ALLOGRAFT INSTRUCTIONS FOR USE AND INFORMATION

Novafix®

Contents

This package contains Human Cellular and Tissue Based Product (HCT/P) as defined in US FDA 21 CFR Part 1271.

Description

The allograft is a sterile, dehydrated amniotic membrane processed by DCI Donor Services Tissue Bank from donated human tissue. DCI Donor Services Tissue Bank is a full service not-for-profit tissue bank accredited by AATB and registered with FDA.

Intended Use

Novafix® is an allograft intended for use in the management of acute and chronic wounds. Novafix® may be applied as a wound covering to a variety of partial- and full-thickness acute and chronic wounds, and wounds with exposed tendon, muscle, joint capsule and bone. Novafix® can be applied from the onset and for the duration of the wound, weekly or at the discretion of the health care practitioner.

Donor Screening for Tissue Procurement

An appropriate blood sample from the donor is tested for relevant communicable diseases by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on live human specimens under the CLIA Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA approved test kits. This tissue was tested for and had negative or non-reactive results for the following:

- anti-HIV-1 and anti-HIV-2
- HIV-1/HBV/HCV NAT
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis B Core total antibody (anti-HBc)
- Hepatitis C antibody (anti-HCV)
- Syphilis
- HTLV I/II
- WNV NAT

Additional tests for other communicable diseases, such as T. Cruzi, Cytomegalovirus and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and DCIDS policies and procedures.

These test results, as well as, a donor risk assessment questionnaire, donor physical examination and other available relevant donor records have been evaluated and deemed eligible for transplant by a Medical Director. Donor eligibility determination was performed by DCI Donor Services – Tissue Bank, 1714 Hayes Street, Nashville, Tennessee 37203.

Processing

Technical Quality Assurance standards are rigorously maintained by DCI Donor Services – Tissue Bank. Tissue is processed aseptically in a controlled, ultra clean environment. This tissue was processed using some or all of the following agents: DMEM and alcohol. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain. Final product is terminally sterilized using a validated gamma irradiation process.

Contraindications

- Active or latent infection in or around the surgical implantation site.
- Sensitivity or allergies to any of the processing agents listed under the processing section of this document.
- Use in immune compromised patients.

Warnings & Precautions

As with all allogeneic materials, it is not possible to provide an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening criteria, laboratory testing, aseptic processing and terminal gamma irradiation of final product.

- **Single patient, single use only.**
- **Do not sterilize or re-sterilize.**
- Return all compromised or flawed packaging to **Triad Life Sciences**.
- Do not use if expiration date has been exceeded.
- The maintenance of the tissue for transplantation, including recommended storage conditions, is the responsibility of the hospital or clinician. Do not use if tissue has not been stored according to the recommended storage instructions.
  Prior to clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product.

Complications and Possible Adverse Effects

Inherent uncertainty exists in medical and social histories and lab testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to, viruses, bacteria and fungi;

- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to **Triad Life Sciences** immediately.

Tissue Preparation/Rehydration

Prior to use, carefully follow the tissue preparation steps as described below. If desired, the dehydrated allografts may be rehydrated in normal physiologic solution of the surgeon's preference.

Non-Sterile Team Member

1. Visually inspect packaging to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
2. Peel open outer heat-sealed package and pass the inner envelope packing onto the sterile field.

Sterile Team Member

3. Visually inspect the envelope to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
4. If no damage is detected, open the inner envelope and remove the graft. The graft may be immediately implanted or may be rehydrated in a sterile solution prior to implantation.
5. Once opened, allografts must be used immediately or discarded. ***Do not return opened, unused allografts to Triad Life Sciences.***

HCT/P Tracking

DCI Donor Services Tissue Bank is required by 21 CFR 1271 to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission standards require that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities."

To comply with these requirements, DCI Donor Services Tissue Bank provides an *Allograft Tracing Record* and preprinted labels with every graft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the *Allograft Tracing Record*. Return the completed form to DCI Donor Services Tissue Bank and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, the *Allograft Tracking Record* completed with the allograft identification information and reason for discard needs to be returned to DCI Donor Services Tissue Bank.

Storage and Handling

It is the responsibility of the user facility and user clinician to maintain allograft tissue in appropriate storage conditions prior to transplant. All dehydrated allografts must be maintained at ambient temperature prior to use. DO NOT FREEZE.

Return Policy

Claims for order discrepancies, shipping errors, damaged allografts or packaging must be reported to Triad Life Sciences within ten (10) business days to be eligible for credit. Prior to shipment return, returning facility must notify Customer Service at:

Email: CustomerService@triadls.com
Phone: (901) 333-6000
Fax: (901) 333-6001

to receive a Returned Goods Authorization (RGA) Form. After a completed RGA Form is returned to Customer Service, an RGA number will be issued with return instructions. Product returned without an RGA number will not be accepted. Credit will be issued for all authorized returns following the inspection and approval of such goods upon return.

Disclaimer

Triad Life Sciences and DCI Donor Services – Tissue Bank make no claims concerning the biologic or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored and distributed according to nationally recognized standards and in compliance with applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Adverse outcomes potentially attributable to the tissue must be reported immediately to Triad Life Sciences.

Processed by:

DCI
an extraordinary commitment to science, health and hope

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