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 (BML)
• 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 BML bone defect on MRI; plan approach and trajectory based on defect location.

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

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

FILL THE BONE DEFECT: Inject AccuFill BSM into the subchondral bone defect.

AccuFill BSM Indications for Use:

AccuFill 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 Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.
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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 defect location(s).
  - 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 (refer to page 20).
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. When performing arthroscopy after injection of BSM, 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).

- 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.

- 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.

- 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.

**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.

• Begin standard hip arthroscopy followed by injection of BSM into the defect (see page 14 for Implant Placement: Filling The Bone Defect).
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).
Preoperative Planning (contd.)

- 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 (refer to page 20).
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.

**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.
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.

- 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

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

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

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. Working time for AccuFill BSM is approximately 15 minutes (maximum time between mix and injection) and mixed material will not set until injected into the patient.

AccuMix Mixing System

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

Note: For AccuFill BSM Bowl Mixing Technique see p.21.

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. If using 3 cc AccuFill BSM, push plunger up until powder is at the top of the syringe just below the funnel.

2. Remove vial of AccuFill powder from jar. Empty powder into funnel; tap until powder enters syringe.

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

Hydrate:

4. Withdraw saline from vial using the saline syringe and adaptor.
   - 5 cc AccuFill BSM
     • 3.0 cc saline
     • Alternative: 3.4 cc whole blood
   - 3 cc AccuFill BSM
     • 2.0 cc saline
     • Alternative: 2.3 cc whole blood
5. Connect saline syringe to white cap; tighten. Inject saline into powder; pull up on syringe plunger to pull excess air into saline syringe. Inject again, to ensure **ALL SALINE FLOWS INTO POWDER**, then repeat to release pressure.

6. Remove saline syringe; set it in the sterile tray. Attach blue plug to cap.

**Mix:**

7. Remove mixing syringe from tray. Remove plunger sleeve from plunger stem. **DO NOT DISCARD SLEEVE!**

8. Thoroughly mix powder and saline for 60 strokes (~60 seconds). Twist and rotate while plunging until mix takes “paste” consistency.

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

**Transfer:**

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

11. Transfer filled syringes to operative field.

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

![Images of surgical procedures](image1.png)

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.*

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.
**AccuFill BSM Bowl Mixing Technique**

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

1. Remove the seal from the clear amber jar and remove the vial containing AccuFill BSM powder. Pour powder into jar.
2. Withdraw saline from vial using the saline syringe and adaptor.
   - 5 cc AccuFill BSM
     - 3.0 cc saline
     - Alternative: 3.4 cc whole blood
   - 3 cc AccuFill BSM
     - 2.0 cc saline
     - Alternative: 2.3 cc whole blood
3. Dispense hydrant into the mixing jar.
4. Using the broader face of the spatula, mix thoroughly for about a minute to form a putty (similar to toothpaste). Use shear force by smearing the material against the side of the bowl, to optimize mixing for best results.
5. Using the spatula, transfer mix into the 5 cc transfer syringe.
6. Transfer mix from 5 cc transfer syringe to the 1 cc syringes.

💡 **Note:** Bowl mixing requires use of the spatula to mix and shear material and saline together. A spatula is not included in SCP Complete Kits, so bowl mixing cannot be completed when using these kits.
## AccuFill BSM Bowl Mixing Technique

### AccuPort Cannulas

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### AccuMix Mixing System

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### AccuFill BSM

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