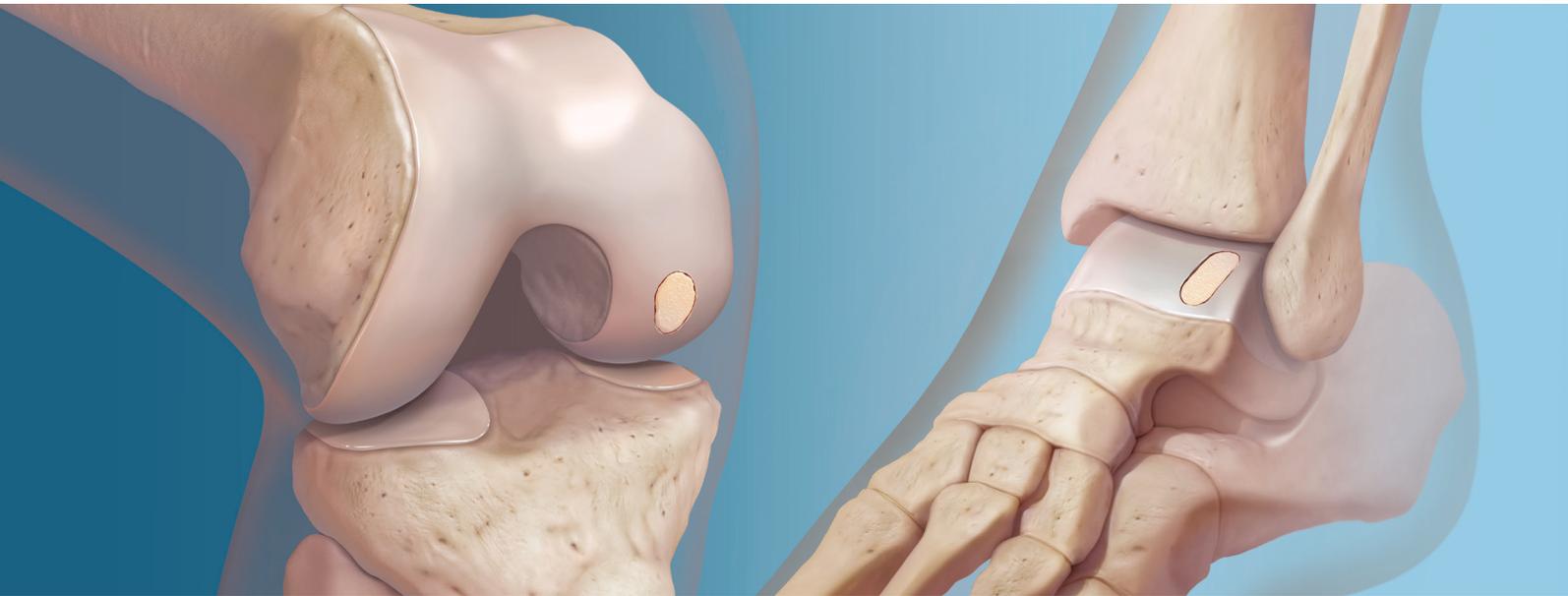




BioCartilage[®]



Cartilage Extracellular Matrix



Arthrex[®] 

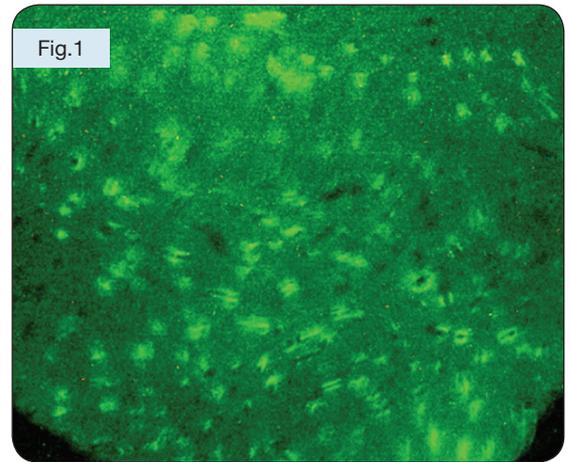
Features and Benefits

Composition: Cartilage Extracellular Matrix

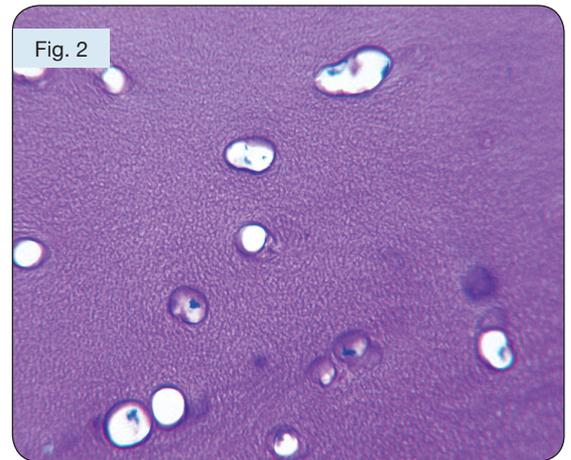
- BioCartilage contains the extracellular matrix that is native to articular cartilage including key components such as type II collagen (Figure 1), proteoglycans (Figure 2), and additional cartilaginous growth factors
- After processing, the dehydrated allograft cartilage has a particle size of 100-300 microns:
 - 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 (Figures 3 and 4 depict the ability of progenitor cells to attach to BioCartilage)
- The principle of BioCartilage is to serve as a scaffold over a microfractured defect, providing a tissue network that can potentially signal autologous cellular interactions
- Marrow elements will travel through the microfracture holes and interact with the scaffold created by BioCartilage instead of being expected to create its own fibrin scaffold as typically anticipated from a marrow stimulation procedure

Processing:

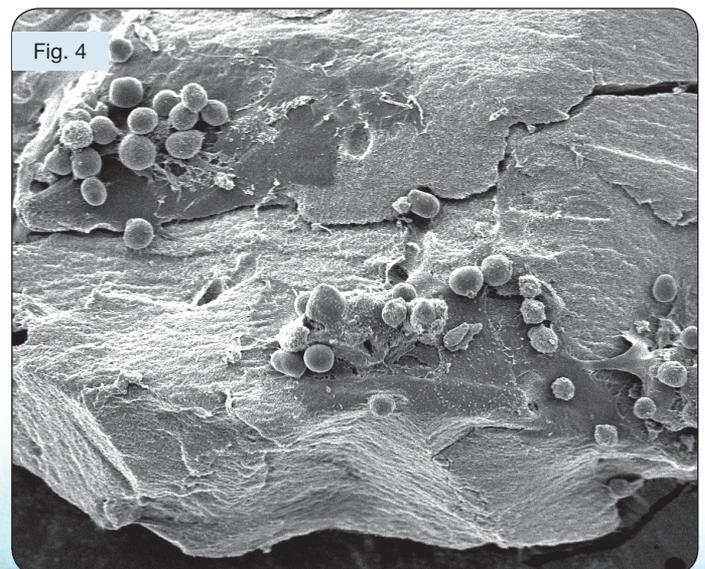
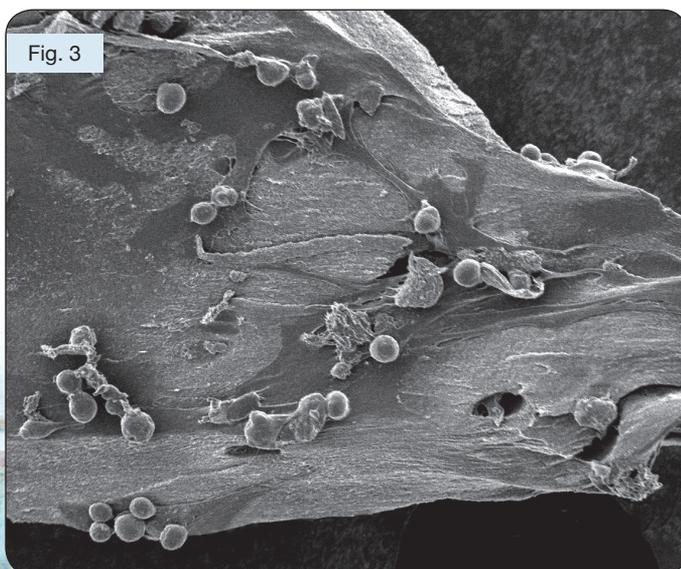
- BioCartilage goes through a specialized, gentle dehydration process (hypothermic dehydration) that allows the water content to be removed, while remaining in a liquid state instead of requiring the tissue, including the water, to be frozen before removal (lyophilization)
- After dehydration, the cartilage goes through a number of proprietary processing steps resulting in a very consistent particle size range
- BioCartilage is then aseptically processed and packaged to allow for ambient temperature storage with a shelf life of five years



Immunohistochemistry staining for type II collagen*



Proteoglycan content as evidenced by the presence of interterritorial granular matrix via toluidine blue staining*



Attachment of progenitor cells to BioCartilage

* The tissue was stained after dehydration, before micronization

Scientific Support for Arthrex® BioCartilage®

BioCartilage was designed to provide a reproducible, simple and inexpensive scaffold to augment traditional microfracture procedures. Scientific evidence exists supporting the premise that a dehydrated, allograft cartilage scaffold used as an adjunct to microfracture should improve the degree and quality of tissue healing within a properly prepared articular cartilage defect.

A porous scaffold derived from native articular cartilage extracellular matrix has been shown to promote growth and chondrogenic differentiation of adult progenitor cells via direct cell-matrix interactions:¹

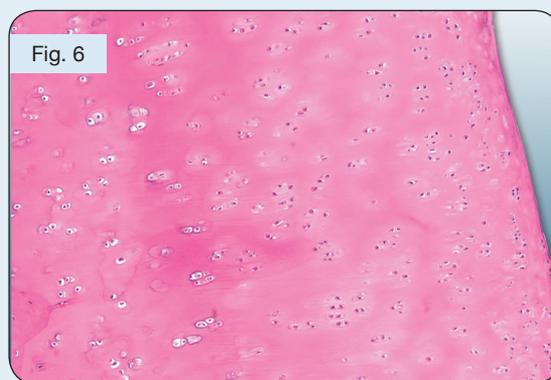
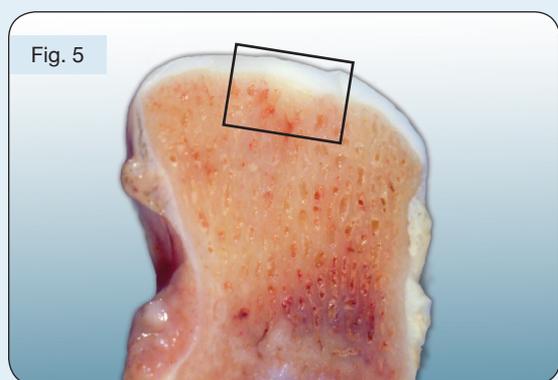
- Adipose-derived adult stem cells (ASCs) were seeded onto dehydrated, articular cartilage scaffold and cultured in standard medium without exogenous growth factors
- After six weeks, the cellular morphology resembled native articular cartilage and the cells were found residing within glycosaminoglycan-rich regions
- Histological and immunohistochemical examination showed abundant production of type II collagen

The porous, cartilage-derived matrix scaffold utilized in the previous study has also been demonstrated to repair focal articular cartilage defects in a preclinical (rabbit) model:²

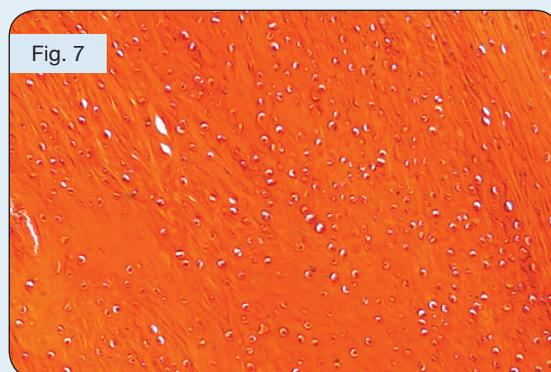
- Medial femoral condyle defects were created and a microfracture technique was used to induce bone marrow bleeding at the base of the defect before the dehydrated, cartilage matrix was press fit into the defect
- The unfilled, control group displayed loss of proteoglycan content similar to a fibrocartilage phenotype; however, the treatment group displayed persistent proteoglycan content
- The control group demonstrated upregulation of type I collagen gene expression typical of fibrocartilage, while the treatment group had significant upregulation of type II collagen and aggrecan

An early design of BioCartilage was utilized to fill osteochondral defects (1.5 cm diameter, 1 cm depth) in a baboon model inducing the formation of chondrogenic reparative tissue compared to controls:³

- Upon gross examination, the reparative tissue had an appearance of hyaline-like cartilage
- Histologic analysis revealed newly formed cartilage cells surrounded by normal appearing proteoglycan content
- The unfilled, control group exhibited enlargement of the defect at early time points and remained open with some uneven patches of tissue at the later time points



Treatment group highlighting resolution of the defect by 14 weeks upon gross and histologic evaluation



Proteoglycan content demonstrated via safranin O staining after 16 weeks

References:

- ¹ Cheng N, 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.
- ² Chadha N, et al, *Porous Cartilage-Derived Matrix Scaffolds for Repair of Articular Cartilage Defects*, ORS, 2012; Poster No. 0735.
- ³ Malinin T, et al, *Induction of regeneration of articular cartilage defects by freeze-dried particulate cartilage allografts*, ICRS, 2009 Meeting; poster presentation.

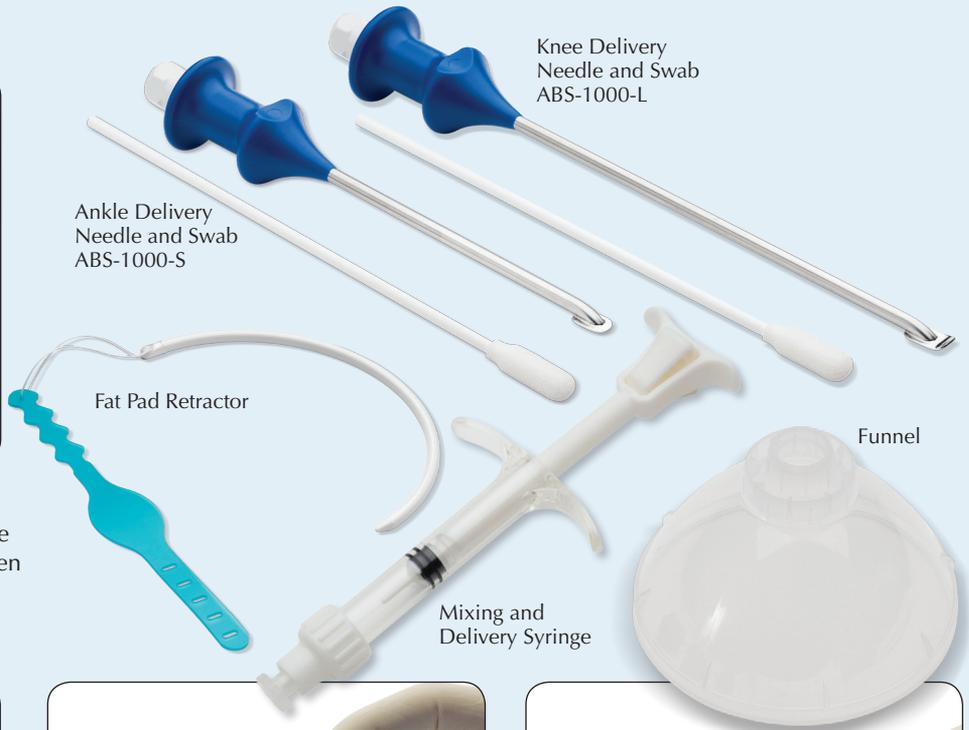
BioCartilage® Technique Guide

Perform the following steps utilizing aseptic technique. Please refer to the Directions For Use packaged with the product for a full list of warnings and instructions on BioCartilage.



1

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 from its container into the funnel.



Ankle Delivery Needle and Swab ABS-1000-S

Knee Delivery Needle and Swab ABS-1000-L

Fat Pad Retractor

Funnel

Mixing and Delivery Syringe



2

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



3

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.



4

To mix the BioCartilage 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.



5

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



6

Snap the pushrod back onto the mixing element.

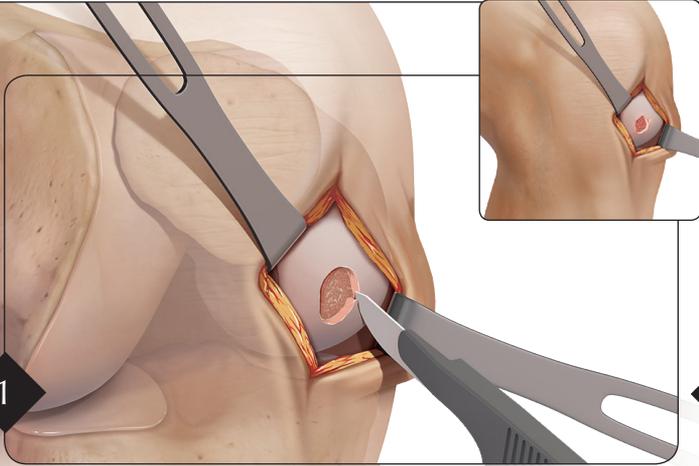


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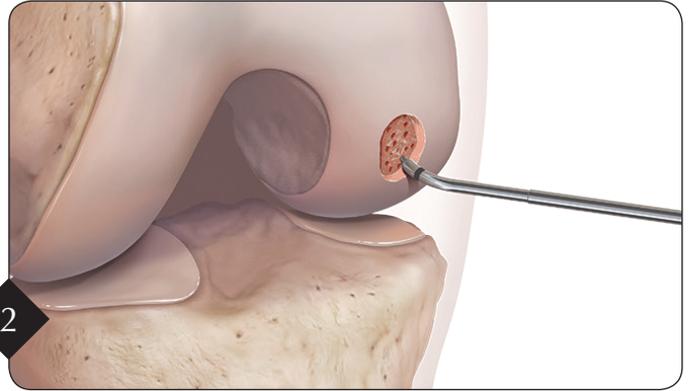
Apply a delivery needle and dispense the BioCartilage mixture out of the mixing syringe into the needle. Use the obturator to deliver the mixture from the needle to the defect.

BioCartilage® Knee Arthroscopy Surgical Technique

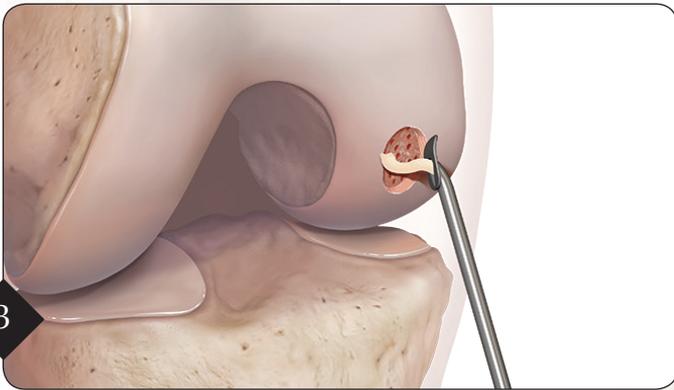
The BioCartilage knee techniques were developed in collaboration with Brian Cole, MD, MBA, Chicago, Illinois



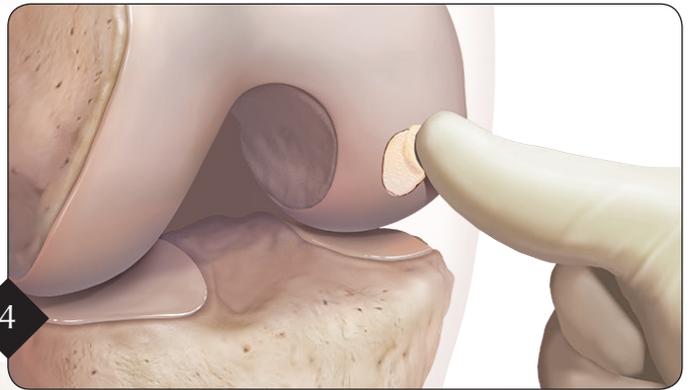
1 Debride the articular cartilage defect to a stable border with perpendicular margins. A scalpel can be used to create the vertical margins and a curette can be used to debride the calcified cartilage layer at the base of the defect.



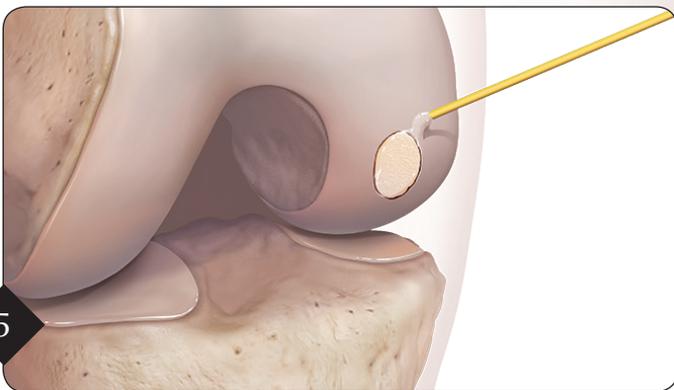
2 Perform bone marrow stimulation using standard microfracture technique. A PowerPick™ may be used to perform this procedure while applying irrigation fluid to avoid thermal necrosis.



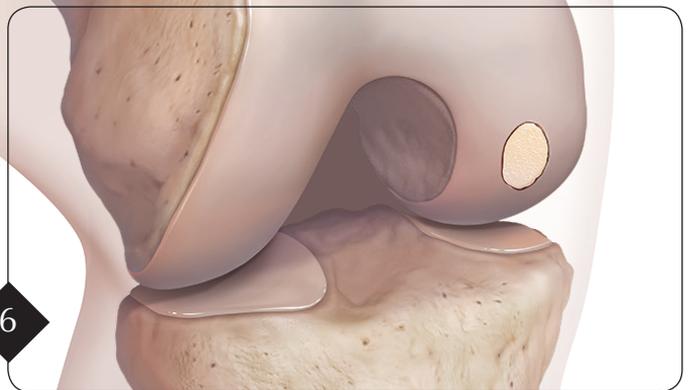
3 Dry the defect thoroughly. After mixing the BioCartilage with an autologous blood solution (1:0.8 ratio) within the mixing syringe, apply the mixture into the defect.



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

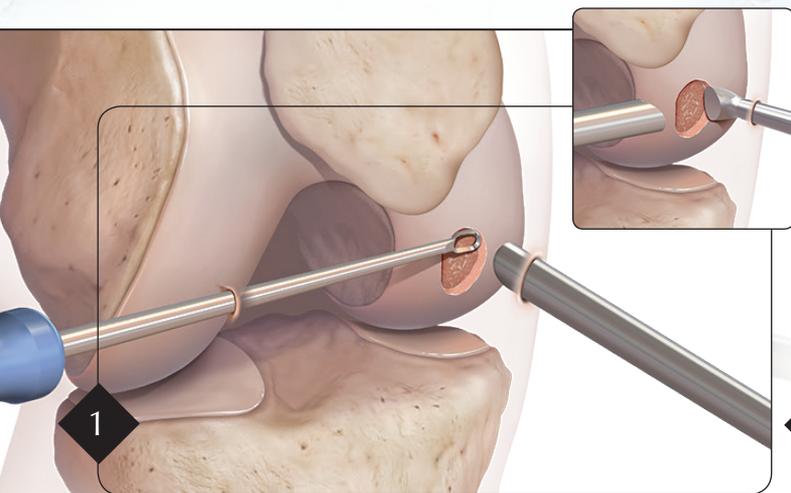


5 Apply fibrin over the top of the BioCartilage. Use enough to cover the defect, but prevent over-usage as this will cause the construct to sit proud in the joint. Use of a dual lumen applicator tip is recommended to apply the fibrin in order to prevent activation and clogging of the fibrin within the needle. Do not manipulate for 5 minutes after application. The knee may be gently ranged before closure to assure BioCartilage adherence.

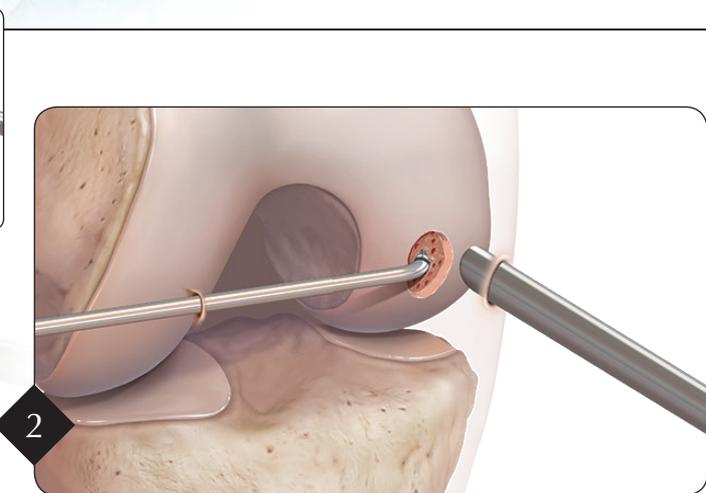


6 At the completion of surgery, a knee immobilizer locked in extension is placed and the patient is made non-weight bearing or protected weight bearing as determined by defect location with delayed onset of range-of-motion for up to one week postoperatively. Thereafter, standard rehabilitation protocols used for the tibiofemoral and patellofemoral joint are implemented.

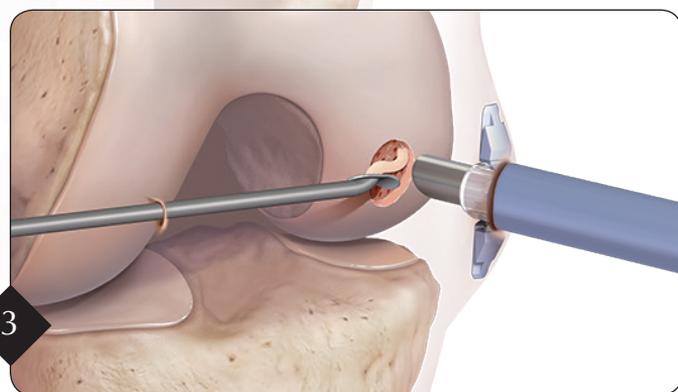
BioCartilage® Knee Arthroscopic Surgical Technique



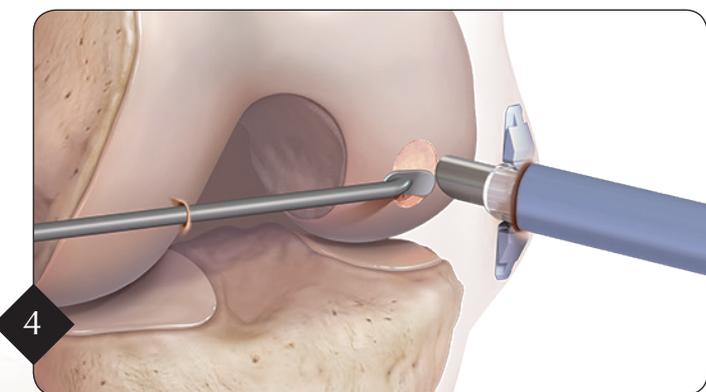
Debride the articular cartilage defect to a stable border with perpendicular margins. A Ring Curette and Cobb Elevator can be used to create the vertical margins and debride the calcified cartilage layer at the base of the defect. Optionally, the Fat Pad Retractor may be used to contain the fat pad and aid in distracting the joint.



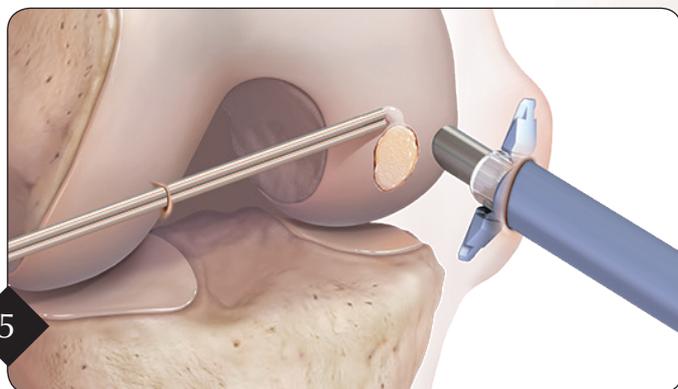
Perform bone marrow stimulation utilizing the PowerPick™. After microfracture, ensure the use of a tourniquet, aspirate the arthroscopic fluid and dry the cartilage defect with the cannulated swabs.



A Gemini Cannula should be utilized in the portal that resides over the defect. Apply distraction of the soft tissue with the cannula to improve visualization of the defect. The BioCartilage can be applied over the defect with the Arthroscopic Delivery Needle (mixing in a 1:0.8 ratio with autologous fluid).



The elevator component on the Arthroscopic Delivery Needle can be used to smooth out the BioCartilage within the defect so that it remains flush or slightly recessed to the surrounding cartilage.



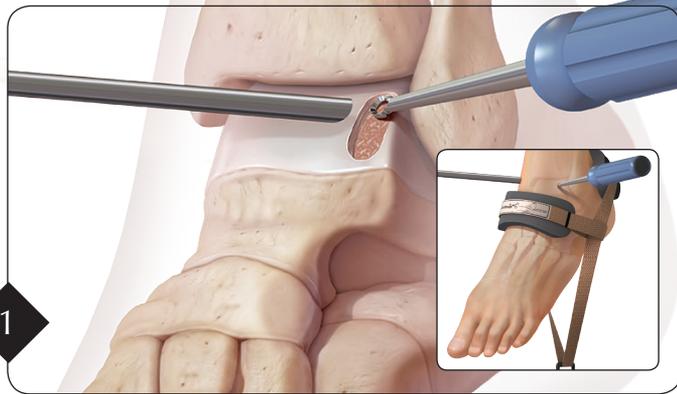
Apply a light layer of fibrin over the BioCartilage through a dual lumen applicator tip; prevent over usage as this will cause the construct to sit proud. If a single lumen needle/cannula is used, this will lead to premature activation of the fibrin. Do not manipulate for 5 minutes after application. The knee may be gently ranged before closure to assure BioCartilage adherence.



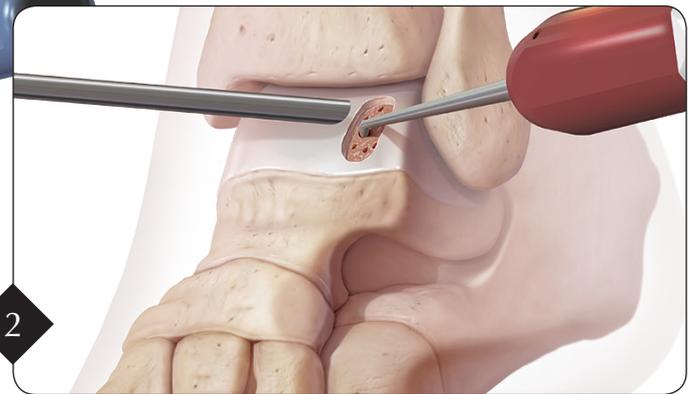
At the completion of surgery, a knee immobilizer locked in extension is placed and the patient is made non-weight bearing or protected weight bearing as determined by defect location with delayed onset of range-of-motion for up to one week post-operatively. Thereafter, standard rehabilitation protocols used for the tibiofemoral and patellofemoral joint are implemented.

BioCartilage® Ankle Arthroscopic Surgical Technique

The BioCartilage ankle technique was developed in collaboration with Eric Giza, MD, Sacramento, California and James McWilliam, MD, New York, New York



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 utilizing PowerPick™. Aspirate all arthroscopic fluid and dry the cartilage defect with the cannulated swabs.



After mixing the BioCartilage with an autologous blood solution (1:0.8 ratio) within the mixing syringe, apply the mixture into the defect utilizing the Arthroscopic Delivery Needle.



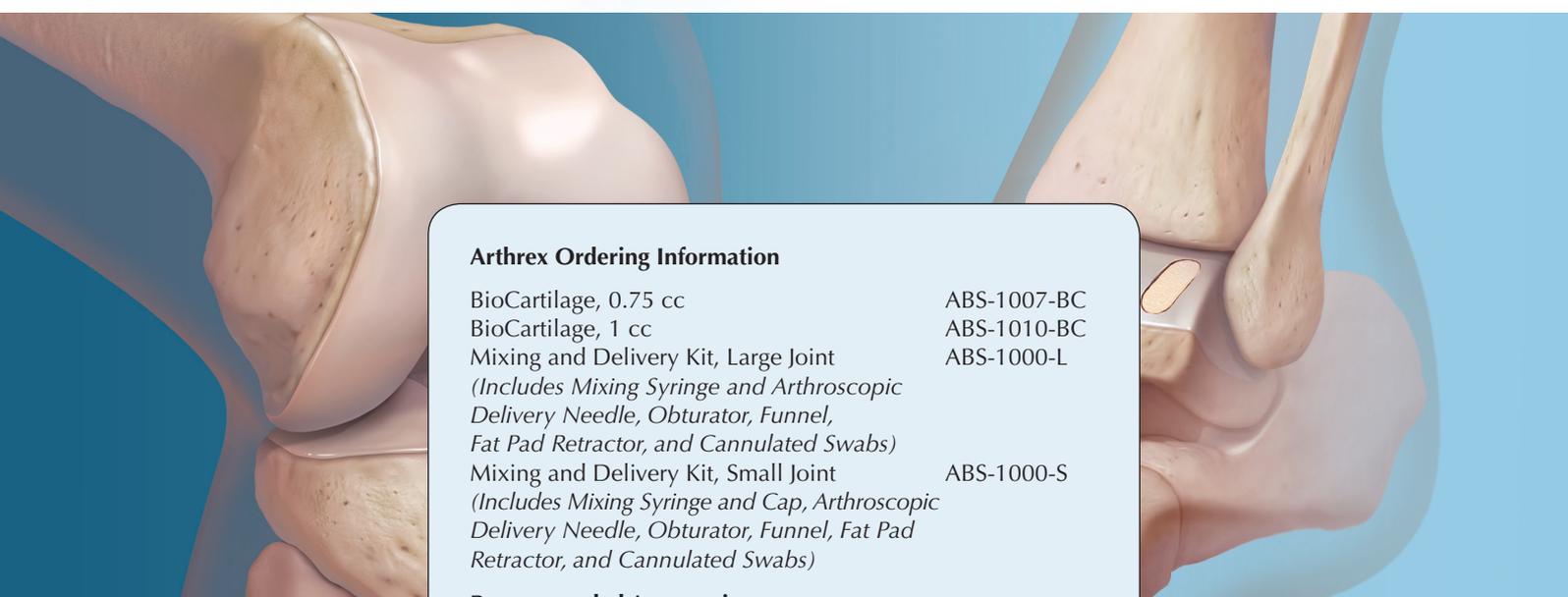
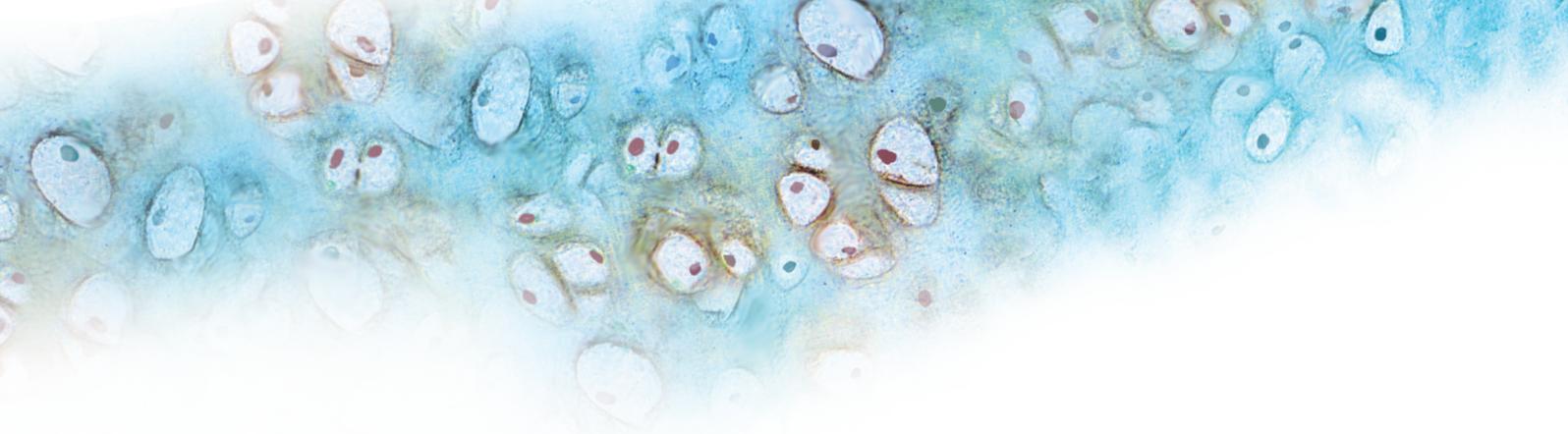
The elevator component on the Arthroscopic Delivery Needle can be used to smooth out the BioCartilage within the defect. Ensure that the BioCartilage remains flush or slightly recessed when compared to the surrounding cartilage.



Apply fibrin over the BioCartilage through a dual lumen applicator tip. Avoid applying too much fibrin to prevent the construct from sitting proud. Do not manipulate for 5 minutes after application. The ankle may be gently ranged before closure to assure BioCartilage adherence.



At the completion of surgery, the ankle is immobilized in neutral position and the patient is made non-weight bearing. Thereafter, standard rehabilitation protocols following microfracture surgery are implemented.



Arthrex Ordering Information

BioCartilage, 0.75 cc	ABS-1007-BC
BioCartilage, 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

Recommended Accessories

Tuohy Delivery Needle and Obturator	ABS-1001
Short Tuohy Delivery Needle and Obturator	ABS-1001-S
Long Tuohy Delivery Needle and Obturator	ABS-1001-L
PowerPick XL, 45°, 6 mm depth	AR-8150PX-45
Gemini SR8 Cannula	AR-6572
Switching Stick, 2.6 mm x 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

To order please call Arthrex, Inc. at 1-800-934-4404
Contact your local Arthrex Representative
for additional information

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.

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