

OsteoCure™

RESORBABLE BEAD KITS



➤ cast & treat bony voids



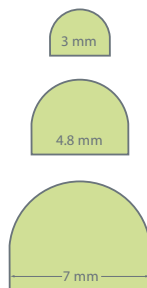
The self contained **OsteoCure™ Bead Kit** allows the surgeon to cast Calcium Sulfate beads to treat bony voids secondary to Osteomyelitis. The beads range in size from 3.0 mm to 7.0 mm to accommodate different anatomical considerations. Two formulations, a standard and a fast cure, allow for intraoperative flexibility.

➤ **The OsteoCure Advantage**

Design Feature	Advantage
Two Formulations	Fast Cure (5-7 minutes to set) and Standard Cure (20 minutes to set)
5 cc / 25 cc Kit (multiple bead sizes)	Allows flexibility in bead size selection specific to void area
Self Contained Kit	Saline, mixing bowl, spatula, and a bead tray are all in one kit

Bead Production

- 3.0 mm mold
250 beads using 5 cc of powder
- 4.8 mm mold
76 beads using 5 cc of powder
- 7.0 mm mold
36 beads using 25 cc of powder



OsteoCure Bead Kits

- CaSO4 powder
- Saline solution
- Mixing bowl
- Spatula
- Bead forceps



> OsteoCure™ Bead Mixing Technique

1 Combine Solution and Powder



Add all of the solution to mixing bowl. Add powder to mixing bowl. Allow to sit and cure for 30 seconds.

2 Mix



Gently mix thoroughly for 30-45 seconds. Do not over mix. When the consistency of the mixture is paste-like (sticks to spatula) it is ready to apply to the bead mold.

3 Fill Mold



With spatula apply an even coat of calcium sulfate paste to the bead mold, press downward to ensure complete filling of each bead cavity. After completely filling the mold, tap on a flat surface to remove air bubbles. Complete Fast Cure within 3-4 min. of beginning of step 1.

4 Bead Removal



Once filled allow the mold to sit.
Caution: The device should not be disturbed while curing.
Fast Set: 5 to min (from beginning of step 1).
Flex the mold to facilitate bead removal.

5 Pack Beads



Gently pack the molded beads into the treatment site. Avoid overfilling the bone void or compressing (see possible complications on back page) the treatment site. Remove excess material from the treatment site. Cover the opening of the bone void with cortical bone window and/or allow healthy periosteum or other soft tissues. Close the site using standard closure techniques. Discard any unused OsteoCure™ materials and instruments.

OsteoCure™ Resorbable Bead Product Information

Ordering Information

Indications:

The paste made with OsteoCure 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.

OsteoCure 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.

OsteoCure Kits are provided sterile for single use only. The device is biodegradable and biocompatible.

The mat is intended for use with the OsteoCure Resorbable Bead Kit to produce calcium sulfate beads.

Contraindications:

The product is not intended to provide structural support during the healing process, therefore, the OsteoCure Resorbable Bead Kits are contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces.

Conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Hypercalcemia
- Renal compromised patients
- Patients with a history of or active Pott's disease

Highly pressurized application of Osteocure into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown

Not intended for treatment of vertebral compression fractures.

Tornier is pleased to bring you a comprehensive suite of lower extremity products.



Conexa™



BioFiber™



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NexFix™ Compression Pin



RFS™ Screw and Pin



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Prior to using any Tornier device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

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