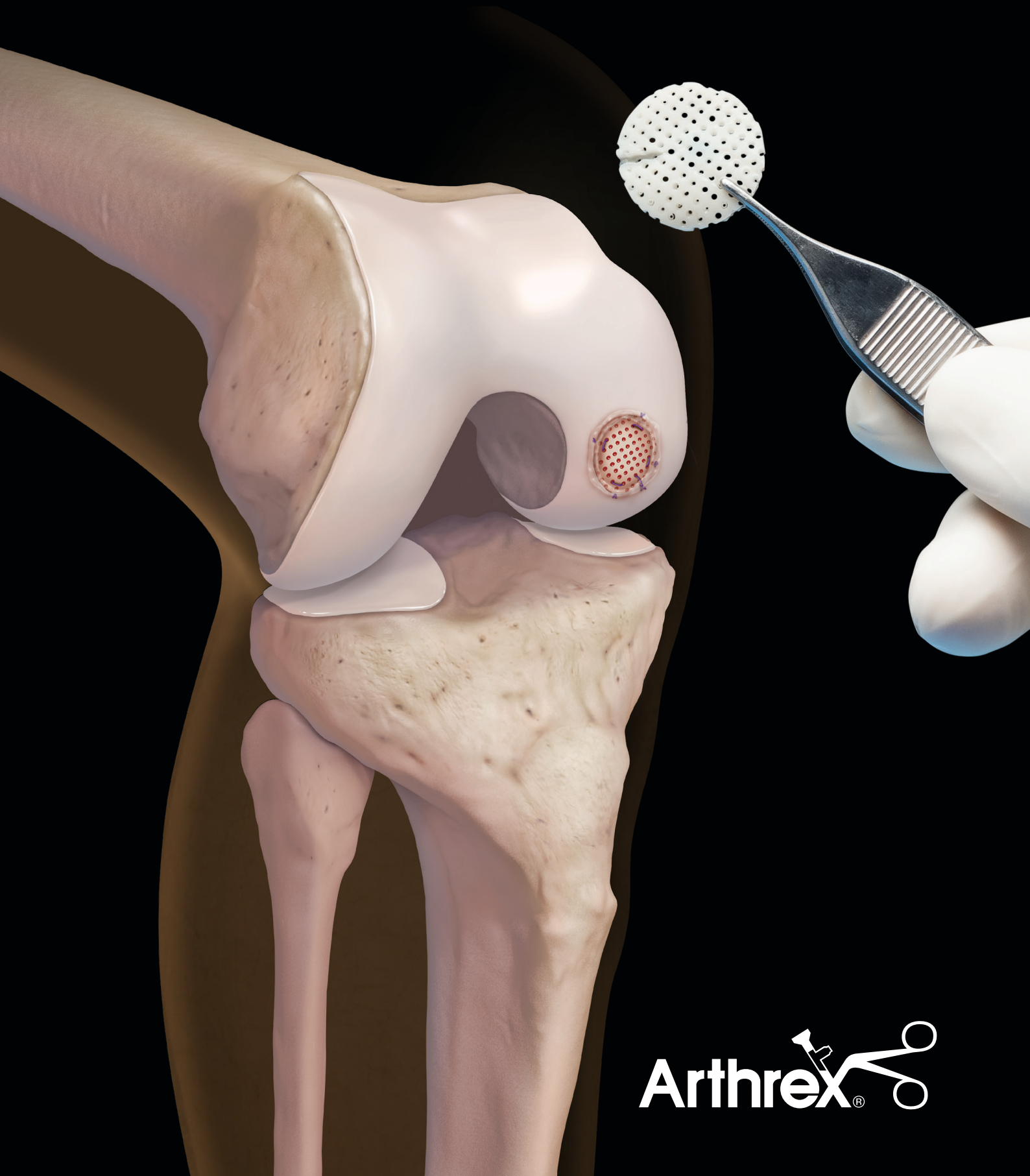
Cartiform®

Viable Osteochondral Allograft



Arthrex®

Cartiform® Viable Osteochondral Allograft

Features and Benefits

Cartiform is a cryopreserved osteochondral allograft composed of viable chondrocytes, chondrogenic growth factors, and extracellular matrix proteins. While maintaining an intact cartilage structure (Figure 1), the bony portion of the osteochondral allograft is minimal, and the graft is porated to offer unique handling characteristics and simple fixation techniques.

Cartiform allograft is recovered with minimal bone and porated for a variety of reasons:

- Minimal bone content and poration impart flexibility to the allograft, thereby improving handling characteristics for implantation and fixation (Figure 2)
- Pores increase the surface area and allow for the proprietary cryopreservative solution to penetrate the tissue and preserve chondrocyte viability throughout the allograft
- Pores allow for host cell infiltration into the graft following implantation in the osteochondral lesion

Cartiform viable osteochondral allograft combines the safety and success of traditional fresh stored osteochondral allografts with ease of use, as the graft is trimmable and flexible to match any lesion size and contour.

Stored in a proprietary cryopreservative solution, Cartiform allograft is readily available with a 2-year shelf life when stored at -80 °C. Experimental testing of Cartiform allograft indicates that >72% cell viability, postthaw, is maintained beyond 2 years (Figure 3).[1]

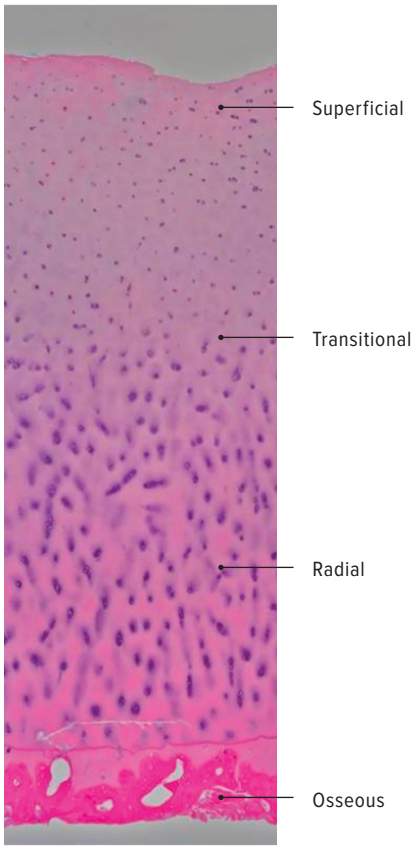


Figure 1. Structural organization of Cartiform allograft: Note microstructural preservation of 3 distinct cartilage zones (superficial, transitional, radial) and an osseous (bone) layer, as evident on histological staining (H&E).

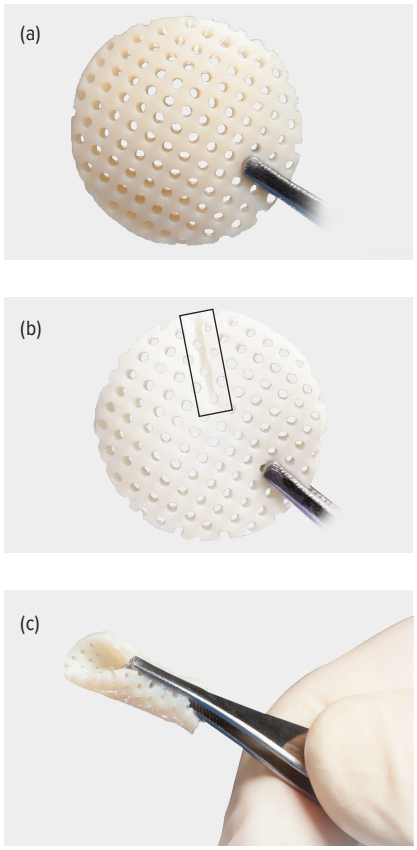


Figure 2. Appearance of Cartiform allograft (20 mm-diameter size), top **(a)**, bottom **(b)**, and side **(c)** views: Note the score mark distinguishing the bottom (bone) side (outlined with black box in **[b]**) and the flexibility that enables folding in **(c)**.

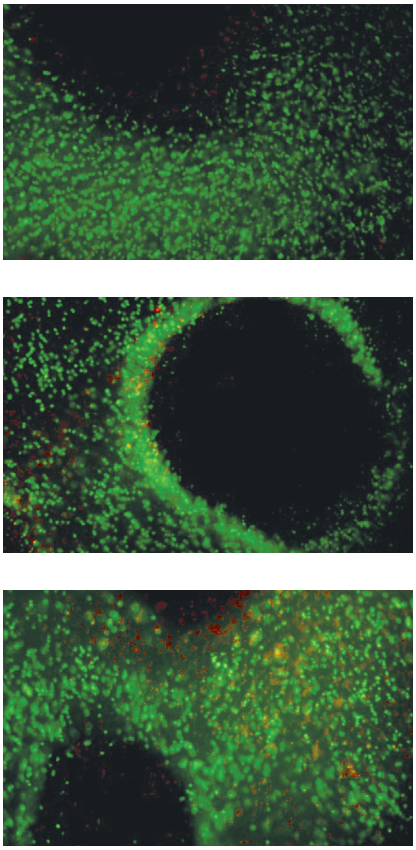


Figure 3. Live (green) and dead (red) cell staining of Cartiform units derived from one donor. Images show fresh Cartiform allograft, prior to cryopreservation (top); cryopreserved Cartiform allograft, postthaw after 6 days storage at -80 °C (middle); and cryopreserved Cartiform allograft, postthaw after 2.7 years storage at -80 °C (bottom).

Scientific Support for Cartiform® Allograft

Cartiform allograft is designed to provide a flexible, trimmable, and readily available osteochondral allograft with viable chondrocytes to surgeons for the treatment of articular osteochondral repair.

Cryopreserved Cartiform viable osteochondral allograft builds upon more than 40 years of safety and efficacy of fresh stored osteochondral allografts.[2,3] In situations of minimal bone loss, Cartiform allograft has been shown to improve the tissue quality in a properly prepared articular cartilage lesion and integrate into the surrounding host tissues.[2]

Cartiform allograft was implanted into osteochondral lesions (6 mm diameter) in a goat model to demonstrate its safety, integration, and ability to induce tissue formation.[4]

- At 3 months, the lesions treated with Cartiform allograft had significantly improved gross morphology and overall lesion fill compared to microfracture controls (Figure 4).
- At 12 months, the lesions treated with Cartiform allograft were filled with highly cellular, hyaline-like repair tissue. Aggrecan content increased and cellular morphology and distribution were comparable to the morphology of normal articular cartilage (Figure 5).[4]

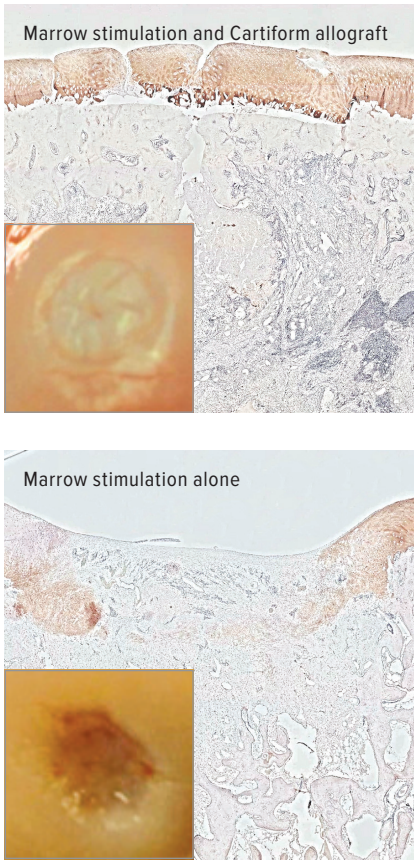


Figure 4. Gross morphology and type II collagen staining of cartilage defect 3 months postsurgery

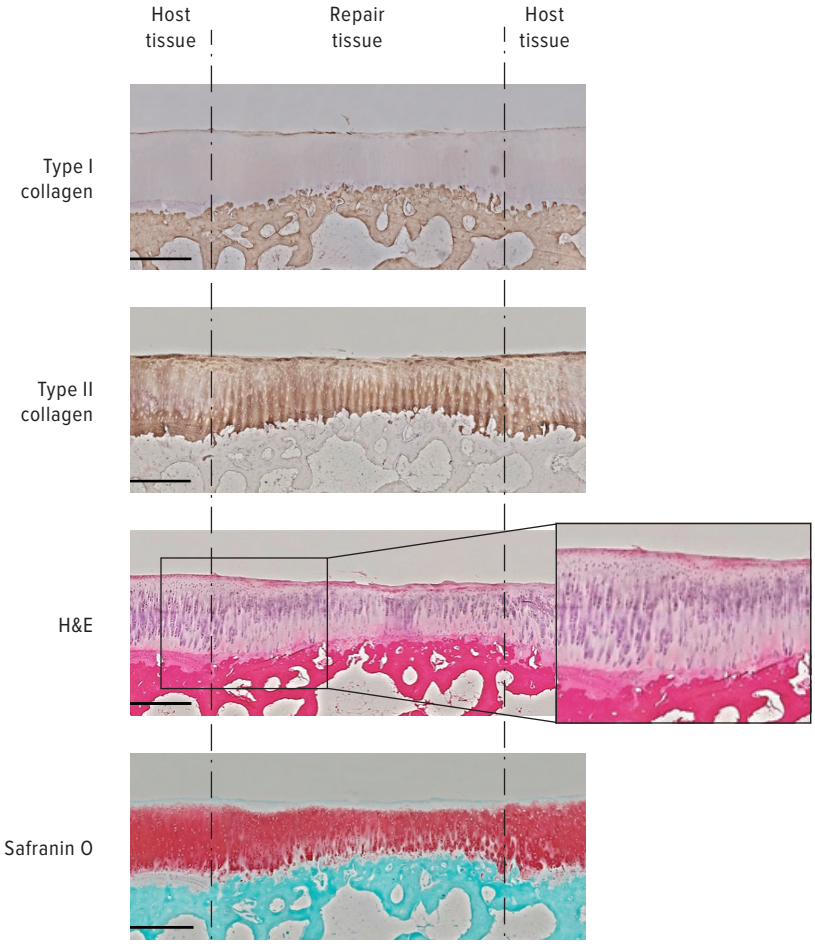


Figure 5. Histological staining in tissue section taken 12 months following Cartiform allograft implantation in goat model

Recovery and Quality Control Process

Cartiform® allograft is recovered from donated human cadaveric tissue that contains pristine articular cartilage upon gross evaluation. The tissue is processed using a proprietary technique, resulting in a porated, cryopreserved allograft consisting of full-thickness articular cartilage and a thin layer of bone. Cartiform allograft is readily available with a 2-year shelf life when stored at -80 °C.

1. Extensive sterility testing is performed on each lot to ensure the allograft tissue is safe for clinical use.
2. Prior to release for clinical use, characterization testing for the presence of viable cells and residual bone is performed for each donor.

Preparation Guide

Note: Graft color may vary as human articular cartilage color varies.

Remove the package insert, patient labels, and Cartiform pouch from the box.

Peel back the chevron pouch.

Using the aseptic technique, transfer the jar into the sterile field.

Place the sterile jar in a sterile basin.

Using the aseptic technique, add sterile saline until the volume reaches just below the lid. Incubate for ~10 minutes, until no ice crystals are visible.

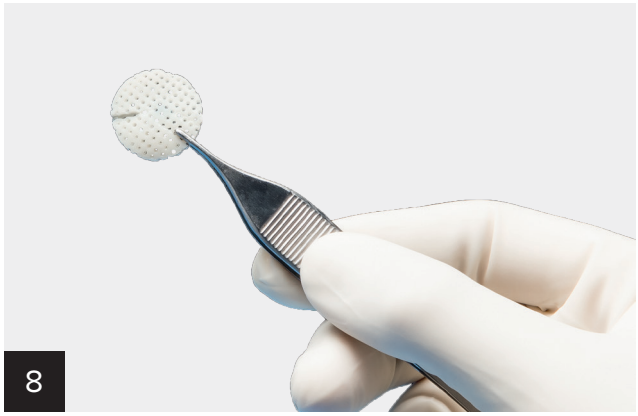
Note: Temperature of thawing solution should not exceed 39 °C (102 °F). Do not thaw for longer than 30 minutes.

Take the thawed Cartiform jar from the basin and unscrew the lid.

7

Using sterile forceps, remove the Cartiform® allograft from the jar. Place it in a sterile rinse basin containing room-temperature sterile saline for 1 minute. The allograft can be kept in sterile saline for up to 2 hours at room temperature prior to implantation.

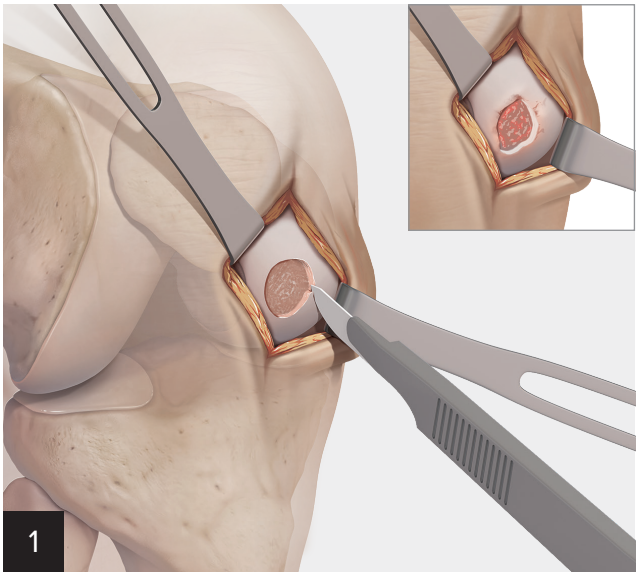
Note: Temperature of thawing solution should not exceed 39 °C (102 °F). Do not thaw for longer than 30 minutes.



8

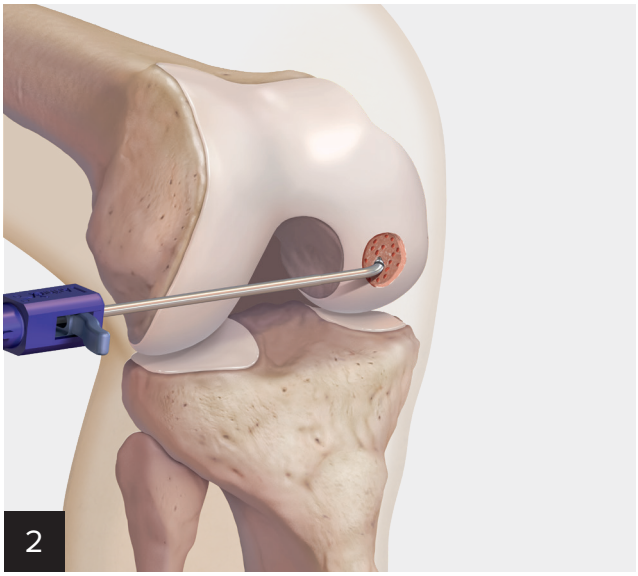
Once rinsed, the Cartiform allograft is ready to use. The side with the score mark is the bottom side of the graft.

Cartiform Allograft: Knee Arthrotomy—Condyle Surgical Technique



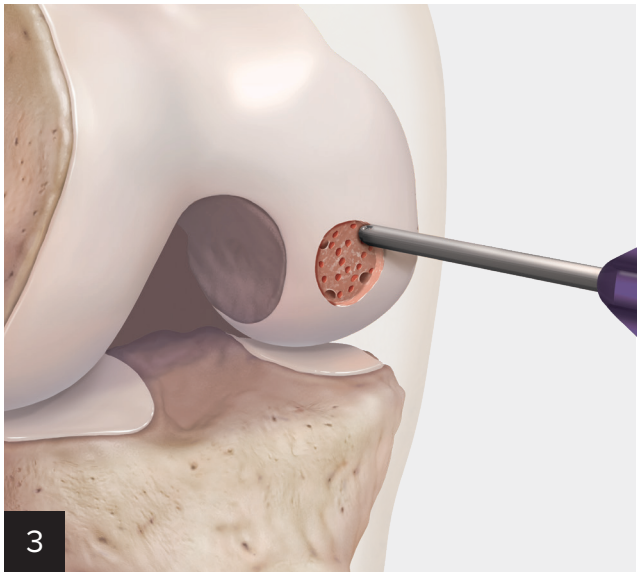
1

Debride the articular cartilage defect to a stable border with perpendicular margins. A scalpel can be used to create vertical margins, and a curette can be used to debride the calcified cartilage layer at the base of the defect.

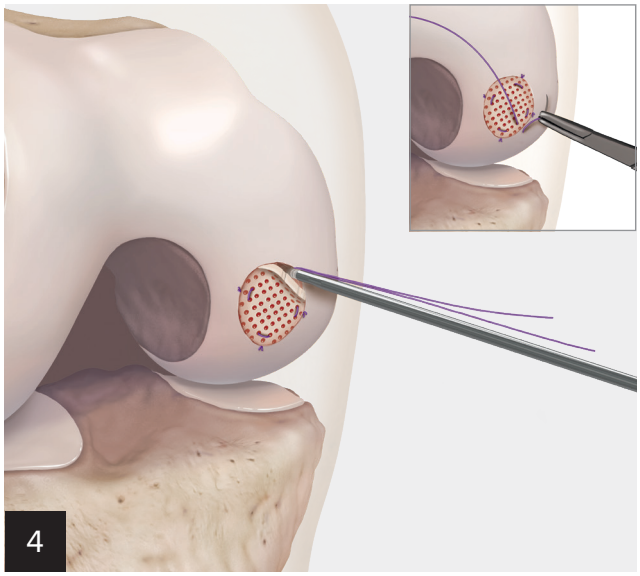


2

Optionally, perform bone marrow stimulation using the PowerPick™ instrument while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.

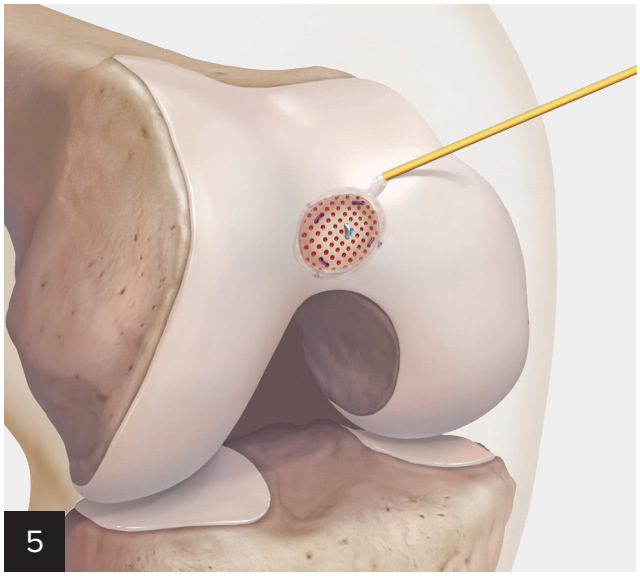


Template the lesion with sterile paper or foil. After thawing and rinsing the Cartiform® allograft, use a scalpel or surgical scissors to trim it to match the template. Place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® anchor fixation points.

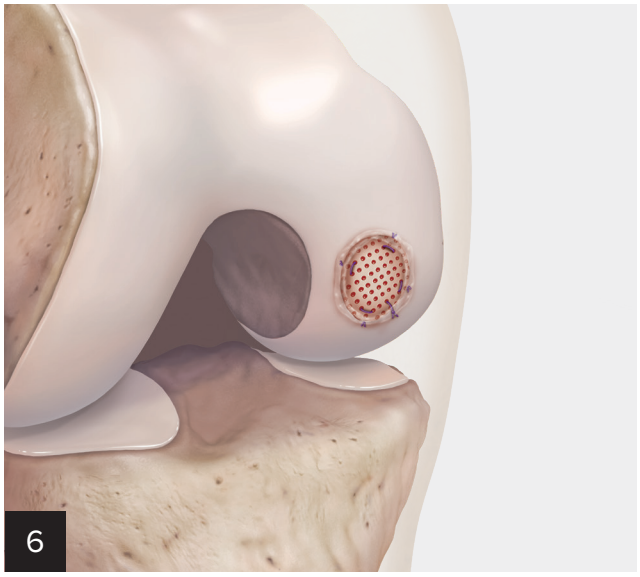


Pass the suture tails inferior to superior, then superior to inferior, to create a mattress stitch in each quadrant of the Cartiform allograft to match the location of the peripheral pilot holes. Working sequentially, fixate each quadrant of Cartiform to the lesion. In knotless anchor configurations, ensure the anchor eyelet is deeply seated prior to drawing tension on the suture, then implant the anchor to fixate.

Note: The side of the Cartiform allograft with the score mark is the bottom (bone) side.

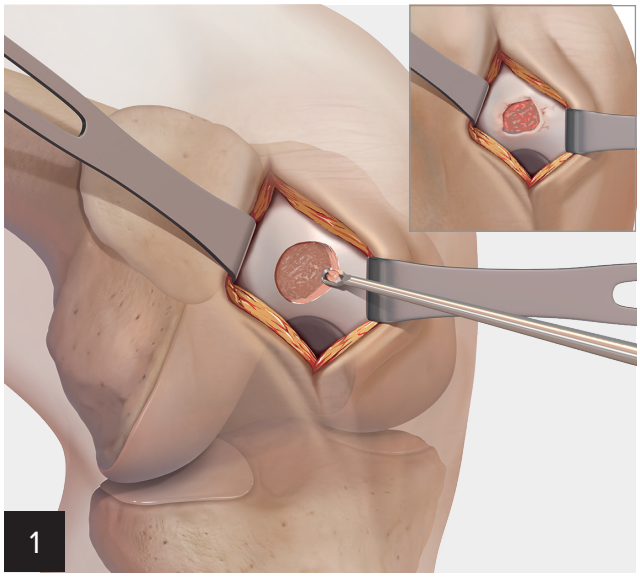


Optionally, apply a thin layer of fibrin glue around the Cartiform allograft periphery. Use a dual-lumen applicator tip for applying the fibrin, to prevent activation and clogging of the fibrin within the needle. Do not manipulate for 5 minutes after application. The knee can be gently ranged before closure to ensure fixation of the Cartiform allograft.

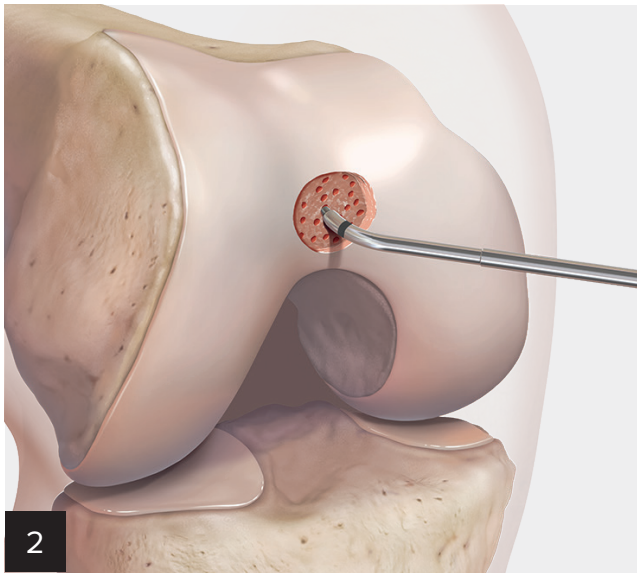


Postsurgery, the patient should use a knee brace to limit range of motion. Depending on the defect location, prescribe non–weight-bearing or protected–weight-bearing load. Subsequently, following osteochondral allograft implantation in the tibiofemoral or patellofemoral joint, implement standard rehabilitation protocols.

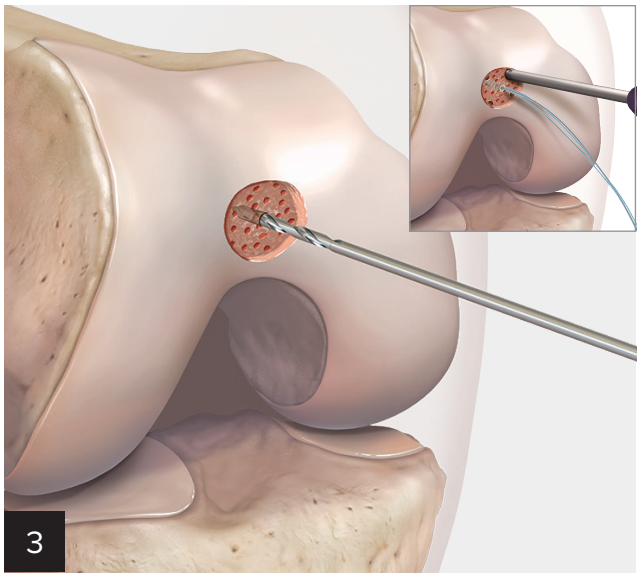
Cartiform® Allograft: Knee Arthrotomy—Trochlear Surgical Technique



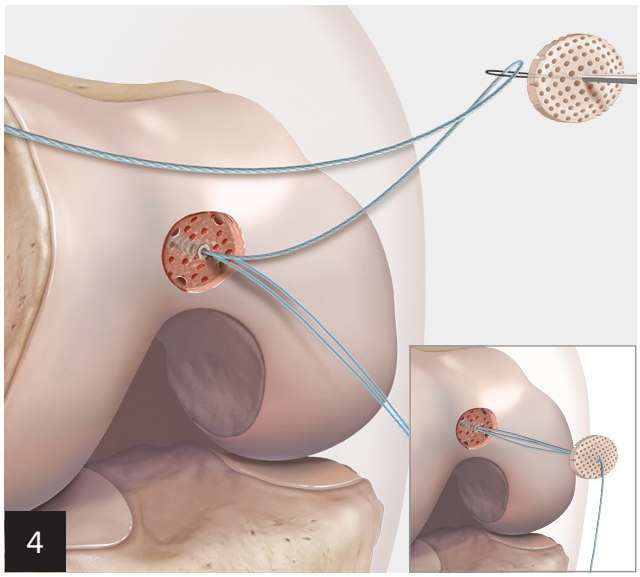
Debride the articular cartilage defect to stable borders with perpendicular margins. A ring curette and Cobb elevator can be used to create vertical margins and debride the calcified cartilage layer at the base of the defect.



Optionally, perform bone marrow stimulation using the PowerPick™ instrument while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.

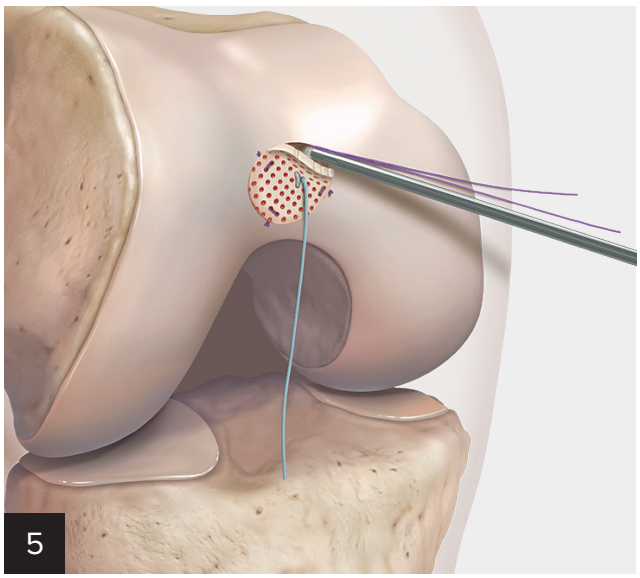


Template the lesion with sterile paper or foil. After thawing and rinsing the Cartiform allograft, use a scalpel or surgical scissors to trim it to match the template. Place a pilot hole in the center of the defect and implant the Knotless SutureTak® anchor. As necessary, place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® anchor fixation points.

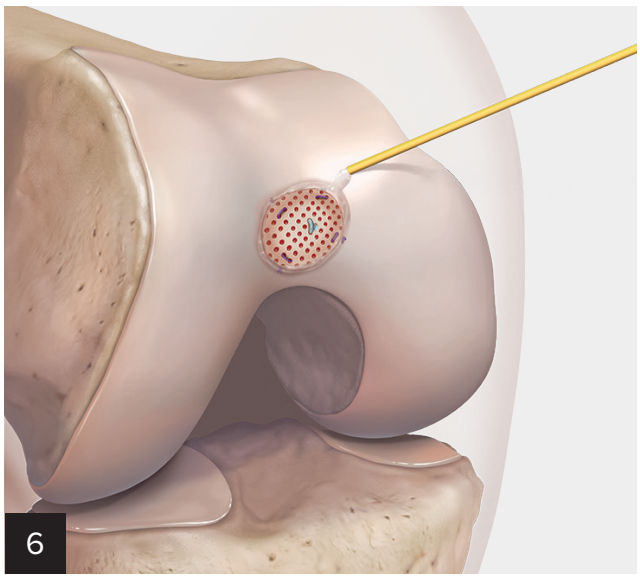


Pass the central anchor suture inferior to superior, then superior to inferior, to create a mattress stitch on the Cartiform allograft. Fixate the suture strand in the anchor by passing the suture tail with the FiberLink™ shuttling suture to create a single suture loop. The suture tail is then passed inferior to superior through the center of the Cartiform allograft, so tension on the strand can be drawn directly on top of the graft.

Note: The side of the Cartiform allograft with the score mark is the bottom (bone) side.

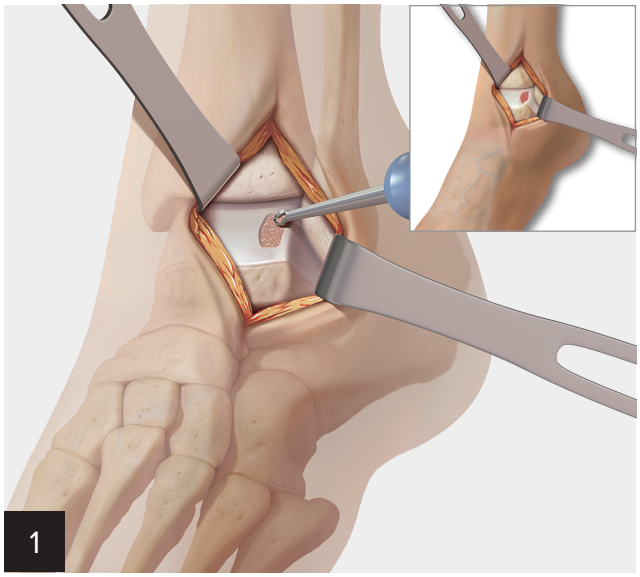


As necessary, further stabilize the graft with peripheral fixation points. Create a mattress stitch in each quadrant of the Cartiform® allograft to match the location of the anchor pilot holes. Sequentially, use the PushLock® anchor to achieve knotless fixation. In this knotless configuration, ensure the anchor eyelet is deeply seated in the pilot hole prior to tensioning the suture, then implant the anchor to fixate the graft. Optionally, use a free suture for additional graft stabilization.

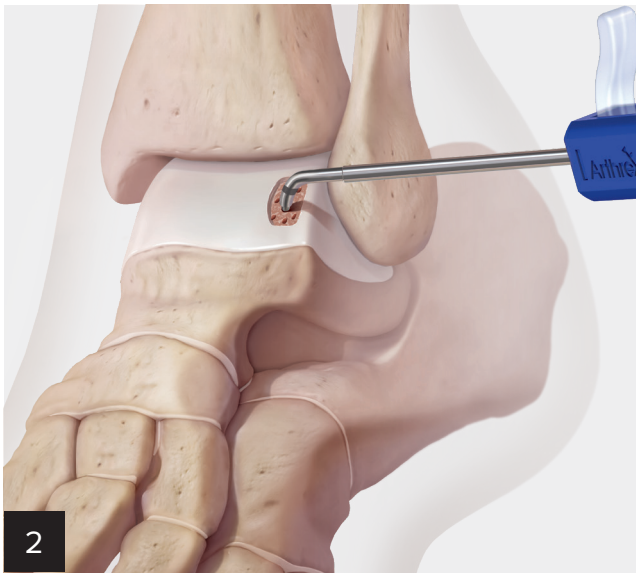


If desired, apply a thin layer of fibrin glue around the Cartiform allograft periphery. Do not manipulate for 5 minutes after application. The knee can be gently ranged before closure to ensure fixation of the Cartiform allograft. Postsurgery, the patient should use a knee brace to limit range of motion. Depending on the defect location, prescribe non–weight-bearing or protected–weight-bearing load. Subsequently, following osteochondral allograft implantation in the tibiofemoral or patellofemoral joint, implement standard rehabilitation protocols.

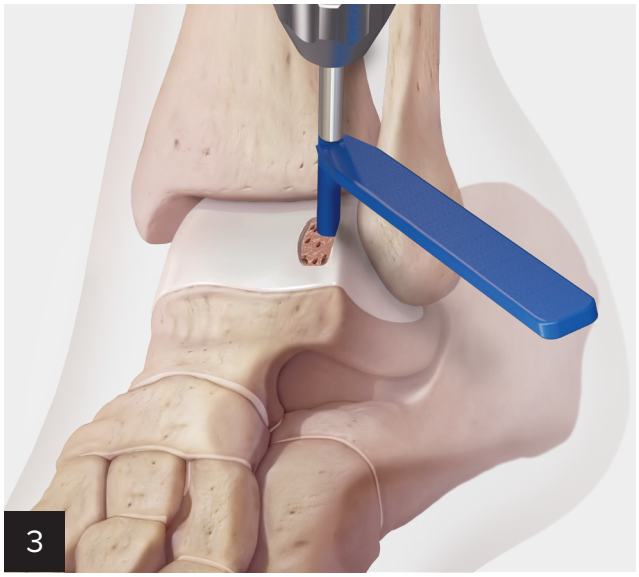
Cartiform® Allograft: Talus Surgical Technique



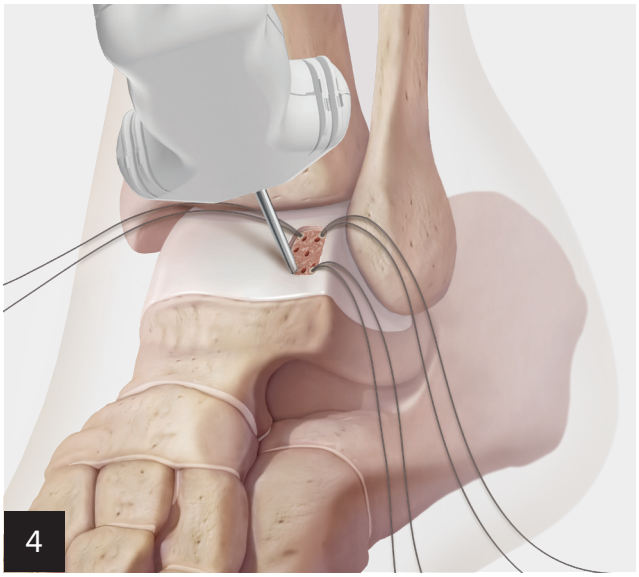
Apply distraction to the tibiotalar joint and debride the articular cartilage defect to a stable border with perpendicular margins. A ring curette can be used to create the vertical margins and debride the calcified layer at the base of the defect.



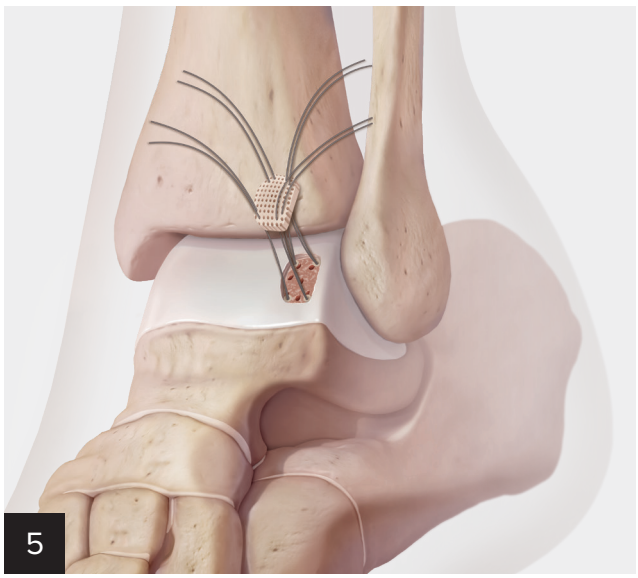
Perform bone marrow stimulation using the PowerPick™ instrument while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.



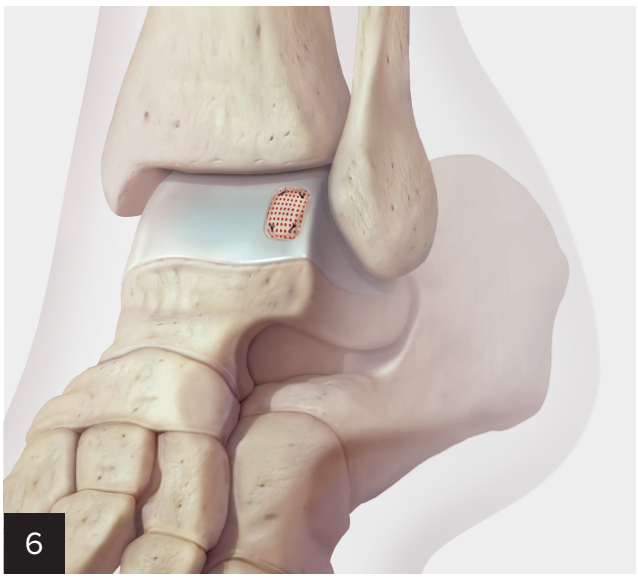
Template the lesion with sterile paper or foil. After thawing and rinsing the Cartiform allograft, use a scalpel or surgical scissors to trim it to match the template. Place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® anchor fixation points.



In a knotted fashion, fixate a single suture strand with each PushLock anchor. The resulting tails from each anchor are set aside for assembly with the Cartiform allograft.



Pass each suture tail inferior to superior through the Cartiform® allograft to match the orientation and position of the anchor placement in the lesion. Working sequentially, place simple knots to fixate the graft to the lesion.



If desired, apply a thin layer of fibrin glue around the Cartiform allograft periphery. Do not manipulate for 5 minutes after application. The joint can be gently ranged before closure to ensure fixation of the Cartiform allograft. Postsurgery, immobilize the ankle in neutral position and prescribe non–weight-bearing load. Thereafter, implement standard rehabilitation protocols similar to those for osteochondral allograft implantation procedures.

Ordering Information

Cartiform® Viable Osteochondral Allografts

Product Description	Item Number
Cartiform Allograft, 10 mm disc	ABS-**1101-10**
Cartiform Allograft, 20 mm disc	ABS-**1101-20**
Cartiform Allograft, 12 mm × 19 mm	ABS-**1102-19**
Cartiform Allograft, 20 mm × 25 mm	ABS-**1102-25**

Additional Products

Product Description	Item Number
PowerPick™ XL instrument, 45°, 6 mm depth	AR-**8150PX-45**
Chondral pick, straight 30° tip	AR-**8655-05**
Ring curette, reverse angled	AR-**8655-04**
Cobb elevator	AR-**8655-10**
Noninvasive ankle distractor set	AR-**1713S**
Ankle arthroscopy distractor strap	AR-**1712**
Ankle arthroscopy set	AR-**8655S**
2.9 mm PushLock® anchor disposable kit	AR-**1923DS**
2.9 mm Biocomposite PushLock anchor	AR-**1923BC**
Mini SutureTak® anchor disposable kit	AR-**1322DSC**
2.5 mm Mini Bio-PushLock™ anchor	AR-**8825B**
Knotless SutureTak anchor disposable kit	AR-**1934DS-2**
3 mm PEEK Knotless SutureTak anchor	AR-**1938PS**
Free 4-0 FiberWire® suture w/ tapered needle	AR-**7248**
Micro SutureLasso™ instrument, minor bend	AR-**8701**
FiberWire scissors	AR-**11796**
Metatarsal reamer, 20 mm	AR-**8944PR-20**
Tenodesis disposable kit, 3 mm × 8 mm	AR-**1530DS**
Biocomposite tenodesis screw, w/ handle inserter, 3 mm × 8 mm	AR-**1530BC**
SutureLasso SD wire loop	AR-**4068-05SD**
2-0 FiberWire suture, 18 in (blue) w/ tapered needle, 17.9 mm ⅜ circle	AR-**7220**
2-0 TigerWire® suture, 18 in w/ tapered needle	AR-**7220T**

Products advertised in this brochure / surgical technique guide may not be available in all countries. For information on availability, please contact Arthrex Customer Service or your local Arthrex representative.

References

1. Osiris Therapeutics, Inc. Data on file (LA1-00007-EN). Columbia, MD; 2015.
2. Bedi A, Feeley BT, Williams RJ 3rd. Management of articular cartilage defects of the knee. *J Bone Joint Surg Am*. 2010;92(4):994-1009. doi:10.2106/JBJS.I.00895
3. Görtz S, Bugbee WD. Allografts in articular cartilage repair. *Instr Course Lect*. 2007;56:469-480.
4. Geraghty S, Kuang JQ, Yoo D, LeRoux-Williams M, Vangsness CT Jr, Danilkovitch A. A novel, cryopreserved, viable osteochondral allograft designed to augment marrow stimulation for articular cartilage repair. *J Orthop Surg Res*. 2015;10:66. doi:10.1186/s13018-015-0209-5

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)

US patent information

arthrex.com