THE ENCLOSED TISSUE IS FOR SINGLE PATIENT USE ONLY AND MAY NOT BE STERILIZED OR RE-STERILIZED BY THE END-USER. THERE IS NO CHARGE FOR THE TISSUE. ACCOMPANYING CHARGES COVER PROCESSING AND DISTRIBUTION EXPENSES.

1.0 INTRODUCTION - Summary of Records / Package Acquisition Inserts

1.1 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. The tissue was recovered and processed aseptically, following rigorous and technical quality standards, in a controlled environment. 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 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 the processing tissue bank and are available upon request. All relevant medical data has been reviewed by a Medical Director (licensed physician) of ITG and the allograft has been deemed eligible for transplantation.

2.0 PROCEDURE - Instructions

2.1 The following information is provided on donor screening; Instructions for use; and Quality Assurance Statements.

2.1.1 Communicable disease testing on a qualified donor blood sample was performed by a laboratory registered with the 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**.

TEST	SYMBOL
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	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	
Rapid Plasma Reagin Screen	RPR*
OR	
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 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.

2.1.2 Non-required screening tests for 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 donors are evaluated on a case-by-case basis by the Medical Director.

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

2.1.3 The accompanying allograft has been subjected to microbiologic studies at recovery or pre-processing to prevent contamination and cross contamination during processing.

2.1.4 Adverse Reactions may include**: presence of infectious diseases, neurological degenerative disease of unknown etiology, and 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.

2.1.5 Contraindication for use: **ALL PRODUCTS MAY CONTAIN TRACES OF GLUTARALDEHYDE SOLUTIONS. INDIVIDUALS WITH KNOWN SENSITIVITIES TO THESE AGENTS SHOULD NOT RECEIVE THIS ALLOGRAFT.**

2.2 By receiving tissues, the facility (Tissue Dispensing Service, Tissue Distribution Intermediary, or Surgical Site), or practitioner (End User) accepts the responsibility for proper storage, handling, use, and tissue tracking. ITG assumes no responsibility for the clinical use of this tissue.

Any adverse outcomes potentially attributable to the tissue must be reported immediately to INTEGOGEN, LLC at the telephone number indicated below.

PROCESSED & ELIGIBILITY DETERMINED BY:

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

2.3 STORAGE REQUIREMENTS AND PREPARATION FOR USE OF ALLOGRAFT – DO NOT FREEZE

The allograft has been processed and sealed in its packaging container, and must be stored at ambient temperature (15°C to 27°C). It is recommended that a sterile person secure the allograft with forceps to remove the allograft from the packaging. The allograft is packaged between two pieces of mesh. The mesh provided inside the packaging is for ***HANDLING PURPOSES ONLY*** and **SHOULD NOT** be implanted as part of the allograft. *Once the package seal is broken, the allograft must be used within 24 hours*.

2.4 TERMINAL STERILIZATION BY IRRADIATION

All tissues are recovered in an aseptic fashion and maintained as such throughout processing and distribution. It is possible, however, for some tissues to demonstrate positive cultures upon recovery as a result of factors related to the recovery process. All tissues are terminally sterilized by Electron Beam Radiation (EBEAM) with an SAL of 10^{-6} with a dose of 15.0 kGy to 30.0 kGy.

2.5 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:

2.5.1 The expiration date has been exceeded;

2.5.2 The product container is not labeled, or the label's information is obliterated or defaced;

2.5.3 The product has not been stored according to acceptable storage conditions mentioned under "Storage Requirements";

2.5.4 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, please notify IntegoGen, LLC immediately.

2.6 INSTRUCTIONS FOR USE

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

2.6.1.1 Utilizing sterile technique, peel open the outer peel pouch from the chevron end and present the inner pouch to the sterile field.

2.6.1.2 Carefully open the inner tear notch pouch and present the allograft to a sterile person.

2.6.1.3 Secure the graft and mesh with forceps, if utilizing with a trocar place the graft and mesh into the chamber for a localized implantation.

2.6.1.4 Remove one side of the mesh and place the allograft directly over the desired site.

2.6.1.5 Remove the second piece of mesh by carefully pulling the mesh away from the allograft.

NOTE: THE ALLOGRAFT MAY BECOME DIFFICULT TO HANDLE IF REMOVED FROM THE MESH PRIOR TO APPLICATION.

2.7 DO NOT IMPLANT MESH, REMOVE BOTH SIDES OF MESH PRIOR TO SURGICAL SITE CLOSURE.

2.8 TISSUE TRACKING INSTRUCTIONS

It is the responsibility of the end-user or 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 TTR card and return to IntegoGen, LLC.