PRO-DENSE™ Bone Graft Substitute
150831-1

The following languages are included in this packet:

English (en)	Deutsch (de)	Nederlands (nl)	Français (fr)
Español (es)	Italiano (it)	Português (pt)	Türkçe (tr)

For additional languages, visit our website www.wright.com
Then click on the **Prescribing Use** 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

PRO-DENSE™ Bone Graft Substitute

(150831-1)

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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 EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
℞ ONLY	For prescription use only
	Do not use if packaging is ripped or damaged

Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
CaSO4	Calcium Sulfate
HA	Hydroxyapatite

GENERAL PRODUCT INFORMATION

PRO-DENSE™ Bone Graft Substitute paste consists of pre-measured surgical grade calcium sulfate and calcium phosphate, pre-measured neutralized glycolic acid mixing solution, and the tools necessary to mix the components into a paste and inject the material into the defect site. When mixed and injected according to directions, PRO-DENSE™ Bone Graft Substitute paste will harden in situ and provide temporary intra-operative support. PRO-DENSE™ Bone Graft Substitute products are provided sterile for single patient use.

A. INDICATIONS

PRO-DENSE™ resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure *in situ*. These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE™ paste cured *in situ* provides an open void/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 support media and is not intended to provide structural support during the healing process.

PRO-DENSE™ is provided sterile for single use only.

For the PRO-DENSE™ Core Decompression Procedure Kit:

The PRO-DENSE™ Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced with bone during the healing process. The bone void filler included in the PRO-DENSE™ Core Decompression Procedure Kit is not intended to be used as a load-bearing device.

B. CONTRAINDICATIONS

The PRO-DENSE™ Bone Graft Substitute injectable paste 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
- Closed bone void/gap
- 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. 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.

Avoid **overfilling** the bone void or **pressurizing** the treatment site.

The provided K-Wires (where supplied) are not intended for implantation.

Use PRO-DENSE™ Bone Graft Substitute injectable paste as supplied and according to the Handling and **Use information provided**. All powder (supplied) and all solution (supplied) must be used when mixing paste.

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.

Warning: Do not use kit if any container is cracked or broken.

For the 4cc kit only: Warning: the stylet of the needles contains nickel which is a known allergen to a small percentage of the population.

<u>Intra-Operative Precautions</u>

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 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
- Potential to pressurize material in a closed void, which could result in fat embolization and/or embolization of the device material into the blood stream.

F. HANDLING AND STERILIZATION

PRO-DENSE™ Bone Graft Substitute injectable paste 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. The PRO-DENSE™ Bone Graft Substitute products should be stored at 15-30°C or 59-86° F.

H. DIRECTIONS FOR USE/MIXING INSTRUCTIONS

The PRO-DENSE™ Bone Graft Substitute injectable paste is supplied in a kit that contains the components and tools required to mix and inject the resultant paste. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

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