Threaded Facet Dowel Instructions for Use

READ BEFORE USING
DONATED HUMAN TISSUE

THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR WHOSE LEGAL NEXT-OF-KIN HAS GIVEN PERMISSION FOR THE BONE AND CONNECTIVE TISSUE TO BE DONATED. 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

MUSCULOSKELETAL TRANSPLANT FOUNDATION (MTF) tissues are supplied for surgical use by qualified healthcare professionals (e.g., physicians, dentists, and/or podiatrists). Processed human bone has been used in a variety of surgical applications and in combination with prosthetic devices.

The Threaded Facet Dowel (TFD) is a surface demineralized monolithic piece of machined cortical allograft bone that is used to fill bony voids such as within the facet joints. The Threaded Facet Dowel is available in individually packed freeze-dried forms. Each unit is 13.5 mm in length and is available in 2 different outside diameters (5.5mm and 6.5mm). The size of allograft necessary for a surgical procedure is based upon an individual surgeon’s preference and the size and type of defect.

Precautions

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF. Transmission of infectious diseases such as HIV or Hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing. 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.

Contraindications

Tissues distributed by MTF are contraindicated in the following circumstances:
- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Port’s disease
- Osteomyelitis at the surgical site
- Septics in or around the surgical site
- Incomplete skull growth
- Inability to cooperate with and/or comprehend post-operative instructions

Adverse Effects

Possible adverse effects of using human tissues include but are not limited to:
- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response
- Neurological injury
- Vascular or visceral injury

Aseptically Processed

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. The allografts are not terminally sterilized. Processing and Packaging are performed under controlled aseptic conditions. Each allograft is aseptically processed and the finished product passed USP <71> Sterility Tests. Some tissues are treated with gamma radiation. For these tissues the container label will specify, “Treated with Gamma Radiation”.

Do not use portions of an allograft from one container on multiple patients. Dispose of excess or unused tissue in accordance with recognized procedures for discarding regulated medical waste material.

Note: Do not rehydrate the Threaded Facet Dowel prior to use. Rehydration of the freeze-dried Threaded Facet Dowel could create a potential interference between the driver and graft.

Cautions

Do not sterilize. Trace amounts of Gentamicin, Primasin, and Amphotericin B antibiotics may be present. Trace amounts of Polysorbate-80, Ethanol, Methanol, Isopropanol, Polyoxyethylene (10) Phenol Ether and Hydrogen Peroxide may be present. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No beta-lactam antibiotics are used during the processing of tissue.

Donor Screening and Testing

Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by MTF’s Medical Board of Trustees. Donor blood samples taken at the time of recovery were tested by a CLIA licensed facility for:
- Hepatitis B surface antigen
- HIV-1/2 antibody
- Hepatitis C antibody
- Syphilis

In addition to the testing listed above, HIV-1 and HCV Nucleic Acid Amplification Testing (NAT) were performed. The results of all serological testing were negative. This allograft tissue has been determined to be suitable for transplantation.

Donor tissue disease test results, consent, 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 1270 and Part 1271 Human Tissue Intended for Transplantation, as applicable. All procedures for donor screening, serologic and microbiologic 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. Whenever possible, the allograft should be securely fixed to the host bone to aid in incorporation and to prevent displacement of the graft.

Storage

Store the Threaded Facet Dowel at ambient temperature. No refrigeration or freezing is required. 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.

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Preparation For Use

The Threaded Facet Dowel should be maintained in an aseptic environment at all times to prevent the possibility of contamination.

Tissues should be implanted or discarded within 24 hours of opening the final tissue container provided the allograft tissue is maintained in an aseptic environment.

Note: Do not rehydrate the Threaded Facet Dowel prior to use. Rehydration of the freeze-dried Threaded Facet Dowel could create a potential interference between the driver and graft.
Instructions for Use

Open packaging using the following procedure:
Note: The inner and outer tray components are sterilized. Use standard aseptic/sterile technique to open the package and make ready for use.

1. Peel back lid of outer tray. NOTE: Once the outer tray is opened, allograft should be implanted within 24 hours. The inner tray alone provides a sterile barrier but is not intended for storage of allograft, as it may not provide an adequate moisture barrier.
2. Grasp the pull-tab on the lid of the inner tray to remove it from the outer tray and pass it into the sterile field.
3. Peel back lid of inner tray. Transfer tissues to a sterile container for reconstitution.

Patient Record

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post transplantation. This will allow MTF to facilitate the investigation of actual or suspected transmission of communicable disease and take appropriate and timely corrective action. A TissueTrace® Tracking Form and peel off stickers have been included with each package of tissue. The serial number and the tissue description have been preprinted on the peel off stickers. 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. **Within the United States**: Once completed, the bottom page of the form should be returned to MTF using the self-addressed, postage paid mailer. Copies of this information should be retained by the hospital 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

1. Current Standards for Tissue Banking, AATB, McLean, VA.

CAUTION: Restricted to use by a physician, dentist and/or podiatrist

Patent Pending:
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CTO: 100024