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OsteoSet®

Resorbable bead kits

Operative technique

OsteoSet® Resorbable bead kits

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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Important

- Removal or revision of the device may be required sometime in the future.
- Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.
- Consult Instructions for Use (https://ifu.wright.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.
- The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.
- An implant whose packaging is open or damaged or whose expiration date has passed must not be used. Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Indications

OsteoSet Pellets, OsteoSet Resorbable Beads, and OsteoSet Resorbable Mini Beads are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. These products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets provide a bone graft substitute that resorbs and is replaced with bone during the healing process. Because the pellets are biodegradable and biocompatible, they may be used at an infected site.

OsteoSet Resorbable Beads and OsteoSet Resorbable Mini Beads contain calcium sulfate powder and saline in premeasured quantities, so that when mixed together in the mixing bowl provided, then placed into the mold provided, the mixture sets to form OsteoSet Resorbable Beads and OsteoSet Resorbable Mini Beads. The biodegradable, radiopaque pellets are resorbed in 30-60 days when used according to labeling.

Contraindications

This product is not intended to provide structural support during the healing process, therefore, OsteoSet Pellets, the OsteoSet Resorbable Bead Kit, and the OsteoSet Resorbable Mini Bead Kit 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
- Where intra-operative soft tissue coverage is not planned or possible

Potential complications

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on personal medical training and experience. Although Stryker cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference.

Precautions

As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

Use OsteoSet Bone Graft Products as supplied and according to the handling and use information provided

Adverse effects

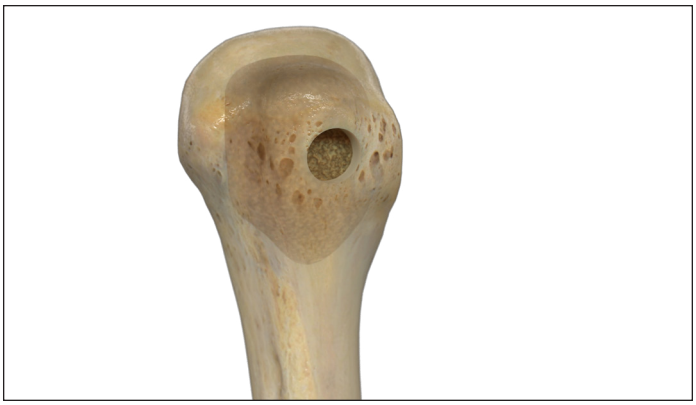
Possible adverse effects of OsteoSet products include but are not limited to:

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

Operative technique

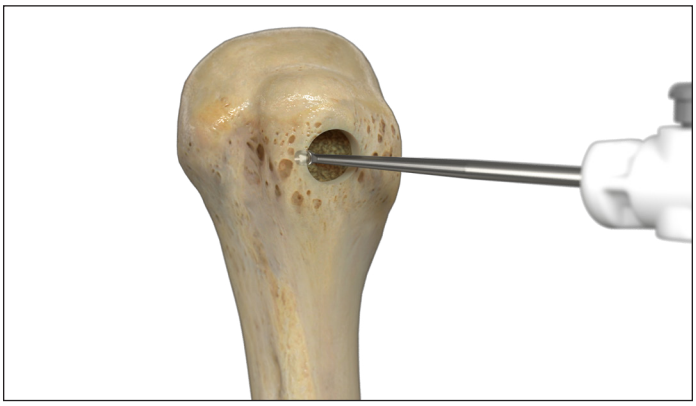
Step 1

Localize and access lesion under fluoroscopic guidance. A cortical window may be required.



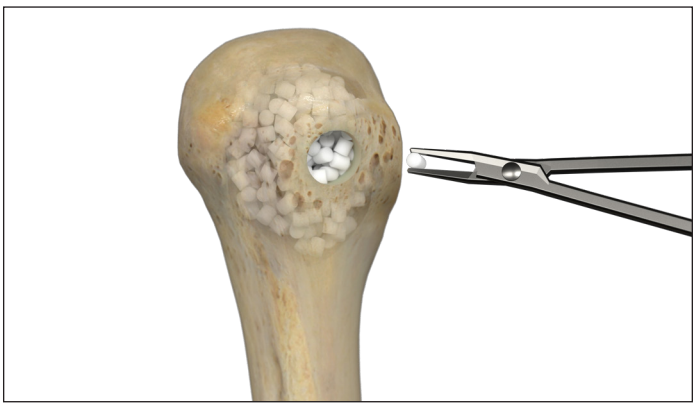
Step 2

Thoroughly debride the lesion.



Step 3

Prep site as desired and then graft by placing prepared beads into the defect. Close in standard fashion.



Catalogue numbers

Ref #	Description
84000211	OsteoSet Resorbable Bead Kit – 25cc Standard Cure (Includes two 7.0mm molds)
84000311	OsteoSet Resorbable Bead Kit – 25cc Fast Cure (Includes two 7.0mm molds)
84000511	OsteoSet Resorbable Mini-bead Kit – 5cc Standard Cure (Includes one 3.0/4.8mm mold)
84000611	OsteoSet Resorbable Mini-bead Kit – 5cc Fast Cure (Includes one 3.0/4.8mm mold)
84000301	7.0mm Pellet Mold (sterile)
84000302	3.0/4.8mm Pellet Mold (sterile)

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Biologics

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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