



Synthecure Rapid Cure 100% Synthetic Calcium Sulfate Kits

DESCRIPTION

Synthecure Synthetic Calcium Sulfate Kits consist of pre-measured medical grade calcium sulfate powder and pre-measured mixing solution, and the tools necessary to mix the components into a paste. The devices are provided sterile for single use. When its components are mixed according to the instructions, biodegradable, radiopaque devices are produced that resorb in approximately 30-60 days, when used according to labeling.

INDICATIONS

The paste made from the Synthecure Synthetic Calcium Sulfate Kits is intended to be injected, digitally packed into bone voids or gaps; or molded into solid pellets that are gently packed into bone voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system (i.e. long bones, extremities, spine and pelvis). The bone voids or gaps may be either surgically created or result from traumatic injury. The device provides a bone void filler that resorbs and is replaced with bone during the healing process.

Synthecure paste cured in situ provides a bone void or gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary scaffold and is not intended to provide support during the healing process.

Synthecure Synthetic Calcium Sulfate Kits are provided sterile for single use only. Because the device is biodegradable and biocompatible, it may be used at an infected site.

INSTRUCTIONS FOR USE

The Synthecure Synthetic Calcium Sulfate Kit components are mixed into a paste that can be transferred into a syringe and injected, or digitally packed into bone voids or gaps; or molded into solid pellets that are gently packed into bone voids or gaps that are not intrinsic to the stability of the bony structure of the skeletal system. Avoid overfilling the bony defect or pressurizing the treatment site. Immediately remove excess material from the site. Close the site using standard closure techniques.

NOTE: do not add any additional substances to the paste since using alternative mixing solutions and/or adding other substances to the mixture may alter the safety and effectiveness of this product and could prevent the device from setting.

Mixing Instructions – Molding

1. Remove the pre-measured medical grade calcium sulfate and pre-measured mixing solution of the Synthecure Synthetic Calcium Sulfate Kits from the packaging tray.
2. Pour all of the Rapid Cure mixing powder into the provided bowl. Add all of the mixing solution to the calcium sulfate without agitation.

3. Mix thoroughly for 30 to 45 seconds with the stir stick or spatula until obtaining a homogeneous paste
4. With the stir stick or spatula, transfer the paste into the mold cavity within a minute.
5. Tap gently on a flat surface to allow trapped air bubbles to escape.
6. Allow to sit undisturbed while curing for 5 minutes
7. Carefully remove the set parts from the mold.

CONTRAINDICATIONS

The Synthecure devices are contraindicated where the device is intended as a structural support in a load-bearing bone and as a structural support in articulated surfaces.

Conditions representing relative contra-indications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Uncooperative patients who will not or cannot follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- Hypercalcemia

POSSIBLE COMPLICATIONS

Possible adverse effects include but are not limited to:

- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery
- Fracture of the Synthecure devices, with or without generation of particulate debris
- Deformity of the regenerated bone at the site
- Incomplete or lack of bone ingrowth into the bone void, as is possible with any bone void filler.

PRECAUTIONS

As with all surgical procedures, care should be exercised in treating individuals with bleeding diatheses of any etiology, individuals receiving anticoagulant, long-term steroid, or immunosuppressive therapy, or individuals with renal compromise. Such pre-existing conditions may affect the success of the surgical procedure.

STERILITY

Synthecure devices are provided sterile for single use only. The package should be inspected prior to use to ensure the sterile barrier has not been damaged. Do not resterilize the product. Discard any unused product once the package has been opened.

Warning: Do not use this device if the package is damaged or cracked.

CAUTION

Federal Law restricts the use of the device to sale, distribution, and use by or on the order of a physician.

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