

Spinal Allograft Spacers in Q-PACK®

INSTRUCTIONS FOR USE READ BEFORE USING

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
Not Terminally Sterilized. Do Not Sterilize.

THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

Description and Indication for Use

Spinal Allograft Spacers in Q-PACK are supplied in a variety of configurations designed for surgical use by qualified health care professionals (e.g., physicians). Processed human bone has been used in a variety of surgical applications and in combination with prosthetic devices. Spinal Allograft Spacers in Q-PACK are packaged in a ready-to-use configuration and can be used for immediate use upon package opening. The amount and size of allograft necessary for a surgical procedure is based upon an individual surgeon's preference and the size and type of implant required. The description of the tissue, serial number, expiration date, product code, size and/or amount, and additional information are printed on the allograft container labeling.

Cautions and Warnings

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. Do not use portions of an allograft from one container on multiple patients, Do not sterilize. Trace amounts of Gentamicin, Primaxin and Amphotericin B antibiotics may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solutions may remain. Caution should be exercised if the patient is allergic to any of these substances.

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

The allograft must not be used under any of the following conditions:

- If the container seal is damaged, or not intact.
- If the container has any physical damage.
- If the container label or identifying bar code is severely damaged, not readable or is missing.
- If the container has been allowed to freeze or has otherwise been damaged.
- If the expiration date shown on the container label has passed.

Use caution in the following circumstances:

- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal insufficiency
- History of, or active Pott's disease
- Sepsis, or infection in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

Precautions

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur. ***Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.***

Adverse Effects

Possible adverse effects of using human tissues include but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Immune response of non-infectious cause, including fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of the newly formed bone
- Disease transmission or undesirable immune response

Processing

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment.

- Tissue that is aseptically processed with no exposure to gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions" and "Passes USP <71> Sterility Tests".
- Tissue that is aseptically processed and treated with low-dose gamma radiation is labeled as follows: "Tissue is recovered and processed under aseptic conditions. Treated with gamma radiation" and "Passes USP<71> Sterility Tests".

Donor Scening and Testing

Prior to donation, the donor's medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

Donor blood samples taken at the time of recovery were tested by a facility that is CIA certified and registered with the FDA. The donor blood samples were tested for:

- Hepatitis B virus (HBV) surface antigen
- HBV core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV -1 NAT
- HCV NAT
- HBV NAT

All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation. The infectious disease test results, authorization, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, including laboratory testing, meet or exceed current standards established by the American Association of Tissue Banks.

Preoperative Preparation

Preparation of the host bed is important for allograft incorporation. The host bed should be free of infection prior to grafting.

Storage

Store containers of the Spinal Allograft Spacers in -PAC at ambient temperature. In order to maintain integrity of the seals, do not freeze. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant. If storage conditions or container seals have been compromised before intended use, the tissue should be discarded.

Instructions for Use

Standard accepted operative practices should be followed.

Spinal Allograft Spacers in Q-PACK should be maintained in an aseptic environment at all times to prevent the possibility of contamination.

Note: This allograft has been aseptically packaged into sterilized packaging components. To make ready for use, open the package using aseptic/sterile techniques.

1. Remove double tray configuration from the carton.
2. Peel back lid of outer tray.
3. Pass inner tray to sterile field.
4. Grasp the inner tray firmly and peel back lid of inner tray. Remove plastic retainer with the tissue.
5. When ready to implant, remove tissue from the retainer.

Note: Spinal Allograft Spacers in Q-PACK are hydrated and ready for immediate use out of the package. Per surgeon's preference, tissue may be rinsed in sterile saline solution prior to implantation.

Note: The inner tray alone provides a sterile and moisture barrier. The tissue is hydrated and therefore droplets of liquid or condensation may be present in the inner tray or retainer. This is considered normal and does not affect the tissue quality or safety. Once the inner tray containing the Spinal Allograft Spacers in -PAC has been opened, the implant should be used as soon as possible. Once removed from the tray, the tissue should be implanted within 20 minutes otherwise, place the tissue in a sterile saline bath for at least 5 minutes before implantation.

Patient Record

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. A TissueTrace Tracking Form and peel-off stickers have been included with each package of tissue. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively, a system for electronic submission may be used and sent to MTF@Sceris.com. **Within the United States:** Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. **Outside of the United States:** Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

Reference: Current MTF policies and procedures are in compliance with current FDA, AATB and other regulatory requirements.

Definitions of label Symbols



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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

**CAUTION: Restricted to use by a physician, dentist and/or podiatrist.
Please note: Human tissue for transplantation shall not be offered,
distributed or dispensed for Veterinary Use.**

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