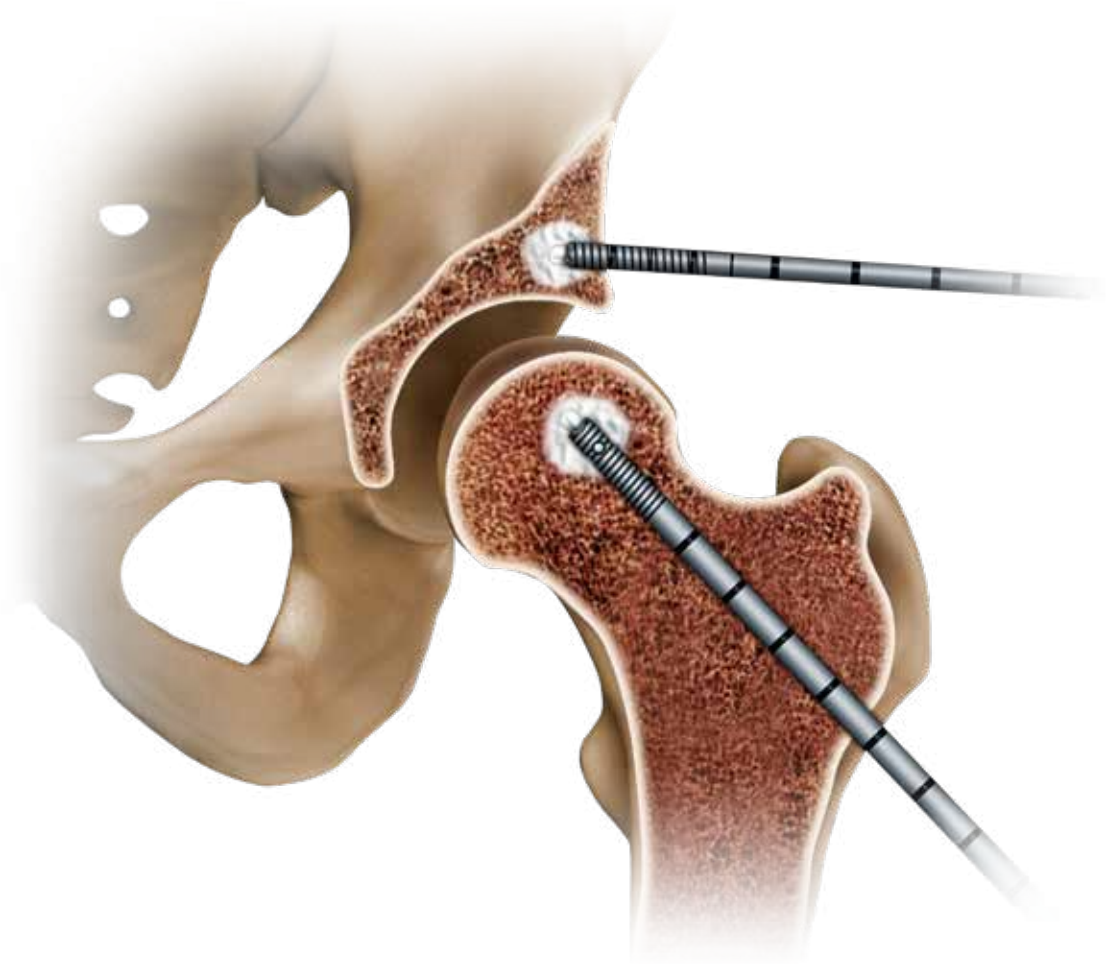
# The Subchondroplasty® (SCP®) Procedure for the Hip

## Surgical Technique



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## Symbols Convention

This document employs the following conventions:

**NOTE:** This symbol is present to provide a general observation or information to procedures, events or practices which are recommended or essential for a successful operation.

**CAUTION:** This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

## The Subchondroplasty® (SCP®) Procedure

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills small subchondral bone defects with AccuFill® Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute. Defects filled in the SCP procedure are those not intrinsic to the stability of the overall structure, including areas of bone damage typically caused by trauma, such as:

- defects associated with bone marrow lesions
- insufficiency or microtrabecular fractures
- repetitive stress injuries of cancellous bone
- cysts

The procedure is usually performed with arthroscopy of the affected hip, for visualization and treatment of findings inside the joint.

## The Subchondroplasty Procedure consists of four components:

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

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

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

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

## AccuFill BSM Indications for Use:

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

# Features and Benefits

## The Subchondroplasty (SCP) Procedure

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

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

## AccuFill Bone Substitute Material (BSM)

**The injectable Calcium Phosphate (CaP) for the SCP Procedure**

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

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

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

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

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

5 OssiPro K062630 (510(K) internal document)

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

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

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

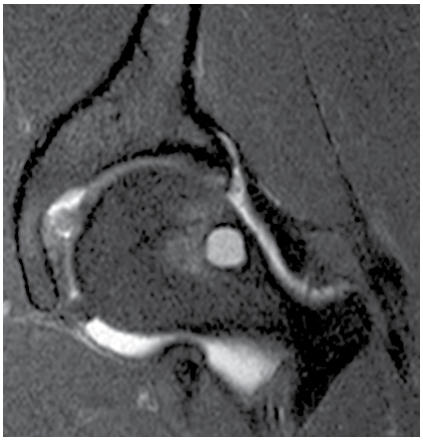
**** based on calcium phosphate Alpha-BSM

# Femoral Head Surgical Technique

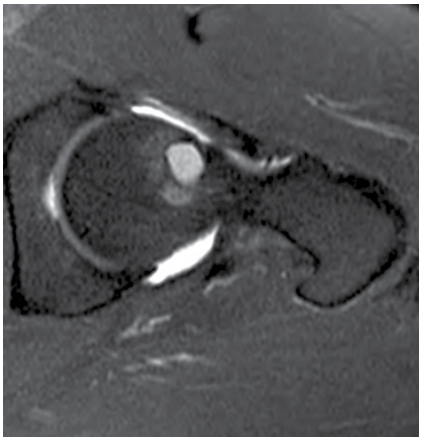
## Preoperative Planning

In the hip, subchondral bone defects may present radiographically as microtrabecular or insufficiency fractures sometimes called bone marrow lesions (BML) – or cystic lesions, or a combination of both. Cystic lesions are often visible on X-ray (plain films or CT), but BML are not visible on X-ray and are only identifiable on MRI. BML are also not visible on intraoperative fluoroscopy, so to target the defect, the surgeon must use the patient's MRI to determine the location of the bony defect relative to radiographic landmarks. This preoperative plan is used intraoperatively to target the defect with fluoroscopy – and arthroscopy, as needed – for optimal AccuFill BSM implantation.

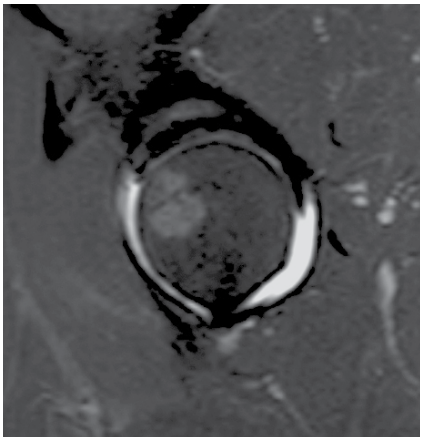
- Using all three MRI views (axial, coronal and sagittal), localize the BML by:
  - Distance from the joint.
  - Soft tissue thickness.
  - Depth - superficial or deep to cortex.
  - Anterior or posterior positioning.
- Plan approach and trajectory based on T1 image defect location.
  - Hip traction is not needed for femoral head cannula insertion. To minimize traction time when treating defects in both the femoral head and acetabulum, place the AccuPort cannula in the femoral head first. Then begin standard hip arthroscopy.
- Determine which AccuPort Cannula(s) will be used.



Coronal T2 FS MRI



Axial T2 FS MRI



Sagittal T2 FS MRI

## Femoral Head Surgical Technique

The Subchondroplasty Procedure for the femoral head is usually performed with arthroscopy, for visualization and treatment of findings inside the joint. The AccuPort cannula should be placed prior to performing arthroscopy to limit traction time and to allow for maneuvering of the hip during cannula placement. Arthroscopy is recommended to be performed after injection of AccuFill BSM to confirm that no extravasation occurred.

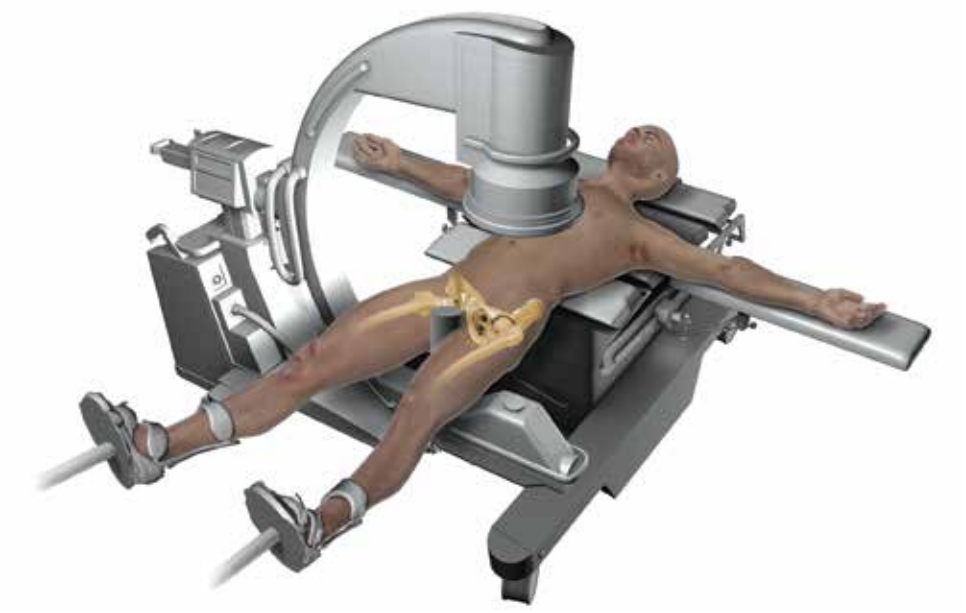
**NOTE:** When performing arthroscopy after BSM injection, remember that the AccuPort cannula must be left in the bone for 10 minutes while the BSM sets, to minimize potential for extravasation

Take care while manipulating the hip during scoping, to avoid bending forces on the cannula that may damage the cannula or surrounding bone.

**Important Safety 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. AccuFill BSM is not intended for the treatment of cartilage defects or injury. AccuFill BSM is not intended to support articular cartilage or cortical bone.

## OR Setup

- Position the patient supine on a fracture table or with hip distractor.
- Internally rotate the operative limb to align the femoral neck parallel to the floor.
- Prep and drape as for hip arthroscopy procedure.
- Position C-Arm on the opposite side of the hip being treated or between the legs.



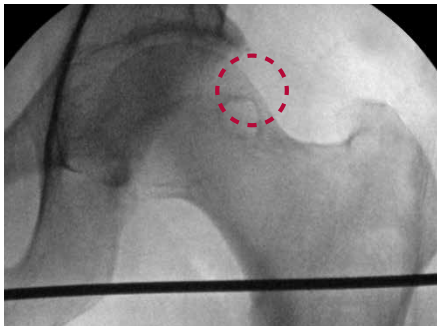
Typical OR setup for left hip procedure

# Targeting and Accessing the Defect

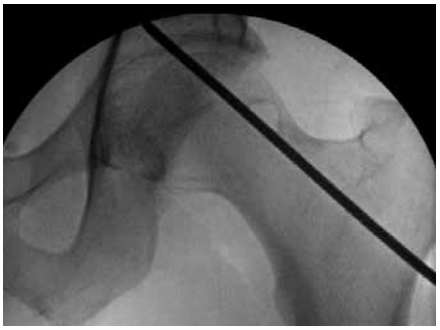
## Femoral Targeting

The targeting technique uses two orthogonal planes of fluoroscopy and recognizable radiographic landmarks to triangulate to the target (subchondral bone defect), as localized on MRI during the pre-operative plan. Critical to accurate triangulation is obtaining perfect AP and frog lateral fluoroscopic views to avoid over-penetration and minimize re-directing of the cannula.

- Internally rotate the leg with the traction table to obtain AP fluoroscopic images with the femoral head centered in the image. Mark the lesser trochanter and neck-shaft angle (NSA) of the proximal femur (and other landmarks and approximate entry points as desired).

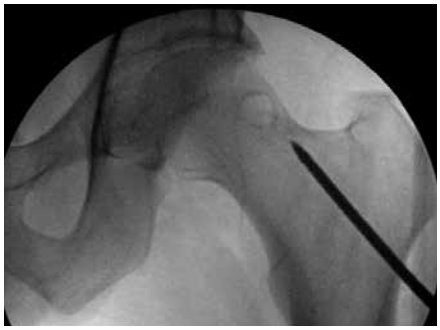


Steinmann pin used to mark lesser trochanter; note circled femoral head cyst

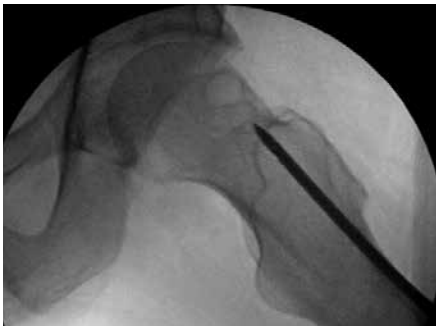


Steinmann pin used to mark neck shaft angle

- Palpate and mark the anterior and posterior margins of the femoral shaft. Take into account the amount of soft tissue between the skin and the lateral femoral cortex to ensure entry above the lesser trochanter. This allows for the end of the cannula to remain outside of the soft tissue. Make an incision in the lateral skin in line with the NSA.
- Couple the chosen AccuPort cannula to a wire driver or chuck. Place the tip of the cannula through the incision against the lateral femoral cortex above the lesser trochanter and confirm with AP fluoroscopy.
- Advance the AccuPort cannula approximately half the distance up the femoral neck.



AccuPort Cannula drilled into the femoral neck



Frog lateral view confirming proper cannula angle

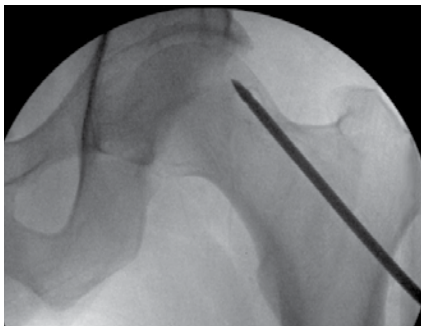
- Unlock the leg rotation on the traction table and flex the hip to varying Dunn lateral views (30°, 45°, etc) up to 90° and obtain a frog lateral view confirming proper lateral entry point and angle toward the femoral head defect.
  – If redirection of the cannula is required, back up the cannula until the trocar tip is outside of the bone and repeat the previous steps.

## Targeting and Accessing the Defect

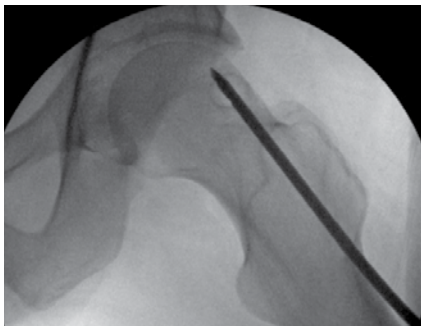
### Femoral Targeting (cont.)

- Finish advancing the cannula to the subchondral bone defect alternating between AP and frog lateral/Dunn views.

**NOTE:** To avoid penetrating the cortex, alternate between AP and frog lateral views to ensure proper cannula placement.



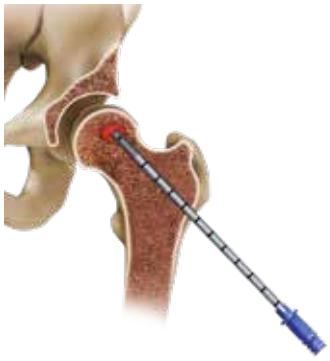
Cannula placed into area of bone defect

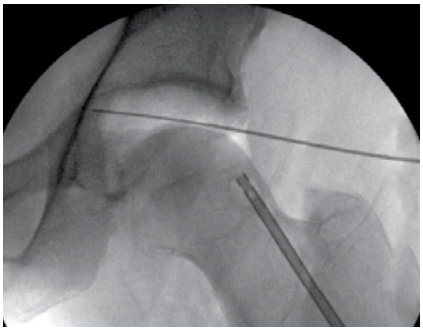


Frog lateral view confirming proper placement into bone defect

- 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. Keep the stylus in the sterile field (Mayo stand or back table). **DO NOT DISCARD!**

**NOTE:** Once the cannula is in place, reverse the wire driver briefly to disengage the stylus from the cannula.





Stylus removed and joint being prepared for arthroscopy

- Begin standard hip arthroscopy followed by injection of BSM into the defect.

**Operative Tip:** Heat may be generated while drilling into dense bone. To reduce cannula temperature, before injecting BSM, flush the cannula with 2 cc of saline.

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

**NOTE:** Reminder to use the T1 image as a reference for targeting accuracy and volume.

# Instructions for using 4.5mm drill & 3.2mm guidewire to drill 8 ga Cannulas

## SCP procedure using Zimmer Biomet Trauma Cannulated Drill Bits

- Triangulate location of defect as usual (using fluoroscopy)
- Mark the lesser trochanter and neck-shaft angle of the proximal femur (and other landmarks) to approximate entry points as desired
- Make incision lateral skin in line with neck-shaft angle
- Couple 3.2mm guidewire to wire driver and pass tip of guidewire through incision against the lateral femoral cortex above the lesser trochanter (confirm with AP fluoroscopy)
- Advance 3.2mm guidewire about half the distance up the femoral neck using AP fluoroscopy
- Confirm proper lateral entry point and angle toward bone defect (redirect if needed by backing up the guidewire until tip is outside of bone and repeat above steps)
- Finish advancing guidewire to bone defect and confirm wire position with AP and lateral fluoroscopic views
- Attach 4.5mm cannulated drill bit to drill
- Slide the drill bit over the guidewire to the lateral femoral cortex
- Advance the drill bit over the guidewire at full drill speed to about half to two-thirds the distance to the defect
- Remove drill bit and separate AccuPort cannula from stylus
- Manually slide cannula over guidewire and pass to the drilled depth; confirm with fluoroscopy
- Remove guidewire; insert AccuPort stylus and couple to wire driver
- Advance cannula using power to desired location; confirm with fluoroscopy
- Begin standard hip arthroscopy, followed by injection of BSM into defect

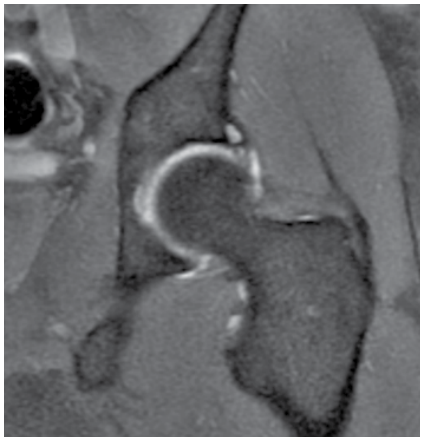
| Zimmer Biomet Items |
|---|
| **Cannulated Drill, 3.2 mm (11 ga equivalent)** |
| **2.4 mm x 9 in Partial Thread Trocar Tip Guide Pin** |
| **2.4 mm x 9 in Smooth Shaft Trocar Tip Guide Pin** |
| **Cannulated Drill, 4.5 mm (8 ga equivalent)** |
| **3.2 mm x 9 in Partial Thread Trocar Tip Guide Pin** |
| **3.2 mm x 9 in Smooth Shaft Trocar Tip Guide Pin** |
| **Guide Pin 3.2 mm x 12 in Partial Thread Trocar Tip** |
| **Guide Pin 3.2 mm x 12 in Smooth Shaft Trocar Tip** |

# Acetabulum Surgical Technique

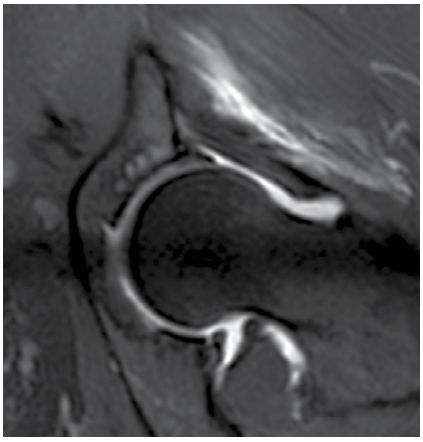
## Preoperative Planning

In the hip, subchondral bone defects may present radiographically as microtrabecular or insufficiency fractures – sometime called bone marrow lesions (BML) – or cystic lesions, or combination of both. Cystic lesions are often visible on X-ray (plain films or CT); but BML are not visible on X-ray and are only identifiable on MRI. BML are also not visible on intraoperative fluoroscopy, so to target the defect, the surgeon must use the patient's MRI to determine the location of the bony defect relative to radiographic landmarks. This preoperative plan is used intraoperatively to target the defect with fluoroscopy – and arthroscopy, as needed – for optimal AccuFill BSM implantation.

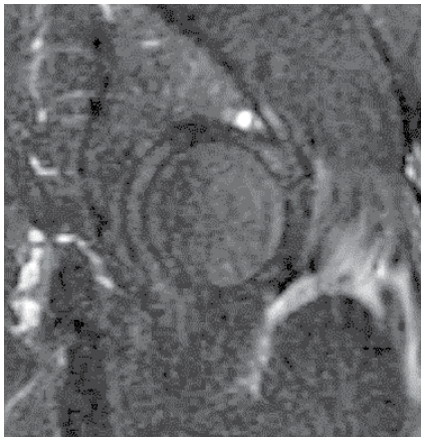
- Using all three MRI views (axial, coronal, and sagittal), localize the defect by:
  - Distance from the joint.
  - Soft tissue thickness.
  - Depth - superficial or deep to cortex.
  - Anterior or posterior positioning.
- Plan approach and trajectory based on defect location(s).



Coronal T2 FS MRI



Axial T2 FS MRI



Sagittal T2 FS MRI

## Preoperative Planning (Cont.)

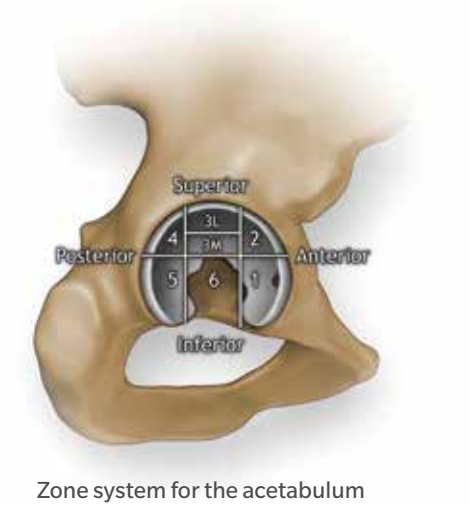
- Common locations for bone defects in the acetabulum and accessory portal options are:

  1. Anterolateral at the area of maximal impingement beneath the anterior inferior iliac spine (AIIS) (zone 2).
     – A superolateral accessory portal can be utilized.

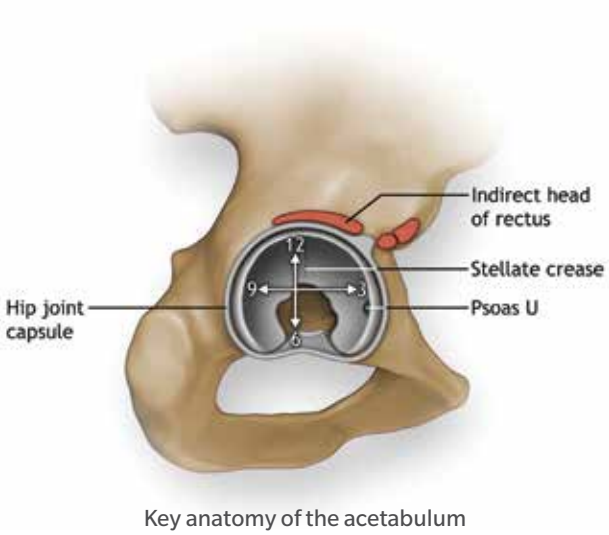
  2. Centrolateral at the superior weight-bearing area lateral to the stellate crease (zone 3L).
     – A posterolateral accessory portal can be utilized.

  3. Anteromedial near psoas U/iliopubic groove (junction of zone 1 & 2).
     – A DALA accessory portal can be utilized.

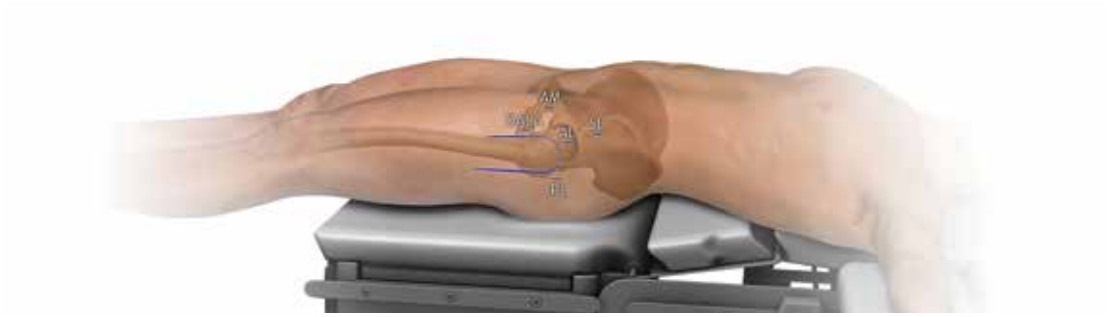
- Determine which AccuPort Cannula(s) will be used.




Zone system for the acetabulum




Key anatomy of the acetabulum



Arthroscopic portal options for the hip

## Acetabulum Surgical Technique

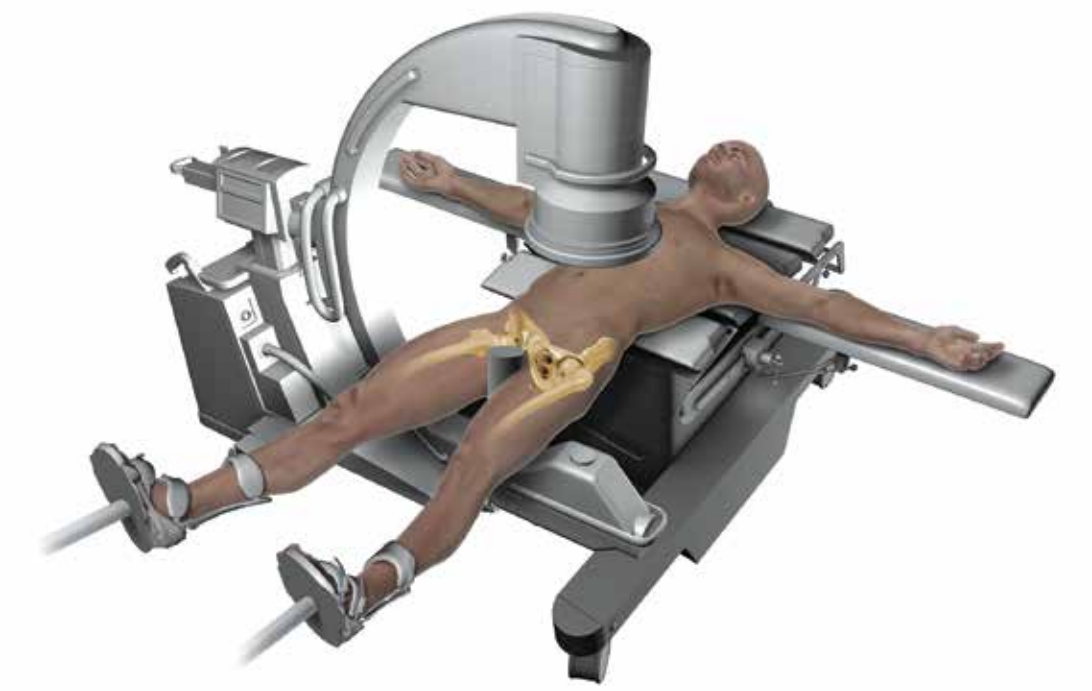
The Subchondroplasty Procedure for the acetabulum is performed with arthroscopy, for visualization and treatment of findings inside the joint. Most surgeons perform arthroscopy first, to evaluate the joint cartilage and cortical bone adjacent to the subchondral bone defect before injecting AccuFill BSM. Procedures including acetabuloplasty, femoroplasty, microfracture and anchor drilling should not be performed until the BSM is allowed to set and the cannula has been removed, to prevent extravasation into the joint.

**NOTE:** When performing arthroscopy after BSM injection, remember that the AccuPort cannula must be left in the bone for 10 minutes while the BSM sets, to minimize potential for extravasation.

**Important Safety 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. AccuFill BSM is not intended for the treatment of cartilage defects or injury. AccuFill BSM is not intended to support articular cartilage or cortical bone.

## OR Setup

- Position the patient for standard hip arthroscopy.
- Affix a traction device to the operative leg at the foot.
- Position C-Arm opposite the leg being treated or between the patient's legs.
- Prep and drape for standard hip arthroscopy; apply traction.
- Create standard hip arthroscopy portals.



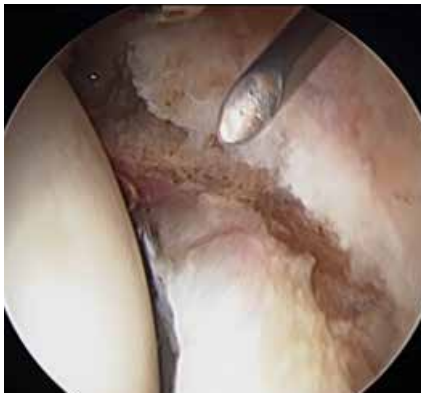
Typical OR setup for left hip procedure

# Targeting and Accessing the Defect

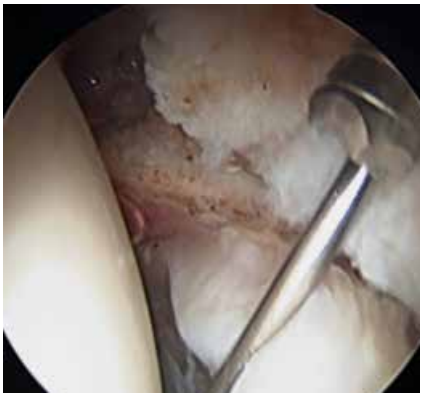
## Acetabular Targeting

- An accessory portal must be created if the surgeon wants to continue arthroscopy while AccuPort cannula is in place and BSM is setting.
  - To create an accessory portal, insert a spinal needle into the joint based on the preoperative plan; remove needle stylus.
  - Insert a 1.1 mm nitinol guidewire through the spinal needle, remove the spinal needle and make a small incision in the skin.
  - Separate the inner stylus from the AccuPort cannula and thread the outer cannula over the nitinol guidewire.
  - Remove the nitinol guidewire and reconnect the stylus with the cannula.

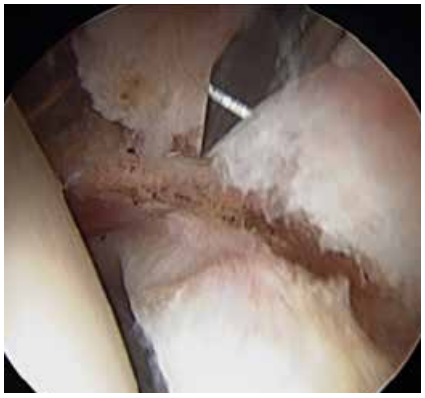
BML identified in Hip



Injection needle placed through superolateral portal while viewing from anterolateral portal

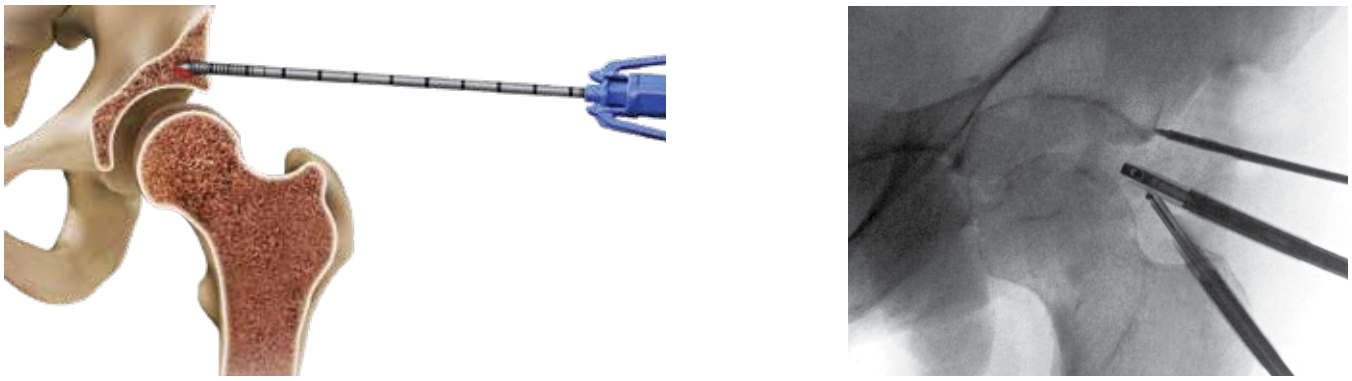


AccuPort Cannula placed over nitinol wire



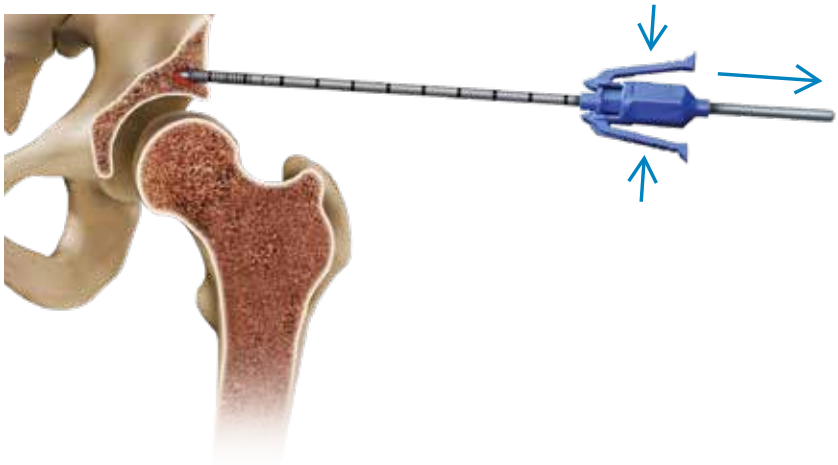
Stylus inserted and reconnected to cannula

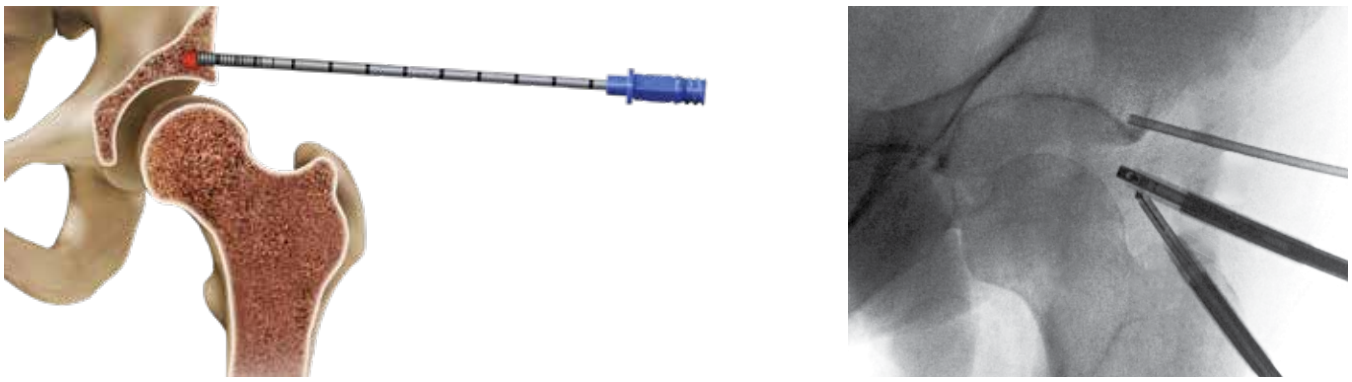
- While monitoring with fluoroscopy, attach the wire driver to the cannula and position 5-10 mm superior to the labrum and corresponding to the location of the defect.
- Reposition the tip of the cannula, as needed, to avoid a trajectory that would penetrate the joint surface.
- Drill the AccuPort cannula into the bone at the area of the defect and confirm cannula position with AP and Judet fluoroscopic views.



AccuPort cannula prior to placement of AccuFill BSM

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





AccuPort Cannula after placement and stylus removed

**Operative Tip:** A nitinol guidewire may be inserted through the cannula to confirm placement in bone.

- **NOTE:** Once the cannula is in place, reverse the wire driver briefly to disengage the stylus from the cannula.
- **NOTE:** Allow AccuPort to cool prior to injection of the AccuFill.
- **NOTE:** Reminder to use the T1 image as a reference for targeting accuracy and volume.

# Implant Placement: Filling the Bone Defect

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





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

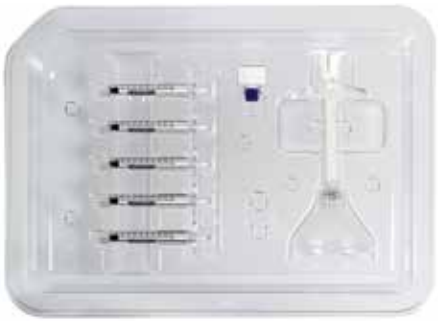
**AccuMix Mixing System**

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

**AccuFill BSM Mixing Technique Setup:**

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

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



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

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

**Hydrate:**

4. Using standard technique, connect the saline syringe and adaptor to the saline vial, injecting air into the saline vial and then draw back the desired amount of saline.

   – 5 cc AccuFill BSM
   - 3.0 cc saline
   - Alternative: 3.4 cc whole blood

   – 3 cc AccuFill BSM
   - 2.0 cc saline
   - Alternative: 2.3 cc whole blood

## Implant Placement: Filling the Bone Defect (cont.)







**AccuFill BSM Mixing Technique**

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

**Mix:**

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

**Transfer:**

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

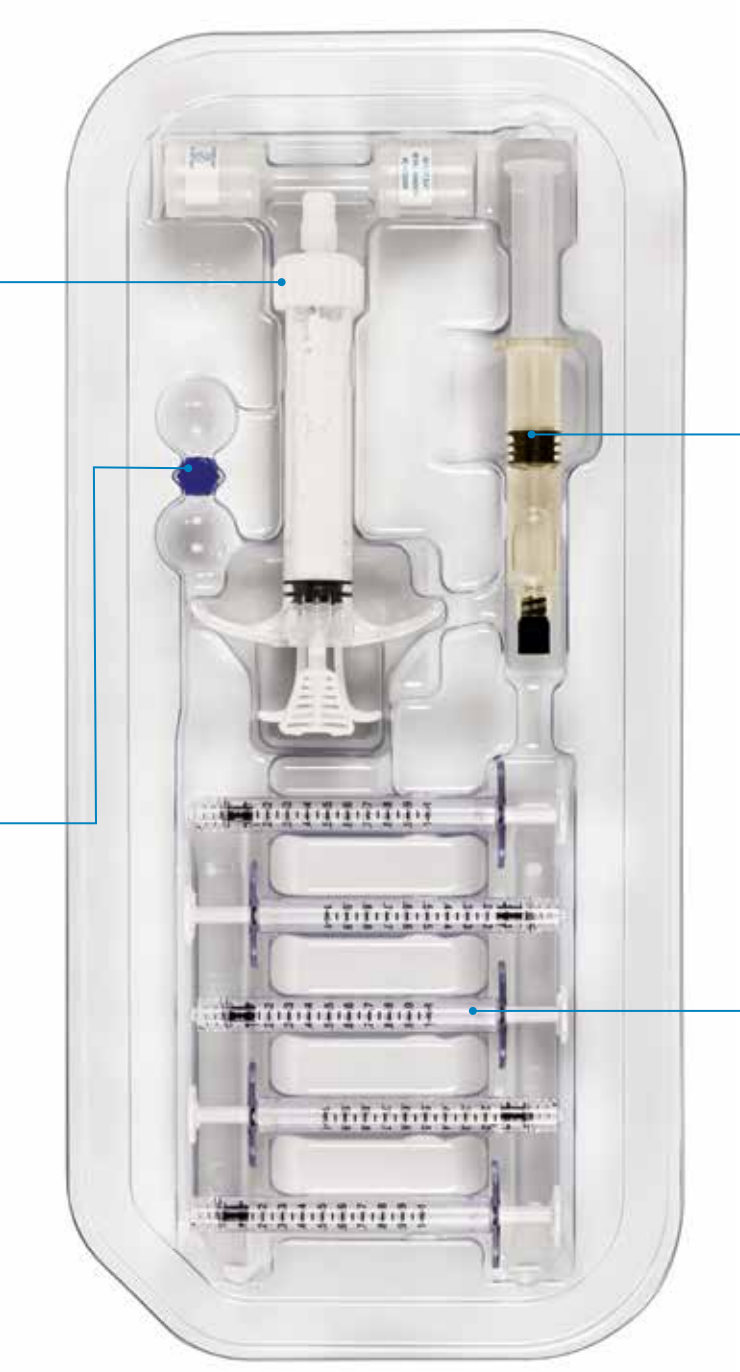
    Connect the first 1 cc syringe. Inject AccuFill BSM into syringe. Repeat for remaining syringes.

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

## Implant Placement: Filling the Bone Defect

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

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



## Implant Placement: Filling the Bone Defect (cont.)

**AccuFill PF BSM Mixing Technique**

**Hydrate:**

1. Transfer the tray to the sterile field (back table). Remove the AccuFill PF BSM prefilled mixing syringe from tray. Pull on plunger tab to extend the stem completely from within the syringe.

   **NOTE:** Before connecting the saline syringe, lightly tap on the full prefilled mixing syringe to loosen the AccuFill Powder, which can get compacted.

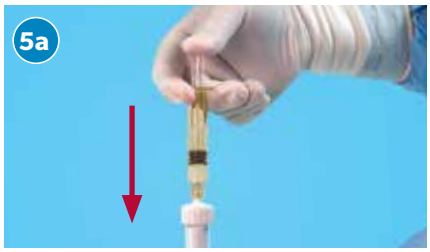
2. Remove and discard the plug from the prefilled mixing syringe.
3. Remove the prefilled saline syringe from tray. Remove and discard the plug.
4. There is no need to expel air from the saline syringe. Holding the mixing syringe vertically, connect and tighten the saline syringe to the mixing syringe. See image for correct orientation.

   **NOTE:** To avoid expelling saline, do not expel air from the prefilled saline syringe.

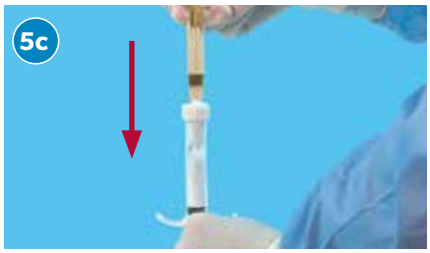
5. Holding the syringes vertically, inject full volume of saline down into the mixing syringe (5a). Pull up on the saline syringe plunger to pull excess air into the syringe (5b). Inject again, to ensure **ALL SALINE FLOWS INTO POWDER** (5c). Repeat to release pressure before removing saline syringe.
6. Attach and tighten the blue LUER lock plug onto the mixing syringe.









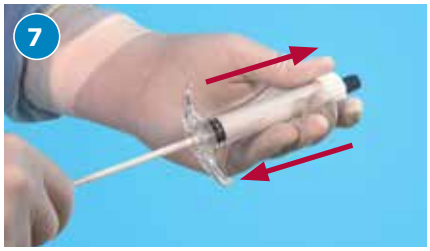



## Implant Placement: Filling the Bone Defect (cont.)

**AccuFill PF BSM Mixing Technique**

**Mix:**

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





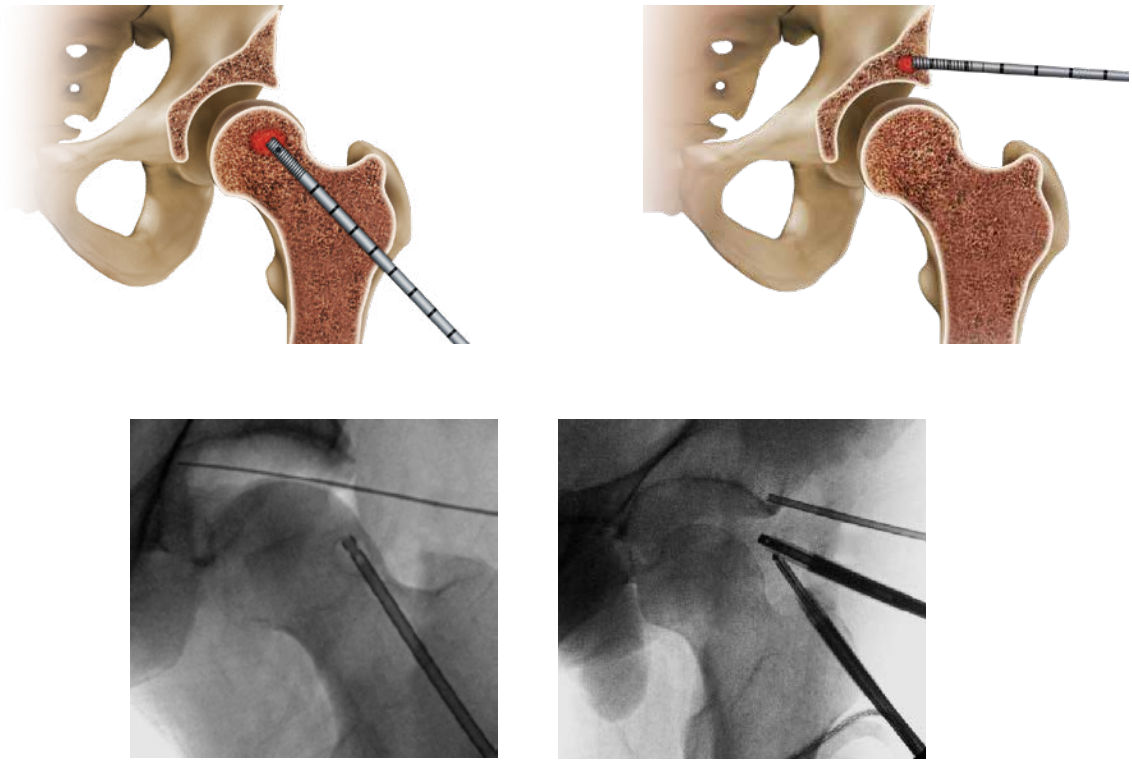

**Transfer:**

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

## Injecting AccuFill BSM

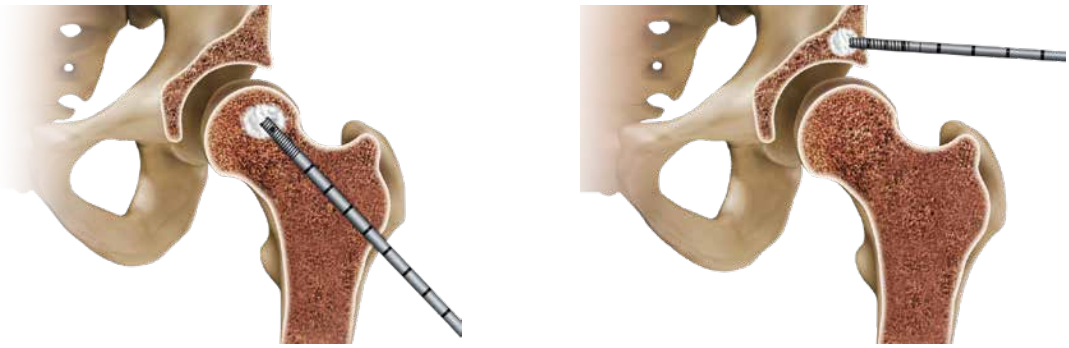
If treating both femoral and acetabular defects, injection of BSM can be performed after both cannulas are inserted.

- Confirm AccuPort cannula placement with AP and lateral fluoroscopy. Manually rotate the cannula to direct flow toward the defect.
- Attach the first 1 cc syringe of AccuFill mix to the cannula hub; firmly tighten the leur lock connector.
- Inject AccuFill BSM using steady manual pressure.



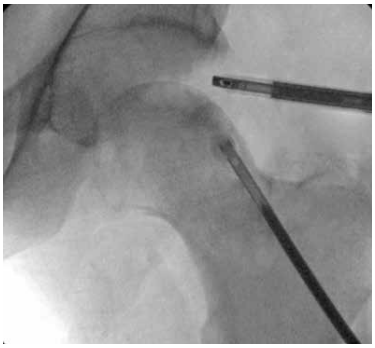
AccuPort cannula ready for BSM injection

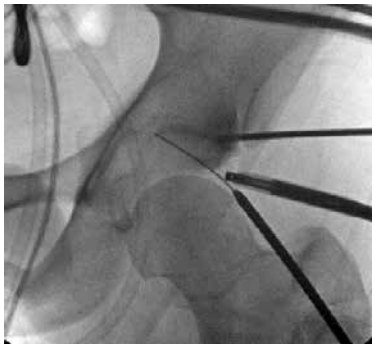
- Remove the first syringe and repeat until desired volume has been injected into the cannula.



Injection of AccuFill BSM

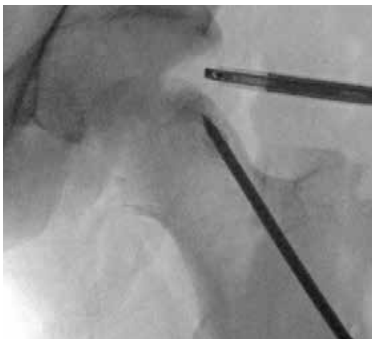
- Insert the stylus back into the cannula slowly to plunge the remaining 1-2 cc of AccuFill BSM; insert the stylus fully until locking wings are secured to the hub.

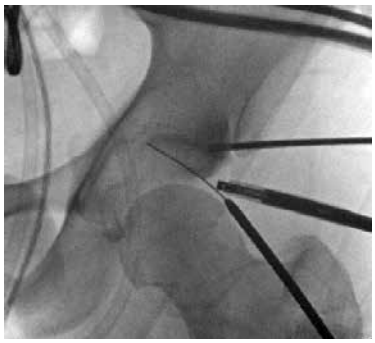




After BSM injection, reinserting the stylus

- Leave the cannula in the bone for 10 minutes to allow BSM to set. Use the scope to evaluate for and evacuate any extravasized material.



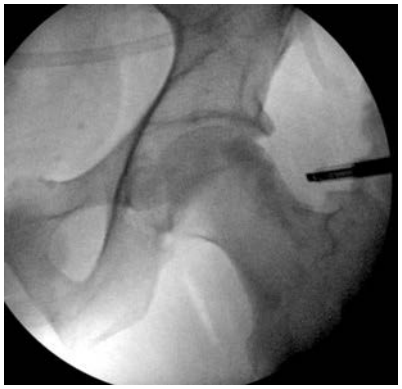


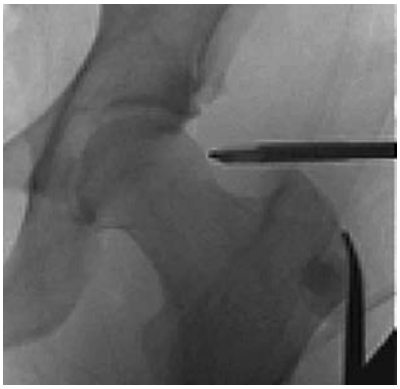
Stylus reconnected with cannula

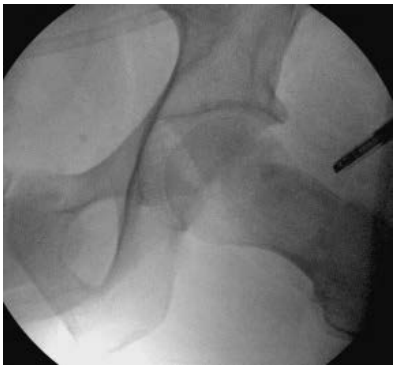
**Operative Tip:** If an accessory portal was used to place the cannula, the surgeon can continue arthroscopy while BSM is setting.

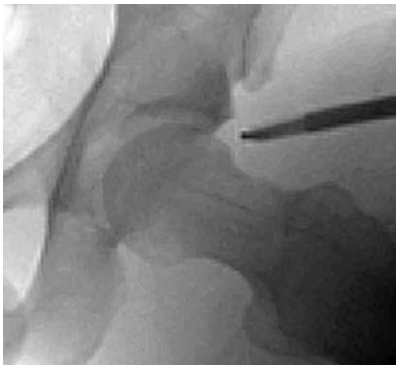
- Remove the cannula: reconnect the wire driver to the cannula stylus; use reverse torque while pulling back.
- Ensure no excess bone substitute emerges from the insertion portal. Using fluoroscopic imaging, ensure that AccuFill implant is properly placed. Seal all incisions.

**Important Safety 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. AccuFill BSM is not intended for the treatment of cartilage defects or injury. AccuFill BSM is not intended to support articular cartilage or cortical bone.









BSM injection complete, cannula removed

## **Injecting AccuFill BSM** (cont.)

**Operative Tips**

- While drilling, the cannula hub can wedge into the stylus. To facilitate removal of the stylus, hit reverse on the wire driver briefly.
- 1 cc of AccuFill BSM fills the 11 ga, 200 mm AccuPort cannula; once the BSM fills the cannula and starts flowing into the subchondral cancellous bone, back pressure will increase. Release digital pressure and then slowly reapply it until the material starts to flow again.
- 2 cc of AccuFill BSM fills the 8 ga, 200 mm AccuPort cannula.
- Monitor flow and volume of the AccuFill BSM into the trabecular bone under fluoroscopy. If the BSM is not readily seen on the C-arm monitor, contrast between bone and BSM may be improved by manually changing fluoroscopy settings more toward bone x-ray settings (decreasing KVP and/or increasing MA) or switching between normal image and negative.
- To avoid having a large amount of AccuFill BSM extravasate into the joint, a small amount of AccuFill BSM can be injected into the cannula initially.
- Using scope, look for extravasation. If extravasation occurs, remove AccuFill with arthroscopy shaver or RF.
- To fill the drill path with AccuFill BSM, the cannula can be slowly removed while plunging the stylus.
- The AccuPort cannula should be left in the bone for 10 minutes to minimize potential for extravasation of unset BSM.
- Allow AccuFill BSM to fully set prior to performing acetabuloplasty, femoroplasty, microfracture or anchor drilling.

**NOTE:** Always confirm AccuPort cannula position with AP and lateral fluoroscopy before injecting!

**NOTE:** Do not overfill the defect site. Over-pressurizing the defect may lead to extrusion beyond the site of intended application and damage to surrounding tissues. For most femoral head defects, 3-5 cc of BSM will fill the defect and for most acetabular defects, 2-3 cc of BSM will fill the defect.*

**NOTE:** Reminder to use the T1 image as a reference for targeting accuracy and volume.

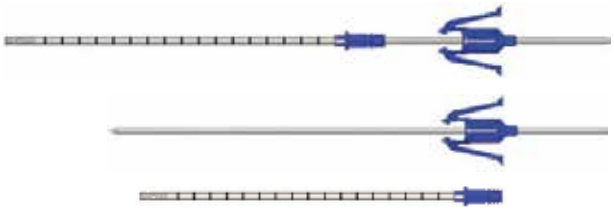
*Hip SCP Surgeon Advisory Group suggestions, Meeting Notes 4/2016.

# Implants and Instruments

## AccuPort Delivery® Cannulas

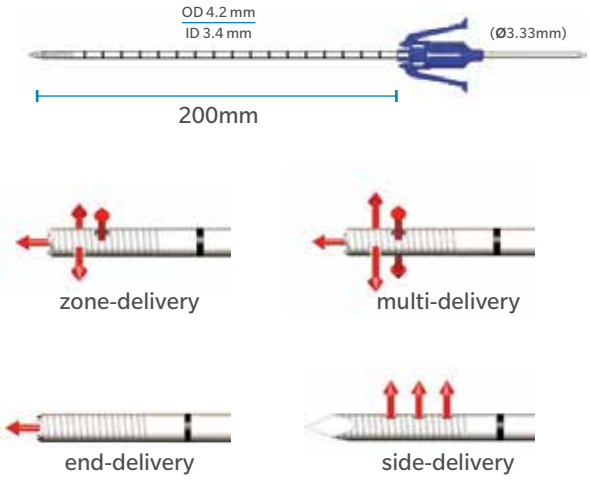
AccuPort Cannulas consist of two components that connect to make one instrument. All cannulas are trocar tipped for cutting ability, and include a stylus that locks to the cannula to allow self-drilling insertion using a standard OR wire driver or chuck.

Choice of appropriate AccuPort Delivery Cannula for injection of AccuFill BSM is dependent on location, size, and quality of the defect.



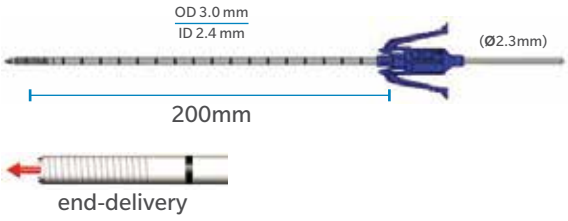
### AccuPort 8 ga, 200 mm Cannulas

- Commonly used for femoral head procedures.
- 200 mm drillable length.
- Outer diameter (OD) 4.2 mm.
- Inner diameter (ID) 3.4 mm.
- Trocar tip extends 7 mm past the end of the cannula (Side-Delivery n/a).
- 2 cc of AccuFill BSM fills the cannula.
- Available in 4 options:
  - Zone-Delivery
  - Multi-Delivery
  - End-Delivery
  - Side-Delivery




### AccuPort 11 ga, 200 mm Cannulas

- Commonly used for acetabulum procedures.
- 200 mm drillable length.
- 3.0 mm OD, 2.4 mm ID.
- Trocar tip extends 4.5 mm past the end of the cannula.
- 1 cc of AccuFill BSM fills the cannula.
- Visual etchings for intraoperative depth control.
- End-Delivery only.

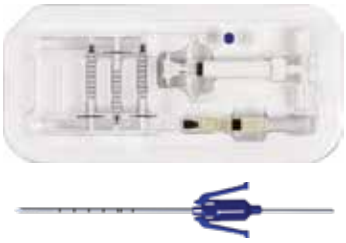
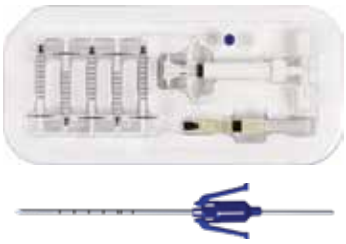


# Ordering Information

## AccuPort

| Product | Description | Part Number |
|---|---|---|
|  | **AccuPort Side-Delivery Cannula; 11 ga (3.0 mm OD), 120 mm Drill Length** | 307.032 |
|  | **AccuPort End-Delivery Cannula; 11 ga (3.0 mm OD), 120 mm Drill Length** | 307.034 |
|  | **AccuPort End-Delivery Cannula; 11 ga (3.0 mm OD), 200 mm Drill Length** | 308.041 |
|  | **AccuPort Multi-Delivery Cannula; 8 ga (4.2 mm OD), 200 mm Drill Length** | 308.083 |
|  | **AccuPort Zone-Delivery Cannula; 8 ga (4.2 mm OD), 200 mm Drill Length** | 308.084 |

## SCP Prefill Kits (Packaged with AccuPort Cannula)

| Product | Description | Part Number |
|---|---|---|
|  3 cc | **SCP Prefill Kit, 3cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm** | 464302 |
| | **SCP Prefill Kit, 3cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm** | 464303 |
|  5 cc | **SCP Prefill Kit, 5cc Side-Delivery, 11 ga (3.0 mm OD) x 120 mm** | 464502 |
| | **SCP Prefill Kit, 5cc End-Delivery, 11 ga (3.0 mm OD) x 120 mm** | 464503 |

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

# Ordering Information (Continued)

## SCP Complete Kits

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

## AccuMix Mixing System

| Product | Description | Part Number |
|---|---|---|
|  | **AccuMix Mixing System** | 311.100 |

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.



**Legal Manufacturer**
Zimmer Knee Creations
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581
USA

**AccuFill BSM manufactured by**
ETEX Corporation
55 Messina Drive
Braintree, MA 02184
USA

ZIMMER BIOMET
Moving You Forward.™

3922.1-US-en-Issue Date 2023-03

**www.zimmerbiomet.com**