BONE VOID FILLERS CONTAINING DONATED HUMAN TISSUE

128040-11

The following languages are included in this packet:

English (en)

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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℞ ONLY

November 2011
Printed in U.S.A.

Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

BONE VOID FILLERS CONTAINING DONATED HUMAN TISSUE (128040-11)

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
2 STERILE	Do not resterilize
℞ ONLY	For prescription use only
	Do not use if package is damaged

I. GENERAL PRODUCT DESCRIPTION

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). Donor eligibility has been determined by the supplying tissue bank's Medical Director (Allosource, 6278 South Troy Circle, Centennial, CO 80111). 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 HIV-1 and HCV using FDA-licensed NAT tests. Additionally, the product meets all applicable serological testing requirements of the country in which it is distributed. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments 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. 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 product with or without generation of particulate debris
- Deformity of the bone at the site
- Incomplete or lack of osseous ingrowth into bone void, as is possible with any bone graft substitute

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.

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 Bone Void Fillers Containing Donated Human Tissue as supplied and according to the **Handling and Use** information provided.

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 WMT's Bone Void Fillers Containing Donated Human Tissue 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. The Cancellous Bone Matrix/Chips (CBM) processing methods were determined to provide some viral inactivation potential for a wide range of potential viruses. In comparison, the CBM processing methods provided less viral inactivation potential than the DBM processing methods; therefore, the risk for disease transmission from the CBM component is greater than the DBM component. However, the risk of disease transmission for these components remains low due to the multiple safeguards employed, i.e. donor selection, laboratory testing, and material processing.

Trace amounts of alcohol and/or hydrogen peroxide, Polymyxin B sulfate, Bacitracin, and Allowash® 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 any of these.

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 this device if the glass vial is cracked or broken.

E. TRACEABILITY

An implant tracking card has been included with the product and should be completed at the time of surgery. 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.

F. HANDLING & USE

WMT's Bone Void Fillers Containing Donated Human Tissue are supplied Electron Beam irradiated, 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. This product is for single patient use

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.

ALLOMATRIX® Injectable Putty, ALLOMATRIX® C, ALLOMATRIX® Custom, ALLOMATRIX® DR, ALLOMATRIX® RCS Putty, and IGNITE® Bone Graft Products are supplied in a kit that contains the components and tools required to mix the components. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

G. 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. This product must be stored in dry conditions between the temperatures of 15-30°C/59-86°F and be protected from sunlight.

H. 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 OSTEOSET® BONE GRAFT SUBSTITUTE, ALLOMATRIX® PUTTY AND IGNITE®. 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.

Allowash® is a registered trademark of LifeNet.

II. SPECIFIC PRODUCT INFORMATION

A. OSTEOSET® 2 DBM PELLETS

DESCRIPTION

OSTEOSET® 2 DBM Pellets are made of surgical grade calcium sulfate incorporating Human Demineralized Bone Matrix (DBM) and stearic acid as a tableting aid.

Each lot of DBM incorporated into OSTEOSET® 2 DBM Pellets is assayed to ensure that only osteoinductive DBM is used in the final product. Please see the enclosed DBM Osteoinductivity Potential Certificate for more information.

The biodegradable, radiopaque pellets are used to fill bone voids and are resorbed in approximately 30-60 days when used according to labeling. This product is supplied sterile for single patient use.

INDICATIONS

OSTEOSET® 2 DBM Pellets are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. OSTEOSET® 2 DBM Pellets 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.

CONTRAINDICATIONS

OSTEOSET® 2 DBM Pellets 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 impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

HANDLING AND USE

Gently pack the OSTEOSET® 2 DBM Pellets 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® 2 DBM Pellets in accordance with the waste disposal policies of your hospital.

B. ALLOMATRIX® INJECTABLE PUTTY

DESCRIPTION

ALLOMATRIX® Injectable Putty is a combination of Human Demineralized Bone Matrix (DBM) with a binding medium of calcium sulfate and carboxymethylcellulose.

For information concerning osteoinductive potential of ALLOMATRIX® Injectable Putty, please see the enclosed Certificate of Osteoinductivity Potential.

ALLOMATRIX® Injectable Putty comes in the form of a kit with a premeasured powder, premeasured mixing solution, and the tools necessary to mix the components and deliver the putty (if desired). The 0.5 cc and 1 cc kits are not supplied with tools to deliver the putty. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

INDICATIONS

ALLOMATRIX® Injectable Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® Injectable Putty is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

CONTRAINDICATIONS

ALLOMATRIX® Injectable Putty 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 impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

HANDLING AND USE

ALLOMATRIX® Injectable Putty is supplied in a kit that contains the components and tools required to mix and deliver (not the 0.5 cc and 1cc kits) the components. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

C. ALLOMATRIX® C AND ALLOMATRIX® DR PUTTY PRODUCTS

DESCRIPTION

ALLOMATRIX® C and ALLOMATRIX® DR Putty Products are a combination of Human Demineralized Bone Matrix (DBM) and cancellous bone matrix/chips (CBM) with a binding medium of calcium sulfate and carboxymethylcellulose.

Each lot of DBM incorporated into ALLOMATRIX® C and ALLOMATRIX® DR Putties is evaluated to ensure only that osteoinductive DBM is included in the final product. Please see the enclosed DBM Osteoinductivity Potential Certificate for more information.

ALLOMATRIX® C and ALLOMATRIX® DR Putty Products come in the form of a kit with a premeasured powder and CBM chips, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

INDICATIONS

ALLOMATRIX® C and ALLOMATRIX® DR Putty Products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® C and ALLOMATRIX® DR Products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

CONTRAINDICATIONS

ALLOMATRIX® C and ALLOMATRIX® DR Putty Products 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 impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

HANDLING AND USE

ALLOMATRIX® C and ALLOMATRIX® DR Putty Products are supplied in a kit that contains the components and tools required to mix the components. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

D. ALLOMATRIX® CUSTOM PRODUCTS

DESCRIPTION

ALLOMATRIX® Custom Putty Products are a combination of Human Demineralized Bone Matrix (DBM) and cancellous bone matrix/chips (CBM) with a binding medium of calcium sulfate and carboxymethylcellulose.

Each lot of DBM incorporated into ALLOMATRIX® Custom Putties is evaluated to ensure only that osteoinductive DBM is included in the final product. Please see the enclosed DBM Osteoinductivity Potential Certificate for more information.

ALLOMATRIX® Custom Products come in the form of a kit with a premeasured powder and CBM chips, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

INDICATIONS

ALLOMATRIX® Custom Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of bony structure. ALLOMATRIX® Custom Putty is intended to be gently packed into bony voids or gaps of the skeletal system as a bone graft extender (spine), and as a bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

CONTRAINDICATIONS

ALLOMATRIX® Custom Products 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 impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

HANDLING AND USE

ALLOMATRIX® Custom Putty Products are supplied in a kit that contains the components and tools required to mix the components. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

E. ALLOMATRIX® RCS PUTTY

DESCRIPTION

ALLOMATRIX® RCS Putty is a combination of Human Demineralized Bone Matrix (DBM) and synthetic resorbable conductive scaffold (RCS) granules with a binding medium of calcium sulfate and hydroxypropylmethylcellulose (HPMC).

Each lot of DBM incorporated into ALLOMATRIX® RCS Putty is evaluated to ensure only that osteoinductive DBM is included in the final product. Please see the enclosed DBM Osteoinductivity Potential Certificate for more information.

ALLOMATRIX® RCS Putty comes in the form of a kit with premeasured powder and synthetic scaffold granules, premeasured mixing solution, and the tools necessary to mix the components. After the powder is hydrated using all the mixing solution supplied in the kit, the resultant putty can then be handled and placed in the appropriate bone voids. This product is supplied sterile for single patient use.

INDICATIONS

ALLOMATRIX® RCS Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. ALLOMATRIX® RCS Putty is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

CONTRAINDICATIONS

ALLOMATRIX® RCS Putty 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 impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

HANDLING AND USE

ALLOMATRIX® RCS Putty is supplied in a kit that contains the components and tools required to mix the components. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

F. IGNITE® BONE GRAFT PRODUCT

DESCRIPTION

IGNITE® Bone Graft products are a combination of Human Demineralized Bone Matrix (DBM) with a binding medium of calcium sulfate and carboxymethylcellulose.

Each lot of DBM incorporated into IGNITE® Bone Graft products is assayed to ensure that only osteoinductive DBM is used in the final product. Please see the enclosed DBM Osteoinductivity Potential Certificate for more information.

IGNITE® Bone Graft products consist of pre-measured medical grade calcium sulfate combined with demineralized bone matrix (IGNITE® powder), mixing solution (where supplied) and tools to mix the graft materials into a resultant putty to be injected into the defect site. The IGNITE® Bone Graft products provide surgeons the option of mixing the IGNITE® powder with included sterile water diluent or mixing with autologous bone marrow aspirate (BMA). These products are supplied sterile for single patient use.

INDICATIONS

IGNITE® Bone Graft products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. IGNITE® Bone Graft products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The bone graft syringe is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The syringe can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

CONTRAINDICATIONS

IGNITE® Bone Graft products 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 impairment
- Patients with a history of or active Pott's disease
- Active or latent infection in or about the surgical site

HANDLING AND USE

IGNITE® Bone Graft products are supplied in a kit that contains the components and tools required to mix and deliver the components. 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.