

OSTEOSET[®]

Resorbable Mini-Bead Kit

For Bone Voids Secondary to
Osteomyelitis in Diabetic Feet

- Mixable
- Customizable
- Resorbable Treatment

 **WRIGHT**[™]
FOCUSED EXCELLENCE



Questions & Answers

Q: What percentage of bone growth should I expect when using the OSTEASET® Resorbable Mini-Bead Kit?

A: Bone repair with OSTEASET® Pellets has been reported as high as 98% at 12 months for contained defects.¹ However, in defects resulting from osteomyelitis, bone repair has been reported as low as 64% at six months.² In defects created by osteomyelitis, expectations for bone repair should be modest.

Q: What type of complications should I be aware of when using this product?

A: Overall, device-related complications with OSTEASET® Pellets has been reported to be 4% (drainage) in a multi-center clinical trial of long bone defects in 109 patients.¹ As with any graft material, reports of drainage are most common in areas with poor soft-tissue coverage where subcutaneous and dermal tissue is utilized for primary closure. Infection and high relative volumes of calcium sulfate are also possible contributing factors.³ Wound seepage has been described as serous in nature and not associated with purulence, wound erythema, or discomfort to the patient. Drainage is theorized to be the result of an osmotic effect caused by the presence of the pellets, that ceases once the pellets are dissolved.

In areas of poor soft tissue coverage, authors of the prospective study collectively recommend an active suction drain be used for 48-72 hours postoperatively to minimize risk of fluid build-up.⁴ Study group members also recommend informing patients of drainage risk prior to utilizing this material.

For a complete list of indications, contraindications, and warnings – please reference the package insert.

1. Kelly, CM; Wilkins, RM; Gitelis, S; The use of Surgical Grade Calcium Sulfate as a Bone Graft Substitute, *Clinical Orthopaedics and Related Research*, No. 382, pp 42-50, January 2001.
 2. Internal Publication; A Retrospective Study of a Bone Graft Substitute. Ref. SK846-199; 1999.
 3. Personal Communication. George Cierny, MD. Atlanta, GA.
 4. Gitelis, S; Piasecki, P; Use of a Calcium Sulfate-Based Bone Graft Substitute for Benign Bone Lesions, *Orthopaedics*, Vol. 24, No. 2, pp 162-166, February 2001.

ORDERING information



8400-0511
 OSTEASET®
 Resorbable
 Mini-Bead Kit
 – 5cc

8400-0611
 OSTEASET®
 Resorbable
 Mini-Bead Kit –
 Fast Cure 5cc



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MIXING TECHNIQUE

STEP ONE



- Add OSTEASET® Powder to mixing bowl
- Add all of diluent
- Allow to sit:
 - Standard Kit (approx. 1 minute)
 - Fast-cure Kit (approx. 30 seconds)

STEP TWO



- Mix thoroughly for 30-45 seconds
- When the consistency is paste-like (i.e. sticks to the spatula), it is ready to apply to mold

STEP THREE



- With spatula, apply an even coat of OSTEASET® Paste to the supplied mold:
 - One side produces 200, 3.0 mm beads = 5cc
 - The other side produces 50, 4.8mm beads = 5cc

- Ensure complete filling of each bead cavity

NOTE: Each kit contains enough material to fill only one half of the supplied bead mold, which totals approximately 5cc final bead volume.

- After completely filling the mold, tap on a flat surface to remove air bubbles

STEP FOUR



- Allow to sit:
 - Standard Kit (approx. 20 minutes)
 - Fast-cure Kit (approx. 5 minutes)

STEP FIVE



- Flex the mold to facilitate bead removal