



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

Nexeon Decellularized Femoral Artery was processed from donated human tissue, resulting from the generous gift of an individual or his/her family. It is processed using a proprietary technology, which safely renders the tissue matrix acellular without compromising the biomechanical properties necessary for its intended surgical applications. Nexeon is terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 1×10^{-6} and is preserved with glycerol.

INDICATIONS FOR USE

Nexeon is intended for use as a conduit for blood flow in the peripheral vasculature.

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.

Nexeon may contain residuals of antibiotics (Ciprofloxacin, Gentamicin, Lincomycin, Meropenem, Polymyxin B Sulfate, and/or Vancomycin), N-Lauroyl Sarcosinate (detergent), Benzonase[®] or Denarase[®] (recombinant endonuclease), glycerol, and/or Dimethyl Sulfoxide (DMSO). 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 could include, but are not limited to, hematoma, aneurysm, stenosis, hemorrhage, thromboembolism, infection, or allergic reaction to residual processing reagents.

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
HBV NAT: Hepatitis B Virus Nucleic Acid Test	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

* Performed as required by international laws and regulations.

STORAGE REQUIREMENTS

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

Storage Temperature	Special Conditions
Store between 15°C – 30°C	Do not freeze or refrigerate.
	Store in its original cardboard sleeve.
	Protect from excessive heat.

The packaging contains a temperature sensitive dot that will turn from white to pink or red if the upper temperature limit has been exceeded. Do not use Nexeon if the temperature dot appears to be a color other than white.

INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use as they are different than those for traditional cryopreserved vascular allografts. Improper preparation technique may adversely affect biocompatibility, 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.
 - * Do not use the bio-implant if the dot appears to be a color other than white, or if the temperature dot is not present on the packaging.
- 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 and Dilution Instructions:

This process helps to dilute the preservation agent, glycerin/glycerol. Failure to follow these instructions could result in graft failure. The graft preparation process will take approximately 20 – 25 minutes. Please coordinate the timing of this procedure with the surgeon. Each graft must be diluted individually.

Sterile Supplies Needed:

- Two 1 L basins
 - One 5 L basin
 - Four 20 cc syringes
 - Six 1 L 0.9% isotonic saline warmed to 37-42°C
 - One Thermometer
 - One Pair of Forceps
 - One Pair of Scissors
 - One Clamp
1. Fill a 1 L basin with 1 L of isotonic saline (37-42°C). Using a sterile 20 cc syringe, draw up 20 cc of saline from this basin and place syringe on sterile table.
 2. Fill a 5 L basin with 4 L of isotonic saline (37-42°C). Using two sterile 20 cc syringes, draw up 20 cc of saline per syringe from the 5 L basin and place syringes on sterile table.
Caution: Ensure the solution temperature does not exceed 42°C for all solutions as this may damage the graft.
 3. Remove the graft from its packaging as described below.
 - a. **Non-Sterile Team Member:** Open the cardboard sleeve and remove the pouch from within.
 - b. Aseptically open the outer peel pack and present inner pouch to the **Sterile Team Member.**
 - c. **Sterile Team Member:** Open the inner peel pouch and remove the plastic tray containing the graft. With the clear side up, grasp either or both of the tabs labeled "Lift" and remove the plastic retaining lid from the tray.
 - d. Using sterile forceps, grasp the cannula attached to the graft and remove graft from the tray.
 - e. Place graft into the 1 L basin of isotonic solution warmed to 37-42°C

Sterile Team Member:

4. Push 20 cc of saline gently through the cannulated end of the graft with the syringe. Gently hand stir the solution surrounding the graft for at least one minute.
5. Using forceps, grasp the graft by the cannula and transfer it to the 5 L basin containing 4 L of isotonic saline warmed to 37-42°C.
6. Gently push 20 cc of saline through the cannulated end of the graft using one of the remaining 20 cc syringes. Leave the graft fully submerged in the 5 L basin for 15 minutes with no agitation.
7. At the end of the 15 minute static rinse, gently push 20 cc of saline through the cannulated end of the graft with the other 20 cc syringe.
8. Fill a 1 L basin with 1 L of fresh isotonic saline (37-42°C). Using a sterile 20 cc syringe, draw up 20 cc of saline from this basin and place syringe on sterile table.
9. Using forceps, grasp the graft by the cannula and transfer it to the 1 L basin with isotonic saline warmed to 37-42°C.
10. Gently push 20 cc of saline through the cannulated end of the graft using one of the 20 cc syringes. Leave the graft fully submerged in the 1 L basin for 5 minutes with no agitation. Keep the graft fully submerged until needed.
11. Prior to implantation, clamp the uncannulated end of the graft and infuse isotonic saline into the graft with a syringe. Inspect graft integrity to ensure no damage occurred during the dilution process.
12. Perform leak testing under pressure prior to implanting.
 - a. Inspect the ties for any loosening.
 - b. Perform additional ligations or reinforcements as needed.
13. Remove the cannula prior to implanting the graft by cutting the graft at least 1 cm away from the end of the cannula barb.
14. The graft must be used for the current procedure or discarded.

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.