IsoTis

DIRECTIONS FOR USE

Ballast®

Demineralized Bone Matrix in Resorbable Mesh

CAUTION: Federal (U.S.) Law restricts the use of this device to sale by or on the order of a physician.

The inner package and its contents are sterile
For single patient use on a single occasion only
The demineralized bone matrix (DBM) in this product is derived from voluntarily donated human tissues.

INDICATIONS FOR USE
Ballast® is intended to fill voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use with autograft as a bone graft extender in the posterolateral spine and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone. Ballast is resorbed/remodeled and replaced by host bone during the healing process.

DESCRIPTION
Ballast is comprised of a resorbable poly(lactic-co-glycolic acid) (PLGA) mesh pouch containing demineralized cortical bone (DBM).

No additional carrier is added to the allograft material. Ballast is provided sterile in a ready-to-use form, in a single patient use container.

CONTRAINDICATIONS
Ballast is contraindicated where the device is intended as structural support in load-bearing bone and in articulating surfaces. Conditions representing relative contraindications include:
- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative bone disease
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol
- Renal impairment
- Active or latent infection in or around the surgical site
- Polymyxin B Sulfate, Bacitracin, Gentamicin and Iodine are used in the processing of the DBM used in Ballast and trace amounts may remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity to these compounds.

PATIENT SELECTION FACTORS
Procedures involving bone grafting can experience highly variable results. Factors to be considered in selecting the bone grafting material and the surgical technique to be utilized are as follows:
- Age of the patient
- Quality of the patient's bone
- Location of the defect
- Anticipated loading conditions
- Proximity of the graft to a suitable blood supply
- Ability to achieve direct apposition of the graft to viable host bone
- Presence/addition of autogenous bone or bone marrow at the graft site
- Elimination of gaps in the graft site
- Ability to suitably stabilize the graft site

INSTRUCTIONS FOR USE
These instructions are intended as guidelines for the use of Ballast as a part of established surgical techniques. They are not intended to replace or change standard procedures for treatment of posterolateral spine fusion involving bone grafting and internal fixation. For best results, extreme care should be exercised to assure the correct graft material is selected for the intended application.

PREOPERATIVE PREPARATION
- Aseptic techniques must be maintained to minimize the risk of post-operative complications. The amount needed is based on the type of procedure and size of the posterolateral spine fusion being treated.
- Ballast does not require rehydration prior to use.
- Radiographic evaluation of the posterolateral spine fusion site is essential to accurately assess the extent of the graft site and to aid in the selection and placement of Ballast and fixation devices.
- Ballast does not possess sufficient mechanical strength to support the reduction of a graft site prior to tissue in-growth. Therefore, rigid fixation, in all planes, should be obtained independent of Ballast.
- For best results, Ballast must fill the posterolateral spine fusion space and contact as much viable bone as possible.
- Ballast must not be used for posterolateral spine fusion where complete soft tissue coverage cannot be achieved.

REMOVING THE PRODUCT FROM PACKAGING
1. Peel open outer foil pouch
2. Using aseptic technique, transfer contents to a sterile field.
3. Peel open inner foil pouch
4. Lay clamshell containing product on table with tab on top. With two fingers, hold base of clamshell. Grasp tab and gently pull upward until clamshell opens

PREPARATION AND PLACEMENT OF GRAFT
1. Harvest the required quantity of autograft per the table below:

Product Description	Amount of Autograft Required
Ballast, 45x11 mm	2.5cc
Ballast, 45x17.5 mm	4 cc
Ballast, 85x11 mm	4.75cc
Ballast, 85x17.5 mm	7.5 cc
Ballast, 115x11 mm	6.5 cc

2. Place prepared autograft into graft site
3. Hydration is optional. Ballast may be hydrated to achieve desired handling characteristics.
4. Place Ballast atop the implanted autograft

POSTOPERATIVE CARE
- Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting.
- Standard postoperative practices should be followed, particularly as applicable to posterolateral spine fusion involving the use of fixation devices.
- The patient should be cautioned against early weight bearing and premature ambulation that could lead to loosening and/or failure or loss of fusion.
- The length of time a fusion bed should remain in a reduced state of loading is determined by the complexity of the fusion site and the overall physical condition of the patient.
- Hardware should not be removed until the fusion bed is healed.

WARNINGS
- The product must be used prior to the expiration date.
- For single use only.
- Do not re-sterilize.
- Do not use if the packaging has been damaged and/or the product has been compromised. In the event packaging has been compromised, discard the product.
- Damaged packaging should be returned to the manufacturer.
- Do not use to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Screws must gain purchase in the host bone as opposed to Ballast.
- Do not use to repair bone defects where soft tissue coverage cannot be achieved as complete post-operative wound closure is necessary.
- Do not overfill the graft site.

POTENTIAL ADVERSE EVENTS
Surgical procedures involving implantation of bone grafts are associated with the following risks:
- Superficial wound infection
- Deep wound infection with or without osteomyelitis
- Nonunion, delayed union and/or malunion
- Wound dehiscence
- Loss of reduction
- Refracture
- Cyst recurrence
- Hematoma
- Cellulitis

Adverse outcomes attributable to the product must be reported promptly to the manufacturer. If any dissatisfaction with the product performance or packaging occurs, notify IsoTis OrthoBiologics, Inc. immediately and promptly return product and/or packaging.

PRECAUTIONS
- Ballast is sterile for the duration of the product's shelf life, provided that the package is in its original sealed condition and that it is unopened and undamaged.
- As with all biological products, the tissue in Ballast has the potential to transmit infectious agents despite processing treatments, extensive donor screening, tissue selection and laboratory testing. To date, there have been no reports of

experimental or clinical viral seroconversion attributed to the use of demineralized bone.
- As with any surgical procedure, the possibility of infection exists.
- Although the production technique is designed to eliminate antigenic properties of the product, the possibility of such a reaction is present.
- Once the container seal has been compromised, the tissue product shall be either transplanted, if appropriate, or otherwise discarded.
- Do not use product if the mesh pouch is torn or unsealed.
- When introducing Ballast, care must be taken to avoid excessive compaction.
- Appropriate placement and/or fixation are critical factors in the avoidance of potentially adverse effects.
- Selection of an oversized implant should be avoided to achieve a tension-free closure of the wound.

HUMAN TISSUE DONOR SELECTION
All tissue used in Ballast is recovered from donors and by tissue banks in the United States in accordance with regulations and standards established by the U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). The tissue bank (as identified on the product's outer packaging) has evaluated the tissue donor and determined that the donor met suitability criteria that were current at the time. The tissue bank's evaluation included review of the tissue donor's infectious disease test results, consent documents, medical and social interview, assessment of the donor's body, available relevant medical records including previous medical history, laboratory test results, review of postmortem examination results (if applicable) and information from other sources or records which may pertain to donor eligibility including tissue procurement test results. The review did not reveal risk factors for, conditions indicating clinical and/or physical evidence of infectious disease, or communicable disease agents or diseases, including HIV (human immunodeficiency virus) or hepatitis, or risk factors for viral or prion-associated disease transmission as specified in 21 CFR 1271 Subpart C and Appendix II of the AATB standards.

SEROLOGICAL TESTING OF HUMAN TISSUE
Donor blood samples taken at the time of recovery were tested by laboratories registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS), and were found negative or non-reactive using FDA licensed, cleared or approved, tests for:
- HIV antibodies type 1 and type 2 (anti-HIV-1 and anti-HIV-2)
- HIV-1 Nucleic Acid testing (HIV NAT)
- Hepatitis B Surface antigen (HBsAg)
- Hepatitis B Core Antigen [anti-HBc (IgG and IgM)]
- Hepatitis B Virus Nucleic Acid Tests (HBV NAT)
- Hepatitis C Virus Nucleic Acid Test (HCV NAT)
- Hepatitis C Virus Antibody (anti-HCV)
- *Treponema pallidum* (Syphilis)

In addition, testing may have been conducted for Human T-Lymphotropic Virus type 1 and type 2 (anti-HTLV-I/II). The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of this human tissue are on file at the tissue bank and are available upon request. This tissue has been determined to be suitable for transplantation based on the results of screening and testing.

VIRAL INACTIVATION
The methods for processing of the DBM contained in Ballast were evaluated for their viral inactivation potential. A selected panel of viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable inactivation potential of the processing methods for a wide range of potential viruses.

OSTEOINDUCTIVE POTENTIAL
The osteoinductive potential of the DBM in the resorbable mesh pouch is verified in an *in vivo* athymic rodent model. It is unknown how osteoinductive potential of the product correlates with human clinical performance.

STERILIZATION
Ballast has been sterilized by electron beam irradiation. The inner package and its contents are sterile. The package should be inspected prior to use to ensure the sterility barrier has not been compromised. This product is for single use only and must not be re-sterilized. The product must not be used beyond the stated expiration date.

DO NOT RE-STERILIZE

STORAGE
- Store at ambient temperature (15°C to 25°C) in a clean, dry place. The product has been validated to withstand temperatures between -10°C to 35°C during transit.
- Do not refrigerate or freeze.
- Do not expose to extreme heat.
- It is the responsibility of the tissue dispensing service and user (facility/clinician) to maintain the product under appropriate conditions prior to use.
- Discard any unused product.

RECIPIENT TRACING
The FDA requires that allograft tissue be traceable from the donor to the recipient. The tissue bank is responsible for traceability from the donor to the consignee (transplantation facility, clinician or hospital), and the transplantation facility is responsible for traceability to the recipient. A Graft Tracing Record and pre-printed peel-off labels are included with each package of tissue. Record the patient name or ID number, the transplantation facility name and address, the allograft tissue identification information (using the peel-off stickers) and comments regarding the use of the tissue on the Graft Tracing Record. Return the completed form to IsoTis OrthoBiologics and retain a copy in the patient medical record. If the tissue has been discarded, please return the Graft Tracing Record to IsoTis OrthoBiologics with the graft identification information and reason for discard.

PRODUCT INFORMATION DISCLOSURE
IsoTis OrthoBiologics, Inc ("IsoTis") HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. IsoTis EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IsoTis SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. IsoTis NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. IsoTis INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

An explanation of the symbols used on product labeling is provided below.

STERILE R	Sterilized using irradiation
	Consult Instructions for Use www.seaspine.com/eifu
	Expiration date (YYYY-MM-DD)
	Do not re-use
	Temperature limitation
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner
REF	Catalog number
LOT	Lot number
	Manufacturer
	Do not use if package is damaged
	Do not re-sterilize

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