

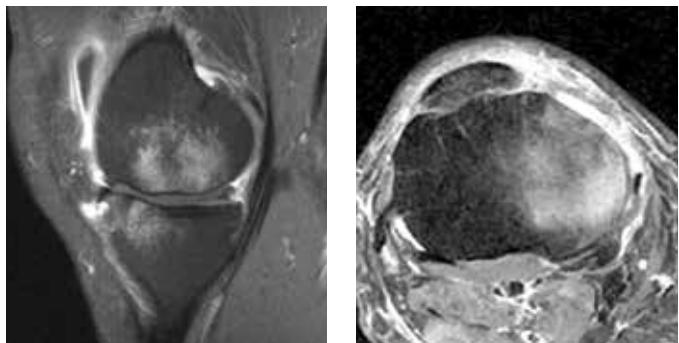
The Subchondroplasty® (SCP®) Procedure



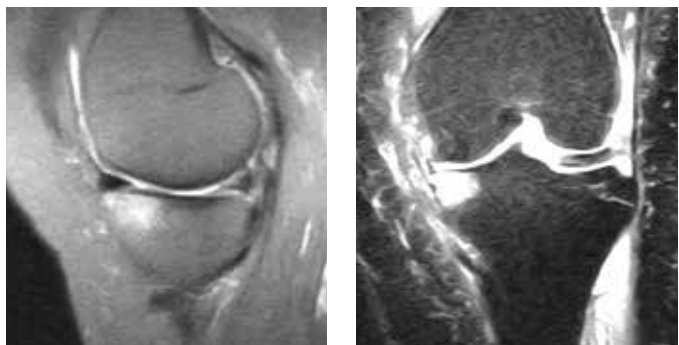
What are your treatment options for this patient?

The Subchondroplasty (SCP) Procedure

What is the Subchondroplasty[®] SCP[®] Procedure?



The Subchondroplasty[®] Procedure is a minimally invasive, fluoroscopic-based procedure that targets and fills subchondral bone defects, often called BML. It is usually performed with arthroscopy for visualization and treatment of findings inside the joint.

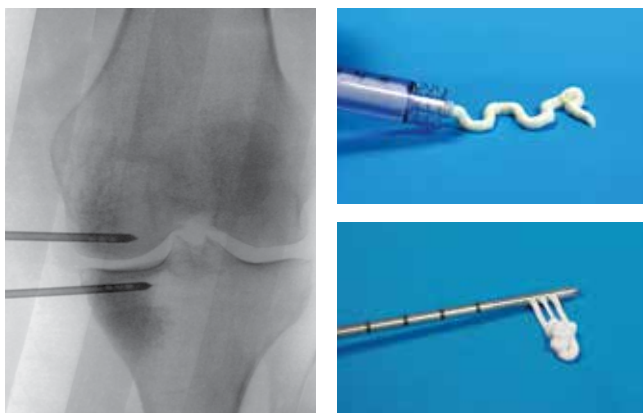


BML have been shown to represent a healing response to trauma, such as microtrabecular fractures of the subchondral bone.¹

BML detected using fat-suppressed MRI

How Does the SCP Procedure Work

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

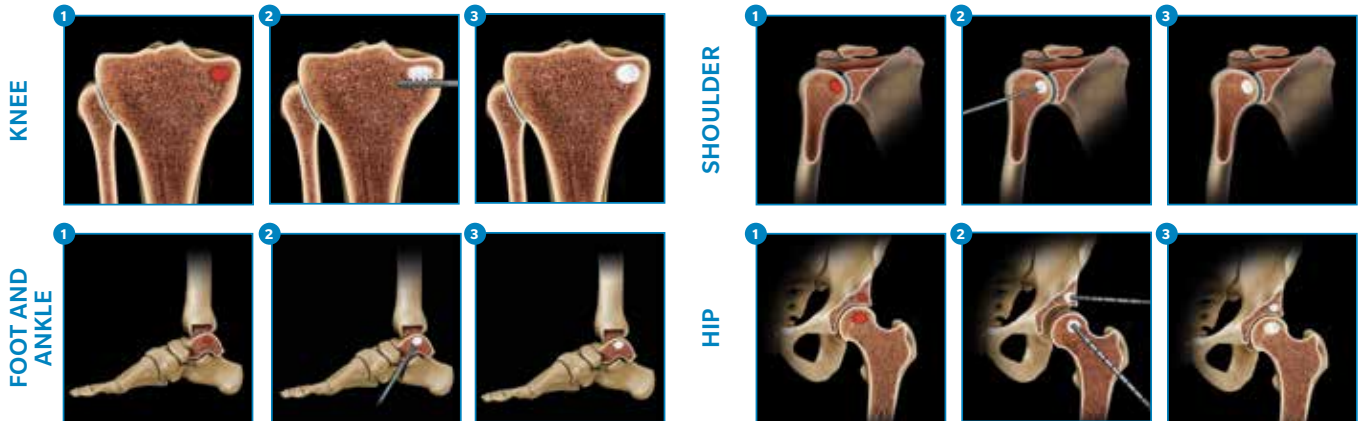


The SCP Procedure fills closed bone defects with AccuFill BSM, a truly injectable bone substitute material.

*BML = Bone Marrow Lesion; BME = Bone Marrow Edema; BML/BME are often used interchangeably by clinicians to indicate subchondral bone defects or damage to the subchondral bone.

How is The SCP[®] Procedure Performed?

- 1 Identify defect associated with Bone Marrow Lesion (BML); plan approach and trajectory.
- 2 Access bone defect using AccuPort[®] Delivery Cannula.
- 3 Fill bone defect with AccuFill[®] Bone Substitute Material.



AccuFill BSM Performance

AccuFill BSM = $\text{Ca}_{10-x}(\text{M})_x(\text{PO}_4)_{6-x}(\text{HPO}_4, \text{CO}_3)_x(\text{OH})_{2-x}^{**} = \text{Bone}^2$

Criteria	Feature	Benefit
Formulation	<ul style="list-style-type: none"> Proprietary, next-generation engineered apatite Chemically similar to apatite of bone³ 	<ul style="list-style-type: none"> Facilitates cell-mediated remodeling
Handling	<ul style="list-style-type: none"> Truly injectable⁴ Remains cohesive⁴ Flowable inside cancellous bone⁴ 15 minutes of working time 	<ul style="list-style-type: none"> No need to remove subchondral bone No phase separation from injection pressure⁴ Interdigitates easily for complete defect fill⁴ Extended time frame for implantation; intra-operative flexibility
Setting	<ul style="list-style-type: none"> Endothermally sets in 10 minutes at 37°C 	<ul style="list-style-type: none"> Sets hard after closure, no thermal necrosis
Structure	<ul style="list-style-type: none"> Osteoconductive Nanocrystalline structure^{3,****} 65% total porosity; 1 to 300 μm pore size ~10 MPa compressive strength 	<ul style="list-style-type: none"> Physical properties comparable to that of cancellous bone Nanocrystalline structure and high surface area facilitate remodeling and bony ingrowth
Remodeling	<ul style="list-style-type: none"> Cell-mediated remodeling^{5,****} Remodeled vs. dissolved^{5,****} 	<ul style="list-style-type: none"> Remodels with new bone growth^{5,****}

** (M) = metal ions, e.g., Mg⁺⁺, etc. Note: surface reactivity relates to metal bonds

*** 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.

SCP® Instrumentation

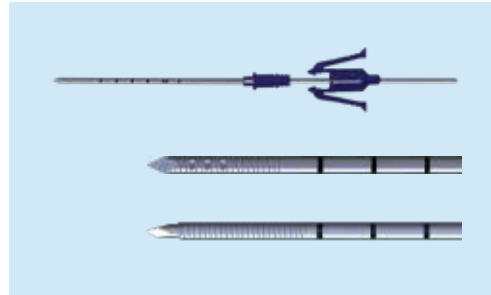
AccuMix® Mixing System

- Hydrates and mixes AccuFill® BSM
- Closed mixing system
 - Controlled, consistent mixing
 - Closed transfer to injection syringes
 - No loss of mix
- User-friendly design and technique



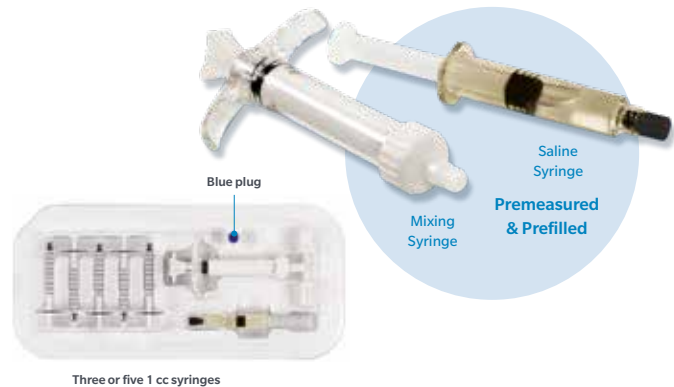
AccuPort® Delivery Cannulas

- Two components: cannula and stylus
 - Stylus locks to cannula hub
- Two delivery options: side and end
- Trocar tip allows for easy advancement into bone
 - Insert with OR wire driver



There is also a pre-fill (PF) option available where the AccuFill BSM and Saline are pre-measured and pre-filled in Mixing and Saline Syringes respectively.

They are part of the AccuFill PF BSM Kit which includes all components to hydrate and mix AccuFill BSM in a convenient, closed mixing system.



Three or five 1 cc syringes

AccuFill BSM Indications for Use:

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

References

1. Eriksen EF, Ringe JD. Bone marrow lesions: a universal bone response to injury? *Rheumatol Int.* 2012; 32 (3): 575-584.
2. Tofghi, et al. New Generation of Synthetic, Bioresorbable and Injectable Calcium Phosphate Bone Substitute Materials: Alpha-*bsm*, Beta-*bsm* and Gamma-*bsm*; *JBBTE.* 2009; 2: 39.
3. Tofghi, et al. New Generation of Synthetic, Bioresorbable and Injectable Calcium Phosphate Bone Substitute Materials: Alpha-*bsm*, Beta-*bsm* and Gamma-*bsm*; *JBBTE.* 2009; 2: 39.
4. Colon et al. Assessment of the injection behavior of commercially available bone BSMs for Subchondroplasty® procedures. *Knee.* 2015 Dec;22(6): 597-603.
5. 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

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