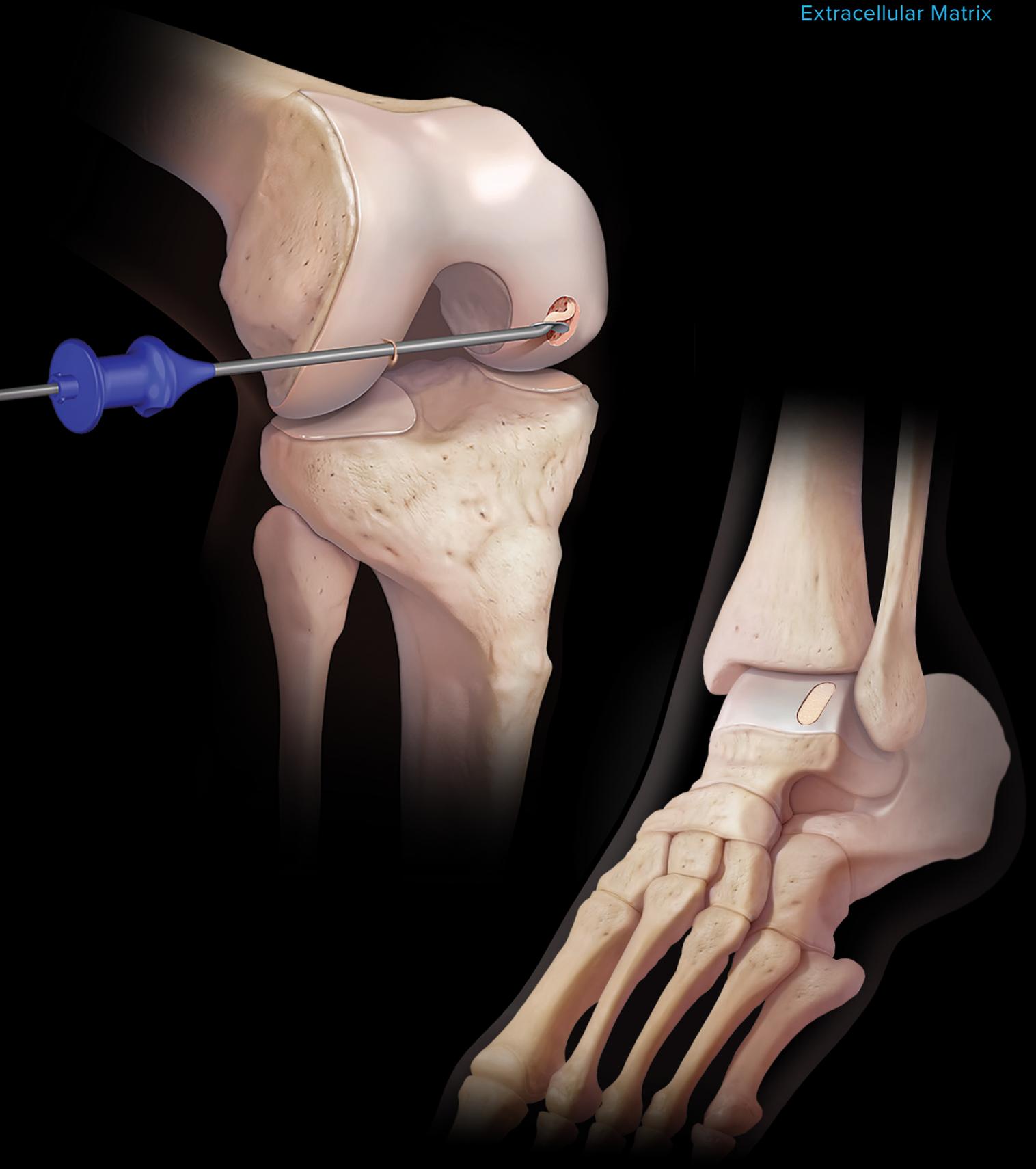


BioCartilage[®]

Extracellular Matrix



Arthrex[®] 

BioCartilage® Extracellular Matrix

Features and Benefits

Composition

- BioCartilage extracellular matrix (ECM) contains the ECM that is native to articular cartilage, including key components such as type II collagen (Figure 1), proteoglycans (Figure 2), and additional cartilaginous growth factors.
- After processing, the dehydrated allograft cartilage has a particle size of 100 µm-300 µm:
 - The small particle size improves its injectable nature after it is mixed with an autologous blood solution, allowing easier delivery to the defect site.
 - The small particle size also increases the surface area, providing attachment sites for the patient's bone marrow cells^{1,2} (Figures 3 and 4 depict the ability of progenitor cells to attach to BioCartilage ECM).
- BioCartilage ECM serves as a scaffold over a microfractured defect, providing a tissue network that can potentially signal autologous cellular interactions.³
- Marrow elements travel through the microfracture holes and interact with the scaffold created by BioCartilage ECM, rather than being expected to create their own fibrin scaffold as typically anticipated from a marrow stimulation procedure.³

Processing

- BioCartilage ECM goes through a specialized, gentle dehydration process (hypothermic dehydration) that allows the water content to be removed, while remaining in a liquid state instead of requiring the tissue, including the water, to be frozen before removal (lyophilization).
- After dehydration, the cartilage goes through a number of proprietary processing steps, resulting in a very consistent particle size range.
- BioCartilage ECM is terminally sterilized via electron beam (e-beam) irradiation to a sterility assurance level (SAL) of 10^{-6} . The graft is packaged to allow for ambient temperature storage with a shelf life of 5 years.

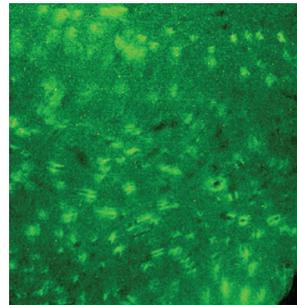


Figure 1: Immunohistochemistry staining for type II collagen

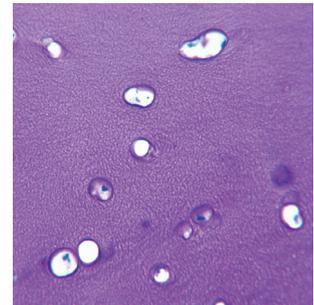


Figure 2: Proteoglycan content as evidenced by the presence of interterritorial granular matrix via toluidine blue staining

Attachment of Progenitor Cells to BioCartilage ECM

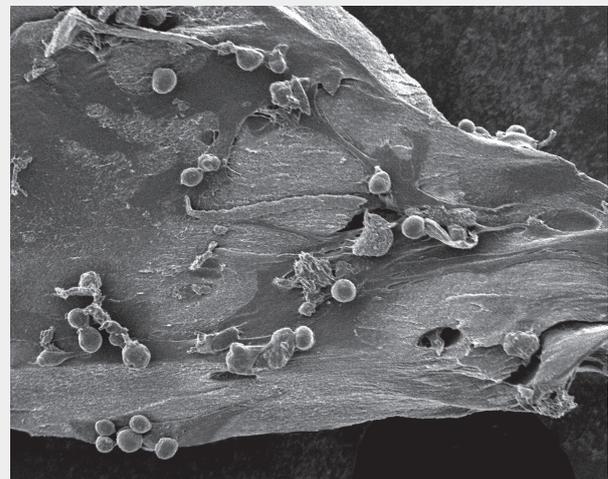


Figure 3

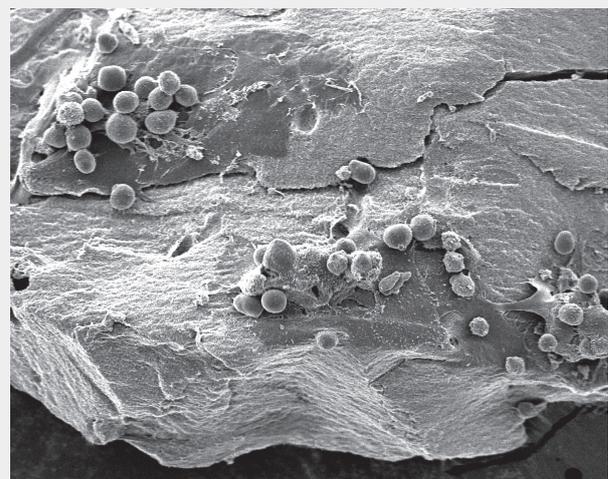
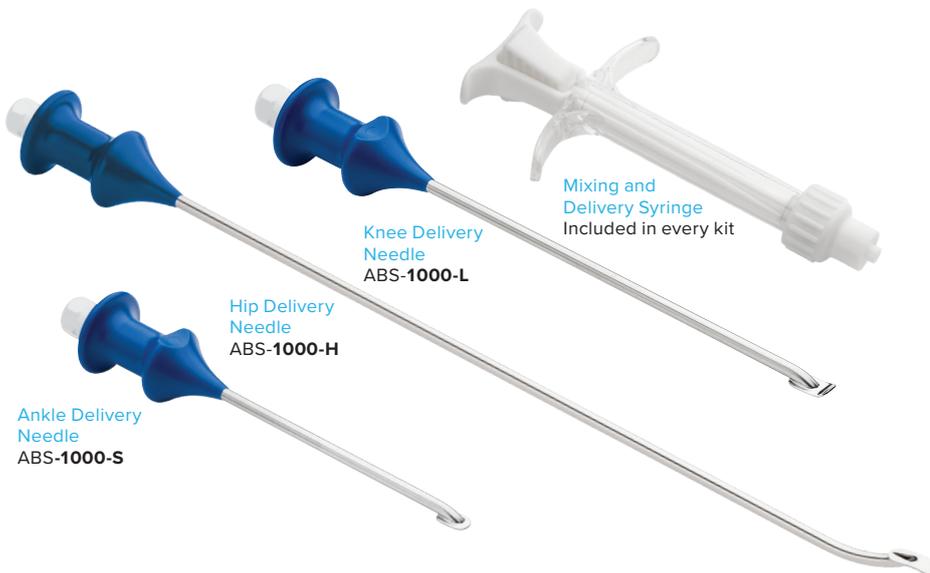


Figure 4

The tissue was stained after dehydration, before micronization

BioCartilage® ECM Technique Guide

Perform the following steps using aseptic technique. Please refer to the directions for use packaged with the product for a full list of warnings and instructions on BioCartilage ECM.



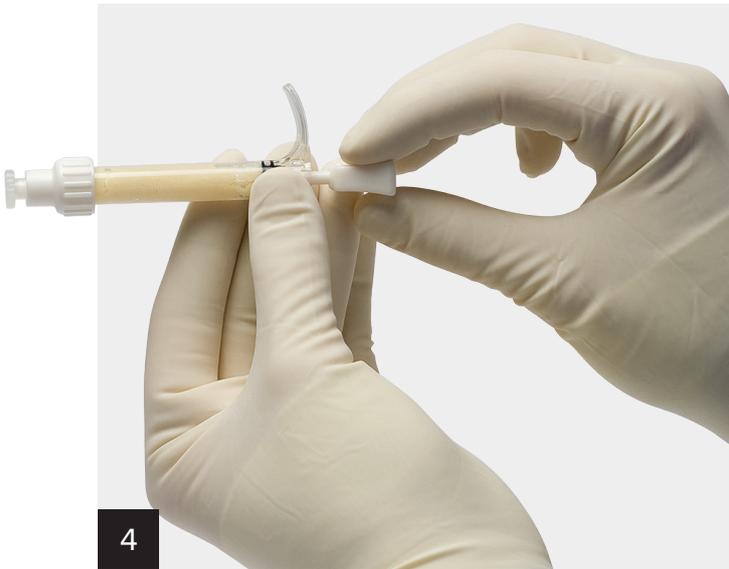
Remove the syringe cap and snap on the funnel to the end of the syringe. Make sure the plunger is at the end of the syringe, then empty the BioCartilage ECM from its container into the funnel.



Remove the funnel and add an autologous blood solution into the mixing syringe with a 1:0.8 ratio (BioCartilage ECM to autologous fluid). Twist on the syringe cap and luer cap.



Unsnap the pushrod from the mixing element by pressing on the tip of the mixing element with counter-pressure on the tip of the pushrod.



To mix the BioCartilage® ECM and autologous blood solution, push and pull the mixing element back and forth while rotating it in a repeated left-to-right motion. Continue until thoroughly mixed.



Pull back on the mixing element to bring it back to its starting position.



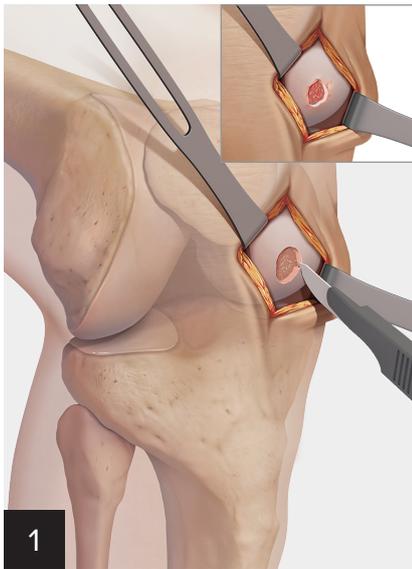
Snap the pushrod back onto the mixing element.



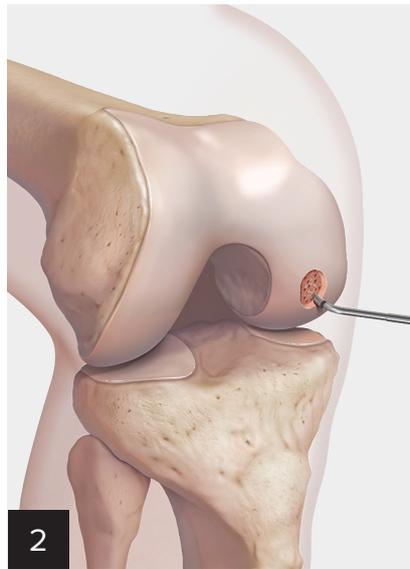
Apply a delivery needle and dispense the BioCartilage mixture out of the mixing syringe into the needle. Use the obturator to deliver the mixture from the needle to the defect.

BioCartilage® ECM Knee Arthroscopy Surgical Technique

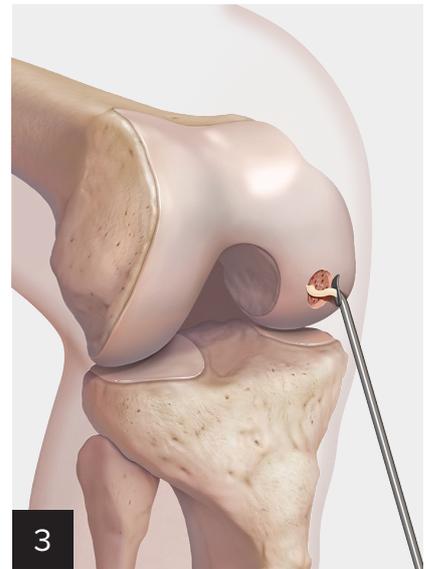
These BioCartilage knee techniques were developed in collaboration with Brian Cole, MD, MBA (Chicago, IL)



1
Debride the articular cartilage defect to a stable border with perpendicular margins. A scalpel can be used to create the vertical margins and a curette can be used to debride the calcified cartilage layer at the base of the defect.



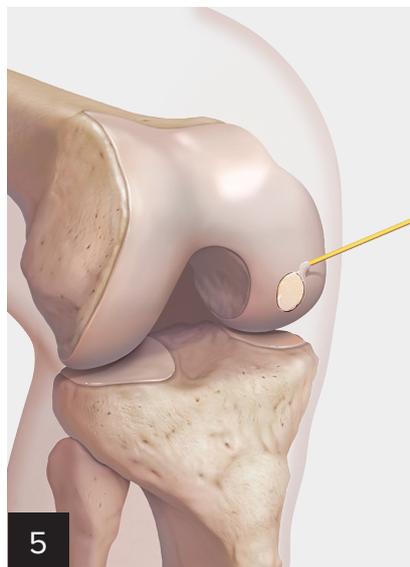
2
Perform bone marrow stimulation using standard microfracture technique. A PowerPick™ device may be used to perform this procedure while applying irrigation fluid to avoid thermal necrosis.



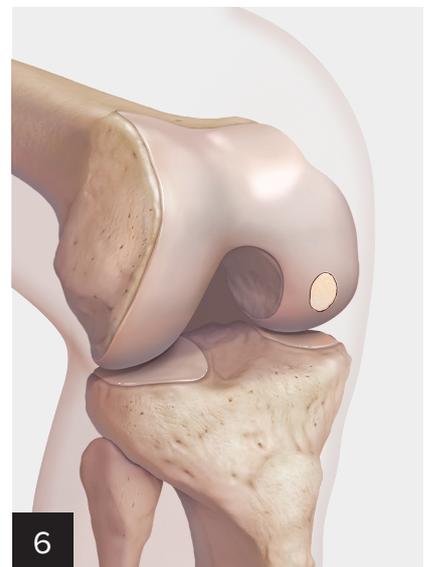
3
Dry the defect thoroughly. After mixing the BioCartilage ECM with an autologous blood solution (1:0.8 ratio) within the mixing syringe, apply the mixture into the defect.



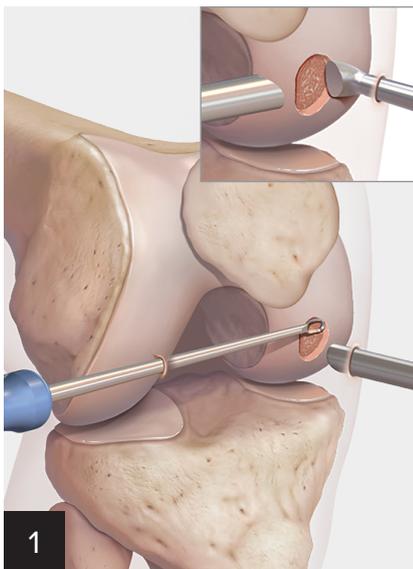
4
Smooth out BioCartilage ECM within the defect. Ensure that the BioCartilage ECM is flush or slightly recessed when compared to the surrounding articular cartilage.



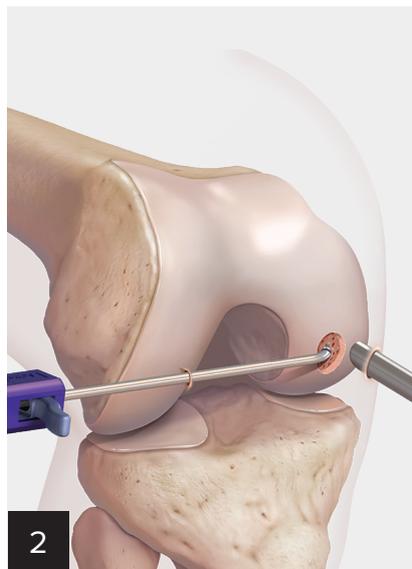
5
Apply fibrin glue over the top of the BioCartilage ECM. Use enough to cover the defect, but prevent over-usage as this will cause the construct to sit proud in the joint. Do not manipulate for 5 minutes after application. The knee may be gently ranged before closure to assure BioCartilage ECM adherence.



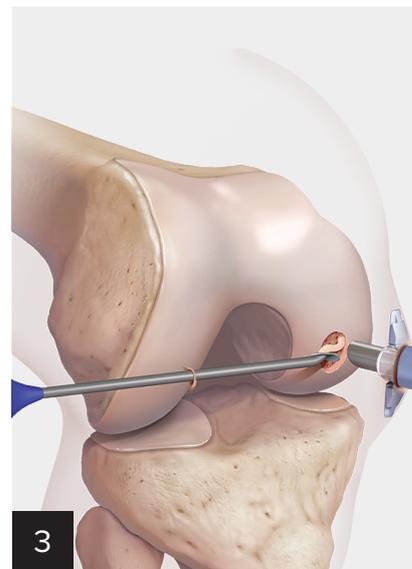
6
At the completion of surgery, a knee immobilizer locked in extension is placed and the patient is made non weight-bearing or protected weight-bearing with delayed onset of range-of-motion for up to one week postoperatively. Thereafter, standard rehabilitation protocols may be implemented.



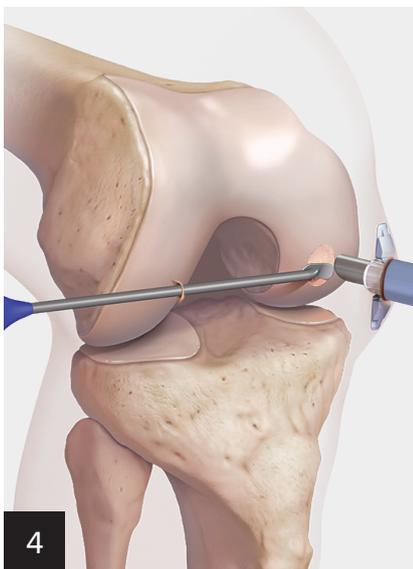
1 Debride the articular cartilage defect to a stable border with perpendicular margins. A ring curette and Cobb elevator can be used to also debride the calcified cartilage layer at the base of the defect. Optionally, the fat pad retractor may be used to contain the fat pad and aid in distracting the joint.



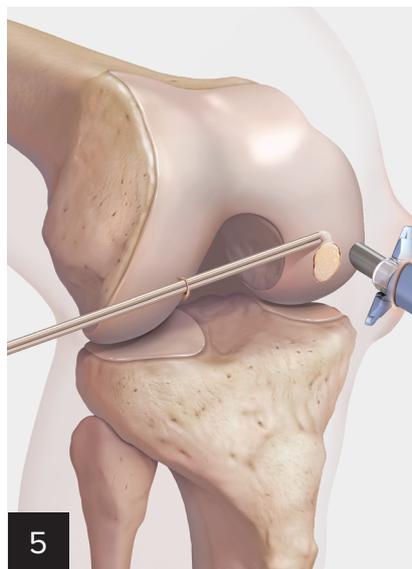
2 Perform bone marrow stimulation using the PowerPick™ device. After microfracture, ensure the use of a tourniquet, aspirate the arthroscopic fluid, and dry the cartilage defect with the cannulated swabs.



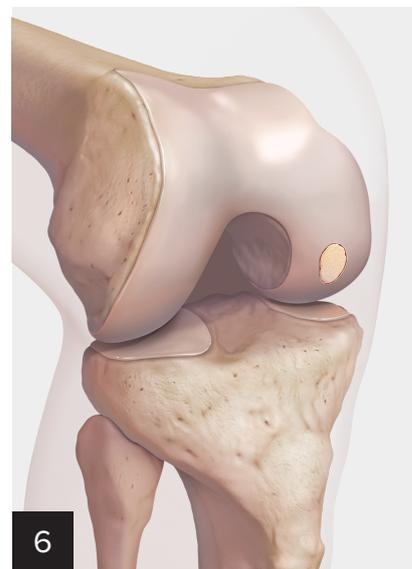
3 A Gemini™ cannula should be used in the portal that resides over the defect. The BioCartilage ECM can be applied over the defect with the arthroscopic delivery needle (mixing in a 1:0.8 ratio with autologous fluid).



4 The elevator component on the arthroscopic delivery needle can be used to smooth out the BioCartilage ECM within the defect so that it remains flush or slightly recessed to the surrounding cartilage.



5 Apply a light layer of fibrin glue over the BioCartilage ECM through a dual-lumen applicator tip; prevent over usage as this will cause the construct to sit proud. Do not manipulate for 5 minutes after application. The knee may be gently ranged before closure to assure BioCartilage ECM adherence.



6 At the completion of surgery place a knee immobilizer, locked in extension. The patient should be non-weightbearing or protected weightbearing, as determined by defect location, with delayed onset of range-of-motion for up to 1 week postoperatively. Thereafter, standard rehabilitation protocols may be implemented.

BioCartilage® ECM Ankle Arthroscopic Surgical Technique

The BioCartilage ankle technique was developed in collaboration with Eric Giza, MD (Sacramento, CA), and James McWilliam, MD (New York, NY)



Under tourniquet control, apply 4 mm of distraction to the tibiotalar joint. Debride the articular cartilage defect to create stable margins. A ring curette can be used to create vertical margins and debride the base. Optionally, the fat pad retractor may be used to aid in distracting the joint.



Perform bone marrow stimulation using PowerPick™ device. Aspirate all arthroscopic fluid and dry the cartilage defect with the cannulated swabs.



After mixing the BioCartilage ECM with an autologous blood solution (1:0.8 ratio) within the mixing syringe, apply the mixture into the defect using the arthroscopic delivery needle.



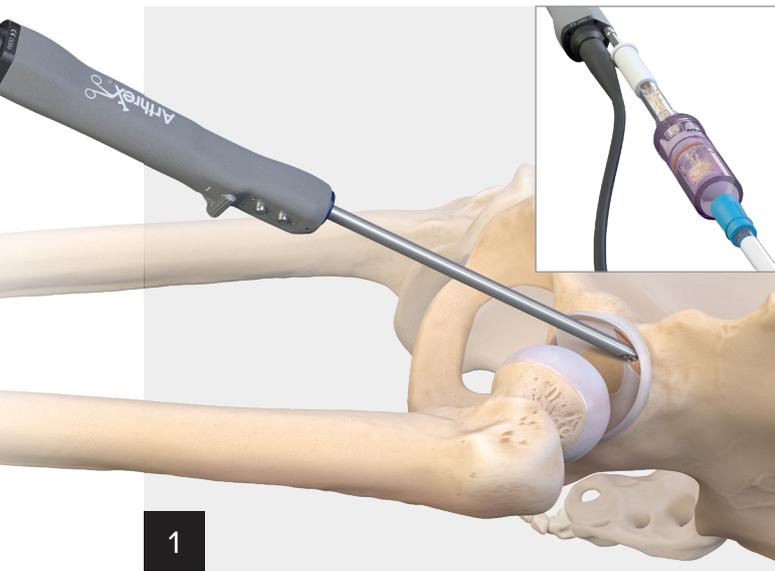
The elevator component on the arthroscopic delivery needle can be used to smooth out the BioCartilage ECM within the defect. Ensure that the BioCartilage ECM remains flush or slightly recessed when compared to the surrounding cartilage.



Apply fibrin glue over the BioCartilage ECM through a dual-lumen applicator tip. Avoid applying too much fibrin to prevent the construct from sitting proud. The ankle may be gently ranged before closure to assure BioCartilage ECM adherence.

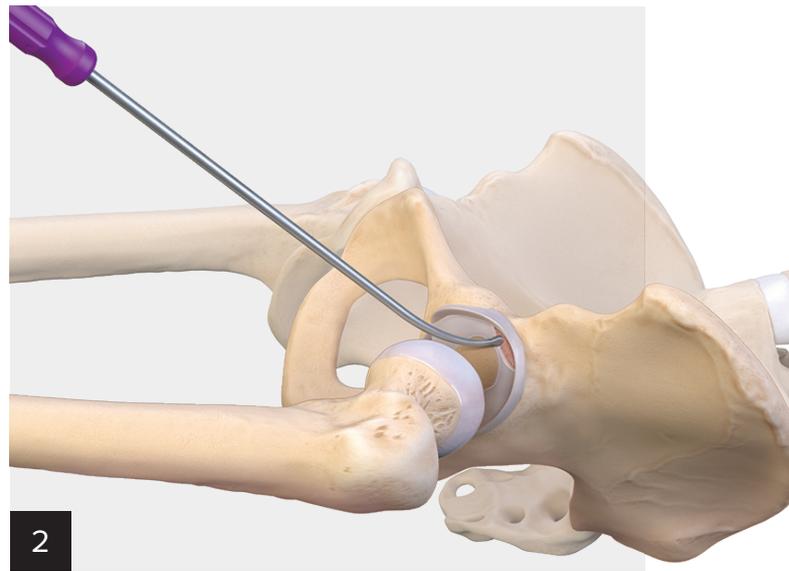


At the completion of surgery, the ankle is immobilized in neutral position and the patient is made non-weightbearing. Thereafter, standard rehabilitation protocols may be implemented.



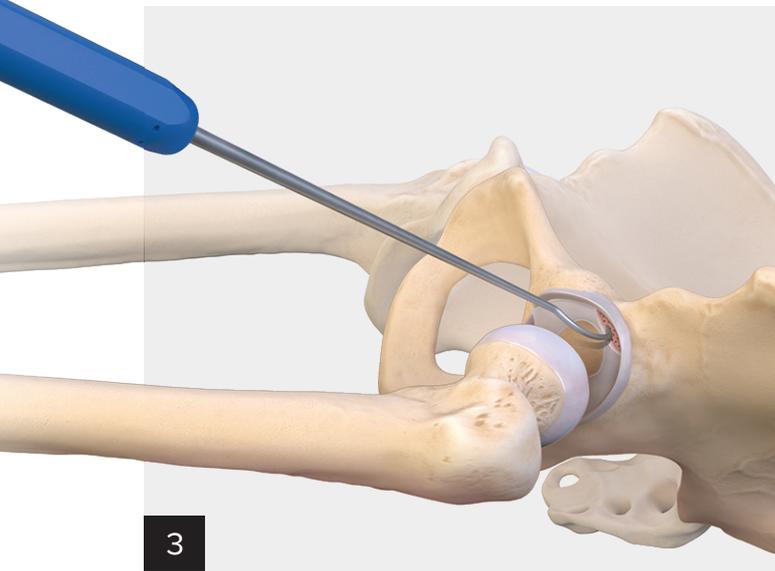
1

Debride the articular cartilage defect using an arthroscopic shaver in oscillate mode. Use the GraftNet™ device, in line with shaver and suction, to capture the articular cartilage fragments for subsequent steps in the procedure.



2

Complete recipient site preparation by creating stable borders with perpendicular margins. Various curettes may be used to create vertical margins and remove the calcified cartilage layer.



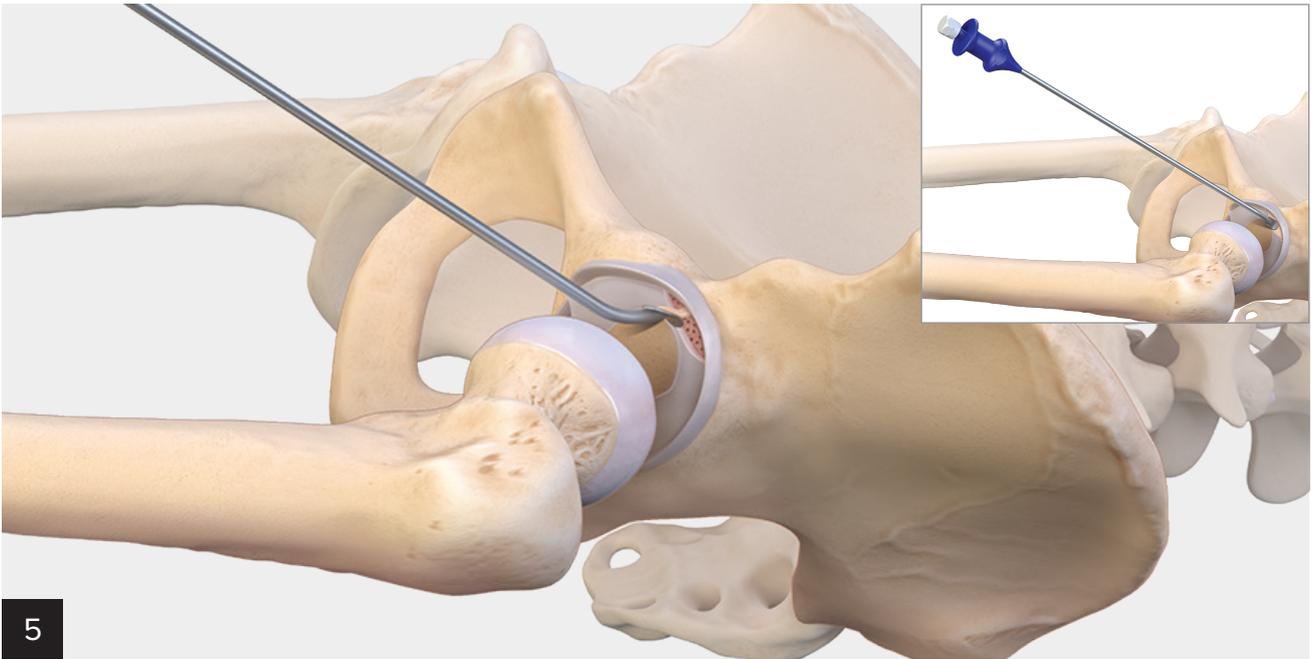
3

A standard microfracture pick may be used to perform the marrow stimulation procedure.

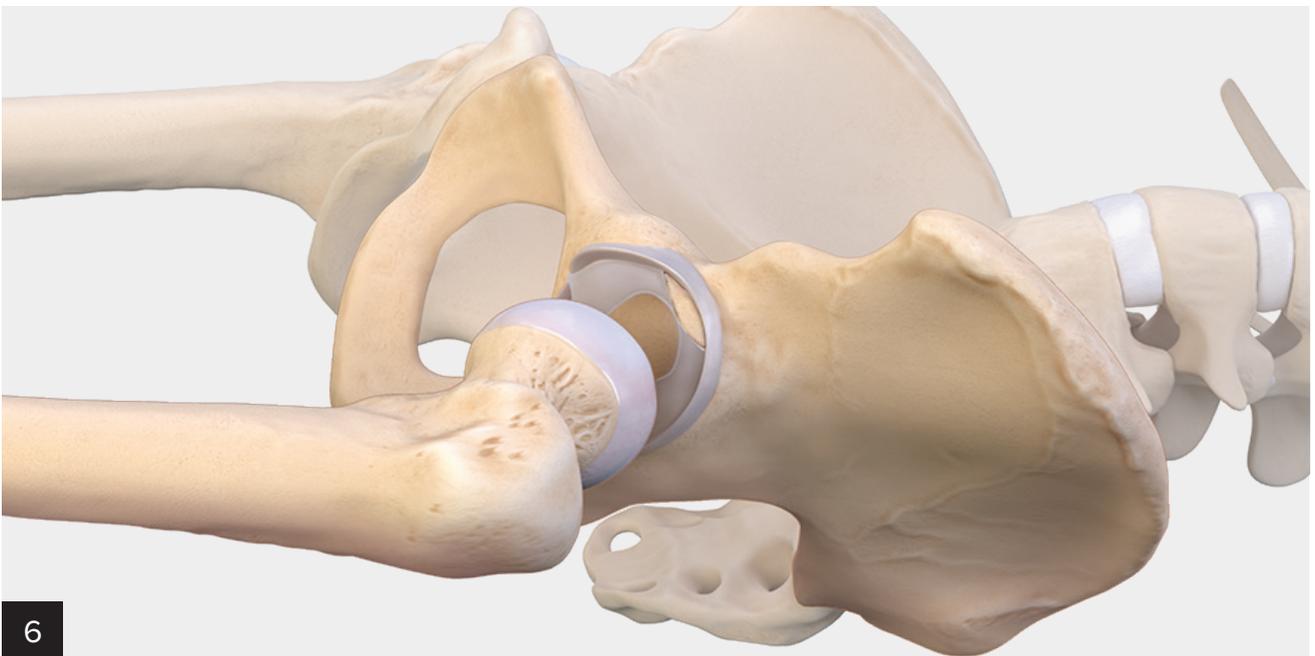


4

Withdraw the recovered autograft tissue and mix in a 1:1:1 ratio with BioCartilage ECM and autologous fluid to prepare the composite articular cartilage graft. Assemble the mixing syringe with the hip delivery cannula and fill the cannula with the BioCartilage mixture.



Aspirate the arthroscopic fluid using the provided suction adapter. Using the ArthroPaddle™ feature of the delivery device, deliver and smooth the BioCartilage mixture into the defect, taking care not to overfill the defect.



Apply a thin layer of fibrin glue over the BioCartilage graft. Maintain a dry joint and do not manipulate the joint for approximately 5 minutes. Standard microfracture rehabilitation protocols may be used.

Ordering Information

Product Description	Item Number
BioCartilage® extracellular matrix, 0.75 cc	ABS-1007-BC
BioCartilage extracellular matrix, 1 cc	ABS-1010-BC
Mixing and delivery kit, large joint (Includes mixing syringe and arthroscopic delivery needle, obturator, funnel, fat pad retractor, and cannulated swabs)	ABS-1000-L
Mixing and delivery kit, small joint (Includes mixing syringe and cap, arthroscopic delivery needle, obturator, funnel, fat pad retractor, and cannulated swabs)	ABS-1000-S
Mixing and delivery kit, hip joint (Includes mixing syringe and cap, arthroscopic delivery needle, obturator, funnel, fat pad retractor, and cannulated swabs)	ABS-1000-H

Recommended Accessories

Product Description	Item Number
GraftNet™ autologous tissue collector	ABS-1050
PowerPick™ device, 30°, 4 mm depth	AR-8150PP-30
PowerPick device, 45°, 4 mm depth	AR-8150PP-45
PowerPick device XL, 45°, 6 mm depth	AR-8150PX-45
Gemini™ SR8 cannula	AR-6572
Switching stick, 2.6 mm × 305 mm	AR-6572S
Chondral pick, straight 30° tip	AR-8655-05
Ring curette, reverse angle	AR-8655-04
Noninvasive ankle distractor set	AR-1713S
Ankle arthroscopy distractor strap	AR-1712
Ankle arthroscopy set	AR-8655S

References

1. Cheng N, Estes B, Awad H, et al. Chondrogenic differentiation of adipose-derived adult stem cells by a porous scaffold derived from native articular cartilage extracellular matrix. *Tissue Engineering*. 2009;15(2):231-41. doi:10.1089/ten.tea.2008.0253
2. Chadha N, Dang A, Sampson E, et al. Porous cartilage-derived matrix scaffolds for repair of articular cartilage defects. Poster presented at: Orthopaedic Research Society Annual Meeting; February 4-7, 2012; San Francisco, CA.
3. Malinin T, Temple HT, Carpenter EM. Induction of regeneration of articular cartilage defects by freeze-dried particulate cartilage allografts. *Cartilage*. 2009;(1 Suppl):93-164. doi:10.1177/194760350900101503



BioCartilage® ECM is manufactured and distributed by Vivex Biologics, Inc.
www.vivex.com



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 and/or outcomes.



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



US patent information

arthrex.com