STRATOGEN™
Flow

FOR SINGLE PATIENT USE ONLY

Tissue ID Number

(Place Sticker Here)

PRODUCT DESCRIPTION

STRATOGEN™ Flow is a chorion free human liquid allograft comprised of amnion and amniotic fluid components. It is provided cryopreserved in a vial. **STRATOGEN™ Flow** is intended for homologous use as a liquid wound covering.

STRATOGEN™ Flow is intended for use in one patient, on a single occasion only. Only qualified health professionals should implant **STRATOGEN™ Flow.** This product is processed aseptically.

"DONATED HUMAN TISSUE": Human tissue for transplantation shall not be offered, distributed, or dispensed for Veterinary Use.

STORAGE CONDITIONS

Specified storage is -80°C ± 15°C until use.

ONCE THAWED, DO NOT RE-FREEZE

INSTRUCTIONS FOR IMPLANTATION OF ALLOGRAFT

1) Remove carton from cold storage.
2) Remove the inner pouch containing the product using aseptic technique. The inner pouch is not sterile and should not be placed directly onto the sterile field.
3) Open the inner pouch and carefully remove the frozen vial containing the product using aseptic technique. Always use sterile gloves or sterile forceps when handling **STRATOGEN™ Flow**. The content of the vial itself is aseptic but not sterile, the vial should not be placed directly onto the sterile field.
4) Allow the vial contents to thaw at ambient temperature for approximately 3-5 minutes.
5) Gently agitate the unopened vial by inverting the vial 4-5 times.
6) Open the vial and withdraw the liquid from the vial using aseptic technique with an 18-gauge needle into a 3 or 5 mL syringe.
7) An equal amount of one of the following diluents, creating a 1:1 mixture with the allograft may be utilized:

    - 1% plain preservative-free lidocaine
    - 1% plain preservative-free Marcaine
    - Normal saline
    - Platelet rich plasma
    - Bone marrow aspirate
    - Patient's blood

8) Apply the product or product mixture using a 22-gauge or larger needle into and/or around the area of interest.
9) After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
10) Once the container seal has been compromised, the allograft shall either be transplanted, if appropriate, or discarded. Product many not be refrozen.

Note: A slight sulfur odor may be detected in the product and is normal. The odor does not affect the quality or safety of the product. The color of the allograft may range from clear to cloudy and pinkish and is normal.

DONOR SCREENING AND TESTING

Prior to processing, the donor's medical and social history were screened for conditions and disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures at Pinnacle Transplant Technologies, LLC (PTT). All policies and procedures for donor screening, serologic and microbiologic testing meet current Standards established by the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB).

Contraindications for allograft donation include but are not limited to presence of identified infectious disease, neurological degenerative disease, disease of unknown etiology, and exposure to toxic substances. Donor blood sample is taken prior to or at the time of tissue recovery and tested for relevant communicable disease agents in accordance with Federal Regulations.

Communicable disease testing 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 Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493, or that has equivalent requirements as determined by the Centers for Medicare and Medicaid Services. 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 PTT and are available to the end-user upon request, except as prohibited by law. Donor blood samples taken prior to or at the time of recovery were tested and found negative/nonreactive using FDA licensed tests for, at minimum:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis
- HTLV I/II: Human T-Cell Lymphotropic Virus
- WNV: West Nile Virus

Based on screening and testing results, this donated human tissue product has been deemed suitable for transplant by the Medical Director and Quality Assurance.

PROCESSING AND STERILITY

Donor tissue is recovered using safe recovery techniques and sterile equipment to minimize bioburden contamination. Allografts are procured via a network of qualified and trained recovery partners, using a stringent screening and recovery protocol, in a highly controlled processing environment, minimizing risk of disease transmission. All tissues are processed aseptically. Do not sterilize.

ADVERSE REACTIONS

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from application of **STRATOGEN™ Flow** include but are not limited to infection, bleeding, swelling, redness and injury to nerves and other soft tissues. Complications may also occur with allograft use, including but not limited to:

- Transmission of disease of unknown etiology
- Transmission of unknown infectious agents including but not limited to HIV, Hepatitis, syphilis and bacteria
- Graft-versus-host immune rejection or other allergic reactions

STRATOGEN™ Flow is provided in solution containing 5% v/v Dimethyl Sulfoxide (DMSO) as a cryopreservant. Caution should be exercised if the patient is known or suspected to be allergic or sensitive to DMSO.

Any adverse outcomes potentially related to product use must be promptly reported to ChoiceSpine at (865) 246-3333.

WARNINGS AND PRECAUTIONS

STRATOGEN™ Flow must not be transplanted under the following conditions:

- If mishandling has caused possible damage and/or contamination
- If the product is past the expiration date printed on the product carton
- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible and/or defaced
- If the allograft has not been stored according to the specifications set forth in this insert

Notify ChoiceSpine immediately at (865) 246-3333 if any of these conditions exist or are suspected.

HCT/P TRACKING

FDA 21 CFR 1271.290, Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained. Joint Commission standard QC.5.310.7 requires 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, a Tissue Tracking/Transplant Record (TTR) and pre-printed labels are provided with each product allograft. Record the patient information, the transplant facility name and address, allograft tissue information (using enclosed stickers) and comments regarding tissue use on the TTR. Return the completed TTR to PTT and retain a copy in the patient's medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification information and reason for discard shall be returned to PTT.

RETURN POLICY

ChoiceSpine is committed to honoring the altruism of tissue donation. In accordance with this commitment, ChoiceSpine may accept returned allografts based on stringent criteria. Please contact ChoiceSpine Customer Service for tissue return criteria and a required return authorization number.

ChoiceSpine Customer Service
865-243-3383
customerservice@chociespine.com

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that recipient records must be maintained for the purpose of tracing tissue post-transplantation. ChoiceSpine, LP will not be liable for any damages, whether direct or indirect, special, incidental or consequential resulting from improper use of this allograft. The instructions for use are specific, and ChoiceSpine waives all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.

LABEL AND PACKAGE SYMBOL DEFINITIONS

	Do not reuse; single patient use only
SN	Serial number (Tissue ID number)
	Expiration Date (MM/DD/YYYY)

DISTRIBUTED BY:

ChoiceSpine
400 Erin Drive
Knoxville, TN 37919

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:

Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd Building #2, Suite 116
Phoenix, AZ 85027