

The Subchondroplasty[®] (SCP[®]) Procedure for the Knee

Surgical Technique





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Symbols Convention

This document employs the following conventions:

-  **NOTE:** This symbol is present to provide a general observation or information to procedures, events or practices which are recommended or essential for a successful operation.
-  **CAUTION:** This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

The Subchondroplasty® (SCP®) Procedure

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects, often called bone marrow lesions (BML), with AccuFill® PF Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute. The procedure is performed along with arthroscopy of the affected knee, to assess the extent of the tibial plateau injury, assist in targeting the underlying plateau defect, and visualize and treat other structures inside the joint.

The Subchondroplasty Procedure consists of four components:

PREOPERATIVE PLAN: Identify the BML bone defect using a T2 and T1 MRI plan approach and trajectory based on defect location.

TARGET THE BONE DEFECT: Using arthroscopy and intraoperative fluoroscopy, localize the bone defect relative to the T2 and T1 MRI findings.

ACCESS THE DEFECT: Drill the appropriate AccuPort® Delivery Cannula to the bone defect.

FILL THE BONE DEFECT: Inject AccuFill BSM into the subchondral bone defect based on the T1 image.

AccuFill BSM Indications for Use:

AccuFill Bone Substitute Material is an injectable, self-setting, macroporous, osteoconductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e., posterolateral spine), and the pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. AccuFill BSM is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Features and Benefits

The Subchondroplasty (SCP) Procedure

The SCP Procedure is a treatment option for chronic bone defects, including BML, not responsive to conservative care.*

The SCP Procedure fills closed bone defects with AccuFill BSM, an injectable bone substitute material. The AccuFill BSM mimics the composition of inorganic bone material. It is replaced with new bone during the healing process.^{2,4,**}

AccuFill Bone Substitute Material (BSM)

The injectable Calcium Phosphate (CaP) for the SCP Procedure

Criteria	Features	Benefits
Formulation	Proprietary engineered apatite Chemically similar to apatite of bone ¹	Undergoes cell-mediated remodeling ^{2,4}
Handling	Injectable ^{2,3} Remains cohesive ^{2,3} Flowable inside cancellous bone ^{2,3} 15 minutes of working time at 25°C ^{1,5}	No need to remove subchondral bone No phase separation from injection pressure ^{2,3} Interdigitates easily for complete defect fill ^{2,3} Extended time frame for implantation Intraoperative flexibility
Setting	Sets in 10 minutes at 37°C ⁵	Sets hard, no thermal necrosis
Structure	Osteoconductive Nanocrystalline structure ^{1,***} 55% total porosity; 1 to 300 µm pore size ² 7 to 9 MPa compressive strength ²	Physical properties comparable to that of cancellous bone ¹
Remodeling	Cell-mediated remodeling ^{2,4,**} Remodeled vs. dissolved ^{2,4,**}	Remodels with new bone growth ^{2,4,**}

1 TRE_061017, Characterization of CaP-Porous Material ; 15-Sep-2006, ETEX Corporation (Internal document)

2 Angle SR, Strunk MR. Novel Macroporous Calcium Phosphate Scaffold To Improve Cell Infiltration and Osseous Integration. Transactions of the 61st Annual Meeting of the Orthopaedic Research Society: 1157, 2015*, ****

3 Colon DA, Yoon BJV, Russell TA, Cammisa FP, Abjornsen C. Assessment of the injection behavior of commercially available bone BSMs for Subchondroplasty procedures. Knee. 2015; 22(6):597-603.

4 Welch R.D 2018 : Rabbit Femoral Core Defect Histology Evaluation : ETEX Study # 104-0621. ****

5 OssiPro K062630 (510(K) internal document)

* Bone Marrow Lesions (BML) and Bone Marrow Edema (BME) are often used interchangeably to identify subchondral bone defects like microtrabecular or insufficiency fractures.

** Animal studies are not necessarily indicative of clinical outcomes.

*** The grain size of the hydroxyapatite (HA) crystals that form as part of the amorphous and crystalline mixture of calcium phosphate sets are on the nanometer scale. The size of the crystalline structures were measured by x-ray diffraction to be less than 100 nanometers.

**** based on calcium phosphate Alpha-BSM

Preoperative Planning

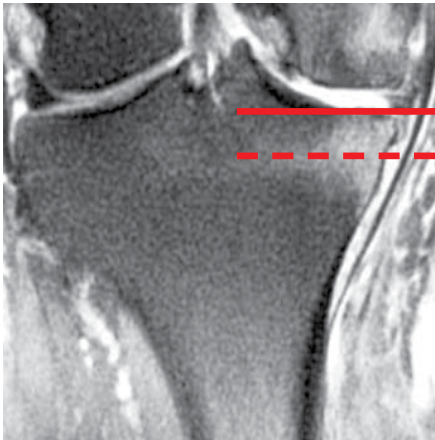
MRI Based Planning

The presence of a BML subchondral bone defect is determined using fat-suppressed MRI (e.g., T1FS after T2FS). BML defects, however, are not visible on intraoperative fluoroscopy. To accurately target the defect, then, the surgeon must use the patient's MRI to determine the location of the bony defect relative to radiographic landmarks. This information is used intraoperatively to target the defect with fluoroscopy for correct AccuFill BSM implantation.

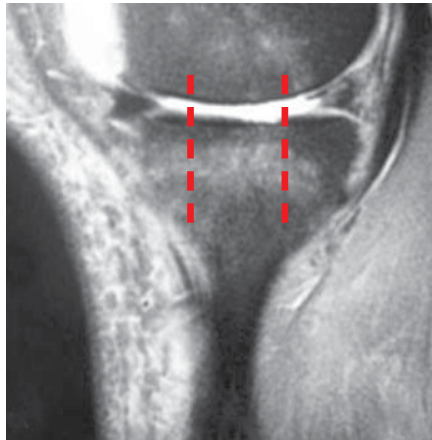
Using all three MRI views (axial, coronal and sagittal), localize the BML by:

Tibia

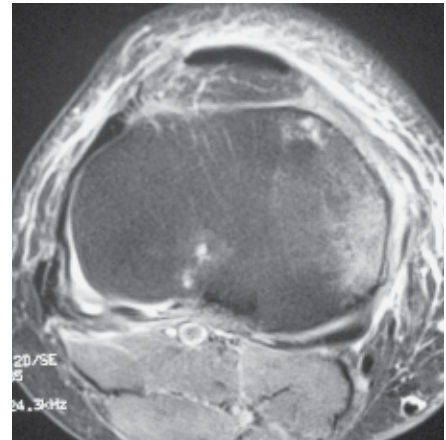
- Distance from the joint cortex
- Position in sagittal and axial view (anterior, central or posterior third)
- Depth relative to near cortex (superficial or deep)



Distance from joint cortex

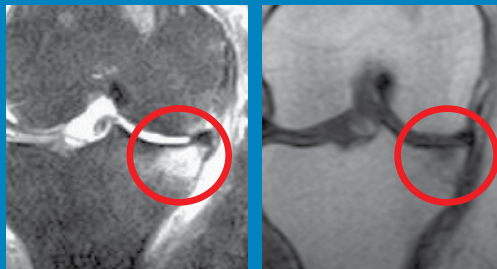


Anterior/central/posterior



Fine tune targeting
using axial image

Tip: BML on a T2FS MRI present as a broad, hazy signal. Use the T1 series to identify and target the epicenter of the bone defect.



Tip: The axial view provides the most information about the location of the BML, as it shows its position in both the coronal and sagittal planes.

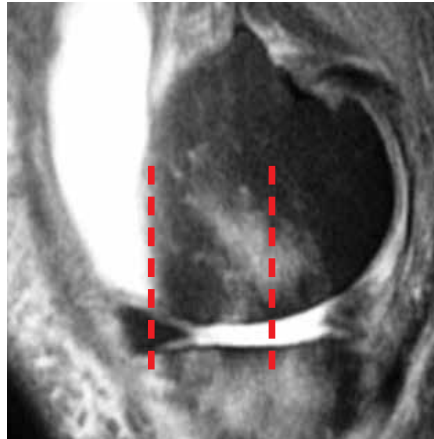
MRI Based Planning

Femur

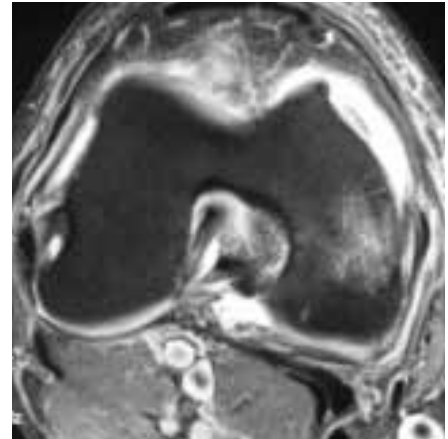
- Position in sagittal view
 - Anterior, central or posterior third
 - Relative to Blumensaat's line
- Depth relative to near cortex (superficial or deep)



Depth from near cortex

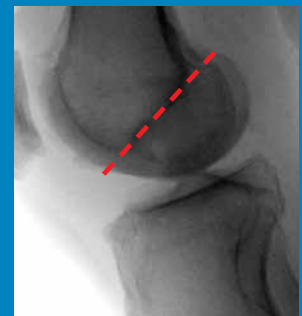


Anterior/central/posterior



Fine tune targeting using axial image

Tip: Scroll sagittal MRI slices from area of bony defect to intercondylar notch to determine defect position relative to Blumensaat's line.



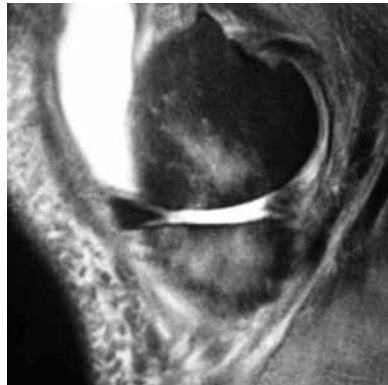
Principles of Free-hand Targeting

Free-hand targeting is based on triangulating to the bony defect using orthogonal fluoroscopic views that match the associated MRI slices: anatomic AP/coronal, and true lateral/sagittal. The X-ray beam can then be used as a tool: targeting is achieved by centering the targeted defect in the beam and then aligning the wire driver and AccuPort cannula with the beam while drilling.

ⓘ **NOTE:** “Anatomic” AP of plateau takes into account normal slope of tibial plateau.

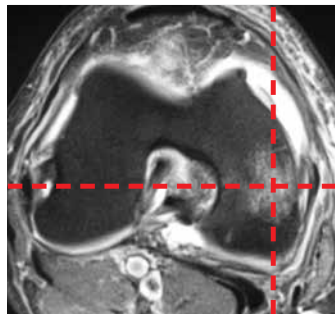


Coronal/Anatomic AP



Sagittal/True Lateral

Match fluoro views to MRI planes

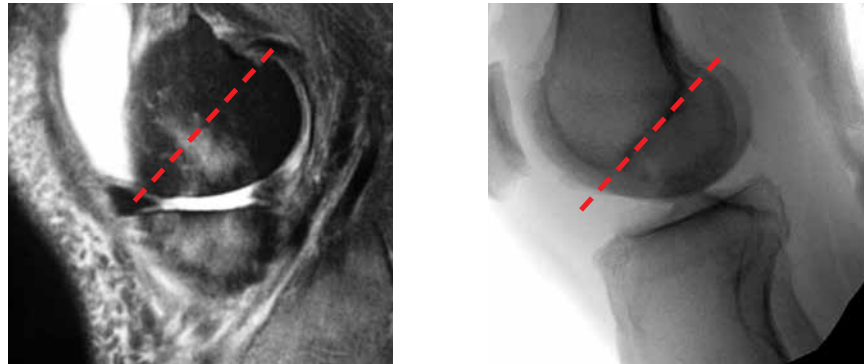


Center the defect in the fluoro beam. Align the cannula with the beam

Principles of Free-hand Targeting

Lateral fluoroscopy is used to localize the cannula entry point and trajectory, relative to MRI-identified landmarks. Accurate localization requires the lateral view to recreate sagittal MR images. With the C-arm horizontal (beam parallel to the floor), reposition the knee until the condyles align in lateral view. Accuracy is sensitive to improper positioning and X-ray projection. Incorrect rotation or angulation of the knee by just a few degrees, for example, leads to projection errors that can cause the cannula to miss the targeted lesion, as shown below.

In the example, the preoperatively-planned cannula entry point is just posterior to the distal margin of the intercondylar notch (Blumensaat's line). In the intraoperative fluoro shot, (1a), the cannula tip is localized to this point. However, the knee is actually externally rotated by a few degrees, causing the projection of the notch to be more posterior on the condyle, as depicted in (1b). When rotation is corrected (2a) the lateral image shows the true position of the cannula tip. The cannula would miss the defect posteriorly, as depicted in (2b).



Preop-planned cannula entry point



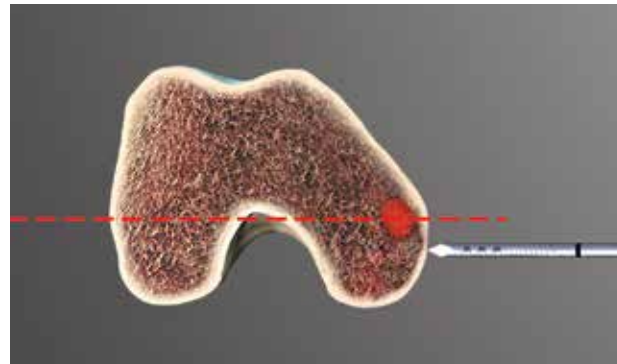
1a



1b



2a



2b

Surgical Technique

The Subchondroplasty Procedure is performed along with arthroscopy of the knee, to assess the extent of the tibial plateau injury and visualize and treat other structures inside the joint. Scoping also aids in targeting the BML defect adjacent to the subchondral cortex, before injecting AccuFill BSM into the defect. After injection, the scope also allows evaluation for and evacuation of any material that has extravasated into the joint.

- ⊖ **NOTE:** The AccuPort injection cannulas must be left in the bone for 10 minutes while the BSM sets, to minimize potential for extravasation.
- ⊖ **NOTE:** While the AccuPort injection cannulas are in, take care while manipulating the knee during scoping, to avoid bending forces on the cannula that may damage the cannula or surrounding bone.

The following technique describes free-hand technique for a patient with bipolar (“kissing”) bone defects of the medial femoral condyle and tibial plateau. The same basic steps can be used for lateral compartment defects, or for single compartments.

For bipolar procedures, it can be advantageous to start with the compartment furthest from the surgeon, so the first cannula is not in the way of inserting the second. In this guide we will start with the femoral condyle and then move to the tibial plateau.

Tip: Insert a spinal needle into the joint, with arthroscopic guidance, and set its tip at the focus of the tibial plateau injury. This provides a clearer target in lateral and AP fluoro, for triangulating the underlying bony defect.

- ⊖ **NOTE:** In every procedure, it is recommended that the scope be used after the AccuFill injection is completed, to look for evidence of extravasation of the BSM into the joint space. Although uncommon, if extravasation occurs, the material should be removed from the joint using the shaver and irrigation.

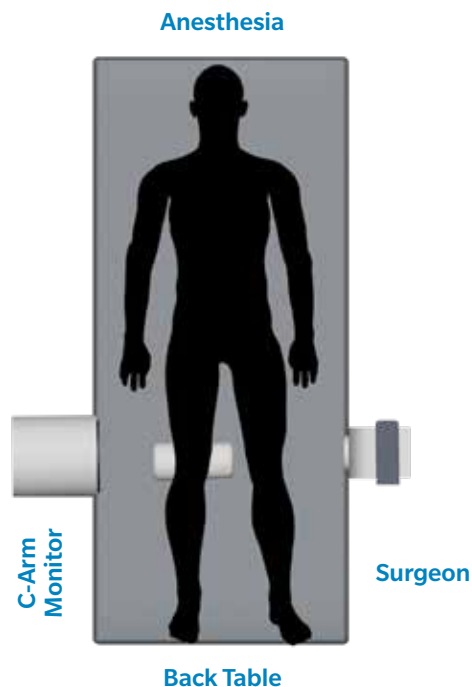


Scope assessment of tibial plateau injury

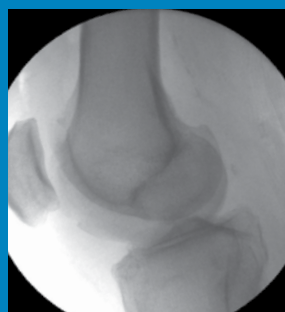
- ⊖ **NOTE:** The use of AccuFill BSM is not intended to be intrinsic to the stability of the bony structure. Radiographic studies should be used to confirm that the adjacent cortical bone is intact.

OR Setup/Patient Positioning

Position the patient supine on a radiolucent OR table; prep and drape as for knee arthroscopy. OR setup also includes operative fluoroscopy. [See setup example, below.] For the SCP procedure, elevate the operative leg with a bump under the ankle or knee, to allow for unobscured lateral fluoroscopy, free of the contralateral leg.



Operative Tip: Using scout lateral shots, with the C-arm horizontal, adjust knee rotation until a true lateral shot of the distal femur is obtained (femoral condyles aligned).



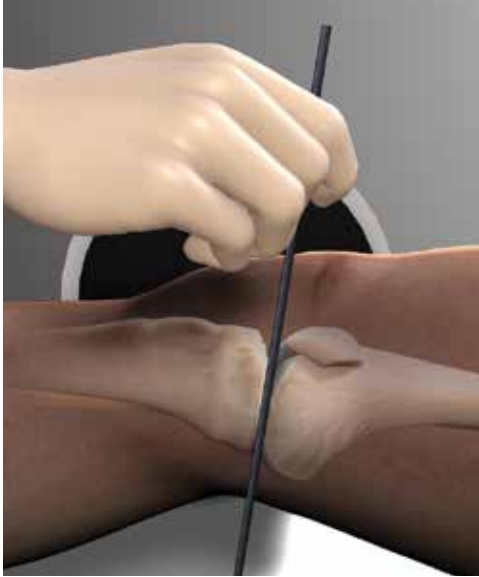
Initial scout lateral



Better lateral:
condyles aligned

OR Setup/Patient Positioning

Identify the joint line (tibial plateau) using lateral fluoroscopy and a Steinmann pin or straight tool; draw a line on the skin. The mark aids in measuring distance from the joint for cannula entry point for tibial defects.



Operative Tip: Use the tip of the pin and lateral fluoroscopy to estimate targeted starting points for tibial and femoral defects, according to the preoperative plan. Mark the skin at these points.



Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting

The principles described earlier apply to both tibial and femoral targeting. However, due to the complex geometry of the femoral condyles—including the slope of the medial wall of the medial condyle, the curvature of the condyles, and the presence of the intercondylar notch and femoral trochlea—more care needs to be taken when triangulating distal femoral defects.



Medial Slope

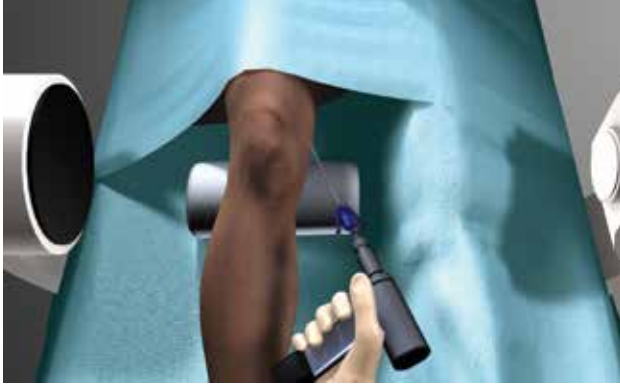
Obtain true AP and true lateral fluoroscopic images of the distal femur with the targeted area centered in the image; note C-arm tilt and position relative to the OR table/patient in each image, to easily return to that position. Mark the plateau line and other landmarks and approximate entry points as desired.



Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (cont.)

Couple the chosen AccuPort cannula to the wire driver. Set the tip of the cannula against the skin at the approximate entry point, under lateral fluoroscopy, with the wire driver out of the X-ray beam.



Set the tip of the cannula against the skin at the approximate entry point

Reposition the tip as needed, in stepwise fashion, until the tip is at the preoperatively-planned location.



Reposition tip of cannula as needed

Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (cont.)

Tilt the wire driver into the beam until the AccuPort cannula is in the center of the X-ray beam (use the C-arm X-ray source as the guide).



Tilt driver and cannula into line of X-ray beam

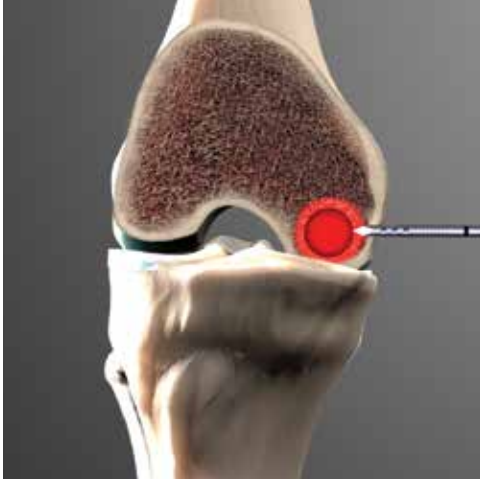
Surgical Checkpoint: Before moving the C-arm to AP, drill the cannula through the cortex, just into the cancellous bone. Disconnect the drill from the cannula and take another lateral image. The cannula should now be seen end-on, as shown in the image, on the right, in line with planned trajectory.



Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (cont.)

Rotate the C-arm into true AP position and confirm “height” (distance from joint surface/distal cortex of the condyle) and trajectory.



Using AP fluoroscopy as needed, continue drilling until the cannula is at the desired depth and, when using the Side-Delivery AccuPort Cannula, all three delivery fenestrations are deep to the cortex.

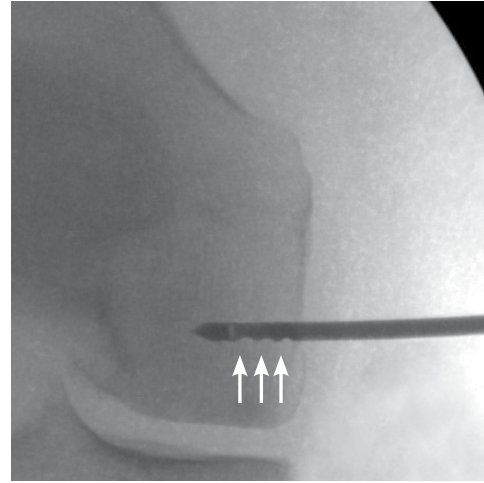
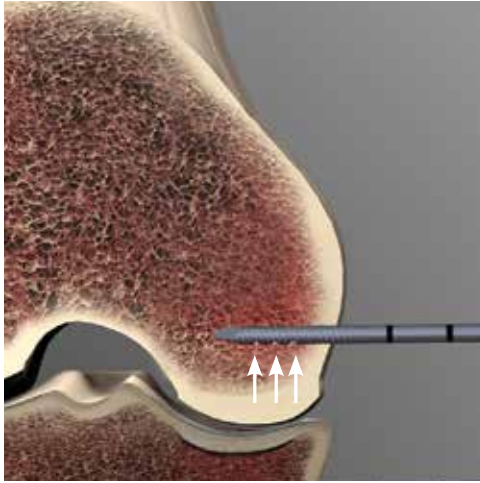


ⓘ **NOTE:** For targeting accuracy and volume, refer to T1 image.

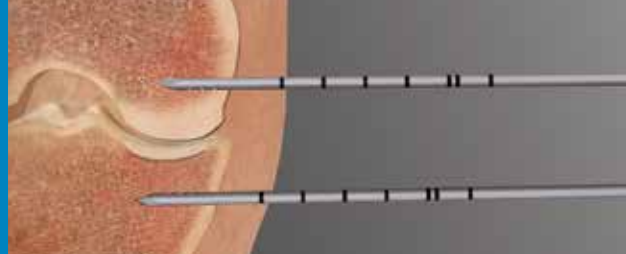
Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (cont.)

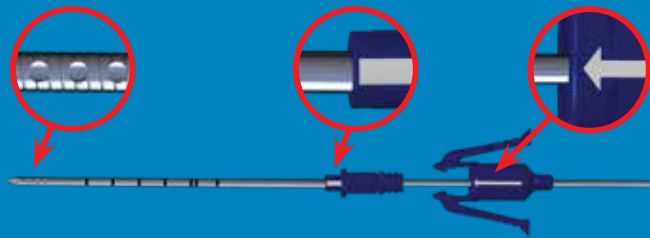
Manually rotate the cannula until the fenestrations are pointed in the desired delivery direction (Side-Delivery AccuPort Cannula), and then proceed to AccuFill BSM injection.



Surgical Tip: Use the markings on the cannula to externally monitor the depth of cannula advancement.



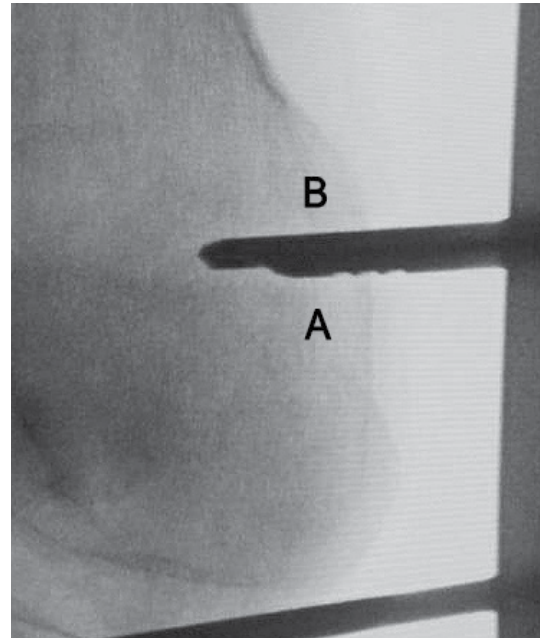
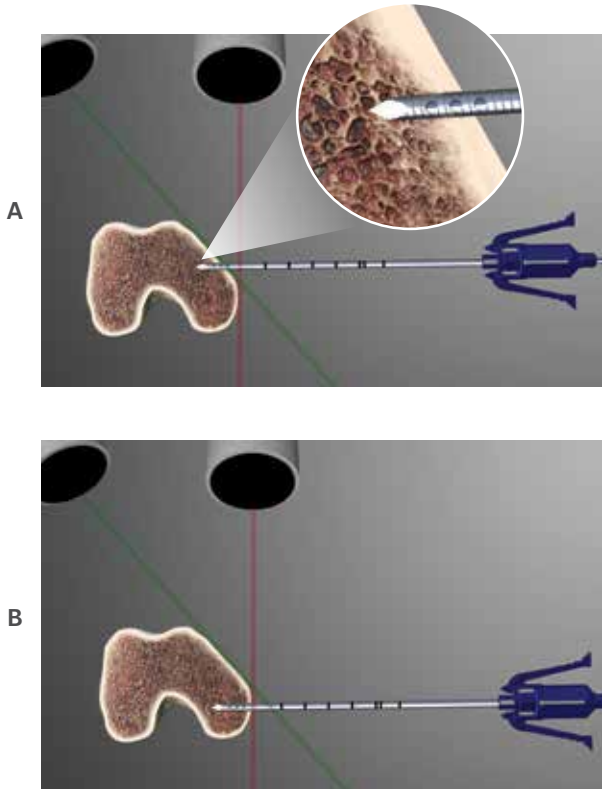
Surgical Tip: The white lines on the hub of the Side-Delivery AccuPort Cannula are in line with cannula fenestrations. Use this external mark to aid in orienting the fenestrations in the desired direction for injection.



Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (cont.)

- NOTE:** To minimize the potential for extravasation of AccuFill BSM (see AccuFill Injection), the delivery holes of the cannula must be deep into subchondral bone and passed the cortex. To confirm this, rotate the C-arm until the beam is tangential to the cortex at the cannula entry point. This is particularly important when targeting an anterior defect in the medial distal femur, because the anterior slope of the condyle can lead to an AP projection that gives the appearance that the cannula is deeper than it really is.



Oblique fluoro shot of cannulas A and B in femoral condyle. Cannula B is fully in bone; Cannula A is not. Note the fenestrations outside the cortex.

- NOTE:** Commit to first trajectory. Avoid creating a second path to reduce extravasation. If undesired trajectory is created:
 - Do not redirect cannula inside the bone, which could damage the cannula or surrounding bone.
 - Leave first pin in the bone to avoid backflow. Then use a new cannula to drill a different path.

Targeting and Accessing the Defect: Free-hand Targeting

Tibial Targeting

Obtain anatomic AP and lateral fluoroscopic images of the tibial plateau, with the plateau centered in the image; note the C-arm tilt and position in each image, to easily return to that position. Mark the plateau line and other landmarks and approximate entry points as desired.

Couple the chosen AccuPort cannula to the wire driver. Set the tip of the cannula against the skin at the approximate entry point, under lateral fluoroscopy, with the drill out of the X-ray beam.



Cannula tip at skin mark; check with Lat fluoro



Reposition tip to planned entry point

Tilt the drill into the beam until the AccuPort cannula is in the center of the X-ray beam (use the C-arm X-ray source as the guide).

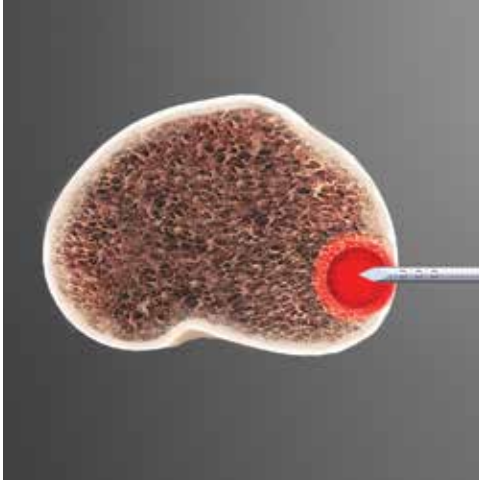
Surgical Checkpoint: Before moving the C-arm to AP, drill the cannula through the cortex, just into the cancellous bone. Disconnect the drill from the cannula and take another lateral image. The cannula should now be seen end-on, as shown in the image, right, in line with planned trajectory.



Targeting and Accessing the Defect: Free-hand Targeting

Tibial Targeting (cont.)

Return the C-arm to anatomic AP position and confirm “height” (distance from plateau) and trajectory.



Cannula and driver aligned with beam



Confirm height and trajectory in AP

Using AP fluoroscopy as needed, continue drilling until the cannula is at the desired depth and, when using the Side-Delivery AccuPort Cannula, all three delivery fenestrations are deep into subchondral bone and passed the cortex.

Manually rotate the cannula so the fenestrations point towards the joint or lesion, and then proceed to AccuFill BSM injection.



Drill in the tibial cannula under AP fluoroscopy



Advance cannulas to desired depth

Implant Placement: Filling the Bone Defect

Mixing Option 1: Using the AccuMix system / SCP Complete Kit



AccuFill BSM is hydrated and mixed before injection, using normal saline (0.9%). The material is mixed using the AccuMix mixing system, a closed syringe device. Allow for mixing time while avoiding down time after cannula insertion. Working time for AccuFill BSM is approximately 15 minutes (maximum time between mix and injection) and mixed material will not set until injected into the patient.

AccuMix Mixing System

AccuMix syringe mixing provides closed mixing of AccuFill BSM with its hydrant and closed transfer to injection syringes. The AccuMix mixing syringe acts as both mixer and transfer syringe, and couples to injection syringes with a standard luer-lock connection.

AccuFill BSM Mixing Technique Setup:

The AccuMix system tray (AccuMix system or SCP Complete Kits) is sterile and provides stability for the mixing syringe during BSM powder transfer.

1. Transfer the tray to the sterile field (back table). Remove the mixing syringe and set upright in the tray groove; lift funnel to extend syringe.
2. Remove vial of AccuFill powder from jar. Empty powder into funnel; tap until powder enters syringe.



3. Remove funnel; fully tighten cap and plug. Remove blue plug and set in sterile tray. **DO NOT DISCARD PLUG!**

ⓘ **NOTE:** Do not empty entire 10 ml of saline vial into AccuFill BSM powder. Measure and use only the exact volume noted below.

Hydrate:

4. Using standard technique, connect the saline syringe and adaptor to the saline vial, injecting air into the saline vial and then draw back the desired amount of saline.
 - 5 cc AccuFill BSM
 - 3.0 cc saline
 - Alternative: 3.4 cc whole blood
 - 3 cc AccuFill BSM
 - 2.0 cc saline
 - Alternative: 2.3 cc whole blood

Implant Placement: Filling the Bone Defect (cont.)



AccuFill BSM Mixing Technique

5. Connect saline syringe to white cap; tighten. Inject saline briskly into powder; pull up on syringe plunger to pull excess air into saline syringe. Inject again, to ensure ALL SALINE FLOWS INTO POWDER, then repeat to release pressure.
6. Remove saline syringe; set it in the sterile tray. Attach blue plug to cap.

Mix:

7. Tilt mixing syringe toward you to remove from the tray. Remove plunger sleeve from plunger stem. **DO NOT DISCARD SLEEVE!**
8. Thoroughly mix powder and saline for 60 strokes (~60 seconds), **MIXING THE FULL LENGTH OF THE CYLINDER**. Twist and rotate while plunging until mix takes “toothpaste” consistency.

9. Reattach sleeve to stem, with stem fully extended. Remove blue plug.

Transfer:

10. Holding syringe with white cap upright, expel excess air from syringe, pushing the plunger approximately 2/3rds up the cylinder until you can visualize the Accufill BSM.

Connect the first 1 cc syringe. Inject AccuFill BSM into syringe. Repeat for remaining syringes.

Transfer the desired number of syringes to the operative field (please refer to suggested volumes by indication).

Implant Placement: Filling the Bone Defect

Mixing Option 2: Using the AccuFill Pre-Fill (PF) BSM Kit

AccuFill PF BSM is hydrated and mixed before injection, using normal saline (0.9%), or whole blood. The material is mixed in a closed system using the prefilled mixing syringe. Working time for AccuFill PF BSM is approximately 15 minutes (maximum time between mix and injection). Mixed material will not set until injected into the patient.

Mixing Syringe:

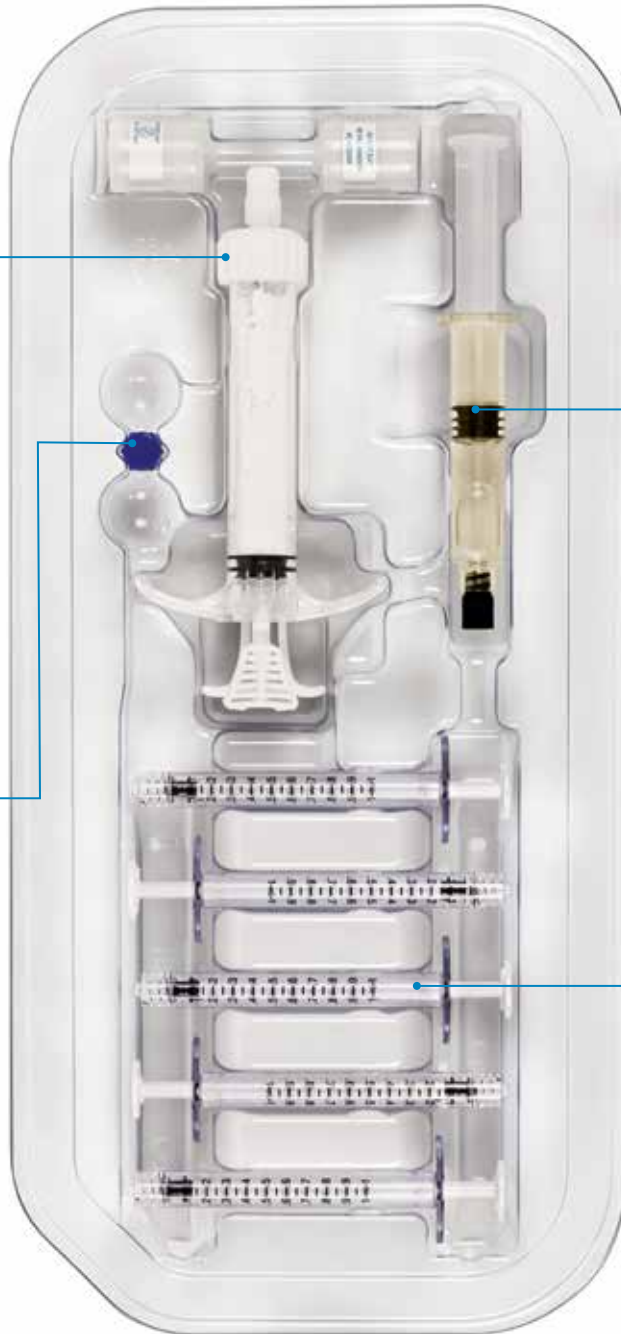
Prefilled with the pre-measured volume of AccuFill PF BSM powder. The prefilled mixing syringe acts as both a mixer and a transfer syringe.

Blue plug for Mixing Syringe:

Saline Syringe:

Prefilled with pre-measured volume of normal saline.

Three or Five 1 cc Syringes

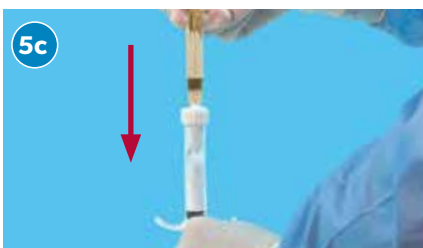
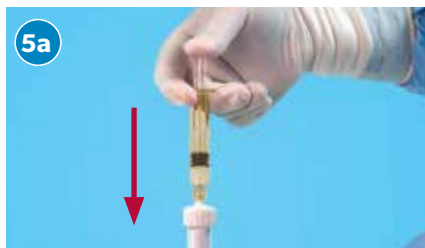


Implant Placement: Filling the Bone Defect (cont.)

AccuFill PF BSM Mixing Technique

Hydrate:

1. Transfer the tray to the sterile field (back table). Remove the AccuFill PF BSM prefilled mixing syringe from tray. Pull on plunger tab to extend the stem completely from within the syringe.
 - ⊖ **NOTE:** Before connecting the saline syringe, lightly tap on the full prefilled mixing syringe to loosen the AccuFill Powder, which can get compacted.
2. Remove and discard the plug from the prefilled mixing syringe.
3. Remove the prefilled saline syringe from tray. Remove and discard the plug.
4. There is no need to expel air from the saline syringe. Holding the mixing syringe vertically, connect and tighten the saline syringe to the mixing syringe. See image for correct orientation.
- ⊖ **NOTE:** To avoid expelling saline, do not expel air from the prefilled saline syringe.
5. Holding the syringes vertically, inject full volume of saline down into the mixing syringe (5a). Pull up on the saline syringe plunger to pull excess air into the syringe (5b). Inject again, to ensure **ALL SALINE FLOWS INTO POWDER** (5c). Repeat to release pressure before removing saline syringe.
6. Attach and tighten the blue LUER lock plug onto the mixing syringe.

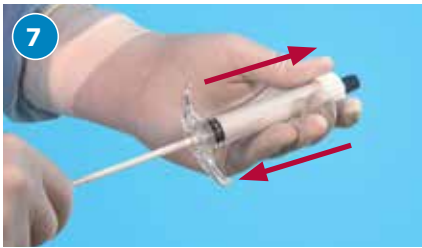


Implant Placement: Filling the Bone Defect (cont.)

AccuFill PF BSM Mixing Technique

Mix:

7. Push the syringe plunger completely in and then pull back and push plunger through the full length of the cylinder to evenly distribute the saline and thoroughly wet the powder.
8. Repeatedly push, pull, and twist the plunger through the material in the syringe and continue for a minimum of 60 strokes/60 seconds. The material must be mixed completely.
 - ⊖ **NOTE:** Push and pull the plunger completely until it stops at each end of the syringe while twisting at least a quarter turn each time.
 - ⊖ **NOTE:** Visually confirm through the syringe barrel that the material is being mixed completely. It will have a paste consistency.
9. After the material has been mixed thoroughly, pull on plunger tab to extend the stem fully from the mixing syringe and attach the plunger sleeve onto the stem.



Transfer:

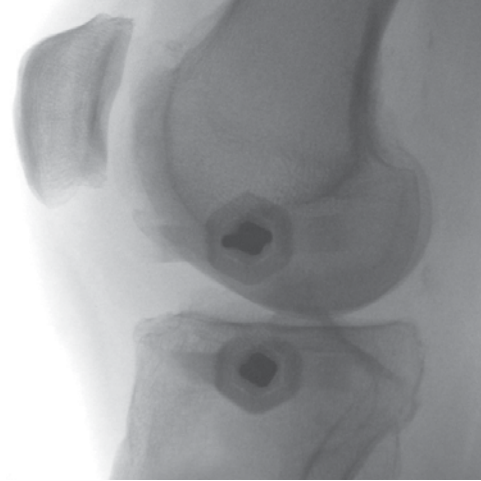
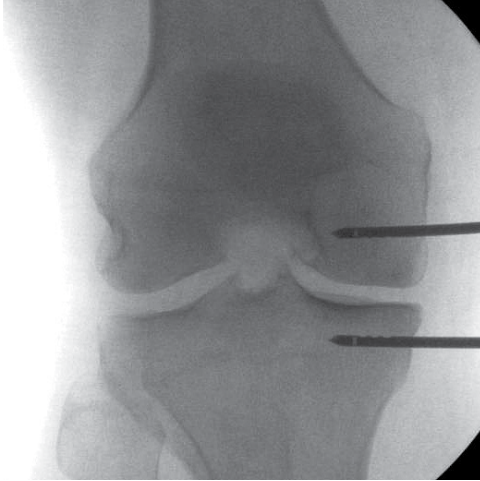
10. Remove the blue luer lock plug from the mixing syringe cap. Holding the mixing syringe with the white cap upright, expel excess air from the syringe. Connect the first 1 cc syringe. Inject AccuFill BSM into the syringe. Repeat for the remaining 1 cc syringes.
11. Transfer the filled 1 cc syringes to the operative field. Implant immediately for the best handling characteristics.



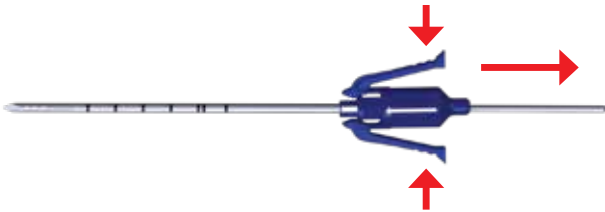
Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM

Confirm AccuPort cannula placement with AP and lateral fluoroscopy. Manually rotate the cannula to direct flow toward the defect, as identified by the white line (Side-Delivery cannula only).



Confirm cannulas in position, fenestrations oriented toward joint (desired direction of flow)

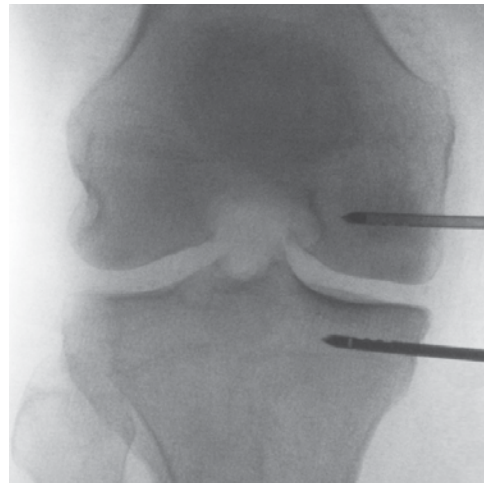


Remove the inner stylus: while holding the cannula body securely with one hand, squeeze together the adaptor locking wings with the other hand and pull the stylus out. Set the stylus on the sterile field (Mayo stand or back table) — **DO NOT DISCARD!**

ⓘ **NOTE:** Allow AccuPort to cool prior to injection of the AccuFill.

Attach the first 1cc syringe of AccuFill mix to the cannula hub; firmly tighten the luer lock connector.

Inject the AccuFill BSM using steady manual pressure.

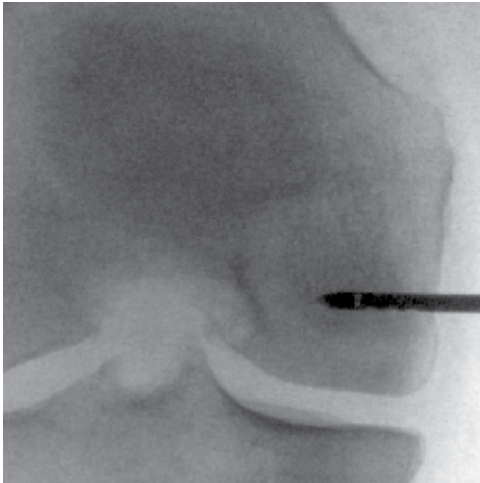


Remove stylus from cannula (femoral);
Attach syringe and inject

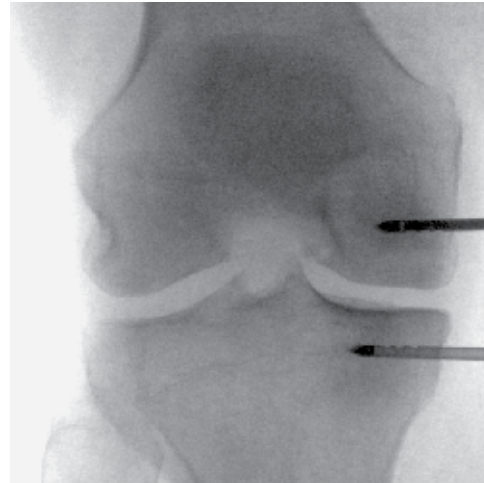
Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM (cont.)

Remove the first syringe and repeat until desired volume has been implanted. Cannula depth can be adjusted manually (see image, below left) to expand area of injection. Reinsert the stylus before adjusting, to avoid clogging the fenestrations, or damaging the cannula.



Adjust cannula position if desired;
Inject desired volume of AccuFill BSM



Replace femoral stylus. Remove tibial
stylus and inject AccuFill BSM



Plunge the stylus back into the cannula to inject residual AccuFill BSM; insert the stylus fully until locking wings are secure to the hub.

For bipolar procedure, repeat steps to inject the adjacent compartment.

NOTE: The use of AccuFill BSM is not intended to be intrinsic to the stability of the bony structure. Radiographic studies should be used to confirm that the adjacent cortical bone is intact.

Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM (cont.)

Leaving the cannula(s) in place while the AccuFill BSM starts to set, reinsert the arthroscope into the knee to evaluate for and evacuate any extravasated material.

Remove the cannula: reconnect the wire driver to the cannula stylus; use reverse torque while pulling back.

Ensure no excess bone substitute emerges from the insertion portal. Using fluoroscopic imaging, ensure that AccuFill implant is properly placed. Seal all incisions.



Injections completed, AccuPort cannulas removed

Operative Tips:

- The first 0.7 cc of mix is filling the cannula itself; once the BSM fills the cannula and starts flowing into the subchondral cancellous bone, back pressure will increase. Let off on digital pressure and then slowly reapply it until the material starts to flow again.
- Monitor flow and volume of the AccuFill BSM into the trabecular bone under AP fluoro. If the AccuFill material is not readily seen on the C-arm monitor, contrast between bone and BSM may be improved by changing fluoroscopy settings toward Bone X-ray settings (decreasing KVP and/or increasing MA) or switching between normal image and “negative”.

- ⊖ **NOTE:** When attaching and removing 1 cc syringes from the cannula, grip the hub firmly to avoid rotating the cannula.
- ⊖ **NOTE:** Do not overfill the defect site. Overpressurizing the device may lead to extrusion beyond the site of intended application and damage to surrounding tissues. Remove any excess material from the subcutaneous tissue at the entry point by gently expressing and irrigating the material. Blot any excess material from the surgical wound as needed.
- ⊖ **NOTE:** The cannula and stylus should be left in the bone for 10 minutes, while the AccuFill BSM hardens, to minimize potential for extravasation of material.
- ⊖ **NOTE:** Reminder to use the T1 image as a reference for targeting accuracy and volume.

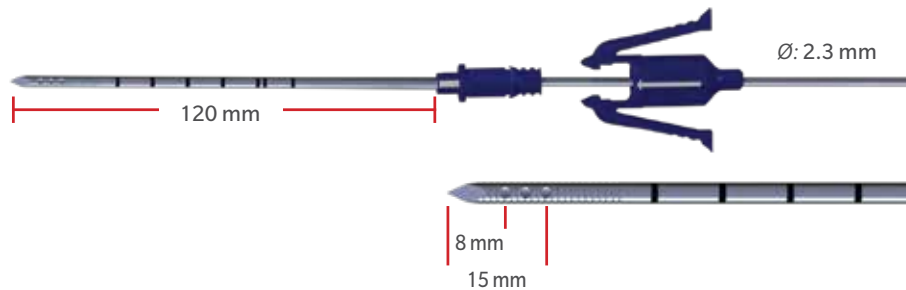
Implants and Instruments

AccuPort Delivery Cannulas

Trocar-tipped, drillable cannulas for minimally-invasive access, and delivery of AccuFill BSM to the bone defect. Each AccuPort cannula includes interconnecting cannula and stylus, for insertion using an OR wire driver.

AccuPort Cannulas, 11 ga

Side-delivery:





- 3 side fenestrations for directed flow of BSM from alongside or margin of bone defect.

End-delivery:

- End aperture for direct delivery of BSM into defect.

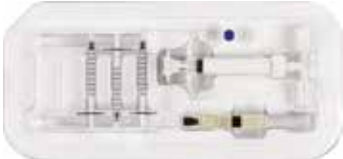

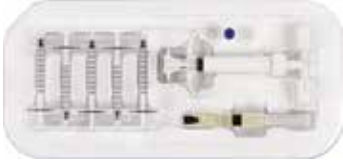



Ordering Information

Product	Description	Part Number
	AccuPort Side-Delivery Cannula; 11 ga (3.0 mm OD), 120 mm Drill Length	307.032
	AccuPort End-Delivery Cannula; 11 ga (3.0 mm OD), 120 mm Drill Length	307.034

Ordering Information (Continued)

SCP Prefill Kits (Packaged with AccuPort Cannula)

Product	Description	Part Number
	SCP Prefill Kit, 3cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm	464302
	SCP Prefill Kit, 3cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm	464303
 <p data-bbox="355 653 402 678">3 cc</p>		
	SCP Prefill Kit, 5cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm	464502
	SCP Prefill Kit, 5cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm	464503
 <p data-bbox="355 1037 402 1062">5 cc</p>		


All new Zimmer Knee Creations products introduced after December 1, 2018, will have six-digit part numbers with no decimal point between the third and fourth digits. This is intentional.

Ordering Information (Continued)

SCP Complete Kits

Product	Description	Part Number
	SCP Complete Kit, 5cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm	414.502
	SCP Complete Kit, 5cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm	414.503
	SCP Complete Kit, 3cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm	514.302
	SCP Complete Kit, 3cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm	514.303

AccuMix Mixing System

Product	Description	Part Number
	AccuMix Mixing System	311.100

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