STERILE I/C GRAFT CHAMBER®

DESCRIPTION

The I/C Graft Chamber® is a delivery device pre-filled with a proprietary ratio of sterile freeze-dried demineralized bone matrix and cancellous chips. The demineralized bone matrix and cancellous chips are processed by LifeNet Health using Allowash XG®, a LifeNet Health patented and proprietary technology. Final product is terminally sterilized by gamma irradiation and meets requirements for sterilization (i.e. SAL 10-6), per AAMI and ISO standards.

The freeze-dried demineralized bone matrix and cancellous chips are processed from Donated Human Tissue, resulting from the gift of an individual and his/her family.

CONTRAINDICATIONS

- Tissue may contain traces of the processing reagents Bacitracin, Gentamicin, Polymyxin B Sulfate, alcohol and/or surfactants. Caution should be exercised if the patient has a known sensitivity or allergy to any of these antibiotics or reagents.
- Infection at the transplantation site is a contraindication for the use of this allograft.

PRECAUTIONS

- Federal law (USA) restricts this tissue to sale by or on the order of a licensed physician.
- Tissue may transmit infectious agents.
- LifeNet Health makes no claims concerning the biologic or biomechanical properties of allograft tissue.
- For single patient use only.
- For use on a single occasion only.
- Do not use if package integrity has been compromised.
- Once opened, the tissue must either be transplanted or discarded.
- Do not re-sterilize.

STORAGE REQUIREMENTS

- Store at ambient temperature.
- Do not freeze.
- The Tissue Dispensing Service and/or the end-user clinician or facility is responsible for storing this product under appropriate conditions prior to transplantation.

DOCUMENTATION REQUIREMENTS

Recipient records must be maintained for the purpose of tracking tissues post-transplantation. Please complete and return the enclosed Graft Implant Tracking Report.

TISSUE RETURNS

Please contact Client Services at 1-888-847-7831 for information regarding LifeNet Health's Tissue Return Policy.

DONOR SCREENING AND TESTING

All tissues have been screened, recovered, processed, stored, and distributed according to current FDA and American Association of Tissue Banks (AATB) standards and regulations.

This human tissue has been determined to be suitable for transplantation by LifeNet Health. A physician medical director has evaluated the following to determine suitability: infectious disease test results, current donor medical history and 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 infectious diseases and found to be negative or non-reactive. LifeNet Health uses FDA-licensed tests. Testing is performed by laboratories that are registered with the FDA and certified under the Clinical Laboratory Improvements of 1988 (CLIA) or equivalent. Testing includes, but is not limited to, the following:

- **HBcAb:** Hepatitis B Core Antibody
- **HBsAg:** Hepatitis B Surface Antigen
- **HCV NAT:** Hepatitis C Virus
- **HCVAb:** Hepatitis C Antibody
- **HBV NAT:** Hepatitis B Virus Nucleic Acid Test*
- **HIV-1 NAT:** Human Immunodeficiency Virus Type 1 Nucleic Acid Test
- **HIV 1/2Ab:** Human Immunodeficiency Virus Types 1/2 Antibody
- **RPR/STS or Equivalent:** Syphillis
- **HTLV I/II Ab:** Human T-Lymphotropic Virus Types I/II Antibody**

**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.*

ADVERSE OUTCOMES

Any adverse events or outcomes must be reported promptly. Please call our Client Services department at 1-888-847-7831 and have the Graft ID number available.

LIFENET HEALTH'S COMMITMENT TO QUALITY

We work hard to provide our customers with the highest quality allograft tissue through a rigorous quality assurance program. If you have any questions or comments, we would like to hear from you. Please contact Client Services at 1-888-847-7831. We are available 24 hours a day to assist you.

LifeNet Health is a full service, not-for-profit tissue bank, an accredited member of AATB, and an ISO 13485:2003 certified company.

PREPARATION FOR USE

I/C Graft Chamber is packaged so that the inner tray is sterile.

1. Visually inspect the packaging to ensure that it is intact and its integrity has not been breached. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
2. Peel back lid of outer tray using standard aseptic technique.
3. Pass the inner sterile tray to sterile field.
4. Peel back lid of inner tray.
5. Remove the chamber from inner tray.

* If not using the I/C Graft Chamber alone, use the DePuy SYMPHONY Graft Delivery System IFU for instructions after removing the chamber from inner tray (step 5.). If using alone, proceed with Step 6.

6. Remove lid from chamber. Do not remove end cap from chamber.
7. Place contents into sterile basin.
8. Mix with hydrating medium of choice until required consistency and handling are achieved. Hydrating media may include I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

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