What Are Your Treatment Options for These Patients?
What is the Subchondroplasty (SCP) Procedure?

The Subchondroplasty Procedure is a minimally-invasive, fluoroscopically-assisted procedure that targets and fills chronic bone defects in the foot and ankle such as bone marrow lesions, cystic lesions, and stress reactions. It is usually performed with arthroscopy, for visualization and treatment of findings inside the joint.

Some procedures may be performed through mini-open or open approach, as needed for access or visualization of joint findings.

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

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

¹BML = 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 Does The SCP Procedure Work?

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.

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

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>FEATURE</th>
<th>BENEFIT</th>
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</thead>
<tbody>
<tr>
<td>Formulation</td>
<td>Proprietary next generation engineered apatite that is chemically similar to the apatite of bone.</td>
<td>Allows cell-mediated remodeling.</td>
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<tr>
<td>Handling</td>
<td>Truly injectable. Remains cohesive. Flowable inside cancellous bone. 15 minutes of working time.</td>
<td>No need to remove weakened subchondral bone. No phase separation from injection pressure. Interdigitates easily for complete defect fill. Long window for implantation; operative flexibility.</td>
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<tr>
<td>Setting</td>
<td>Isothermically sets in 10 minutes at 37 degrees C.</td>
<td>Sets hard, no thermal necrosis.</td>
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<td>Structure</td>
<td>Osteoconductive. Nanocrystalline* structure. 55% total porosity; 1-300 µm pore size. 7-9MPa compressive strength.</td>
<td>Nanocrystalline* structure &amp; high surface area allow remodeling &amp; bony growth. Compressive strength is comparable to cancellous bone; helps prevent stress shielding/attrition of healthy bone.</td>
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AccuFill® BSM = Ca_{10-x}(M)^x(PO_4)_{6-x}(HPO_4,CO_3)_x(OH)_{2-x}** = Bone^2

* 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.

** (M) = metal ions, e.g., Mg++, etc. Note: surface reactivity relates to metal bonds.
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
- Trocar-tip for cutting ability
- Insert with OR wire driver
- 2 sizes
  - 11 gauge cannula
    - Side or end-delivery
  - 15 gauge cannula
    - End-delivery
    - Smaller lumen and shorter length. A good choice for use in the smaller bones of the midfoot and forefoot

AccuFill BSM Indications for Use:

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


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For additional product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.subchondroplasty.com.