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 including Bone Marrow Lesions (BML), using AccuFill® Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute material. The procedure is usually performed along with arthroscopy of the affected joint, to assist in targeting the underlying bony lesion, and for visualization and treatment of other structures inside the joint.

The Subchondroplasty Procedure consists of four components:

1. **Preoperative plan:** Identify the BML on fat-suppressed MRI; plan approach and trajectory based on lesion location
2. **Target the BML:** Using intraoperative fluoroscopy, localize the BML bone defect relative to findings
3. **Access the lesion:** Drill the appropriate AccuPort® Delivery Cannula to the defect
4. **Fill the bony defect:** Inject AccuFill BSM into the bony defect and surrounding subchondral bone

AccuFill Porous Bone Substitute is an injectable, self-setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the lower extremities (pelvis through foot) 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 including bone marrow lesions. AccuFill is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

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PreOperative Planning

- **A** Tibial Guide
- **B** Femoral Guide
- **C** Handle
- **D** 15° Antegrade Hole
- **E** Plateau Wire
- **F** Transverse Holes

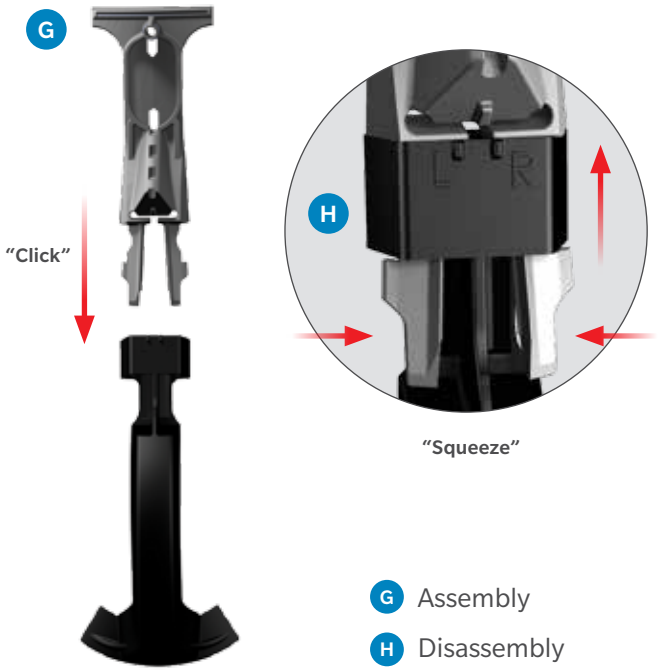
Introduction to SCP Navigation Guides

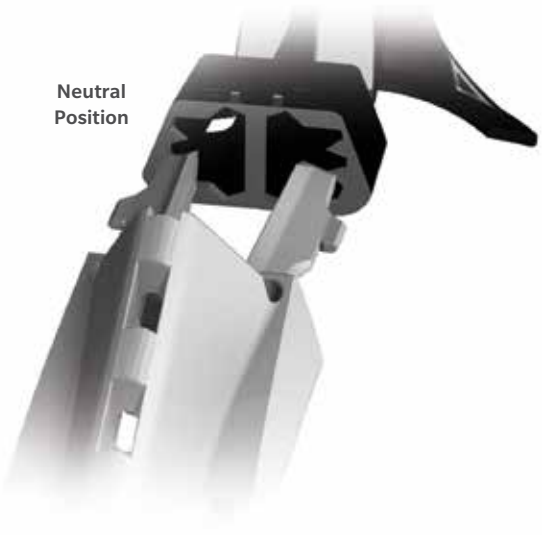
The presence of a BML is determined using fat-suppressed MRI (e.g., T2FS). BML, however, are not visible on intraoperative fluoroscopy. To accurately inject the BML defect, then, the surgeon must use the patient's MRI to determine the location of the BML defect relative to radiographic landmarks. This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

Guides provide a stable jig for 11 ga. (Ø 3.0 mm) AccuPort® Delivery Cannulas, for controlled aiming and drilling. The guides are radiolucent ABS plastic but incorporate stainless steel markers to aid in targeting. Handles are designed to fit the patient's anatomy for stable positioning, and keep hands out of the fluoroscopy beam. Guides are sterile-packed and disposable, intended for single-use.

AccuAim Targeting Guide

- Assists freehand fluoroscopic targeting of lesion
  - Metal bushings for "perfect circle" targeting in lateral fluoroscopy.
  - Antegrade hole option for femoral lesions.
  - Plateau wire for aligning with joint.
- Stabilizes AccuPort Delivery Cannulas when drilling
  - Requires use of Adaptor Sleeve or Depth Control Sleeve in targeting holes.
- One handle, two targeting guides.





Introduction to SCP Navigation Guides (cont.)

Determining Position of the Guide

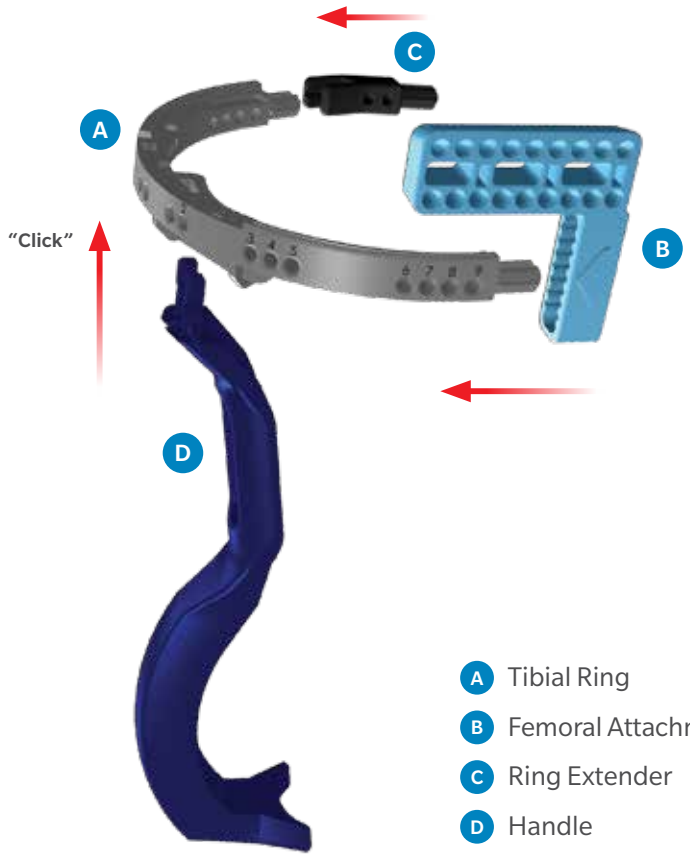
Guides can be coupled to Handle in three positions to adapt fit to leg anatomy: Neutral, Left, Right. Neutral position provides best fit in most instances.

Use of Adaptor Sleeve or Depth Control Sleeve with Guides

Either the Adaptor Sleeve or the Depth Control Sleeve must be used in the targeting hole of the AccuAim guide, to stabilize the AccuPort Delivery Cannula during drilling. The Adaptor Sleeve is more frequently used; it may be assembled to the guide before or after the guide is set into position using fluoroscopy.

When cannula depth control is desired, use the Depth Control Sleeve in the targeting hole, not the Adaptor Sleeve. The Depth Control Sleeve should be inserted into the bushing only after positioning the guide, to better visualize the target.

See p. 6 and 7 and Surgical Technique sections for more information.

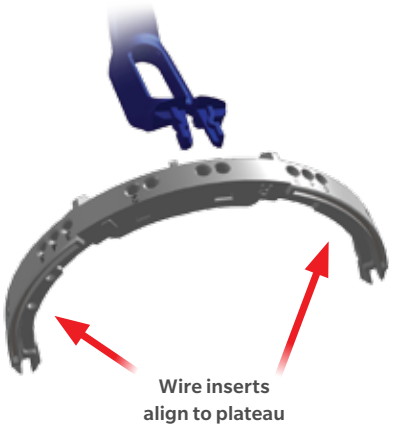


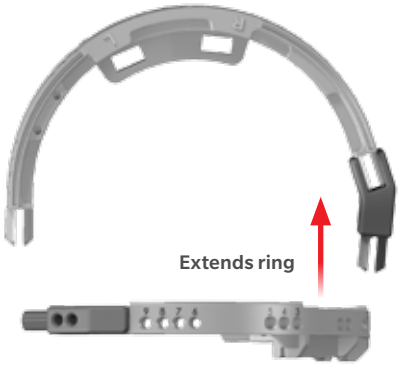
- **A** Tibial Ring
- **B** Femoral Attachment (L&R)
- **C** Ring Extender
- **D** Handle

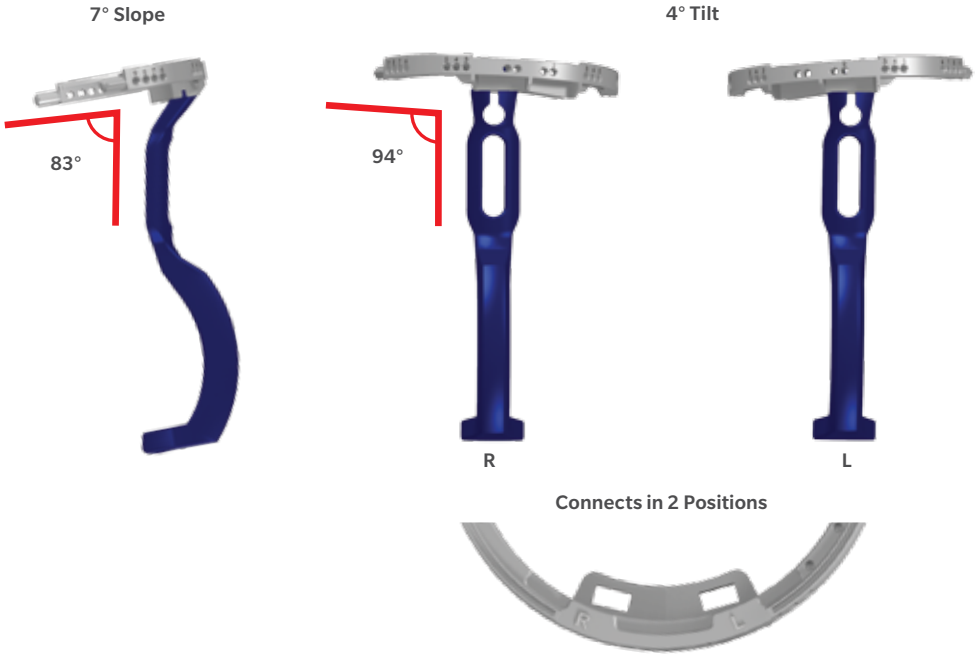
Introduction to SCP Navigation Guides (cont.)

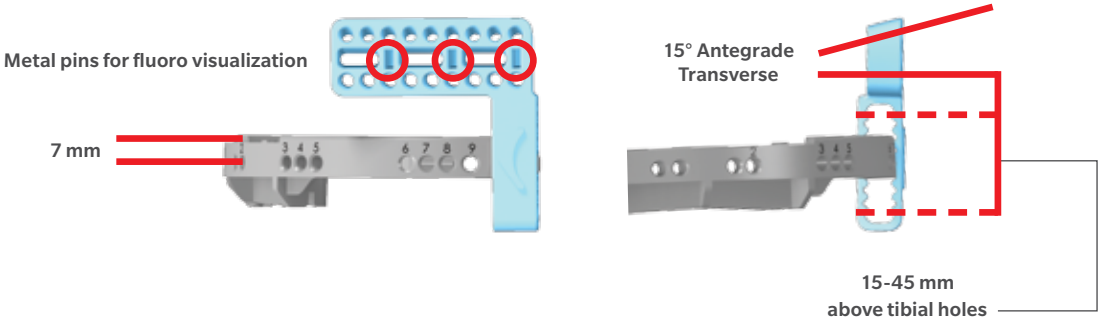
AccuZone Navigation Guide

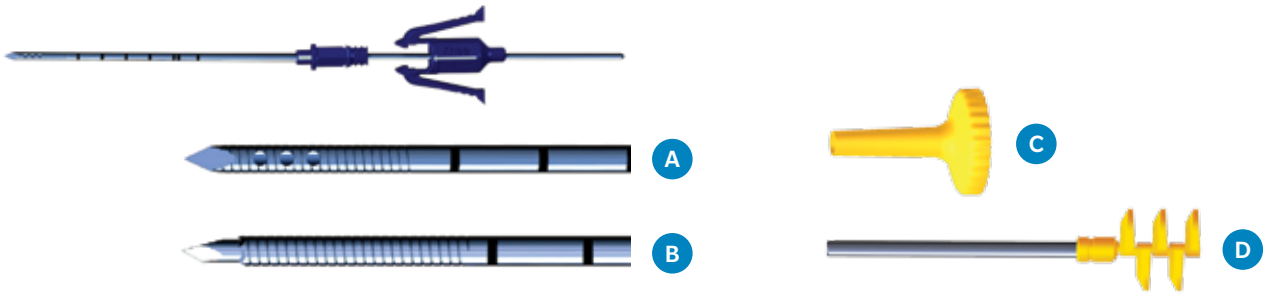
- Works with MRI preoperative planning for tibial BML.
  - Multiple targeting approach options.
  - Fluoroscopic confirmation of targeting.
- Stabilizes aiming and drilling with AccuPort 11ga. (Ø 3.0 mm) Delivery Cannulas.
  - Requires use of Adaptor Sleeve or Depth Control Sleeve in targeting holes.
- Femoral attachments provide variety of approaches to femoral compartment lesions:
  - Adjustable height above joint; antegrade and transverse aiming.
- Readily held to leg with sterile elastic bandage (e.g. CoFlex® wrap); helps keep hands out of fluoroscopy.


Wire inserts
align to plateau


Extends ring


7° Slope
83°
4° Tilt
94°
R
L
Connects in 2 Positions


Metal pins for fluoro visualization
7 mm
15° Antegrade
Transverse
15-45 mm
above tibial holes



Introduction to SCP Navigation Guides (cont.)

AccuPort Delivery Cannulas

Trocar-tipped, drillable, 11 ga. (Ø 3.0 mm) cannulas for delivery of AccuFill Bone Substitute Material to the BML bone defect. 3.0 mm diameter, 120 mm drillable length; designed to provide minimally-invasive access to the defect. Each AccuPort cannula includes interconnecting cannula and stylus, for insertion using an OR wire driver.

Two Delivery Options

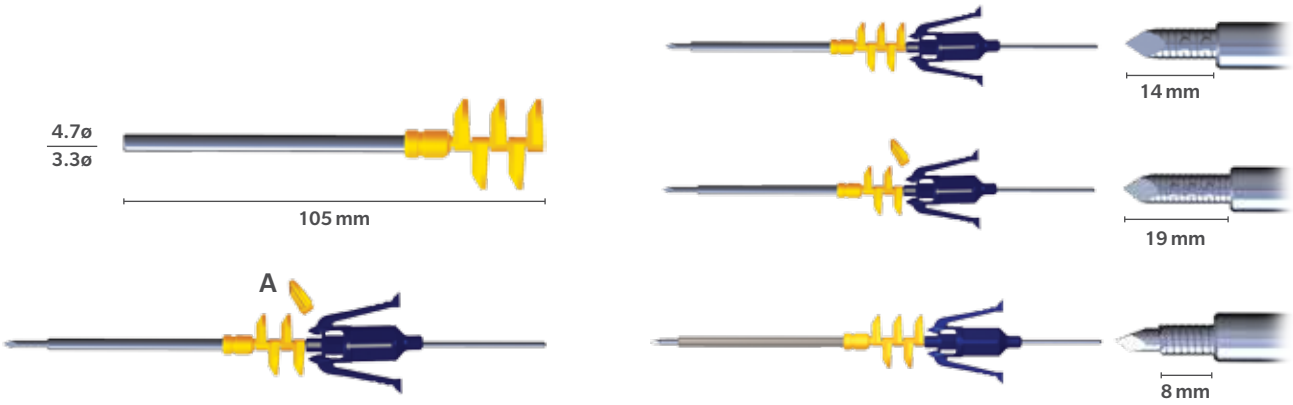
Side-delivery: 3 side fenestrations for directed flow of BSM from alongside or margin of bone defect (A).

End-delivery: end aperture for direct delivery of BSM into defect (B).

Adaptor Sleeve and Depth Control

Either the Adaptor Sleeve (C) or the Depth Control Sleeve (D) must be used in the targeting holes of the SCP Navigation Guides, to stabilize the AccuPort Delivery Cannula during drilling. Sleeves provide controlled fit and guidance of the cannula, with two usage options:

- **Adaptor Sleeve:** designed to stabilize AccuPort cannulas in targeting holes. Works with or without stab incision, for percutaneous drilling.
- **Depth Control Sleeve:** designed to provide depth control and tissue protection when drilling. Requires stab incision +/- blunt dissection to the cortex for use.



Introduction to SCP Navigation Guides (cont.)

Depth Control Sleeve Technical Information

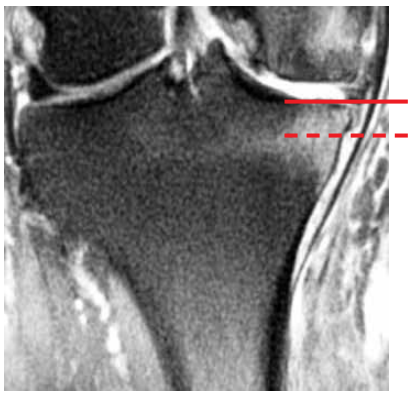
- 4.7 mm OD/3.3 mm ID; 105 mm length (all tabs intact).
- Plastic tabs break away to adjust drill depth.
  - Adjustable in 5 mm increments
  - break away tab (A)
  - advance cannula 5 mm deeper

Depth Control for Cannula Drilling

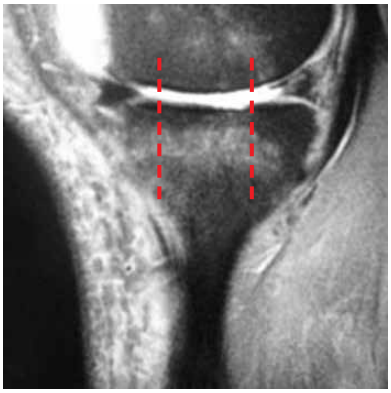
For Side-Delivery AccuPort Cannula, the first tab MUST always be removed, to ensure all fenestrations are in the bone.

For End-Delivery AccuPort Cannula, 8 mm is in bone at full depth, with no tabs removed (stylus removed).

Note: Never break tabs without AccuPort Cannula in the sleeve; more than one tab might breakaway.



Distance from joint



Anterior/central/posterior

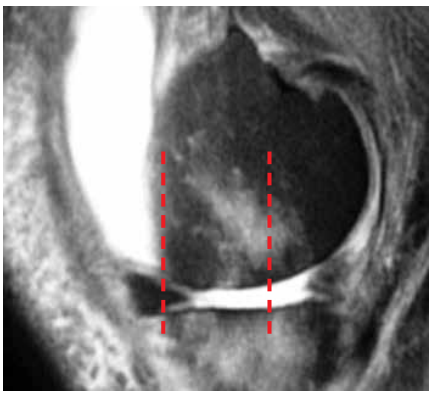
Planning for FreeHand Technique or AccuAim Targeting Guide

FreeHand targeting is based on triangulating the BML defect using lateral and AP fluoroscopy, following the MR preoperative plan. The basic surgical procedure for FreeHand technique is the same as that for the AccuAim Targeting Guide (see Surgical Technique). The AccuAim Targeting Guide, however, acts as a "perfect circle" jig to localize the BML and stabilize the AccuPort cannula while drilling it to the lesion.

Using a minimum of two MRI views (typically coronal and sagittal), localize the BML by:

Tibia

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



Anterior/central/posterior

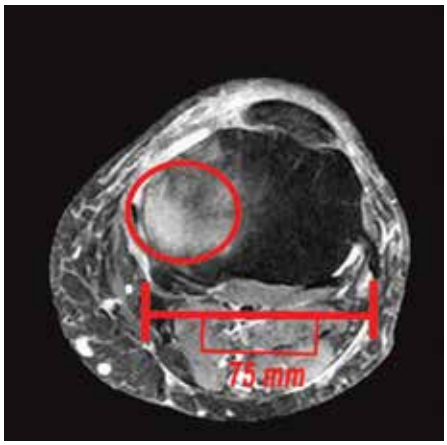
Depth from cortex

Planning for FreeHand Technique or AccuAim Targeting Guide (cont.)

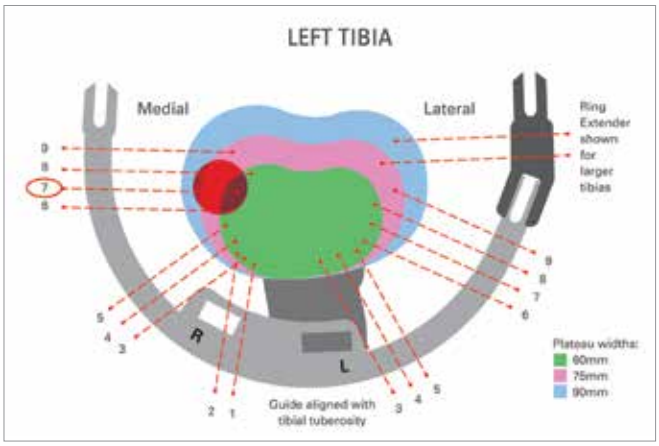
Femur

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

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



Axial MR image of left tibia



Trajectory map of lesion drawn on schematic; projection indicates surgeon perspective from above, facing patient

Planning for use with the AccuZone Navigation Guide

AccuZone Navigation Guide provides a more-"hands-free" approach to targeting bony defects associated with BML.

The guide is aligned to the tibia using standard radiographic landmarks and then "flexibly" held in place while the surgeon drills the AccuPort cannula into place. The Tibial Ring provides a number of options for targeting lesions, around the circumference of the plateau. Preoperative planning for plateau lesion consists of marking the location of the patient's BML on the appropriate axial MR slice, then using standardized templates (AccuZone Navigation Guide Trajectory Mapping Tear Pad, 0940.1-EMEA) to identify which hole(s) best targets the lesion for injection of AccuFill BSM.

For femoral lesions, a preoperative trajectory map corresponding to Femoral Attachment targeting holes cannot be created, since the Navigation Guide is held in place relative to the tibia, not the distal femur. Preoperative planning should therefore follow that described for FreeHand Technique (p. 8 and 9).

Preoperative Trajectory Mapping for Tibial Plateau Lesions

Identify BML location with MRI axial, coronal and sagittal slices.

- Note the location of BML.
- Determine plateau width at lesion (slice ~7 mm below plateau, corresponding to the height of the guide's aiming holes from the plateau).
- Mark BML on the appropriate size template schematic (matching plateau width), corresponding to the MR axial slice.
- Identify best fit trajectory(ies).

Note: Accuracy of template is dependent on actual intraoperative AccuZone guide position and orientation on tibia, relative to the patient's tibial tubercle and line of the plateau (see Targeting and Accessing the Lesion: "Accuzone Navigation Guide", p. 27). The surgeon must confirm trajectory with fluoroscopy before inserting and drilling the AccuPort cannula.

Surgical Technique

Planning for use with the AccuZone Navigation Guide (cont.)

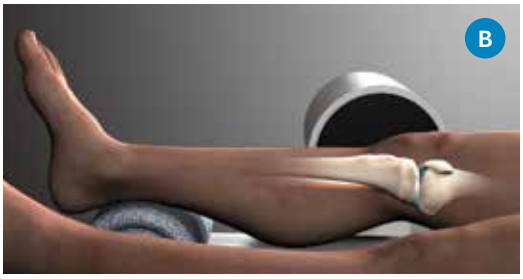
The Subchondroplasty Procedure is usually performed with arthroscopy, for visualization and treatment of structures inside the joint and to assist in targeting the underlying BML. Arthroscopy may be performed before AccuFill BSM Injection or after. Some surgeons prefer to scope first, to evaluate the cartilage overlying the bony lesion and look for potential discontinuity in the immediate subchondral bone cortex, before injecting the AccuFill BSM into the BML defect. When scoping after the BSM injection, however, note that the AccuPort injection cannulas must be left in the bone for 10 minutes while the BSM sets to minimize potential for extravasation see AccuFill Injection (Implant Placement: "Filling the BML Bone Defect", p. 31). Care must be taken to avoid applying bending forces on the cannula while manipulating the knee during scoping, to avoid damage to the cannula or surrounding bone.

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

For bipolar lesions, 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.

Note: In every procedure, it is recommended that the scope be reintroduced into the knee 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: 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 (A)]. 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 (B).

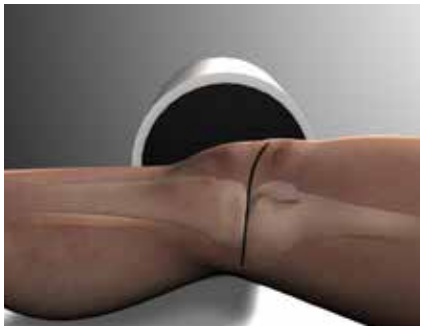
For AccuZone and AccuAim guides, bump under the ankle to keep the knee extended for optimal use of the guides.

Operative Tip: Take scout AP images to determine true AP for tibial plateau. 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).

Good AP:
aligned to plateau

Initial scout lateral

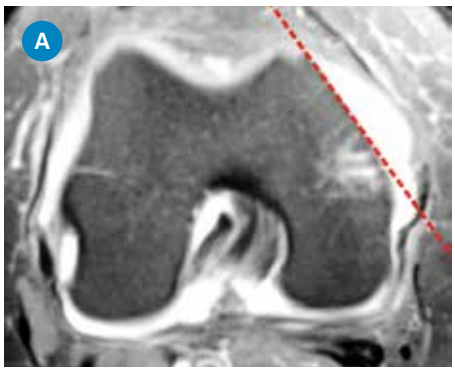
Better lateral:
condyles aligned



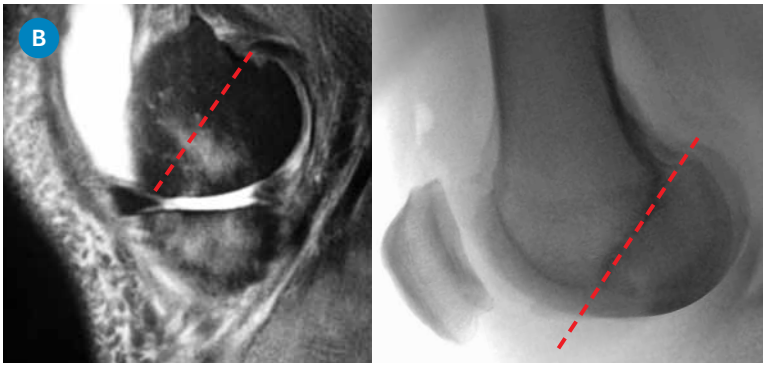
OR Setup/Patient Positioning (cont.)

Identify the joint line (tibial plateau) using lateral fluoroscopy and a Steinmann pin or straight tool; draw a line on the skin. The mark will be used as reference for aligning the navigation guide on the leg or starting FreeHand targeting of plateau lesions.

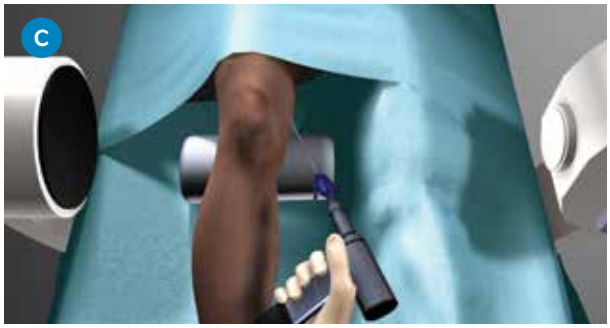
Operative Tip: Use the tip of the pin and lateral fluoroscopy to estimate targeted starting points for tibial and femoral lesions, according to the FreeHand or AccuAim preoperative plan. Mark the skin at these points.



Medial Slope



Location of lesion relative to Blumensaat's line



Targeting and Accessing the Lesion: FreeHand Targeting

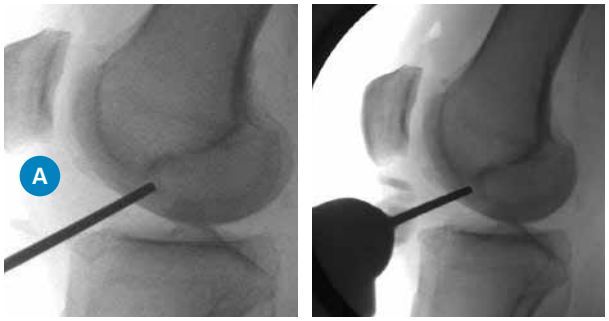
FreeHand Targeting technique uses two orthogonal planes of fluoroscopy and recognizable radiographic landmarks to triangulate to the target (BML bony defect), as localized on MRI during the preoperative plan. Critical to accurate triangulation is obtaining perfect AP and lateral fluoroscopic images, with the knee centered in the X-ray beam, and then following the principle of aiming and drilling along the center of the beam.

Femoral Targeting

The principles described above apply to both tibial and femoral FreeHand targeting. However, due to the more-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 lesions.

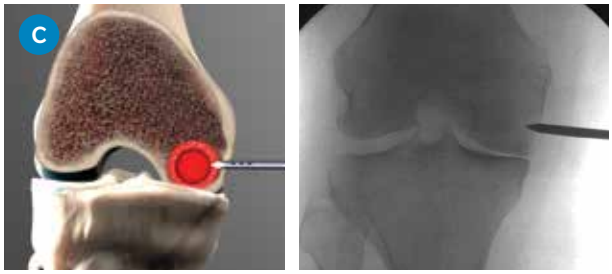
Obtain true AP (A) and true lateral (B) fluoroscopic images of the distal femur (the condyles should align in profile), with the joint line centered in the image; note C-arm tilt and position relative to the OR table/patient in each image, to easily return to that position. Mark the plateau line (and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

Couple the chosen AccuPort cannula to the wire driver (C). 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 (D).



Reposition tip of cannula as needed

Tilt driver and cannula into line of X-ray beam



Targeting and Accessing the Lesion: FreeHand Targeting (cont.)

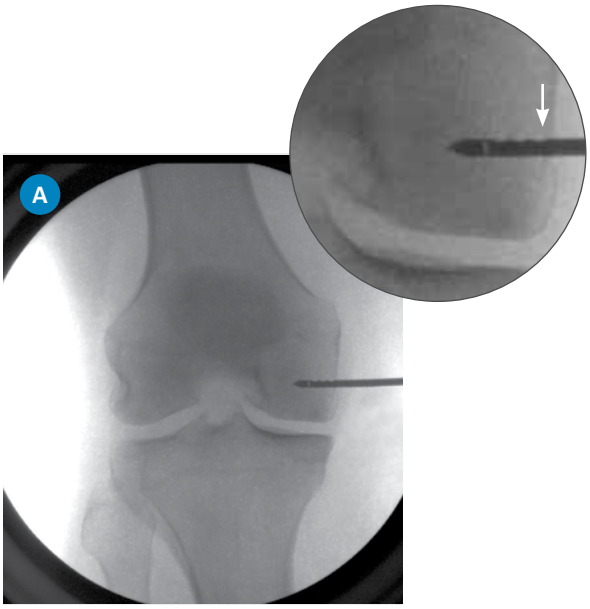
Femoral Targeting (cont.)

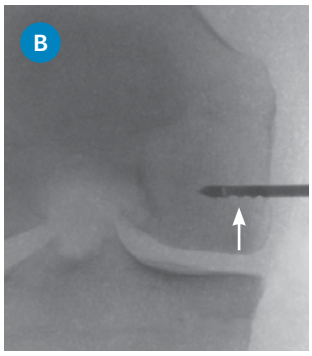
Reposition the tip as needed, in stepwise fashion, until the tip is at the preoperatively-planned location (A).

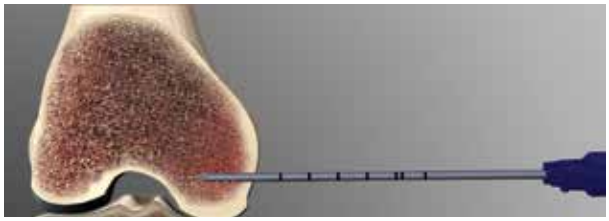
Tilt the wire driver into the beam until the AccuPort cannula is in the center of the X-ray beam (use the C-arm X-ray source as the guide) (B).

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

Surgical Tip: 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, below, in line with planned trajectory.







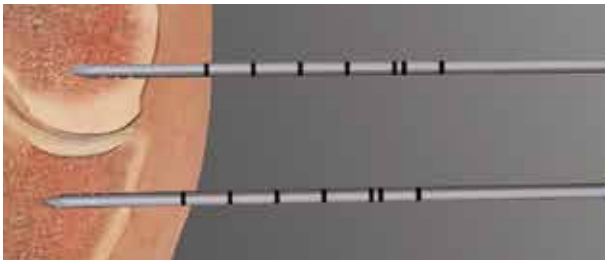
Continue Driling until the cannula is at desired depth

Targeting and Accessing the Lesion: FreeHand Targeting (cont.)

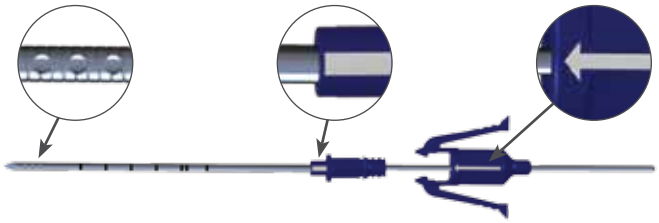
Femoral Targeting (cont.)

Keeping the drill in the center of the beam (aligned with the X-ray source), drill through the cortex, into the bone. 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 (A).

Reconfirm position relative to preoperative plan, with AP and lateral fluoroscopy. Manually rotate the cannula until the fenestrations are pointed in the desired delivery direction (Side-Delivery AccuPort cannula) (B), and then proceed to AccuFill Injection (Implant Placement: "Filling the BML Bone Defect", p. 31).



Surgical Tip 1



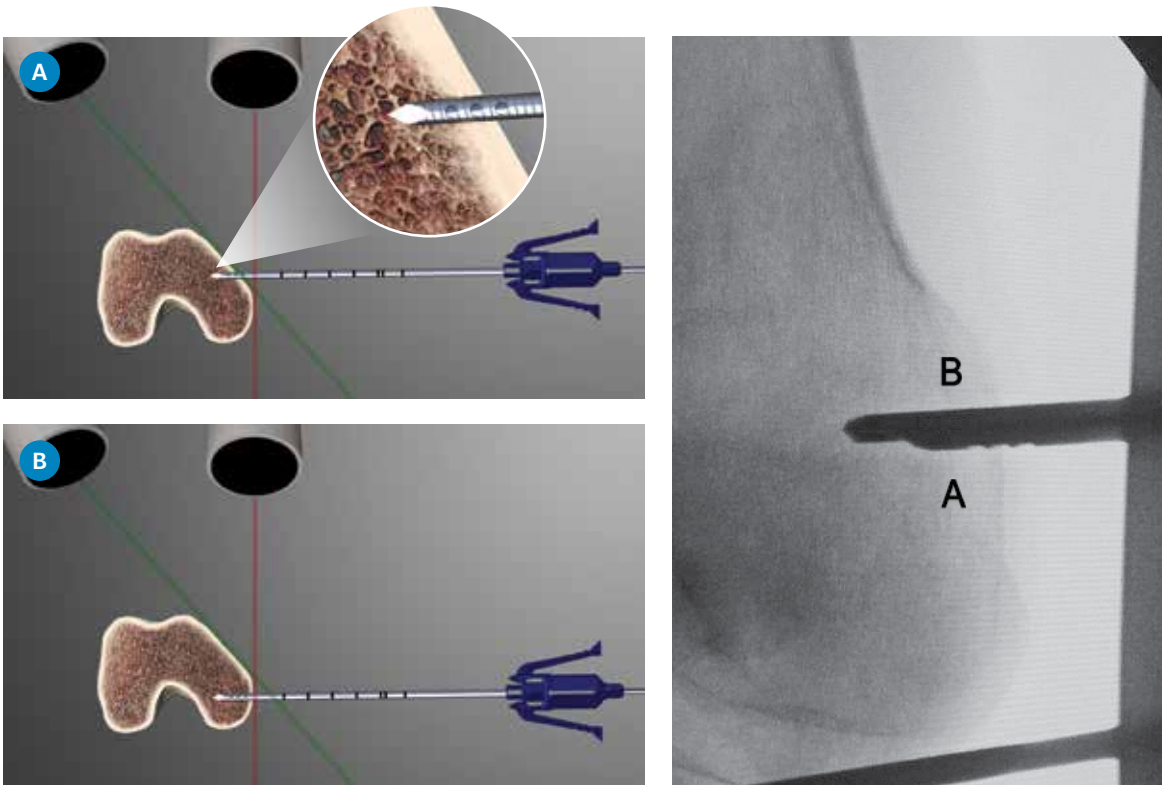
Surgical Tip 2

Targeting and Accessing the Lesion: FreeHand Targeting (cont.)

Femoral Targeting (cont.)

Surgical Tip: Use the 1 cm 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.



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.

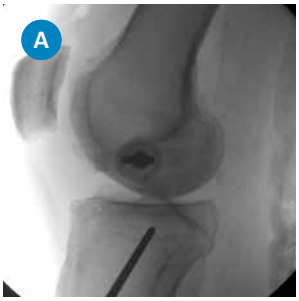
Targeting and Accessing the Lesion: FreeHand Targeting (cont.)

Femoral Targeting (cont.)

Note: To minimize the potential for extravasation of AccuFill BSM (see AccuFill Injection, Implant Placement: "Filling the BML Defect", p. 35), 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 lesion 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.

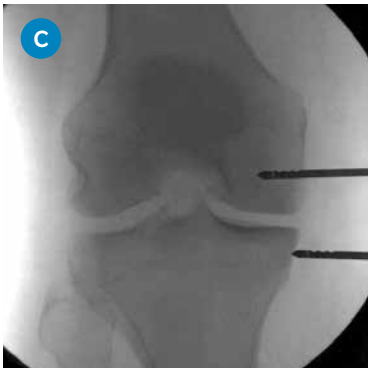
Note: Commit to first trajectory. Avoid creating a second path to reduce extravasation. If undesired trajectory is created:

- Do not attempt to 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.

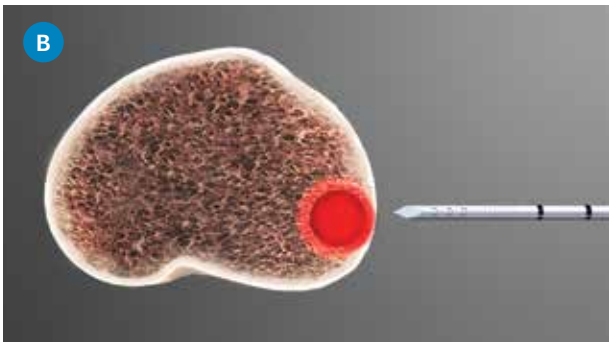


Cannula tip at skin mark; check with Lat fluoro

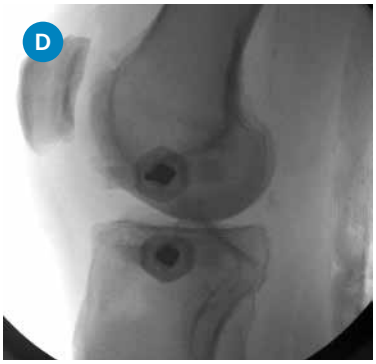
Reposition tip to planned entry point



Confirm height and trajectory in AP



Tilt drill up into X-ray beam



Cannula seen end-to-end

Targeting and Accessing the Lesion: FreeHand Targeting (cont.)

Tibial Targeting

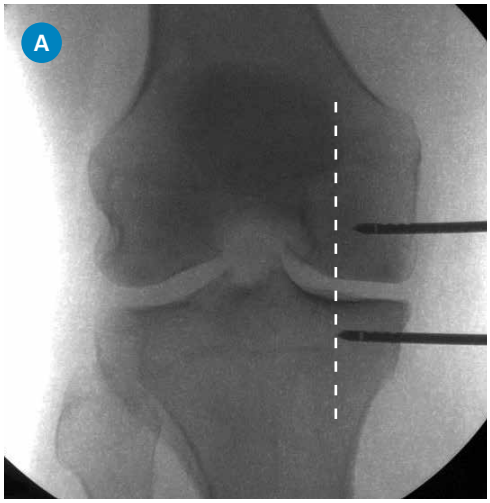
Obtain true AP and lateral fluoroscopic images of the tibial plateau, with the plateau centered in the image (A); note the C-arm tilt and position in each image, to easily return to that position. Mark the plateau line (and other landmarks and approximate entry points as desired).

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.

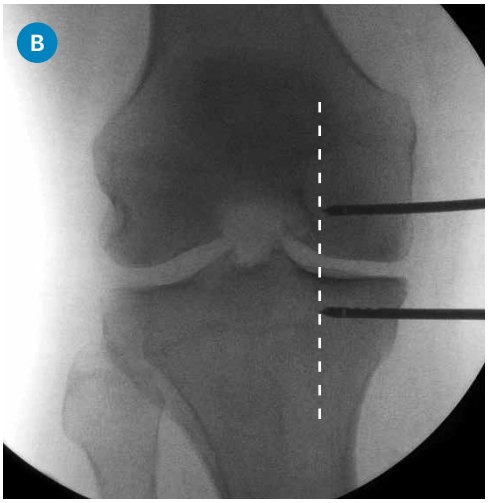
Tilt the drill into the beam until the AccuPort cannula is in the center of the X-ray beam (use the C-arm X-ray source as the guide) (B).

Return the C-arm to true AP position and confirm "height" (distance from plateau) and trajectory.

Surgical Tip: 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.



Drill in the tibial cannula under AP fluoroscopy



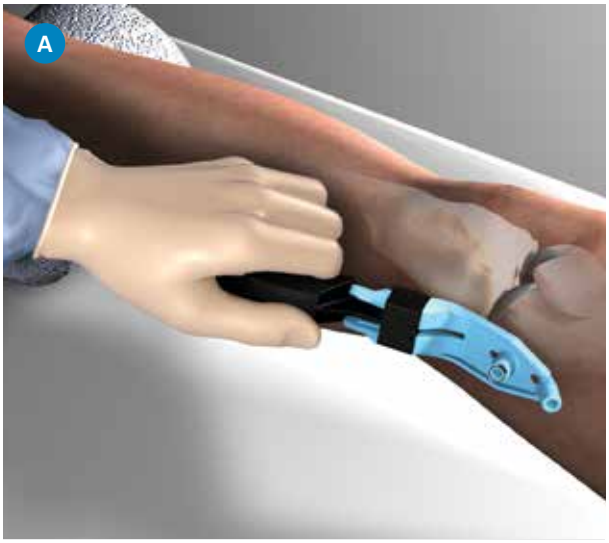
Advance cannulas to desired depth

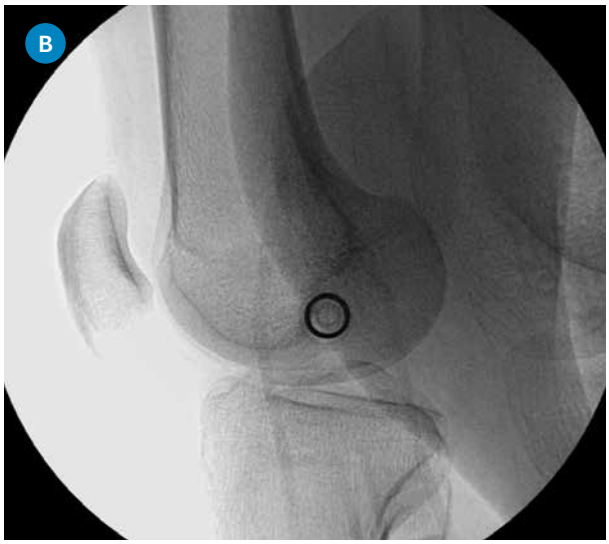
Targeting and Accessing the Lesion: FreeHand Targeting (cont.)

Tibial Targeting (cont.)

Keeping the drill in the center of the beam (aligned with the X-ray source), drill through the cortex, into the bone. 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.

Reconfirm position relative to preoperative plan, using AP and lateral fluoro, and then proceed to AccuFill BSM injection (Implant Placement: "Filling the BML Bone Defect", p. 35).





Target hole bushing "perfect circle"

Targeting and Accessing the Lesion: AccuAim Targeting Guide

For patients with bipolar BML (bone defects in adjacent femoral and tibial compartments), target the femoral defect first so the tibial AccuPort cannula does not interfere with Femoral Guide placement.

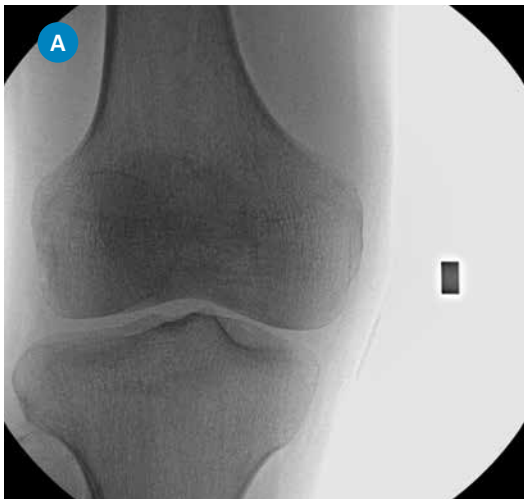
AccuAim Femoral Targeting

Assemble the Femoral Guide to the Handle. Lay the guide on the medial aspect of the leg (for medial condylar BML), with the handle held firmly against the calf (A).

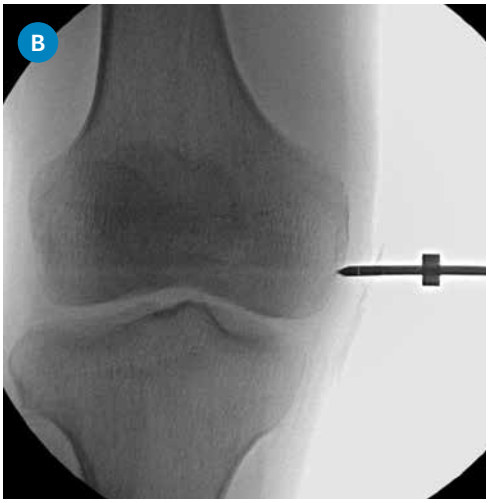
Operative Tip: If a femoral starting point was marked on the skin (see "OR Setup/Patient Positioning", p. 13), set the guide with the target bushing atop the mark.

Under lateral fluoroscopy, adjust the position of the guide until the "perfect circle" of the target (B) hole metal bushing aligns over the preoperatively-determined lesion access. [The trajectory of the bushing will lie within the frontal plane.]

Operative Tip: Wrapping sterile 2-4 inch (5-10 cm) wide elastic bandage (e.g. CoFlex bandage) around the handle and calf can temporarily hold the position of the guide on the leg and allow minute adjustments of guide position.



Confirm bushing "height" under AP fluoroscopy



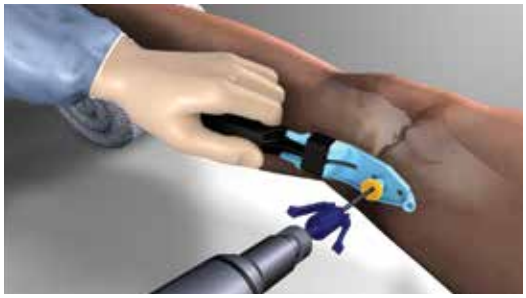
Adaptor Sleeve in aiming hole;
Insert cannula into sleeve; pass to bone

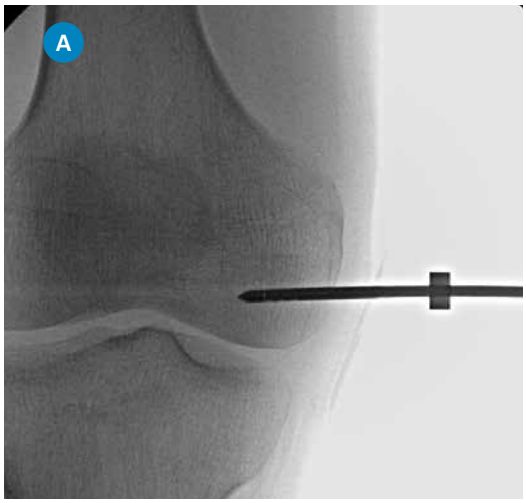
Targeting and Accessing the Lesion: AccuAim Targeting Guide (cont.)

AccuAim Femoral Targeting (cont.)

Insert the chosen Adaptor Sleeve or Depth Control Sleeve into the target hole bushing. Under AP fluoroscopy, confirm proximal-to-distal position ("height") and trajectory of the target bushing, relative to preoperative plan (A).

Assemble the chosen Side- or End-delivery AccuPort Cannula into a surgical wire driver; insert the cannula into the sleeve. Firmly maintaining position of the guide with one hand, pass the cannula through the soft tissue, to the near cortex (B).





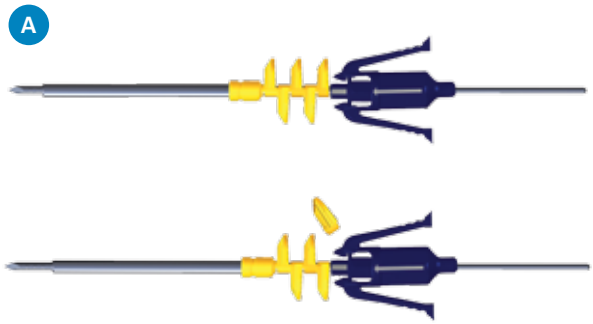
Advance cannula to desired depth. Confirm position with AP and lateral fluoro.

Targeting and Accessing the Lesion: AccuAim Targeting Guide (cont.)

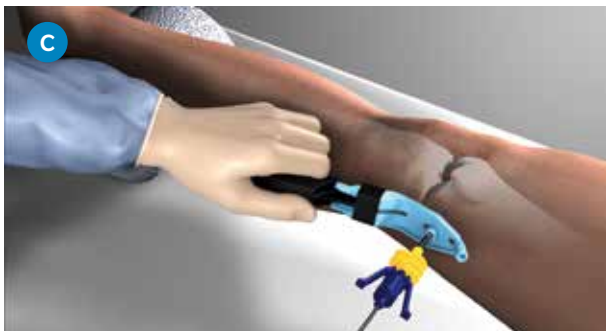
AccuAim Femoral Targeting (cont.)

Reconfirm position and trajectory of the cannula with AP fluoroscopy; fine tune if needed. Then, using full power, drill the AccuPort delivery cannula to the preoperatively-planned, desired depth in the bone, under live or spot AP fluoroscopy:

- Remove the wire driver from the cannula; confirm cannula position with AP and lateral fluoroscopy.
- For isolated femoral compartment lesions, proceed to injection of AccuFill BSM (Implant Placement: "Filling the BML Bone Defect", p. 31).
- For bipolar lesions, detach the handle from the femoral guide and proceed to Tibial Targeting.



Stab incision through slot to insert Depth Control Sleeve to the cortex



Drill cannula to depth stop

Targeting and Accessing the Lesion: AccuAim Targeting Guide (cont.)

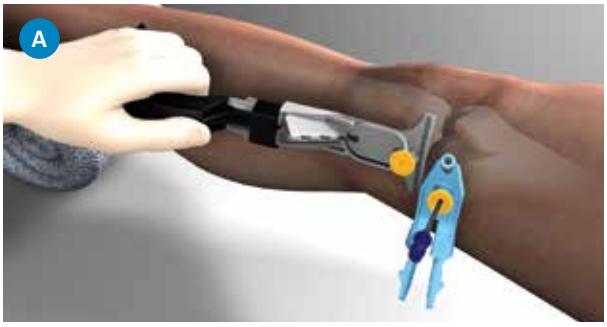
Important Technique Points
Using the Depth Control Sleeve

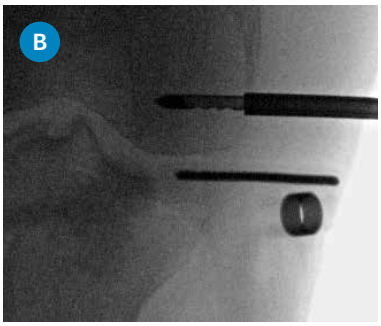
When using the Depth Control Sleeve, always insert the sleeve and cannula together, pre-assembled. Bending pressure on the depth sleeve without the cannula inserted could break tabs prematurely.

As noted earlier (p. 7), when using a side-delivery AccuPort cannula (A), the outermost tab must always be removed to help ensure that all three delivery fenestrations are deep to the cortex. Additional tabs can be removed, as desired, to advance the cannula deeper, in 5 mm increments.

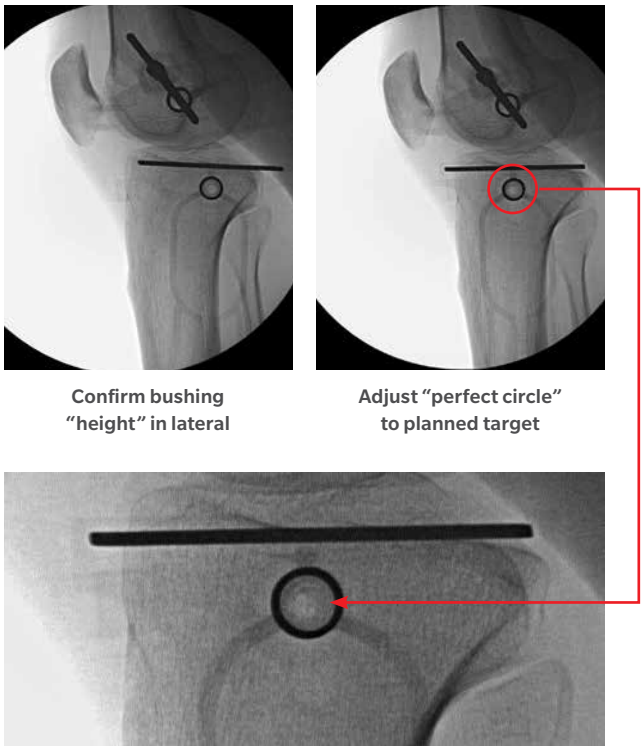
A stab incision to the bone is often required for the depth sleeve to reach the cortex for proper depth control. Make the stab incision using a #11 or 15 blade through the slot beneath the target bushing (B) or a Beaver-type arthroscopy blade through the bushing itself. Reinsert the sleeve and cannula, manually advance the sleeve to the cortex and reconfirm height and trajectory before drilling the cannula into the bone (C).

- Drill AccuPort cannula to depth stop of the sleeve
- Confirm cannula depth, and fenestration orientation and position with AP fluoroscopy (see Implant Placement: "Filling the BML Bone Defect", p. 35)
- Break off additional tabs as needed to drill deeper





Plateau wire and target bushing on AP fluoroscopy



Confirm bushing "height" in lateral

Adjust "perfect circle" to planned target

Perfect circle: smaller circle (ID of Adapter Sleeve) within ring (target bushing)

Targeting and Accessing the Lesion: AccuAim Targeting Guide (cont.)

AccuAim Tibial Targeting

Attach the Tibial Guide to the handle; insert the Adaptor Sleeve into the target hole bushing. Lay the guide on the medial aspect of the tibia (for medial lesion), aligning the top of the guide with the plateau line marked on the skin (A).

Under AP fluoroscopy, confirm that the Guide plateau wire is at (or approximate to) the plateau (B).

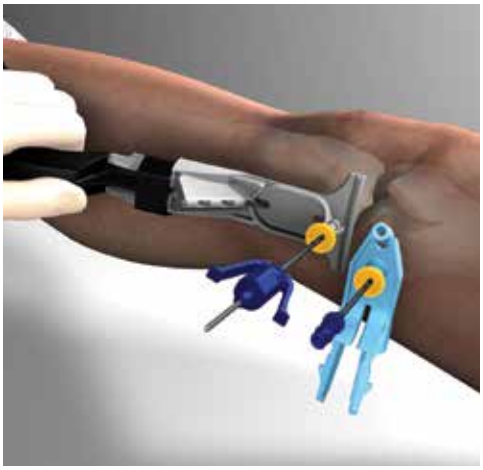
Note: the target hole metal bushing shows up as a rectangle or oval in this shot; it indicates the location for the drill sleeve and AccuPort cannula.

Operative Tip: If a tibial starting point was marked on the skin (p. 12), set the guide with the target bushing atop the mark.

Flip the C-arm to lateral and confirm proximal-to-distal position ("height") of the device using the plateau wire as a guide.

Then, using the target hole metal ring as a "perfect circle" guide, adjust anterior-posterior position to align with the preoperatively-determined lesion access. [The trajectory of the bushing will lie within the frontal plane.]

Operative Tip: A sterile CoFlex wrap can temporarily hold the position of the guide on the leg and allow fine-tuning of guide position (see Femoral Targeting, above).



Targeting and Accessing the Lesion: AccuAim Targeting Guide (cont.)

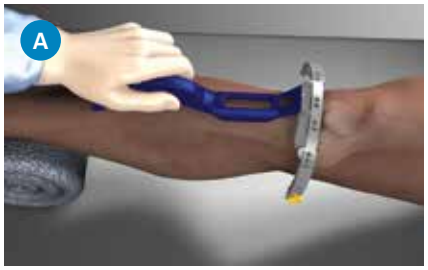
AccuAim Tibial Targeting (cont.)

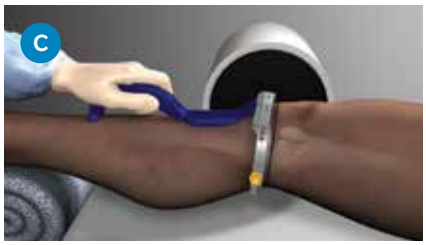
Insert the AccuPort cannula into the Adaptor Sleeve; advance the cannula through the skin to the cortex. Confirm position on lateral fluoro, as needed; then flip the C-arm to AP and confirm height and trajectory of the cannula.

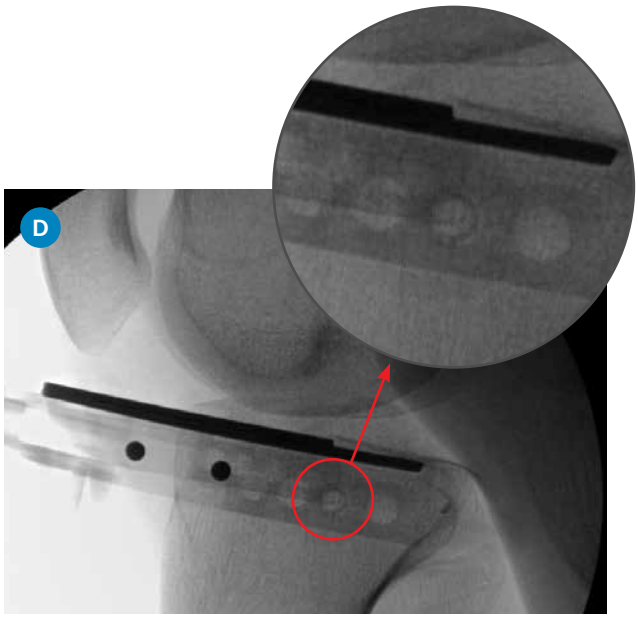
Then, using full power, drill the AccuPort delivery cannula to the preoperatively-planned, desired depth in the bone, under AP fluoroscopy.

Note: When using the Depth Control Sleeve instead of the Adaptor Sleeve, follow the important technique points noted: Femoral Targeting, (see AccuAim Targeting Guide: "AccuAim Femoral Targeting", p. 21).

Remove the Handle from the Tibial Guide; disconnect the wire driver from the AccuPort cannula, and proceed to injection of AccuFill BSM (Implant Placement: "Filling the BML Bone Defect", p. 31).







Perfect circle: smaller circle (ID of Adaptor Sleeve) within Hole 8 of tibial ring

Targeting and Accessing the Lesion: AccuZone Navigation Guide

AccuZone Tibial Targeting

Attach the AccuZone Handle to the Tibial Ring; insert the Adaptor Sleeve into the preoperatively-chosen targeting hole.

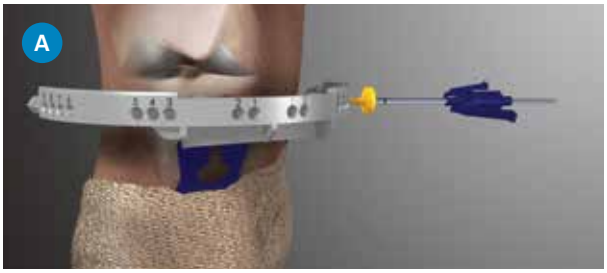
Set the AccuZone guide on the anterior aspect of the leg, with the oblong ring of the Handle centered over the tibial tubercle. [Use the joint line marked on the skin to aid in positioning (A).]

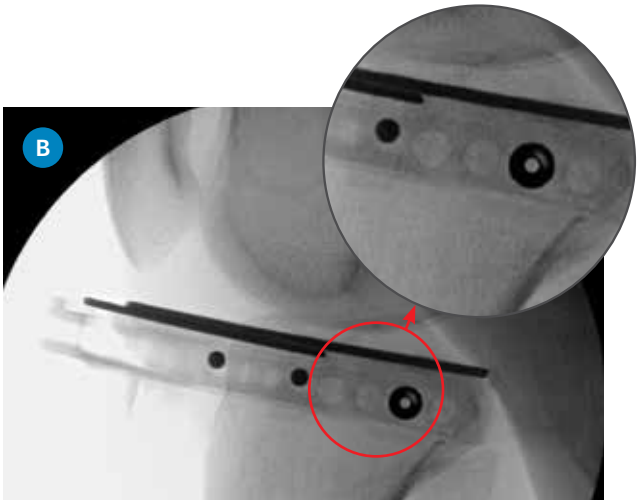
Operative Tip: Wrap sterile 2" or 4" (5-10 cm) CoFlex or other elastic bandage around the handle and leg to hold the guide in position for subsequent steps (B). Small position adjustments are still possible, freeing a hand and simplifying AccuPort insertion and drilling (B).

Under Lateral Fluoroscopy (C)

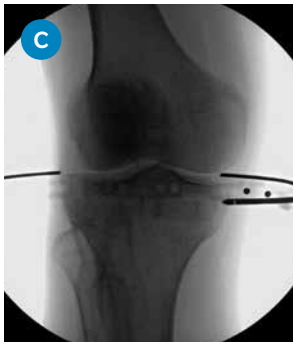
Adjust guide position until the ring wire is aligned with the joint line (plateau) or the target holes are the desired distance distal to the plateau (D) (note: holes are 7 mm below plateau wire, on center).

ID and confirm position of selected target hole, and adjust chosen target hole as needed (reposition Adaptor Sleeve to another hole).

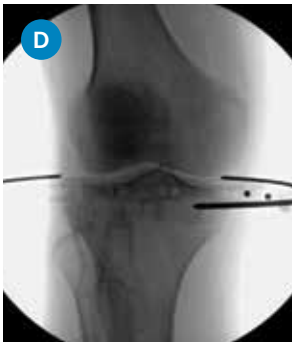




Confirm position under lateral Fluoro



Confirm height and trajectory in AP



Advance cannula to planned depth

Targeting and Accessing the Lesion: AccuZone Navigation Guide (cont.)

AccuZone Tibial Targeting (cont.)

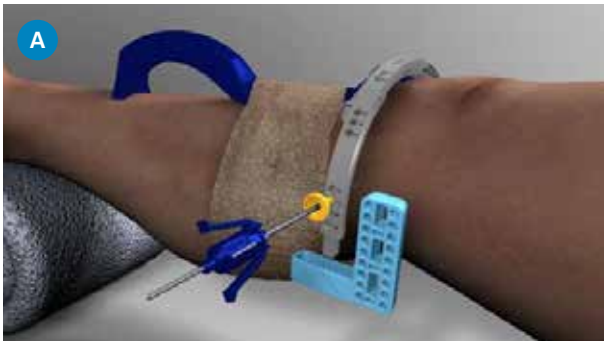
Insert the chosen AccuPort cannula through the Adaptor Sleeve (A), to the skin; confirm position under lateral fluoro (B).

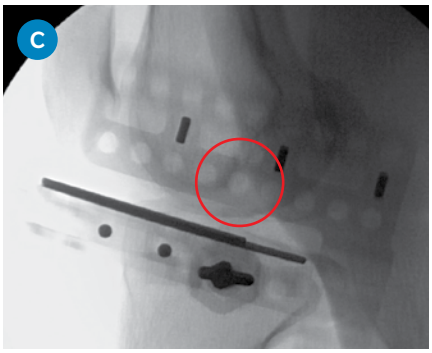
Flip the C-arm to AP and confirm cannula height and trajectory (C). Using full power, advance the cannula through the skin and drill into the bone, to the planned depth and position. Remove the wire driver from the cannula (D).

- For isolated tibial compartment lesions, proceed to injection of AccuFill BSM (Implant Placement: "Filling the BML Bone Defect", p. 31).
- For bipolar lesions, proceed to Femoral Targeting. (p. 29)

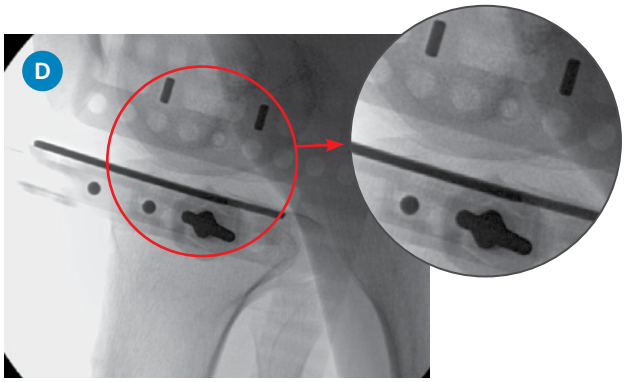
Operative Tip: Use one of the transverse-oriented holes (6-9) and the Depth Control Sleeve to help confirm position of the tibial ring, relative to the preoperative plan, for target correctness:

- Insert the depth sleeve into one of the transverse holes (hole 8, image B, Close Up).
- Under lateral fluoro, adjust the axial rotation of the AccuZone guide until the metal tube of the depth sleeve appears as a dark “perfect circle” in lateral projection (B).
- Note the trajectory of the hole, relative to posterior/central/anterior position of the plateau, as seen in the preoperative plan.
- Accept ring position and reinsert the Adaptor Sleeve into the preselected hole, or move the sleeve to an adjacent hole to better target the area of the lesion.





Attach Femoral Guide to Ring;
ID optimal transverse hole to target lesion



Smaller circle (ID of Adaptor Sleeve in target hole)
aligned to lesion location

Targeting and Accessing the Lesion: AccuZone Navigation Guide (cont.)

AccuZone Femoral Targeting

Preoperative planning for femoral lesions generally follows FreeHand technique, as noted before. However, the Femoral Attachment can be assembled at a KNOWN height (15-45 mm, 5 mm increments) above the plateau line of the Tibial Ring (A, B). By preoperatively determining the desired cannula trajectory on coronal MRI, and then measuring the height of that line above the plateau, the Femoral Attachment can be attached to the Tibial Ring with the transverse targeting holes at that height.

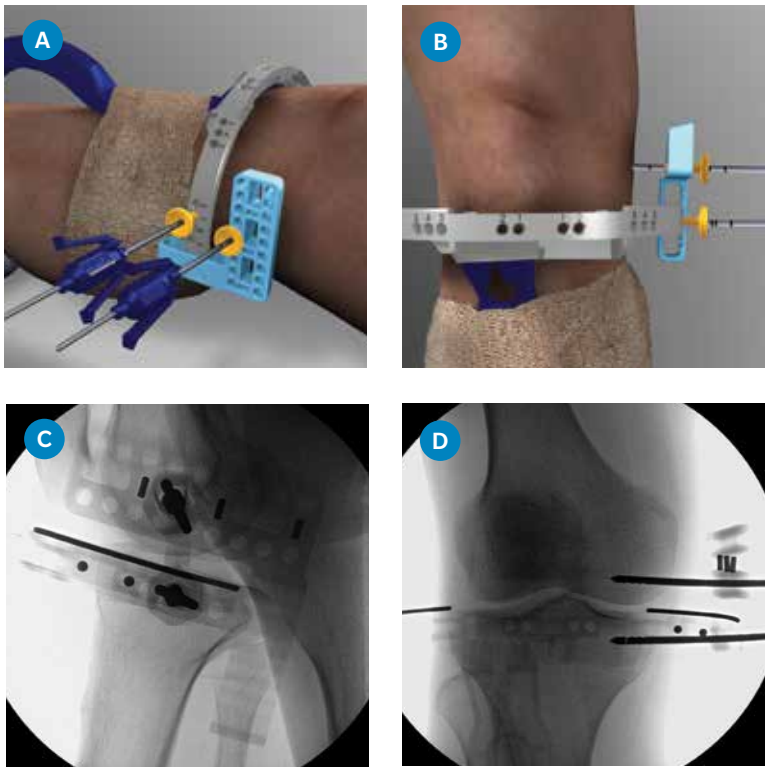
Attach the appropriate Femoral Guide (Attachment) to the Tibial Ring.

Under Lateral Fluorscopy

Note height of the (transverse) lower row of holes, relative to the planned start point and trajectory; adjust height of attachment if needed (5 mm increments).

Note the position of the wire markers in guide, relative to radiographic anatomic landmarks—they can help identify which target hole (A-P) to use, that best matches the preoperative plan (C, D).

Insert the Adaptor Sleeve or Depth Control Sleeve and AccuPort Cannula into the chosen target hole.



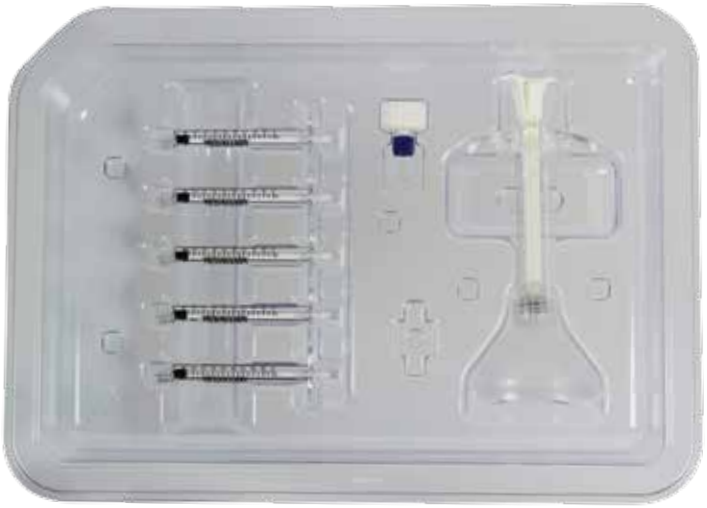
Targeting and Accessing the Lesion: AccuZone Navigation Guide (cont.)

AccuZone Femoral Targeting (cont.)

Insert AccuPort Cannula into Adaptor Sleeve; manually advance cannula to the bone (A, B). Confirm position under lateral fluoro (C).

Swing the C-arm to AP:

- Confirm height and trajectory of the cannula. Couple the drill to the cannula and drill to the desired depth (D).
- Confirm cannula placement and fenestration orientation with AP and lateral fluoro, then proceed to injection of AccuFill BSM (Implant Placement: "Filling the BML Bone Defect", p. 31).



Implant Placement: Filling the BML Bone Defect

AccuFill Bone Substitute Material (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 (see technique) while avoiding down time after cannula insertion. Working time for AccuFill BSM is approximately 15 minutes (maximum time between mix and injection) — 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.

Implant Placement: Filling the Bone Defect

AccuFill BSM Mixing Technique – Setup

The AccuMix system tray (AccuMix system) is sterile, providing 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!**

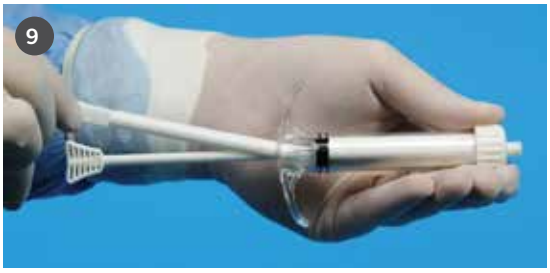
Hydrate

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

   P/N 201.050 (5 cc AccuFill BSM)
   - 3.0 cc Saline
   - Alternative: 3.4 cc Blood

   P/N 201.030 (3 cc AccuFill BSM)
   - 2.0 cc Saline
   - Alternative: 2.3 cc Blood

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.



Implant Placement: Filling the Bone Defect (cont.)

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 adaptor upright, expel excess air from syringe. Connect the first 1cc 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 (cont.)

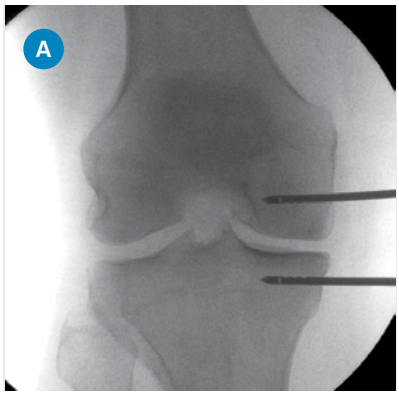
AccuFill BSM Mixing Technique – Bowl Mixing

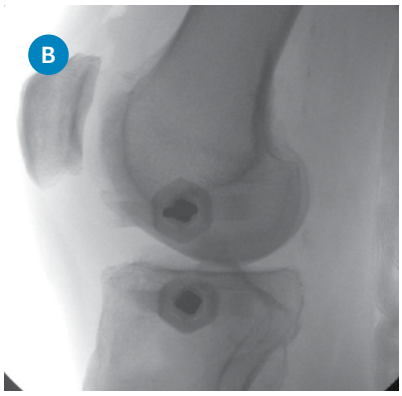
If desired, bowl mixing may be used as an alternative to AccuMix syringe mixing. To avoid drying or stiffening of the AccuFill BSM, bowl mixing should be completed closer to expected injection time. If injection is delayed, protect the mixed BSM and minimize drying potential by covering the material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

1. Remove the seal from the blue jar and remove the vial containing AccuFill BSM powder. Pour powder into jar.
2. Withdraw saline from vial using the saline syringe and adaptor.

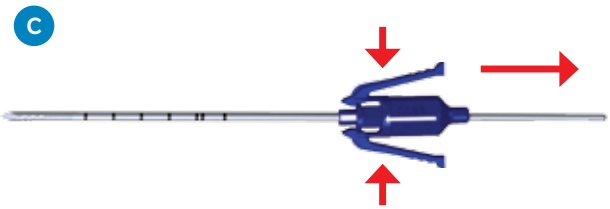
   P/N 201.050 (5 cc AccuFill BSM)
   - 3.0 cc Saline
   - Alternative: 3.4 cc Blood

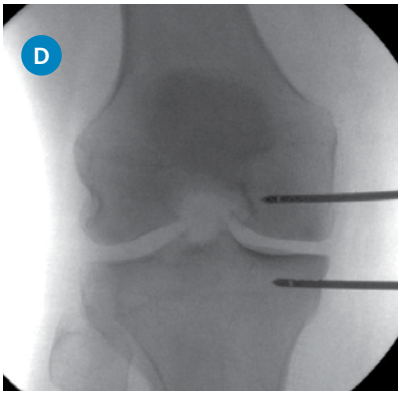
   P/N 201.030 (3 cc AccuFill BSM)
   - 2.0 cc Saline
   - Alternative: 2.3 cc Blood
3. Dispense hydrant into the mixing jar.
4. Using the broader face of the spatula, mix thoroughly for about a minute to form a putty (similar to toothpaste). Use shear force by smearing the material against the side of 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.





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





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

Implant Placement: Filling the Bone Defect (cont.)

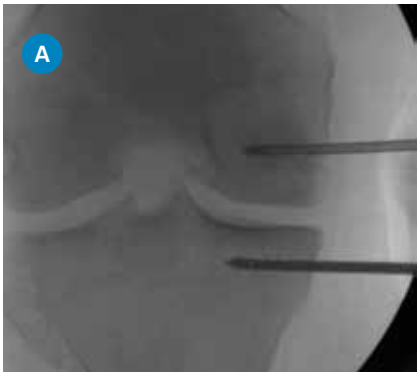
Injecting AccuFill BSM

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

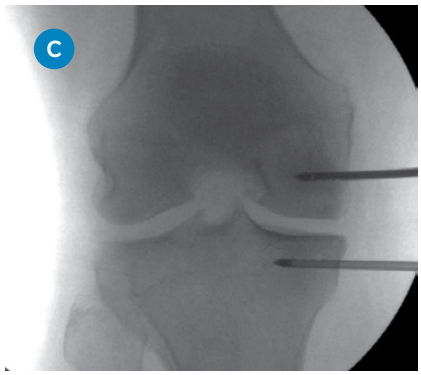
Remove the inner stylus: while holding the cannula body securely with one hand, squeeze together the adaptor locking wings with the other hand and pull the stylus out (C). Set the stylus on the sterile field (Mayo stand or back table) — **DO NOT DISCARD!**

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.



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



Replace femoral stylus.
Remove tibial stylus and inject AccuFill BSM.

Implant Placement: Filling the Bone Defect (cont.)

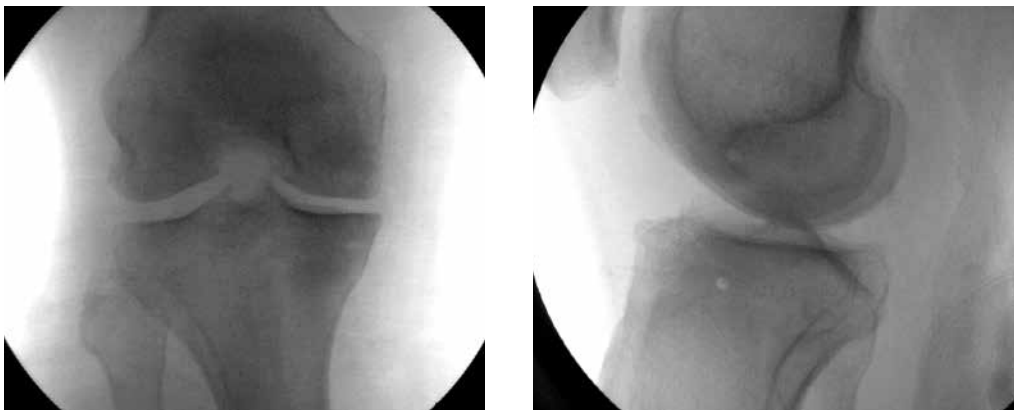
Injecting AccuFill BSM (cont.)

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

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

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

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.



Injections completed, AccuPort cannulas removed

Implant Placement: Filling the Bone Defect (cont.)

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 extravasized 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.

Operative Tip: When attaching and removing 1cc syringes from the cannula, grip the hub firmly to avoid rotating the cannula.

Operative Tip: The first 0.7cc 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.

Operative Tip: 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".

Operative Tip: 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.

Ordering Information

AccuPort Cannulas

Product	Description	Part Number
	**AccuPort Side-Delivery Cannula; 11 Ga (Ø 3.0 mm), 120 mm**	307.032
	**AccuPort End-Delivery Cannula; 11 Ga (Ø 3.0 mm), 120 mm**	307.034
	**AccuPort End-Delivery Cannula; 15 Ga (Ø 1.6 mm), 60 mm Drill Length**	308.151

SCP Navigation Guides

Product	Description	Part Number
	**AccuZone Navigation Guide**	310.100
	**AccuAim Targeting Guide**	323.100

AccuMix Mixing System

Product	Description	Part Number
	**AccuMix Mixing System**	331.100
	Replacement Parts for AccuMix Mixing System	311.102
	SCP Delivery Syringe 5-Pack	303.250

AccuFill BSM

Product	Description	Part Number
	**AccuFill Bone Substitute Material, 5 cc**	201.150
	AccuFill Bone Substitute Material, 3 cc	201.130

Notes

This material is intended for health care professionals and the Zimmer Biomet sales force. Not intended for surgeons practicing medicine in France. Distribution to any other recipient is prohibited.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. The treating surgeon is responsible for determining the appropriate treatment, techniques(s), and product(s) for each individual patient.

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AccuPort®, AccuMix®, AccuZone®, and AccuAim® are Manufactured by: Zimmer Knee Creations, 841 Springdale Drive, Exton, PA 19341 USA. AccuFill® is Manufactured by: ETEX Corporation, 38 Sidney Street, Cambridge, MA 02139 USA.

For complete product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.

Check for country product clearances and reference product specific instructions for use.

Not for distribution in France.

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