Optium® DBM
Instructions for Use

LifeNet Health
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Source Establishment: LifeNet Health CTO #100038

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Optium® DBM

Read this entire package insert carefully prior to use.

Federal law (USA) restricts this device to sale by or on the order of a licensed physician.

DESCRIPTION
This device was processed from donated human tissue, resulting from the gift of an individual or his/her family. Optium DBM is comprised of freeze-dried demineralized bone matrix that is processed using LifeNet Health's patented and proprietary technology and combined with USP grade glycerol.

INDICATIONS FOR USE
These products are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. They are indicated to be placed into bony voids or gaps of the skeletal system (e.g. extremities, spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products provide a bone void filler that remodels into the recipient's skeletal system.

CONTRAINDICATIONS
- This device should not be implanted into sites with an active infection.
- Gentamicin, alcohol, and/or surfactants are used in the processing of this allograft and trace amounts may remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity to any of these processing agents.

Additional contraindications (as required for Canadian market):
- Treatment of spinal insufficiency fractures
- Epiphyseal areas of patients whose growth plates have not yet closed
- Pregnancy
- Renal-compromised patients

WARNINGS AND PRECAUTIONS
- Tissue may transmit infectious agents.
- For single patient use only.
- For use on a single occasion only.
- Once the packaging has been opened, the tissue must either be transplanted or discarded.
- Do not use if package integrity has been compromised.
- Do not re-sterilize.

STORAGE REQUIREMENTS
- Store at ambient temperature.
- Do not freeze.
- The distributor, intermediary and/or the end-user clinician or facility is responsible for storing this product under appropriate conditions prior to further distribution or implantation.

TRACEABILITY
It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation. As a courtesy to the end-user clinician or facility, LifeNet Health has enclosed a Graft Implant Tracking Card to assist with post-implantation tracking. Please refer to the enclosed card for additional instructions.

DONOR SCREENING AND TESTING
All donors have been screened and tissue recovered, processed, stored, tested and distributed in accordance with current U.S. Federal regulations as promulgated in 21 CFR 1270, 1271 and 820, and current Standards for Tissue Banking set forth by the American Association of Tissue Banks.

This allograft was deemed suitable for implantation by LifeNet Health. A physician medical director has 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:

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
HBV NAT: Hepatitis B Virus Nucleic Acid Test*	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 prior to December 16, 2016. Performed as required by international laws and regulations.
**Not required for donors recovered after March 31, 2010. Performed as required by International laws and regulations.

FINAL GRAFT TESTING
A representative sample of each lot of finished product is screened for osteoinductive potential in an athymic rodent assay and found to be osteoinductive, equivalent to osteoinductivity index (OI) score of > 1 OI units on the Edwards[1] scale. Findings from an animal-based model are not necessarily predictive of human clinical results.

This device is terminally sterilized by gamma irradiation and meets requirements for sterilization (i.e. SAL 10^{-6}) per AAMI and ISO standards.

[1] Edwards JE, Diegmann MH, Scarborough NL: Osteoinduction of human demineralized bone: Characterization in a rat model. Clin Orthop Rel Res 357:219-228, April, 1998.

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

Glycerol may lead to hyperglycemia. Clinicians involved in implanting glycerol containing bone void fillers have reported solitary cases of urinary anastomosis, leg edema, fever, operative site infection, and graft failure as being potentially attributable to the glycerol containing bone void filler.

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

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 allograft 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.

PREPARATION FOR USE
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

1. These products are packaged in a double peel pack pouch.
2. Open the outer peel pack pouch and using aseptic technique, present the sterile inner pouch onto the sterile field.
3. Open the sterile inner pouch package and remove product.
4. OPTIUM DBM requires no rehydration prior to use.
5. If desired, a small amount of fluid such as bone marrow aspirate, blood, sterile water, or sterile saline may be added to DBM Putty in order to adjust its consistency or handling characteristics.

Symbol Index	
	Manufacturer, Produttore, Fabricante, Fabricant, 製造商, 제조업체, الجهة المصنعة
	Caution, Attenzione, Precaución, Attention, 警示, 주의, تنبيه
	Single Use, Monouso, Un único uso, Usage unique, 單次使用, 1회용, للاستخدام مرة واحدة
	For use by a licensed clinician only, Solo per uso da parte di un medico autorizzato, Uso restringido a médicos con licencia, Pour utilisation par un médecin agréé uniquement, 僅供持有執照醫師使用, 면허가 있는 임상의만 사용 가능함, للاستخدام بواسطة طبيب معتمد فقط
	Use by date, Usare entro la data di scadenza, Fecha de caducidad, Utiliser avant le, 在此日期前使用, 유통기간, تاريخ انتهاء الصلاحية
	Temperature Limitation, Limiti di temperatura, Límite de temperatura, Limitations de températures, 溫度限制, 온도 제한, حدود درجة الحرارة
	Sterilized using irradiation, Sterilizzato mediante irraggiamento, Esterilizado mediante irradiación, Stérilisé par irradiation, 已使用射線進行除菌, 방사선으로 살균됨, معقم بالإشعاع
	Consult instructions for use, Consultare le istruzioni per l'uso, Consulte las instrucciones de uso, Consulter les instructions d'utilisation, 請參閱使用指示, 사용 전 설명서 필독, راجع إرشادات الاستخدام
	Minimize excessive exposure to light and protect from excessive heat, Ridurre il più possibile l'esposizione alla luce e proteggere da eccessivo calore, Reduzca al mínimo la exposición excesiva a la luz y protéjalo del calor excesivo, Conserver à l'abri de la lumière et d'une chaleur excessive, 儘可能減少暴露在陽光下，並避免過度加熱, 빛에 노출을 최소화하고 과도한 열로부터 보호하십시오, يجب تقليل تعرض المنتج للضوء بشكل مفرط وحمايته من الحرارة المفرطة