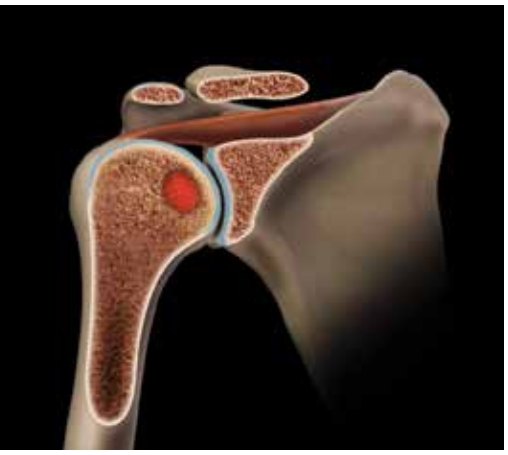
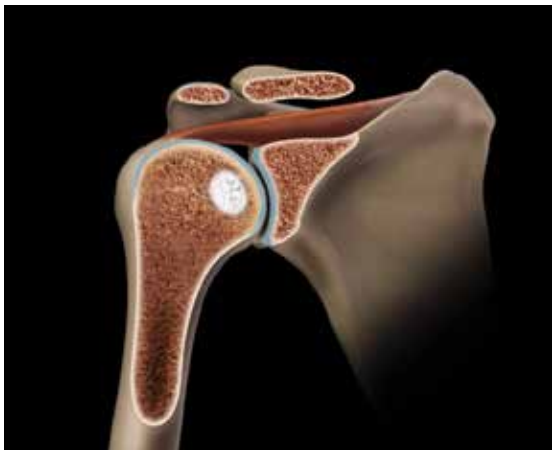
The Subchondroplasty® (SCP®) Procedure for the Shoulder

Surgical Technique





ZIMMER BIOMET
Moving You Forward.™

Table of Contents

Symbols Conventions **4**

The Subchondroplasty® (SCP®) Procedure **5**

Features & Benefits **6**

Preoperative Planning **7**

Surgical Technique **9**

OR Setup/Patient Positioning 9

Lateral Decubitus 10

Beach Chair 11

Targeting and Accessing Bone Defects 13

Humeral Head 13

Implant Placement: Filling the Bone Defect 15

- Mixing option 1: Using the AccuMix system / SCP Complete Kit 15
- Mixing option 2: Using the AcuFill Pre-Fill (PF) BSM Kit 17

Injecting AccuFill BSM 20

Considerations for Targeting 23

Greater Tuberosity 23

Glenoid 24

Implants and Instruments **27**

AccuPort Delivery Cannulas 27

Ordering Information 27

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.

WARNING: This symbol is present when a warning alerts you to a potential danger to health or life.

The Subchondroplasty® (SCP®) Procedure

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects, often called bone marrow lesions (BML), with AccuFill® PF Bone Substitute Material (BSM), a hard-setting, biomimetic bone substitute. The procedure is performed along with arthroscopy of the affected knee, to assess the extent of the tibial plateau injury, assist in targeting the underlying plateau defect, and visualize and treat other structures inside the joint.

The Subchondroplasty Procedure consists of four components:

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

TARGET THE BONE DEFECT: Using arthroscopy and intraoperative fluoroscopy, localize the bone defect relative to the T2 and T1 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 based on the T1 image.

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

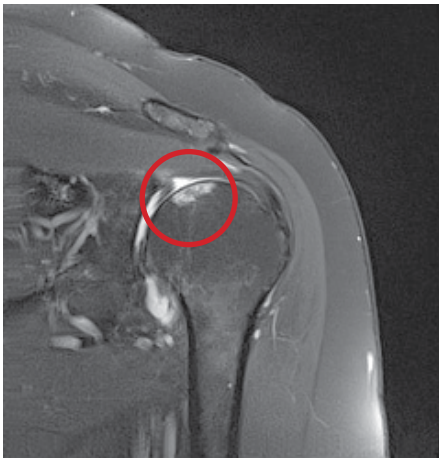
* Bone Marrow Lesions (BML) and Bone Marrow Edema (BME) are often used interchangeably to identify subchondral bone defects like microtrabecular or insufficiency fractures.

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

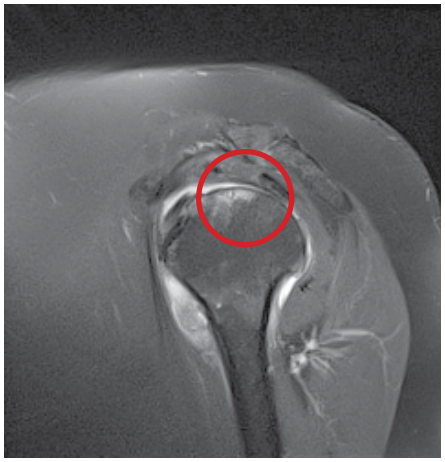
*** The grain size of the hydroxyapatite (HA) crystals that form as part of the amorphous and crystalline mixture of calcium phosphate sets are on the nanometer scale. The size of the crystalline structures were measured by x-ray diffraction to be less than 100 nanometers.

**** based on calcium phosphate Alpha-BSM

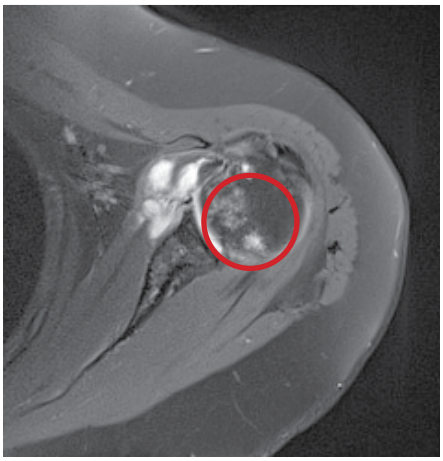
Preoperative Planning



Coronal T2 FS MRI



Sagittal T2 FS MRI



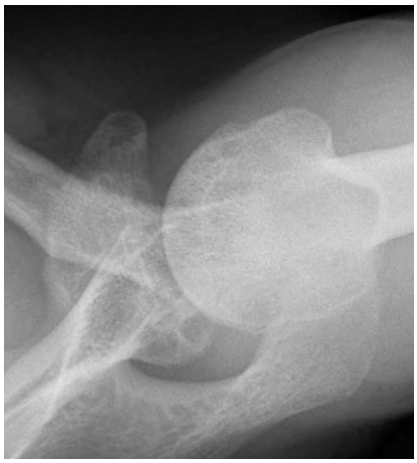
Axial T2 FS MRI

Preoperative Plan

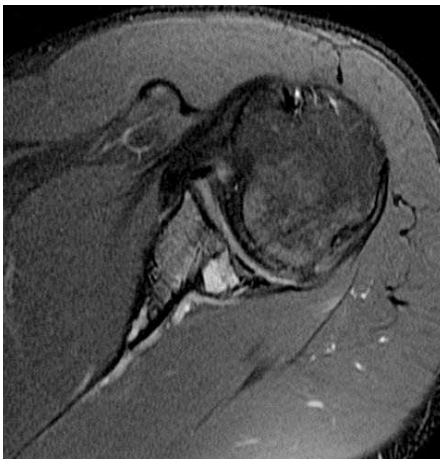
In the shoulder, subchondral bone defects may present radiographically as microtrabecular or insufficiency fractures-sometimes called bone marrow lesions (BML)-or cystic lesions, or a combination of both. Cystic lesions are often visible on X-ray (plain films or CT); but BML are not visible on X-ray 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:

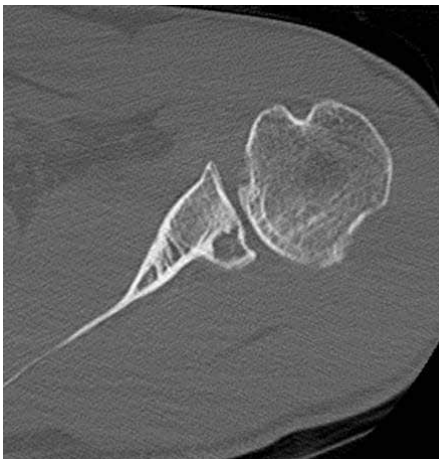
- Depth – superficial or deep to the near cortex.
- Location relative to the adjacent joint.
- Location relative to radiographic- or arthroscopically-recognizable landmarks.



Preop X-ray



T2 FS MRI



CT Scan

Preoperative Plan (cont.)

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.
- Estimate volume of AccuFill BSM to be injected based on size and location of the bone defect.
- Use multiple imaging series - especially CT scan where appropriate - to understand the location, size and nature of the bone defect.

Surgical Technique

OR setup with patient in lateral decubitus

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, 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.

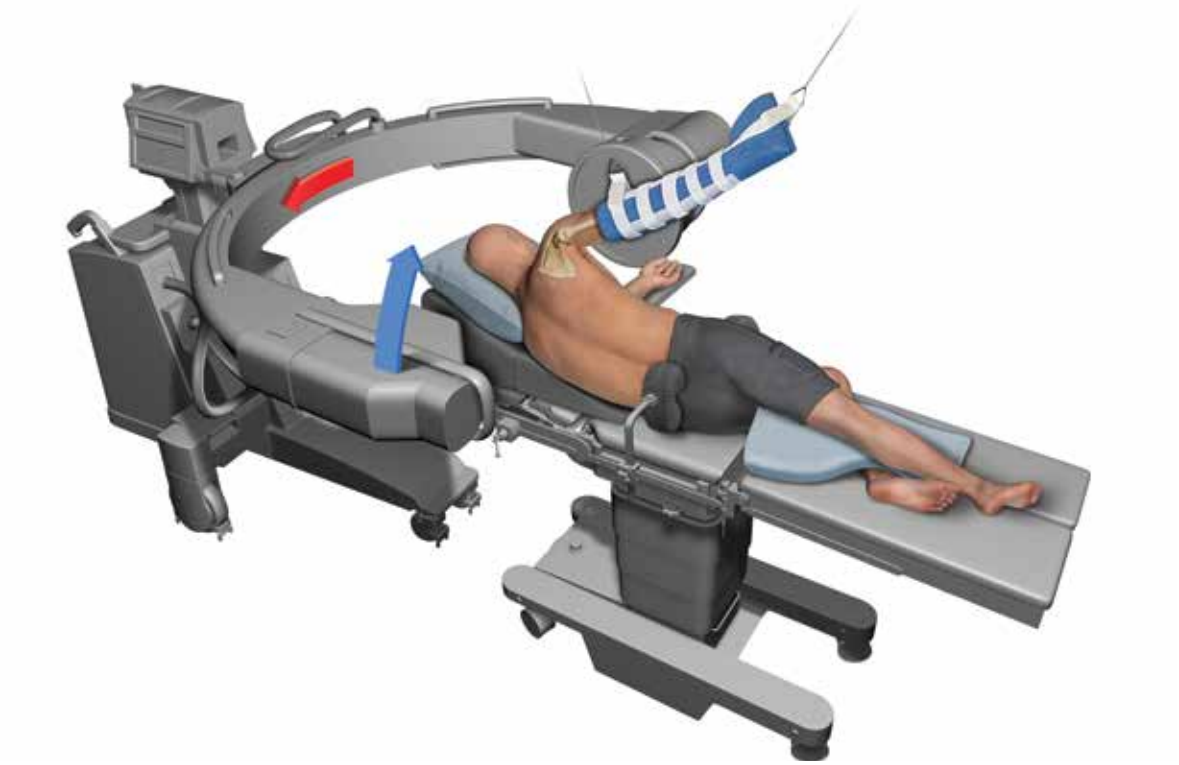
NOTE: Additional arthroscopic procedures involving the operative bone, including anchor drilling, should not be performed until the BSM is allowed to set and the cannula has been removed, to prevent extravasation of unset material into the joint.

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.

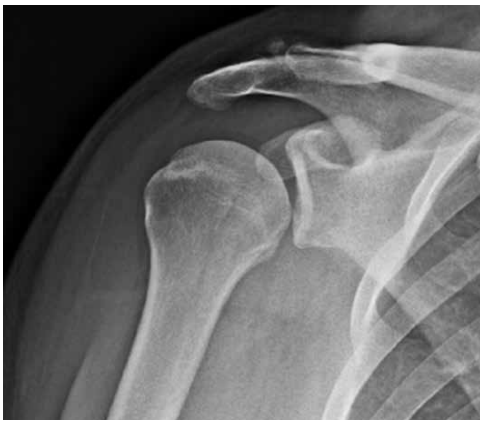
OR Setup/Patient Positioning

- 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.

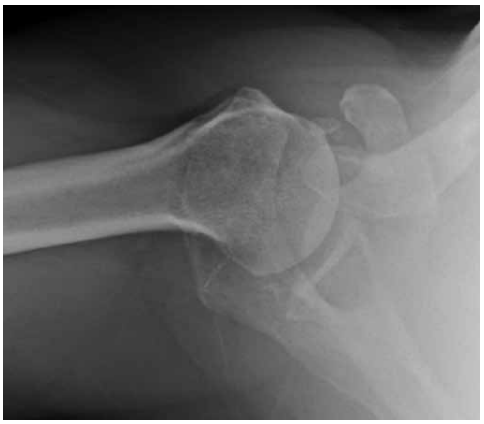


Lateral Decubitus Position

- 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) in above image 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) in above image.



Grashey view

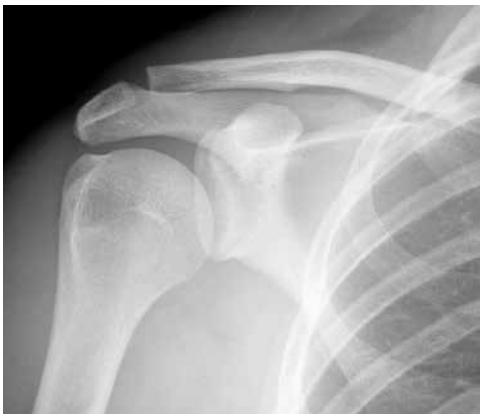


Axillary lateral view

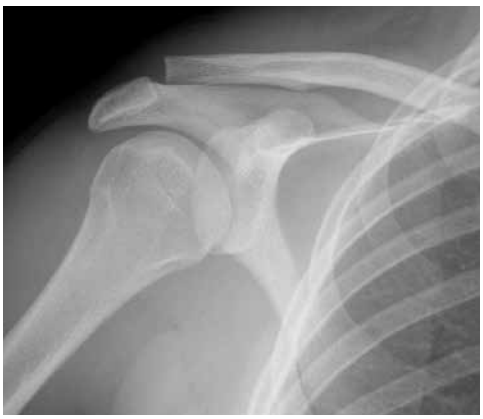
OR Setup/Patient Positioning (cont.)

Beach Chair Position

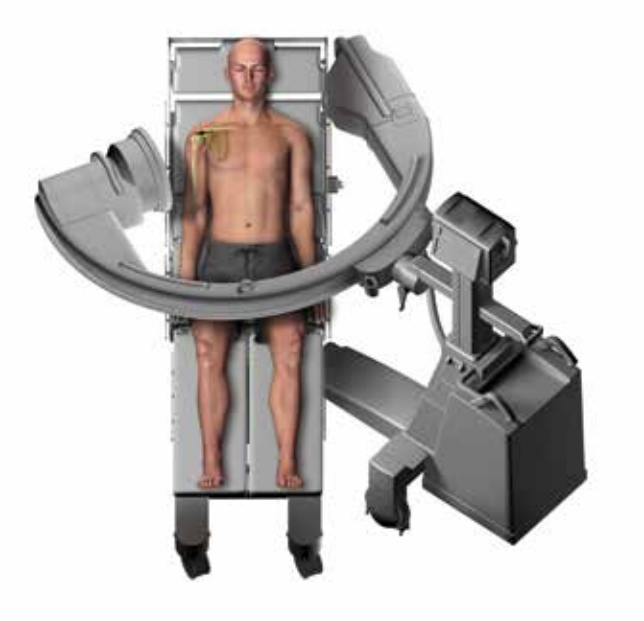
- Position the fluoro machine on the contralateral side of the patient, tilted for AP fluoroscopy (see image on the right).
- Transition between AP views with the humerus in neutral rotation and internal rotation, to obtain multiple views of the proximal humerus for targeting bone defects in the humeral head.



AP – neutral rotation



AP – internal rotation



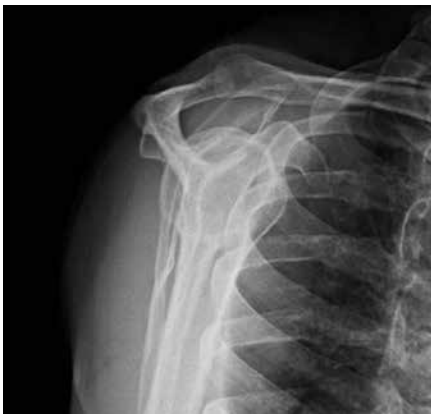
OR Setup/Patient Positioning (cont.)

Beach Chair Position – Alternative C-arm Setup

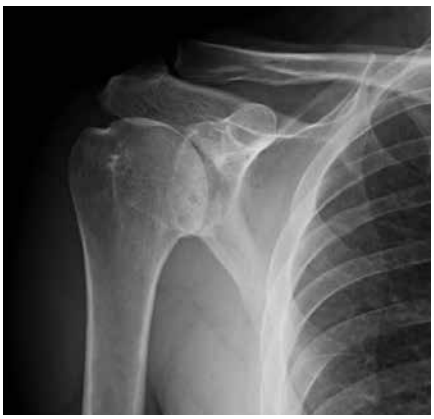
In some patients, particularly those with a large soft tissue envelope around the joint, rotating the patient's arm to obtain AP and lateral views might place undue bending stress on the cannula. To avoid this, an alternative fluoro machine setup allows the C-arm to be moved between AP and scapular Y 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).

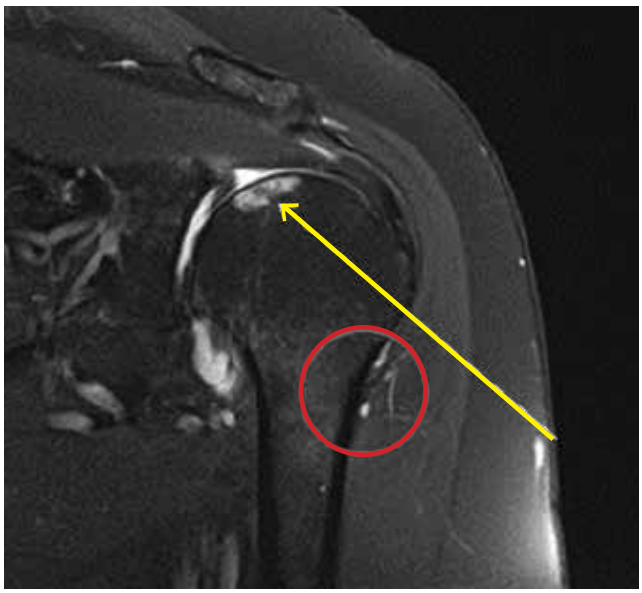
- First, find optimal machine position by setting up to obtain a scapular Y view (image on top right).
- Then, rotate the C-arm to AP until an optimal AP image is obtained (image on bottom right).
- Use both views to target the bony defects of the humeral head.



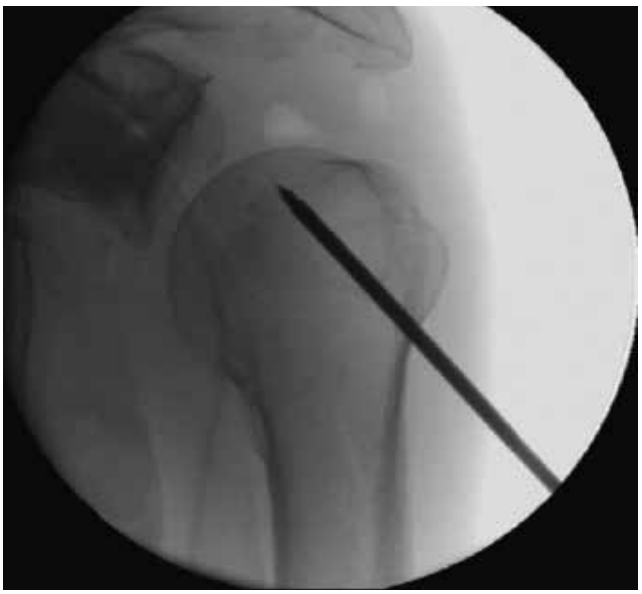
Scapular Y view



AP view



**MRI-planned trajectory to lesion;
Note location of axillary nerve**



**Fluoroscopically identify trajectory with cannula;
Mark the skin along the cannula**

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.

Obtain true AP and true lateral fluoroscopic images of the distal femur with the targeted area centered in the image; note C-arm tilt and position relative to the OR table/patient in each image, to easily return to that position.

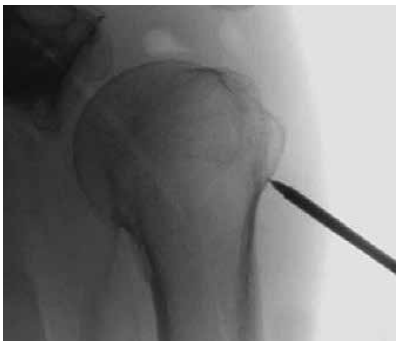
Mark the plateau line and other landmarks and approximate entry points, as desired.

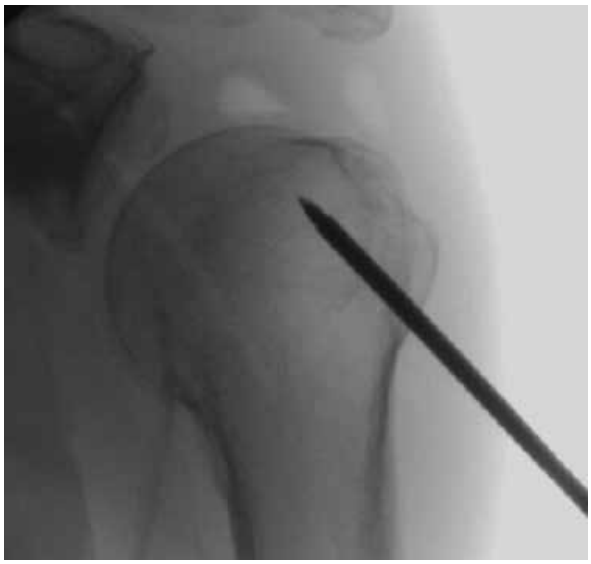
NOTE: The axillary nerve lies approximately 5 cm below the acromion.*

- 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.

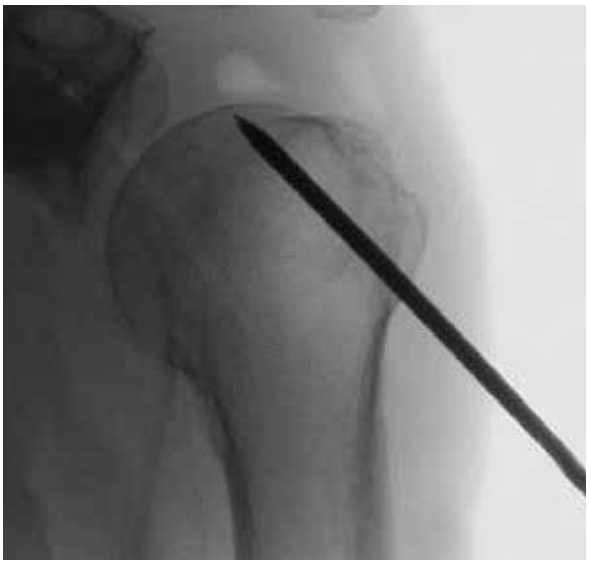
*Thompson JC, Netter FH. Netter's Concise Orthopaedic Anatomy. 2nd ed. Philadelphia, PA: Saunders Elsevier 2010; 3: 113.

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.





Monitor cannula drill depth with AP fluoro



AccuPort cannula in position to inject

- 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 (cont.)

- 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.
- 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.

⚠ **WARNING:** Do not redirect the cannula inside the bone, which could damage the cannula or surrounding bone

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

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.

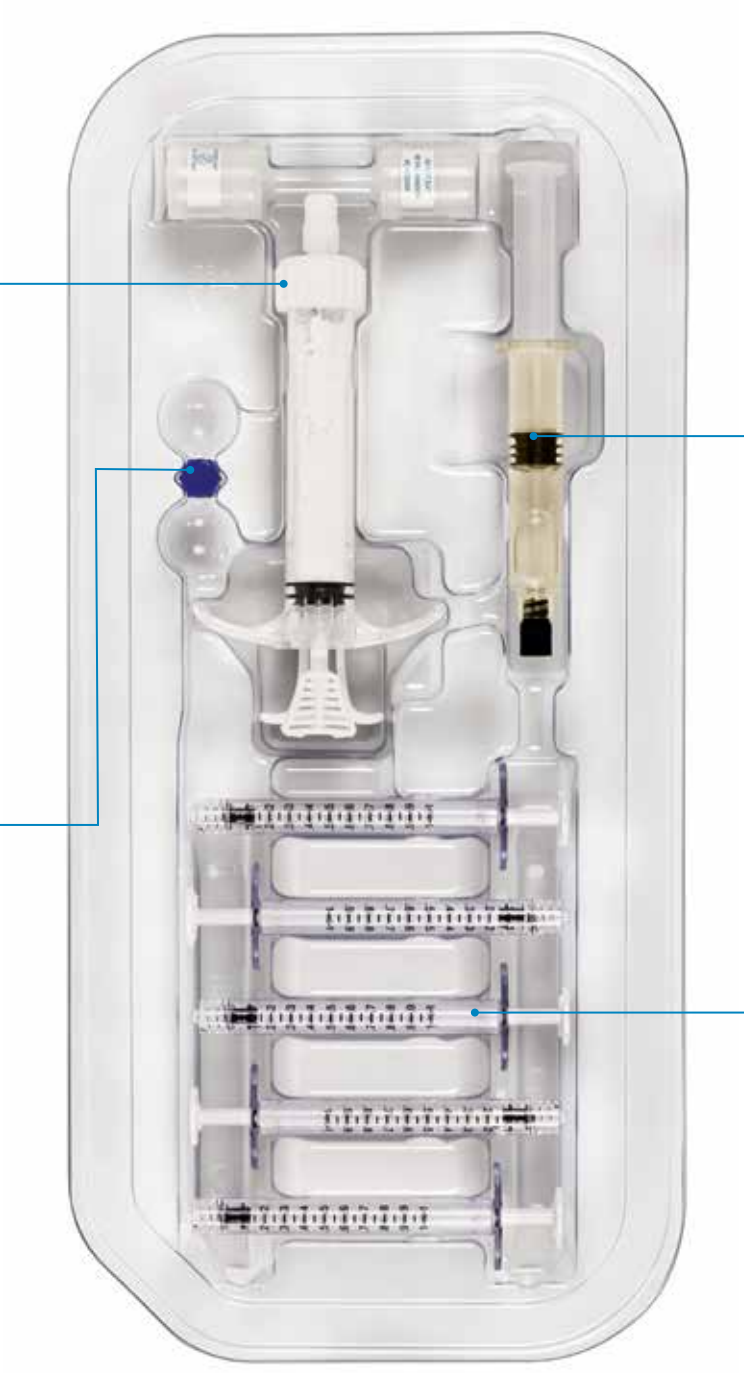
    Connect the first 1 cc syringe. Inject AccuFill BSM into syringe. Repeat for remaining syringes.

    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:

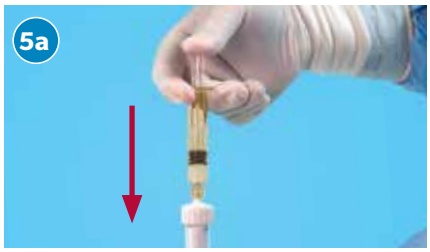
1. Transfer the tray to the sterile field (back table). Remove the AccuFill PF BSM prefilled mixing syringe from tray. Pull on plunger tab to extend the stem completely from within the syringe.

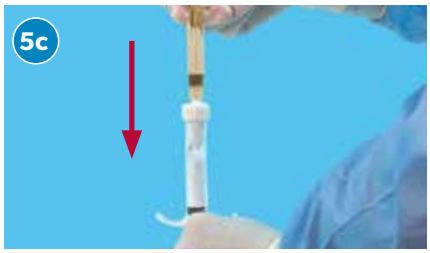
   NOTE: Before connecting the saline syringe, lightly tap on the full prefilled mixing syringe to loosen the AccuFill Powder, which can get compacted.

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.



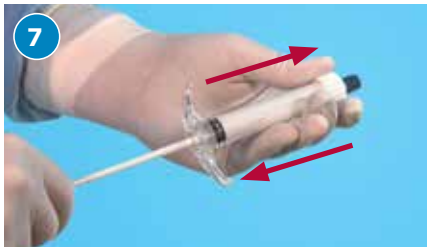


Implant Placement: Filling the Bone Defect (cont.)

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.



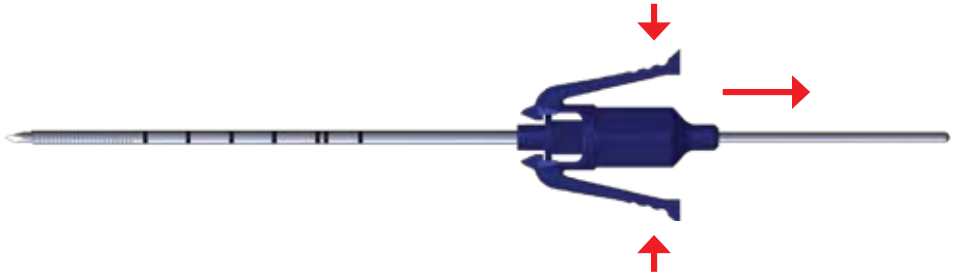
Transfer:

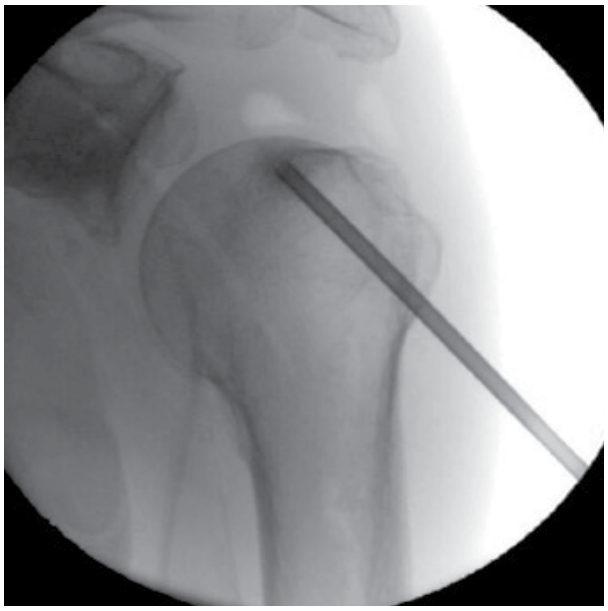
10. Remove the blue luer lock plug from the mixing syringe cap. Holding the mixing syringe with the white cap upright, expel excess air from the syringe. Connect the first 1 cc syringe. Inject AccuFill BSM into the syringe. Repeat for the remaining 1 cc syringes.
11. Transfer the filled 1 cc syringes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

Implant Placement: Filling the Bone Defect (cont.)

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 (cont.)

Injecting AccuFill BSM

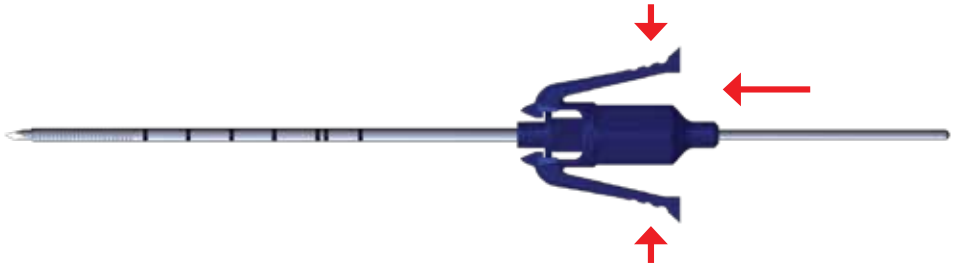
- Remove the first syringe and repeat until desired volume has been implanted. Total injection volume is variable, and dependent on the nature of the bone defect; with cystic lesions often accepting a higher volume of BSM implant.

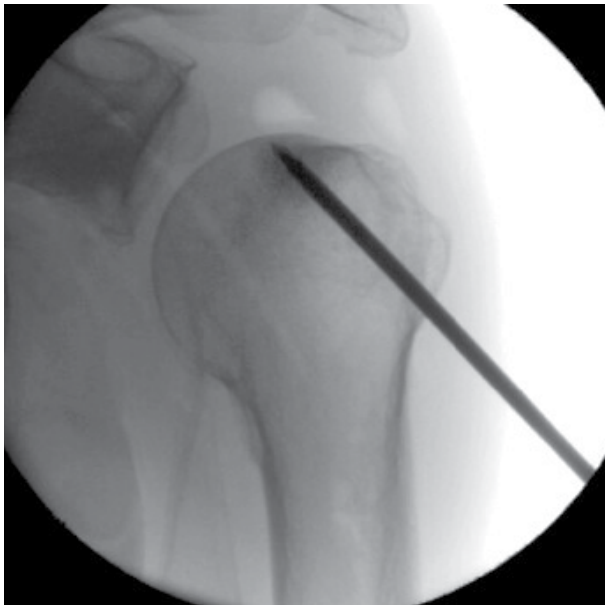
BONE	AccuFill BSM (cc)*
Humeral Head	1.0-3.0 cc
Greater Tuberosity	2.0-3.0 cc
Glenoid	1.0-3.0 cc

*Shoulder Advisory Group recommendations 08/2017.

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

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.





Replace AccuPort stylus

Implant Placement: Filling the Bone Defect (cont.)

Injecting AccuFill BSM

- Leaving the cannula in place while the AccuFill BSM sets, use the scope to evaluate for and evacuate any extravasized 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:

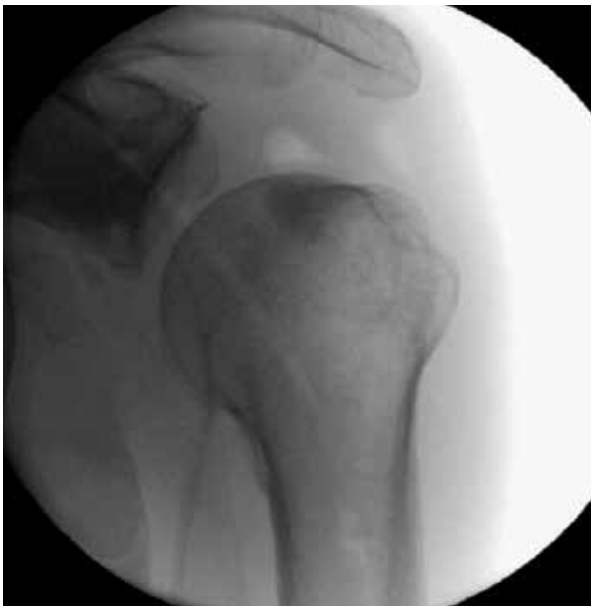
- The first 0.7 cc of mix is filling the cannula itself; once the BSM fills the cannula and starts flowing into the subchondral cancellous bone, back pressure will increase. Let off on digital pressure and then slowly reapply it until the material starts to flow again.
- Monitor flow and volume of the 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.
- 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.

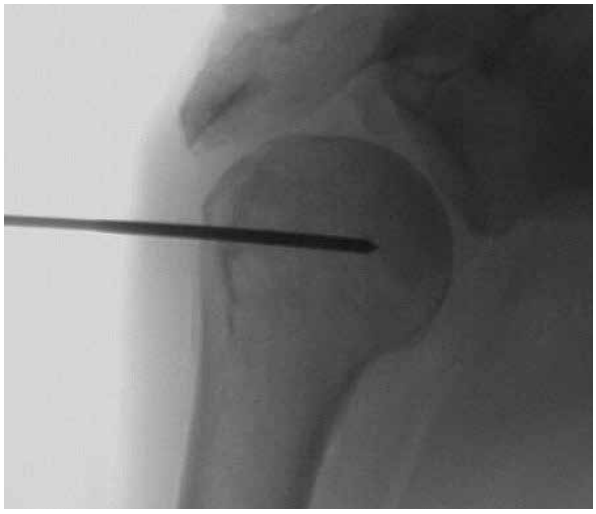
⚠ **WARNING:** Do not overfill the defect site. Overpressurizing the device may lead to extrusion beyond the site of intended application and damage to surrounding tissues. Remove any excess material from the subcutaneous tissue at the entry point by gently expressing and irrigating the material. Blot any excess material from the surgical wound as needed.

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

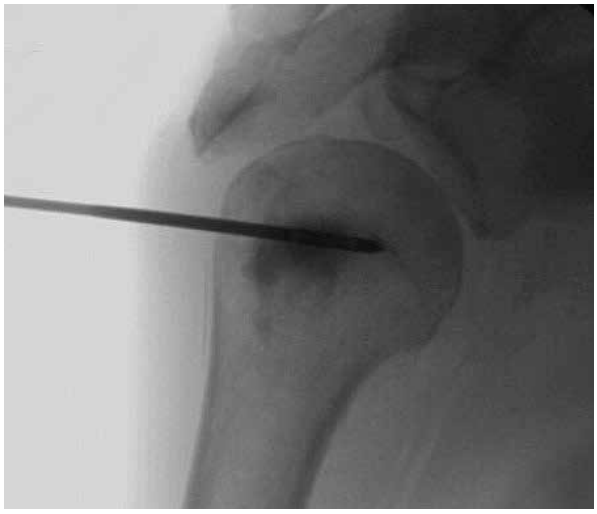


Injection completed, AccuPort cannula removed

Direct Lateral Approach

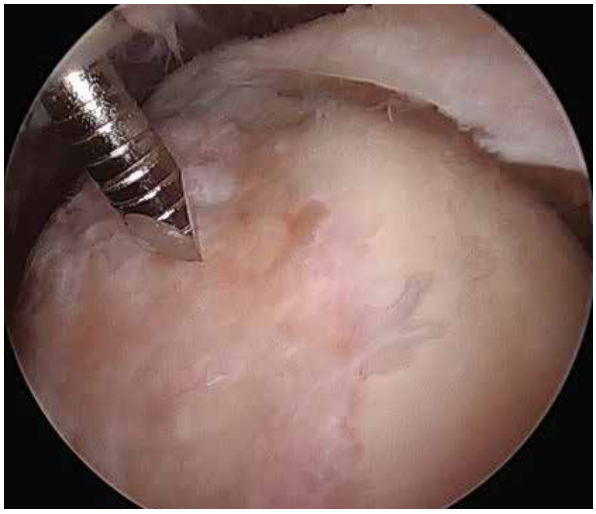


Cannula at desired drill depth

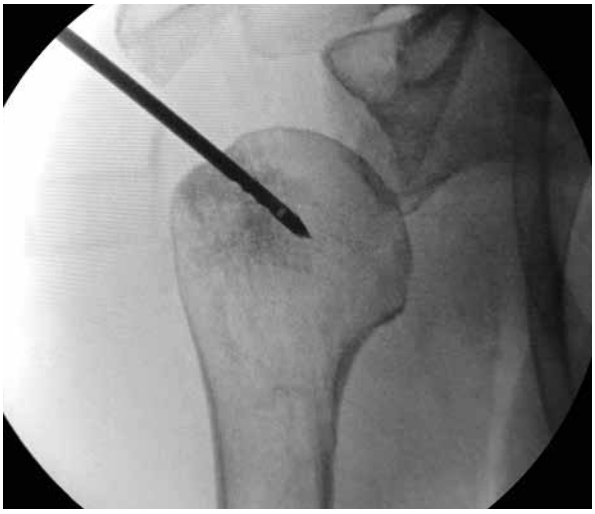


Fluoroscopically monitor implant flow

Medial Footprint Approach



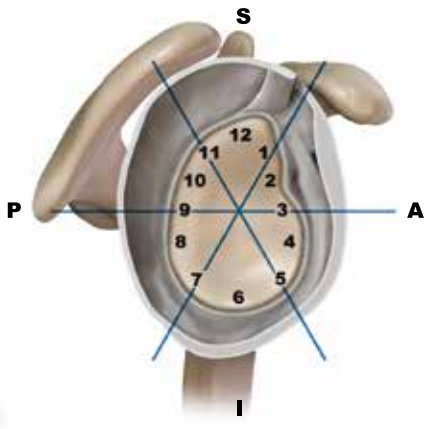
Arthroscopically find cannula entry point

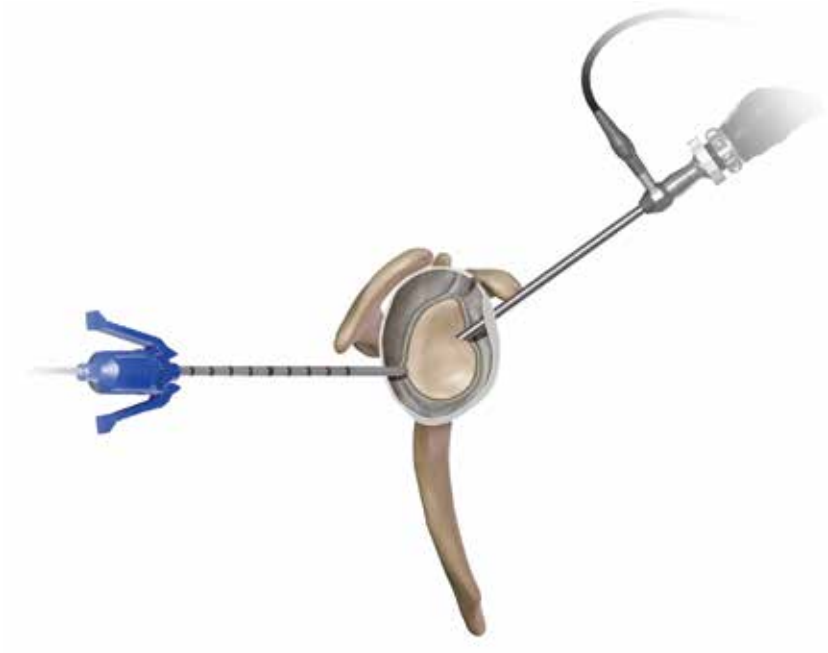


Medial footprint approach to access bone defect

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.





Confirm cannula entry point with the scope

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

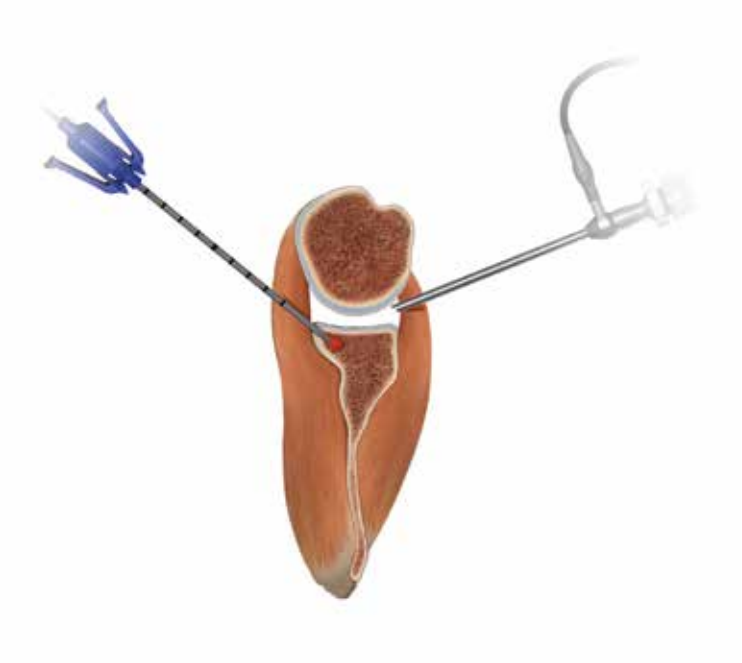
Preoperatively identifying the location of the glenoid defect, following the clock face method, may be helpful for scope-assisted intraoperative targeting. Defects are found more often in the posterior aspect of the glenoid (7-11 o'clock), associated with other posterior joint pathologies.*

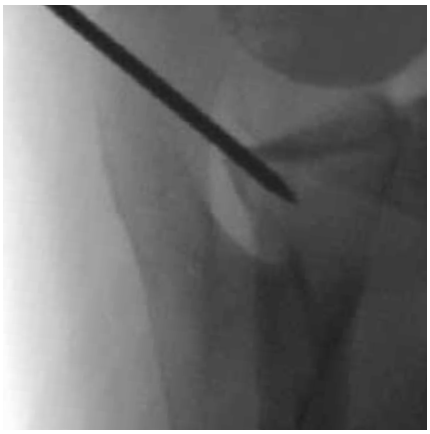
- For targeting a posterior glenoid defect, use a posterior lateral portal for the AccuPort cannula and an anterior portal for viewing.
- Pass the AccuPort cannula tip to the glenoid rim, using the scope to confirm entry point and trajectory (angulation to the glenoid face) toward the defect.

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.

*S Yu, J et al. (1998). Osteochondral defect of the glenoid fossa: cross-sectional imaging features. Radiology. Volume 206, No. 1.



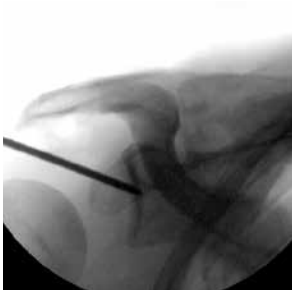


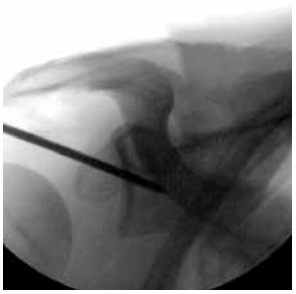
Monitor drill depth on axillary lateral

Considerations for: Glenoid Defects

Scope-assisted Rim Approach (cont.)

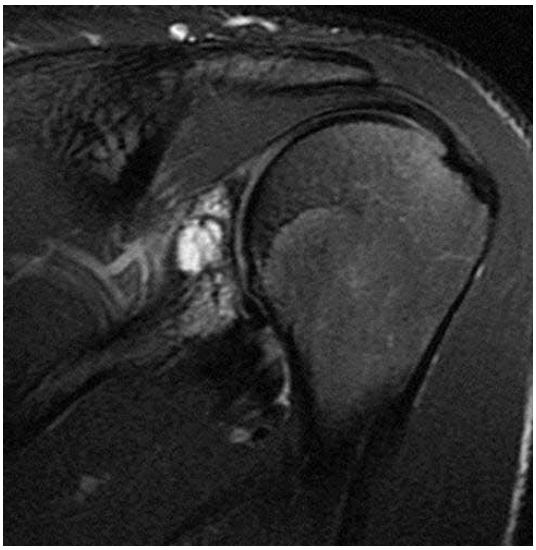
- Drill the AccuPort cannula into the glenoid rim. Once in bone, use axillary lateral fluoro to monitor cannula drill depth.
- When using a side-delivery cannula, use fluoro and/or the scope to confirm all fenestrations are deep to the cortex and pointed in the desired direction of AccuFill BSM flow.

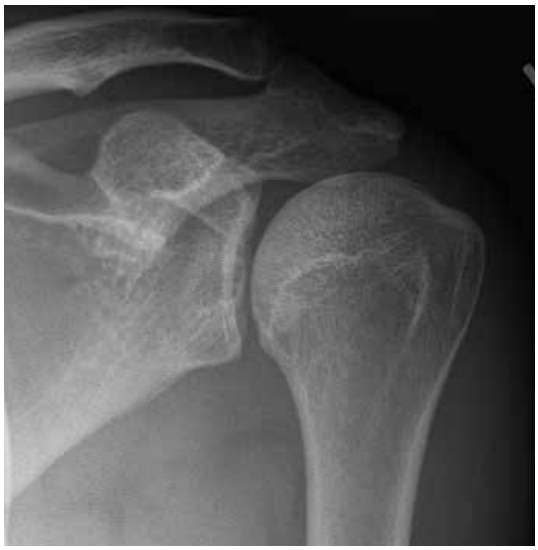




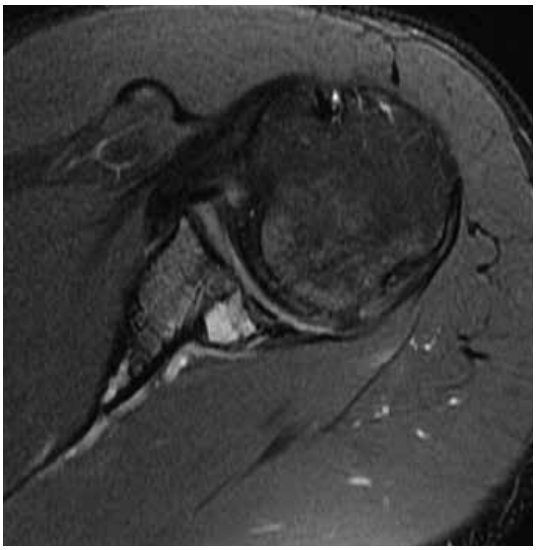
Operative Tip:

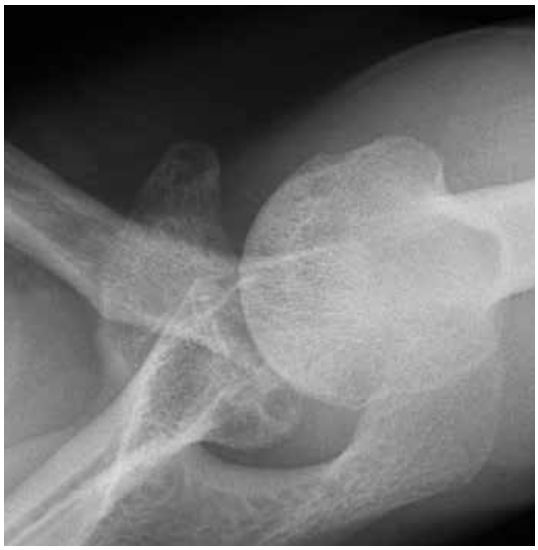
- Consider using AP oblique fluoro to localize entry point superior to inferior on the glenoid rim.
- In beach chair position, this view can be used to monitor drill depth as an alternative to an axillary lateral.





Coronal/ AP oblique





Axial/ axillary lateral

Considerations for: Glenoid Defects

Parallel Approach

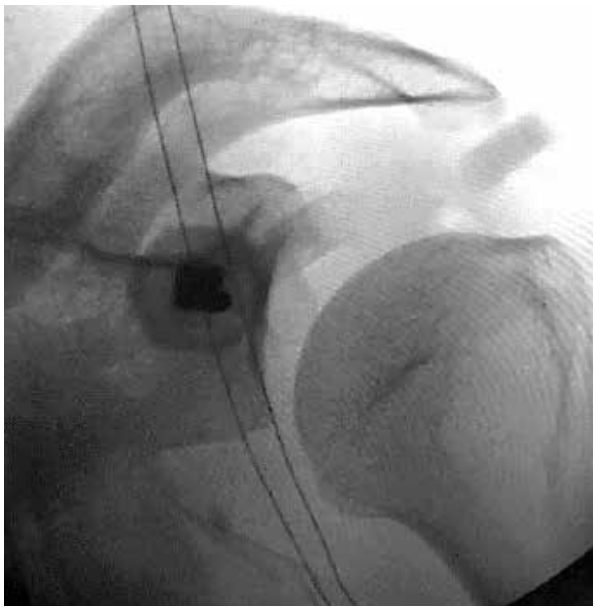
The parallel approach relies heavily on fluoroscopic guidance and principles of free-hand targeting to accurately target bone defects in the glenoid. This technique uses two views, AP oblique and axillary lateral, to triangulate to the defect based on the associated coronal and axial MRI slices, and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

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.

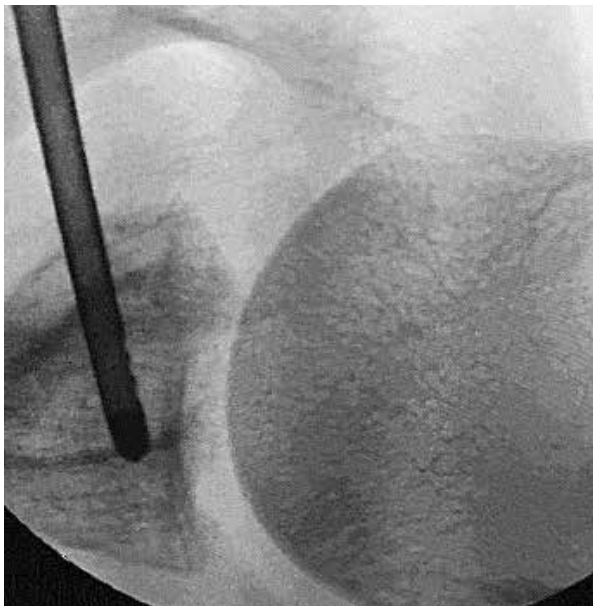
Considerations for: Glenoid Defects

Parallel Approach (cont.)

- 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.



Cannula and glenoid face in line with the beam



Cannula position confirmed on axillary lateral

Implants and Instruments

AccuPort Delivery Cannulas

Trocar-tipped, drillable cannulas for minimally-invasive access, and delivery of AccuFill BSM to the bone defect. Each AccuPort cannula includes interconnecting cannula and stylus, for insertion using an OR wire driver.

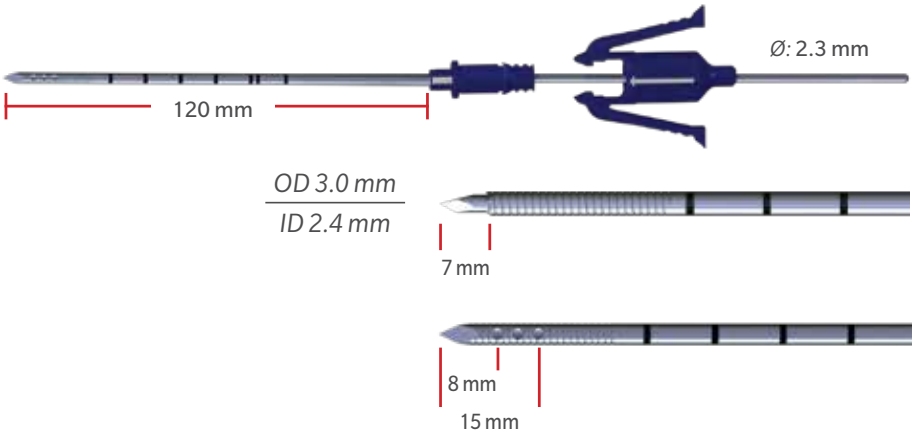
AccuPort Cannulas, 11 ga

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.

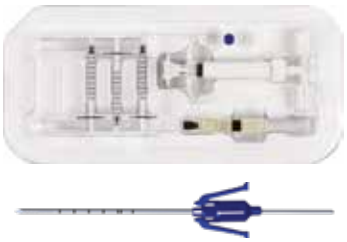
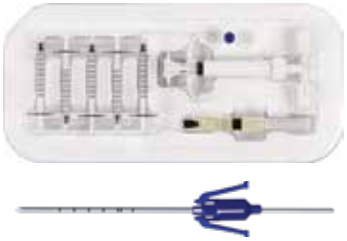


Ordering Information

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

Ordering Information (Continued)

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.™

3656.2-US-en-Issue Date 2023-03

www.zimmerbiomet.com