PI -172, Rev 3, 02/2024
RM –2526

READ BEFORE USING

Virtuos™
Lyograft

DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.

Aseptically Processed. Passes USP <71> Sterility Tests. Virtuos Is 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 INDICTIONS FOR USE

Virtuos™ Lyograft is a shelf-stable cellular bone allograft containing cancellous bone and demineralized cortical bone that has been lyophilized after processing. It is designed for surgical use by qualified healthcare professionals. Processed human bone has been used in a variety of surgical applications and in combination with prosthetic devices.

Virtuos Lyograft is an allograft intended for the treatment of musculoskeletal defects. 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 defect. The description of the tissue, serial number, expiration date, product code, size and/or amount, and additional information are printed on the allograft container label.

CAUTIONS AND WARNINGS FOR USE

Do not sterilize. The tissue is exposed to processing solutions that may contain detergents and alcohol and is processed in the presence of a proprietary preservative solution containing sugars and antioxidants. Trace amounts of processing solutions may remain. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No antibiotics were used in the manufacturing process.

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 expiration date shown on the container label has passed.
- If not used within 2 hours after rehydration or has been stored at a temperature not recommended.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening & Testing Section). 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.

PRECAUTIONS

Caution should be used for the following conditions:

- Uncontrolled diabetes
- Hypercalcemia
- Local or systemic infection
- 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)
- 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.

***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.**

ALLOGRAFT INFORMATION

Processing and packaging are performed under controlled aseptic conditions in an ISO Class 4 environment. During tissue processing and packaging this allograft was tested and showed no evidence of microbial growth, complying with the requirements of USP <71>Sterility Tests. **Do not subject allograft to additional sterilization procedures.**

INSTRUCTIONS FOR USE

Allograft tissue should be maintained in an aseptic environment at all times to prevent the possibility of contamination. The inner jar and its outer tray are sterilized if handling medium, large, and extra large units. The inner foil pouch and its outer Tyvek pouch are sterilized if handling small units. Use standard aseptic/sterile technique to open the package and make ready for use. Inner jar or inner pouch alone is not intended for storage and may not provide adequate sterile or moisture barrier.
Note: Virtuos Lyograft should not be implanted prior to rehydration/rinsing and until Steps 4-6 below are complete.

1. Peel back the lid of the outer tray or outer pouch.
2. For small units, present the inner foil pouch to the sterile field. Slowly peel open foil pouch and place units in a sterile vessel to contain tissue.
3. Medium, large and extra large units are contained in individual jars. Present the inner jar to the sterile field by grasping the top and bottom of the jar. Remove the threaded cap by twisting.

Rehydration:

4. Add 5% Dextrose in Lactated Ringer's Solution or Saline to the top of the jar (approximately 60mL). For small units, add approximately 30mL of solution.
5. Allow tissue to sit in solution for at least 2 minutes.
6. Prior to use, decant excess solution.
7. Implant within 2 hours of rehydration
   Note: Virtuos Lyograft has been validated for a 2-hour window post-rehydration for optimal performance.

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.

STORAGE

The recommended storage temperature is ambient. Only open packaging of tissue when ready to rehydrate and implant. 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.

DONOR SCREENING & TESTING

Prior to donation the donor's medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissue 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 virus (HBV) surface antigen
- HBV core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV-1 NAT
- HCV NAT
- HBV NAT

Additional testing of SARS-CoV-2 virus, HTLV I & II and/or West Nile Virus (as applicable) may also have been performed. 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 meet or exceed current standards established by the American Association of Tissue Banks.

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 comment regarding the use of the tissue on the TissueTrace® Tracking Form. Once completed, a system for electronic submission may be used and sent to MTFTTC@Sceris.com or returned using the self-addressed mailer. Copies of this information may be retained or provided to the local allograft representative.

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

Note: Not all tissue forms are available for International distribution.

Definitions of Label Symbols

 **Consult instructions for use**

 **Do Not Reuse**

For Translation of Instructions for Use

www.mtfbiologics.org

PROCESSED BY:

Processed by: Musculoskeletal Transplant Foundation
125 May Street, Edison, NJ 08837, USA
Within the United States: 800.433.6576
Outside of the United States: +1.732.661.0202
All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

REPRESENTED BY:

Orthofix US, LLC
3451 Plano Parkway
Lewisville, TX 75056
USA

Virtuos™ Lyograft Sizes

Part #	Sizes	Volume
440001	Small	1.2cc
440002	Medium	5.3cc
440003	Large	10.6cc
440004	Extra Large	16cc

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

CTO: 100024