OSTEOSET® XR BONE VOID FILLER

150841-0

The following languages are included in this packet:

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

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.

CE 0086*

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
U.S.A.

EC REP

Wright Medical UK Ltd
3rd Avenue
Letchworth
Herts, SG6 2JF
UK

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

℞ ONLY

October 2013
Printed in U.S.A

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

WRIGHT MEDICAL
OSTEOSET® XR BONE VOID FILLER
(150841-0)

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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
EC REP	Authorized EC Representative in the European Community
STERILE R	Sterilized using radiation

℞ ONLY	For prescription use only
Abbreviation	**Material**
CaPO4	Calcium Phosphate
CaSO4	Calcium Sulfate

GENERAL PRODUCT INFORMATION

OSTEOSET® XR consists of surgical grade calcium sulfate and calcium phosphate pellets and the tools necessary to place the material into the defect site (where applicable). These products are provided sterile for single patient use.

A. INDICATIONS

The intended use for the OSTEOSET® XR bone void filler is to be gently packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The pellets provide a bone void filler that resorbs and is replaced with bone during the healing process.

OSTEOSET® XR pellets are provided sterile for single patient use only.

B. CONTRAINDICATIONS

The OSTEOSET® XR bone void filler is 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

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.

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. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

Avoid **overfilling** the bone void.

Use OSTEOSET® XR bone void filler as supplied and according to the **Handling and Use** information provided.

E. ADVERSE EFFECTS

Possible adverse effects 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

OSTEOSET® XR bone void filler is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product should not be resterilized. The kits are 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 kits must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. OSTEOSET® XR bone void filler products should be stored at 15-30 °C or 59-86 °F.

H. DIRECTIONS FOR USE/MIXING INSTRUCTIONS

Use the OSTEOSET® XR bone void filler products aseptically according to the following surgical technique:

Gently pack the OSTEOSET® XR Pellets into the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques. Discard any unused OSTEOSET® XR Bone Graft products.

OSTEOSET® XR Pellet Injector

Place the OSTEOSET® XR Pellet Injector in the void where you wish the OSTEOSET® XR 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® XR Pellets into the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques. Discard any unused OSTEOSET® XR Pellets and discard the disposable OSTEOSET® XR Pellet Injector.

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

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.

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.

CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.

Patents:

One or more of the following patents may apply:

United States Patents

7,066,942, 6,149,623

Additional patents pending.