



## **ALLOMATRIX® Injectable Putty**

**146617-1**

The following languages are included in this packet:

English (en)

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



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**Rx ONLY**  
June 2011  
Printed in U.S.A.

*Attention Operating Surgeon*  
**IMPORTANT MEDICAL INFORMATION**  
**ALLOMATRIX® Injectable Putty**  
**(146617-1)**

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**I. GENERAL PRODUCT DESCRIPTION**

**A. DONOR SELECTION**

All tissue used in Wright Medical Technology's (WMT) ALLOMATRIX® Injectable Putty 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. 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 type I antibody (anti-HTLV I). The serum tested negative for syphilis using a FDA licensed confirmatory test. The donor also tested negative for HIV using Polymerase Chain Reaction (PCR) technology or an FDA-licensed NAT test.

Communicable disease testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of

1988 (42 U.S.C. 263a) and 42 CFR Part 493; or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions.

Additionally, the product meets all applicable serological testing requirements of the country in which it is distributed.

### **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.**

### **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 ALLOMATRIX® Injectable Putty as supplied and according to the **Handling and Use** information provided.

ALLOMATRIX® Injectable Putty is 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 ALLOMATRIX® Injectable Putty 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.

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, or immunosuppressive therapy or high dose radiation therapy.

Trace amounts of alcohol and/or hydrogen peroxide, Polymyxin B sulfate, Bacitracin, and Allowash® solution (contains detergents, such as polyoxyethylene-r-lauryl ether, octylphenoethyleneoxide, 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.

**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 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.

#### **F. HANDLING & USE**

WMT's ALLOMATRIX® Injectable Putty is 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 not 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. Report any adverse events to Wright Medical Technology, Inc.

ALLOMATRIX® Injectable 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.

#### **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. 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. 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 for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects

#### **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 the components. Detailed mixing and handling instructions are included on the Mixing Instructions Card.

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