The Subchondroplasty® (SCP®) Procedure for the Shoulder

Surgical Technique
The Subchondroplasty® (SCP)® Procedure

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects with AccuFill® Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute. It is usually performed with arthroscopy of the affected shoulder, for visualization and treatment of findings inside the joint. Some procedures may be performed through a 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 bone defect on fat-suppressed MRI; plan approach and trajectory based on defect location.

TARGET THE BONE DEFECT: Using intraoperative fluoroscopy and arthroscopy, as needed, 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 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

In the shoulder, 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 defect by:

- Depth – superficial or deep to the near cortex.
- Location relative to the adjacent joint.
- Location relative to radiographic- or arthroscopically-recognizable landmarks.

Coronal T2 FS MRI  
Sagittal T2 FS MRI  
Axial T2 FS MRI
Preoperative Plan

Additional Preoperative Planning Tips

- Determine which AccuPort cannula will be used: 11 ga x 120 mm side-targeting, or 11 ga x 120 mm end-targeting are commonly used, but other cannulas (e.g., 15 ga x 60 mm, 11 ga x 200 mm) may be considered.

- Estimate volume of AccuFill BSM to be injected based on size and location of the bone defect (see Implant Placement, p. 15).

- Use multiple imaging series - especially CT scan where appropriate - to understand the location, size and nature of the bone defect.
Surgical Technique

The Subchondroplasty Procedure is performed along with arthroscopy of the shoulder, for visualization and treatment of findings inside the joint. After injection of AccuFill BSM into the defect, the scope also allows evaluation for and evacuation of any material that has extravasated into the joint. Note, however, that while the AccuPort injection cannulas are in place (see Implant Placement, p. 14), take care while manipulating the arm and shoulder during scoping, to avoid bending forces on the cannula that may damage the cannula or surrounding bone.

NOTE:

Additional arthroscopic procedures involving the operative bone, including anchor drilling, should not be performed until the BSM is allowed to set and the cannula has been removed, to prevent extravasation of unset material into the joint.

NOTE:

Although uncommon, if extravasation of AccuFill BSM occurs, the material should be removed from the joint using the shaver and irrigation.

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

OR Setup / Patient Positioning

- Position the patient in beach chair or lateral decubitus with or without distraction on a radiolucent OR table.
- Prep and drape for standard shoulder arthroscopy.
- OR setup also includes operative fluoroscopy.
  - Position the machine at the head of the bed for lateral decubitus (see setup example, below).
  - Position the machine on the contralateral side for beach chair position.
OR Setup/Patient Positioning

Lateral Decubitus Position

- Orient the C-arm parallel to the floor, as shown.
- To target bone defects in the shoulder use two orthogonal views for triangulating to the defect. With the patient in the lateral decubitus position, those views will be an AP oblique (Grashey) and axillary lateral view.

• To obtain a Grashey view, align the C-arm for an AP view, then tilt the arm (blue arrow) until the fluoro beam is in the plane of the glenoid face, superimposing the anterior and posterior aspects of the glenoid rim.
• To obtain a true axillary lateral view, rotate the C-arm (red arrow).
OR Setup/Patient Positioning

Beach Chair Position

- Position the fluoro machine on the contralateral side of the patient, tilted for AP fluoroscopy (see image below).

- Transition between AP views with the humerus in neutral rotation and internal rotation, to obtain multiple views of the proximal humerus for targeting bone defects in the humeral head.
OR Setup / Patient Positioning

Beach Chair Position – Alternative C-arm Setup

In some patients, particularly those with a large soft tissue envelope around the joint, rotating the patient’s arm to obtain AP and lateral views might place undue bending stress on the cannula. To avoid this, an alternative fluoro machine setup allows the C-arm to be moved between AP and scapular Y views without moving the patient’s arm.

Position the fluoro machine on the contralateral side of the operative shoulder, with the C-arm base angled 45° to the table axis (images, above).

- First, find optimal machine position by setting up to obtain a scapular Y view (image on left).
- Then, rotate the C-arm to AP until an optimal AP image is obtained (image on right).
- Use both views to target the bony defects of the humeral head.
Targeting & Accessing Humeral Head Defects

The following technique describes the steps for targeting bone defects in the humeral head. These same basic steps can be used for targeting defects in the greater tuberosity or the glenoid, with special considerations mentioned where applicable.

The principles of targeting bone defects in the shoulder can be applied for patient positioning in beach chair or lateral decubitus. Regardless of patient position, it is important to note the position of the axillary nerve when targeting a defect in the humeral head. Triangulating to the defect is achieved by obtaining multiple views of the proximal humerus through manipulating the C-arm position, or rotating the patient’s arm under AP fluoroscopic guidance. Either a side or end-delivery cannula can be used, with the side-delivery being a good choice for larger lesions in the central humeral head, and the end typically better for lesions adjacent to the joint.

 NOTE: The axillary nerve lies approximately 5 cm below the acromion.*

- Obtain AP fluoroscopic image of the proximal humerus with the targeted area centered in the image.
- Lay the AccuPort cannula against the skin between the image intensifier and the humerus, to align with the preoperatively-planned cannula entry point and trajectory. Adjust as needed. Mark the skin along the cannula as a trajectory reference for later cannula insertion.
- Palpate the anterior and posterior margins of the humeral head, to approximate the center of the humeral shaft. Mark the skin at this point, along the planned trajectory.
- Assemble the chosen AccuPort cannula to a surgical wire driver. Set the tip of the cannula against the skin at the marked entry point, under AP fluoroscopy.

Targeting & Accessing Humeral Head Defects

- Make a stab incision at the chosen point and pass the cannula to the bone, in line with the marked trajectory line. Reposition the tip as needed, under AP fluoroscopy, until the cannula tip and trajectory align to the defect, according to the preoperative plan.

**OPERATIVE TIP:**

Using AP fluoro, reposition the cannula tip until there is no overlap of the tip and bone. This indicates that the tip is at the apex of the shaft in this view, and thus in the center of the bone in the lateral projection.

- Drill the cannula through the cortex, just into the cancellous bone (5-10 mm deep). Rotate to lateral projection and confirm cannula trajectory.

- Using AP and lateral fluoro as needed, continue drilling until the cannula is at the desired depth.

- When using a side-delivery cannula (i.e., a more-central humeral head defect), radiographically ensure all three fenestrations are deep to the cortex. Proceed to AccuFill BSM injection.

**NOTE:**

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

- Do not redirect the cannula inside the bone, which could damage the cannula or surrounding bone. Either:
  - Back the cannula out until the tip is at the near cortex, redirect to the correct trajectory, and reinsert the cannula, or
  - Leave first cannula in the bone to avoid backflow of BSM, then insert a second cannula on a different path to the desired trajectory.
Implant Placement: Filling the Bone Defect

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

AccuMix Mixing System

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

**NOTE:**

For AccuFill BSM Bowl Mixing Technique see p.23

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AccuFill BSM Mixing Technique

Setup:

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

1. Transfer the tray to the sterile field (back table). Remove the mixing syringe and set upright in the tray groove; lift funnel to extend syringe.

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

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

Hydrate:

4. Withdraw saline from vial using the saline syringe and adaptor.
   - 5 cc AccuFill BSM
     - 3.0 cc saline
     - Alternative: 3.4 cc whole blood
   - 3 cc AccuFill BSM
     - 2.0 cc saline
     - Alternative: 2.3 cc whole blood
Implant Placement: Filling the Bone Defect

AccuFill BSM Mixing Technique

5. Connect saline syringe to white cap; tighten. Inject saline into powder; pull up on syringe plunger to pull excess air into saline syringe. Inject again, to ensure ALL SALINE FLOWS INTO POWDER, then repeat to release pressure.

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

Mix:

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

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

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

Transfer:

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

11. Transfer filled syringes to operative field.

**NOTE:**

Do not empty entire contents of saline vial into AccuFill BSM powder. Measure and use only the exact volume noted above.
Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM

- Confirm cannula position using AP and lateral fluoroscopy. When using a side-delivery cannula, manually rotate the cannula to direct flow toward the defect, as indicated by the white line.
- Remove the inner stylus while holding the cannula body securely with one hand, squeeze together the adaptor locking wings with the other hand, and pull the stylus out.
- Set the stylus on the sterile field (Mayo stand or back table). DO NOT DISCARD!

- Attach the first 1cc syringe of AccuFill mix to the cannula hub; firmly tighten the luer lock connector.
- Inject AccuFill BSM using steady manual pressure.

Remove stylus from cannula; Inject desired volume of AccuFill BSM
Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM

- Remove the first syringe and repeat until desired volume has been implanted. Total injection volume is variable, and dependent on the nature of the bone defect; with cystic lesions often accepting a higher volume of BSM implant.

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<tr>
<th>BONE</th>
<th>AccuFill BSM (cc)</th>
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<tbody>
<tr>
<td>Humeral Head</td>
<td>1.0-3.0 cc</td>
</tr>
<tr>
<td>Greater Tuberosity</td>
<td>2.0-3.0 cc</td>
</tr>
<tr>
<td>Glenoid</td>
<td>1.0-3.0 cc</td>
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**Important Information:** The use of AccuFill BSM is not intended to be intrinsic to the stability of the bony structure. Radiographic studies should be used to confirm that the adjacent cortical bone is intact.
Implant Placement: Filling the Bone Defect

Injecting AccuFill BSM

- Leaving the cannula in place while the AccuFill BSM sets, use the scope to evaluate for and evacuate any extravasated material.
- Remove the cannula: reconnect the surgical wire driver to the cannula stylus; use reverse torque while pulling back.
- Confirm no excess BSM emerges from the entry or incision site. Using fluoroscopic imaging, ensure that AccuFill implant is properly placed. Seal all incisions.

OPERATIVE TIPS:
- The first 0.7 cc of mix is filling the cannula itself; once the BSM fills the cannula and starts flowing into the subchondral cancellous bone, back pressure will increase. Let off on digital pressure and then slowly reapply it until the material starts to flow again.
- Monitor flow and volume of the AccuFill BSM into the trabecular bone under AP fluoro. If the AccuFill material is not readily seen on the C-arm monitor, contrast between bone and BSM may be improved by changing fluoroscopy settings toward Bone X-ray settings (decreasing KVP and/or increasing MA) or switching between normal image and “negative”.

NOTE:
- When attaching and removing 1 cc syringes from the cannula, grip the hub firmly to avoid rotating the cannula.
- 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.
- The cannula and stylus should be left in the bone for 10 minutes, while the AccuFill BSM hardens, to minimize potential for extravasation of material.
- Allow AccuFill BSM to fully set prior to performing additional procedures such as anchor drilling.
Considerations for: Greater Tuberosity Defects

Two types of approach are used to access bony defects in the greater tuberosity: a direct lateral approach and a medial footprint approach. In the lateral approach, the AccuPort cannula enters the greater tuberosity from directly lateral, under fluoroscopic guidance to target the defect. In the medial footprint approach, the cannula entry point is determined under guidance of the scope, at an approach typically used for medial row anchors, fluoroscopy is then used to monitor drilling depth in the bone.

Direct Lateral Approach

![Cannula at desired drill depth](image1)

![Fluoroscopically monitor implant flow](image2)

Medial Footprint Approach

![Arthroscopically find cannula entry point](image3)

![Medial footprint approach to access bone defect](image4)
Considerations for: Glenoid Defects

Glenoid bone defects are often cystic in nature, and may or may not include associated BML bone defects. When targeting these lesions, the SCP procedure is used to fill both the cyst and, if applicable, the surrounding microtrabecular fracture. Two approaches to accessing bone defects are used in the glenoid: a scope-assisted rim approach, or a joint-parallel approach. Due to the complex geometry of the glenoid and scapular neck, free-hand targeting of these defects is technically challenging, with both approaches relying heavily on arthroscopic and/or fluoroscopic assistance.

Scope-assisted Rim Approach

Preoperatively identifying the location of the glenoid defect, following the clock face method, may be helpful for scope-assisted intraoperative targeting. Defects are found more often in the posterior aspect of the glenoid (7-11 o’clock), associated with other posterior joint pathologies.*

- For targeting a posterior glenoid defect, use a posterior lateral portal for the AccuPort cannula and an anterior portal for viewing.
- Pass the AccuPort cannula tip to the glenoid rim, using the scope to confirm entry point and trajectory (angulation to the glenoid face) toward the defect.

**OPERATIVE TIP:**
- A spinal needle can be used in an outside-in technique to understand the appropriate portal position and angle to target the defect, prior to percutaneously inserting the AccuPort cannula.

Considerations for: Glenoid Defects
Scope-assisted Rim Approach (contd.)

• Drill the AccuPort cannula into the glenoid rim. Once in bone, use axillary lateral fluoro to monitor cannula drill depth.

• When using a side-delivery cannula, use fluoro and/or the scope to confirm all fenestrations are deep to the cortex and pointed in the desired direction of AccuFill BSM flow.

OPERATIVE TIPS:
• Consider using AP oblique fluoro to localize entry point superior to inferior on the glenoid rim.
• In beach chair position, this view can be used to monitor drill depth as an alternative to an axillary lateral.
Considerations for: Glenoid Defects

Parallel Approach

The parallel approach relies heavily on fluoroscopic guidance and principles of free-hand targeting to accurately target bone defects in the glenoid. This technique uses two views, AP oblique and axillary lateral, to triangulate to the defect based on the associated coronal and axial MRI slices, and corresponding CT images where appropriate. For more information on the principles of free-hand targeting, please refer to Knee Creations document LBL 903.116.

**NOTE:**

This approach is challenging for beach chair position, as obtaining an axillary view is difficult and access to a posterior entry point may be obstructed.

*Contact your local representative or visit www.subchondroplasty.com to access this document.*
Considerations for: Glenoid Defects

Parallel Approach (contd.)

- AP oblique fluoroscopy is used to localize the cannula entry point and trajectory relative to radiographic landmarks and MRI-based plan. By centering the targeted defect in the fluoro beam, and aligning the AccuPort cannula with the beam, glenoid defects can be targeted accurately.

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

- Monitor drill depth and trajectory under axillary lateral fluoroscopy until the cannula is at the desired depth and, when using a Side-Delivery AccuPort Cannula, all three delivery fenestrations are deep to the cortex.

- Manually rotate the cannula until the fenestrations are pointed in the desired delivery direction (Side-Delivery AccuPort Cannula) with the white line pointed toward the defect.
AccuPort Delivery Cannulas
Trocar-tipped, drillable, 11 ga cannulas for delivery of AccuFill BSM to the bone defect. 3.0 mm diameter, 120 mm drillable length; provides minimally-invasive access to the defect. Each AccuPort cannula includes interconnecting cannula and stylus, for insertion using an OR wire driver.

AccuPort Cannulas, 11 ga
- 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.

AccuPort End-Delivery Cannula, 15 ga
- 60 mm drillable length with etched markings every 5 mm.
- End-delivery: end aperture for direct delivery of BSM into defect.
AccuFill BSM Bowl Mixing Technique*

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

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

*NOTE:

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

### SCP Complete Knee Kits

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<tr>
<td>414.502</td>
<td>SCP Complete Knee Kit, 5 cc, Side-Delivery, 11 ga x 120 mm</td>
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<tr>
<td>444.502</td>
<td>SCP Complete Knee Kit, 5 cc, Side-Delivery, 11 ga x 120 mm, 4-Pack</td>
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<tr>
<td>414.503</td>
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<tr>
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### AccuPort Cannulas

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<tr>
<td>307.034</td>
<td>AccuPort End-Delivery Cannula, 11 ga x 120 mm</td>
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<td>308.151</td>
<td>AccuPort End-Delivery Cannula, 15 ga x 60 mm</td>
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### AccuMix Mixing System

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### AccuFill BSM

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<td>201.050</td>
<td>AccuFill Bone Substitute Material, 5 cc</td>
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<td>241.050</td>
<td>AccuFill Bone Substitute Material, 5 cc, 4-Pack</td>
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<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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