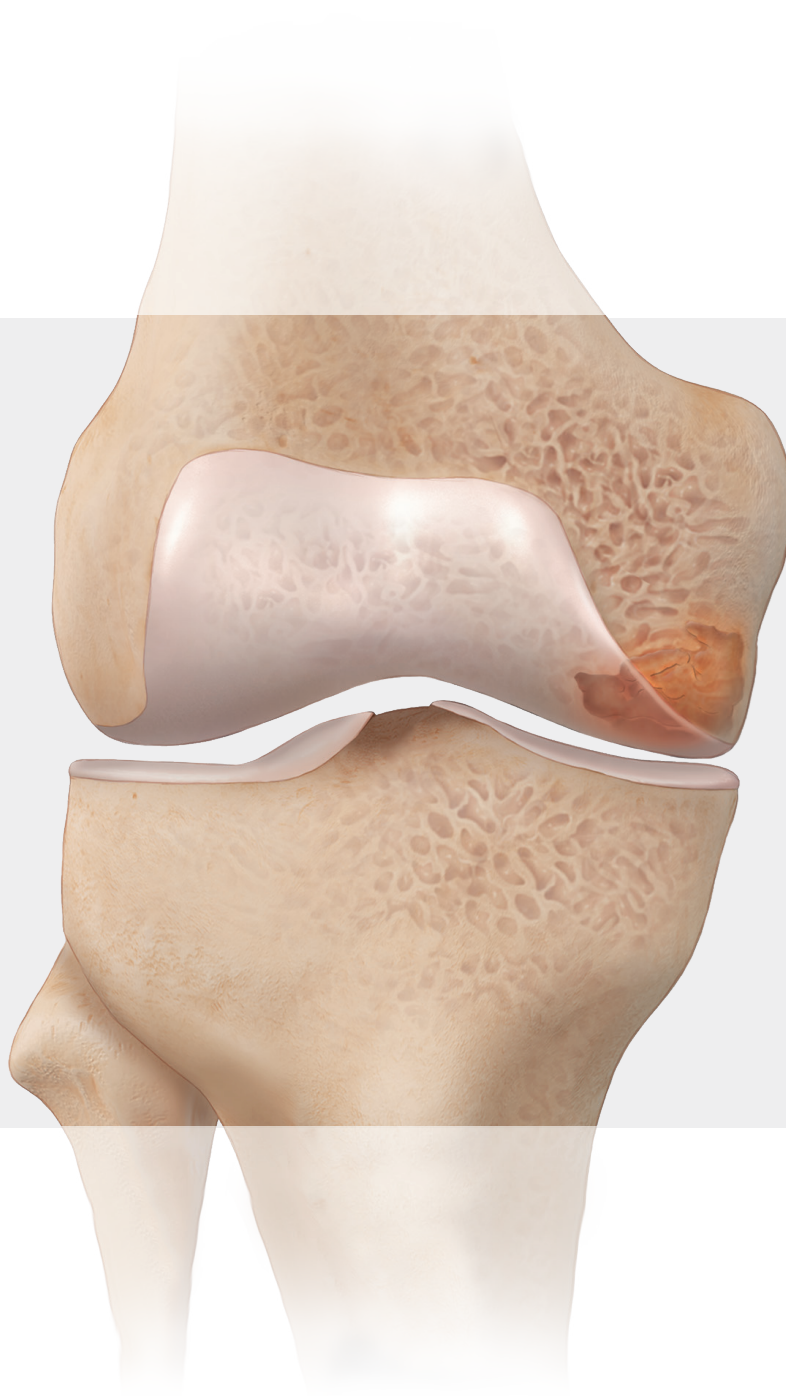


IntraOsseous BioPlasty[®]

Surgical Technique



IntraOsseous BioPlasty® Surgical Technique

The IntraOsseous BioPlasty® (IOBP) procedure is a biologic treatment for bone pathologies resulting from acute or chronic injury, including bone marrow lesions associated with insufficiency fracture, osteoarthritis, persistent bone bruises, avascular necrosis, and osteonecrosis. Arthrex offers multiple options for the biologic treatment of these pathologies, including decompressing the lesion and the delivery of a platelet-rich plasma concentrate from bone marrow aspirate (cPRP_{BMA}) using the Arthrex Angel® cPRP and bone marrow processing system. The IOBP® technique is intended to encourage physiologic bone remodeling and repair to achieve normal bone anatomy and function.

AlloSync™ Pure Demineralized Bone Matrix

AlloSync Pure is a dehydrated osteoinductive demineralized bone matrix (DBM) derived from 100% human allograft bone with no extrinsic carriers. AlloSync Pure bone matrix resists irrigation and can be used in a fluid environment (Figure 1). The clinician can control the handling properties of AlloSync Pure bone matrix, which includes decreasing the viscosity for injectable applications. The proprietary rice-shaped fiber technology used to process AlloSync Pure DBM increases the osteoinduction and osteoconductive surface area to accelerate cellular ingrowth.¹

Angel cPRP and Bone Marrow Processing System

Technology is what sets the Angel system apart from the competition. The Arthrex Angel cPRP and bone marrow processing system uses a proprietary platelet sensor and 1-button automation to prepare customized cPRP_{BMA}. Bone marrow is a rich source of platelets, nucleated cells, and progenitor cells. The Angel device is the only one to provide PRP concentrate from BMA with adjustable cellular levels.



AlloSync Pure DBM



Arthrex Angel system centrifuge

Process for Mixing DBM With Autologous Fluid



1
Transfer the cPRP_{BMA} into a separate sterile basin and draw into a syringe.



2
Fill the mixing and delivery syringe with AlloSync™ Pure DBM. Use a female-to-female luer adapter to connect to the cPRP_{BMA} syringe. Add the autologous fluid to the mixing and delivery syringe in a 5:3 ratio of DBM to fluid.



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. Push and pull the mixing element back and forth until thoroughly mixed.



4
Pull back on the mixing element and snap the pushrod back onto the mixing element.



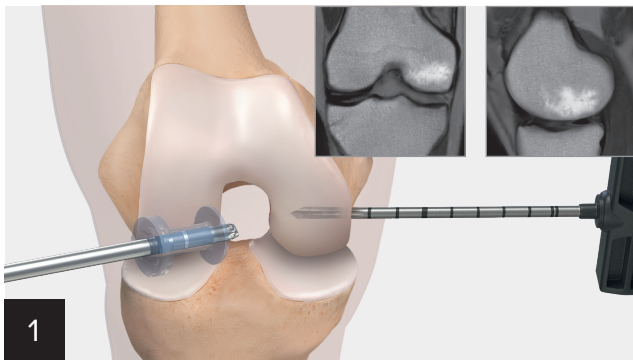
5
Reattach the female-to-female luer connector and transfer the material into 1 cc syringes.



6
Following transfer into smaller-volume syringes, the AlloSync Pure DBM and autologous fluid mixture is ready to deliver.

Direct-Delivery IntraOsseous BioPlasty® Procedure

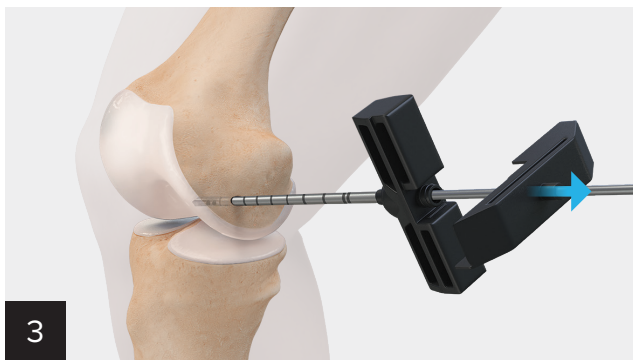
This technique is courtesy of Sam Akhavan, MD, and Jason M. Scopp, MD



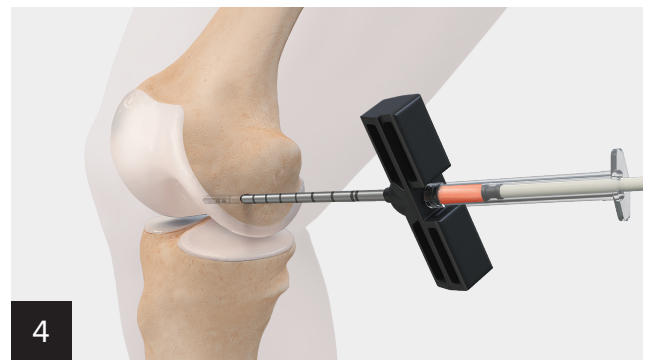
To perform a direct IOBP® procedure, assemble the delivery cannula onto a pin driver and approximate the location of the bone marrow lesion using the preoperative MRI and intraoperative fluoroscopy.



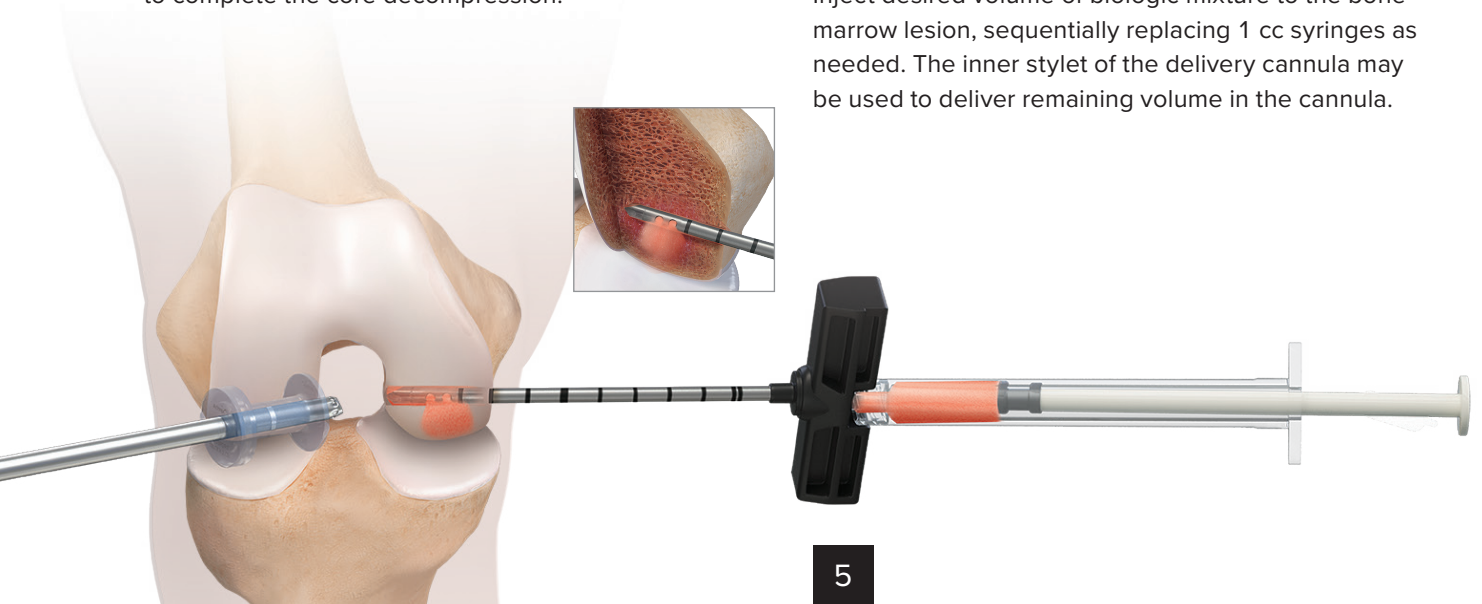
Insert the delivery cannula through the bone marrow lesion, taking care to avoid penetrating the opposite cortex.



Remove the inner stylet of the delivery cannula to complete the core decompression.



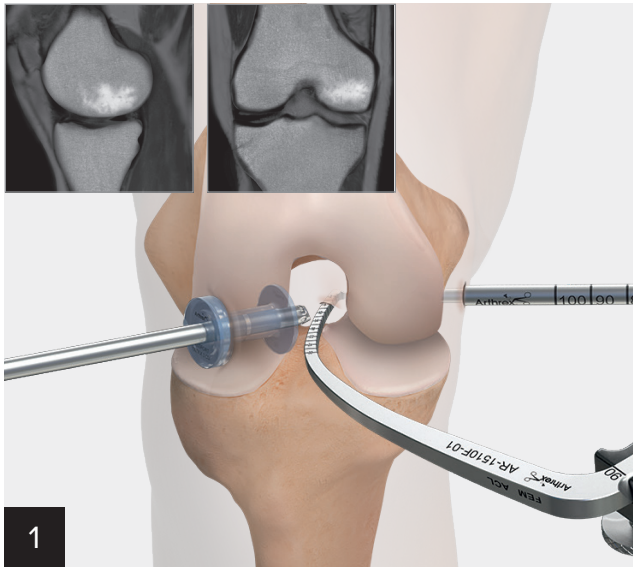
Assemble the delivery syringe onto the delivery cannula. Inject desired volume of biologic mixture to the bone marrow lesion, sequentially replacing 1 cc syringes as needed. The inner stylet of the delivery cannula may be used to deliver remaining volume in the cannula.



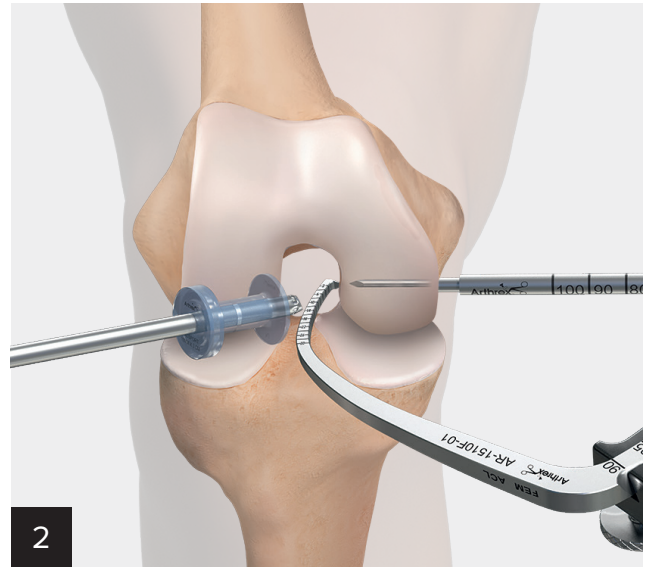
Arthroscopic visualization may be used to ensure the material is delivered into the bone marrow lesion and not into the joint space.

Guided-Delivery IntraOsseous BioPlasty® Procedure

This technique is courtesy of Bert R. Mandelbaum, MD, and Thomas R. Carter, MD

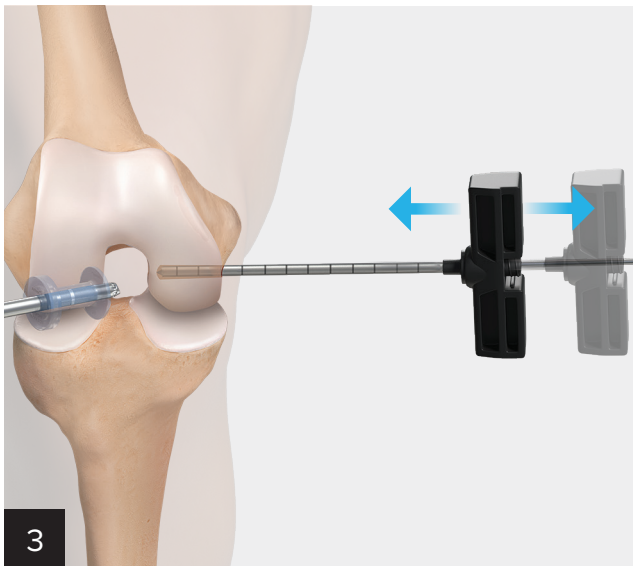


Use the side-release RetroConstruction™ handle with the femoral ACL marking hook and 3.5 mm guide pin sleeve to triangulate the approximate location of the lesion according to the MRI.

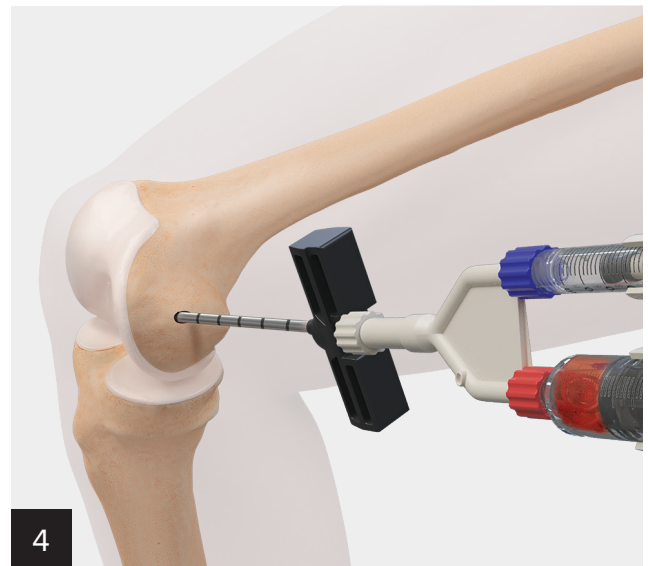


Advance the guide pin through the lesion. Take care not to violate the far cortex or create a full tunnel. It is also recommended to visualize the entire procedure arthroscopically.

Note: Use fluoroscopy throughout the procedure to confirm position.



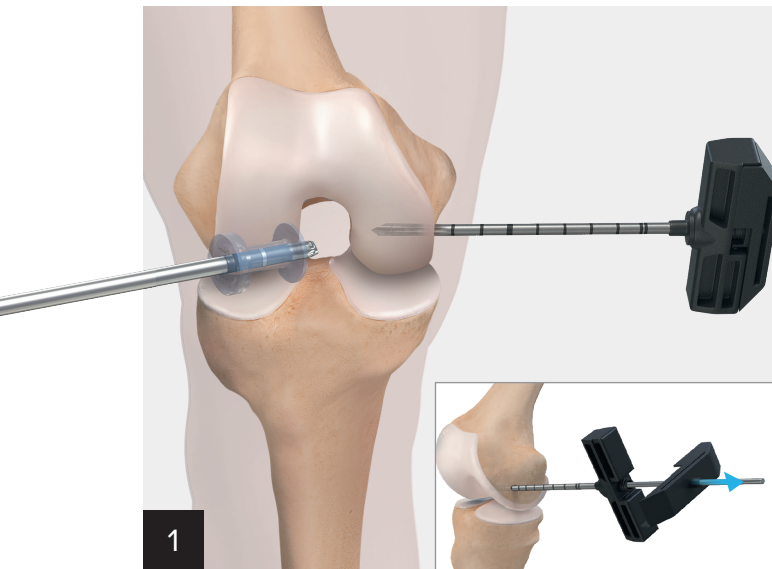
Remove the handle by unlocking the side-release mechanism. After removing the stylet, advance the delivery cannula over the guide pin to the desired depth.



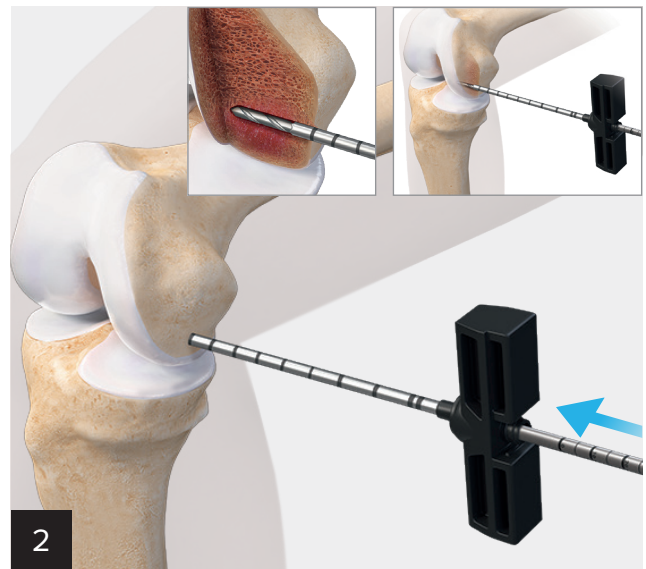
The biologic mixture may then be directly applied to the subchondral edema or fracture. Use the stylet to empty the delivery cannula if desired.

IntraOsseous BioPlasty® Procedure With Decompression Device

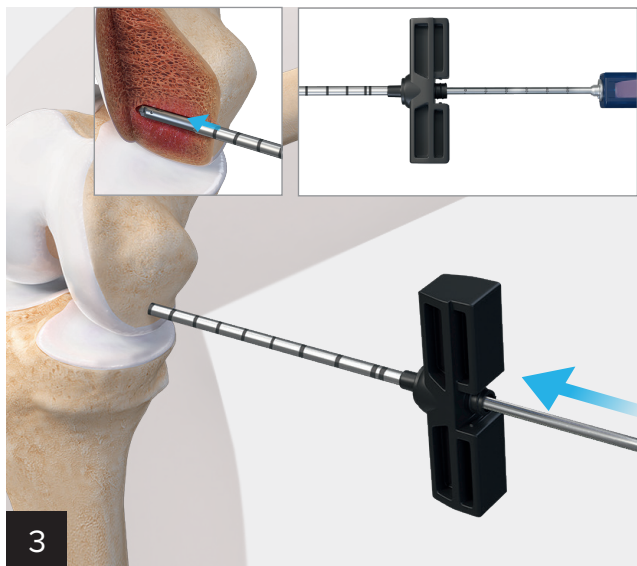
This technique is courtesy of Bert R. Mandelbaum, MD, and Thomas R. Carter, MD



Position the open-tip delivery cannula in the desired trajectory toward the bone marrow lesion. Confirm the approach using intraoperative fluoroscopy and according to the MRI. Advance the delivery cannula toward the desired depth to achieve a stable position, then remove the inner stylet of the delivery cannula.

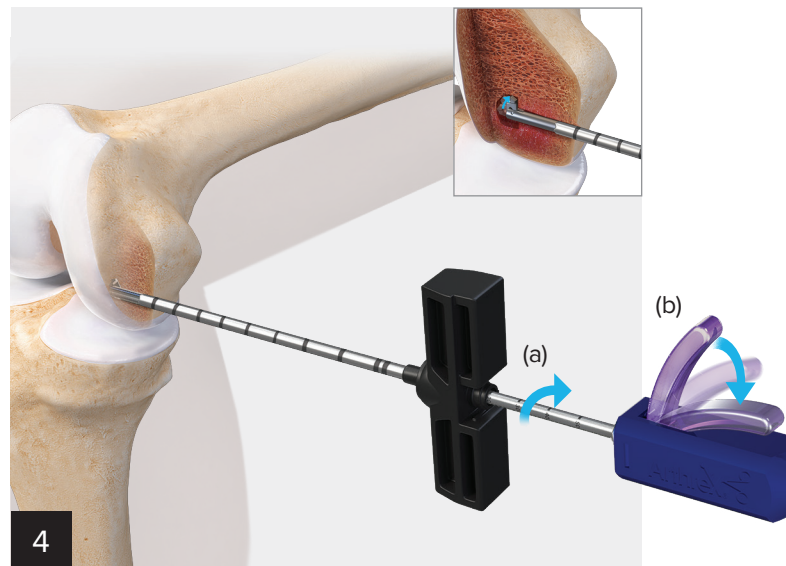


Advance the 3.3 mm guide pin through the delivery cannula to the desired depth through the bone marrow lesion. Reference the depth markings of the guide pin in relation to the depth beyond the tip of the delivery cannula. Optionally, a guided approach may be performed with the RetroConstruction™ handle by drilling the 3.3 mm guide pin to approach the lesion, then assembling the delivery cannula.

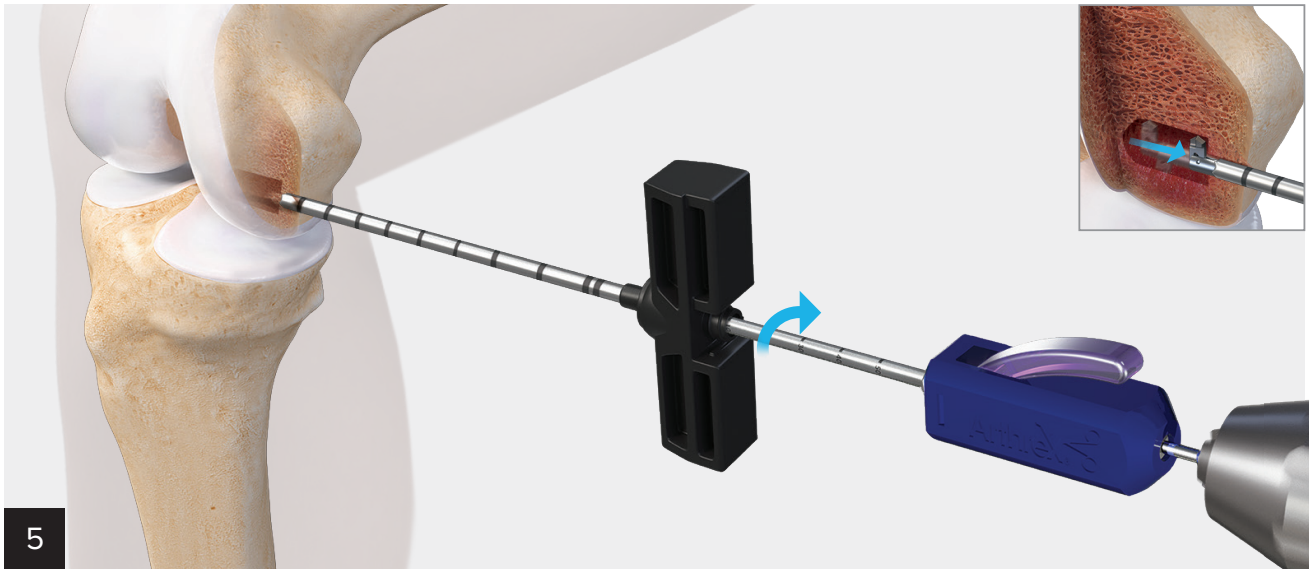


Advance the decompression device through the delivery cannula and to the most distal end of the prepared decompression site.

Note: The depth of the decompression device beyond the delivery cannula may be referenced by the laser markings.

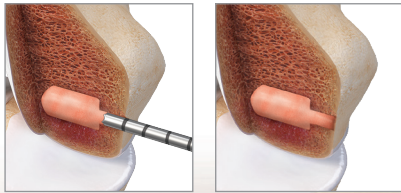


Firmly grasp the blue decompression device handle; do not engage the trigger yet. Use the opposite hand to fully engage power and rotate the decompression device (a). Once drilling has begun, slowly engage trigger mechanism to flip the cutting feature (b).



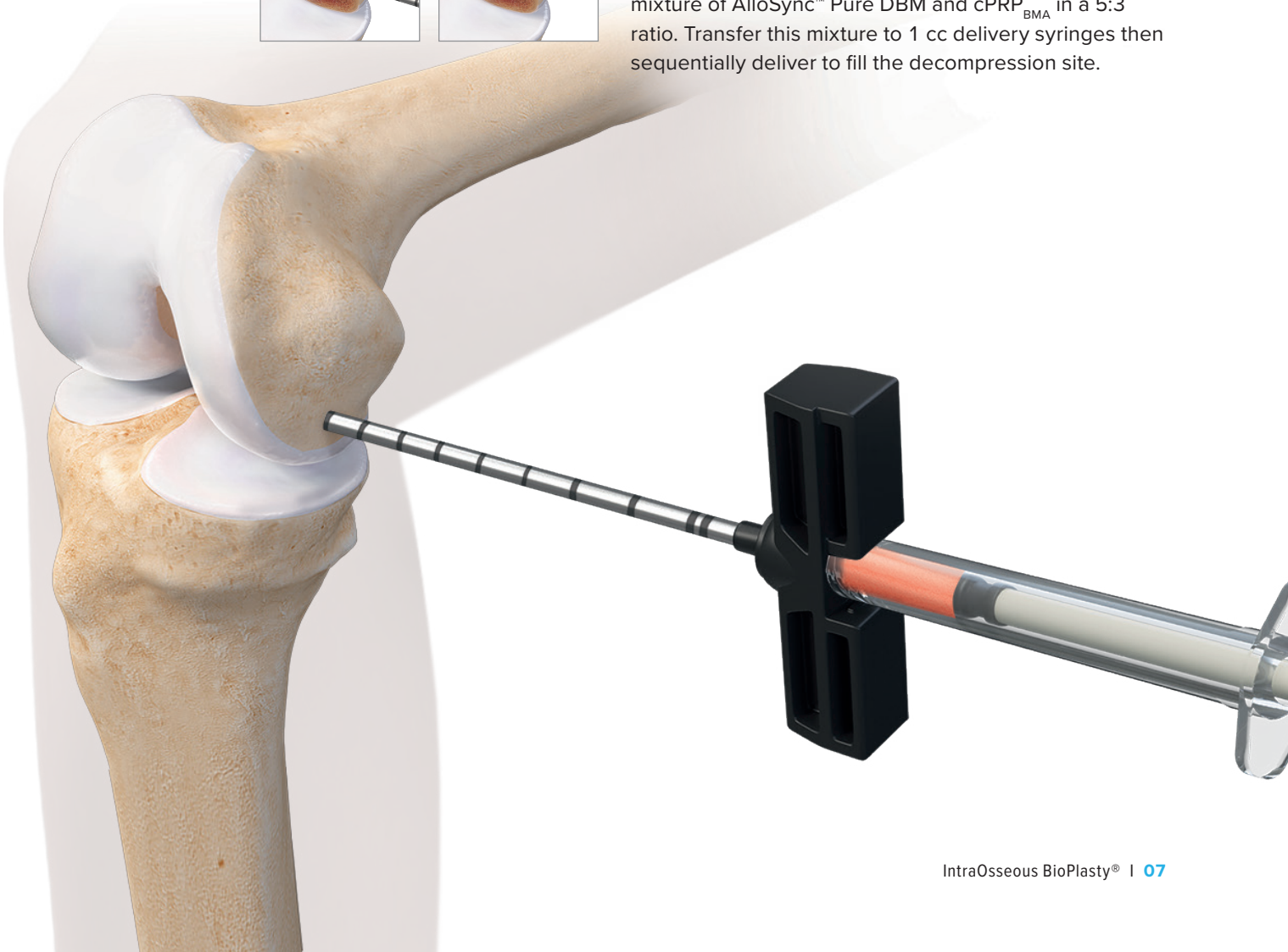
5

While drilling, begin to pull back on the device to achieve the desired decompression. Reference the depth marking of the device to prevent interference with the tip of the delivery cannula. Once the desired decompression is complete, release the trigger and withdraw the device while maintaining the position of the delivery cannula.

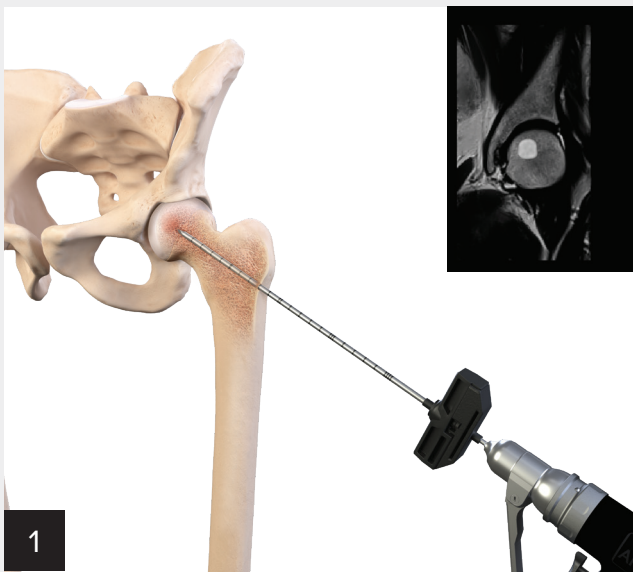


6

With the 14 cc mixing and delivery syringe, prepare a mixture of AlloSync™ Pure DBM and cPRP_{BMA} in a 5:3 ratio. Transfer this mixture to 1 cc delivery syringes then sequentially deliver to fill the decompression site.



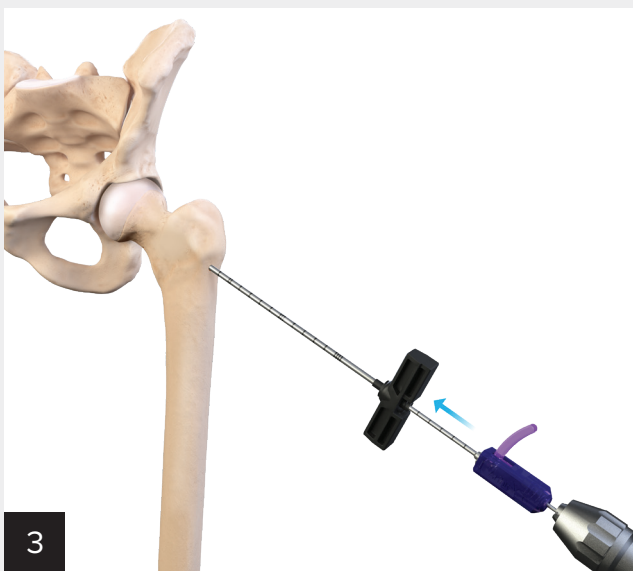
Direct-Delivery Procedure for Femoral Head Lesions With Decompression Device



1
Position the open-tip delivery cannula in the desired trajectory toward the bone marrow lesion, according to the MRI. Confirm the approach using intraoperative fluoroscopic guidance. Advance the delivery cannula toward the desired depth to achieve a stable position, then remove the inner stylet of the delivery cannula.

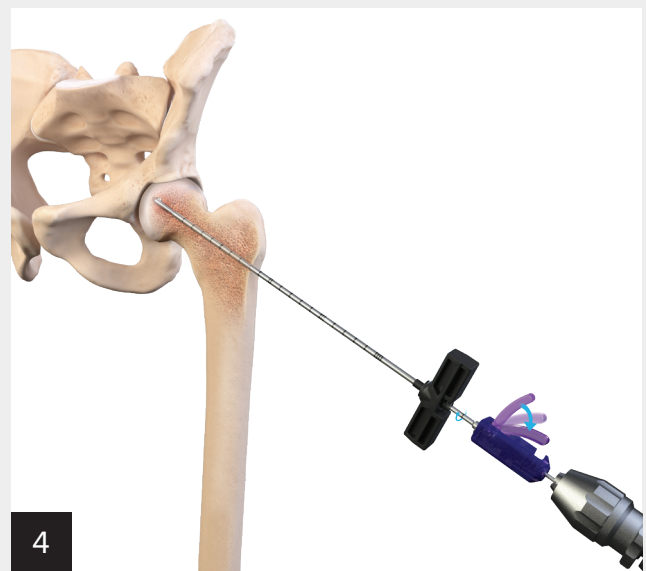


2
Advance the 3.3 mm guide pin to the desired decompression depth through the bone marrow lesion, taking care not to breach the cartilage surface. Reference the depth markings of the guide pin in relation to the depth beyond the tip of the delivery cannula.



3
Advance the IOBP® decompression device through the delivery cannula to the most distal end of the prepared decompression site.

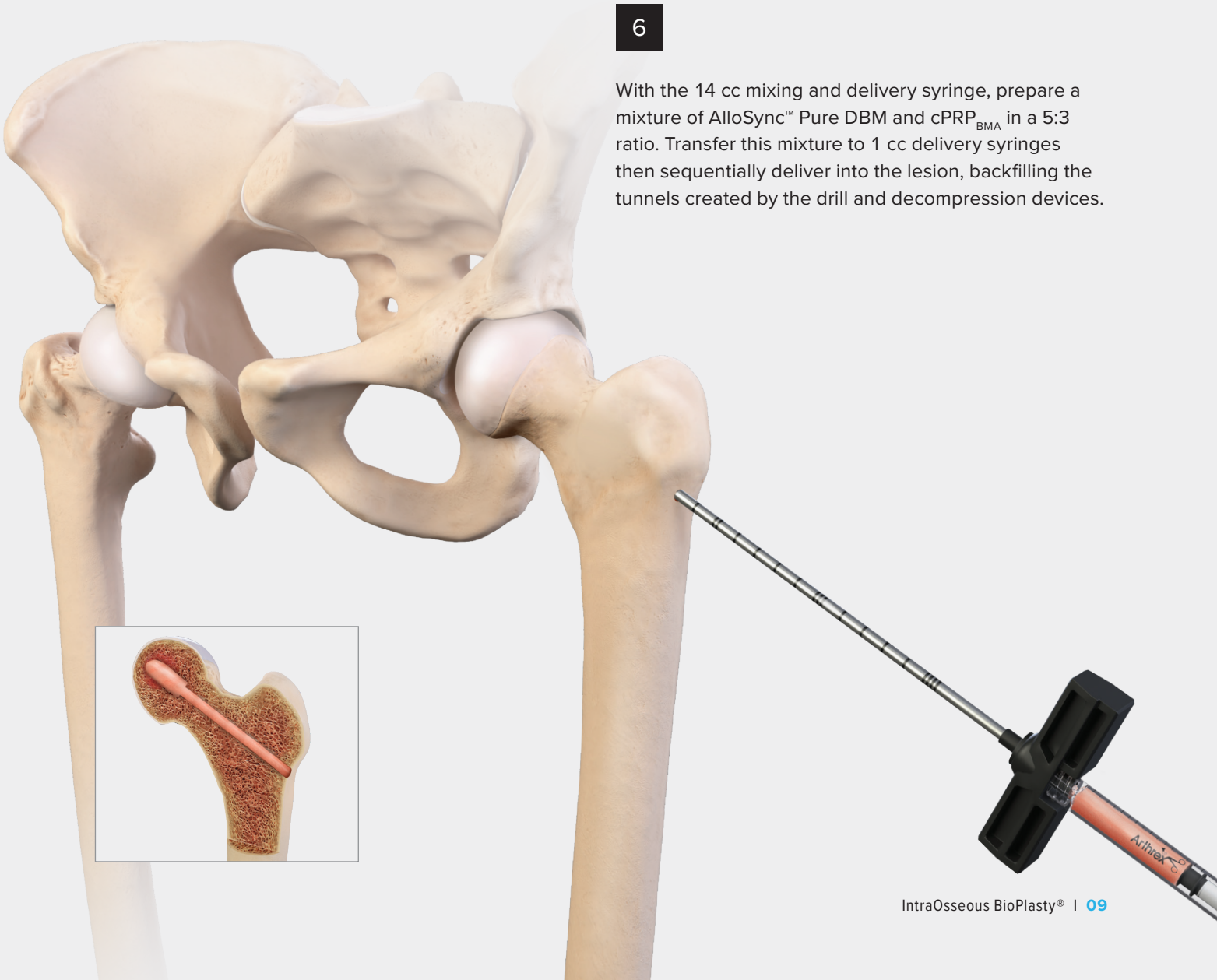
Note: The depth of the decompression device beyond the delivery cannula may be referenced using the laser markings.



4
Firmly grasp the blue decompression device handle; do not engage the trigger yet. Use the opposite hand to fully engage power and rotate the decompression device. Once drilling has begun, slowly engage the trigger mechanism to flip the cutting feature.

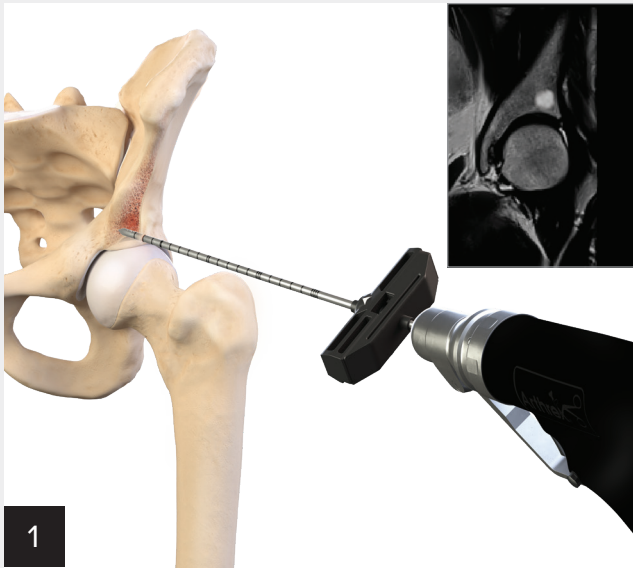


While drilling, begin to pull back on the device to achieve the desired decompression. Reference the depth marking of the device to prevent interference with the tip of the delivery cannula. Once the desired decompression is complete, release the trigger and withdraw the device while maintaining the position of the delivery cannula.

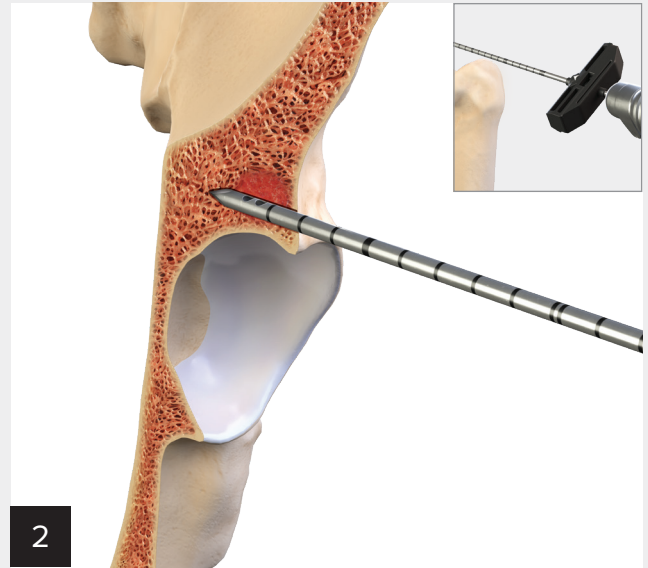


With the 14 cc mixing and delivery syringe, prepare a mixture of AlloSync™ Pure DBM and cPRP_{BMA} in a 5:3 ratio. Transfer this mixture to 1 cc delivery syringes then sequentially deliver into the lesion, backfilling the tunnels created by the drill and decompression devices.

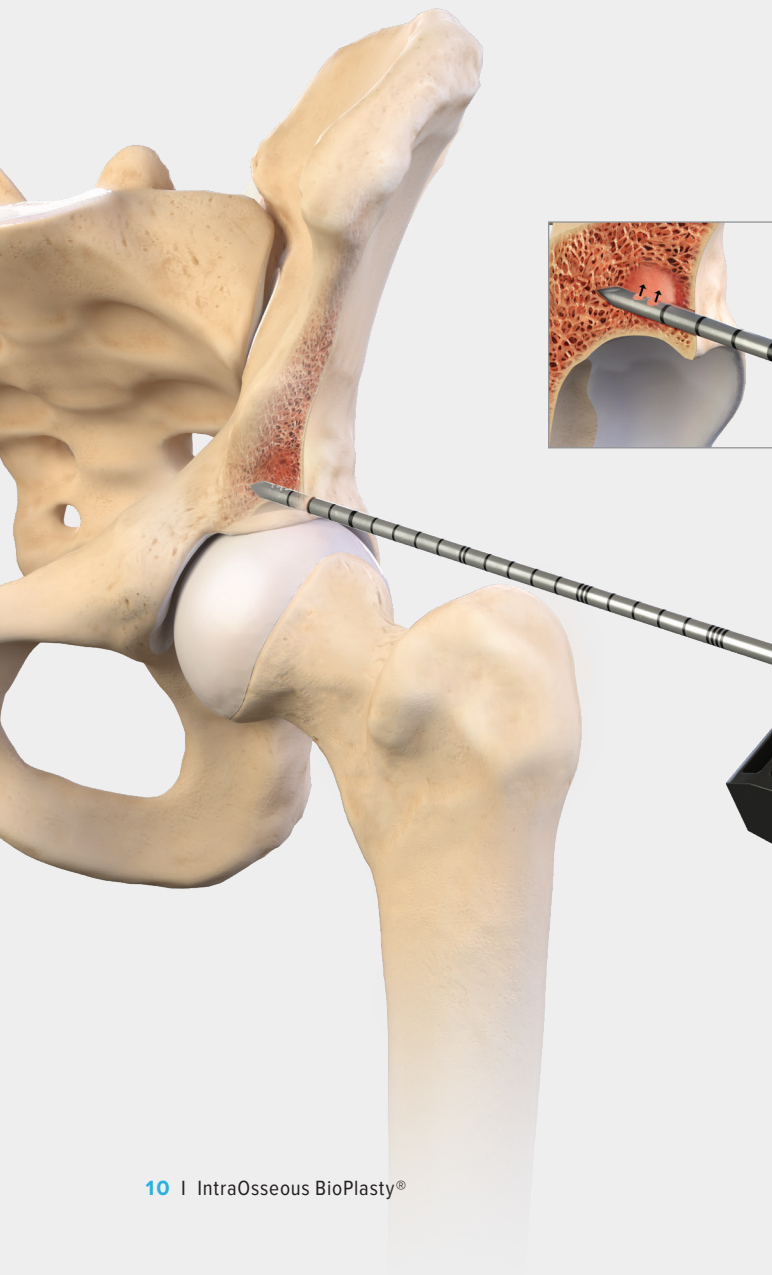
Procedure for Acetabular Lesions



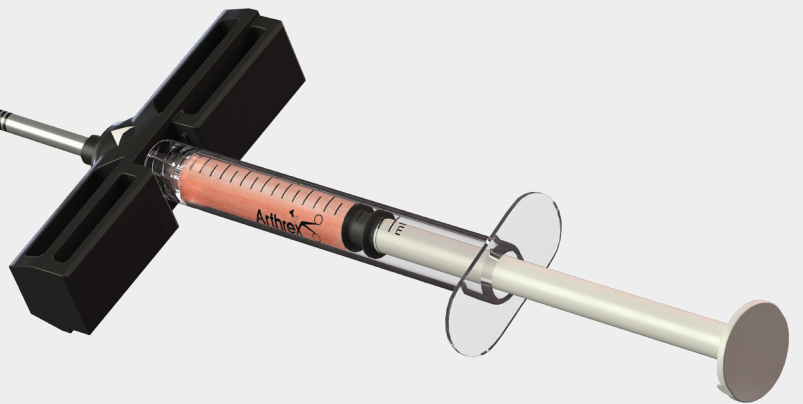
Position the closed-tip cannula toward the lesion according to the MRI, then drive the needle into the acetabulum using fluoroscopic guidance.



Position the holes of the tip of the needle toward the lesion, using the white arrow on the handle for reference. Remove the inner stylet to complete the core decompression.



Deliver the Allosync™ Pure DBM and cPRP_{BMA} mixture directly into the lesion.



Direct-Delivery Ankle Arthroscopic Procedure

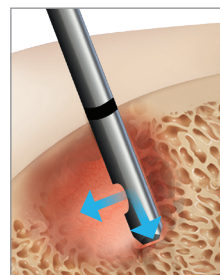
The direct approach may be used if an articular cartilage lesion is present. If the articular surface remains intact, the guided approach may be preferred.



1 Under tourniquet control, apply limited distraction to the ankle joint. Debride the articular cartilage defect to create stable margins using a ring curette. Use arthroscopic and fluoroscopic guidance throughout the procedure to aid visualization.

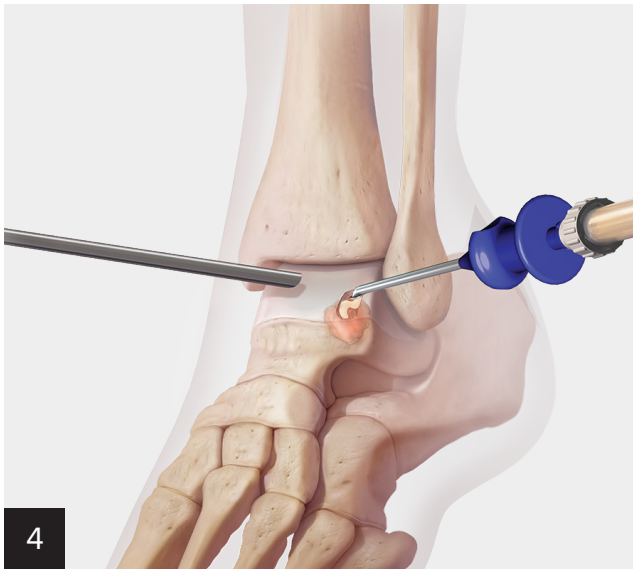


2 Advance the 13-ga cannula through the articular defect and into the bone marrow lesion. Remove the inner trocar from the delivery cannula to complete the core decompression.



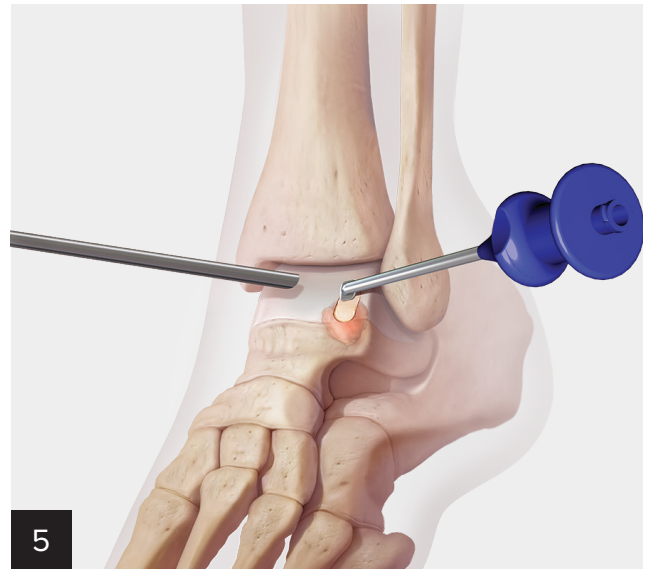
3

Following positioning of the delivery cannula, mix AlloSync™ Pure DBM with the cPRP_{BMA} at a 1:1 ratio, within the mixing syringe, then transfer to 1 cc syringes. Deliver the DBM gel and cPRP_{BMA} mixture to the bone marrow lesion to treat the subchondral edema or fracture. The trocar may be used to empty the delivery cannula, and the cannula may be removed.



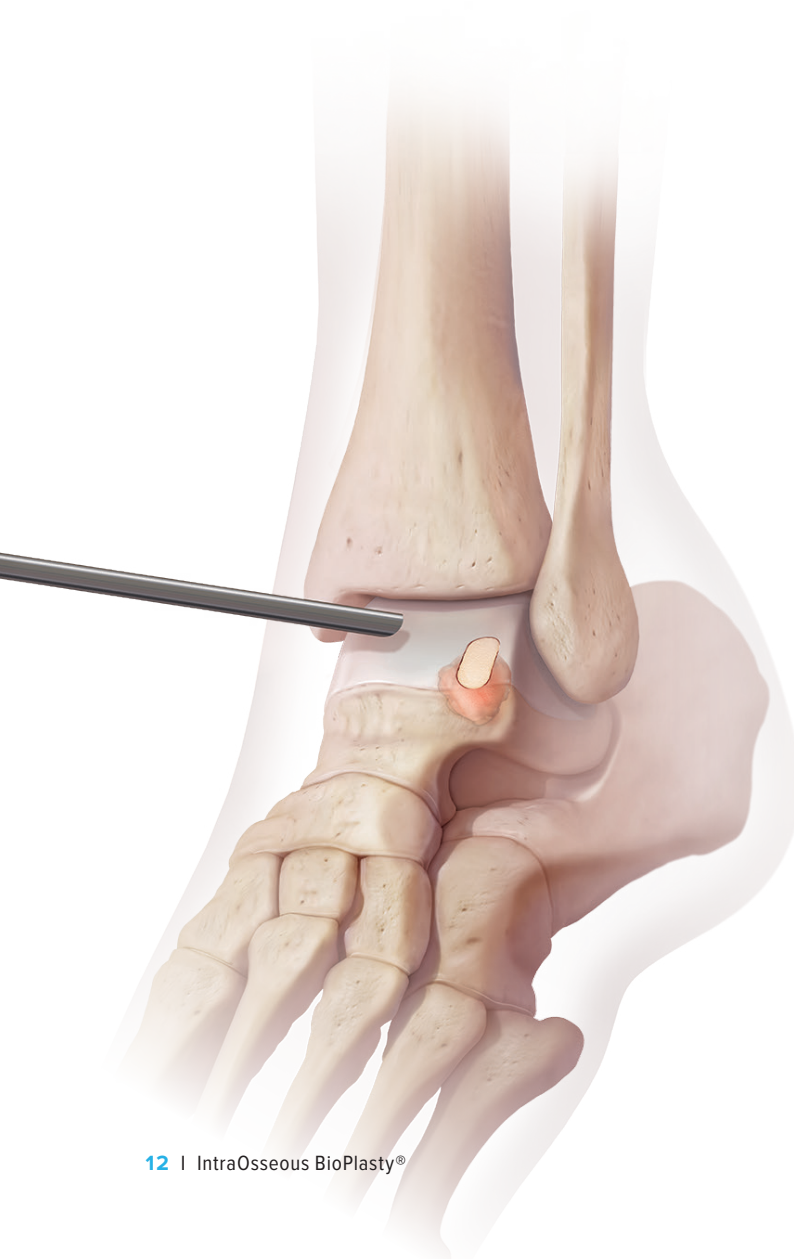
4

Aspirate all arthroscopic fluid and dry the cartilage defect with the cannulated swabs from the BioCartilage® mixing and delivery kit. After mixing the BioCartilage extracellular matrix with an autologous blood solution (1:0.8 ratio) within the mixing syringe, apply the mixture into the defect using the ArthroPaddle™ delivery needle.



5

Use the elevator component on the ArthroPaddle device to smooth the BioCartilage extracellular matrix into the defect. Ensure the BioCartilage extracellular matrix remains flush or slightly recessed to the surrounding articular cartilage. Use a dual-lumen applicator to apply fibrin glue over the BioCartilage implant.

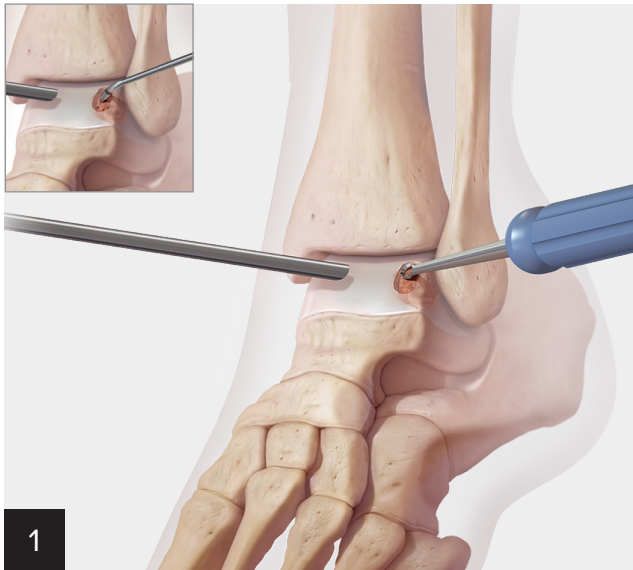


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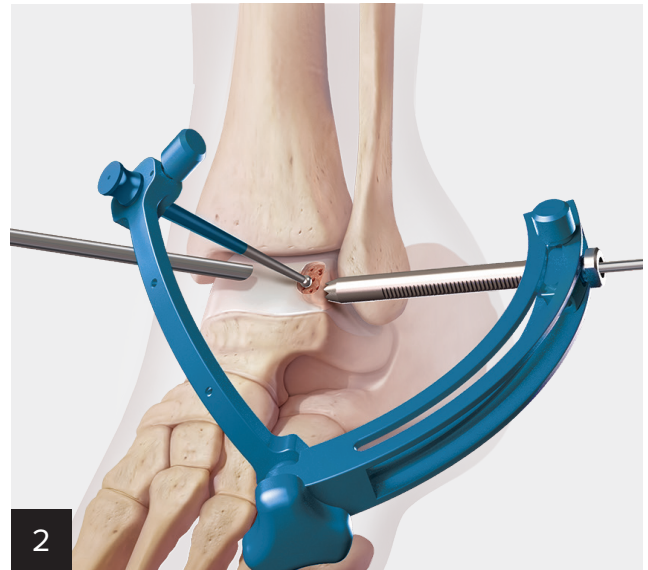
Gently flex and rotate the ankle before closure to assure adherence of the BioCartilage implant. At the completion of surgery, immobilize the ankle in neutral position. The patient should be non-weightbearing. Thereafter, follow standard rehabilitation protocols post marrow stimulation.

Guided-Delivery Ankle Arthroscopic Procedure

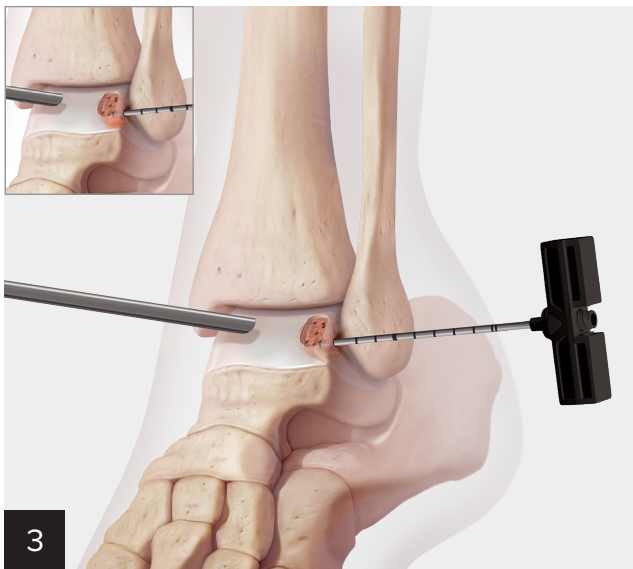
The guided approach may be used with or without an articular cartilage lesion present. The IOBP® ankle techniques were developed in collaboration with Christopher D. Kreulen, MD.



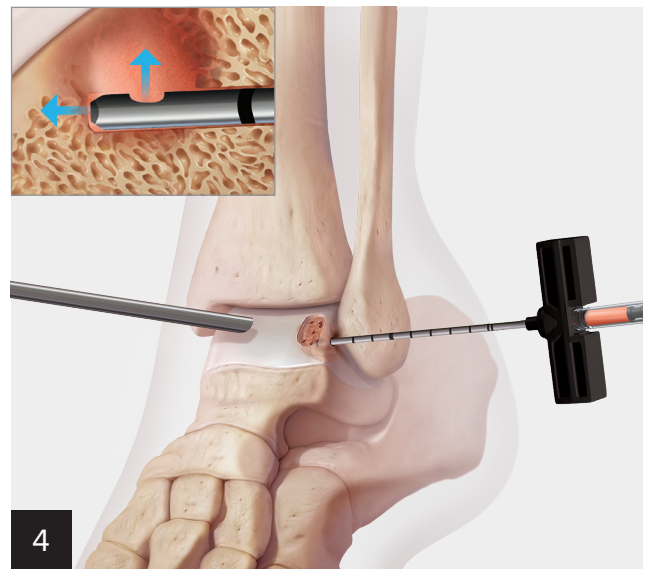
Under tourniquet control, apply 4 mm of distraction to the tibiotalar joint. Debride the articular cartilage defect to create stable margins using a ring curette. Use arthroscopic and fluoroscopic guidance throughout the procedure to aid visualization.



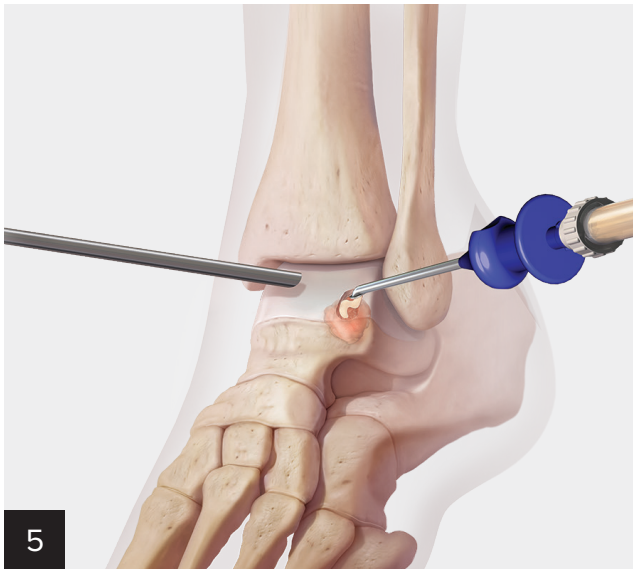
Using the GPS targeting guide with 2 mm insert, deliver a 2.4 mm guide pin to the bone marrow lesion. The GPS targeting guide is point-to-point, so care should be taken to avoid penetrating the articular surface. Remove the guide, leaving the 2.4 mm guide pin in position.



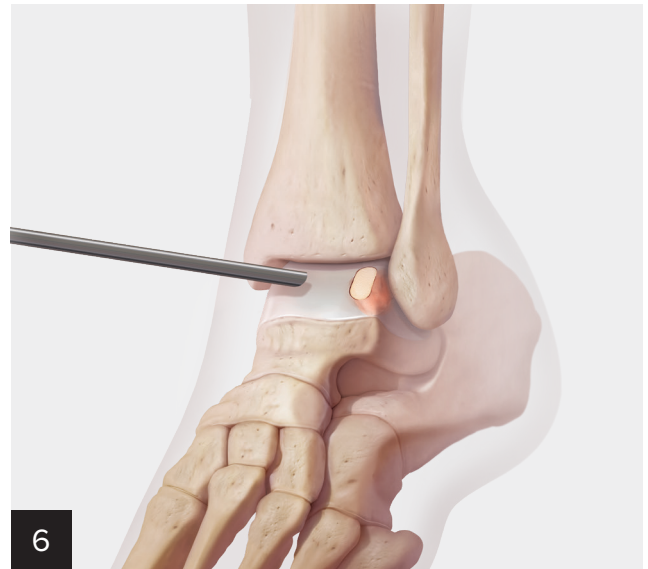
Remove the inner trocar from the delivery needle and advance the 13-ga cannula into the bone marrow lesion. Remove the 2.4 mm guide pin to complete the core decompression.



Following positioning of the delivery cannula, mix AlloSync™ Pure DBM with cPRP_{BMA} at a 1:1 ratio, within the mixing syringe, then transfer to 1 cc syringes. Deliver the DBM and cPRP_{BMA} mixture to the bone marrow lesion to treat the subchondral edema or fracture. Use the trocar to empty the delivery cannula, and then remove the cannula.



Aspirate all arthroscopic fluid and dry the cartilage defect with the cannulated swabs from the BioCartilage® mixing and delivery kit. After mixing the BioCartilage extracellular matrix with an autologous blood solution (1:0.8 ratio) within the mixing syringe, deliver and smooth the mixture into the defect using the ArthroPaddle™ delivery needle.



Following approximately 5 minutes after fibrin glue application, gently flex and rotate the ankle before closure to assure adherence of the BioCartilage implant. At the completion of surgery, immobilize the ankle in neutral position. The patient should be non-weightbearing.

Viscous Delivery System

A gelled solution may be used to seal biologics in the IOBP® treatment site. The viscous low-velocity ratio applicator is used for the homologous mixture of two fluids. The fluids are simultaneously transferred from the dual syringes into the mixing chamber and dispensed. The individual pieces delivered in each package are easy to assemble and disassemble quickly. The Viscous-Spray™ low-viscosity applicator has a shorter 3 cm mixing tip.

Recipe for Formation of Gelling Agent Solution

The ingredients for formation of the gelling agent solution are:

- A gelling agent powder containing 4800 to 5000 IU (international units)
- A gelling agent liquid containing 5 mL of 10% calcium chloride solution

Mix every 1000 IU of gelling agent powder with 1 mL of gelling agent liquid (1000 IU/mL ratio of powder to liquid).

- For a bottle with 5000 IU of gelling agent powder, mix with 5 mL of gelling agent liquid
- For a bottle with 10,000 IU of gelling agent powder, mix with 10 mL of gelling agent liquid, and so on...
- This process creates the gelling agent solution

For every 1 mL of autologous fluid administered with the ratio applicator, 0.1 mL of gelling agent solution will be dispensed.

- 10:1 ratio of autologous fluid to gelling agent solution

Process for Clotting PRP Concentrate From BMA (cPRP_{BMA})

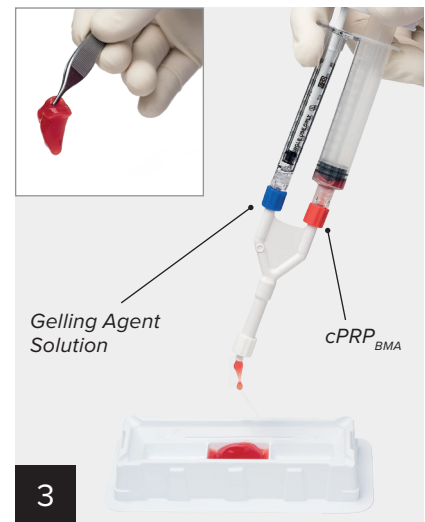


Prepare the cPRP_{BMA} in standard fashion using the Arthrex Angel® cPRP and bone marrow processing system. The cPRP_{BMA} and gelling agent solution should be drawn from a sterile basin within the sterile field.



Transfer the cPRP_{BMA} into the larger syringe in the mixing kit. Transfer the gelling agent solution into the 1 cc syringe. The ratio of cPRP_{BMA} to gelling agent solution is 10:1.

Attach the low-viscosity tip (Viscous-Spray™ applicator) to the end of the syringes. Place the snap-on piece over the syringe plungers.



Depress the plungers to mix the cPRP_{BMA} and gelling agent solution via the mixing elements within the applicator tips. The cPRP_{BMA} is mixed with bone graft and delivered to an activated state.

Ordering Information

Product Description	Delivery Cannula	1 cc Syringes Included	Item Number
Knee IOBP® Procedures			
IOBP Core Decompression and Delivery Kit, open tip Includes: open-tip 8 ga × 11 cm delivery cannula, 14 cc mixing syringe, 2.4 mm guide pin, 7 mm low-profile reamer, luer cap, female-to-female luer adaptor	Open Tip, 8 ga × 4.5"	No	ABS-2000-OT
IOBP Delivery Kit w/ Decompression Device Includes: open-tip 8 ga × 11 cm delivery cannula, 7 mm IOBP decompression device, 14 cc mixing syringe, 3.3 mm guide pin, 5 × 1 cc delivery syringes, luer cap, female-to-female luer adaptor	Open Tip, 8 ga × 4.5"	Yes	ABS-2001-OT
IOBP Core Decompression and Delivery Kit, closed tip Includes: closed-tip 8 ga × 11 cm delivery cannula, 14 cc mixing syringe, 5 × 1 cc delivery syringes, luer cap, female-to-female luer adaptor	Closed Tip, 8 ga × 4.5"	Yes	ABS-2000-CT
Hip IOBP Procedures			
IOBP Delivery Kit w/ Decompression Device, open tip Includes: open-tip 8 ga × 23 cm delivery cannula, 7 mm IOBP decompression device, 14 cc mixing syringe, 3.3 mm guide pin, 5 × 1 cc delivery syringes, luer cap, female-to-female luer adaptor	Closed Tip, 8 ga × 9"	Yes	ABS-2010-OT
IOBP Core Decompression and Delivery Kit, closed tip Includes: closed-tip 8 ga × 23 cm delivery cannula, 14 cc mixing syringe, 5 × 1 cc delivery syringes, luer cap, female-to-female luer adaptor	Closed Tip, 8 ga × 9"	Yes	ABS-2010-CT
Foot and Ankle IOBP Procedures			
IOBP Core Decompression and Delivery Kit, foot and ankle Includes: open-tip 13 ga × 11 cm delivery cannula, 14 cc mixing syringe, 1.5 mm guide pin, 5 × 1 cc delivery syringes, luer cap, female-to-female luer adaptor	Open Tip, 13 ga × 4.5"	Yes	ABS-2020-OT

Reference

1. Kanim LEA, Houman J, Zhao L, et al. Composition of demineralized bone matrix-based products on spinal fusion rate. Poster presented at Annual Meeting of the Orthopedic Research Society; February 4-7; San Francisco, CA.



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