Activate™ Matrix

Placental-Derived Allograft

Allograft Package Insert
Read Before Using

DONOR SCREENING AND TESTING

The enclosed donated human tissue allograft supplied by Nvision is for use by, or on order for, a licensed physician for single patient use on a single occasion only. The donor and donor tissue have been subjected to biological and medical screening to guard against the possibility of recipient exposure to, or transmission of, communicable diseases or exclusionary medical conditions. These screening procedures are performed in accordance with standards, regulations, statutes and/or directives of the American Association of Tissue Banks (AATB)[1], the U.S. Food and Drug Administration (FDA)[2], applicable State Licensing Agencies.
Communicable disease testing on a qualified donor blood sample was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). All required communicable disease tests listed below were found to be nonreactive or negative:

-Human Immunodeficiency Virus (HIV)
HIV-1/2 Antibodies (HIV-1/2-Ab)
Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)
-Hepatitis B Virus (HBV)
HBV Surface Antigen (HBsAg)
HBV Core Antibody IgG & IgM (HBcAb)
Nucleic Acid Test for HBV DNA (HBV NAT)
-Hepatitis C Virus (HCV)
HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)
-Syphilis*
Rapid Plasma Reagin Screen (RPR) -Or-
Serologic Test for Syphilis (STS) -Or-
Fluorescent Treponemal Antibody (FTA) -Or-
T. pallidum IgG
-West Nile Virus (WNV NAT)

*Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Non-required screening tests for exposure to other viruses or parasites such as those listed below may have been performed on the donor by health care provider or other agencies involved in the donation process. A negative/nonreactive result is not required for these tests other than HTLV I/II -Ab; however, all donors are evaluated on a case-by-case basis by the Medical Director.

-Human T-Cell Lymphotropic Virus I/II Antibody (HTLV-I/II-Ab)
-Cytomegalovirus (CMV Ab IgG & IgM)
-Epstein Barr Virus (EBV Ab IgG & IgM)
-Toxoplasma gondii (Toxoplasma Ab IgG & IgM)
-Trypanosoma cruzi (T. cruzi Ab IgG & IgM)

All records and test data has been reviewed by the manufacturer's Medical Director (licensed physician) and the allograft has been deemed suitable for transplantation.

Should the end-user require information[3] regarding medical background screening or production, a formal request should be made in writing to:
Nvision Biomedical Technologies, 4590 Lockhill Selma Rd, San Antonio, TX 78249.

PROCESSING AND STERILIZATION

All tissue is recovered and processed using aseptic techniques. This aseptic handling of the tissue continues throughout processing. This allograft was prepared from DONATED HUMAN TISSUE that was processed using aseptic techniques in a controlled, clean environment. The manufacturer incorporates terminal sterilization by exposure to Gamma irradiation following production. Final release is based on microbiological analysis of a validated sterilization process.
DO NOT RE-STERILIZE

PACKAGING AND LABELING

A serialized inventory control number for tracking and traceability uniquely identifies distributed grafts. This graft is packaged in sterile, single patient use pouches and the lot number (donor ID), expiration date, description, product code, size, and additional information are listed on the package label.

PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS

This allograft may contain trace amounts of PBS, and IPA, processing solutions, and/or reagents. The allograft may have come in contact with latex gloves during processing which may cause an allergic reaction.
Individuals with known sensitivities to any of these agents should not receive this allograft.

By receiving tissues, the facility or practitioner accepts the responsibility for proper storage, handling, use, and tissue tracking. Nvision and the manufacturer assumes no responsibility for the clinical use of this tissue.

Although all efforts have been made to ensure the safety of the allograft, current technologies may not preclude the transmission of all diseases. Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing have been used in the eligibility and suitability qualification of all tissue donors. Despite the extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of an infectious disease through the use of this tissue graft is still possible.

Possible adverse effects include:

1) Complications associated with surgery such as hematoma, infection, and other complications;
2) Immune rejection of the introduced tissue; and
3) The transmission of known pathogens including Human Immunodeficiency Virus 1/2, Hepatitis B and C, Human T-Lymphotropic Virus 1 and 2, Syphilis, bacteria, and fungus.

The patient is to be made aware of general risks associated with treatment and possible adverse effects. There are no guarantees regarding biological or biomechanical properties of the provided product.

Any adverse outcomes potentially attributable to this graft must be reported immediately to Nvision Biomedical Technologies at 210-545-3713, or at Regulatory@Nvisionbiomed.com.

CONTRAINDICATIONS

Contraindications for the use of this allograft include, but are not limited to:

1) The presence of infection at the surgical site and/or distant foci of infections that may spread to the surgical site;
2) Uncooperative patient or a patient with neurologic disorders who is incapable of following directions, including weight control and activity levels;
3) Pregnancy

STORAGE

Activate™ Matrix packaged in a foil packaging system should be stored in a clean, dry place at a controlled ambient temperature of 15-30°C (59-86°F). **DO NOT FREEZE or REFRIGERATE.**

See package label for expiration date. It is the responsibility of the healthcare facility and/or the end user to maintain this allograft in the appropriate storage conditions prior to transplant.

PRECAUTIONS

The allograft was processed and packaged aseptically and must be handled in an aseptic manner to prevent contamination.
Once the user breaks the seal, the allograft MUST be transplanted (if appropriate) or discarded.
Because of potential violations of sterility, this product must not be used under the following conditions:

- The expiration date has been exceeded;
- The product container is not labeled, or the label's information is obliterated or defaced;
- The product has not been stored according to acceptable storage conditions mentioned under "Storage"; and/or
- If any of the package or product elements appear to be missing, damaged, illegible, or tampered with.

If any of the aforementioned conditions exist or are suspected, this allograft should NOT be used and Nvision should be notified immediately.

INSTRUCTIONS FOR USE

Once the package seal has been compromised the tissue shall be either transplanted, if appropriate, or otherwise discarded. Used allograft pouches should be disposed of in accordance with recognized procedures for discarding medical waste material.

1. Thoroughly inspect the outer packaging prior to opening to ensure that the integrity has not been compromised.
2. Carefully open the outer non-sterile packaging. Paperwork and the outer packaging are non-sterile items and should be handled appropriately.
3. Using appropriate aseptic technique, open the outer foil pouch and deliver the inner most sterile sealed pouch containing the graft material to the sterile field.
4. Using sterile technique, open the inner sterile sealed pouch and deliver the graft to the sterile field.
5. Graft may be placed within the surgical site without any rehydration. In the event rehydration is necessary, it is recommended that normal saline or sterile water be utilized.
6. Allograft must be used within 8 hours of opening or hydration. If not, it must be discarded.

PATIENT RECORD

Complete the enclosed Allograft Tissue Utilization Record Card and return it to Nvision. It is the responsibility of the end-user to provide this information, which enables Nvision to maintain records for purpose of tracing the product from receipt to transplant or any other final disposition (e.g., product not used and discarded) as required by government regulations and industry standards.

Use the peel-off stickers provided for the patient's records.

CONTACT INFORMATION

Donor Suitability Determination Made By:
Sequence Life Science, Inc.
4590 Lockhill Selma Rd
San Antonio, TX 78249
210-545-3713

Tissue Processed By:
Sequence Life Science, Inc.
4590 Lockhill Selma Rd
San Antonio, TX 78249
210-545-3713

1. Standards for Tissue Banking; American Association of Tissue Banks, Current Edition
2. Code of Federal Regulations, Title 21 Part 1271 – Donor Eligibility and Good Tissue Practice (GTP) regulations for Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps), U.S. Food and Drug Administration, Current
3. Information that would infringe upon the donor's confidentiality rights is excluded from information provided per HIPAA