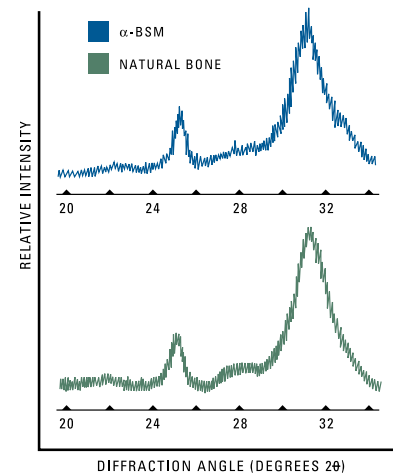


α -BSM: A BIORESORBABLE BONE GRAFT SUBSTITUTE

- α -BSM[®] is a resorbable calcium phosphate bone graft substitute intended for the treatment of bone voids.
- α -BSM undergoes endothermic setting in situ at body temperature. This allows an extended surgical working time and injectability/moldability at room temperature.
- α -BSM's chemical composition is very close to the mineral phase of human bone.
- α -BSM is available in three kit sizes: 2.5, 5 and 10 cc. The kits are designed using a patented, all-inclusive package to ensure a simple and user-friendly mixing and delivery technique.

PHYSICAL CHARACTERISTICS



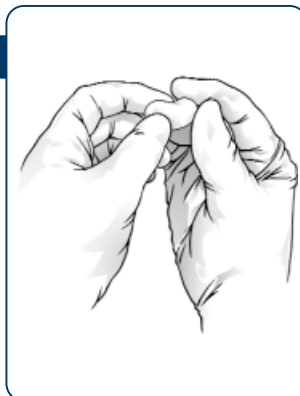
X-ray diffraction spectra of hardened α -BSM and natural bone.

α -BSM ADVANTAGES

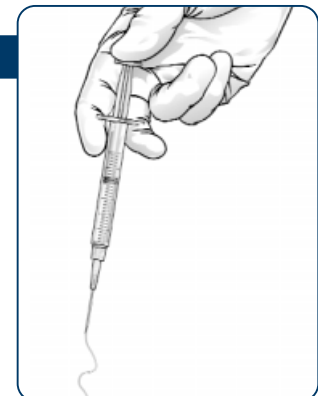
- Simple to prepare
- Injectable/moldable
- Endothermic hardening
- Bioresorbable
- All-inclusive kit
- Naturally remodeled

HANDLING CHARACTERISTICS

Moldable



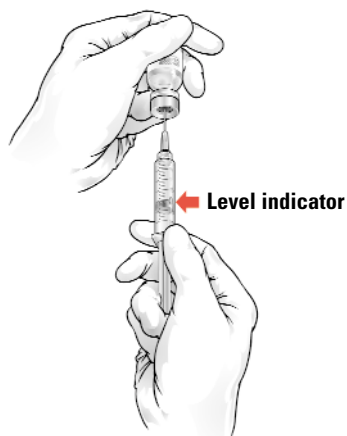
Injectable



BEGIN THE MIXING PROCESS ONLY WHEN THE DEFECT IS READY FOR IMPLANTATION.

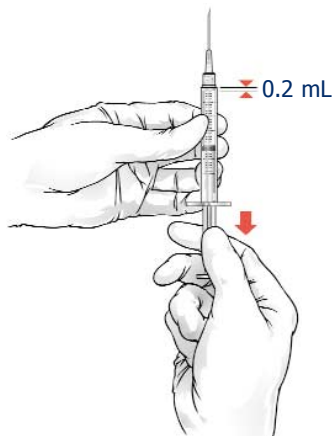
mixing instructions

1



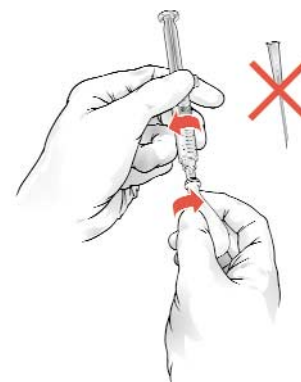
Withdraw saline to the level indicated by the red arrow on the syringe.

2



Draw in an air bubble of exactly 0.2 mL.

3



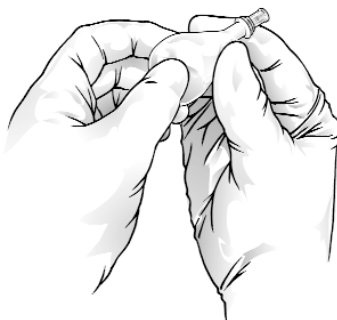
Remove the needle and attach the syringe to the mixing bulb.

4



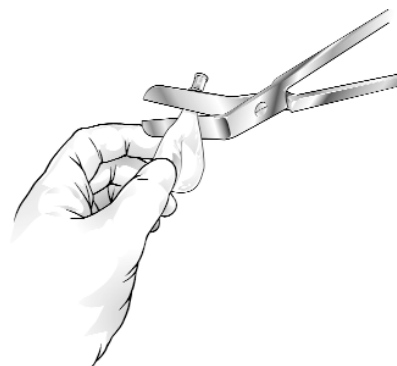
Ensure the mixing bulb is held down and the air bubble is furthest away from the mixing bulb. Inject saline into the mixing bulb.

5



Remove the syringe and thoroughly mix the material by kneading until a smooth consistency is reached (about one minute).

6



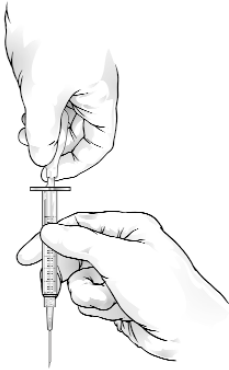
Cut below the Luer lock end of the mixing bulb and check the α-BSM[®] paste for consistency (as described on the next page).



delivery options

Inject α -BSM

1



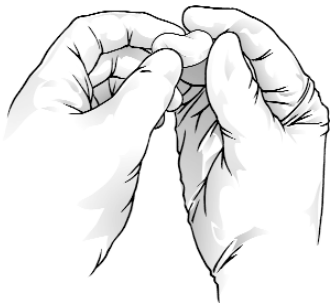
Place the α -BSM paste into the syringe directly from the mixing bulb. Use the supplied syringe and 16 gauge needle. If using a 10 cc kit, divide the paste between two 5 cc syringes.



Inject immediately with firm and even pressure until all the material is extruded. Pack in the material to ensure the defect is entirely filled.

Implanting α -BSM as a putty

2



Mold the α -BSM paste to fit the defect and pack it in place.



NOTE: After implantation, gently blot excess blood with sterile gauze and close only after the material is sufficiently hardened (15-20 minutes).

α -BSM suggestions

Material is too wet if it sticks to glove. If material is too wet, place material between two sterile dry gauze pads and gently pat until the desired consistency is achieved.

Material is too dry if it cannot be molded without crumbling. If material is too dry, simply add saline, a drop at a time, and remix thoroughly.

Consistency of material should be similar to modeling clay, such that it can be firmly molded without sticking to the gloves.

Important

Verify consistency of α -BSM prior to delivery

Ensure implant site is as dry as possible prior to implantation.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

α -BSM Bone Substitute Material is a registered trademark of and manufactured by Etex Corporation, Cambridge, Mass.

