THE ENCLOSED TISSUE IS FOR SINGLE PATIENT USE ONLY AND MAY NOT BE STERILIZED OR RE-STERILIZED BY THE END-USER

1.0 INTRODUCTION - Summary of Records

The enclosed donated human tissue allograft is manufactured and distributed by IntegoGen, LLC (ITG). This allograft is for use by, or on order for, a licensed physician licensed by the state to use and order the tissue product. The tissue was recovered and processed aseptically, following rigorous and technical quality standards, in a controlled environment. The Donor and Donor tissues have been subjected to serological testing 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 U.S. Food and Drug Administration (FDA), and other licensing and / or accrediting agencies.
Communicable disease testing and screening requirements have been completed. Names and addresses of testing laboratories, interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at IntegoGen, LLC and are available upon request. All relevant medical records data have been reviewed by the Medical Director (licensed physician) of ITG and the allograft has been deemed suitable for transplantation.

2.0 DISEASE TESTING

Infectious Disease Testing on a qualified Donor sample was performed by a laboratory registered with the FDA to perform Donor Testing and is 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 **infectious disease tests** listed below were found to be **nonreactive** or **negative,** as appropriate.

TEST	SYMBOL
HUMAN IMMUNODEFICIENCY VIRUS (HIV)	
HIV-1/2 plus O Antibodies	HIV-1/2 plus O Ab
Nucleic Acid Test for HIV-1 RNA	HIV-1 NAT
HEPATITIS B VIRUS (HBV)	
HBV Surface Antigen	HBsAg
HBV Core Antibody	HBcAb
Nucleic Acid Test for HBV DNA (if applicable)	HBV NAT
HEPATITIS C VIRUS (HCV)	
HCV Antibody	HCVAb
Nucleic Acid Test for HCV RNA	HCV NAT
SYPHILIS	
T. Pallidum (IgG & IgM)	T. pallidum (IgG & IgM)*
HUMAN T-LYMPHOTROPIC VIRUS (HTLV)	
Human T-Lymphotropic	HTLV I / II
WEST NILE VIRUS	
West Nile Virus	WNV NAT

***Tissues from a Donor with a reactive result from the non-treponemal specific assay, are found to be Eligible only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Non-required, non-routine screening tests for the possible exposure to other viruses or parasites such as those listed below may have been performed on the Donor by other agencies involved in the donation process. A negative/nonreactive result is not always required for these tests, however, all Donor testing that is performed is evaluated on a case-by-case basis by the Medical Director and found to be acceptable.

Cytomegalovirus	CMV Ab (IgG & IgM)
Epstein Barr Virus	EBV Ab (IgG & IgM)

The accompanying allograft has been subjected to microbiological testing at recovery or at pre-processing to prevent contamination and/or cross contamination during processing.

3.0 ADVERSE REACTIONS

Adverse Reactions may include the presence of infectious diseases, neurological degenerative diseases of unknown etiology and the exposure to toxic substances. Although all efforts have been made to ensure the safety of the allograft, current technologies may not preclude the transmission of all diseases.
By receiving tissues, the facility (Tissue Dispensing Service, Tissue Distribution Intermediary, Surgical Site, etc.), or practitioner (End User) accepts the responsibility for the proper storage, handling, use, and tissue tracking. ITG assumes no responsibility for the clinical use of this tissue. **ALL TISSUE IS PROCESSED & ELIGIBILITY IS DETERMINED BY INTEGOGEN, LLC**

Any Adverse Reactions potentially attributable to the tissue must be reported immediately to:

INTEGOGEN, LLC
2849 PABLO AVENUE, SUITE 2, TALLAHASSEE, FL 32308
TEL: (850) 328-0340 FAX: (850) 391-0663

4.0 CONTRAINDICATIONS FOR USE: There are no known contraindications for use of this product.

5.0 STORAGE REQUIREMENTS – DO NOT FREEZE

The allograft has been processed and sealed in its packaging container and must be stored at ambient temperatures between 15°C to 27°C.

6.0 TERMINAL STERILIZATION BY IRRADIATION

All tissues are recovered in an aseptic fashion and maintained as such throughout processing. It is possible, however, for some tissues to demonstrate positive cultures upon recovery or as a result of factors related to the recovery process. All tissues are terminally sterilized by Electron Beam Radiation (EBEAM) with a SAL of 10^{-6}.

7.0 PRECAUTIONS

The allograft was processed and packaged aseptically and must be handled in an aseptic manner to prevent any potential contamination. **Once the user opens the package seal, the tissue MUST be transplanted 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 the acceptable storage conditions identified under "Storage Requirements";
- If any of the package or product elements appear to be missing, damaged, illegible, or tampered with, e.g. the two clear tamper-proof seals have been compromised.

If any of the aforementioned conditions exist or are suspected, notify IntegoGen, LLC immediately.

8.0 INSTRUCTIONS FOR USE

The dual layer allograft is aseptically packaged in two pouches. THE INNER POUCH IS CONSIDERED STERILE.

- Utilizing sterile technique, peel open the outer peel pouch from the chevron end and present the inner pouch onto the sterile field.
- Utilizing sterile technique, carefully open the inner tear notch pouch.
- It is recommended that a sterile person carefully remove the dual layer allograft from the inner pouch by securing the allograft with sterile forceps.

9.0 INTENDED USE

This human allograft tissue is regulated as a human cells, tissues, and cellular and tissue-based product (HCT/P) as defined by FDA 21 CFR Part 1271. This tissue product is intended solely for homologous use, e.g., the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. This tissue product may serve as a covering and offer protection from the surrounding environment. This tissue product may be applied to the area from the onset and for the duration at the discretion of the clinician.

10.0 RETURN POLICY

All Product Returns must be in their original, unopened carton and exhibit no evidence of third-party labeling. The only Exception to this Policy will be the return of Damaged and/or Defective Products which will be returned as Complaint Samples within the Product Complaint Program. A Return Authorization (RA) must be acquired by calling IntegoGen (ITG) at (850) 328-0340 Extension 103.

A Return Authorization is Required before returning any product.

- ITG will assign a RA # for the Return.
- The RA # MUST accompany all Returns and be visible on the outside of the shipping container.
- The original Packing Slip will be returned with the shipping container & the product being returned.
- Any Returns shipped w/o the RA # clearly showing on the outside of the shipping container will not be accepted and the Customer will be responsible for payment of the products received.
- For damaged products and/or products shipped in error, ITG, at the option of the Customer, may replace the products or issue a credit.
- In the event the product arrives damaged, the Customer MUST retain the original product unit(s) along with the shipping container(s) and notify ITG immediately to arrange for a carrier inspection and pickup of the damaged product(s).
- Shipping charges may be credited for defective products, damaged products and/or products shipped in error.
- ITG recommends the Customer return the product via FEDX or UPS using a tracking number to avoid loss and/or confusion relating to the products being returned.
- No "freight due" Returns will be accepted except for damaged and/or defective product(s) being returned as a Product Complaint.

11.0 TISSUE TRACKING INSTRUCTIONS

It is the responsibility of the end-user, e.g., the clinician to provide IntegoGen, LLC with information pertaining to the traceability of the implanted tissue. For this purpose, a *Tissue Traceability Record* (TTR) card is provided with the allograft. Once the allograft is implanted, peel off the small tracking labels provided on the product packaging and affix on the TTR card and applicable patient records. Complete the required information on the TTR card and return to IntegoGen, LLC.