

The Subchondroplasty® (SCP®) Procedure for the Knee

Sales Playbook



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INTRODUCTION

The SCP Procedure is a minimally invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects, often called Bone Marrow Lesions (BML) through delivery of AccuFill Bone Substitute Material (BSM), a nanocrystalline*, porous injectable calcium phosphate (CaP).

Clinical Need

SCP patients have chronic, non-responsive pain from a subchondral bone defect, where the defect is the primary source of the patients' symptoms. In the knee, subchondral bone defects, otherwise known as bone marrow lesions (BML) are typically present in patients with chronic osteoarthritis¹. In addition to osteoarthritis, BML are also associated with chronic post-traumatic defects or stress reaction/repetitive stress injury. Historically there has been a treatment gap between less invasive conservative care and more invasive procedures. For the correct patient, the SCP procedure may fill that gap in patient care.

Patients typically present with chronic (3+ months) pain, antalgic gait, and some level of disability, with little to no benefit from conservative measures (bracing, PT, injections, NSAIDs, and arthroscopic debridement of intra-articular lesions). Diagnosis is made using history and physical exam. Fat suppressed MRI is then used to confirm the presence of the BML defect.

Until the SCP procedure, conservative treatments have not directly addressed symptomatic subchondral bone defects.

Millions of people each year are diagnosed with knee pain. There is a variety of causes of these symptoms ranging from synovitis, to other soft tissue sources, to bone. Years of clinical research has shown that a major contributor to symptoms in these patients is the presence of subchondral bone defects, often called BML. The clinical relevance of BML defects is that:

- They are a primary source of pain¹
- Radiologically and histologically they represent microtrabecular fractures of the subchondral bone²
- Left untreated, they are extremely likely to progress to the need for TKA³

Chronic pain/symptoms

Knee pain can arise from a variety of anatomic sources including^{4,5}:

- Articular cartilage: avascular/aneural
- Synovium: some pain receptors; more baroreceptors
- Ligaments: more proprioceptors
- Meniscus: pain receptors only in vascular (peripheral) zone
- Subchondral bone: nociceptors

Baroreceptors: Sensors that respond to changes in pressure

Proprioceptors: Sensory receptors in muscles, joint capsules and surrounding tissues that signal information about position/movement of body parts (tendons, ligaments, muscles).

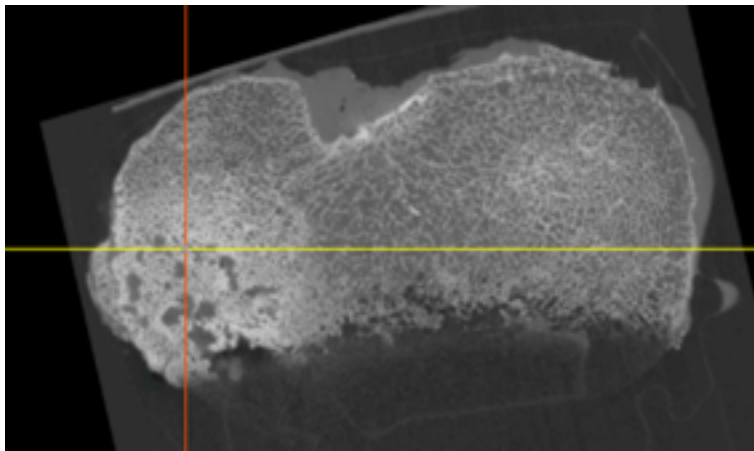
Nociceptors: Pain receptors

*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

Although this correlation between pain and BML has been present in radiology and rheumatology literature since the 1980s⁶, it has only recently been presented in orthopedic journals⁷. Yet, despite the deep pool of knowledge for over 30 years, no treatment options have been developed for patients who have failed conservative care, but aren't ready for a more invasive surgery.

Pathology of BML^{2,8}

Radiographic and histologic studies indicate the true pathology of BML defects. CT scans and histology of resected bone taken from tibial cuts during TKA show damage to the subchondral bone in the form of microtrabecular fractures. These areas contain excessive fibrosis and some osteonecrosis – very similar to the patterns often seen after fatigue fractures or non-unions.



Micro CT from patient with BML defect

Progression to TKA

Given the chronic nature of these BML defects, the pathology often worsens if left untreated⁹. Some of the existing literature has found that patients with BML defects are up to 9x more likely to progress rapidly to TKA³. Other studies show an increased risk of subchondral bone attrition in larger defects⁹. And at that point, it's possible that arthroplasty surgery is the only plausible treatment option³.

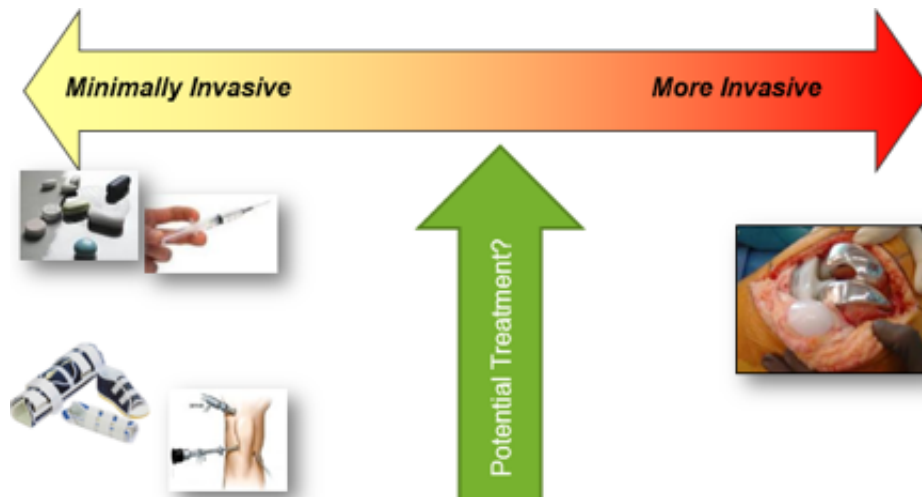
*For further reading on the scientific knowledge of BML, please see reference list on page 25

Until recently, very few treatment options existed to directly address these bone defects. Conservative measures – NSAIDs, bracing, HA injections, PT, corticosteroid injections, and arthroscopic debridement – are typically used as a first line of treatment, but often are not effective in resolving chronic BML.

- NSAIDs – Non steroidal anti-inflammatory drugs – often first line of treatment for patients with OA. Help reduce soft tissue changes and symptoms associated with OA, but do little to address bony changes such as BML
- Bracing – can effectively redistribute forces on the joint, but benefit is limited because patients are often non-compliant (do not wear them)
- HA injections – may provide benefit for intra-articular symptoms, but often not durable relief, especially if the primary source of pain is in the bone

- Corticosteroid injections (cortisone, Kenalog, etc) – More effective anti-inflammatory than oral meds; most SCP faculty indicate limited and short-term benefit in reducing bone defect symptoms
- Arthroscopic debridement – may address intra-articular mechanical symptoms, but relief is often not durable, especially if the primary source of the pain is in the bone

If those options fail, then the next alternatives are much more invasive, like osteotomy, UKA or TKA. These procedures are certainly well established for the right patient group, but may not be desired for those looking to continue conservative, less-invasive care.

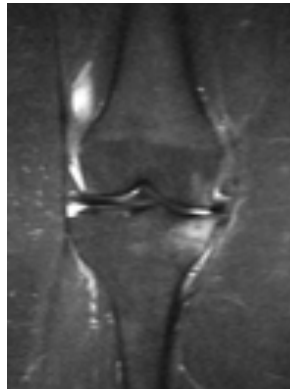


The Subchondroplasty Procedure offers a minimally-invasive treatment to access and fill subchondral bone defects, aka bone marrow lesions, and provide a scaffold for new bone growth in the area of the defect. For patients with knee symptoms who have had little to no benefit from other conservative measures, or those who aren't yet ready for an end-stage procedure, SCP could be an option.

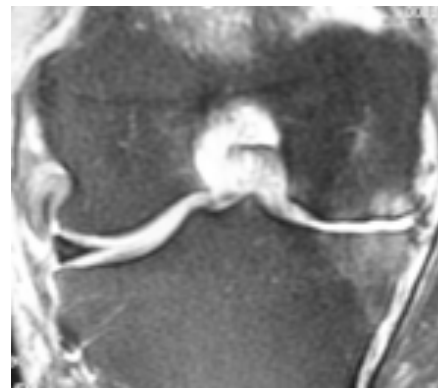
KNEE APPLICATIONS



Femur



Tibia



Kissing

- Tibial plateau BML
- Femoral condyle BML
- Bipolar (“kissing”) lesion
- Patellofemoral pathology – trochlear and or patellar BML

Patient Selection

Most patients exhibit more significant symptoms with weight bearing - walking standing, or running - or after an active day. It is common that patients are able to localize the pain to a specific area (i.e. medial tibial plateau). They may even say that “my bone hurts.” Other factors often include:

- Average age 45-65, but many patients treated outside that range.
- Often with intra-articular comorbidities – cartilage loss or defect, meniscal tear.
- Post-traumatic (3 months+), persistent, unresolved BML with symptoms after treatment with conservative care.
- Chronic pre-stress or stress fracture, or chronic insufficiency fracture; non-responsive to conservative care.
- Radiographic studies should be used to confirm that the adjacent cortical bone is intact

Additionally, patient expectations and patient preferences are important to consider when applying this technology. Patients who exhibit the following may be better candidates for SCP:

- Are too young to consider UKA/TKA
- Have the goal of reducing symptoms from the bone defect, but not necessarily eliminating all symptoms.
- Do not want UKA or TKA surgery.
- Have other medical conditions (obesity, age, etc) that may prevent them from having a more extensive surgery.

SURGICAL TECHNIQUE OVERVIEW

(For full technique, see The Subchondroplasty (SCP) Procedure Knee Technique Guide LBL 909.008 Rev B)



Preoperative plan

- Identify the BML on fat-suppressed MRI (T2 Fat Suppressed), review all three planes (coronal, sagittal and axial)
- Look at multiple sequential images
- Plan to have these images in the OR, to reference during surgery
- After identifying the BML on T2 MRI, reference the T1 MRI for focused targeting. BML often appear as a smaller signal on T1, representing the epicenter of the bone defect.
 - This is especially important if the T2 image shows an extensive, diffuse area of edema – the T1 may help narrow the target
 - STIR images may be best for localizing defect
- Plan approach and trajectory
- Decide on instrumentation – Side-delivery vs. End-delivery AccuPort Cannula
- Plan AccuFill BSM volume based on MRI review of lesion
- AccuFill BSM volume recommendations by Zimmer Knee Creations Knee Advisory Group:
 - Tibial lesions: 3-5cc of AccuFill BSM*
 - Femoral lesions: 2-4cc of AccuFill BSM*
- Some experienced users write their operative plan on the OR board for reference during surgery

* Knee Advisory Group suggestions, Meeting Notes 09/2016

Preoperative plan: Tips and Tricks

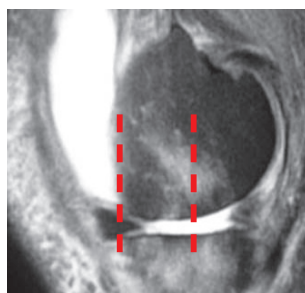
- Make sure all necessary product is present for the case. This includes:
 - 1 SCP Complete Knee Kit (414.502 or 414.503) OR 1 SCP Kit (402.202 or 402.203)
 - *If using SCP kit, a separate AccuMix Mixing System (311.100) is needed
 - 1 back up 5cc or 3cc AccuFill BSM Kit (201.050) or (201.030)
 - 1 Back up Side-delivery AccuPort Cannula (307.032)
 - 1 Back up End-delivery AccuPort Cannula (307.034)
 - 1 Back up AccuMix Mixing System (311.100)

Target the BML defect

- First, obtain perfect AP of tibial plateau, and perfect lateral of femoral condyle. This allows for recognition of anatomic landmarks relative to MRI location of BML.
- Using intraoperative fluoroscopy, target the BML defect based on the preoperative plan
 - Have MRIs in OR to reference images with intraop fluoro
 - For femoral condylar lesions, also note Blumensaat's line as a reference for location of intercondylar notch relative to the BML



Depth from cortex

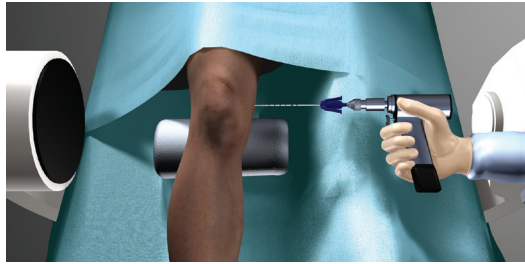


Anterior/central/posterior

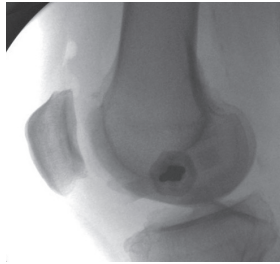


- Starting with AP x-ray, determine the cannula position relative to the joint (typically 7-10mm from the joint line)
- Next, use lateral x-ray to determine anterior – posterior position

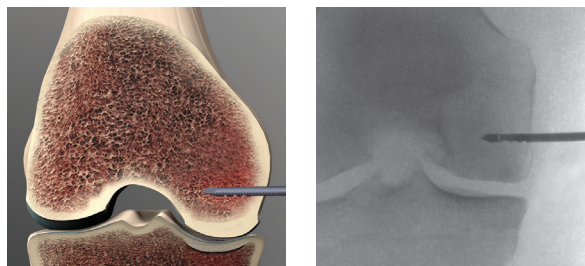
- Confirm position relative to location of the BML, and raise the drill into the line of the x-ray beam, parallel to the table, and prepare to drill into the bone.



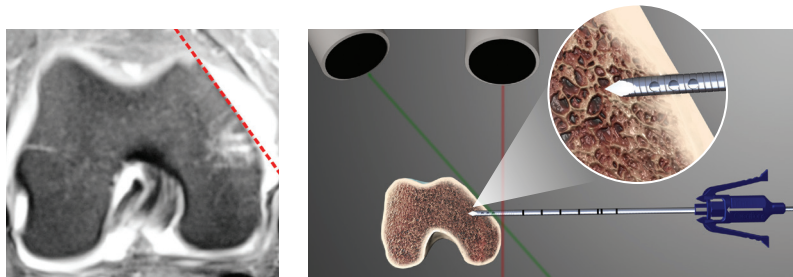
- AccuPort cannula should appear inline with the x-ray beam (below).
- Set the wire driver to the drill setting, not ream.



- Before drilling to full depth, go back to AP x-ray, and confirm depth of the cannula relative to the cortex.
- Do not redirect the cannula after initial drill path has been created. Redirecting the cannula will create an unintended path for the AccuFill BSM.

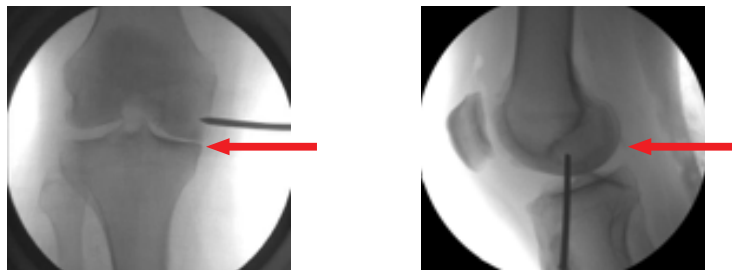


- If using the Side-delivery AccuPort Cannula, confirm that all three fenestrations are in the bone
 - To ensure cannula is inserted into the bone at the proper depth, a tangential shot (orient the c-arm tangential to the cortex) can be utilized.

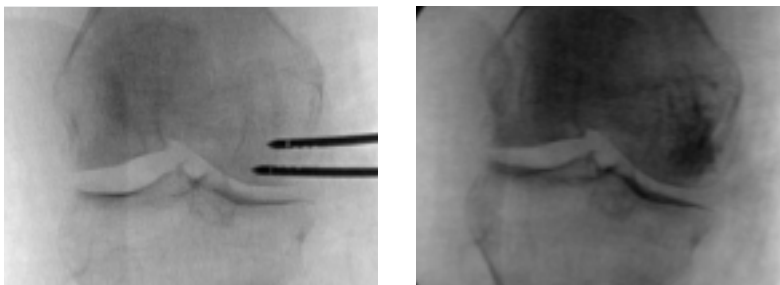


Target the BML: Tips and Tricks

- Targeting
 - Ensure that the targeted area (i.e. tibial plateau or femoral condyle) is in the center of the x-ray image
 - Take fluoro, and target lesions in two orthogonal planes – one within the sagittal plane (AP) and one within the coronal plane (lateral, parallel to the floor).
 - A perfect AP image will show a flat tibial surface (perfectly overlapping anterior and posterior aspects of the bone).
 - A perfect lateral image will show the medial and lateral condyles perfectly overlapping.



- Scoping before or after SCP?
 - Scoping before (inserting cannulas): Identify and treat intra-articular pathology that is present, and avoids bending cannula while flexing knee during scoping.
 - Scoping after: Avoids scoping twice
 - Always place the scope in after SCP procedure to ensure no AccuFill BSM has extravasated
- What to do if you miss the BML
 - Leave the first cannula in place – do not remove it, as that will create an unintended path for the AccuFill BSM
 - Open a new AccuPort cannula, and drill in the desired spot, using the original cannula as a reference point
 - After injection, leave both cannulas in the bone for 10 minute setting period, then remove once AccuFill BSM is hardened

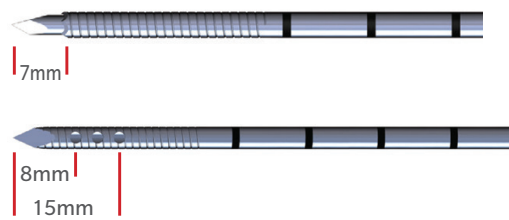


Inject AccuFill BSM

- Using light, digital pressure, inject the AccuFill BSM.
- After desired volume is injected, fully insert the stylus in the cannula until the stylus wings are locked to the cannula hub.
- Leave the stylus and cannula in the bone for 10 minutes after injection to allow for necessary setting time of the AccuFill BSM.

Inject AccuFill BSM: Tips and Tricks

- When attaching and removing the 1cc injection syringes from the cannula, grip the hub firmly to avoid rotating the cannula inadvertently.
- The first 0.7cc fills the 1 g cannula – so the back pressure is non-existent.
- After the first 0.7cc has been injected, expect an increase in pressure, as the AccuFill BSM is now flowing into the bone.
- If there is little to no increase in pressure after the first 0.7 cc, then it is possible that the fenestrations are not all in the bone.
- Take an x-ray after the first full 1cc injection, and monitor for any soft tissue extravasation.
- Consider distributing the material across a broad area – this can be done by changing the direction of the fenestrations or manually backing up the cannula.
- If you feel excess pressure, back off and begin again using less pressure. The harder you push, the harder it pushes back. If that does not work, manually rotate or back up the cannula a couple mm, and reattempt.
- If you still have trouble injecting, use the stylus to push the material through the cannula (instead of the next 1cc syringe). It is possible that you are in an area of sclerotic bone, or that bone has clogged at the end of the cannula during drilling.
- If the AccuFill 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.”
- Irrigate any extravasated AccuFill BSM from the subcutaneous tissue at the entry point using saline and bulb syringe as needed.
- Use the etched lines on the cannulas to help monitor insertion depth.
- The trochar tip on the end-delivery cannula extends 7mm past the cannula tip.
- The third hole on the side-delivery cannula is 15mm from the cannula tip.



Postop

- Some patients experience a high level of pain in the first few days to a week. Physicians performing SCP typically order narcotic pain relievers for the first few days.
- Post-operative protocols typically include WBAT or WBAT with crutch support for the first 48-72 hours.

PRODUCT INFORMATION

AccuFill BSM:

AccuFill BSM is an engineered calcium phosphate compound. It flows readily to fill subchondral bone defects, then crystallizes and sets in an isothermic reaction at 37° C to form a nanocrystalline*, macroporous scaffold in the bone. AccuFill BSM is replaced with new bone during the healing process.

AccuFill BSM's handling ability, performance characteristics, and properties make it uniquely suitable for a closed application like the Subchondroplasty procedure.

Handling

- Easily mixed in the AccuMix Mixing System
- Maintains paste form throughout 15 minute working time
- Sets hard in 10 minutes at body temperature
- May be mixed with saline or whole blood

*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

Performance¹⁰

- AccuFill BSM has unique flow properties, allowing it to flow into and interdigitate with closed cancellous bone under light, digital pressure
- Inclusion of a binding agent (CMC [carboxymethylcellulose]) facilitates flowability and prevents the saline and powder from phase separating under pressure.
- A surgically created void is not required to accommodate injection¹⁰

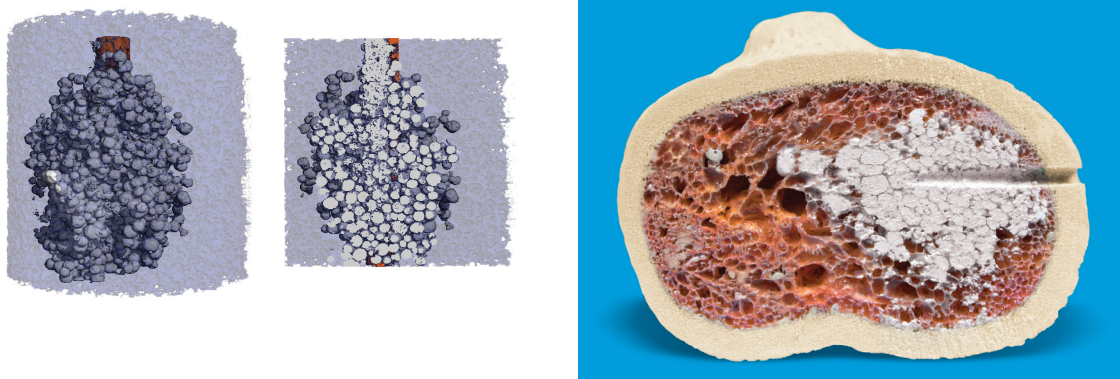


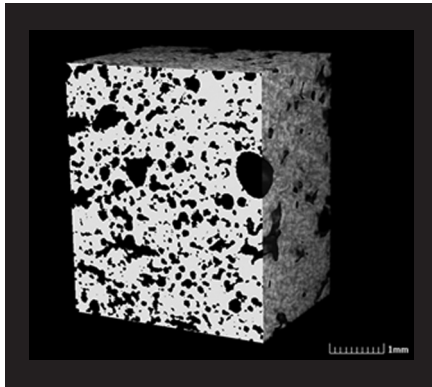
Image above: Assessment of the injection behavior of commercially available bone BSMs for Subchondroplasty® procedures by Colon, Dinely A. et al. from The Knee Journal

Properties^{11,12}

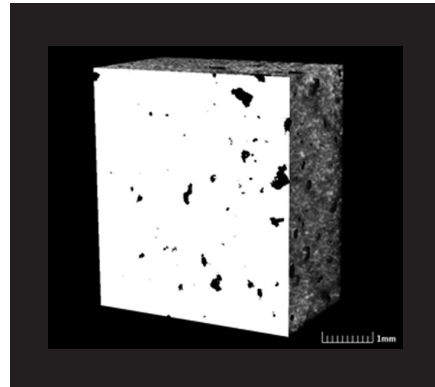
- AccuFill BSM has a comparable chemical composition and crystal structure to natural human bone mineral.
 - These properties result in a material that is similar to the inorganic component of bone
 - Inclusion of metal ions (M) keep crystal domain size in the range of natural bone

Material	Chemical Composition	Average Nano Crystal			Total Volume (mm ³)
		Length (nm)	Width (nm)	Height (nm)	
Human Bone Mineral	$\text{Ca}_{10-x}(\text{M})_x(\text{PO}_4)_{6-x}(\text{HPO}_4, \text{CO}_3)_x(\text{OH})_{2-x}$	23-32	6.7 - 8.0	6.7 - 8.0	1,485
AccuFill BSM	$\text{Ca}_{10-x}(\text{M})_x(\text{PO}_4)_{6-x}(\text{HPO}_4, \text{CO}_3)_x(\text{OH})_{2-x}$	26	8	8	1,664

- 55% porosity, with pores up to 300µm provides greater surface area for cellular activity
- An effervescent agent (sodium bicarbonate) releases carbon dioxide during the setting process to increase the porosity of AccuFill BSM



AccuFill BSM



Low Porosity Material

- Compressive strength of 7-9MPa is about the same as cancellous bone
 - Similar density material, less risk of stress shielding
- Material undergoes cell-mediated remodeling as the body heals

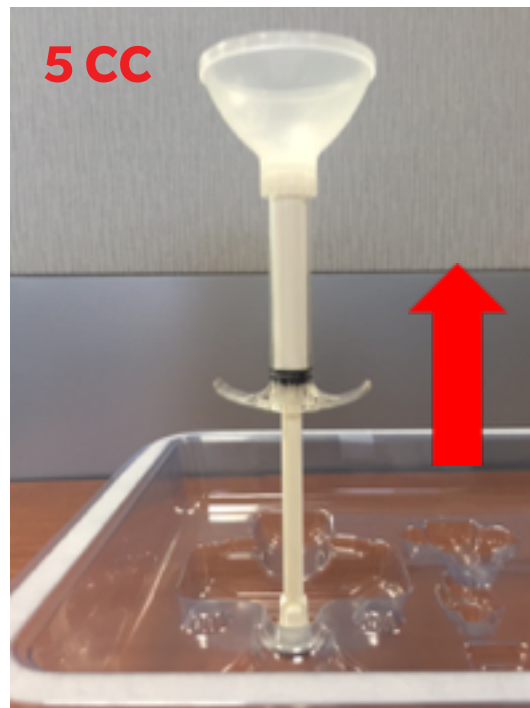
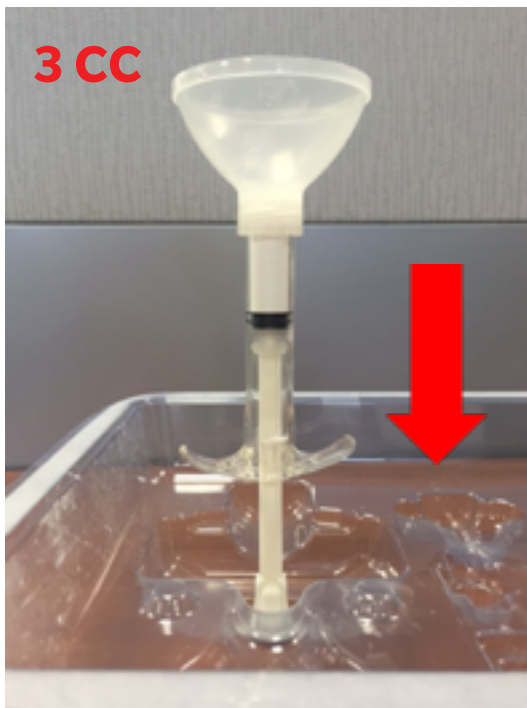
510(k) Information for AccuFill BSM - K062630, K093447, K101557

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 is regulated by the FDA as a Resorbable Calcium Salt Bone Void Filler under regulation 21 CFR 888.3045 as a Class II device.

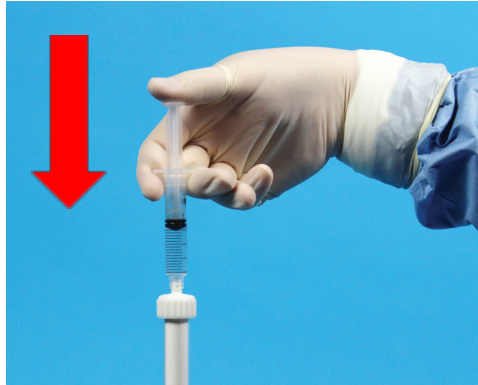
ACCUMIX MIXING SYSTEM

Mixing AccuFill BSM

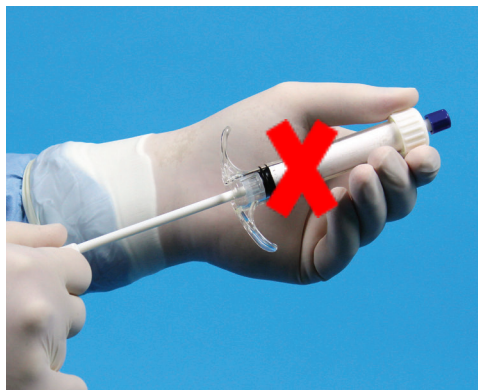
- AccuFill BSM may be hydrated and mixed with normal saline (0.9%) or whole blood.
- The saline vial is filled with 10ml of saline. Saline volume required is noted below.
 - 5 cc AccuFill BSM requires 3.0 cc saline
 - 3 cc AccuFill BSM requires 2.0 cc saline
- AccuFill BSM can also be hydrated with whole blood. Blood volume required is noted below.
 - Whole blood volume for 5cc AccuFill BSM: 3.4 cc
 - Whole blood volume for 3cc AccuFill BSM: 2.3 cc
- When mixing 5cc, pull mixing syringe all the way up over plunger to ensure ample room for the BSM powder.
- When mixing 3cc, after loading BSM powder into syringe, push down on syringe until powder is to the level of the neck of funnel. This eliminates air space between the powder and the top of mixing syringe and ensures injection of saline directly into powder.



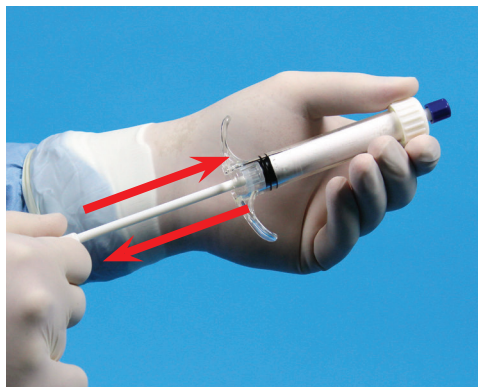
- When injecting saline, inject with force through the powder. After injecting saline, pull up on syringe plunger to pull excess air into saline syringe. Inject again, to ensure all saline flows into powder then repeat to equalize pressure.



- Do not hold mixing syringe barrel while mixing so as not to apply heat to BSM.



- The first mixing syringe plunger strokes should be straight down and back to pull all saline through powder; then begin to twist and rotate plunger for remaining 60 strokes.



- Powder will look dry and unmixed until half way through the mixing process; don't panic, keep mixing. If powder feels dry or stuck, twist plunger to loosen, mortar and pestle style, and continue mixing.
- When filling 1 cc syringe, apply slight back pressure on plunger of 1 cc syringe before removing from mixing syringe to avoid "tailing".
- Bring demo mixing syringe to the OR for visual mixing instructions to the OR staff. The best way is to show them! Order demo mixing system for free on sales portal of SCP website.

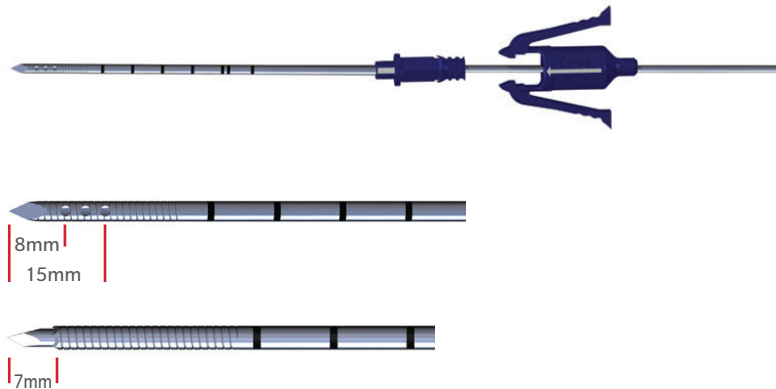
Bring demo mixing syringe to the OR for visual mixing instructions to the OR staff.

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ACCUPORT CANNULAS

120mm 11 gauge AccuPort End- or Side-Delivery Cannulas are used for knee procedures.

- AccuPort Cannulas include two components – cannula and trochar.
- Most surgeons choose the Side-Delivery cannula for ability to direct flow of material.
- Etched markings on cannula every 10mm – monitor drill depth at skin.
- The cannula itself holds 0.7cc of AccuFill BSM.
- Outer diameter (OD) of cannula: 3.0mm; inner diameter (ID) of cannula: 2.4mm.



SELLING POINTS

Talking Points

Get Their Attention		
What do you do for a patient with a BML who hasn't responded to conservative treatment?	OR	Do you have patients who have T2 MRIs that look like this? (show them the MRI w BML on Brochure). BML have been shown to represent a healing response surrounding insufficiency fractures
Create Interest		
You may be able to use the SCP Procedure to help these patients.	OR	The SCP Procedure targets and fills defects associated with BML with AccuFill BSM.
Build Enthusiasm		
Many patients have been able to avoid further surgical intervention	OR	AccuFill BSM mimics the composition of subchondral bone, as well as the porosity and compressive strength, unlike competitive materials.
Drive Action		
There are courses held across the county. Would you like to register for one to learn more?	OR	We have several surgeon experts who can speak with you one on one if you are interested in learning more.

Competitive Points

Many orthopedic device companies sell calcium phosphate (CaP), calcium sulfate (CaS) or other synthetic bone void fillers. Most CaP or CaS products, however, are used in conjunction with fixation hardware for filling traumatic voids or for filling surgically-created voids (e.g., core decompressions).

Some of these products are being promoted as injectable alternatives to the SCP Procedure, but none have the performance characteristics, physical properties or system of instrumentation of the SCP Procedure.

The main difference between AccuFill BSM and the competition include:

- 1. Performance** - AccuFill BSM flows readily and consistently under low pressure. Others require significantly more pressure to deliver less material into the injection site.
- 2. Properties** - AccuFill BSM is similar to bone apatite in its chemical formulation and crystal structure. Other materials appear differently on crystallography. AccuFill BSM porosity and pore size give it a greater surface area for cellular activity.
- 3. Handling** - AccuFill BSM working time and setting time allow for intraoperative ease of use.
- 4. Experience** – ZKC is the market leader in SCP experience, clinical data and IP.

For more information, reference [AccuFill BSM Injection Study](#), [AccuFill BSM vs Quickset Competitive Matrix](#) and [AccuFill BSM Competitive Overview](#).

FAQS

Surgical Procedure

Is it typical for patients to experience high levels pain the first few days after an SCP procedure?

- Some patients experience a high level of pain in the first few days to a week. Physicians performing the SCP Procedure typically prescribe narcotic pain relievers for the first 48-72 hours

What does a surgeon do if his first trajectory of the cannula into the bone is incorrect?

- To minimize the potential for extravasation of AccuFill BSM or cannula damage, avoid redirecting the cannula inside the bone. Leave the first cannula and stylus in place to avoid backflow. Insert a new cannula to drill a different path.

Is a full sized C-Arm necessary?

- Yes, in order for adequate working room for the surgeon, a full sized C-Arm should be used.

What does the surgeon do if AccuFill BSM extravasates into the joint?

- If extravasation of AccuFill BSM into the joint occurs, it can be removed with the arthroscopic shaver.

Are there limitations to patient selection on basis of Body Mass Index (BMI) or malalignment?

- Patients with high BMI or significant angular deformity (varus or valgus alignment) knees are not contraindicated for the SCP procedure. However, these patients should have more limited expectations.

AccuFill BSM

Why is blood volume higher than saline?

- The volume of hydrant (hydration solution such as saline) needed is equivalent to the volume of available water in the hydrant. 0.9% Saline is 99.1% water, or essentially 100%. However, blood, on average, is only 92% water. So to calculate the amount of blood needed to provide the required volume of water, divide the water volume by 0.92. [3.0cc water/0.92=3.26cc blood; 3.2cc water/0.92=3.48cc blood.]
- An interesting side note is that the 92% includes intracellular water, not just that in the serum. That intracellular water is only available because the cells are lysed/sheared.

Why does our current literature call for 3.0cc of saline for 5cc AccuFill, or 2.0cc for 3cc AccuFill, when our IFU states additional saline can be added drop by drop if the mix is dry?

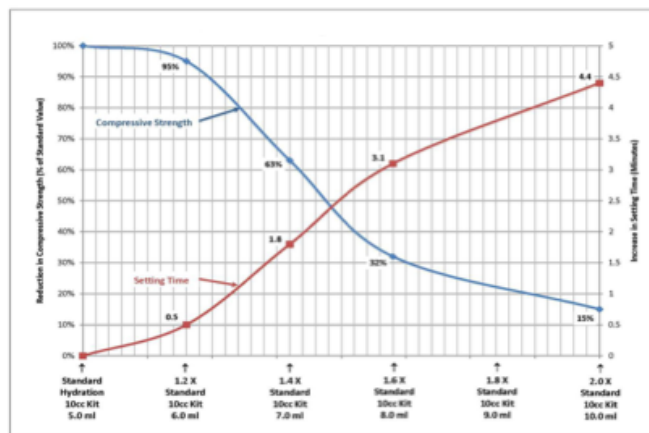
- Official testing and regulatory documents cite the volumes 3cc and 2cc as what was validated for appropriate hydration levels. So current literature is aligned with these official testing documents.
- However, in practice, the additional fraction of saline would cover potential mismeasurement and/or loss of small amounts of saline in the transfer into the mixing syringe.
- It's important to note that if measurement and transfer of saline are conducted perfectly, the additional small fraction of saline will not adversely affect the hydration and reaction of AccuFill. This is shown clearly in hydration testing performed at Etex, covered below.

If 3.0cc saline is correct for 5cc AccuFill mix, why is 2.0cc saline correct for 3cc mix, given that 2cc saline is 66.7% of 3cc, while 3cc mix is only 60% of 5cc mix? Wouldn't 2cc saline tend to overhydrate the 3cc mix?

- 3cc AccuFill kit in fact creates 3.3cc mix, NOT 3.0cc. and 3.3cc mix is 66.7% of 5cc mix!

Hydration/mixing curve

- Accuracy in measuring and delivering the recommended amount of hydrant is critical, as shown in this chart. Over-hydrating AccuFill will increase setting time for the mix and decrease compressive strength of the material once it has set.
- As shown on this chart, an increase in hydrant value up to 20% will have only a small effect on either property. But at volumes >20% higher, strength falls off quickly and setting time increases significantly. So for 3.0cc of saline, any volume greater than 3.6cc should never be considered. And for 2.0cc, 2.4cc is the maximum acceptable.



Effect of Over-Hydration on AccuFill BSM*

*Etex Technical Data Sheet; March, 2011

Is AccuFill radiopaque/radiodense? Why don't we add an additional contrast material to it?

- Radiodensity of a material is a function of the amount of X-ray that is absorbed, reflected or scattered by the material before it strikes the X-ray plate/image intensifier. This is determined mostly by the density of the nuclei of the atoms / molecules of the material, but also by the concentration/density of the material itself in an object and the thickness of the material the X-ray is passing through.
- In general, materials/objects have one of four types of density, from lowest to highest:
 - Air
 - Lipids (fat tissue)
 - Water (muscle, fluids)
 - Mineral/metal

- Bone is “radiopaque” (has higher radiodensity than other tissue) because of the metal (mineral) in bone: the calcium in normal bone apatite. AccuFill is essentially the same as the normal apatite in bone, with the same calcium concentration. So it has the same radiodensity as bone. And, since injecting AccuFill into the bone increases the volume and density of mineral in the area, it increases the overall radiodensity of that area of bone when compared to surrounding bone, showing a visible “blush”.
- Some other BSM increase the radiodensity even further by adding a more-radiodense material to the hydrant (contrast medium), such as Barium or Iodine (iohexol). AccuFill has not received FDA clearance for the addition of contrast material, so although it is known that the addition of iohexol does not adversely affect crystallization or other properties of AccuFill, use of it would be off label.

My surgeon sometimes has difficulty seeing the blush of AccuFill in the bone, as described above. Why is that? What can she do to improve it?

Visibility of material on X-ray is affected by many factors:

1. Patient size or anatomy being radiographed - The larger the anatomy or patient the X-ray beam is shooting through, the lower the X-ray penetration and contrast between tissues.
2. X-ray/fluoro machines—newer fluoro machines (C-arms) have better image intensifiers and imaging software that provide better contrast and sharper X-ray images than earlier models.
3. Fluoro settings—X-ray penetration and image contrast is affected by two settings: kVp and mAs.

kVp (kilovolt peak) is a measure of the “quality” of the X-ray beam. Higher kVp provides a broader grayscale of an image (number of gradations between black and white), reducing the sharpness of contrast.

mAs (milliampere seconds) indicates the quantity of X-rays in the beam. Higher mAs is required to shoot through material with higher radiodensity (e.g. bone). Typically higher mAs, which is typical for orthopaedic protocols, is offset by lowering the kVp, which also improves radiographic sharpness/contrast, making denser materials more obviously visible.

To improve visibility of any given patient/anatomy, do one or more of the following:

1. If the machine has Inverse or Negative setting (switches from fluoroscopy white and black to classic X-ray black and white), do a quick swap to Negative. The injected AccuFill BSM will “pop” out as a brighter white blush in the bone.
2. Set the C-arm on Orthopaedic settings, not abdominal/pelvic (this automatically increases mA and decreases kV).
3. If Ortho setting is not available, turn off Automatic exposure (go manual) and drop kV to about 70% of normal
4. If necessary, ask the tech to go live fluoro and move the C-arm in a rainbow arc over the area. The eye sees motion better than static images so the AccuFill blush stands out more vividly within the surrounding bone.

AccuMix Mixing

Can one mixing system be used for two mixes on the same patient?

- The AccuMix mixing system was developed and validated as a single-use, single-mix, disposable instrument. It is recommended that a second system should be used for a second mix in any case.

AccuPort Cannulas

What is the distance between markings on the AccuPort cannulas?

- The markings on the cannula can be used to estimate depth of cannula in bone. The 11 gauge cannulas have markings every 10mm.
- What are the matching white lines on the stylus and cannula hub on the 11 gauge side-targeting delivery cannulas?

The white markings line up with the direction the fenestrations are facing.

- What is the outer diameter (OD) and inner diameter (ID) of the AccuPort Cannulas?
 - 11 gauge OD: 3.0mm; ID: 2.4mm

What is the distance from the tip of the 11 gauge cannula to the fenestration farthest from the tip?

- 15.3mm

GENERAL QUESTIONS

What is the best way to describe to a surgeon the type of MRI needed?

- The images needed are part of any standard MRI series, but when ordering an MRI your surgeon should say “to rule out BML or insufficiency fracture.” A fluid sensitive or fat suppressed MRI will be generated as part of the series. T2 FS MRI, PDFS or STIR will identify a BML.

Can AccuFill BSM be used in other parts of the body?

- Yes, AccuFill BSM is FDA-cleared to be used as a bone void filler to fill bony voids or gaps 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.
In fact, foot and ankle, hip and shoulder surgeons have been treating patients with BML defects since 2012.

Is selling SCP the same as selling a calcium phosphate?

- No, we need to focus on selling the treatment of painful subchondral bone defects representing fractures associated with chronic BML and provide details as to why AccuFill BSM is different.

How is a chronic BML different from a bone bruise?

- By definition, an acute bone bruise is result of impact event to the bone. Most bone bruises will heal with conservative care. Chronic BML, however are a result of chronic trauma or repetitive injury to the bone, and often do not resolve with conservative management. The SCP procedure fills subchondral bone defects associated with chronic BML, which have not resolved after a course of conservative treatment.

RESOURCES

For SCP Questions, contact SCP Territory Specialist and ZKC Regional Sales Director

Customer Service – to place an order

Zimmer Knee Creations is not integrated on either the Zimmer or Biomet ordering or inventory systems, so all accounts must be set up separately with us using the 'New Customer Form' if they are not already an existing Subchondroplasty user.

Email: KC.customerservice@zimmerbiomet.com

Phone: 855-727-5818; or 484-887-8902

FAX: 484-887-8830

Literature and Demo inquiries

Online order forms are available on www.subchondroplasty.com. Betty O'Reilley: 484-879-4527; betty.oreilley@zimmerbiomet.com will fill the orders received online.

To schedule your surgeon for an SCP Course through the Zimmer Institute:

<http://www.zimmerbiomet.com/medical-professionals/zimmer-biomet-institute.html>

Reimbursement

- Reimbursement Hotline: 855-727-0909

Website

Visit the SCP website at subchondroplasty.com. It includes:

- Surgeon portal
- Sales portal – all literature and videos may be accessed here. Online ordering of print materials, demos and models is also done through the sales portal.
 - For sales portal access, go to subchondroplasty.com -> sales portal -> register -> ZKC marketing will approve within 24 hours
- Surgeon Finder
 - To add surgeon, go to subchondroplasty.com -> sales portal -> add a surgeon -> ZKC marketing will approve within 24 hours
- Patient page

Available Knee Literature and Demo:

- 909.008 Knee Technique Guide
- Subchondroplasty Overview (PDF only)
- 903.001 SCP Surgeon Brochure
- 903.066 Subchondroplasty Navigation Guide Overview (PDF only)

Other Available Literature and Demo:

- 903.053 Foot and Ankle Technique Guide
- 903.138 Surgeon Brochure for SCP for Foot and Ankle
- 909.113 Hip SCP Technique Guide
- 999.000 2017 Price List
- 903.016 SCP Product Catalog
- 903.042 SCP Patient Guide
- 903.019 SCP Coding Reference Guide (available through market access website)
 - <http://www.zimmer.com/medical-professionals/support/reimbursement/coding-guides.html>
 - Document controlled by market access – check website for updates
- 903.012 Reimbursement Hotline Cards
- 903.048 AccuFill Injection Study Technical Bulletin
- 903.029 AccuFill BSM Competitive Analysis Brochure (for Sales Rep training- internal use only)
- 903.113 AccuFill BSM vs QuickSet Competitive Overview
- 903.043 AccuMix Release Flyer
- 903.073 AccuMix Replacement parts
- 903.047 AccuMix Technique OR Poster (11x17 laminated)
- 903.023 ZKC Iceberg Folder (for creating literature packets)
- 903.072 SCP Resources USB Drive

Available Videos:

- 909.105 Knee SCP Surgical Technique Video (Chris Baker, MD)
- 903.094 AccuFill BSM Remodeling Animation
- 903.045 AccuMix Mixing System Technique Video

Studies and journal reprints specific to knee SCP

- 903.008 Journal Reprint: Subchondroplasty for Treating Bone Marrow Lesions (Cohen 2015)

Subchondroplasty Publications

- Cohen, SB, Sharkey, PF. Subchondroplasty for Treating Bone Marrow Lesions, Journal of Knee Surgery, Dec. 2015.
 - Retrospective study on the first 66 consecutive patients who underwent the Subchondroplasty procedure. Data collected on survivorship, and pain and function improvements at 2 years postop.
 - Authors' Summary: clinically significant improvements in pain and function, and 70% did not convert to knee replacement at 2 year follow up.

- Cohen SB, Sharkey PF. Surgical Treatment of Osteoarthritis Pain Related to Subchondral Bone Defects or Bone Marrow Lesions: Subchondroplasty. *Techniques in Knee Surgery*. 2012;11(4):170-175.
 - Study on history, pathology, applications and technique for the Subchondroplasty procedure. Further detail provided on imaging, approach and postoperative management.
 - Authors' Summary: SCP is possible treatment method for BML defects, more information needed on patient selection.
- Chatterjee et al. Subchondral Calcium Phosphate is Ineffective for Bone Marrow Edema Lesions in Adults with Advanced Osteoarthritis *Clin Orthop Relat Res*. 2015 Jul; 473(7):2334-42
 - Study on 33 Subchondroplasty patients treated by 4 surgeons. All patients had grade 3-4 chondral lesions. Data collected on KOOS and Tegner-Lysholm scores.
 - 7/22 patients had poor outcomes, 3/22 had fair outcomes, 5/22 had good outcomes and 7/22 had excellent outcomes
 - Authors concluded that SCP should not be recommended for patients with advanced OA despite 19/22 patients showing statistically significant and clinically meaningful improvement. Justification for this conclusion was based on the proportion of patients with poor outcomes.
- Knee Arthroplasty After Subchondroplasty: Early Results, Complications, and Technical Challenges. Yoo JY, O'Malley MJ, Matsen Ko LJ, Cohen SB, Sharkey PF. *J Arthroplasty*. 2016 May 10. pii: S0883-5403(16)00018-8. doi: 10.1016/j.arth.2015.12.051.
 - 22 patients who had previously undergone SCP and converted to TKA were matched 2:1 to patients undergoing TKA without prior surgery. Study conducted to assess any challenges or complications that the SCP procedure had on performing knee arthroplasty.
 - Authors' Summary: SCP treatment prior to arthroplasty does not compromise the outcomes, performance or increase the complications of arthroplasty.

Subchondroplasty Public Presentations

- Short and Mid-term outcomes of the Subchondroplasty Procedure for the Treatment of Bone Marrow in Patients with Knee Osteoarthritis
 - Allegheny Health Network
Arthroscopy 2017
Authors: Sam Akhavan, MD, Jennifer Byrd, MD, Patrick DeMeo, MD, Darren Frank, MD
 - 172 Subchondroplasty patients studied with outcomes presented for patient groups <2 yr and >2 year post-operative. Data collected on survivorship, VAS and patient satisfaction.
 - Authors' Summary: Average VAS score decreased from 8.3 to 3.4 in both groups. 82% of short-term group was willing to undergo SCP again, vs. 95% of the mid-term group. 89% of the short-term group would recommend SCP as a treatment option vs. 96% of the mid-term group. 25% of total patients progressed to TKA, with 69% occurring before 2 years.

BML Articles

- Eriksen EF, Ringe JD. Bone marrow lesions: a universal bone response to injury? *Rheumatol Int.* 2011;32(3):575–584
 - Review of pathology, etiology, histology and imaging of bone marrow lesions.
 - Authors' Summary: BML are significant sources of pain and lead to worsening progression of disease. They represent bone injury from increased forces or inflammatory injury.
- Felson et al. The Association of BML with Pain in Knee OA *Annal Internal Med* 2001; 134: 541-549
 - 401 patient, cross-sectional observational study based on MRI evaluation, showing that BML were found in 77.5% of people with painful knees.
 - Authors concluded that BML are strongly associated with symptoms in patients with knee OA.
- Felson et al. Bone Marrow Edema and its Relation of Progression of Knee OA *Annal Internal Med* 2003; 139:330-336
 - 256 patient study conducted to determine if patients with BML are at a higher risk for worsening progression of clinical symptoms.
 - Authors concluded that BME is a risk factor for structural damage in knee OA, and its relation to disease progression may be partly explained by its association with alignment.
- Taljanovic et al. Resonance Imaging and Correlation with Clinical Examination, Radiographic findings, and histopathology *Skeletal Radiol* 2008; 37: 423-431
 - Study on the correlation of BML on MRI and their relation to clinical and histopathological findings. 19 patients who underwent hip arthroplasty had bone resections taken and evaluated.
 - Authors' Summary: Results showed that the patient group with BML had statistically significant correlations with pain and the presence of microfractures in the bone.
- Zanetti et al. Bone Marrow Edema Pattern in Osteoarthritic Knee: Correlation Between MR Imaging and Histologic Findings, *Radiol* 2000; 215:835-840
 - Comparison of BML on MRI, to histologic evaluation of BML after knee arthroplasty. 16 patients who underwent knee arthroplasty had preop imaging compared with histologic evaluation of plateau resections.
 - Authors confirmed that pathology of BML includes a combination of normal tissue, plus necrotic areas, fibrosis, edema and bleeding of the bone marrow. Histologic evidence is provided on the pathology of BML in osteoarthritic knees.

AccuFill BSM

- Russell et al. Comparison of Autogenous Bone Graft and Endothermic Calcium Phosphate Cement for Defect Augmentation in Tibial Plateau Fractures. A Multicenter, Prospective, Randomized Study *JBJS* 2008;90:2057-2061
 - Level 1 study comparing use of autograft in tibial plateau fractures vs Alpha-BSM* in 119 patients.
 - Alpha-BSM showed superior results vs. autograft in prevention of subsidence.

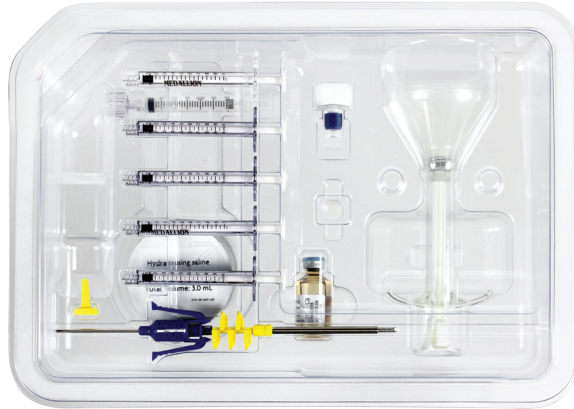
*Alpha-BSM is chemically identical to the calcium phosphate found in AccuFill BSM

PART NUMBERS/ DESCRIPTION (see Product Catalog for additional information)

5cc, 11 Gauge SCP Complete Knee Kits

SCP Complete Kits can replace the following individual components for a single SCP procedure:

- AccuMix Mixing System: 311.100
- AccuFill BSM (5cc): 201.050
- AccuPort 11 ga Cannula: 307.032 or 307.034



SCP Complete Kit, 11 Gauge, Side-delivery, 5cc

- Kits include: AccuPort 11 Ga Side- or End-Delivery Cannula (with 308.011 Depth Control Sleeve and 308.013 Adaptor Sleeve, optional); 201.050 AccuFill Bone Substitute Material (5cc); 311.100 AccuMix Mixing System (no spatula is included so bowl mixing isn't an option)

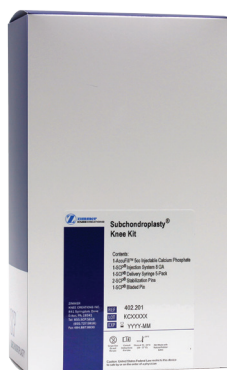
5cc, 11 Gauge SCP Complete Kits

Part	4 PK Part#	Description
414.502	444.502	SCP Complete Knee Kit; 5cc, Side-Delivery, 11 Ga x 120mm
414.503	444.503	SCP Complete Knee Kit; 5cc, End-Delivery, 11 Ga x 120mm

SCP kits include

- AccuPort 11 ga cannula: 307.032 or 307.034
- AccuFill BSM (5cc): 201.050
- SCP Delivery Syringe (5-Pack): 303.250

*note - SCP kits do not contain an AccuMix Mixing System, so that must be used separately if desired



5cc, 11 Gauge SCP Kits

Part	4 PK Part#	Description
402.202	444.502	SCP Kit; 5cc, Side-Delivery, 11 Ga x 120mm
402.203	444.503	SCP Kit; 5cc, End-Delivery, 11 Ga x 120mm

AccuPort Delivery Cannulas

Part	Description
307.032	AccuPort Side-Delivery Cannula, 11 Ga, 120mm
307.034	AccuPort End-Delivery Cannula, 11 Ga, 120mm

AccuFill Bone Substitute Material

Part	4 PK Part#	Description
201.050		AccuFill Injectable Bone Substitute Material, 5cc
	241.050	AccuFill Bone Substitute Material, 5cc
201.030		AccuFill Injectable Bone Substitute Material, 3cc
	241.030	AccuFill Bone Substitute Material, 3cc

AccuMix Mixing System

Part	4 PK Part#	Description
311.100		AccuMix Mixing System
	341.100	AccuMix Mixing System
311.102		Replacement Parts for AccuMix Mixing System

Note: 8 packs also available for product packaged in 4 packs.

References

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- Tofghi et al. Setting Reactions Involved in Injectable Cements Based on Amorphous Calcium Phosphate. Key Engineering Materials Vols. Pages 192-195 (2001)