synthecure
synthetic calcium sulfate

DESCRIPTION
Synthecure Synthetic Calcium Sulfate is provided sterile for single patient use. Synthecure Synthetic Calcium Sulfate contains calcium sulfate powder and mixing solution in pre-measured quantities so that when mixed together in a sterile mixing bowl, the resultant paste is to be digitally packed into open bone void/gap to set in situ or placed into the mold provided, the mixture sets to form beads. The biodegradable, radiopaque beads are resorbed in approximately 30-60 days when used in accordance with the device labeling. Synthecure Synthetic Calcium Sulfate is manufactured from synthetic implant grade calcium sulfate that resorbs and is replaced with bone during the healing process. Also, as the bone void filler beads are biodegradable and biocompatible, they may be used at an infected site.

INDICATIONS
Synthecure Synthetic Calcium Sulfate is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Synthecure Synthetic Calcium Sulfate resorbs and is replaced with bone during the healing process.

Synthecure is provided sterile for single use only. Synthecure is biodegradable and biocompatible and may be used at an infected site.

INSTRUCTIONS FOR USE
The Synthecure Synthetic Calcium Sulfate components are mixed into a paste that can be 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. Since the device does not provide structural support, adequate fixation is required. 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. Use only the mixing solutions provided. Using alternative mixing solutions and/or adding other substances to the mixture may alter the setting time significantly. Some substances such as bone marrow and blood will prevent the paste from setting.

Mixing Instructions – Molding

1. Remove the pre-measured medical grade calcium sulfate and pre-measured mixing solution of Synthecure Synthetic Calcium Sulfate from the packaging tray.
2. Pour all of the mixing solution into the powder bowl and begin stirring.
3. Mix thoroughly for 45 seconds with the stir stick or spatula until obtaining a homogeneous paste. Do not over mix.
4. Select the size of bead required. With the stir stick or spatula, transfer the paste into the corresponding mold cavity within two minutes and thirty seconds.
5. Tap gently on a flat surface to allow trapped air bubbles to escape.
6. Allow to sit undisturbed until fully cured.
7. Remove backer board and flex the bead mat to carefully remove the cured 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
- Renal compromised patients

POSSIBLE COMPLICATIONS OR ADVERSE EVENTS
Possible adverse effects include but are not limited to:

- Revisions and/or removals
- Wound complications including hematoma, site drainage, fluid accumulation, wound dehiscence, bone fracture, infection, and other complications that are possible with any surgery
- Allergic/immune response
- 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, or individuals receiving anticoagulant, long-term steroid, or immunosuppressive therapy. 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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Symbols Glossary:

Manufacturer

Use-by Date

Batch Code

Catalog Number

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

Sterilized using gamma irradiation

Do not re-use

Caution