




INSTRUCTIONS FOR USE

 Read this entire package insert carefully prior to use.

 Federal law (USA) restricts this allograft for use by a licensed clinician only.

DESCRIPTION

PliaFX® Flo was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. This device is a human bone allograft that is comprised of demineralized bone fibers combined with USP grade glycerol. It 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® Flo is pre-filled in a 3cc or 14c delivery syringe based on final product volume. An optional female luer cap is provided with the 3cc syringe configuration.

INDICATIONS FOR USE

PliaFX® Flo is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated to be placed into the bony voids or gaps of the skeletal system (e.g., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone. This product provides a bone void filler that remodels into the recipient's skeletal system.

CONTRAINDICATIONS

- Presence of active infection at the implantation site
- Use in any patient who has a known or suspected allergy to any of the processing reagents listed in this package insert
- Treatment of spinal insufficiency fractures
- Epiphyseal areas of patients whose growth plates have not yet closed
- Pregnancy
- Renal-compromised patients

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 device containing allograft tissue, the potential for transmission of infectious agents exists.
- For single patient use only during a single procedure. Do not re-sterilize this device.
- This device may contain residuals of alcohol, glycinate buffer, and glycerol. Caution should be exercised if the patient has a known or suspected allergy to any of these reagents.
- Once the packaging has been opened, the device must be used for the current procedure or discarded.
- Do not use the device if the package integrity has been compromised.
- Do not over-pressurize the delivery syringe or over-fill the defect site as this may lead to extrusion of the device material beyond the site of its intended application and damage to the surrounding tissues.
- Do not over-pressurize the defect site as this may lead to fat embolization or embolization of the device material into the bloodstream.

POTENTIAL ADVERSE EVENTS

Potential adverse events 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 allograft. (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 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:

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 on the Edwards' 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 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.

STORAGE REQUIREMENTS

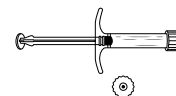
The distributor, intermediary and/or end-user clinician or facility is responsible for storing this device under appropriate conditions prior to further distribution or implantation. This device must be stored as listed in the table below. Do not use this device after the expiration date as indicated on the label.

Storage Temperature	Special Conditions
Store at ambient temperature	Do not freeze

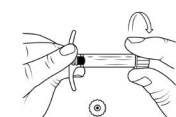
OPENING INSTRUCTIONS

 Caution: PliaFX Flo is contained in a delivery syringe that is packaged in a double peel pack pouch. In the 0.5cc, 1.0cc, and 2.5cc product configurations, an optional threaded delivery cap tip is included in the pouch. The 5cc and 10cc product configurations do not include the optional threaded delivery cap tip.

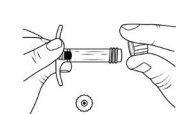
1. Non-Sterile Team Member: Peel open outer peel pack pouch and aseptically present inner contents to the Sterile Team Member.



2. Sterile Team Member: Peel open the inner peel pack pouch and remove the delivery syringe containing the graft and, if applicable, the optional threaded delivery cap tip.



3. Remove the closure cap from the delivery syringe. If desired, screw the optional threaded delivery cap tip onto the delivery syringe using the Assembly Instructions provided on the subsequent page of this IFU.



Once the packaging has been opened, the device must be used for the current procedure or discarded.



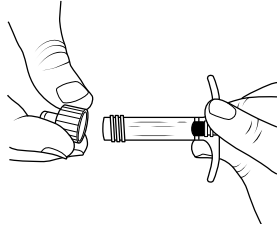
PREPARATIONS FOR USE

PliaFX Flo does not require rehydration. Use the plunger to extrude the allograft from the delivery syringe.

ASSEMBLY INSTRUCTIONS FOR OPTIONAL DELIVERY CAP TIP

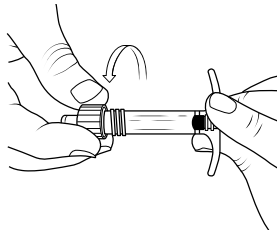
STEP ONE:

Place the threaded delivery cap tip on the threaded end of the delivery syringe.



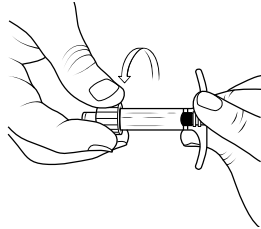
STEP TWO:

Twist the threaded delivery cap tip in a clockwise direction to affix it firmly to the delivery syringe.



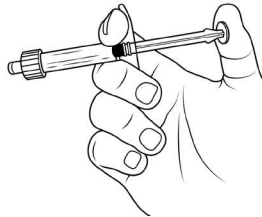
STEP THREE:

Ensure the threaded delivery cap is tightened securely to the syringe.



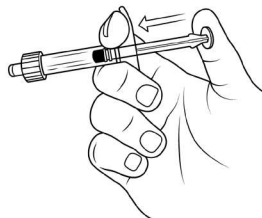
STEP FOUR:

Use your pointer and middle fingers to hold the delivery syringe wings and place your thumb on the flat surface at the end of the plunger.



STEP FIVE:

Use your thumb to extrude the allograft by applying firm, even pressure to the plunger.



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 Customer Experience (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 properties cannot be guaranteed by LifeNet Health.

SYMBOL INDEX

Symbol	Title	Description of Symbol
	Manufacturer	Indicates the medical device manufacturer.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	Do not re-use	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	Unique device identifier	Indicates a carrier that contains unique device identifier information.
	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.

Manufactured by:
 LifeNet Health 1864 Concert Drive Virginia Beach, VA 23453, USA
 1.888.847.7831 (inside the U.S.) +1.757.464.4761 (outside the U.S.)
 LifeNetHealth.org

Source Establishment: LifeNet Health CTO #100038

For patent information, please visit www.lifenethealth.org/patents

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