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Source Establishment: LifeNet Health CTO #100038

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ALLOGRAFT BIO-IMPLANT



Read this entire package insert carefully prior to use.



Federal law (U.S.A.) restricts this allograft bio-implant for use by a licensed clinician only.

DESCRIPTION

This allograft bio-implant was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. The bio-implant was cleaned and disinfected under aseptic conditions through a proprietary process and terminally sterilized via low dose, low temperature gamma irradiation to achieve a Sterility Assurance Level of 10⁻⁶. PliaFX Pak is comprised of a mix of demineralized bone fibers and cancellous or corticocancellous chips that are osteoconductive as well as osteoinductive in an athymic rodent assay.*

*Findings from an animal-based model are not necessarily predictive of human clinical results.

INDICATIONS FOR USE

PliaFX Pak is indicated to fill bony voids or gaps that are not intrinsic to the stability of the bony structure in the skeletal and craniomaxillofacial systems (e.g. extremities, spine, pelvis, periodontal and cranial defects). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

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.

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 bio-implant may contain residual reagents including Gentamicin, Meropenem, Vancomycin, Ciprofloxacin, Anidulafungin, alcohol, surfactants, Dimethyl Sulfoxide (DMSO), and/or Human Serum Albumin (HSA). 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, 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 allograft bio- implant (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 1271, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required.

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
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.

STORAGE REQUIREMENTS

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

Storage Temperature	Special Conditions
Store at ambient temperature*	Do not freeze

*While ambient room temperature has not been defined by regulatory bodies, LifeNet Health would recommend storage at 2°C to 37°C with excursions of less than 24 hours up to 40°C. If an excursion outside this range occurs, please contact LifeNet Health.

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 bio-implant must be used for the current procedure or discarded.
- Inspect the bio-implant, inner and outer packaging, and labels carefully:
 - Do not use past the expiration date as indicated on the label.
 - Do not use if the bio-implant 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 bio-implant stored according to recommended storage instructions until preparing it for implantation.

OPENING INSTRUCTIONS:

1. Non-Sterile Team Member: Peel open outer tray foil lidstock and present inner contents to the Sterile Team Member.
2. Sterile Team Member: Firmly grasp the “Peel Here” tab on the inner tray and remove from outer tray.

PREPARATIONS FOR USE:

Rehydrate until desired consistency and handling are achieved. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

1. The bio-implant can be rehydrated within the inner tray packaging or can be removed and placed in a sterile basin.
2. Rehydrate the bio-implant using the following volumes of media (see chart below). Volume of media can be adjusted based on desired consistency and handling.
3. Some manual manipulation of the bio-implant may be necessary to achieve full rehydration.

PliaFX Pak Graft Volume	Suggested Hydrating Media Volume for Rehydration
1 cc	1 cc
2.5 cc	2.5 cc
5 cc	5 cc
10 cc	7 cc
20 cc	15 cc
30 cc	18 cc

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 in the post-implantation tracking. Please refer to the enclosed card for additional instructions.

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 bio-implant’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, Hersteller, Fabricante, Fabricant
	Caution, Achtung, Precaución, Attention
	Single Use, Einmalgebrauch, Un único uso, Usage unique
	For use by a licensed clinician only, Nur für den Gebrauch durch einen zugelassenen Arzt bestimmt, Uso restringido a médicos con licencia, Pour utilisation par un médecin agréé uniquement
	Use by date, Verwendbar bis, Fecha de caducidad, Utiliser avant le
	Temperature Limitation, Temperaturgrenze, Límite de temperatura, Limitations de températures
	Sterilized using irradiation, Durch Strahlung sterilisiert, Esterilizado mediante irradiación, Stérilisé par irradiation
	Consult instructions for use, Gebrauchsanweisung lesen, Consulte las instrucciones de uso, Consulter les instructions d'utilisation
	Minimize excessive exposure to light and protect from excessive heat, Vor übermäßiger Lichtexposition und übermäßiger Hitze schützen, 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