



# Accufill™

Caution: U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

## Injectable Calcium Phosphate

### INSTRUCTIONS FOR USE

#### DESCRIPTION

Accufill Injectable Calcium Phosphate is a synthetic, biocompatible bone graft substitute material that forms a poorly crystalline hydroxyapatite at body temperature. It is provided in single patient, single use kits in various volumes appropriate to the surgical site.

#### INTENDED USE / INDICATIONS

Accufill Injectable Calcium Phosphate is an injectable, self setting, macro-porous, osteo-conductive, 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 Calcium Phosphate is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

#### DURATION OF ADMINISTRATION

Accufill Injectable Calcium Phosphate is intended for permanent implantation.

#### PRODUCT STORAGE

- Store Accufill Injectable Calcium Phosphate at controlled room temperature within 15 to 25°C (59 to 77°F).
- The expiration date is printed on the outer package label and Patient Record labels.
- DO NOT USE expired product.

#### METHOD OF STERILIZATION

- Accufill Injectable Calcium Phosphate is provided STERILE via gamma irradiation (Cobalt <sup>60</sup>Co).
- Contents are STERILE unless the barrier packaging is open or damaged; DO NOT USE if the package is open or damaged.
- Contents are non-pyrogenic.

#### CONTRAINDICATIONS

Do not use this product if one or more of the following conditions are present:

- Existing acute or chronic infections, especially at the site of the operation
- Nonviable bone
- Areas where surrounding bone is not viable or not capable of supporting and anchoring the implant
- Altered calcium metabolism
- Metabolic bone disease
- Immunologic abnormalities
- Systemic disorders which result in poor wound healing
- Inflammatory bone disease
- Acute traumatic injuries with open wounds close to the defect which are likely to become infected

#### WARNINGS

- DISCARD UNUSED PORTIONS; Accufill Injectable Calcium Phosphate is a SINGLE PATIENT, SINGLE USE product.
- DO NOT RESTERILIZE; the safety and effectiveness of reused or resterilized Accufill Injectable Calcium Phosphate is unknown.

- Because Accufill Injectable Calcium Phosphate is indicated for use in defects that are not intrinsic to the stability of the bony structure, it is critical that adequate fixation be provided for unstable defects by other means.
- The safety and effectiveness for patients having received or to receive chemotherapy or radiation therapy at or near the implant site is not known
- The safety and effectiveness when used in conjunction with other legally marketed devices having similar indications is not known.
- The safety and effectiveness for use in children or elderly patients is not known.
- The effect in patients with documented renal disease is not known.
- The effect in patients that are pregnant/nursing is not known.
- The effect in patients with cardiovascular disease precluding elective surgery is not known.
- The effect in patients having had infection during the last 3 months is not known.
- Prepare Accufill Injectable Calcium Phosphate using only the specified Mixing Solutions; the effect of preparing with other substances is unknown and may adversely affect product performance.

#### PRECAUTIONS

- Only for use by surgeons familiar with the material, appropriate surgical techniques, and bone repair procedures.
- Use aseptic technique to minimize the risk of infection.
- Mix with the specified volume of Mixing Solution; deviations will alter the consistency of the material and may adversely affect the setting reaction and the effectiveness of the implant.
- Care must be taken to prevent the creation of emboli. Highly pressurized application of Accufill Injectable Calcium Phosphate into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.
- Do not overfill the defect site. Over-pressurizing the device may lead to extrusion beyond the site of intended application and damage to surrounding tissues. Remove any excess material within 2 minutes following implantation.
- Do not disturb the material after implantation as disruption may affect the characteristics of the hardened material.
- Do not irrigate the defect site immediately after implantation; wait until the material is hard to touch (about 12 minutes at 37°C, 98°F).
- Follow general surgical protocol regarding use of fixation.
- Post-operative use of a closed suction drain is recommended.

#### POSSIBLE COMPLICATIONS

Re-operation to remove or replace the implant may be required occasionally due to medical reasons or device failure; if corrective action is not taken, one or more of the following complications may occur:

- Tissue thinning over implant site
- Tenderness/redness/edema
- Seroma/hematoma or infection
- Swelling/fluid collection
- Loss of contour
- Migration, extrusion, dehiscence, fracture and sloughing of Accufill Injectable Calcium Phosphate can occur as a result of excessive trauma or post-operative load bearing
- Neurovascular injuries due to surgical tr