



## STRATOGEN™ Membrane

**FOR SINGLE PATIENT USE ONLY**

Tissue ID Number

Place Sticker Here

### PRODUCT DESCRIPTION

**STRATOGEN™ Membrane** is a resorbable, chorion free human amnion allograft derived from donated human birth tissue. **STRATOGEN™ Membrane** is supplied dry. These allografts are intended for homologous use as a wound covering.

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

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

### STORAGE CONDITIONS

Specified storage is 15-30°C (59-86°F) until use.

### INSTRUCTIONS FOR IMPLANTATION OF ALLOGRAFT

- 1) Remove carton from storage.
- 2) Open carton and remove the outer pouch, or tray, containing the product using aseptic technique. The outer pouch, or tray, is not sterile and should not be placed directly onto the sterile field.
- 3) Peel open the outer pouch, or tray, and remove the inner pouch, or tray, using aseptic technique. The inner pouch, or tray, is sterile and may be placed onto the sterile field.
- 4) Open the inner pouch, or tray, using aseptic technique and aseptically remove the package containing the **STRATOGEN™ Membrane** always use sterile gloves or sterile forceps when handling the allograft.
- 5) **STRATOGEN™ Membrane:**
  - Using sterile scissors, cut open the package.
  - Apply **STRATOGEN™ Membrane** to the area of interest.
  - **STRATOGEN™ Membrane** may be sutured, glued or placed into position without attachment.
  - **Membrane** larger than 4x8 cm is packaged with a white polymesh applied to one side of the membrane. After removing the membrane from the inner pouch, using sterile forceps, gently peel the polymesh away, removing it from the membrane. Do not leave the poly-mesh in place when implanting the membrane.
- 6) For large membranes, ensure all polymesh is removed from **STRATOGEN™ Membrane** and is not left in or on the patient.
- 7) 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.
- 8) Once container seal has been compromised, the allograft shall either be transplanted, if appropriate, or discarded.

### 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 the safest 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 and sterilized using Gamma irradiation. Do not re-sterilize.

### ADVERSE REACTIONS

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from application of **STRATOGEN™ Membrane** include but are not limited to infection, bleeding, swelling, redness, and injury to nerves and other soft tissue. Complications may 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

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

### WARNINGS AND PRECAUTIONS

**STRATOGEN™ Membrane** must not be transplanted under the following conditions:

- If mishandling has caused possible damage or contamination
- If the allograft is past its expiration date printed on the product carton
- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible or defaced

- If the allograft has not been stored according to 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, Tissue, 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 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 Sales Support  
865-243-3383  
salessupport@choicespine.com

**DISTRIBUTED BY:**  
ChoiceSpine LLC  
400 Erin Drive  
Knoxville, TN 37919

**PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:**  
Pinnacle Transplant Technologies  
1125 W. Pinnacle Peak Rd Building #1  
Phoenix, AZ 85027

**LABEL AND PACKAGE SYMBOL DEFINITIONS**

	Do not reuse; single patient use only
<b>SN</b>	Serial number (Tissue ID number)
<b>STERILE</b> <b>R</b>	Sterile by Gamma Irradiation
	Expiration Date (MM/DD/YYYY)

**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, LLC 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.