OSTEOSET® BONE GRAFT PRODUCTS

150832-0

The following languages are included in this packet:

English (en)
Deutsch (de)
Nederlands (nl)
Français (fr)
Español (es)
Italiano (it)
Português (pt)
中文- Chinese (sch)
Türkçe (tk)

For additional languages, visit our website www.wmt.com. Then click on the **Prescribing Information** option.

For additional information and translations please contact the manufacturer or local distributor.

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*** The CE-Marking of Conformity is applied per catalog number and appears on the outer label, if applicable.**

℞ ONLY

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EN

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
OSTEOSET® BONE GRAFT PRODUCTS
(150832-0)

OUTLINE:

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Storage temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
STERILE R	Sterilized using radiation
℞ ONLY	For prescription use only
EC REP	Authorized EC Representative in the European Community
	Do not use if package is damaged

GENERAL PRODUCT INFORMATION

All OSTEOSET® Bone Graft Products are supplied sterile for single patient use. The biodegradable, radiopaque pellets are used to fill bone voids and are resorbed in approximately 30-60 days when used according to labeling.

OSTEOSET® Bone Graft Pellets are made of medical grade calcium sulfate. Included in the carton of OSTEOSET® Bone Graft Pellets is one vial of medical grade calcium sulfate.

OSTEOSET® Resorbable Bead Kits and OSTEOSET® Resorbable Mini Bead Kits consist of pre-measured surgical grade calcium sulfate (plus an accelerant for the fast cure kits), pre-measured mixing solution, and the tools necessary to mix the components into a paste. The beads are used to fill bone voids and may be used at an infected site.

The Wright Bead Templates, included with the OSTEOSET® Resorbable Bead Kit or the OSTEOSET® Resorbable Mini Bead Kit, are used to produce calcium sulfate beads. The single-use mold for the OSTEOSET® Resorbable Bead Kit consists of two interlocking pieces which, when filled with the calcium sulfate paste, produce up to 30 beads of approximately 7mm in diameter. A groove in the template allows the surgeon to link the beads with a suture, if desired. The single use mold for the OSTEOSET® Resorbable Mini Bead Kit consists of a single mold which, when filled with calcium sulfate paste, will produce 200, 3.0mm or 50, 4.8mm diameter beads.

The OSTEOSET® Resorbable Bead Kit and the OSTEOSET® Resorbable Mini Bead Kit contain a vial of calcium sulfate, a vial of sterile saline, a spatula and bowl for mixing, and a bead template.

The OSTEOSET® Resorbable Bead Kit-Fast Cure and the OSTEOSET® Resorbable Mini Bead Kit-Fast Cure contain a vial of calcium sulfate with an accelerator, a vial of sterile saline, a spatula and bowl for mixing, and a bead template.

The OSTEOSET® Pellet Injector is a biocompatible, polypropylene disposable device provided pre-loaded and pre-sterilized for single patient use. The injector delivers controlled, precise, and efficient placement of the OSTEOSET® Pellets. The disposable injector provides the ideal mechanism for the careful placement of each pellet. The OSTEOSET® Pellet Injector are packaged with one (1) injector of 3.0mm or 4.8mm diameter beads of calcium sulfate.

A. 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.

B. 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

C. 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 Wright Medical cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference.

D. 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.

Intra-Operative Precautions

Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.

- Inspect devices **prior to use** for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices **immediately upon removal from the patient** for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
    a. The material composition of the fragment (if known);
    b. The size of the fragment (if known);
    c. The location of the fragment;
    d. The potential mechanisms for injury, e.g., migration, infection;

e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

E. 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

F. HANDLING AND STERILIZATION

The OSTEOSET® Bone Graft Products are provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. This product is for single patient use and should never be reused. Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

G. STORAGE CONDITIONS

All OSTEOSET® products must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. The OSTEOSET® products should be stored at 15°C/30°C – 59°F/86°F.

H. DIRECTIONS FOR USE

OSTEOSET® Resorbable Bead Kit / OSTEOSET® Resorbable Mini Bead Kit will set in approximately 20-25 minutes at ambient temperature.

OSTEOSET® Resorbable Bead Kit / OSTEOSET® Resorbable Mini Bead Kit - Fast Cure will set in approximately 2-4 minutes at ambient temperature.

Use the OSTEOSET® Bone Graft products aseptically according to the following surgical technique:

Gently pack the OSTEOSET® Pellets, cured OSTEOSET® Resorbable Beads, or cured OSTEOSET® Resorbable Mini Beads into the treatment site. Avoid overfilling the bone void or compressing the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques. Discard any unused OSTEOSET® products.

OSTEOSET® Pellet Injector

Place the OSTEOSET® Pellet Injector in the void where you wish the OSTEOSET® Pellets to be placed. Begin with the half-length plunger to begin dispensing the first 25 pellets in to the bony void. Dispense the remaining pellets with the full-length plunger. Gently push the plungers using hand pressure to dispense OSTEOSET® Pellets into the treatment

site. If required the injector tip can flex 10° to 15° degrees to facilitate delivery into a bony void. Gently pack the OSTEOSET® Pellets into the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques. Discard any unused OSTEOSET® Pellets and discard the disposable OSTEOSET® Pellet Injector.

Warning: Do not use these devices if the glass vial is cracked or broken.

Warning: Do not force the injector into any void or try to over-flex the Injector. Do not use excessive force on the rod or use as a trocar.

Warning: Do not use these devices in the spine if the spinal dura has been nicked or torn and is not repairable.