RE-LIVE™ Triangular Multi-Point™ Structural Allograft
by Alevio® Spine

Product Description

The Re-Live Multi-Point Structural Allograft System consists of: (1) pre-packaged sterile structural allograft implants machined from human cortical bone approximately 9mm in diameter and 25mm in length; and (2) various surgical instruments intended to be used to prepare the graft site and insert the implant.

Surgical Instrument System

The Re-Live Multi-Point Structural Allograft System includes various surgical instruments made from surgical grade materials such as stainless steel. All system instruments need to be cleaned and sterilized prior to use. Components of the system include, but are not limited to, the following:

- ***Joint Locator***
  A stainless steel rod with a tapered distal end used to locate the Sacroiliac joint.
- ***Drill Guide***
  A stainless-steel tube with handle that is used to guide the drill and graft inserter.
- ***7mm Drill Bit (single use)***
  A stainless-steel drill bit that is used to drill an osteotomy for proper fitment and placement of the structural allograft implant.
- ***Graft Inserter***
  A stainless-steel tube with a resilient locking distal end for grasping the structural allograft implant and securely placing it in the graft site.
- ***Inserter Tamp***
  A stainless-steel rod that is placed through the Graft Inserter to tamp the Graft in place.
- ***3.2mm Steinmann Pins (single use)***
  A stainless-steel guide pin that is used to guide the system instruments to the proper location during use.

Indications for Use

The Re-Live Multi-Point Structural Allograft System instruments are intended for use in combination with the structural allograft implants included in the system. They are designed to facilitate the location of the sacroiliac (SI) joint, the alignment of instruments, the preparation of the graft site, and the insertion of the implants.

Contraindications

Contraindications for use of the Re-Live Multi-Point Structural Allograft System includes, but is not limited to, patients with the following:

- Infection
- Tumor
- Severe osteoporosis
- Mental or physical impairments that limit a patient's ability to comply with necessary limitation of postoperative instructions

Warnings and Precautions

The surgeon should be familiar with the procedure and use of the Re-Live Multi-Point Structural Allograft System instruments prior to surgery.

The outcome and results obtained from this surgical procedure, as with any surgery, are highly dependent on the knowledge of surgical techniques, placement of implants used, management of the patient both pre and post operation, including the general health of the patient.

The system implants are provided STERILE. Product packaging should be inspected for continuity and the components should be handled appropriately to ensure sterility.

Potential Adverse Events

- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Loss of or increase in spinal mobility or function.

Care and Handling of Instruments

The Re-Live Multi-Point Structural Allograft System instruments are provided NON-STERILE and must be properly cleaned and sterilized prior to initial use.

Single-Use Instruments

The Drill Bits and Steinmann Pins used with this system are single-use instruments that are to be disposed of after use.

Cleaning

Diligent execution of all steps is extremely important. Before being used for the first time and as soon as possible after each subsequent use, thoroughly clean all instruments and trays, following these steps to ensure safe handling of biologically contaminated instruments:

1. Pre-Cleaning
Remove any packaging materials including tip protectors prior to cleaning.

Disassemble all instruments that can be disassembled.

Keep instruments moist and do not allow blood and/or bodily fluids to dry on instruments.

Remove gross contaminants with a steady stream of lukewarm/cool water (below 110°F). Be sure to rinse each instrument thoroughly. Do not use saline or chlorinated solutions (bleach) for any of the cleaning processes, as these can promote corrosion.

2. Cleaning
Hand wash using a low-sudsing, neutral pH (7-9 pH), protein dissolving detergent. Follow the detergent manufacturer's directions regarding the proper concentration, temperature and time.

Totally immerse instruments during the cleaning process in order to prevent aerosolization. Use appropriate-sized, soft nylon brushes – Do Not Use steel wool, wire brushes, pipe cleaners or abrasive detergents.

For cleaning cannula, lumen or hole, use a tight-fitting soft, non-metallic cleaning brush, pushing brush in and out and use a twisting motion to remove debris.

To avoid coagulation of mucus, blood or other body fluids, do not soak instruments in hot water, alcohol, disinfectants or antiseptics. Do not exceed two hours soaking in any solution.

3. Ultrasonic Cleaning
For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level, concentration and temperature.

Do not place dissimilar metal instruments in contact with each other.

When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.

Rinse instruments thoroughly with tap water, deionized water or distilled water. Thoroughly rinse all internal lumens.

4. Decontamination/Disinfection
Warning: The decontamination process does not sterilize instruments. Refer to and process as outlined in the STERILIZATION section.

Select a proper product for high-level disinfection (examples include the glutaraldehyde-family of disinfectant products). Follow the cleaning agent's recommended directions regarding the proper concentration, temperature, contact time and solution re-use.

Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection, such as bleach, bi-chloride of mercury. Completely immerse instruments in disinfecting solution - force solution into all areas and cavities.

Using a large syringe or pulsating water jet, thoroughly flush all channels and lumens with the disinfecting solution to remove debris.

5. Rinsing
Thoroughly rinse all instruments and internal lumens with warm tap water or distilled water for a minimum of three minutes to remove all traces of the disinfecting solution. **Use sterile water for the final rinse.**

6. Drying
Instruments must be thoroughly dried to remove all residual moisture before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Filtered compressed air or a 70% alcohol rinse can also be used to aid the drying process.

7. Testing / Preparation for Sterilization
Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Instruments should be visually inspected and prepared for sterilization following disinfection. If the device is determined to not be visually clean at the end of processing, the user should repeat the relevant, previous cleaning steps or alternatively, safely dispose of the device.

Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments, as well as worn instruments in which the proper function of the instrument may be compromised.

Sterilization

Warning: Alevio does not recommend Flash or Chemical sterilization.

The system instruments are supplied NON-STERILE and are contained within trays that can be sterilized directly. The system is able to withstand multiple sterilizations. Do not stack trays during sterilization. Based on AAMI and current JCAHO standards, the instruments should be wrapped in an FDA cleared wrap and sterilized using a vacuum cycle, using the following guidelines:

Method	Temperature	Exposure Time	Minimum Dry Time
Steam Pre-Vacuum	270°F (132°C)	4 minutes	30 minutes

The above steam sterilization cycle has been validated in accordance with proper quality guidelines. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

Storage

Per our authorized tissue processor, the system implants are made of human allograft and must be stored and maintained at room temperature (59-86°F or 15-30°C).

Shelf Life

The shelf life of the system allograft implants depends on the date of processing. Refer to each individual package label for specific information.

Customer Service

Additional information about the Re-Live Multi-Point Structural Allograft System, including a comprehensive surgical technique guide and instructions for use, is available directly from Alevio at any time, or contact your local Alevio sales representative.

ALEVIO® SPINE
Sacroiliac Joint Fusion System Moving Life Forward™

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