Induce Biologics NMP™

Natural Matrix Protein Bone Graft

Induce Biologics InduceXT™

Natural Matrix Protein Bone Graft

Tissue Insert and Usage Form

www.inducebiologics.com

QC-605-F-104 Ver 2

Symbol Glossary

Consult Instructions For Use	Do Not Reuse
Use By Date	SN Serial Number
Manufacturer	Do Not Use If Package Is Damaged
LOT Batch Code	STERILE R Sterilized Using Irradiation
REF Catalogue Number	MR Magnetic Resonance Safe
Do Not Resterilize	Rx Only Prescription Use Only

All symbols may not appear in labeling

Description

Donated Human Tissue. Tissue grafts are recovered from deceased human donors. All tissue is recovered, processed, stored, and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB). Tissue is manufactured in a clean room environment, following rigorous quality assurance standards.Tissue labeled as STERILE R has been sterilized with gamma irradiation to a SAL of 10-6 (Sterility Assurance Level). The procedures executed to manufacture this graft including recovery, donor screening, testing, processing, packaging, labeling, storage, and distribution were performed in compliance with all applicable local, state, and federal regulations, including the U.S. Food and Drug Administration (FDA) regulations published at 21 CFR Part 1271, and the current edition of the American Association of Tissue Banks Standards for Tissue Banking. Induce Biologics USA Inc. has ascertained its NMP™ products meet the criteria for regulation solely under section 361 of FDA PHS Act and 21 CFR Part 1271 "as bone void fillers for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure."

Screening and Testing

Donor has been determined to be eligible by a Solvita Medical Director at 349 S. Main St. Dayton, OH 45402 based on the results of screening and testing. Screening includes a review of medical and social history, hospital records, infectious disease screening, autopsy report (if performed), andphysical exam. Donors are tested and found negative (acceptable) for anti-HIV 1/2, HBsAg, anti-HBc, anti-HCV, HIV NAT, HBV NAT, HCV NAT and syphilis. FDA licensed test kits are used when available. Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. Communicable disease testing has been performed by a laboratory registered with 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 determine by the Centers for Medicare and MedicaidServices (CMS).

Storage

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. Tissue may not be stored at liquid nitrogen (LN_2) vapor phase or LN_2 liquid temperatures.
FREEZE-DRIED tissue must be stored at ambient temperature or colder.
DO NOT FREEZE.

NMP™ Formats	
NMP™ Fibers	derived from human cortical bone
NMP™ FiberMatrix	Contains NMP™ Fibers and NMP™ Micro Particulates
NMP™ FiberMatrixC	Contains NMP™ Fibers, NMP™ Micro Particulates, and mineralized cancellous
NMP™ Particulates	derived from human cortical, cancellous or cortico-cancellous bone
NMP™ Cancellous	derived from trabecular bone
InduceXT™	Contains NMP™ Fibers, NMP™ Micro Particulates, and mineralized cancellous

Tissue Preparation

FREEZE-DRIED TISSUE

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 outer pouch and aseptically deliver inner package to the sterile field or sterile team member.
4. Open the inner pouch and remove the jar containing allograft tissue. Allograft can be rehydrated in jar or placed in a sterile basin. To rehydrate, cover allograft with whole blood, bone marrow aspirate (BMA), Lactated Ringers, normal saline, or other isotonic solution of choice. For best results, avoid excess fluid being left after rehydration.

Unit Size	Volume to add
Dental	0.1 to 0.2mL
XX-Small	0.2 to 0.5mL
X-Small	0.3 to 1.0mL
Small	1.0 to 2.0mL
Medium	3.0 to 4.0mL
Large	5.0 to 8.0mL
X-Large	8.0 to 12.0mL
InduceXT 1.5	0.5 to 1.0mL
InduceXT 3.0	1.0 to 2.5mL
InduceXT 10	5.0 to 8.0mL
Tall Strip	1.0 to 1.5mL
Long Strip	1.5 to 3.0mL
X Long Strip	2.0 to 4.0mL

5. Antibiotics of choice may be added.
6. Allograft should be reconstituted for approximately 5 to 20 minutes. Rehydration times may vary with the type and size and intended use of the allograft, with the cancellous strips typically taking more than 10 minutes.
7. 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 at 1 to 10°C. When storing rehydrated tissues use proper precautions to prevent contamination.
8. Once container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.
9. Final determination of allograft preparation or reconstitution should be made by the physician prior to use.

Indications and Usage

- Intended for use as a bone void filler for filling voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure.
- Intended for use in one patient, one a single occasion only.
- Only qualified health care professionals (e.g. physicians, dentists, podiatrists, etc.) should transplant donated human tissue allografts.
- Do not use if package integrity has been compromised. Once the user breaks the container seal, the tissue graft must be transplanted or discarded.
- Tissue may not be sterilized or re-sterilized.
- Human tissue for transplantation shall not be offered, distributed, or dispensed for Veterinary Use.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- Adverse outcomes potentially attributable to this tissue must be reported promptly to Induce Biologics USA at 888-864-4906 or email CustomerService@InduceBiologics.com.
- Tissue has been processed with Bacitracin, Polymyxin B, and/or Gentamicin and traces may remain. Demineralized tissue has also been processed with chemicals including HCl, alcohol, sodium phosphate (monobasic and dibasic) and traces may remain.

Induce Biologics NMP™
(Natural Matrix Protein)

Allograft Tissue Usage Form

FDA Regulations and Joint Commission Standards require tissue usage systems in all facilities using allograft tissue for transplantation. In order to comply with these requirements, please complete this form.

How to return this form:	
Email	tissueusage@solvita.org
Fax	937-222-2538
Mail	Solvita Attn: Tissue Usage 2900 College Dr. Kettering, OH 45420

Patient ID or Date of Birth: _____

Date of Surgery: _____

Surgical Procedure: _____

Completed By: _____ Date: _____

Comments: _____

One patient, one procedure per usage form. Place peel-off label for up to 3 allografts or write tissue ID# in the spaces provided.

Solvita does not consider the information requested on this form to be protected health information (PHI), as defined under the HIPAA regulations. Information considered to be PHI by the originator should not be released to Solvita .

Allograft Tissue ID#	Allograft Tissue ID#	Allograft Tissue ID#
Place Peel-Off Label Here	Place Peel-Off Label Here	Place Peel-Off Label Here

Tissue Insert Continued

Tissue Tracking

Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Complete the enclosed Allograft Tracking Form and return to Solvita . Federal Regulations (21 CFR 1271.290(b)) and Joint Commission Standards (TS.03.02.01, EP 7) require proper tracking of this tissue. It is the responsibility of the end-user to provide this information, which enables Solvita to maintain records for the purpose of tracing the tissue post-transplant.

Solvita is accredited by the American Association of Tissue Banks. Solvita is ISO 13485 certified. Health Canada Registration: 100076.

Solvita makes no claims concerning the biological or biomechanical properties of the provided tissue. Solvita disclaims all liability and responsibility for any misuse of tissue provided for clinical application.

Please contact Solvita at 937-222-0228 or 800-684-7783 should you require further information.

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