NEODERM ADM
ALLOGRAFT INSTRUCTION FOR USE

All tissues have been collected, processed, stored and distributed according to the Current Standards for Tissue Banking of the American Association of Tissue Banks (AATB), and Food and Drug Administration (FDA) Regulations and Ministry of Food and Drug Safety (MFDS) Regulations.

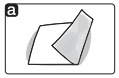
DESCRIPTION
Neoderm ADM is aseptically processed to remove epidermis and dermal cells to prevent immune responses triggered and then is freeze-dried to remove moisture while preserving biological components and 3-dimentional structure of the dermal matrix. Hence, **Neoderm ADM** provides a pathway for fibroblasts to flow into dermis layer and provides a scaffold for blood vessel and nerve generation.

INDICATIONS
Neoderm ADM is to be used for periodontal diseases.

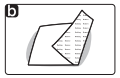
CONTRAINDICATIONS
Neoderm ADM is contraindicated for use in any patient who is sensitive to any of the antibiotics(Penicillin, Streptomycin, Gentamycin, Amphotercin-B). Without any prescription by your surgeon, **Neoderm ADM** shall not be used in bacteria infected area or infected area surrounding the surgical area.

INSTRUCTION FOR USE
Rehydration Tips
- Warm saline solution(37°C) may reduce the time required for rehydration. Nevertheless, do not heat saline above 37°C.
- When rehydrating multiple pieces, ensure the pieces are not overlapping or clumping together as this may delay the process. Use multiple dishes, if necessary.
- **Neoderm ADM** fully submerged by weighing it down, e.g., with sterile forceps.
- Using a sterile gloved hand or forceps, remove and discard the paper backing once it separates from the tissue.
- **Neoderm ADM** is fully rehydrated, it is soft and pliable throughout.
- **Neoderm ADM** will appear to be of uneven thickness and have a mottled appearance if it is not fully rehydrated.
- Once **Neoderm ADM** is removed from the packaging, it should be rehydrated within 24 hours and can be stored up to 4 hours prior to use.

Orientation



a) Procedure for determining orientation with blood test
The dermal side absorbs blood. The basement membrane side repels blood. When patient's blood is added to **Neoderm ADM**, the dermal side will appear red.



b) Procedure for determining orientation with paper backing
Dermal side has paper backing attached while basement membrane does not. This dermal side absorbs blood and should be placed onto the wound.

Periodontal Use (Gingival augmentation, Root coverage, etc)

1. Rehydration: Submerge the **Neoderm ADM** in saline for 10 minutes.
2. After 10 minutes, peel off the paper backing from the dermal side of **Neoderm ADM** using forceps.
3. Apply the dermal side of **Neoderm ADM** against the most vascular tissue onto the wound, complying with Procedure for determining orientation with blood test.

PACKAGING AND LABELING
Neoderm ADM has a backing paper attached. The inner pouch is the primary packaging, secondary packaging is a tyvek pouch, and the outer pouch, 3rd packaging, is an aluminum pouch. Sterility is maintained until the seal on the tyvek pouch is opened.

The packaged **Neoderm ADM** is supplied in an external paper box.

STORAGE
Neoderm ADM should be stored at room temperature in a clean, dry place. Do not expose to extreme heat. Do not refrigerate. It is the responsibility of the tissue distributing service and user to maintain the product under appropriate conditions prior to use. Product returns should be handled through your distributor.

STERILIZATION
Neoderm ADM is sterilized with Ethylene oxide gas (EO gas) after processing and packaging. The effectiveness of the sterilization procedure is verified to decrease the contamination level of bacteria and fungi. An indicator is attached to the product to verify sterilization. The indicator changes from brown to green after sterilization, and the phrase 'GREEN IS EO EXPOSED' is clearly visible inside. **DO NOT RE-STERILIZE.**

WARNINGS
- As biological products, the tissue has the potential to transmit infectious agents in spite of processing treatments, donor screening, tissue selection and laboratory tests.
- DO NOT use if label has been defaced or the packaging is not intact and it should be reported back to your distributor. (No responsibility is assumed for consequential damage of packaging by careless handling by users)
- DO NOT use after expiration date indicated on the label.
- All preparation should be performed using aseptic technique.
- Care must be taken to prevent contamination and discard any contaminated products.

PRECAUTIONS
- This product is for single use only.
- Do not use if any possibility of adverse events are present.
- Restricted to use by a licensed clinician.
- Adverse outcomes potentially attributable to the product must be promptly reported to your distributor.
- Once the inner pouch has been opened, the tissue must either be transplanted, if applicable, or discarded.
- Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implanting **Neoderm ADM** as such conditions may compromise successful implantation.
- Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.
- **Neoderm ADM** has a distinct basement membrane and dermal surface. (See ORIENTATION.)
- Do not bend **Neoderm ADM** before rehydration.
- Normal rehydration of **Neoderm ADM** is usually accomplished in 10 minutes.
- If any hair is visible, remove before implantation.
- **Neoderm ADM** may be aseptically trimmed to required dimensions, if necessary.
- In case of 1X1 size of **Neoderm ADM** Implant, it does not have the Paper backing.

DONOR ELIGIBILITY
Donor eligibility(screening and testing) is performed in accordance with AATB standards, FDA regulations and MFDS regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation. Donor eligibility has been determined by HansBiomed Medical Director.

SEROLOGICAL TESTING
The following required testing was performed and found to be negative or non-reactive. Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I & II (HTLV I & II), may have been performed at the time of donor screening, and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed can be provided upon request. Serological testing is performed using FDA-licensed test kit 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 42CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).
- Antibodies to the human immunodeficiency virus, type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Nucleic acid test (NAT) far the hepatitis B virus (HBV)
- Total antibodies to hepatitis B core antigen (anti-HBc-total, meaning IgG and IgM)
- Antibodies to the hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HCV
- Syphilis (a non-treponemal or treponemal-specific assay may be performed.)

MICROBIOLOGICAL TESTING
Tissue is subjected to microbiological testing at recovery and in the course of processing, and must be free of specific aerobic / anaerobic bacteria and fungi contaminants whose presence would preclude tissue processing or transplantation.

PATIENT RECORD AND TRACING
Product recipient records must be maintained by the physician, transplant facility or hospital for the purpose of tracing tissue post-implantation. A Traceability record and peel-off chart labels have been included in the packaging of this product. This record must be completed at the time of the surgical procedure. Please record the name and address of the transplant facility, physician name, allograft tissue information (use a chart label), and comments on use of the product. The original form or copy must be sent back to your distributor when completed and the rest should be retained by the transplant facility or physician for future reference. If the entire tissue product is discarded, filled out the reason and method for discarding the product and this record must be sent back to your distributor.

AVAILABILITY
0.9 – 1.6 mm thickness:
10x20 mm, 10x40 mm, 20x20 mm & 20x40 mm

LABELING SYMBOLS:
Symbols may be used on some package labeling for easy identification.


Symbol for «Do Not Ruse»


Symbol for «See Instructions for Use»


Symbol for «Temperature Limitation»

Symbol for «Method of Sterilization using ethylene oxide»

MEMBRANES

NEODERM ADM

Acellular Human Dermis Membrane

Distributed by:
Citagenix Inc.

Laval, Quebec, Canada H7T 2H6

Tel.: 1 877-243-6724 · +1 450 688-8699
www.citagenix.com · info@citagenix.com

Health Canada CTO Registration: 100084

Manufacturer:

HansBiomed Corp.
64, Yuseong-Daero 1628beon-gil
Yuseong-gu, Daejeon, Republic of Korea (34054)
Tel. 82-42-478-9001 | Fax 82-42-478-9006

Health Canada CTO Registration: 100201

CITAGENIX
The Regen Company

CB210-2008R0
GP-20022.0 (2020/07)

CITAGENIX
The Regen Company

www.citagenix.com · info@citagenix.com

MEMBRANES

NEODERM ADM

Acellular Human Dermis Membrane

ALLOGRAFT TRACKING FORM

In order to comply with these requirements, please complete ALL fields on this form and return to Citagenix by email at info@citagenix.com or via fax at 1 888-258-0760 (North America) or +1 450-688-1977.

FDA Regulations and Joint Commission Standards require tissue tracking systems in all hospitals, clinics and doctor's offices using allografts for transplantation.

Patient ID:
(DO NOT PROVIDE PATIENT NAME) _____

Hospital/Clinic/Doctor's Office: _____

City: _____ State/Prov.: _____ Zip/Postal Code _____

Physician: _____ Surgery Date: _____

Surgical Procedure: _____

Completed by: _____ Date: _____

Comments: _____

_____

Place peel-off label for up to 4 allografts or write tissue ID# in the spaces provided.
One patient, one procedure per tracking form.
Retain this completed document with the patient's file.

Allograft Tissue ID#

_____

OR Place Peel-Off Label Here

CB211-2008R0
GP-20024.0 (2020/07)