READIGRAFT® BLX DBM PUTTY PRODUCTS

READ THIS ENTIRE PACKAGE INSERT CAREFULLY PRIOR TO USE.

FEDERAL LAW (USA) RESTRICTS THIS ALLOGRAFT BIO-IMPLANT FOR USE BY A LICENSED CLINICIAN ONLY.

DESCRIPTION

This device was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. ReadiGRAFT® BLX DBM Putty products consist of human demineralized bone matrix, a homogenized connective tissue carrier, glycerol and a radioprotectant. The ReadiGRAFT BLX DBM and CC Putty also contains non-demineralized corticocancellous bone.

STERILE R Bio-implants that are indicated as sterile on the label are sterilized via low-dose gamma irradiation and achieve a sterility assurance level (SAL) of 10^{-6}.

INDICATIONS FOR USE

ReadiGRAFT® BLX DBM Putty products are bone void fillers intended to fill bony voids or gaps that are not intrinsic to the stability of the bony structure. This device may also be combined with autologous tissue or fluid for use as a graft extender.

CONTRAINDICATIONS

The contraindications include, but are not limited to:

- Use in any patient who has a known or suspected allergy to any of the antibiotics and/or processing reagents listed in this package insert.
- Presence of infection at the implantation site.
- Any case where stabilization of the defect is not possible.

WARNINGS AND PRECAUTIONS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any allograft bio-implant, the potential for transmission of infectious agents exists.

This device may contain residuals of antibiotics (Bacitracin, Gentamicin and/or Polymyxin B Sulfate), alcohol, aminoguanidine, glycerol, and/or surfactants. Caution should be exercised if the patient has a known sensitivity to any of these antibiotics and/or reagents.

POTENTIAL ADVERSE EVENTS

Potential adverse events or outcomes include, but are not limited to, disease transmission, infection, allograft tissue rejection, allergic reaction to residual processing reagents, reoperation and/or death.

Promptly report any adverse event(s) or outcome(s) potentially attributable to the device (See **COMPLAINTS AND RETURNS** section).

DONOR SCREENING AND TESTING

All donors have been screened and tissues recovered, processed, stored, tested and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270, 1271 and 820, current *Standards for Tissue Banking* set forth by the American Association of Tissue Banks (AATB) This allograft bio-implant was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed).

All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft bio-implant:

Required Infectious Disease Testing	
Test	**Acceptance Criteria**
HBcAb: Hepatitis B Total Core Antibody	Negative/Non-Reactive
HBsAg: Hepatitis B Surface Antigen	Negative/Non-Reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/Non-Reactive
HCVAb: Hepatitis C Antibody	Negative/Non-Reactive
HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test	Negative/Non-Reactive
HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody	Negative/Non-Reactive
RPR/STS or Equivalent: Syphilis	Confirmatory Negative/Non-Reactive
HTLV I/II Ab: Human T-Lymphotropic Virus Types I/II Antibody*	Negative/Non-Reactive

**Not required for donors recovered after March 31, 2010. Performed as required by international laws and regulations.*

DEVICE TESTING

Product is tested for osteoinductive potential. Findings from this testing are not necessarily predictive of human clinical results.

STORAGE REQUIREMENTS

The distributor, intermediary and/or end-user clinician or facility is responsible for storing this device under appropriate conditions prior to further distribution or implantation. This device must be stored as listed in the table below.

Preservation Method	Storage Temperature	Special Conditions
Freeze-Dried	Store between 15˚C and 30˚C.	Do not freeze.

INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties and/or performance.

GENERAL INSTRUCTIONS

- Use on a single occasion for a single patient only.
- Once the packaging is opened, the device must be used for the current procedure or discarded.
- Inspect the device, inner and outer packaging and labels carefully:
  - Do not use past the expiration date as indicated on the label.
  - Do not use if the device is damaged or the packaging integrity is compromised.
  - Do not use if there are discrepancies in label information.
- Use aseptic technique at all times.
- Do not re-sterilize.
- Keep the device stored according to recommended storage instructions until preparing it for implantation.

Preparation of the bone graft bed is important for graft incorporation and bone formation, as are other factors such as blood supply, source of marrow elements, loading, stability and absence of infection at the graft site. The volume of graft material used in each procedure is determined by the judgment of the clinician.

OPENING INSTRUCTIONS

Using aseptic technique, remove the contents of the internal packaging material and place them directly on the operative field.

PREPARATIONS FOR USE

1. ReadiGRAFT® BLX DBM Putty products do not require rehydration prior to use.
2. Remove cap plug from syringe.
3. Extrude desired amount of DBM Putty product by pushing the syringe plunger.
4. If desired, autologous or allogeneic tissue or fluid may be added to ReadiGRAFT® BLX DBM Putty products.

TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation.

COMPLAINTS AND RETURNS

For further information on returns or to report a complaint or adverse event, please contact your authorized distributor or LifeNet Health Client Services (available 24 hours a day) at 1-888-847-7831 (inside the U.S.) or 00+1-757-464-4761 ext. 2000 (outside the U.S.) and have the device's identification number available (see label).

WARRANTY STATEMENT

Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by LifeNet Health.

Symbol Index	
	Manufacturer
	Caution
	Single Use
	For use by a licensed clinician only
	Use by date
	Temperature Limitation
	Sterilized using irradiation
	Consult instructions for use
	Minimize excessive exposure to light and protect from excessive heat

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