PI -82, Rev 2, 08/2016
RM – 1540

Allograft Bone Plug INSTRUCTIONS FOR USE
READ BEFORE USING
DONATED HUMAN TISSUE

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

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 Allograft Bone Plug is a monolithic piece of machined human cortical bone that has been demineralized so that the thinnest proximal section and the thickest distal section become conformable/deformable. The end of the distal section is closed. At the proximal end is a tab that serves as a visual aid during placement.

Following adequate rehydration of the graft, the proximal portion of the Allograft Bone Plug becomes conformable/deformable thereby allowing the plugs to conform/deform to and fill cavities. Allograft Bone Plugs are prepared in a freeze-dried state and must be rehydrated prior to usage.

Note: The freeze-dried Allograft Bone Plug may look bent, crooked, small, and/or have white coloring on the inside or outside walls. This is not a defect. The implant will be restored to normal condition after sufficient rehydration.

The Allograft Bone Plug is available in individually packed freeze-dried forms. Each unit is 40 mm in length and is available in 3 different outside diameters (5mm, 6mm and 7mm). Distal slots along the sides of the Allograft Bone Plug allow for the expansion of the implant when used with an autograft/allograft (e.g. bone pin/bone dowel). The size of allograft necessary for a surgical procedure is based upon an individual surgeon's preference and the size and type of defect. The description of the tissue, serial number, expiration date, product code, size, and additional information are printed on the allograft container label.

Cautions

ALL ALLOGRAFTS ARE FOR SINGLE PATIENT USE ONLY. Do not use portions of an allograft from one container on multiple patients. The allografts are not terminally sterilized. 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 in accordance with recognized procedures for discarding regulated medical waste materials.

This 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 freeze-dried allograft container has been allowed to freeze or has otherwise been damaged.
- If the allograft has not been rehydrated to restore flexibility.
- If the outer tray has been opened for more than 24 hours.
- If the expiration date shown on the container label has passed.

Use caution in the following circumstances:

- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypocalcaemia
- Renal-compromised patients
- History of or active Pott's disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Incomplete skull growth
- 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. 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.**

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

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 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 the MTF Medical Board of Trustees.

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

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

All infectious disease tests were negative. This allograft tissue has been determined to be suitable for transplantation.

The infectious 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 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, 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.

Storage

Store containers of the Allograft Bone Plug at ambient temperature. In order to maintain integrity of seal, 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 seal have been compromised before intended use, the tissue should be discarded.

Instructions for Use:

Open tissues packaged in nested plastic trays 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.

Reconstitution/Rehydration Procedure

The Allograft Bone Plug must be rehydrated in normal saline prior to use. To obtain the best clinical results and prevent graft failure, the procedure and recommendations listed below should be followed.

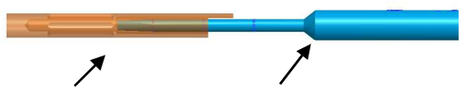
Preparation For Use

Recommended instruction for handling and rehydrating of the Allograft Bone Plug:

- The Allograft Bone Plug should be maintained in an aseptic environment at all times to prevent the possibility of contamination.
- The Allograft Bone Plug must be submerged in a bath of normal sterile saline prior to use.
- Antibiotics may be used with the irrigant according to surgeon preference. Patient sensitivity to antibiotics used to rehydrate allograft tissues should be checked prior to use. Concentration of antibiotic solutions should be less than normally indicated for I.V. administration.
- The table below shows the rehydration time in saline

Saline	Saline Temperature		Approximate Rehydration Time (Minutes)	
	Celsius	Fahrenheit	Ready for Use	Fully Rehydrated
Warm	38-43	100-110	5-6	≥ 10
Cold	16-21	60-70	10-12	≥ 15

- The Allograft Bone Plug is considered sufficiently rehydrated if:
  - the tab located at the proximal end can be bent and
  - the appropriate size instrument can be inserted into the Allograft Bone Plug until the instrument tip touches the step inside.



Step in the Plug

General Surgical Dilator and Bone Tamp

- Other than for rehydration testing as directed above, Allograft Bone Plug should not be folded or twisted prior to implantation.
- Allograft Bone Plug should be implanted within 24 hours of opening the outer tray provided the allograft tissue is maintained in an aseptic environment.

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 and sent to MTFTTC@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. All recovery, processing and distribution costs were paid for by MTF, a non-profit organization. ***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

See IFU

Do Not Reuse

Processed and distributed by:

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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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