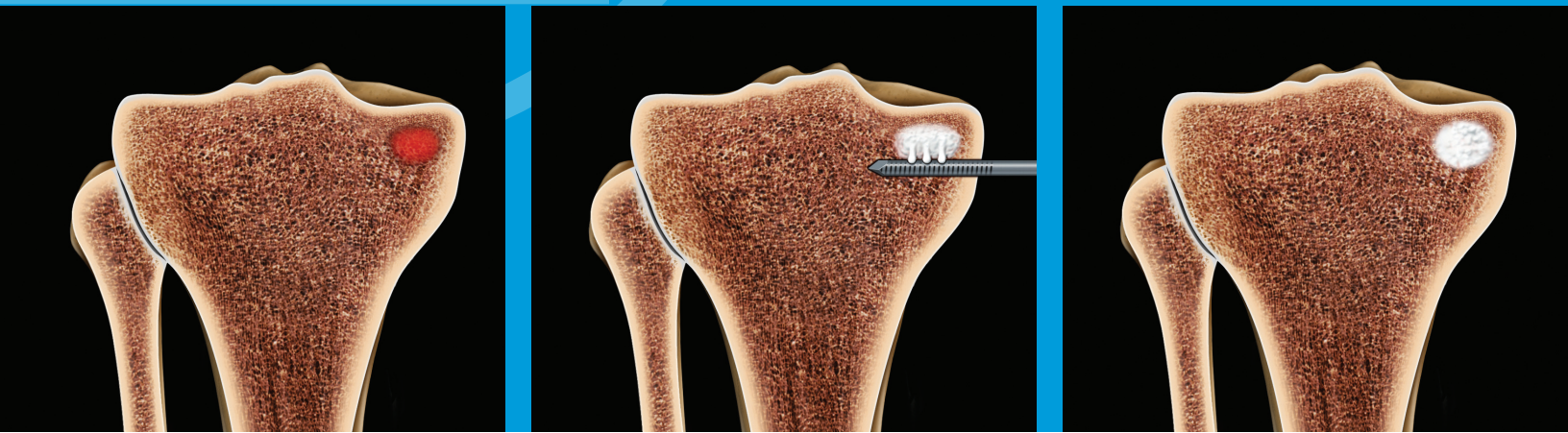


The Subchondroplasty® (SCP®) Procedure



Surgical Technique



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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® 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.

Targeting may be performed without guides—free-hand technique—or using a SCP Navigation Guide. For surgical technique specific to SCP Navigation Guides, please refer to Knee Creations document LBL 903.117.

The Subchondroplasty Procedure consists of four components:

PREOPERATIVE PLAN: Identify the BML bone defect on fat-suppressed MRI; plan approach and trajectory based on defect location

TARGET THE BONE DEFECT: Using arthroscopy and intraoperative fluoroscopy, localize the bone defect relative to 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

AccuFill BSM Indications for Use:

AccuFill Injectable 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 Injectable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

SCP

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MRI Based Planning

The presence of a BML subchondral bone defect is determined using fat-suppressed MRI (e.g., 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.

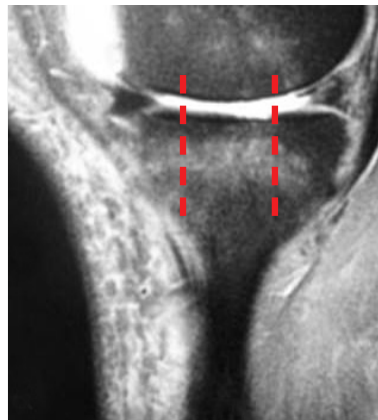
Using all three MRI views (axial, coronal and sagittal), localize the BML by:

Tibia

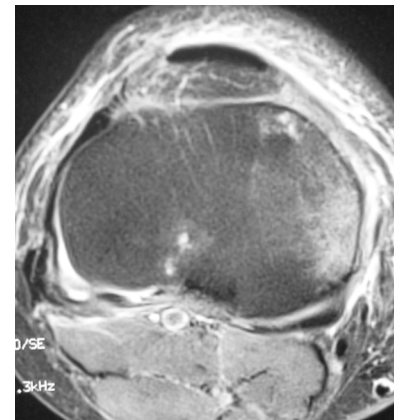
- Distance from the joint cortex
- Position in sagittal and axial view (anterior, central or posterior third)
- Depth relative to near cortex (superficial or deep)



Distance from joint cortex



Anterior/central/posterior



Fine tune targeting using axial image

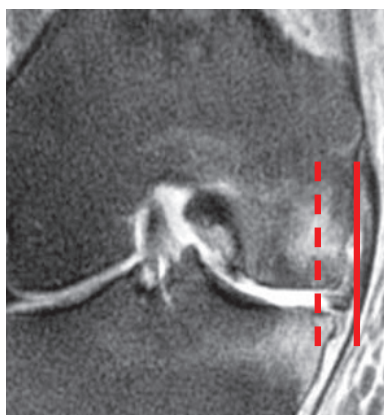
TIP:

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.

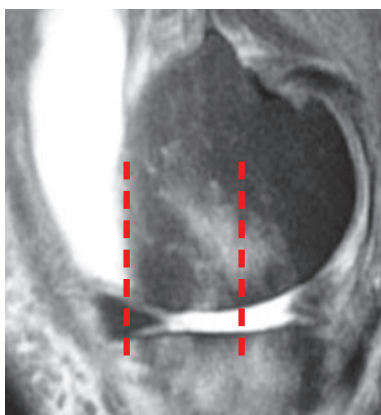
MRI Based Planning

Femur

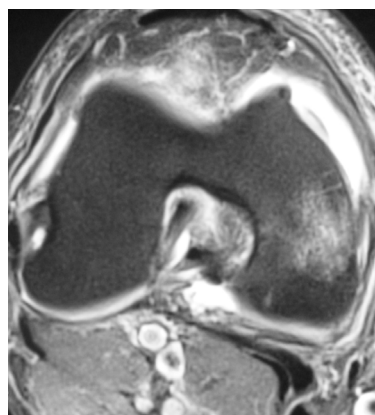
- Position in sagittal view
 - Anterior, central or posterior third
 - Relative to Blumensaat's line
- Depth relative to near cortex (superficial or deep)



Depth from near cortex



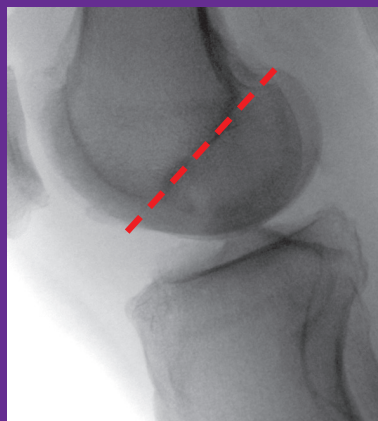
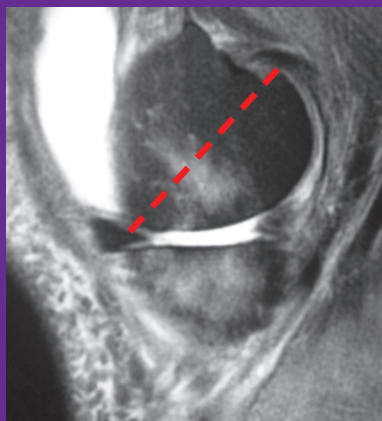
Anterior/central/posterior



Fine tune targeting using axial image

TIP:

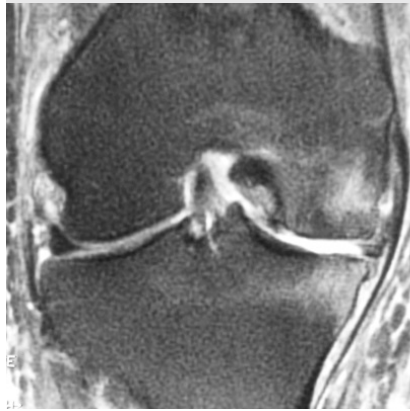
- Scroll sagittal MRI slices from area of bony defect to intercondylar notch to determine defect position relative to Blumensaat's line.



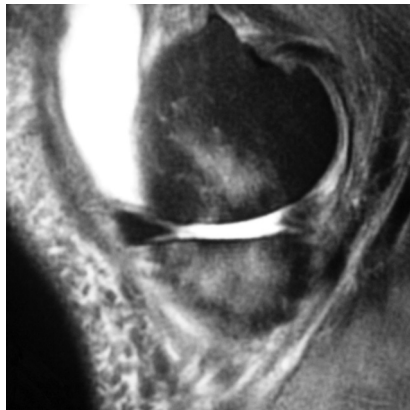
Principles of Free-hand Targeting

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.

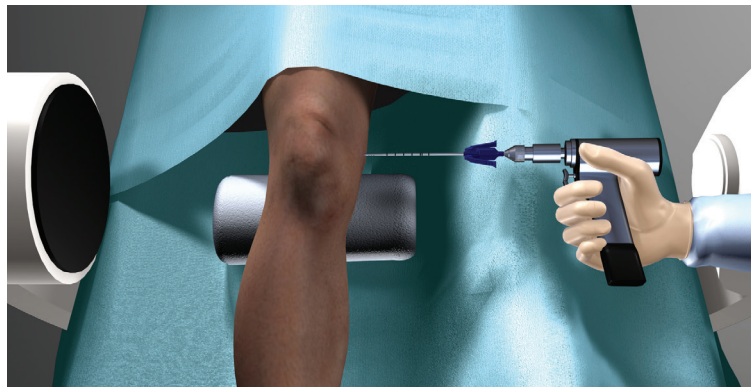
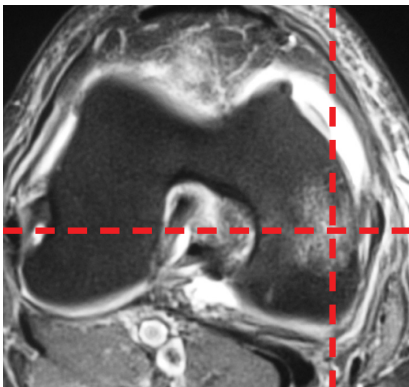


Coronal/
Anatomic AP



Sagittal/
True Lateral

Match fluoro views to MRI planes

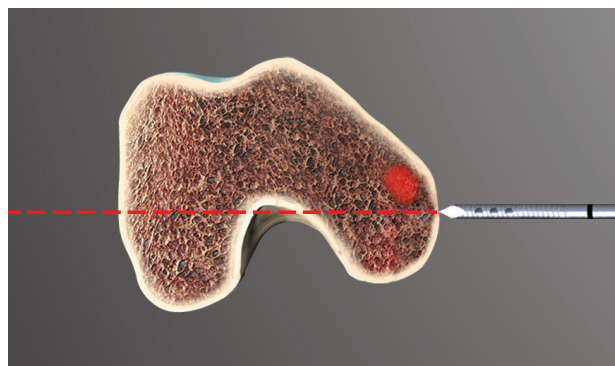
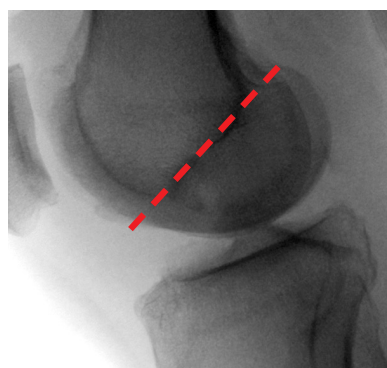
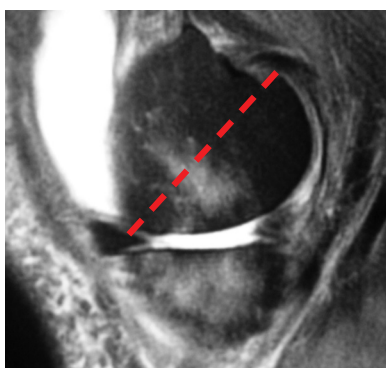


Center the defect in the fluoro beam. Align the cannula with the beam

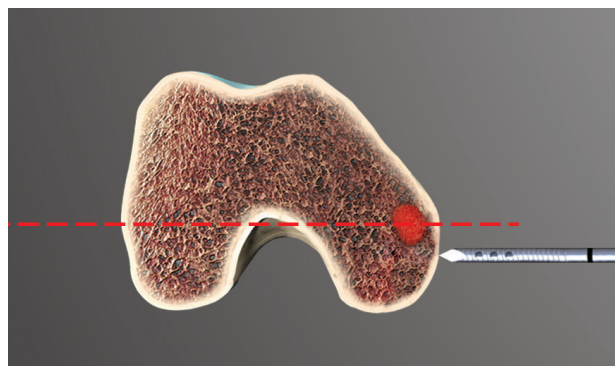
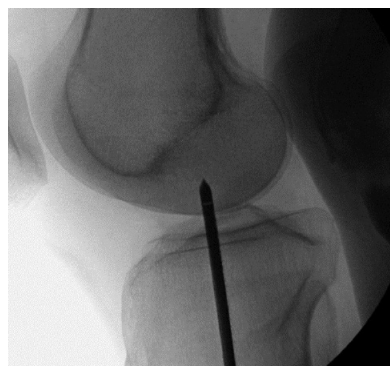
Principles of Free-hand Targeting

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 below, 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.



1 a/b



2 a/b

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, however, that while the AccuPort injection cannulas are in place (see Injection Technique, p. 22), 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.

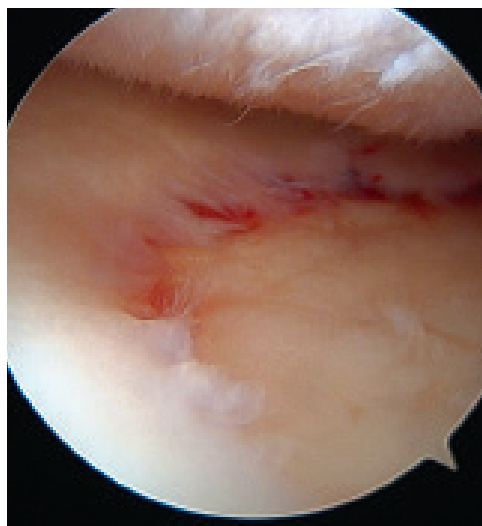
TIP:

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.

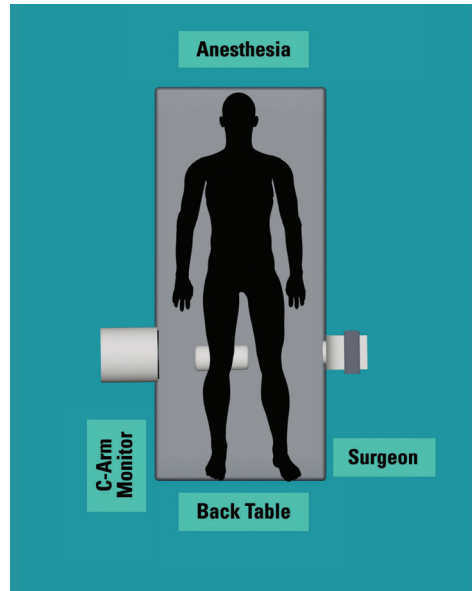
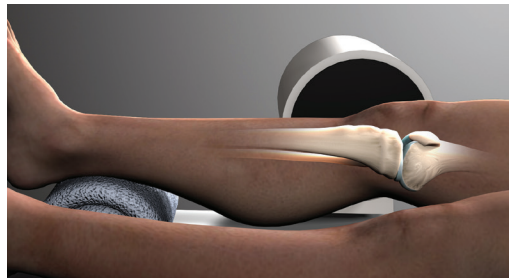
Important Information: The use of AccuFill BSM is not intended to be intrinsic to the stability of the bony structure. Radiographic studies should be used to confirm that the adjacent cortical bone is intact.



Scope assessment of tibial plateau injury

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

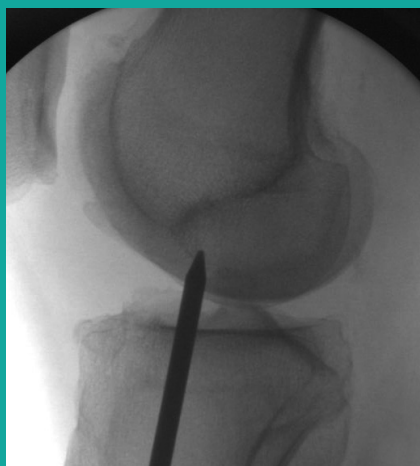
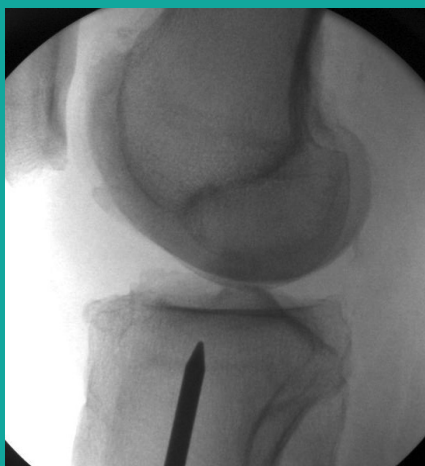
OR Setup/Patient Positioning

- 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.

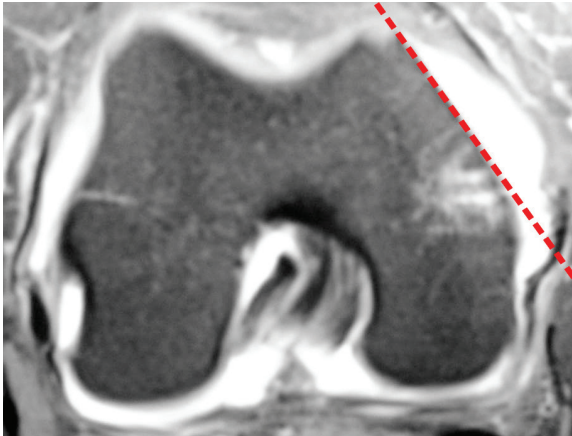


OPERATIVE TIP:

- 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



Medial Slope

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.

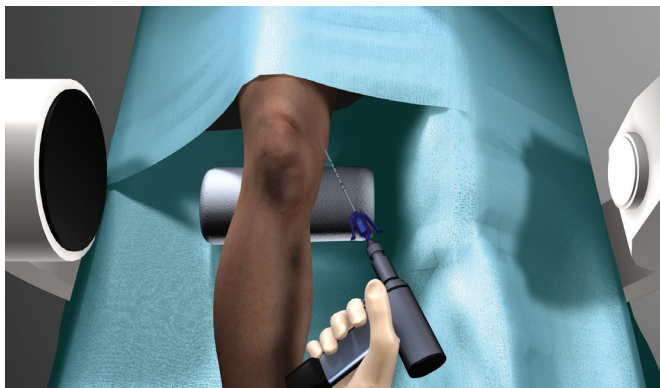
- Obtain true AP and true lateral fluoroscopic images of the distal femur with the targeted area centered in the image; note C-arm tilt and position relative to the OR table/patient in each image, to easily return to that position. Mark the plateau line and other landmarks and approximate entry points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



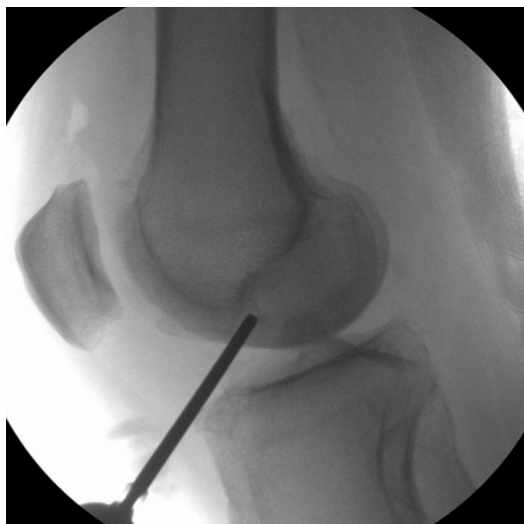
Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (contd.)

- 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.



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

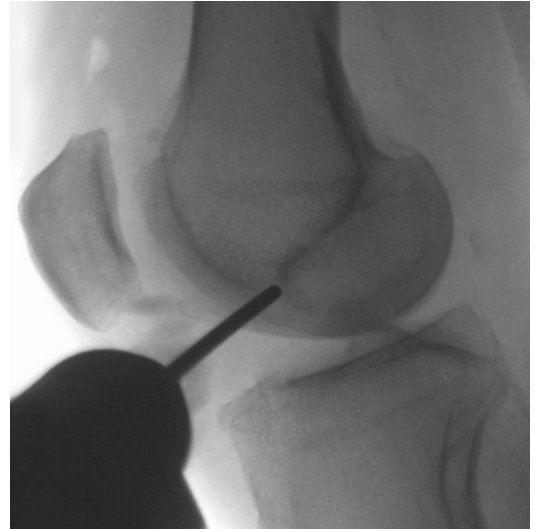
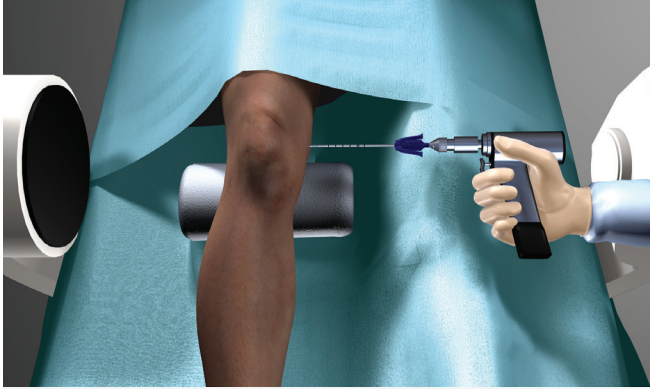


Reposition tip of cannula as needed

Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (contd.)

- 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:

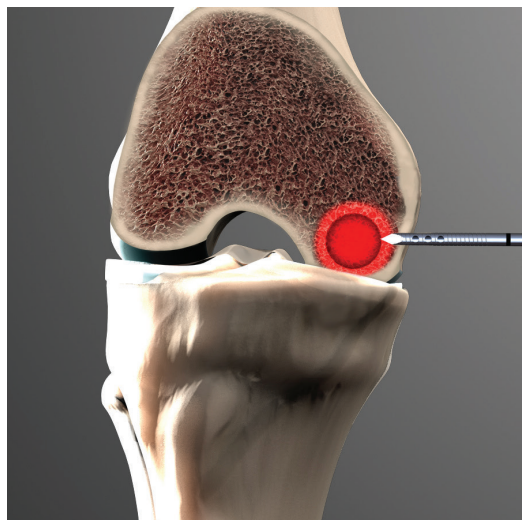
- Before moving the C-arm to AP, drill the cannula through the cortex, just into the cancellous bone. Disconnect the drill from the cannula and take another lateral image. The cannula should now be seen end-on, as shown in the image, right, in line with planned trajectory.



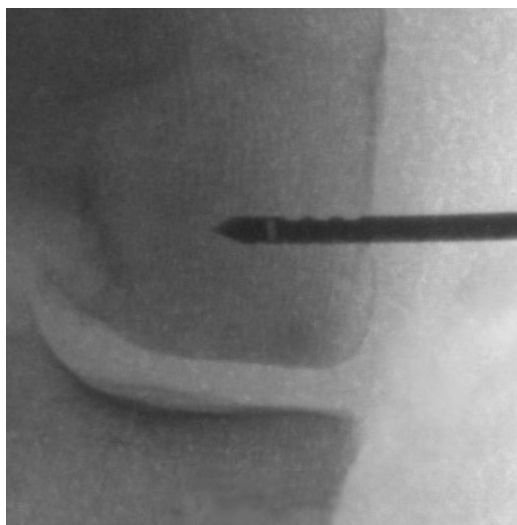
Targeting and Accessing the Defect: Free-hand Targeting

Femoral Targeting (contd.)

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



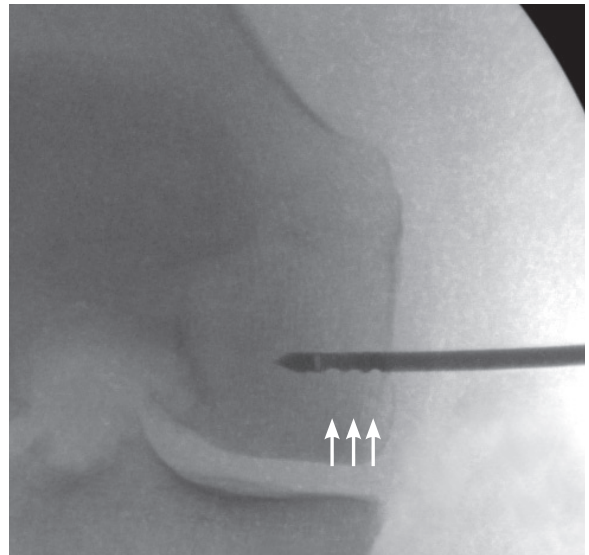
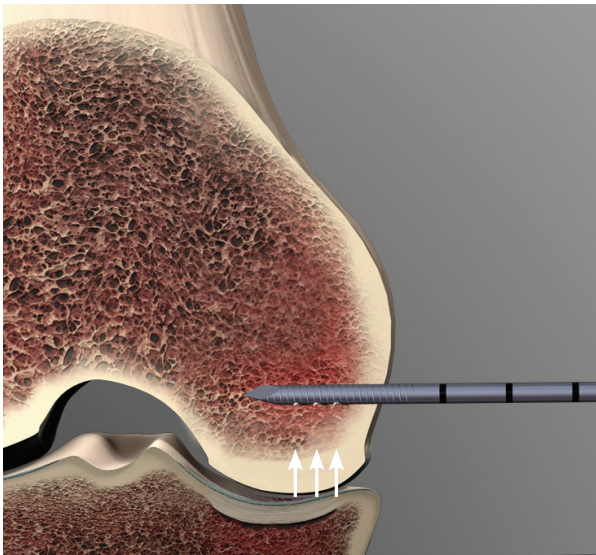
- Using AP fluoroscopy as needed, continue drilling until the cannula is at the desired depth and, when using the Side-Delivery AccuPort, all three delivery fenestrations are deep to the cortex.



Targeting and Accessing the Defect: Free-hand Targeting

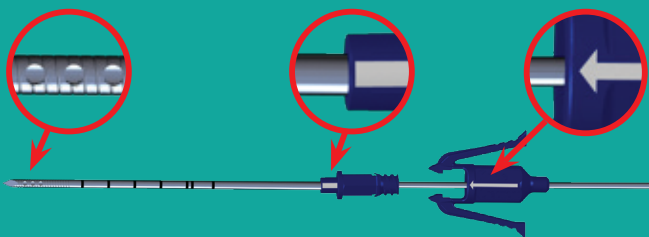
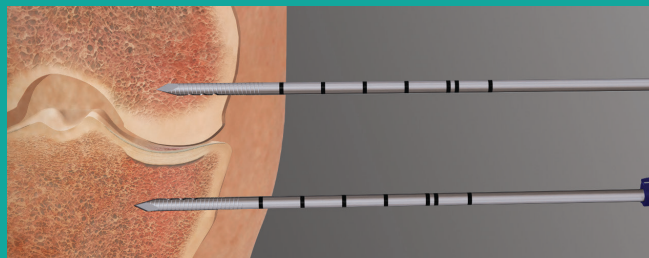
Femoral Targeting (contd.)

- 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 (p. 22).



SURGICAL TIPS:

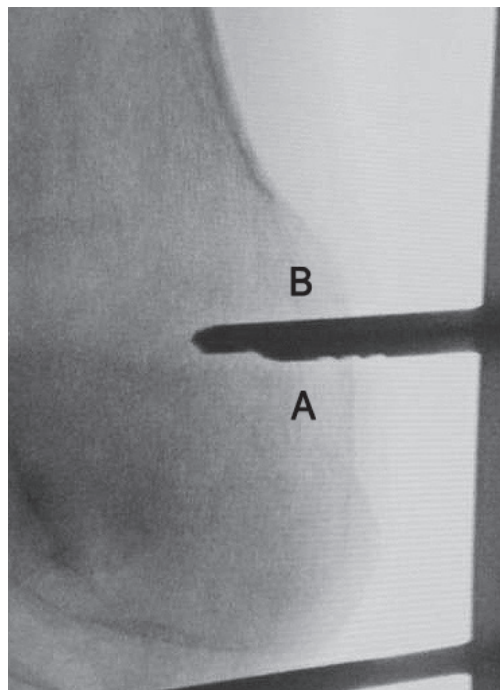
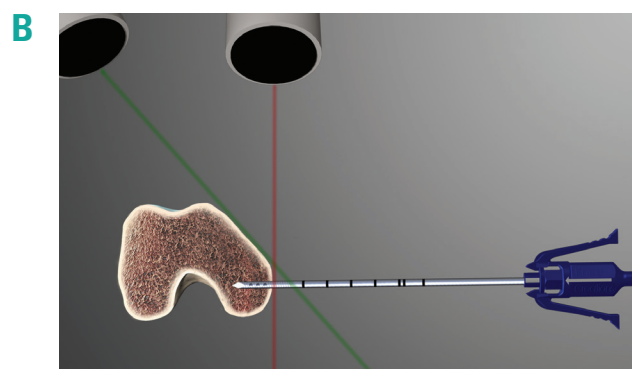
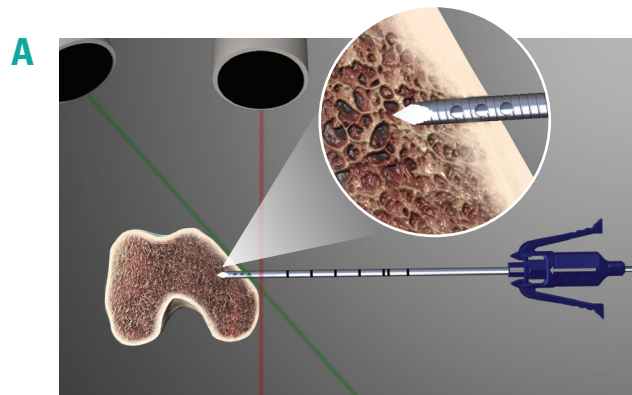
- Use the markings on the cannula to externally monitor the depth of cannula advancement.
- The white lines on the hub of the Side-Delivery AccuPort cannula are in line with cannula fenestrations. Use this external mark to aid in orienting the fenestrations in the desired direction for injection.



Targeting and Accessing the Defect: Free-hand Targeting

NOTES:

- To minimize the potential for extravasation of AccuFill BSM (see AccuFill Injection), the delivery holes of the cannula must be deep to the entry point 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.



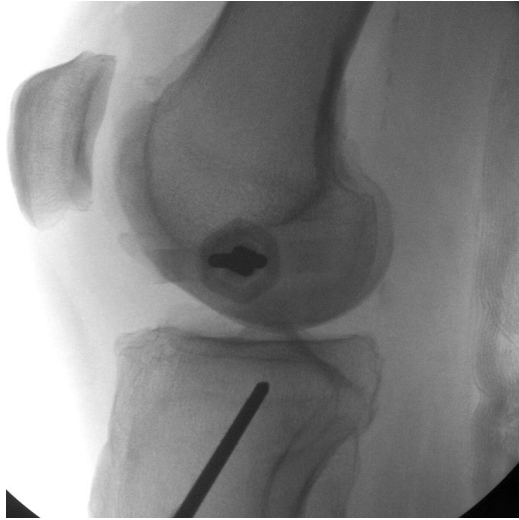
Oblique fluoro shot of cannulas A and B in femoral condyle. Cannula B is fully in bone; Cannula A is not—note the fenestrations outside the cortex.

- 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.

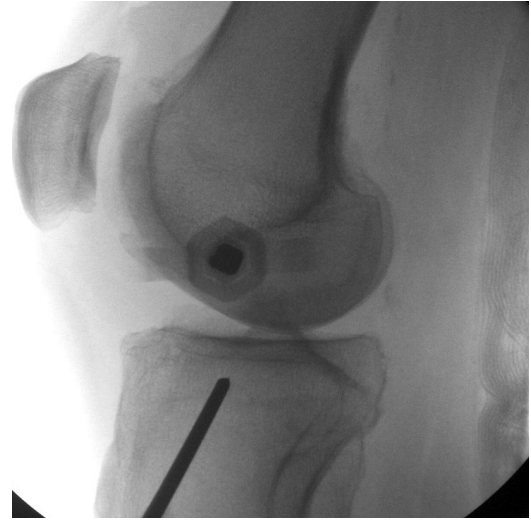
Targeting and Accessing the Defect: Free-hand Targeting

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:

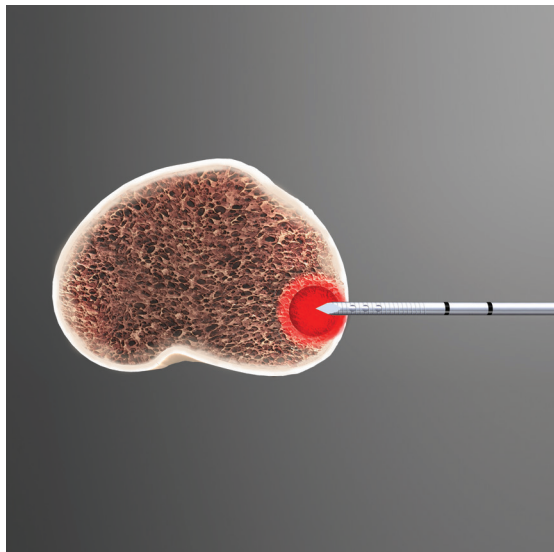
- Before moving the C-arm to AP, drill the cannula through the cortex, just into the cancellous bone. Disconnect the drill from the cannula and take another lateral image. The cannula should now be seen end-on, as shown in the image, right, in line with planned trajectory.



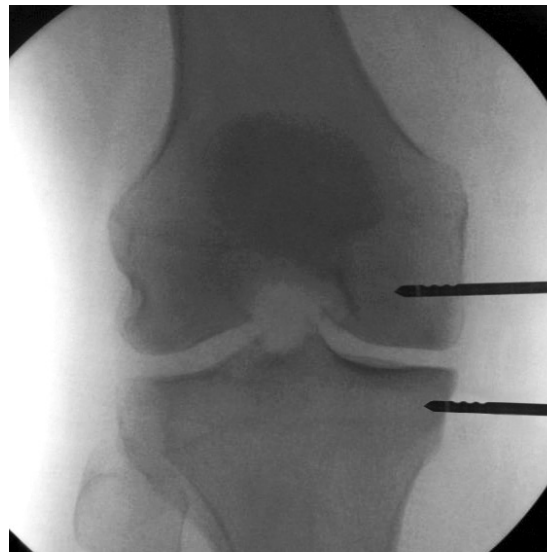
Targeting and Accessing the Defect: Free-hand Targeting

Tibial Targeting (contd.)

- 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, all three delivery fenestrations are deep to the cortex.
- Manually rotate the cannula so the fenestrations point towards the joint or lesion, and then proceed to AccuFill BSM injection (p. 22).



Drill in the tibial cannula under AP fluoroscopy



Advance cannulas to desired depth

Implant Placement: Filling the Bone Defect

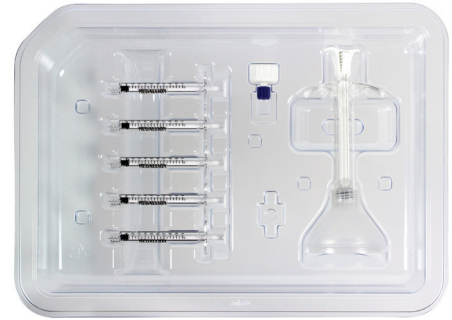
AccuFill BSM is hydrated and mixed before injection, using normal saline (0.9%). The material is mixed using the AccuMix mixing system, a closed syringe device. Allow for mixing time while avoiding down time after cannula insertion. Working time for AccuFill BSM is approximately 15 minutes (maximum time 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.

NOTE:

For AccuFill BSM Bowl Mixing Technique see p.27



AccuFill BSM Mixing Technique

Setup:

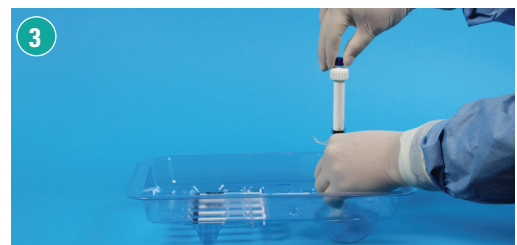
The AccuMix system tray (AccuMix system or SCP Complete Kits) is sterile and provides stability for the mixing syringe during BSM powder transfer.

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!

Hydrate:

4. Withdraw saline from vial using the saline syringe and adaptor.
 - 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

AccuFill BSM Mixing Technique

5. Connect saline syringe to white cap; tighten.
Inject saline 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:

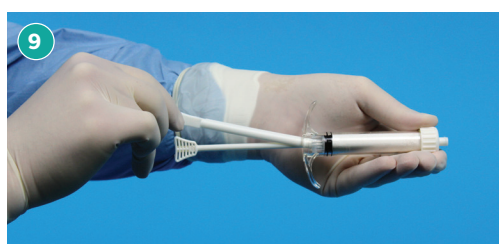
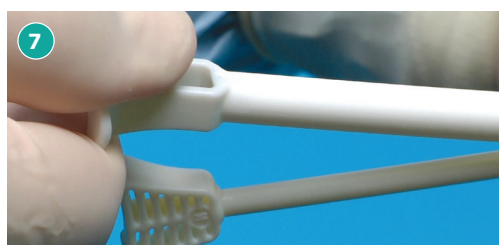
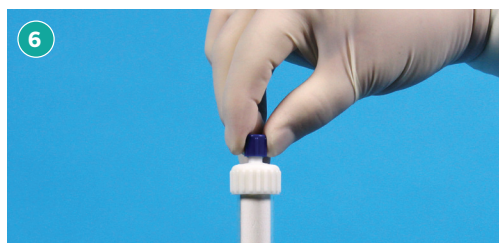
7. Remove mixing syringe from tray. Remove plunger sleeve from plunger stem.
DO NOT DISCARD SLEEVE!
8. Thoroughly mix powder and saline for 60 strokes (~60 seconds). Twist and rotate while plunging until mix takes “paste” consistency.
9. Remove blue plug. Reattach sleeve to stem, with stem fully extended.

Transfer:

10. Holding syringe with white cap upright, expel excess air from syringe. Connect the first 1 cc syringe. Inject AccuFill BSM into syringe. Repeat for remaining syringes.
11. Transfer filled syringes to operative field.

NOTE:

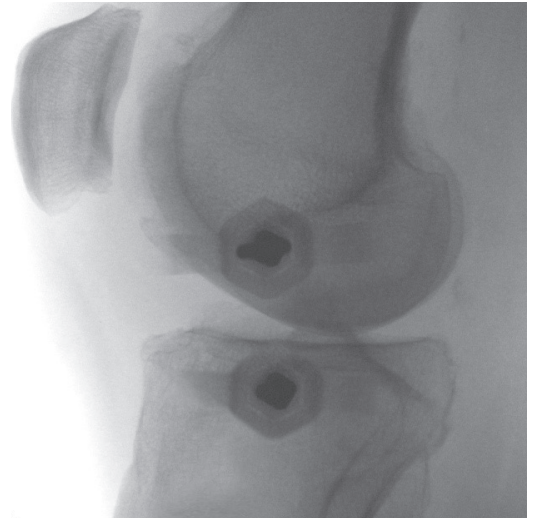
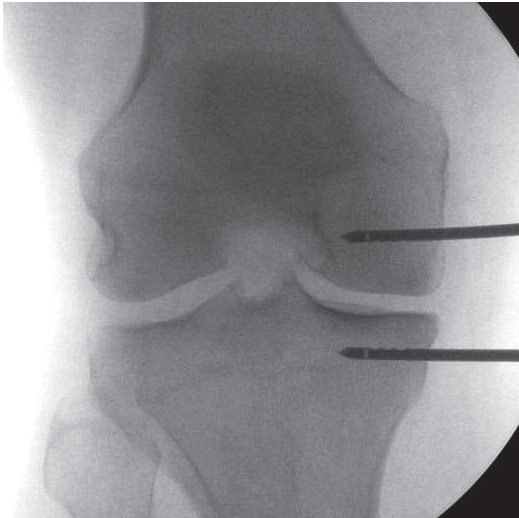
Do not empty entire contents of saline vial into AccuFill BSM powder. Measure and use only the exact volume noted above.



Implant Placement: Filling the Bone Defect

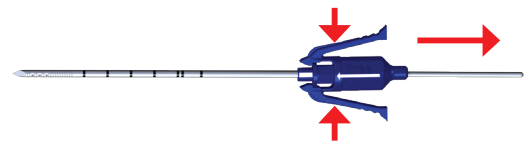
Injecting AccuFill BSM

- 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).

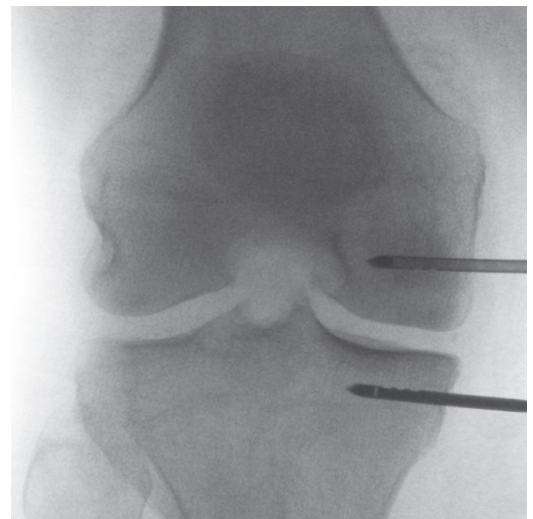


Confirm cannulas in position, fenestrations oriented toward joint (desired direction of flow).

- 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!**



- 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.

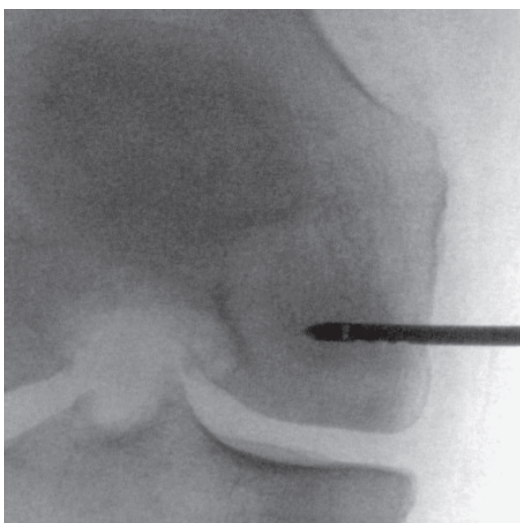


Remove stylus from cannula (femoral).
Attach syringe and inject.

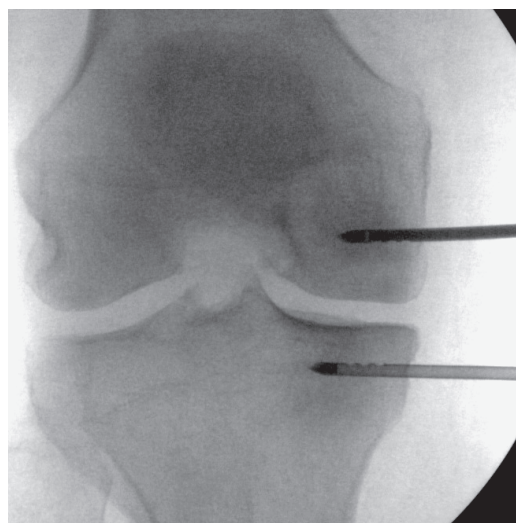
Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM

- 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.



Important Information: 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

- 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.



Injecting completed, AccuPort cannulas removed

OPERATIVE TIPS:

- When attaching and removing 1 cc syringes from the cannula, grip the hub firmly to avoid rotating the cannula.
- 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”.
- The cannula and stylus should be left in the bone for 8-10 minutes, while the AccuFill BSM hardens, to minimize potential for extravasation of material.

NOTE:

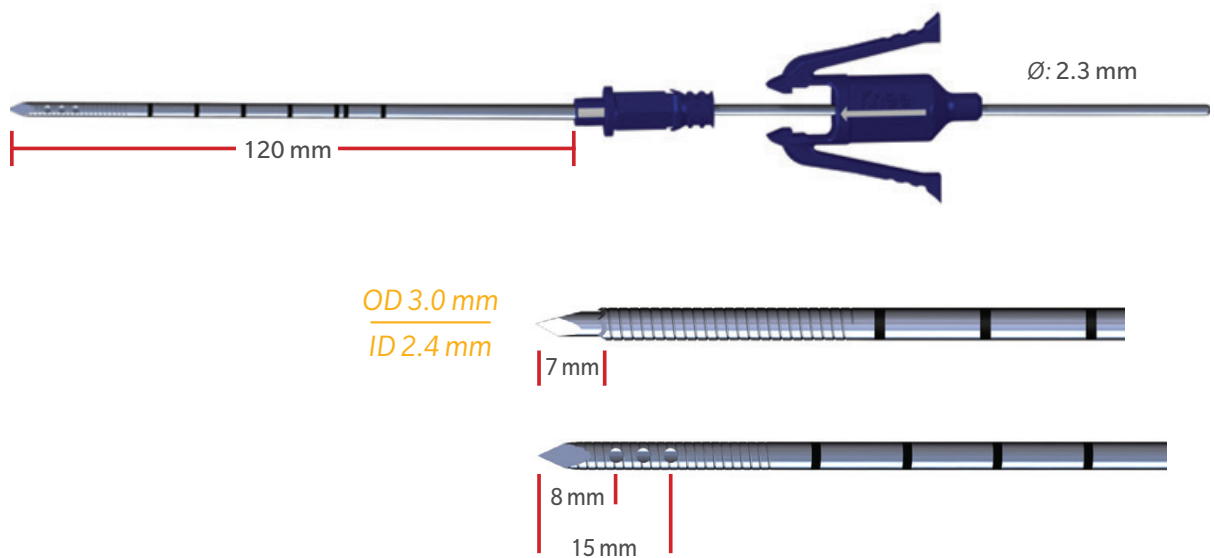
Do not overfill the defect site. Overpressurizing the device may lead to extrusion beyond the site of intended application and damage to surrounding tissues. Remove any excess material from the subcutaneous tissue at the entry point by gently expressing and irrigating the material. Blot any excess material from the surgical wound as needed.

AccuPort Delivery Cannulas

Trocar-tipped, drillable, 11 ga cannulas for delivery of AccuFill BSM to the bone defect. 3.0 mm diameter, 120 mm drillable length; provides minimally-invasive access to the defect. Each AccuPort cannula includes interconnecting cannula and stylus, for insertion using an OR wire driver.

Two Delivery Options

- 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.



AccuFill BSM Bowl Mixing Technique

If desired, bowl mixing may be used as an alternative to AccuMix syringe mixing. To avoid drying or stiffening of the AccuFill BSM, bowl mixing should be completed closer to expected injection time. If injection is delayed, protect the mixed BSM and minimize drying potential by covering the material with saline-moistened sterile gauze.


1. Remove the seal from the clear amber jar and remove the vial containing AccuFill BSM powder. Pour powder into jar.
2. Withdraw saline from vial using the saline syringe and adaptor.
 - 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
3. Dispense hydrant into the mixing jar.
4. Using the broader face of the spatula, mix thoroughly for about a minute to form a putty (similar to toothpaste). Use shear force by smearing the material against the side of the bowl, to optimize mixing for best results.
5. Using the spatula, transfer mix into the 5 cc transfer syringe.
6. Transfer mix from 5 cc transfer syringe to the 1 cc syringes.

NOTE:

Bowl mixing requires use of the spatula to mix and shear material and saline together. A spatula is not included in the AccuMix system or in SCP Complete Kits, so bowl mixing cannot be completed when using these kits.



Ordering Information

SCP Complete Knee Kits		
• 414.502	SCP Complete Knee Kit; 5 cc, Side-Delivery, 11 ga x 120 mm	
• 444.502	SCP Complete Knee Kit; 5 cc, Side-Delivery, 11 ga x 120 mm, 4-Pack	
• 414.503	SCP Complete Knee Kit; 5 cc, End-Delivery, 11 ga x 120 mm	
• 444.503	SCP Complete Knee Kit; 5 cc, End-Delivery, 11 ga x 120 mm, 4-Pack	
SCP Kits		
• 402.202	SCP Kit; 5 cc, Side-Delivery, 11 ga x 120 mm	
• 402.205	SCP Kit; 5 cc, Side-Delivery, 11 ga x 120 mm, 4-Pack	
• 402.203	SCP Kit; 5 cc, End-Delivery, 11 ga x 120 mm	
• 402.206	SCP Kit; 5 cc, End-Delivery, 11 ga x 120 mm, 4-Pack	
AccuPort Cannulas		
• 307.032	AccuPort Side-Delivery Cannula; 11 ga, 120 mm	
• 307.034	AccuPort End-Delivery Cannula; 11 ga, 120 mm	
• 308.151	AccuPort End-Delivery Cannula; 15 ga, 60 mm	

Ordering Information

SCP Navigation Guides	
<ul style="list-style-type: none"> • 310.100 AccuZone Navigation Guide 	
<ul style="list-style-type: none"> • 323.100 AccuAim Targeting Guide 	
AccuMix Mixing System	
<ul style="list-style-type: none"> • 311.100 AccuMix Mixing System 	
<ul style="list-style-type: none"> • 341.100 AccuMix Mixing System, 4-Pack 	
<ul style="list-style-type: none"> • 311.102 Replacement Parts for AccuMix Mixing System 	
AccuFill BSM	
<ul style="list-style-type: none"> • 201.050 AccuFill Bone Substitute Material, 5 cc 	
<ul style="list-style-type: none"> • 241.050 AccuFill Bone Substitute Material, 5 cc, 4-Pack 	
<ul style="list-style-type: none"> • 201.030 AccuFill Bone Substitute Material, 3 cc 	
<ul style="list-style-type: none"> • 241.030 AccuFill Bone Substitute Material, 3 cc, 4-Pack 	

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subchondroplasty.com
1-855-727-5818 | kc.customerservice@zimmerbiomet.com

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MANUFACTURER
Zimmer Knee Creations
841 Springdale Drive
Exton, PA 19341
USA



AccuFill BSM
MANUFACTURED BY:
ETEX Corporation
38 Sidney Street,
Cambridge, MA 02139
USA