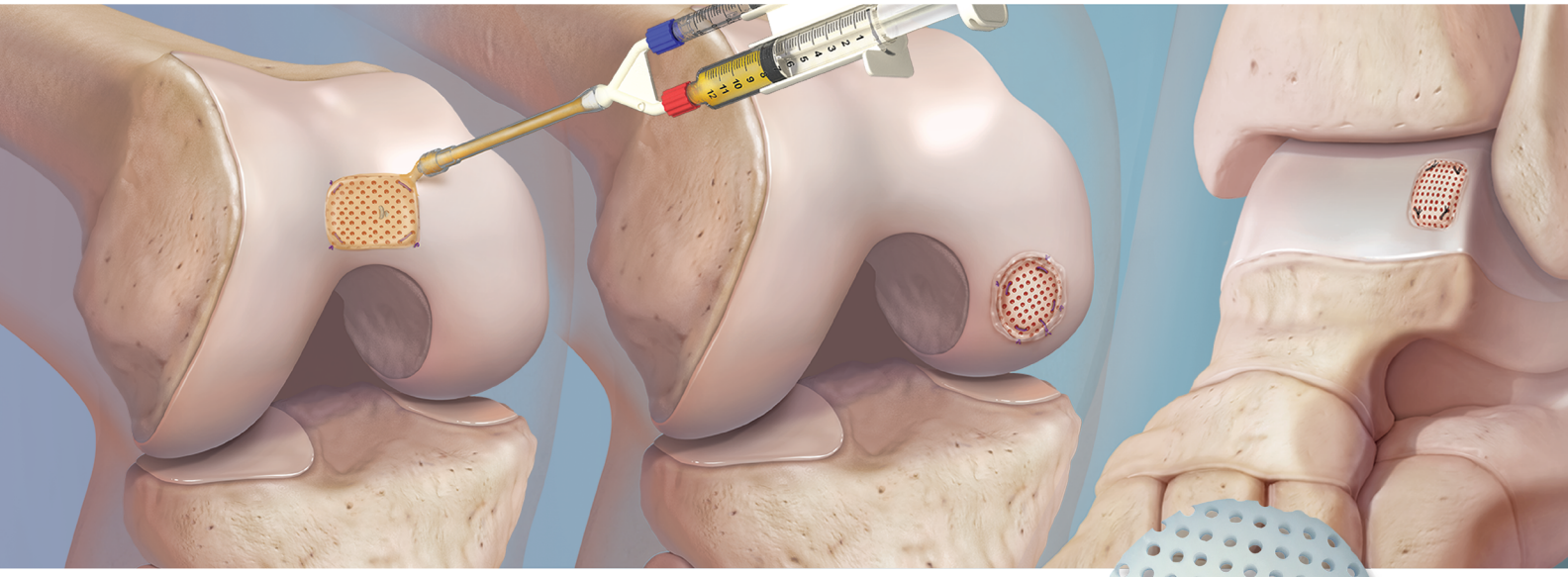
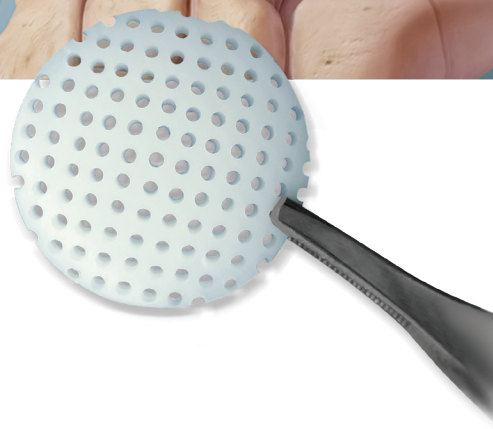
Cartiform®





Viable Osteochondral Allograft

Arthrex®

Cartiform®

Viable Osteochondral Allograft

Features and Benefits

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

1. The minimal bone and pores impart flexibility to the allograft, thereby improving handling characteristics for implantation and fixation ***(Figure 2)***.
2. The pores increase the surface area and allow for the proprietary cryopreservative solution to penetrate the tissue and preserve chondrocyte viability throughout the allograft.
3. The pores facilitate enhanced growth factor release and allow for progenitor cell migration 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 an easy-to-use graft that is trimmable and flexible to match any lesion size and contour.

Stored in a proprietary cryopreservative solution, Cartiform viable osteochondral allograft is readily available and is stored at -80 ± 5° C. ***(Figure 3)***.[1]

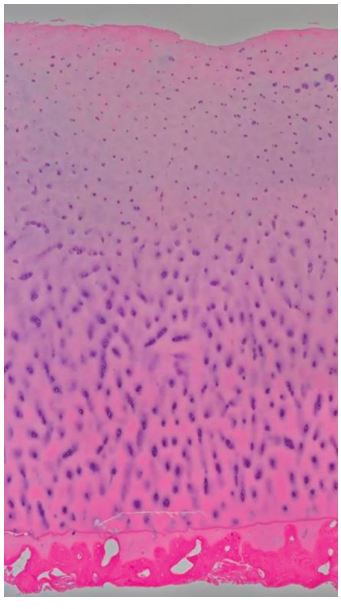


Figure 1. Structural organization. As revealed by histologic hematoxylin and eosin (H&E) staining, Cartiform viable osteochondral allograft preserves the microstructure of 3 distinct cartilage zones (superficial, transitional, radial) and an osseous layer.

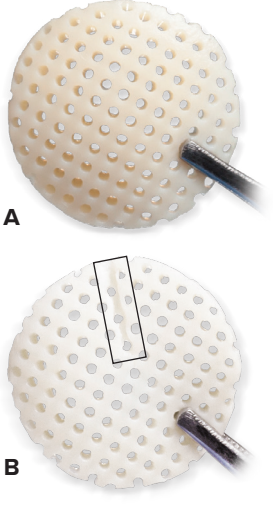


Figure 2. Appearance of Cartiform viable osteochondral allograft (20 mm diameter size): top (A), and bottom (B) views. Note the score mark distinguishing the bottom (bone) side (outlined with black box in B).

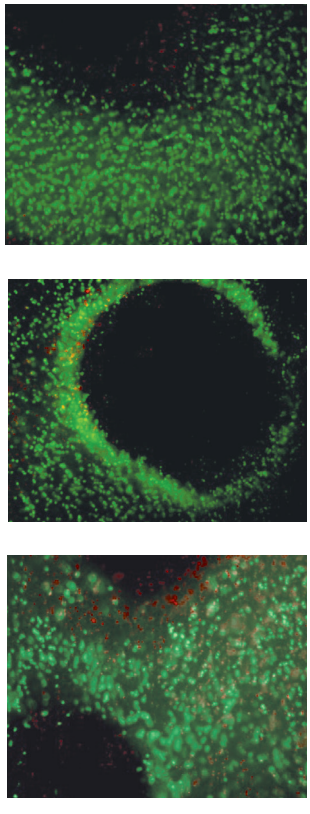
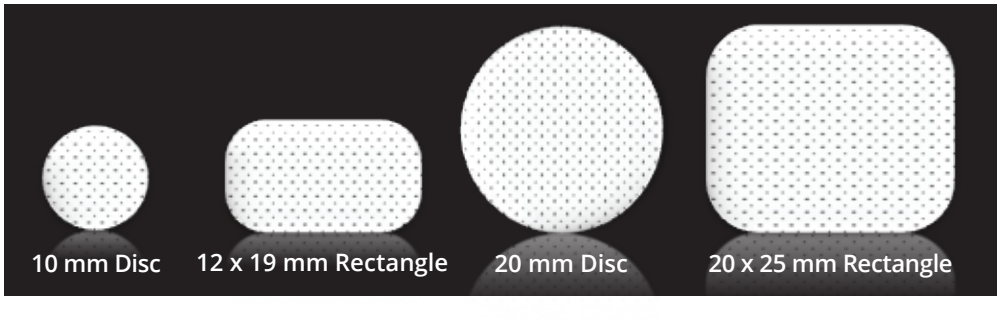


Figure 3. Live (green) and dead (red) cell staining of Cartiform allograft units derived from one donor. Images show: fresh Cartiform allograft, prior to cryopreservation (top); cryopreserved Cartiform allograft, post-thaw after 6 days storage at -80°C (middle); and cryopreserved Cartiform allograft,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



Scientific Support for Cartiform® Viable Osteochondral Allograft

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

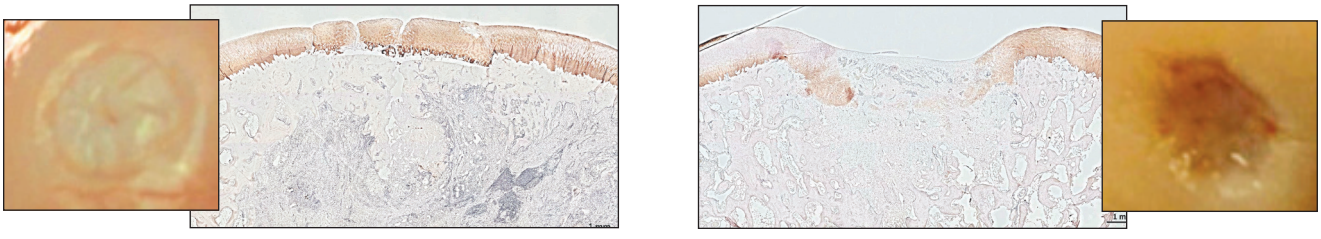
As a cryopreserved, viable osteochondral allograft, Cartiform allograft builds upon more than 40 years of safety and efficacy of fresh-stored osteochondral allografts.[2,3] In situations of minimal bone loss, Cartiform viable osteochondral allograft has been shown in the study below to improve the tissue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

Cartiform viable osteochondral allograft was implanted into osteochondral lesions (6 mm diameter) in a goat model to demonstrate safety, integration, and the induction of tissue formation.

a. At 3 months, the lesions treated with Cartiform viable osteochondral allograft had a significantly improved gross morphology and overall lesion fill compared to microfracture controls ***(Figure 4)***.

b. At 12 months, the lesions treated with Cartiform viable osteochondral 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.



Marrow stimulation and Cartiform viable osteochondral allograft

Marrow stimulation alone

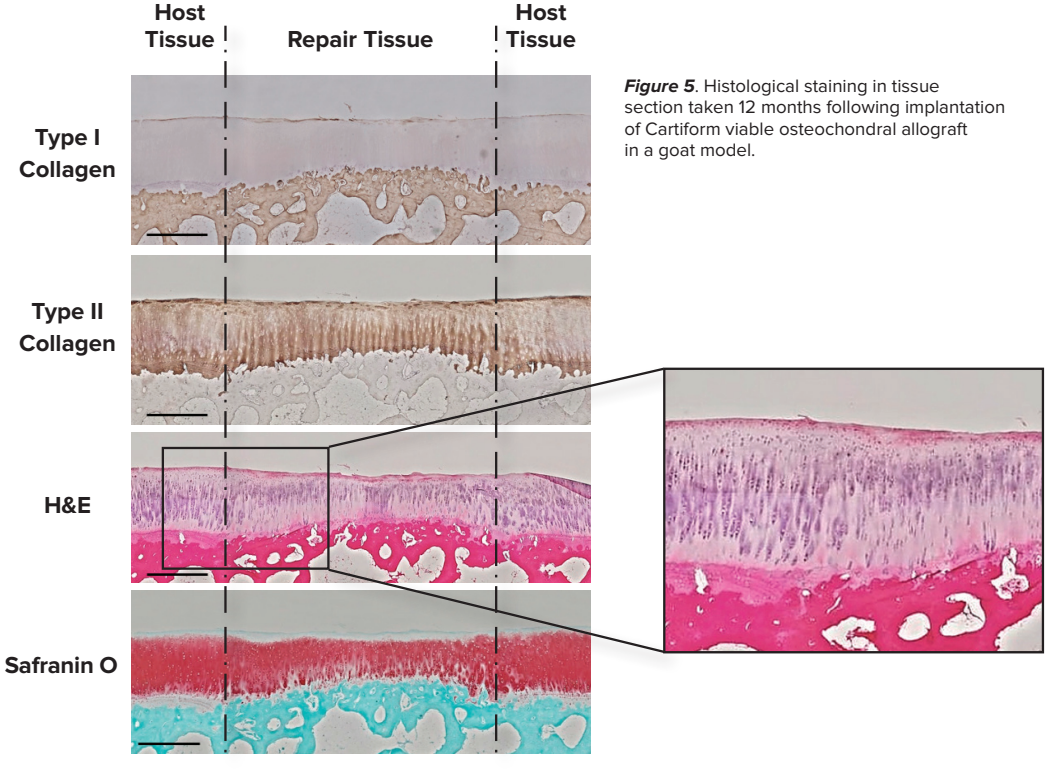


Figure 5. Histological staining in tissue section taken 12 months following implantation of Cartiform viable osteochondral allograft in a goat model.

References

1. Osiris Therapeutics, Inc. Data on file (LA1-00007-EN). Columbia, MD; 2015.
2. Bedi A, Feeley BT, Williams TJ 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, et al. 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.

Cartiform®

Viable Osteochondral Allograft

Recovery and Quality Control Process

Cartiform viable osteochondral 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 viable osteochondral allograft is readily available and is stored at -80 ± 5° C.

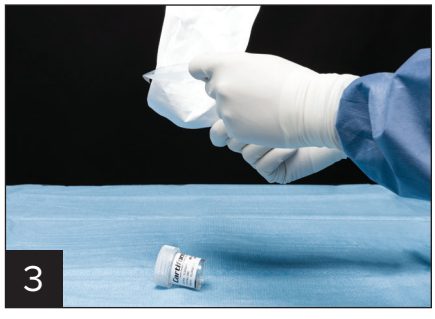
1. Sterility testing is performed on each lot to ensure the allograft tissue is safe for clinical use.
2. Prior to release for clinical use, characterization testing for the presence of viable cells and residual bone is performed for each donor.

Preparation Guide *NOTE: Graft color may vary as human articular cartilage color varies.*

Please consult the Instructions For Use packaged with the product for a full list of instructions and warnings.

Remove package insert, patient labels, and Cartiform viable osteochondral allograft pouch from box.

Peel back chevron pouch.

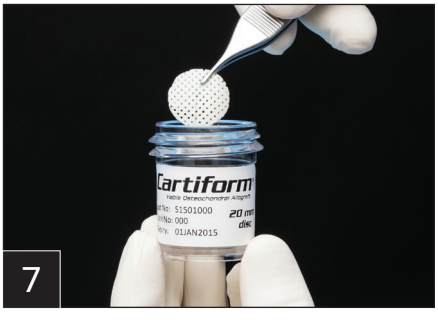


Using aseptic technique, transfer jar into sterile field.

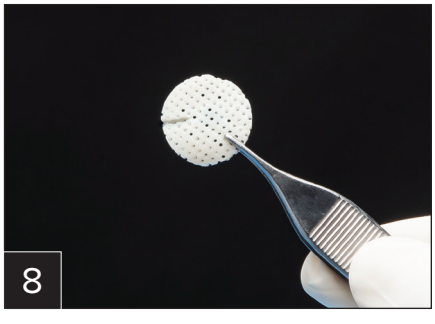
Place the sterile jar into a sterile basin.

Using aseptic technique, add sterile saline until volume is below the lid. Thaw for ~10 minutes until no ice crystals are visible.*

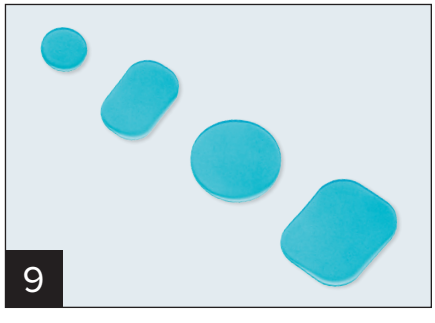
Take the thawed jar from the basin and unscrew the lid.



Using sterile forceps, remove Cartiform viable osteochondral allograft from the jar and place in a sterile rinse basin at room temperature containing sterile saline for 1 minute. It can be kept in sterile saline for up to 2 hours at room temperature prior to implantation.*

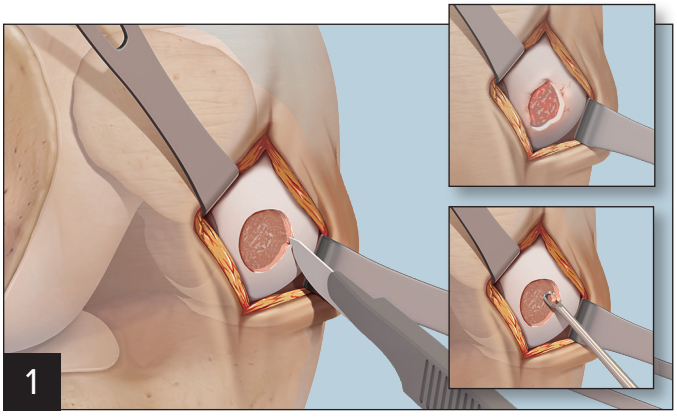


Once rinsed, Cartiform viable osteochondral allograft is ready to use. The side with the score mark is the bottom of the graft.

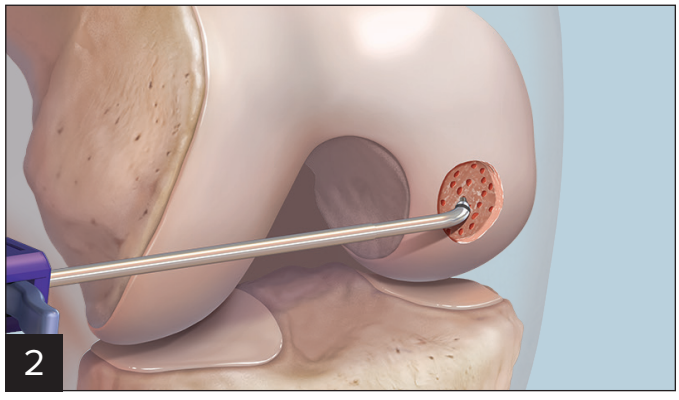


Cartiform viable osteochondral allograft may be trimmed to fit the articular cartilage lesion. Templates are available to aid in preparation of the graft.

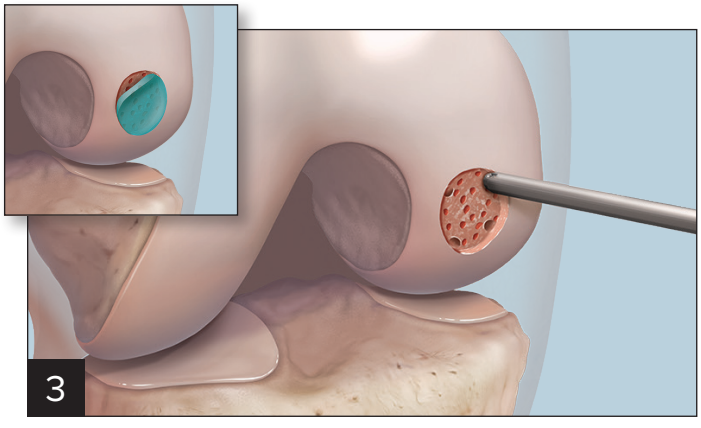
*Temperature of thawing solution should not exceed 39°C (102°F). Do not thaw for longer than 30 minutes.



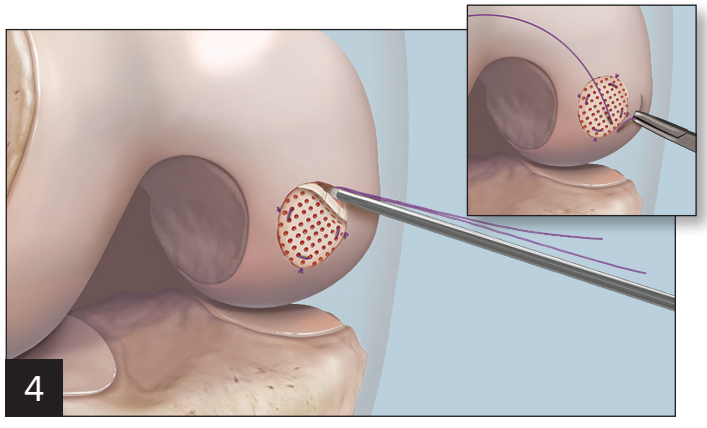
Debride the articular cartilage defect to a stable border with perpendicular margins. A scalpel can be used to create vertical margins and a curette can be used to debride the calcified cartilage layer at the base of the defect.



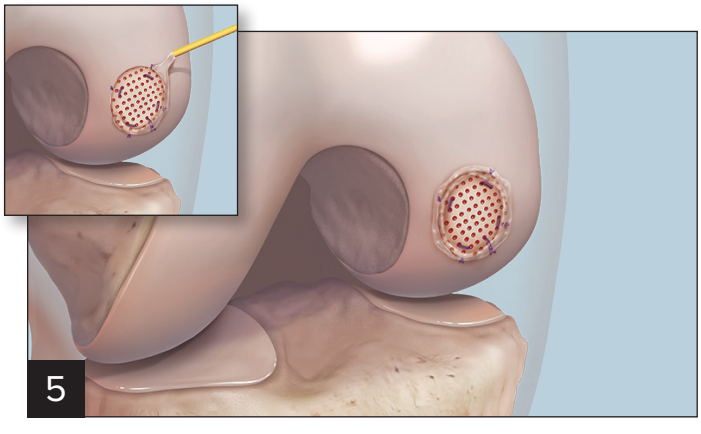
Perform bone marrow stimulation, if desired, using the PowerPick™ microfracture instrument while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.

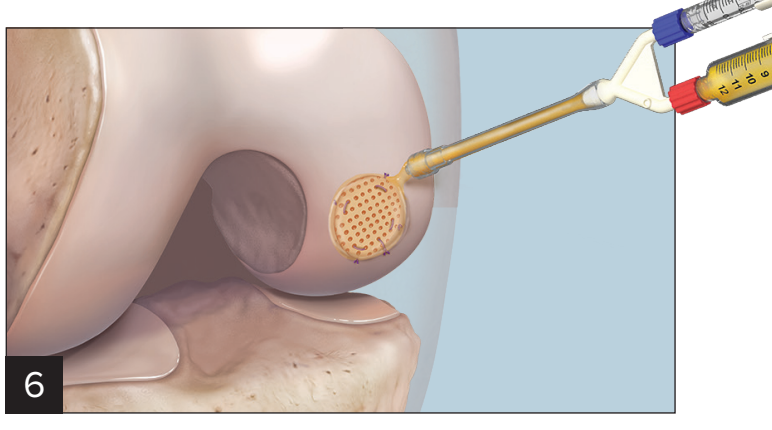


Template the lesion with sterile paper or foil. After thawing and rinsing Cartiform viable osteochondral allograft, use a scalpel or surgical scissors to trim the graft to match the template. Place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® anchor fixation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



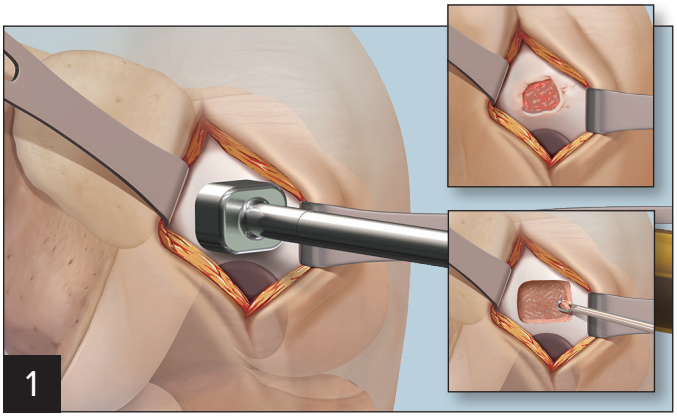
Pass suture tails inferior to superior, then superior to inferior to create a mattress stitch in each quadrant of the Cartiform viable osteochondral allograft to match the location of the peripheral pilot holes. Working sequentially, fixate each quadrant of the allograft to the lesion. In knotless anchor configurations, ensure the anchor eyelet is seated deep prior to drawing tension on the suture, then implant the anchor to fixate. *Note: The side of the allograft with a score mark is the bottom (bone) side.*



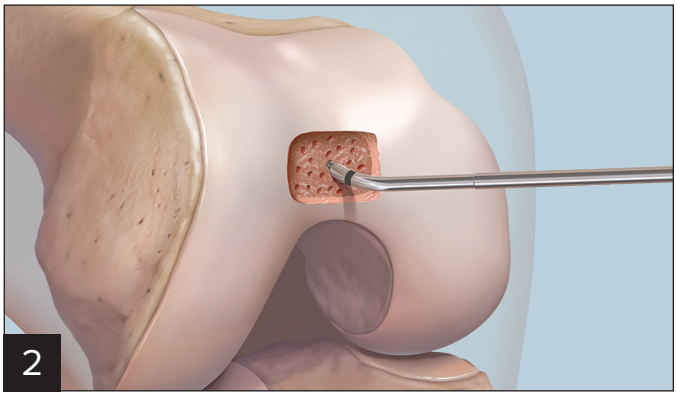


Optionally, apply a thin layer of fibrin glue along the periphery of the Cartiform viable osteochondral allograft. To help prevent activation and clogging within the needle, it is recommended that the fibrin be applied using a dual-lumen applicator tip. Do not manipulate for 5 minutes after application. The knee may be gently ranged before closure to assure allograft fixation.

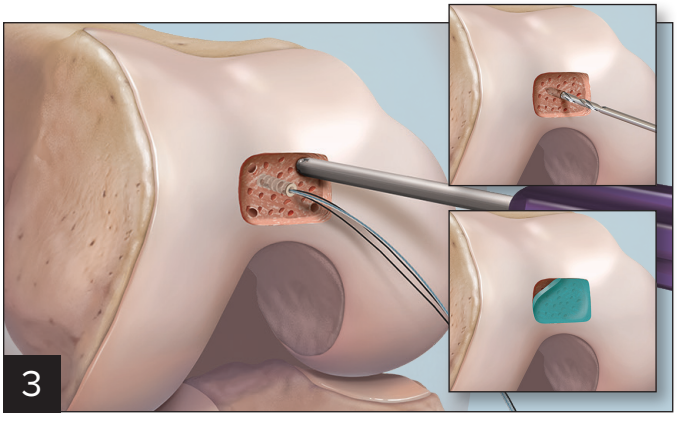
A knee brace with limited range of motion should be used postsurgery. The patient should be non-weightbearing or protected weightbearing as determined by the defect location. Thereafter, standard rehabilitation protocols are implemented.



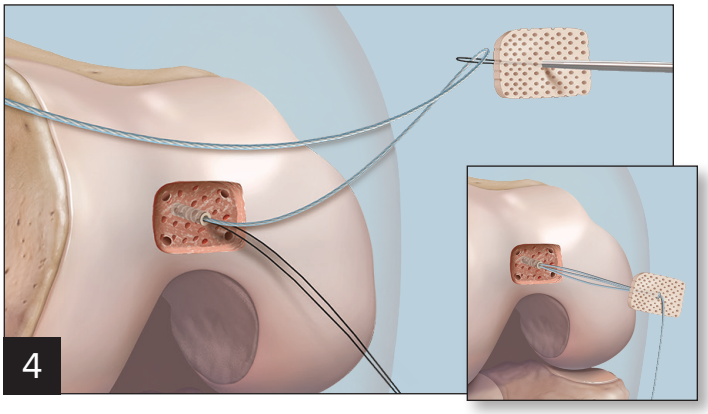
Debride the articular cartilage defect to stable borders with perpendicular margins. A ring curette and Cobb elevator can be used to create vertical margins and debride the calcified cartilage layer at the base of the defect.



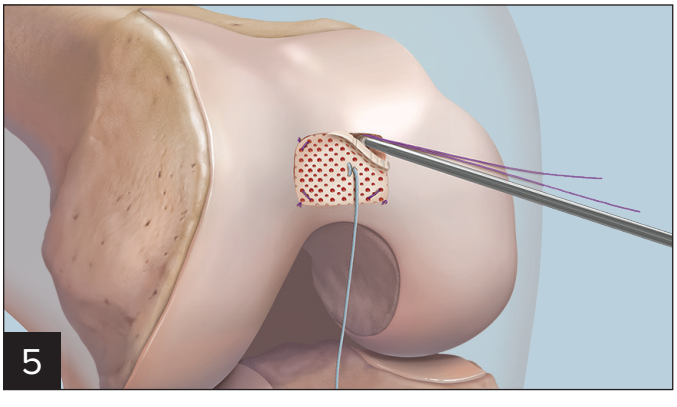
Optionally, perform bone marrow stimulation using the PowerPick™ microfracture instrument. Template the lesion with sterile paper or foil. After thawing and rinsing the allograft, use a scalpel or surgical scissors to trim the graft to match the template.



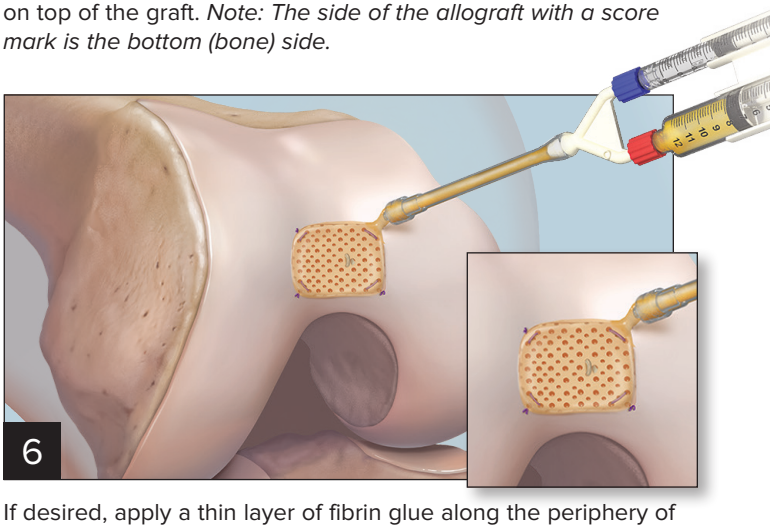
Place a pilot hole in the center of the defect and implant the Knotless SutureTak® anchor. As necessary, place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® anchor fixation points.



Pass the central anchor suture inferior to superior, then superior to inferior to create a mattress stitch on the 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 allograft so tension on the strand may be drawn directly on top of the graft. *Note: The side of the allograft with a 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 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 seated deep 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.

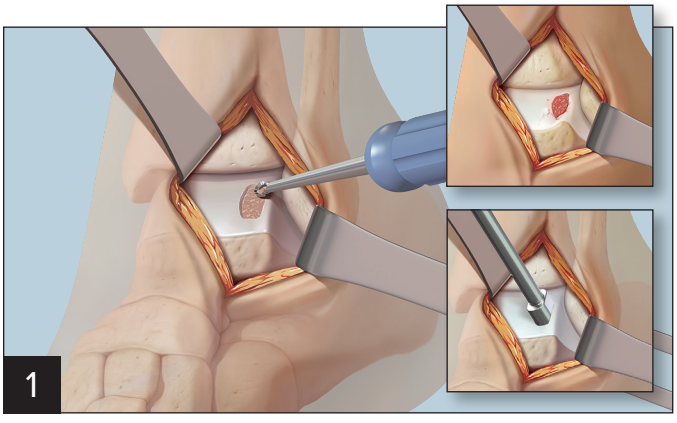


If desired, apply a thin layer of fibrin glue along the periphery of the Cartiform viable osteochondral allograft. Do not manipulate for 5 minutes after application. The knee may be gently ranged before closure to assure allograft fixation. A knee brace with limited range of motion should be used postsurgery. The patient should be non-weightbearing or protected weightbearing as determined by the defect location. Thereafter, standard rehabilitation protocols are implemented.

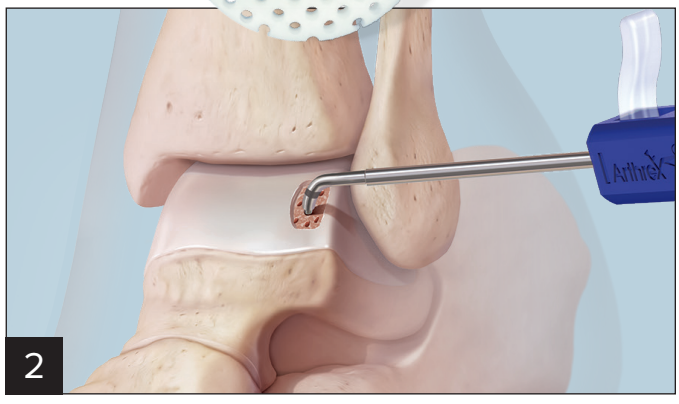
The Cartiform viable osteochondral allograft foot and ankle technique was developed in collaboration with James R. McWilliam, MD, (New York, NY) and Arthrex.

Cartiform® Viable Osteochondral Allograft Ankle Arthrotomy – Talus

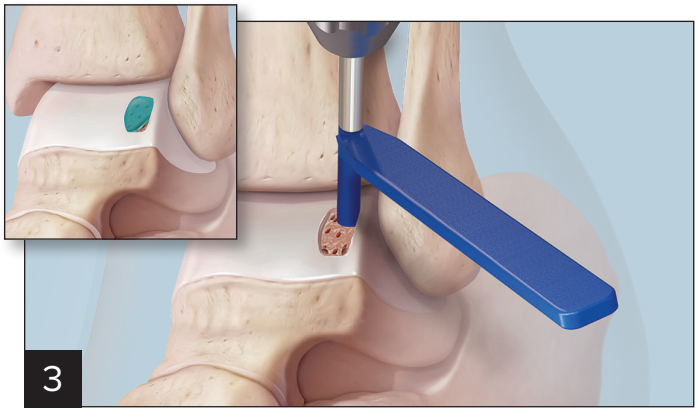
Surgical Technique



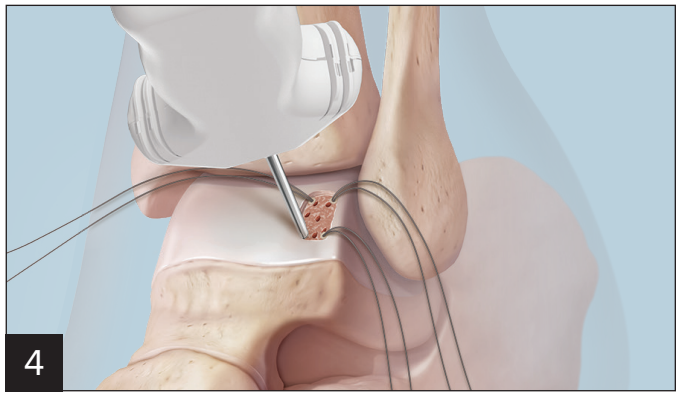
Apply distraction to the tibiotalar joint and debride the articular cartilage defect to a stable border with perpendicular margins. A ring curette can be used to create the vertical margins and debride the calcified layer at the base of the defect.



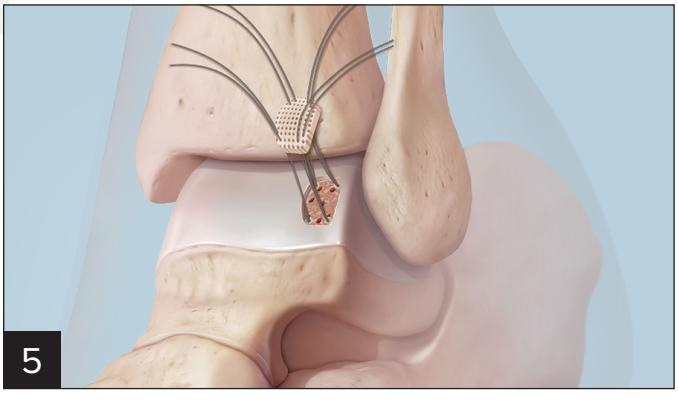
Perform bone marrow stimulation using the PowerPick™ microfracture instrument while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.



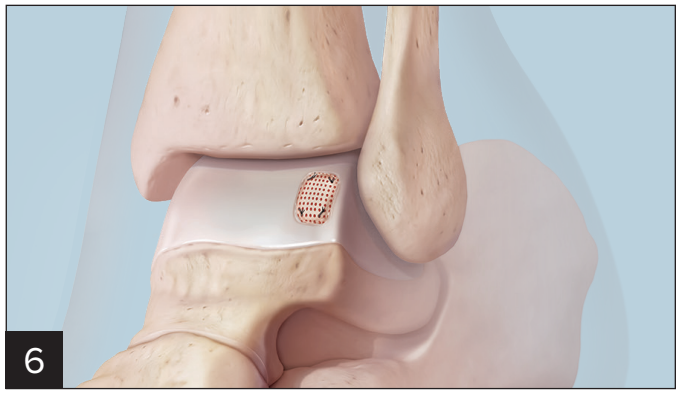
Template the lesion with sterile paper or foil. After thawing and rinsing the allograft, use a scalpel or surgical scissors to trim the graft to match the template. Place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® anchor fixation points.



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 Cartiform viable osteochondral allograft.



Each suture tail is passed inferior to superior through the allograft to match the orientation and position of the anchor placement in the lesion. Working sequentially, simple knots are placed to fixate the Cartiform viable osteochondral allograft to the lesion.



If desired, apply a thin layer of fibrin glue to the periphery of the Cartiform viable osteochondral allograft. Do not manipulate for 5 minutes after application. The joint may be gently ranged before closure to assure allograft fixation. At the completion of surgery, the ankle is immobilized in neutral position and the patient is made non-weightbearing or protected weightbearing as determined by the defect location. After, standard rehabilitation protocols similar to osteochondral allograft implantation procedures are implemented.

Ordering Information

Implants/Disposables

Cartiform® Viable Osteochondral Allograft, 10 mm disc	ABS-1101-10
Cartiform Viable Osteochondral Allograft, 20 mm disc	ABS-1101-20
Cartiform® Viable Osteochondral Allograft, 12 mm x 19 mm	ABS-1102-19
Cartiform Viable Osteochondral Allograft, 20 mm x 25 mm	ABS-1102-25
Articular Cartilage Scorer, 10 mm	ABS-1101-10S
Articular Cartilage Scorer, 12 mm x 19 mm	ABS-1102-19S
Articular Cartilage Scorer, 20 mm	ABS-1101-20S
Articular Cartilage Scorer, 20 mm x 25 mm	ABS-1102-25S
Cartiform Viable Osteochondral Allograft Templates	ABS-1100-T
PowerPick™ XL Microfracture 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 Disposables Kit	AR-1934DS-2
3.0 mm PEEK Knotless SutureTak Anchor	AR-1938PS
Free 4-0 FiberWire® Suture w/ Tapered Needle	AR-7248
Micro SutureLasso™ Suture Passer, minor bend	AR-8701
FiberWire Scissors	AR-11796
Metatarsal Reamer, 20 mm	AR-8944PR-20
Tenodesis Disposables Kit, 3 mm x 8 mm	AR-1530DS
Biocomposite Tenodesis Screw, w/ handle inserter, 3 mm x 8 mm	AR-1530BC
SutureLasso SD Wire Loop	AR-4068-05SD
2-0 FiberWire Suture, 18 in, in (blue) w/ tapered needle, 17.9 mm 3/8 Circle	AR-7220
2-0 TigerWire Suture, 18 in, w/ tapered needle	AR-7220T
Femoral Impactor Handle	AR-1200FIH

To order, please call Arthrex at 1.800.934.4404.

Cartiform®
Viable Osteochondral Allograft

Cartiform is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Osiris Therapeutics, Inc. is registered with the FDA as a tissue establishment and accredited by the American Association of Tissue Banks (AATB).

Store frozen -75°C to -85°C.

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Osiris®
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This description of technique is provided as an educational demonstration 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.