

The Subchondroplasty® (SCP®) Procedure

SCP® Instrumentation

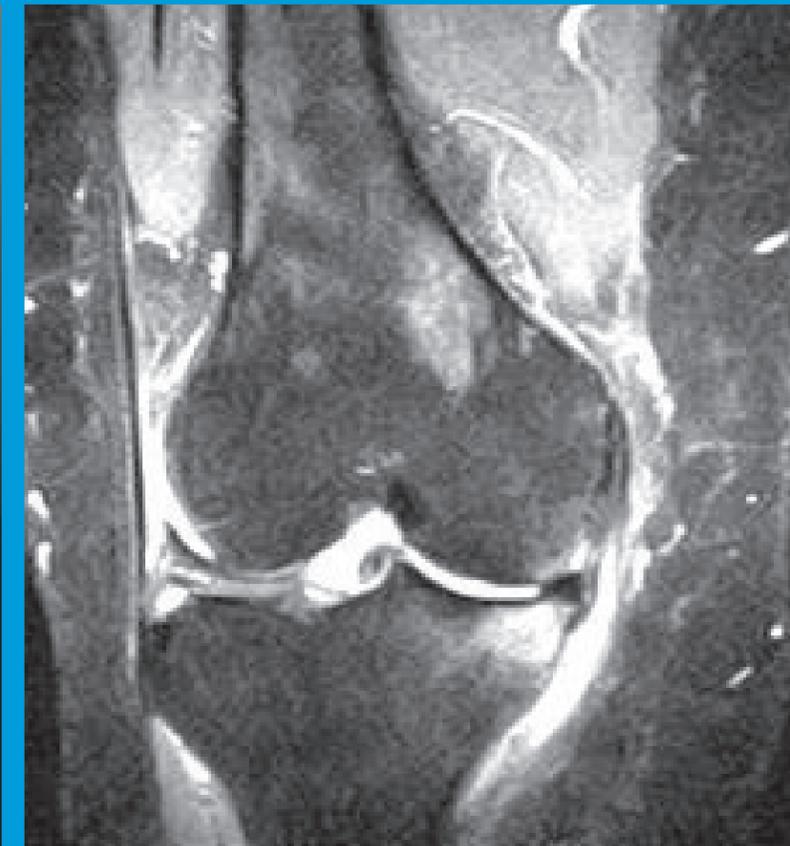
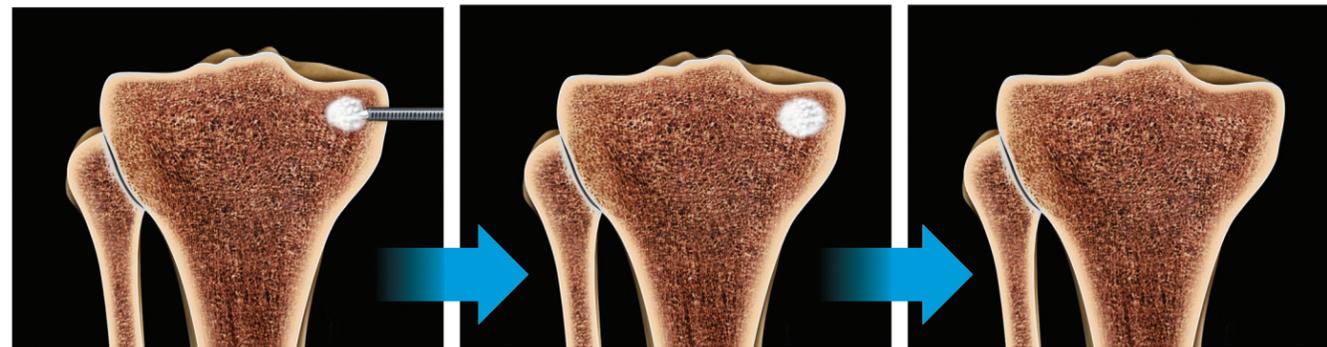
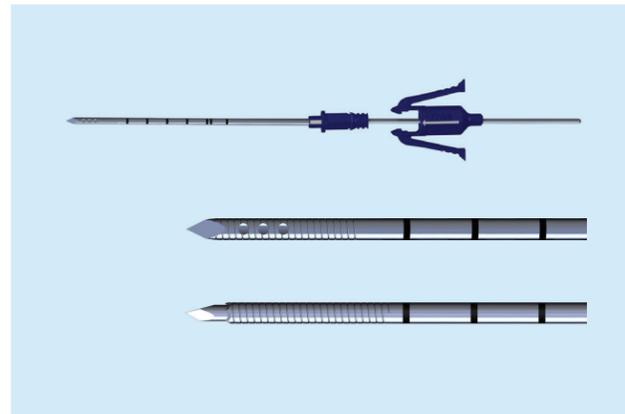
AccuMix® Mixing System

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



AccuPort® Delivery Cannulas

- 2 components: Cannula + stylus
 - Stylus locks to cannula hub
- 2 delivery options: Side & End
- Trocar-tip for cutting ability
 - Insert with OR wire driver



What Are Your Treatment Options for This Patient?

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.

¹ Eriksen EF, Ringe JD. Bone marrow lesions: a universal bone response to injury? *Rheumatol Int.* 2012; 32 (3): 575-584.

² Tofighi, 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.



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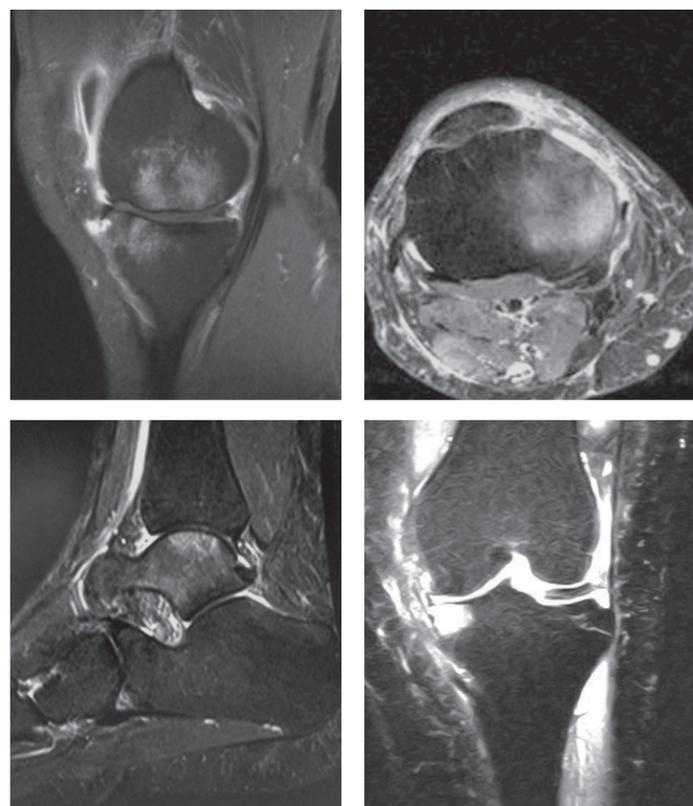
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What is the Subchondroplasty® SCP® Procedure?

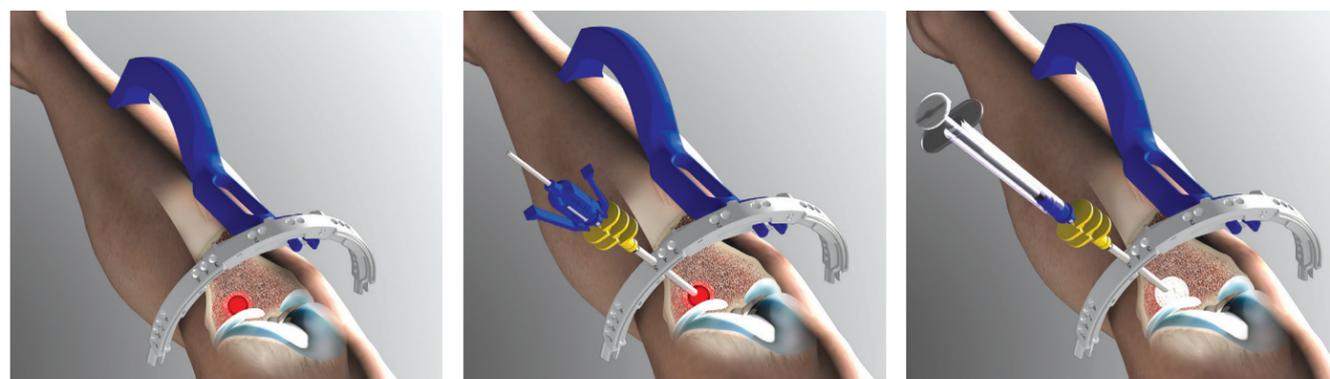


The Subchondroplasty® Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills subchondral bone defects, often called BML. It is usually performed with arthroscopy, for visualization and treatment of findings inside the joint.

BML Have Been Shown to Represent a Healing Response to Trauma, such as Microtrabecular Fractures of the Subchondral Bone.¹

BML Are Detected Using Fat-Suppressed MRI

How is The SCP® Procedure Performed?

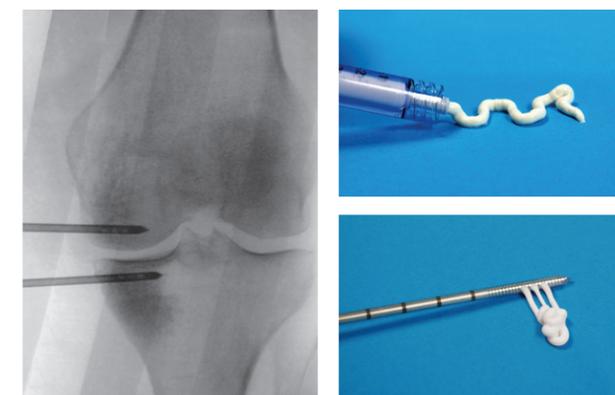


1. Target subchondral bone defect using AccuZone® Navigation Guide

2. Access bone defect using AccuPort® Delivery Cannula

3. Fill Bone Defect with AccuFill® Bone Substitute Material

How Does The SCP® Procedure Work?



The SCP® Procedure Fills Bone Defects with AccuFill® BSM, a Truly-Injectable Bone Substitute Material

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

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.

AccuFill® BSM Performance

CRITERIA	FEATURE	BENEFIT
Formulation	Proprietary next generation engineered apatite. Chemically similar to apatite of bone.	Facilitates cell-mediated remodeling.
Handling	Truly injectable. Remains cohesive. Flowable inside cancellous bone. 15 minutes of working time.	No need to remove subchondral bone. No phase separation from injection pressure. Interdigitates easily for complete defect fill. Long window for implantation; intraoperative flexibility.
Setting	Endothermally sets in 10 minutes at 37°C.	Sets hard after closure, no thermal necrosis.
Structure	Osteoconductive. Nanocrystalline structure. 65% total porosity; 1-300 µm pore size. ~10 MPa compressive strength.	Nanocrystalline structure and high surface area facilitate remodeling and bony ingrowth. Physical properties comparable to cancellous bone.
Remodeling	Cell-mediated remodeling. Remodeled vs. dissolved.	Remodels with new bone growth.



*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.

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