Nevos® Sponge

SPINAL elements

STERILE R
Sterilized by Irradiation

DONATED HUMAN TISSUE

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant).

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Nevos Sponge is a demineralized freeze-dried allograft. The allograft was aseptically recovered with consent from qualified donors. Nevos Sponge has been processed using aseptic techniques, incubated in an antibiotic solution (Gentamicin and either Vancomycin or Bacitracin), and lyophilized. The allograft is aseptically packaged, either in a one tear pouch and one peel pouch configuration or in a one barrier bag and two peel pouches configuration and secured in a box to ensure allograft integrity. The allograft has been sterilized using electron beam radiation.

INTENDED USE
Nevos Sponge is intended for use as a scaffolding matrix.

CONTRAINDICATIONS
Nevos Sponge is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin, hydrochloric acid or hydrogen peroxide.

DONOR ELIGIBILITY
Nevos Sponge was recovered from a qualified donor and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. The donor has been screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing have been reviewed by the Medical Director (or licensed physician designee) of Vivex Biologies, Inc. and the donor has been deemed suitable for transplantation.

Communicable disease testing was performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests were found to be nonreactive or negative:

- Human Immunodeficiency Virus (HIV)
  - HIV-1/2 Antibodies (HIV-1/2-Ab)
  - Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)

- Hepatitis B Virus (HBV)
  - HBV Surface Antigen (HBsAg)
  - HBV Core Antibody (IgG & IgM) (HBeAb)
  - Nucleic Acid Test for HBV DNA (if performed) (HBV NAT)

- Hepatitis C Virus (HCV)
  - HCV Antibody (HCVAb)
  - Nucleic Acid Test for HCV RNA (HCV NAT)

- Human T Cell Lymphotrophic Virus I/II*
  - HTLV-I/II (Antibody HTLV-I/II-Ab)

- Syphilis**
  - Rapid Plasma Reagin (RPR) Screen
  - T. Pallidum IgG

* A donor with a reactive result for the HTLV-I/II Antibody test is suitable for use only when the result from a confirmatory assay is nonreactive.

** A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is suitable for use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

- Cytomegalovirus
- CMV Ab (IgG & IgM)

- Epstein Barr Virus
- EBV Ab (IgG & IgM)

- Toxoplasma gondii
- Toxoplasma Ab (IgG & IgM)

- Trypanosoma cruzi
- T. cruzi Ab (IgG & IgM)

WARNINGS
The donor of Nevos Sponge has been screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). Nevos Sponge was processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY.

DO NOT STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide or other chemical sterilants may render the allograft unfit for use.

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PRECAUTIONS

Nevos Sponge was processed and packaged using aseptic techniques and must be handled in an aseptic manner to prevent contamination.

ADVERSE EVENTS

Allogenic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE

Nevos Sponge must be stored at ambient temperature (2°C to 30°C). It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

ALLOGRAFT PREPARATION

THE CHEVRON PEEL POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

ONCE THE ALLOGRAFT CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be reconstituted and transplanted within 24 hours, if appropriate, or otherwise discarded.

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

THE INNER POUCH IS CONSIDERED STERILE.

Step 1: Remove the pouch containing the allograft from the box packaging.
Step 2: Utilizing aseptic technique, peel open the peel pouch from the chevron end and present the inner pouch to the operative field.
Step 3: Locate the tear notch on the pouch, and tear open. Place the allograft into a sterile basin.
Step 4: Pour sterile solution of choice into the basin until the allograft is completely immersed in solution. Antibiotics of the physician’s preference may be added to the solution. After the prescribed reconstitution time, the allograft is ready for use.

In the event that the allograft is not implanted within 2 hours, place the allograft into a sterile basin containing the solution of choice and cover and seal the basin with a sterile Vi-Drape or similar adhesive drape and double wrap the sealed basin with sterile waterproof wrappers. Store in the refrigerator at 1 to 10°C for no longer than 24 hours.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide Vivex Biologics, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to Vivex Biologics, Inc., scan and e-mail to tur.s@vivex.com, or fax to (888) 630-4321.

ADVERSE OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to the Nevos Sponge must be promptly reported to Vivex Biologics, Inc. at (888) 684-7783. Any other complaints must be promptly reported to Spinal Elements at (760) 607-0121.

RETURNED GOODS POLICY

Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from Spinal Elements prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

Distributed By:
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