Induce Biologics NMP™
(Natural Matrix Proteins)

STERILE HUMAN ALLOGRAFT: INSTRUCTIONS FOR USE

Tissue ID Number:

Place Sticker Here

DESCRIPTION

This unit of allograft is derived from DONATED HUMAN TISSUES as defined in U.S. FDA 21 CFR 1271.3. Induce Biologics NMP™ (Natural Matrix Protein) is an allograft produced from donated human bone tissue and supplied in various formats. The allograft was prepared from a donor determined to be suitable for transplant based on the results of screening and testing. Recovery was performed using sterile surgical procedures and the controlled tissue processing environment is designed to ensure tissue allograft bio-implant quality and safety. A proprietary series of disinfection soaks is applied to the allograft to significantly reduce bioburden prior to terminal sterilization via gamma irradiation. This allograft was prepared from tissues which may have been treated with betadine, 70% isopropyl alcohol, Triton-X 100, hydrogen peroxide, hydrochloric acid, phosphate buffer solution, surfactant nonoxynol 9, and antibiotics (Polymyxin with Bacitracin) and may contain trace residuals of these agents. Caution should be exercised if the patient has a known sensitivity or allergy to any of these reagents.

STORAGE

Freeze-dried/lyophilized allografts can be stored at ambient temperature (15°C to 30°C) until expiration date shown on allograft label.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR USE

It is recommended to rehydrate allografts in whole blood, bone marrow aspirate (BMA), Lactated Ringers, normal saline, or other isotonic solution of the surgeon's preference.

1. Inspect for package integrity and expiration date prior to opening package. Do not use if package integrity has been compromised.
2. Open carton and remove pouch.
3. Using standard sterile technique, peel open pouches and hand over innermost pouch or container to sterile team member.
4. Open the jar or pouch and remove the allograft.
5. Place the allograft in a sterile basin (or equivalent) and add blood, BMA or isotonic solution of choice. Avoid excess fluid being left after rehydration for best results

Unit Size	Volume to add
XX-Small	0.2 to 0.5mL
X-Small	0.5 to 1.0mL
Small	1.0 to 2.5mL
Medium	3.0 to 5.0mL
Large	6.0 to 8.0mL
X-Large	10.0 to 15.0mL
Tall Strip	1.0 to 1.5mL
Long Strip	1.5 to 3.0mL
X Long Strip	2.0 to 4.0mL

6. Addition of antibiotics of surgeon's choice is optional.
7. NMP Fibers, Particulates and Strip (e.g., cortical, cancellous, cortico-cancellous, cortical particulates, etc.) should be rehydrated for approximately 5 to 20 minutes. Rehydration times may vary with the type and size and intended use of the allograft.
8. Allograft should be implanted as soon as possible after reconstitution. Tissue should be used within 6 hours of opening container if stored at ambient temperature, or within 24 hours if stored refrigerated with proper precautions to prevent contamination.
9. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.
10. Final determination of allograft preparation or rehydration should be made by physician prior to use.

TREATMENT WITH GAMMA IRRADIATION

Donor tissue is recovered using the aseptic recovery techniques and sterile equipment to minimize bioburden contamination. All allograft tissues are procured via a network of qualified and trained allograft recovery partners, one of the most stringent tissue donor screening and recovery protocols, tissue cleaning and validated sterilization processes, and a highly controlled processing environment. Subsequently, all allografts are terminally sterilized using gamma irradiation. The effects of low dose irradiation on the biological properties of human allograft tissues are not fully understood at this time.

INDICATIONS AND USAGE

This allograft may be used in situations where an autograft is appropriate, such as in spinal fusion procedures. It should be restricted to homologous use for the repair, replacement, or reconstruction of musculoskeletal defects.

- Intended for use in one patient, on a single occasion only
- Only qualified health care professionals (e.g., physicians, dentists, podiatrists, etc.) should transplant donated human tissue allografts.
- Allograft is provided sterile and may not be re-sterilized
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.
- Induce Biologics and Pinnacle Transplant Technologies assume no responsibility for the clinical use of this allograft tissue.
- Allograft tissues may transmit infectious disease agents. Any adverse outcomes that may be attributable to the implantation of this allograft tissue must be reported to Induce Biologics as soon as possible.

DONOR SCREENING AND TESTING

Only tissue donors from federally designated Organ Procurement Organizations (OPOs) or qualified tissue recovery partners are accepted. Pinnacle Transplant Technologies (PTT) is responsible for donor screening, tissue processing, and distribution services for our partners. Each tissue recovery partner is routinely audited to ensure their recovery practices meet current FDA regulations, American Association of Tissue Banks (AATB) standards and PTT's own stringent guidelines. Prior to release for transplantation, each tissue donor is subjected to a thorough eligibility evaluation including review of the donor's medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical assessment. Testing* includes, but is not limited to, the following:

- 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 testing may have been performed, if testing was performed results were found to be negative/nonreactive.

All required communicable disease tests are negative/nonreactive. 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 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). Names and addresses of testing laboratories, 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 through Induce Biologics, except such information that may infringe upon the confidentiality of the tissue donor information. Based on all the screening and testing results this donated human tissue product has been determined to be suitable for transplant by the PTT Medical Director and Quality Assurance.

PRECAUTIONS

Because of potential violations of sterility, this allograft must not be transplanted under the following conditions:

- The container in which the product is stored is damaged compromising packaging integrity
- The tissue outer packaging is damaged or missing
- The expiration date has been exceeded
- The allograft is not labeled, or the label's information is damaged, defaced or illegible
- The allograft has not been stored according to acceptable storage conditions outlined in this Package Insert
- If any of the allograft or package elements appear to be missing, damaged or tampered with
- If the product label or identifying barcode is severely damaged, illegible or missing.
- If any of the aforementioned conditions exist or are suspected, please notify Induce Biologics immediately for resolution.

CONTRAINDICATIONS, SIDE-EFFECTS AND HAZARDS

No contraindications are known to exist. Trace amounts of Triton X-100, isopropyl alcohol, hydrogen peroxide, hydrochloric acid, phosphate buffered saline, betadine, surfactant nonoxynol 9, and antibiotics (Polymyxin with Bacitracin) may be present and caution should be exercised if the patient is allergic to any of these agents. A relative contraindication would include the presence of infection in the host bed where the allograft is implanted. Limitations of allografts include slow and/or incomplete incorporation and/or resorption which may be due to the difference in histocompatibility factors between the donor and recipient. Bacterial infection at the site of implantation may occur. This complication may not be apparent for long periods of time (6-24 months) after transplantation. Transmissions of infectious disease may occur despite rigorous donor selection and testing.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Inherent uncertainties exist in medical and social histories and lab testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Transmission of disease of unknown etiology.
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.
- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to Induce Biologics immediately.

HCT/P TRACKING

Per 21 CFR 1271.290(e), documentation about the tissue disposition to enable tracking from the donor to the consignee or final disposition must 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 Transplant Record (TTR) and preprinted labels are provided with every allograft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the TTR. Return the completed TTR to Pinnacle Transplant Technologies 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 needs to be returned to Pinnacle Transplant Technologies.

RETURN POLICY

Induce Biologics is committed to honoring the altruism of tissue donation. In accordance with this commitment, Induce Biologics may accept returned allografts for credit or exchange (less a handling fee) based on stringent criteria. The specific criteria for returning allograft tissue products ensure that the allograft has not been compromised and is still suitable for implantation.

- Packaging must be intact and unopened.
- Packaging must not contain any additional marks or labels beyond those provided by Induce Biologics or PTT.
- Allograft must have been maintained according to the specified storage conditions.
- Responsibility for facilitating shipping arrangements must be assumed by the returning healthcare organization or healthcare provider.
- Returning facility must complete, sign and return an Induce Biologics Return Authorization Form. Contact Induce Biologics Customer Service department at 888-864-4906 or email CustomerService@InduceBiologics.com for a Return Material Authorization Number (RMA #) prior to shipment return. Credit cannot be issued if the Return Authorization Form has not been completed by the returning facility and received by Induce Biologics.

MARKETED BY:

Induce Biologics USA Inc.
1646 West Snow Ave.
Suite 188
Tampa, FL 33606 USA
888-864-4906
www.InduceBiologics.com

TISSUE PROCESSING, DISTRIBUTION, DONOR ELIGIBILITY DETERMINED BY:

Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd Building #1
Phoenix, AZ 85027

Canada CTO #: 100224

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. Induce Biologics and Pinnacle Transplant Technologies 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 Induce Biologics and Pinnacle Transplant Technologies waive all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.