORD applied to repair

Repair of Ruptured Achilles Tendon With AMNIOCORD

Daniel J. Cuttica, DO | Orthopedic Surgery | Falls Church, VA

Clinical History

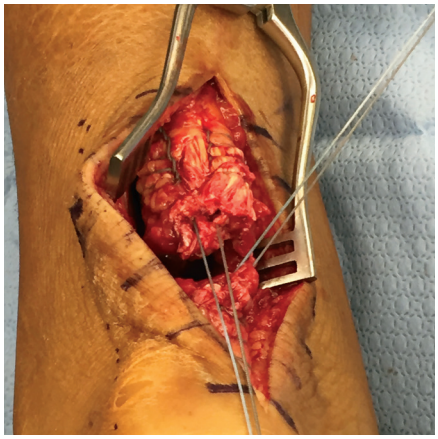
A 45-year-old male suffered an Achilles tendon rupture while playing basketball. The patient had no previous history of injury to the affected ankle. Upon physical examination, the patient had swelling, bruising, and tenderness. There was a palpable defect present in the watershed region of the Achilles tendon and an absent Thompson test. Lateral X-ray of the ankle was normal. Ultrasound was performed and revealed a complete rupture of the Achilles tendon. Due to the patient's activity level and the complete nature of the rupture, surgical repair was the selected course of action.

Surgical Intervention

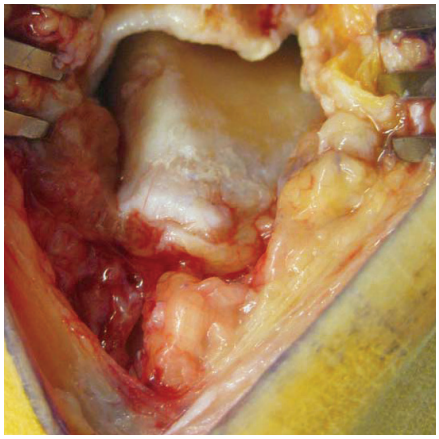
A Flexor Hallucis Longus (FHL) fasciotomy was performed prior to the tendon repair to allow blood supply to the Achilles repair site and a tension-free peritenon closure. The Achilles was then repaired in standard fashion, and an epitenon suture was utilized circumferentially to reinforce the repair. A 3 cm x 5 cm AMNIOCORD was placed directly over the repair site. AMNIOCORD adhered well to the tendon.

Follow-Up

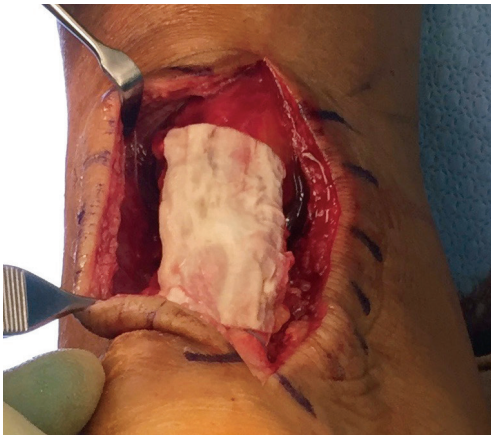
The patient achieved closure uneventfully. At 6 weeks postop, physical therapy was initiated.



Placement of sutures to repair the ruptured Achilles tendon



Achilles tendon rupture repaired



AMNIOCORD placed as an onlay directly over the repair site

US-ME-2100057 v3.0

Total Ankle Replacement With AMNIOCORD

Steven K. Neufeld, MD | Orthopedic Surgery | Falls Church, VA

Clinical History

A 65-year-old male presented with long-standing tenderness, swelling and stiffness in his right ankle. He was diagnosed with ankle arthritis. He failed conservative treatment including changing shoes, taking arthritis medications, cortisone injections, custom orthotics, and physical therapy. X-rays showed arthritis, and the patient was scheduled for a total anke replacement.

Challenge

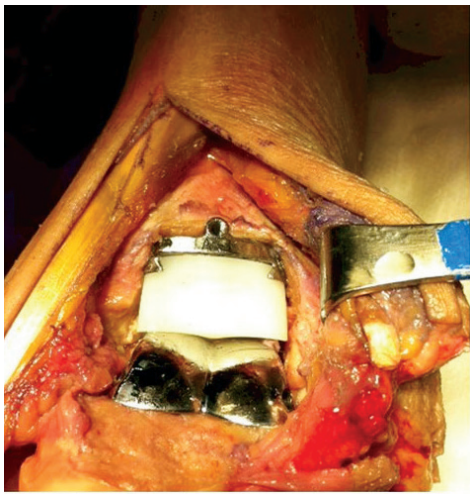
The extensor tendons, specifically the extensor halluces longus tendon, frequently become "stuck" in scar tissue, resulting in a stiff and painful ankle. Additionally, there is very little soft tissue between the ankle joint and the skin, posing increased risk for wound complications.

Surgical Intervention

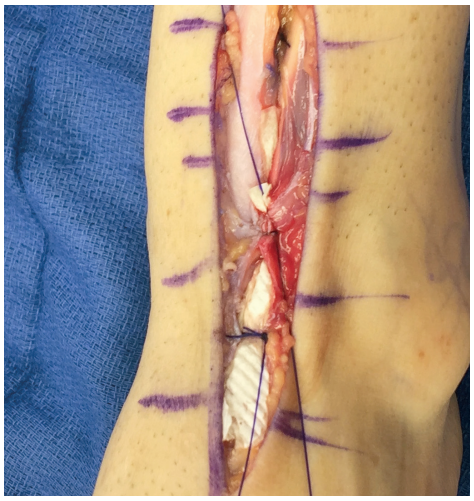
The patient underwent a total ankle replacement. A standard, layered closure was done: deep capsule followed by tendon sheaths, subcutaneous tissue, then skin. AMNIOCORD was cut and applied around the extensor tendons. The soft tissue and skin were closed over the AMNIOCORD, securing it in position.

Follow-Up

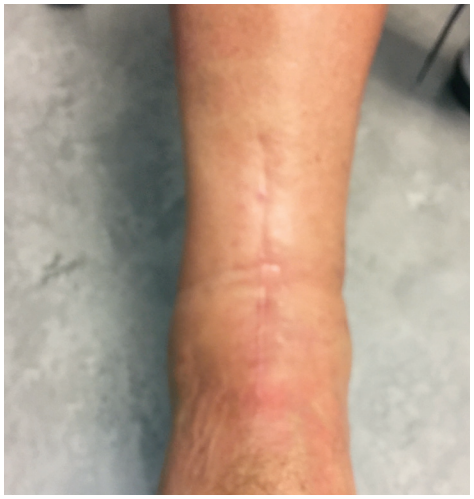
The patient was placed in a splint postoperatively and encouraged to ice and elevate the foot during the 1st postoperative week. Early range of motion exercises were started once the incision closed. He was able to return to his normal activities, including wearing normal shoes, three months after the procedure with no discomfort.



Total ankle replacement



AMNIOCORD applied to extensor tendons / under skin closure



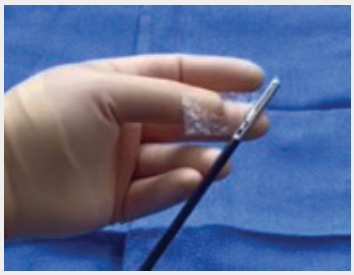
Closed incision

Tips for Minimally Invasive Procedures

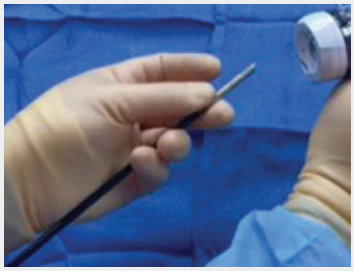
- Cut allograft to desired size, if needed, prior to introduction into the port.
- A minimum 8 mm port is recommended.
- Assure an optimal field of view by suction/aspiration/evacuation of the relevant surgical field. This will optimize exposure and prevent accidental poor positioning or accidental removal of the allograft.
- Surgical equipment and surgical site should be dry and clean of debris (pass gauze in and out of cannula).
- Ensure allograft is not hydrated / wet prior to introduction.
- Use an atraumatic grasper to introduce the allograft sheet through the assistant port.

Smaller Sheet Method

1. For a smaller sheet (e.g., 2 cm x 6 cm), grasp corner of allograft.



2. Wrap allograft around atraumatic grasper.

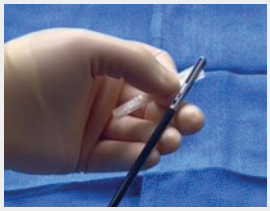


3. Hold the end of allograft in place while slowly and gently inserting it through cannula.

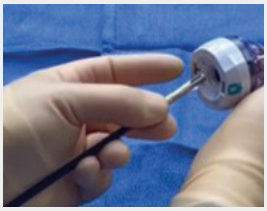
4. Release allograft from grasper and apply it to treatment area.

Larger Sheet Method

1. For a larger sheet (e.g., 4 cm x 6 cm), roll or fold allograft on a dry flat surface.



2. Grasp corner of allograft and wrap the remaining end of sheet around the grasper.



3. Hold the end of allograft in place while slowly and gently inserting it through cannula.

4. Release allograft from grasper.

5. Unfold or unroll the allograft and apply it to treatment area.

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Please Call: 866.477.4219 Email: customerservice@mimedx.com

REFERENCES 1. Koob TJ, Lim JJ, Massee M, Zabek N, Denozière G. Properties of dehydrated human amnion/chorion composite grafts: Implications for wound repair and soft tissue regeneration. J Biomed Mater Res B Appl Biomater. 2014;102(6):1353-1362. **2**. Lei J, Priddy LB, Lim JJ, Massee M, Koob TJ. Identification of Extracellular Matrix Components and Biological Factors in Micronized Dehydrated Human Amnion/Chorion Membrane. Adv Wound Care (New Rochelle). 2017;6(2):43-53. **3.** Bullard JD, Lei J, Lim JJ, Massee M, Fallon AM, Koob TJ. Evaluation of dehydrated human umbilical cord biological properties for wound care and soft tissue healing. J Biomed Mater Res B Appl Biomater. 2019;107(4):1035-1046.

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