PRO-STIM® Injectable Inductive Graft Containing DONATED HUMAN TISSUE 150842-0

The following languages are included in this packet:

English (en)

For additional information please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

OUTLINE:

- DEFINITIONS
- GENERAL PRODUCT INFORMATION
  - A. DONOR SELECTION
  - B. SEROLOGICAL TESTING
  - C. INDICATIONS
  - D. CONTRAINDICATIONS
  - E. POTENTIAL COMPLICATIONS
  - F. PRECAUTIONS
  - G. ADVERSE REACTIONS
  - H. HANDLING & STERILIZATION
  - I. TRACEABILITY
  - J. STORAGE CONDITIONS
  - K. DIRECTIONS FOR USE/MIXING INSTRUCTIONS
  - L. LIMITED WARRANTY & LIMITATION OF LIABILITY

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
	Do not resterilize
℞ ONLY	For prescription use only
	Do not use if packaging is ripped or damaged
Abbreviation	**Material**
$CaSO_4$	Calcium Sulfate
$CaPO_4$	Calcium Phosphate
DBM	Demineralized Bone Matrix

GENERAL PRODUCT INFORMATION

PRO-STIM® paste consists of pre-measured surgical grade calcium sulfate and calcium phosphate, demineralized bone matrix, pre-measured 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-STIM® paste will harden *in situ* and provide temporary intra-operative support. PRO-STIM® products are provided sterile for single patient use.

A. DONOR SELECTION

All tissue used in Wright Medical Technology's (WMT) Bone Void FIllers Containing Donated Human Tissue is recovered by U. S. tissue banks. A completed donor chart for the enclosed product including but not limited to: serology results, recovery culture results, medical and social history evaluation and serodilution calculation that was conducted by or contract tested by and for the tissue bank, has been reviewed and approved for transplantation by the tissue bank's medical director. Donor screening and testing is performed in accordance with American Association of Tissue Banks (AATB) standards and U.S. Food and Drug Administration (FDA) regulations. Donor eligibility has been determined by the supplying tissue bank's Medical Director (Allosource, 6278 South Troy Circle, Centennial, CO 8011). All processing documentation has been reviewed and approved by the tissue bank's Quality Assurance department.

Each lot of product is manufactured using tissue from a single donor. There is no pooling of donor tissue.

B. SEROLOGICAL TESTING

A donor serum sample was tested non-reactive using FDA-licensed screening tests for antibodies to human immunodeficiency virus type 1 and type 2 (anti-HIV 1 and anti-HIV 2), hepatitis B surface antigen (HbsAg), hepatitis B core antibody (HbcAb), antibodies to the hepatitis C virus (anti-HCV), and the human T-lymphotrophic virus types I and II antibodies (anti-HTLV I and anti-HTLV II) where required. The serum tested negative for syphilis using an FDA-licensed confirmatory test. The donor also tested negative for HIV1 and HCV using FDA-licensed NAT tests. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Ammendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

C. INDICATIONS

PRO-STIM® 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-STIM® 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.

The PRO-STIM® 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 by bone during the healing process. The bone void filler included in the PRO-STIM® Core Decompression Kit is not intended to be used as a load bearing device.

PRO-STIM® paste is provided sterile for single use.

D. CONTRAINDICATIONS

The PRO-STIM® 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 filler
- Pregnancy
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Hypercalcemia
- Renal impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

E. 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.

F. 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.

Use PRO-STIM® 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.

WMT's Bone Void Fillers Containing Donated Human Tissue are sterile during the stated shelf life as long as the package is not opened and/or damaged.

As with any biological product, the tissue in PRO-STIM® paste has the potential to transmit infectious agents. Processing treatments, donor screening, and laboratory testing follow strict specifications that are used to reduce the risk of transmitting infectious disease. Additionally, testing to evaluate the viral inactivation potential of the processing methods was conducted. The Demineralized Bone Matrix (DBM) processing methods were determined to provide significant viral inactivation potential for a wide range of potential viruses.

Trace amounts of alcohol and/or hydrogen peroxide, Polymyxin B sulfate, Bacitracin, and Allowash® (LifeNet Health) solution (contains detergents, such as polyoxyethylene-r-lauryl ether, octylphenolethyleneoxide, and poly(ethylene glycol)-p-nonyl-phenyl-ether), may be present and caution should be exercised if the recipient is allergic to these antibiotics.

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. Effectiveness data is not available for the use of this device in the epiphyseal areas of patients whose growth plates have not yet closed.

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

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.

G. 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.

In the event of a severe adverse reaction to the product, a second surgery may be required to remove any remaining product.

Please contact Wright Medical to promptly report any unanticipated or adverse events, or should you require further information.

H. HANDLING AND STERILIZATION

PRO-STIM® injectable paste is provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. Once the inner packaging has been opened, this product should be used, if appropriate, or otherwise discarded. The lyophilized DBM is aseptically processed by the tissue supplier. This product should not be resterilized. The devices/kits are labeled for single patient use only and 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. Report any adverse events to Wright Medical Technology, Inc.

I. TRACEABILITY

An implant tracking card has been included with the product and should be completed at the time of surgery and returned to Wright Medical Technology, Inc. Record the name and address of the medical facility, implant information (using the peel off stickers) and comments regarding the use of the implant on the tracking card. The completed form should be returned to Wright Medical Technology, Inc. Copies should be retained by the medical facility in the patient medical record for tracking tissue post-transplantation.

J. STORAGE CONDITIONS

It is the responsibility of the medical facility or physician to maintain this product according to recommended storage conditions. Do not use if this product has not been stored according to the following storage conditions: All kits must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature. PRO-STIM® products should be stored at 15-30 ° C or 59-86 ° F.

K. DIRECTIONS FOR USE/MIXING INSTRUCTIONS

The PRO-STIM® 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.

L. LIMITED WARRANTY & LIMITATION OF LIABILITY

Supplier of the tissue represents and warrants that the DBM will conform to the company's specifications and comply with AATB standards and FDA standards, as such standards may be amended from time to time, for donor screening and evaluation.

SUPPLIER OF THE TISSUE MAKES NO OTHER EXPRESS OR IMPLIED WARRANTIES REGARDING THE DBM INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. WITHOUT LIMITING THE FOREGOING, SUPPLIER OF THE TISSUE MAKES NO REPRESENTATIONS OR WARRANTIES REGARDING THE FITNESS OF THE DBM FOR COMBINATION WITH CALCIUM SULFATE OR ANY OTHER APPLICATION AND MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE DBM AS COMBINED WITH CALCIUM SULFATE OR ANY OTHER SUBSTANCE, INCLUDING PRO-STIM®. SUPPLIER OF THE TISSUE HEREBY ADVISES THE COMPANY AND ALL USERS OF PRODUCTS CONTAINING DBM THAT THERE IS AN INHERENT RISK OF DISEASE TRANSMISSION IN THE USE OF THE DBM FOR ANY PURPOSE, INCLUDING IN COMBINATION WITH CALCIUM SULFATE.

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

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