BioEnthesis

Biphasic Cancellous Allograft

Instructions for Use and Tissue Allograft Information

Description: BioEnthesis is a biphasic allogenic, acellular, cancellous bone allograft that is placed inter-positionally between the decorticated humeral head and torn tendon(s) in, most commonly, a transosseous equivalent double row arthroscopic rotator cuff repair; to provide a matrix for the repair and reconstruction of the bone at the enthesis within the rotator cuff. BioEnthesis undergoes a proprietary process resulting in a mineralized layer and a demineralized layer of the graft. This biphasic composition offers the structural characteristics and handling of a soft tissue allograft, with an intact porous collagenous matrix for soft tissue ingrowth and, a highly calcified layer to promote osseointegration.

Indication for Use: BioEnthesis is indicated to provide a matrix for the repair or reconstruction of the bone of the enthesis within the rotator cuff.

Contraindications: BioEnthesis is contraindicated for use in any patient in whom soft and hard tissue implants are contraindicated. This includes any pathology that would limit the blood supply and compromise healing, or evidence of a current infection. BioEnthesis is contraindicated where the allograft is intended as structural support in load-bearing bone, and articular cartilage surfaces.

WARNINGS AND PRECAUTIONS:

- This allograft is intended for use in one patient, on a single occasion only.
- Do not use if the package integrity has been compromised. Once the user breaks the seal on the inner-most pouch, the tissue graft must be implanted or discarded.
- The tissue allograft must not be sterilized or re-sterilized by your facility.
- This tissue is intended for use by qualified healthcare specialists, such as physicians and surgeons.
- Although this tissue has been tested and screened for relevant communicable diseases and disease agents, and processed under aseptic conditions, human derived tissue allografts may still transmit infectious agents, known or unknown.
- Allografts are processed using some or all of the following agents: physiological buffers, acids, organic solvents, glycerin, citric acid, ethoxylated surfactant, N,N-dimethyloctadecylamine oxide, 2ethoxyethyl 2-cyanoacrylate and traces of these may remain. Caution should be exercised if the patient is allergic to any of these types of substances.

Storage: BioEnthesis should be stored at ambient temperature. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary or End-User 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 must be discarded.

How Supplied: BioEnthesis is packaged in a polymeric tray within a double chevron peel pouch configuration. Sparta Biopharma BioEnthesis allografts are supplied in a standard size unit designed for surgical reconstruction of the rotator cuff enthesis by qualified health care professionals (e.g., orthopaedic surgeons). This tissue allograft has been sterilized, via Gamma irradiation, to a SAL of 10^{-6} (Sterility Assurance Level).

Directions for Use: These procedural steps and recommendations are designed to serve as general guidelines. These steps are not intended to be used in lieu of standard accepted operative practices and clinical decisions should be made by the clinician.

1. Inspect the integrity of the product packaging prior to use. If damaged, do not use. If the product is expired, do not use. If the labels are severely damaged, illegible, or missing, do not use. The directions for use must be read before use.
2. Open cardboard shelf box and remove the pouch. **Note:** The inner pouch, its contents, and the inside of the outer pouch are sterile. The outside of the outer pouch is not sterile. Use standard aseptic/sterile technique to open the pouches.
3. Starting at the end with the chevron seal, peel open the outer poly/Tyvek pouch. Using aseptic technique, transfer inner pouch and contents to a sterile field.
4. Starting at the end with the chevron seal, peel open inner package and remove the tray containing the allograft. **Note:** The inner pouch provides the sterile and moisture barrier for the product. Once the inner pouch has been opened, the implant should be used as soon as possible.
5. **Rehydration: Do not suture allograft prior to rehydration**. Aseptically remove the top lid of the clamshell leaving the allograft in the lower portion of the clamshell "reservoir." Add room temperature sterile saline (0.9%) or other sterile isotonic solution to the reservoir and hydrate for a minimum of 15 minutes. **Note:** Clinician should ensure the rehydrated graft has the desired handling characteristics. If the handling characteristics are not met, continue rehydrating the graft. Once the tissue is rehydrated, it must be implanted or discarded within 6 hours provided the allograft is maintained in an aseptic environment.
6. **Preparation of the Implant Site:** Preparation of the implant site is important for allograft incorporation. The top layer of the footprint of the greater tuberosity of the humeral head should be decorticated to promote access to cellular and endogenous factors of the marrow and provide a vascular supply from the underlying cancellous bone.
7. Once the implant site has been prepared on the humeral head, the size of the graft should be determined. The graft can be cut to size using standard surgical scissors. The size of allograft necessary for a surgical procedure is based upon surgeon preference, the size and type of defect, and surgical reconstruction strategy.
8. **Delivery of BioEnthesis into the Arthroscopic Space:** BioEnthesis may be delivered into the arthroscopic space through a cannula or percutaneously. If a cannula is used, it must be a soft, single-dam cannula greater than or equal to 12mm in diameter. If delivering percutaneously, care must be taken to ensure the percutaneous portal is adequately sized and cleared.

9. **Surgical Implantation of BioEnthesis:** The exact method of surgical graft implantation is ultimately at the discretion of the surgeon. However, one strategy that provides clinicians an efficient and reliable method to deliver and secure BioEnthesis is detailed below:

Surgical Implantation (continued)

Once BioEnthesis has been hydrated according to Step 5, cut to size according to Step 7, and a delivery portal has been identified and prepared according to Step 8, the surgeon should implant their medial row of suture anchors. Each of these suture anchors should have one extra sliding suture, one limb of each of which should be passed through BioEnthesis ex-vivo. These suture limbs should be used to tie an arthroscopic knot on top of BioEnthesis. Using a atraumatic tissue grasper that will not pinch the graft at the pivot point of the jaws, BioEnthesis is folded, delivered into the arthroscopic space, and compressed to the humeral footprint by pulling the free ends of suture that knotted on top of BioEnthesis. The surgeon will then implant their first lateral anchor, after which the suture knot can be removed from the arthroscopic space altogether. Alternatively, the suture knot may remain on top of BioEnthesis arthroscopically until both lateral anchors are implanted, and then removed.

Donated Human Tissue: In accordance with FDA Article 21 CFR Part 1271, this package contains donated human cells, tissues, and cellular and tissue-based products (HCT/Ps). This human tissue allograft was processed, packaged, and labeled by Surgenex®. All tissue was recovered, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB), FDA requirements for Human Cellular and Tissue Based Products (HCT/Ps 21 CFR Part 1271), and applicable State regulations.

Donor Screening and Testing: Surgenex® has determined the Donor to be eligible, based on the results of screening and testing. Screening includes a review of medical and social history, available hospital records, infectious disease testing, autopsy report (if performed), and physical examination of the Donor. The Donor has been tested using FDA licensed, approved, or cleared donor screening test kits and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus, Hepatitis B Virus and Hepatitis C Virus Nucleic Acid Test(s) (HIV 1/HBV NAT/HCV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

Additional tests, including but not limited to HTLV I/II, CMV or West Nile Virus, may have been performed and were found to be acceptable for transplantation. Communicable disease testing has been performed by a laboratory, registered with the FDA to perform donor testing in accordance with the 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).

Adverse Outcomes: Adverse outcomes potentially attributable to this tissue must be reported promptly to Surgenex®, LLC.

Tissue Tracking: The Joint Commission and FDA requires patient records to be properly maintained by storing the allograft ID number (LOT NUMBER) for purposes of tracking the allograft from the donor to the recipient. Please go to our website, www.surgenex.com/allograftrecords and register by using the LOT NUMBER located on the product label.

Label Symbols and Definitions:

LOT	This symbol shall be adjacent to the manufacturer's batch code. The batch code may also be referred to as the lot number or batch number.		Indicates an allograft that is intended for one use, or for use on a single patient during a single procedure
REF	Indicates the manufacturer's catalog number so that the allograft can be identified	STERILE R	Indicates an allograft that has been sterilized using irradiation
	Indicates the date after which the allograft is not to be used.		Indicates the need for the user to consult the instructions for use.
5°C 30°C	Indicates the upper and lower temperature limitations on either side of the symbol.	Rx ONLY	Caution: Federal law restricts this allograft to sale on or by the order of a physician.
STERILIZE	Indicates an allograft that is not to be re-sterilized.		Indicates the manufacturer
	Indicates an allograft that should not be used if the package has been damaged or opened.		

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