Human Allograft Structural Cervical Spacer

MANUFACTURED AND DISTRIBUTED BY:
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Caution: U.S. Federal Law restricts this product to sale by or on the order of a physician or hospital.

RADIATION STERILIZED


SINGLE USE ONLY

DO NOT RESTERILIZE

INSTRUCTIONS FOR USE

IMPORTANT PRODUCT INFORMATION
Please read before use

ENGLISH

These instructions-for-use refer specifically to Human Allograft Structural Cervical Spacer

Donated Human Tissue. Tissue recovery was performed using aseptic techniques. Once processed, the tissue is sterilized by gamma irradiation.

Description
The human allograft structural cervical spacer is processed human bone tissue that has been precision milled from cortical bone. Depending on the design, a cancellous plug may have been inserted in the center of the cervical spacer. The allograft provides a scaffold around which new bone can grow.

Intended Use
The cervical spacer is intended for use in load-bearing spinal fusion application.

Contraindications
Do not use the graft in the presence of any contraindication. Other conditions representing relative contraindication include:
- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- pregnancy
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function.

Warnings
The graft is sterilized by gamma irradiation. Content of package is STERILE unless opened or damaged. Contact distributor and manufacturer and do not use if packaging is damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
It is recommended to use the graft within one hour of opening the package.
Dosage is for SINGLE USE ONLY. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the graft.
While every effort has been made to ensure the quality of this allograft, Berkeley Advanced Biomaterials makes no claims concerning its biological or biomechanical properties. As with any allograft, despite strict screening/testing procedures, this allograft has the potential to transmit infectious agents to the recipient.
This allograft may contain trace amounts of processing/cleaning agents such as iodine, ethanol, glycerol, or hydrogen peroxide.

Precautions
It is important to ensure that the area where the graft have been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Attempts should not be made to modify the size of the graft or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of the graft on patients with the following conditions is unknown:
- documented renal disease
- pregnancy and nursing
- long-term infection
- metabolic bone disease
- radiation bone therapy
- cardiovascular disease precluding elective surgery.

The implant must be secured to prevent potential migration. The implants should only be used in surgical procedures where bone grafts are adequately contained.

Adverse Reactions
A graft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). It is possible for a host site to become infected. The graft may also lead to a deformity of the bone at the site. The graft may cause an inflammatory response. While efforts are made to ensure the safety of the tissue, current technologies may not preclude the transmission of disease, including hepatitis and HIV.

Reporting Adverse Reactions
The surgeon is responsible for reporting all adverse reactions potentially attributed to the allograft within 15 days of the occurrence. In such a case, contact Berkeley Advanced Biomaterials at +1.510.883.0500.

Donor Selection
All donor tissue is recovered, processed and distributed according to standards established by the American Association of Tissue Banks. Donor screening exclusion criteria is performed via donor physical inspection, interview with a person who knew the donor, review of available medical records, and a review of autopsy findings (when applicable). Individuals considered to be at high risk for AIDS or hepatitis as defined by the FDA and CDC are excluded from donorship. Using FDA licensed, approved, or cleared test kits in a laboratory registered with the FDA and certified under CLIA or equivalent requirements, a serum sample from the donor has passed a hemodilution review and tested non-reactive for the following:
- Human immunodeficiency virus antibody (anti-HIV1 and anti-HIV2)
- Nucleic acid test (NAT) for HIV-1
- Hepatitis B surface antigen (HBsAg)
- Total antibodies to Hepatitis B core antigen (anti-HBc-total, IgG/IgM)
- Antibodies to the Hepatitis C virus (anti-HCV)
- Nucleic acid test (NAT) for HBV (effective Dec. 2016) and HCV
- Rapid plasma reagin (RPR) or serological tests for syphilis (STS).

Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation.
Donor eligibility was performed by Alamo Tissue Service (ATS), 5844 Rocky Point, San Antonio, TX; or Community Tissue Services (CTS), 349 S. Main St., Dayton, OH.

Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

Surgical Procedure
All procedures should be performed in the operative room under aseptic conditions. Open both outer and inner pouches. Open the container to dispense the graft. Follow accepted procedures for grafting with fixation. When excess fluid is present in the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. Bone marrow aspirate can be added to the graft. The marrow aspirate is obtained by the standard bone marrow collection techniques, and the donor sites include iliac crest, fracture, or other sites. Exercise care not to collect blood. If marrow from the fracture site is used, it is important that the marrow has not been contaminated. If the material is not positioned satisfactorily, remove the implant and start over with a new dose of the graft.

Preparation For Use
Grafts that have been freeze-dried may be rehydrated with sterile saline, blood, bone marrow, or other specific blood components until required consistency and handling are achieved as preferred by physician.

Storage Conditions

Store at ambient temperature in a secure and dry environment. Do not expose product to temperatures lower than 0°C (32°F) and greater than 50˚C (122˚F); product may lose functionality if exposed to temperatures outside this range for extended time periods. 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.

Shelf Life and Disposal

The expiration date is printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. Packaging materials are recyclable. The graft comes sterile. Residual materials may be dispensed with other medical waste.

Tissue Tracing

It is the responsibility of the user surgeon to complete recipient records for the purpose of tracing tissue post transplant. Complete the enclosed *ALLOGRAFT USAGE REPORT* in detail and return as indicated.

Other Information

The implants are packed individually in containers that are sealed in translucent double pouches within an additional box for transport and storage. Included with this instructions-for-use leaflet are supplementary labels for patient documentation and an allograft usage report for traceability.

Note: Responsibility for proper selection of patients, for adequate training, for experience in the choice and placement of the graft, and for the choice of post-operative follow-up procedures rests entirely with the physician. In case of complaint or for further information on the product and its uses, please contact Berkeley Advanced Biomaterials at the address printed on this leaflet.