The Subchondroplasty® (SCP®) Procedure for Foot & Ankle

Surgical Technique
The Subchondroplasty® (SCP®) Procedure

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects, often called BML, with AccuFill® Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute. It is usually performed with arthroscopy, for visualization and treatment of findings inside the joint.

Some procedures may be performed through mini-open or open approach, as needed for access or visualization of joint findings.

The Subchondroplasty Procedure consists of four components:

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

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

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

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

AccuFill BSM Indications for Use:

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

The SCP Procedure treats chronic subchondral bone defects, often called bone marrow lesions (BML), by injecting AccuFill BSM into the defect. The SCP Procedure targets and fills osseous defects in the forefoot, midfoot, and hind foot. The presence and location of the BML is identified with fat suppressed MRI (e.g., T2FS, PDFS, STIR). BML defects are not visible on intraoperative fluoroscopy.

To accurately inject the AccuFill BSM with a minimally-invasive technique, the surgeon must determine the location of the bony defect relative to radiographic landmarks, using the patient’s MRI.

This preoperative plan is then used intraoperatively to target the defect with fluoroscopy, for optimal AccuFill BSM implantation.

Localize the BML on fat-suppressed T2 MRI slices

- Use two or more planes to determine:
  - Position on coronal and sagittal views
  - Distance from joint
  - (Depth) superficial or deep to cortex
- Plan approach and trajectory based on defect location.
- Determine which AccuPort Cannula will be used: 11 ga side-targeting, 11 ga end-targeting, or 15 ga end-targeting.
- The Subchondroplasty Procedure may be performed with arthroscopy, for visualization and treatment of structures inside the joint. Arthroscopy may be performed before or after the SCP Procedure.
- For midfoot and forefoot bones, where scoping is not possible, an open approach will allow direct visualization of the bone.

AccuPort Cannula & AccuFill BSM Volume Suggestions*

<table>
<thead>
<tr>
<th>BONE</th>
<th>CANNULA</th>
<th>VOLUME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talus</td>
<td>11 ga End</td>
<td>1.0-1.5 cc</td>
</tr>
<tr>
<td>Distal Tibia</td>
<td>11 ga Side or End</td>
<td>1.0-2.0 cc</td>
</tr>
<tr>
<td>Calcaneus</td>
<td>11 ga End or Side</td>
<td>1.0-2.0 cc</td>
</tr>
<tr>
<td>Midfoot (Navicular**, Cuneiforms)</td>
<td>15 ga</td>
<td>0.5 cc</td>
</tr>
<tr>
<td>Midfoot (Cuboid)</td>
<td>15 ga or 11 ga End</td>
<td>0.5-1.5 cc</td>
</tr>
<tr>
<td>Forefoot (Metatarsal heads)</td>
<td>15 ga</td>
<td>0.25-0.5 cc</td>
</tr>
</tbody>
</table>

* F&A Advisory Group suggestions, Meeting Notes 3/2016
**Navicular: for large or very hard bone, the 11 ga end-delivery cannula may be a good choice.
Note: Volume determination will vary from patient to patient and is dependent on pathology and radiographic appearance.
Surgical Technique

The Subchondroplasty Procedure is usually performed with arthroscopy, for visualization and treatment of findings inside the joint. Arthroscopy may be performed before AccuFill BSM injection or after. Some surgeons prefer scoping first, to evaluate the joint cartilage and cortical bone adjacent to the BML before injecting AccuFill BSM into the subchondral bone defect. When scoping after 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.

Care must be taken to avoid applying bending forces on the cannula while manipulating the ankle during scoping, to avoid damage to the cannula or surrounding bone.

**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.

OR Setup

**Position, prep, drape patient**

- The ankle should be positioned on a radiolucent table to allow for true anteroposterior (AP) / mortise and lateral views, and elevated by placement on a sterile bump for ease of obtaining a lateral fluoroscopic view.
- Prep and drape as for ankle arthroscopy.

**NOTE:**

If performing arthroscopy or another procedure along with the SCP Procedure, position equipment such that C-Arm is easily accessible throughout the procedure.

Target the Defect

- Using intraoperative fluoroscopy, localize the bony defect relative to MRI findings.
- With the MRI as a reference, the cannula is triangulated into the defect, confirmed with AP/mortise and lateral views.
Access the Bone Defect

AccuPort Cannulas are available in both 11 ga (3.0 mm OD) and 15 ga (1.8 mm OD) sizes (see page 13 for more information). The 11 ga cannula has two delivery options:

- Side-delivery: 3 side fenestrations for directed flow of BSM from alongside or margin of bone defect.
- End-delivery: End aperture for direct delivery of BSM into defect.

The 15 ga cannula is available in end-delivery only.

- Confirm starting position and trajectory of AccuPort Cannula under fluoroscopy.
- An incision may be made for insertion of the cannula.
- Using an orthopaedic wire driver, advance cannula to the cortex.
- Insert cannula into the bone. Confirm position with fluoroscopy.
- Drill the cannula to desired depth and location. Confirm position with AP and lateral fluoroscopy.

⚠️ **CAUTION:** Ensure the AccuPort Cannula is inserted within the confines of the bone prior to injection. To minimize extravasation the delivery holes of the cannula must be within the cortex. Multiple drill paths into the bone are to be avoided as this may lead to extravasation of the AccuFill BSM.

⚠️ **CAUTION:** Avoid excessive or prolonged drilling into bone as it may cause increased temperatures in cannula and surrounding bone. Before injection allow cannula to cool to body temperature.

**OPERATIVE TIPS:**

- Set the surgical driver to the drill setting, not ream.
- Insert the drill to the hub of the AccuPort Cannula.
- If using the 15 ga AccuPort Cannula, the use of the sleeve limits the penetration depth of the 15 ga AccuPort Cannula to 6 mm.
Implant Placement: Filling the Bone Defect

AccuFill BSM is hydrated and mixed before injection, using normal saline (0.9%). The material is mixed using the AccuMix mixing system, a closed syringe device. 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 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. If using 3 cc AccuFill BSM, push plunger up until powder is at the top of the syringe just below funnel.

3. Remove funnel; fully tighten cap and plug. Remove blue plug and set in sterile tray. DO NOT DISCARD PLUG!
Implant Placement: Filling the Bone Defect
AccuFill BSM Mixing Technique

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.
Implant Placement: Filling the Bone Defect

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

NOTE:

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

- Confirm AccuPort Cannula placement with AP and lateral fluoroscopy. If using the 11 ga side-delivery cannula, manually rotate the cannula to direct flow toward the defect, as identified by the white line on the hub of the cannula.
- 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. Set the stylus on the sterile field (Mayo stand or back table)—DO NOT DISCARD!
- Attach the first 1cc syringe of AccuFill mix to the cannula hub; firmly tighten the luer-lock connector.
- Inject the AccuFill BSM using steady manual pressure.
- Remove the first syringe and repeat until desired volume has been implanted. For most procedures, between 0.5 to 2 ccs will fill the defect.
- Reinsert the stylus back into the cannula to inject residual AccuFill BSM. Insert the stylus fully until locking wings are secured to the hub.
- Leave the cannula in place while the AccuFill BSM sets. The stylus/cannula should be left in the bone for 10 minutes to minimize potential for extravasation of unset 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 BSM is properly placed. Seal all incisions.

NOTE:
It is recommended that the scope be reintroduced into the ankle after the AccuFill BSM injection is completed to look for evidence of extravasation of the BSM into the joint. Although uncommon, if extravasation occurs, the material should be removed from the joint using the shaver and irrigation.
Implant Placement: Filling the Defect
Injecting AccuFill BSM Implant

**OPERATIVE TIPS**

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

- For the 11 ga AccuPort Cannulas, the first 0.7 cc of AccuFill BSM fills the cannula itself; 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.

- For the 15 ga AccuPort Cannulas, the first 0.1 cc of AccuFill BSM fills the cannula itself.

- Monitor flow and volume of the AccuFill BSM into the trabecular bone under fluoro. If the AccuFill BSM material 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”.

- The stylus/cannula should be left in the bone for 10 minutes to minimize potential for extravasation of unset material.

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**CAUTION:** Always confirm AccuPort Cannula position with AP and lateral fluoroscopy before injecting!
- Verify that cannula is completely inside the bone.
- Commit to 1st trajectory; avoid creating 2nd path and potential for extravasation.
- If undesired trajectory is created:
  - Do not redirect cannula inside the bone; the cannula could break.
  - Leave 1st cannula in bone to block backflow; then insert a new cannula along a different path.

**CAUTION:** It is important to avoid applying bending stresses to the cannula while manipulating the foot and ankle during scoping, to minimize the potential for cannula damage.

**CAUTION:** 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. Remove any excess material from the subcutaneous tissue at the entry point by gently expressing and irrigating the material. Blot any excess material from the surgical wound as needed.
AccuPort Delivery Cannulas

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. AccuPort Cannulas are available in 15 ga (1.8 mm OD) and 11 ga (3.0 mm OD) sizes.

AccuPort End- and Side-Delivery Cannulas 11 ga, 3.0 mm OD

- 120 mm drillable length with etched markings every 10 mm.
- 3.0 mm OD, 2.4 mm ID.
- Commonly used in distal tibia, hind foot, and larger midfoot bones.
  - End-delivery more commonly used in hindfoot indications, but side-delivery can be beneficial depending on defect location.

AccuPort End-Delivery Cannula 15 ga, 1.8 mm OD

- 60 mm drillable length with etched markings every 5 mm.
- 1.8 mm OD, 1.4 mm ID.
- Commonly used in small bones, including midfoot and forefoot.
- Can be used for any defect where a 60 mm drillable length is adequate.

Intraop images of 15 ga AccuPort End-Delivery Cannula.
## Ordering Information

<table>
<thead>
<tr>
<th>SCP Complete Kits for Foot &amp; Ankle</th>
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<tbody>
<tr>
<td>• 514.302 SCP Complete Foot &amp; Ankle Kit;</td>
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<tr>
<td>3 cc, Side-Delivery, 11 ga (3.0 mm OD) x 120 mm</td>
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<tr>
<td>• 544.302 SCP Complete Foot &amp; Ankle Kit;</td>
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<tr>
<td>3 cc, Side-Delivery Cannula, 11 ga, 4-PACK</td>
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<td>• 514.303 SCP Complete Foot &amp; Ankle Kit;</td>
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<td>• 544.303 SCP Complete Foot &amp; Ankle Kit;</td>
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<td>3 cc, End-Delivery Cannula, 11 ga, 4-PACK</td>
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<td>• 514.315 SCP Complete Foot &amp; Ankle Kit;</td>
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<td>3 cc, End-Delivery, 15 ga (1.8 mm OD) x 60 mm</td>
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<td>• 544.315 SCP Complete Foot &amp; Ankle Kit;</td>
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<td>3 cc, End-Delivery Cannula, 15 ga, 4-PACK</td>
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<td>• 514.502 SCP Complete Foot &amp; Ankle Kit;</td>
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<td>5 cc, End-Delivery, 11 ga (3.0 mm OD) x 120 mm</td>
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<td>• 544.503 SCP Complete Foot &amp; Ankle Kit;</td>
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<td>5 cc, End-Delivery Cannula, 11 ga, 4-PACK</td>
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<tbody>
<tr>
<td>• 307.032 AccuPort Side-Delivery Cannula;</td>
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<tr>
<td>11 ga (3.0 mm OD), 120 mm Drill Length</td>
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<tr>
<td>• 307.034 AccuPort End-Delivery Cannula;</td>
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<tr>
<td>11 ga (3.0 mm OD), 120 mm Drill Length</td>
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<tr>
<td>• 308.151 AccuPort End-Delivery Cannula;</td>
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<td>15 ga (1.8 mm OD), 60 mm Drill Length</td>
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### Ordering Information

#### AccuMix Mixing System

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<td>311.100</td>
<td>AccuMix Mixing System</td>
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<tr>
<td>341.100</td>
<td>AccuMix Mixing System 4-PACK</td>
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<tr>
<td>311.102</td>
<td>Replacement Parts for AccuMix Mixing System</td>
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#### AccuFill BSM

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<tbody>
<tr>
<td>201.030</td>
<td>AccuFill Bone Substitute Material, 3 cc</td>
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<tr>
<td>241.030</td>
<td>AccuFill Bone Substitute Material, 3 cc, 4-PACK</td>
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<tr>
<td>201.050</td>
<td>AccuFill Bone Substitute Material, 5 cc</td>
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<tr>
<td>241.050</td>
<td>AccuFill Bone Substitute Material, 5 cc, 4-PACK</td>
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</table>
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