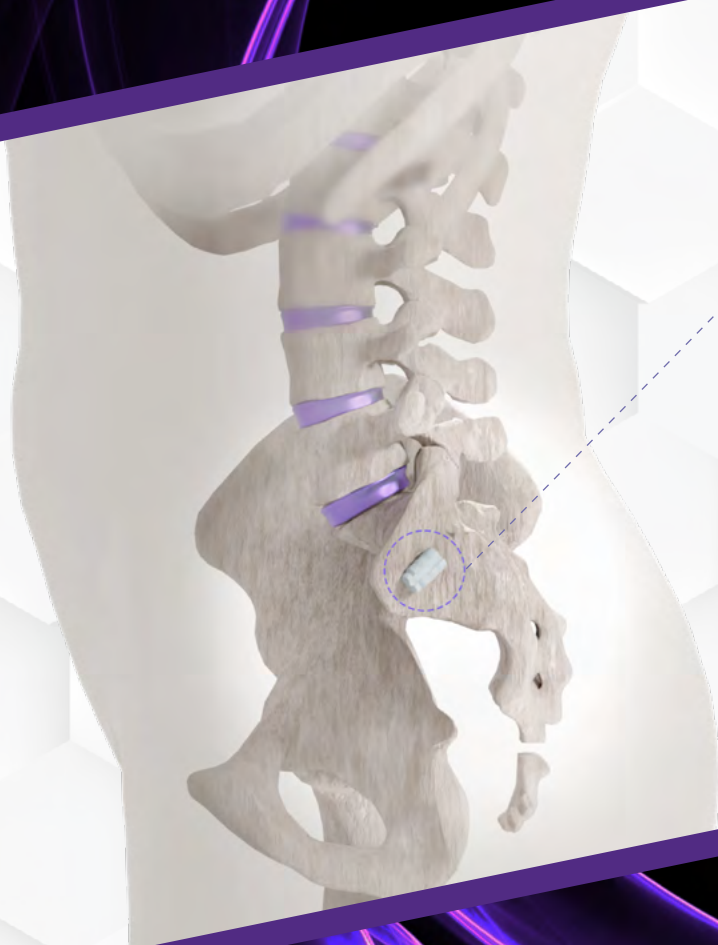




Posterior SI Joint Fusion System



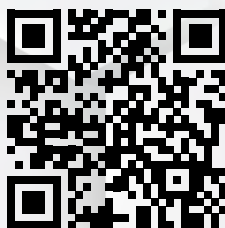
SiLO[™]
Si
Joint Fusion

Surgical Technique Guide

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Check out the SiLO™ Surgical technique Guide Animation!
Just scan the QR code:



aurora-spine.com



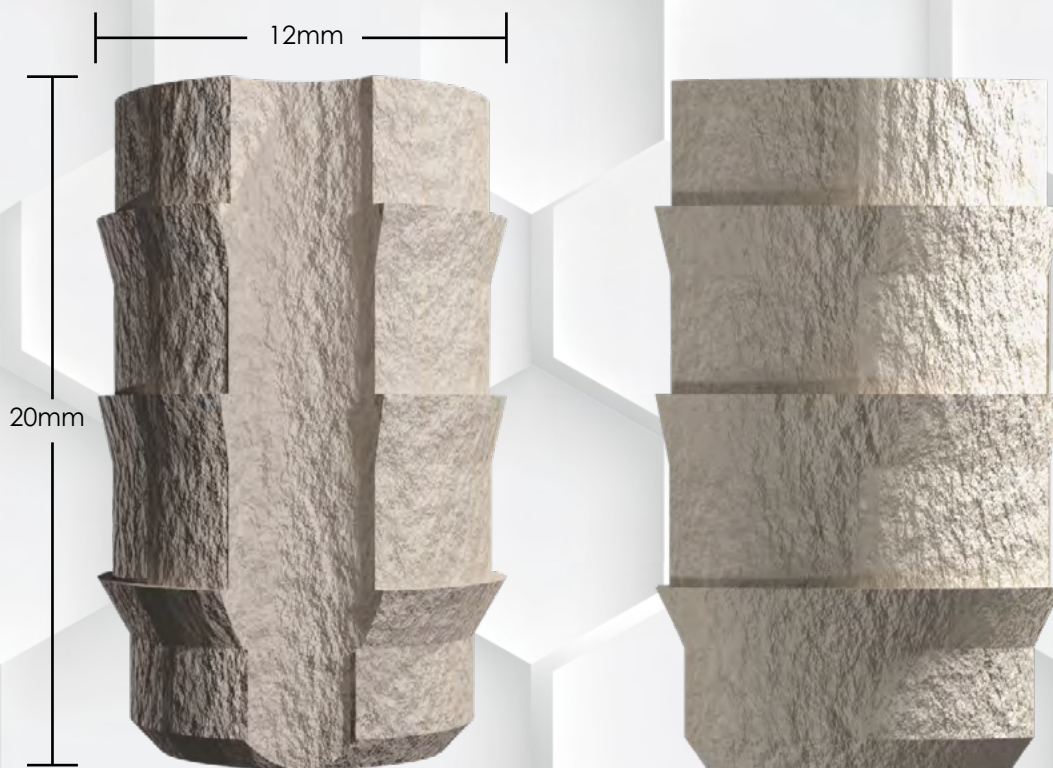
Description

SIMPLE, SAFE...SiLO™

SiLO™ is a single implant posterior Si-Fusion system made of human cortical bone and was developed to provide a simple, safe & reproducible method of fusing the Sacroiliac Joint.

SiLO™ is the only implant that was designed specifically for transfixing posterior sacroiliac joint fusions.

The implant design consists of three levels of ridges along its circumferential solid body to increase implant retention and solidity through its unique "Dowel Anchorage Design". The SiLO™ implant is shaped for enhanced 360 degree bone incorporation along with dual, vertical side-channels. These channels can hold additional bone graft material during implant insertion for enhanced stability.



Part Number	Description (Diameter x Height)
113-01220	SiLO™, Ø 12mm x 20mm

Indications

SiLO™ is a machined cortical bone allograft intended for transplant in small bone fusion procedures. SiLO™ allografts are manufactured aseptically using Computer Numerically Controlled (CNC) machining technology for dimensional reproducibility and conforming fit within the bone space. The finished allograft is freeze-dried (lyophilized) and terminally sterilized. SiLO™ is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for transplant in procedures on a single occasion by a licensed physician or surgeon.

CATALOG #	INSTRUMENTS DESCRIPTION
110-364-2	SiLO Guidepin Ø2.4mm
113-300	SiLO Joint Finder
113-308-1	SiLO Striking Cap
110-361-1	Mallet
113-309-1	SiLO Ghost Tube
113-304-30	SiLO Reamer
110-710	SiLO Axial Handle Ratcheting
113-314-1	SiLO Funnel
113-314-2	SiLO Funnel Plunger
113-306-1	SiLO Introducer
113-305	SiLO Tamp
113-600	SiLO Instrument Case
AVAILABLE UPON REQUEST	
113-310-3	SiLO Power Drive Adapter
113-301	Vamp Tube



Instruments Layout



Simple, Safe... SILO™

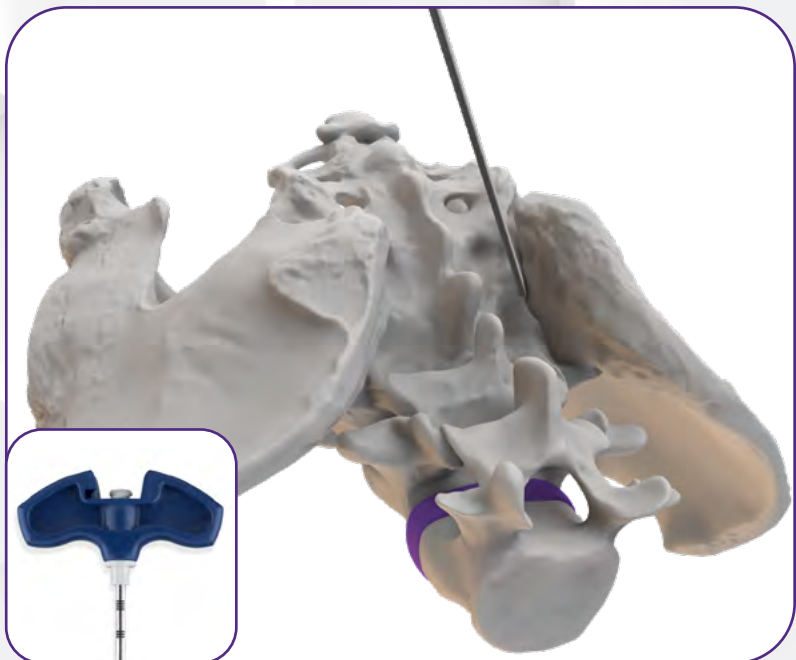
1. Patient Positioning:

The patient should be placed in a prone position in order to facilitate a posterior approach into the SI joint.



2. Guidepin Placement:

The guidewire is advanced into the sacroiliac joint under AP and lateral fluoroscopy.



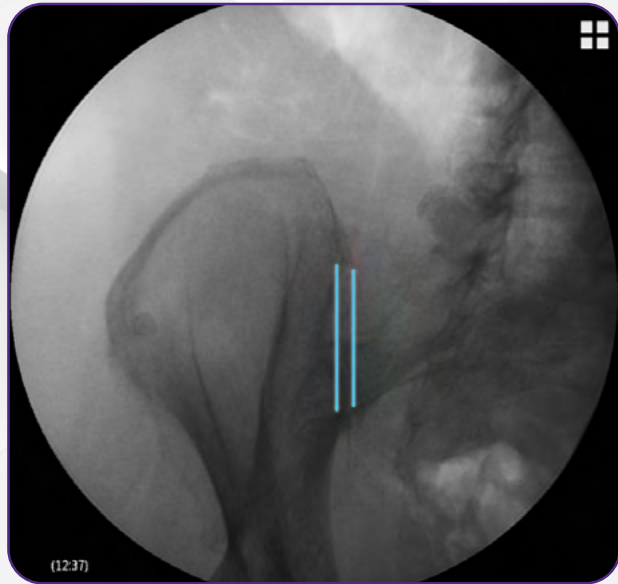
A Jamshidi needle may be used to assist with placement.

Fluoroscopic Anatomy of the Sacroiliac Joint

In the AP oblique view the anterior medial and lateral cortical borders are smooth straight lines. The posterior cortical borders are curvy and serpiginous. Note the sharpness of the cortical edge in the lateral blade of the ilium.

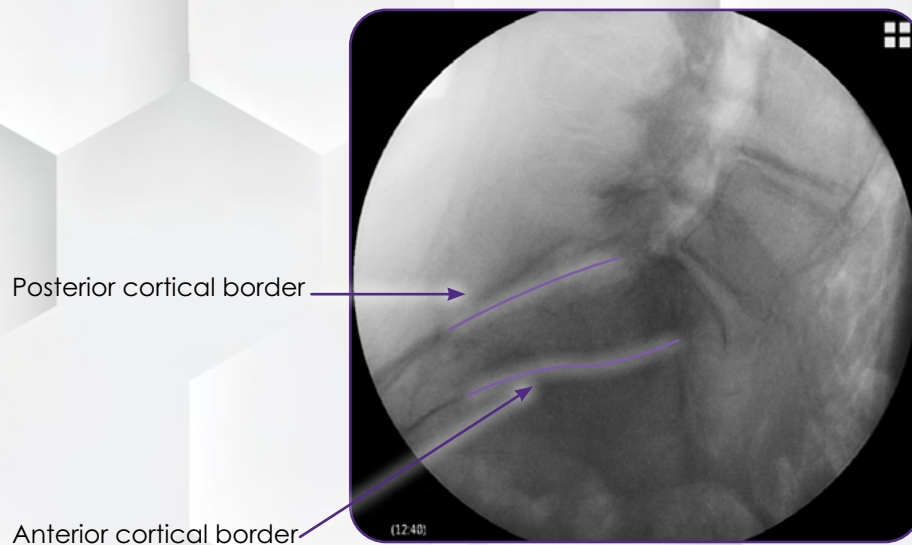


Posterior



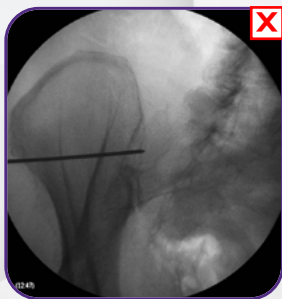
Anterior

In the lateral view the posterior cortical line, the anterior cortical line, and the sacral alar lines are visualized

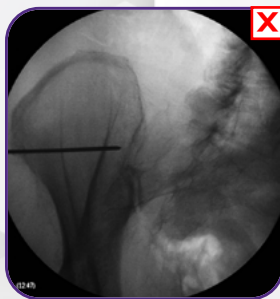


Fluoroscopic Guidepin Placement

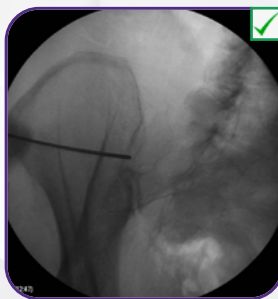
Position the c-arm in AP view and oblique the image 10°-30° contralateral until a sharp cortical edge appears lateral to the joint in the ilium. Use the tip of the Guidepin to locate the center of the joint lines near S1/S2 in the middle third of the joint. Lift the tail of the Guidepin to align with the fluoroscopic view, a perfect circle should be visualized. Advance the pin slightly to provisionally fix it in the joint.



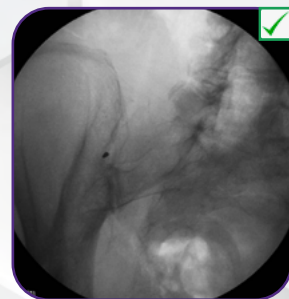
Medial to joint



Lateral to joint

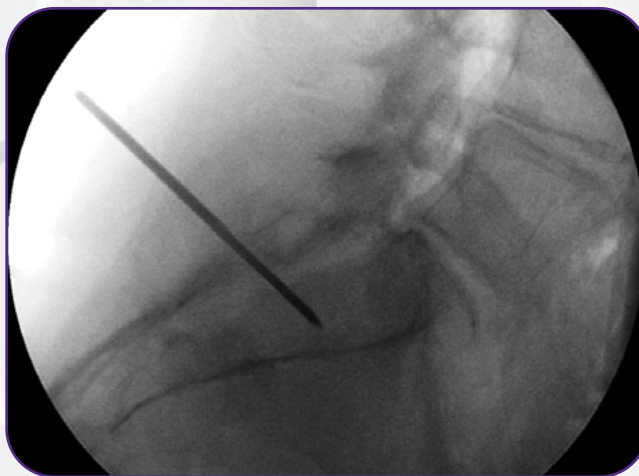


Middle of joint

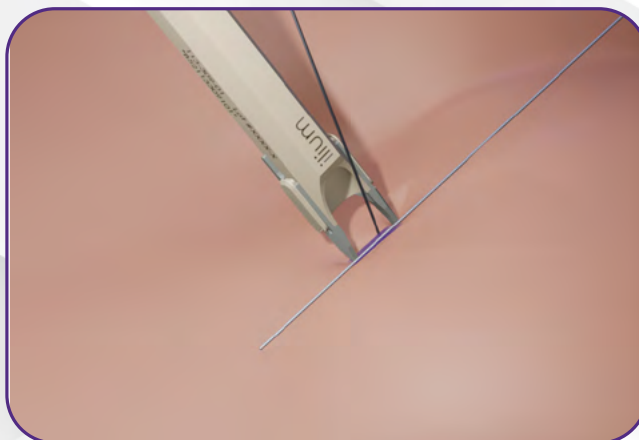


Guidepin looks like a perfect circle, when parallel with fluoroscope view

Position the c-arm for a lateral image and confirm the Guidepin is advanced past the posterior cortical line of the sacrum. Advance the Guidepin towards the apex of the sacral ala. Advance the Guidepin past the posterior cortical border of the sacrum and stop before the anterior cortical border of the sacrum.

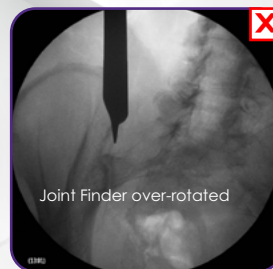


Make the incision by placing the Working Channel against the skin, using it as a template to mark for the incision size. Dissect down to the posterior border of the sacroiliac joint.



Sacroiliac Joint Finding

Pass the Joint Finder over the Guidepin and down into the incision. Position the large profile cut towards the ilium. Note the medial and lateral Sacroiliac joint lines in a fluoroscopic AP view. Align the Joint Finder to the joint by visualizing the square profile of the tip.



Switch to a lateral fluoroscopic view and advance the Joint Finder into the joint using the Striking Cap and Mallet. Alternate views during insertion to ensure the tip of the instrument is placed in the center of the joint lines. Advance the Joint Finder until the instrument's medial shelf contacts the posterior sacrum.



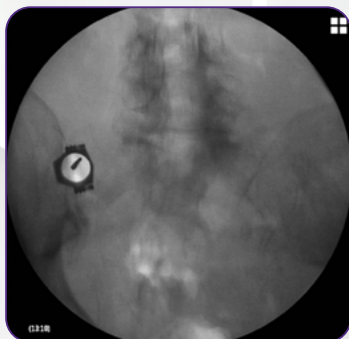
Position the Ghost Tube over the Joint Finder and turn the large profile cut towards the ilium. Pass the Ghost Tube down over the Joint Finder and into the incision. Use the alignment indicators on the Joint Finder combined with an AP fluoroscopic view to position both forks of the Ghost Tube in the center of the joint lines.



Switch to a lateral fluoroscopic view and advance the Ghost Tube into the joint using the Striking Cap and Mallet. Alternative views during insertion to ensure both forks are placed in the center of the joint lines. Advance the Ghost Tube until the instrument's medial shelf contacts the posterior sacrum.



Remove the Joint Finder from the joint and switch to an AP Oblique view for a final check of Working Channel placement. Position the C-Arm view to look "down the barrel" of the Ghost Tube. Note the center of the sacroiliac joint lines is clearly visualized down the tube.



Decorticating The Sacroiliac Joint

Remove the Guidepin from the joint. Connect the reamer to the Quick Connect Handle. Place the reamer down the Ghost Tube. In a lateral fluoroscopic view, advance the reamer into the joint. Advancing until positive stop with the Ghost Tube will ream to a 30mm depth (SiLO Height 20mm).

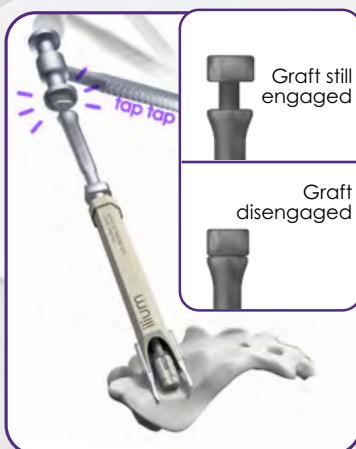


Graft Insertion

Remove the reamer from the Ghost Tube and use the graft Funnel and Plunger to place biologics in the reamed channel. Place the SiLO Graft between the prongs of the Introducer. Point the nose of the graft towards the tip of the instrument. Insert the Plunger through the inserter and Mallet until positive stop with Introducer. Remove the Introducer and use the tamp with the Mallet for final placement of the graft.



Initial Placement



Graft still engaged

Graft disengaged

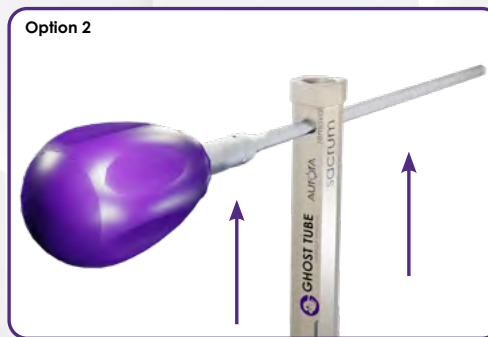
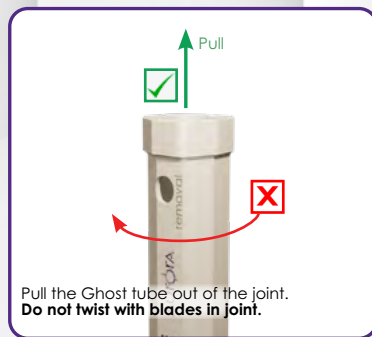
Final Placement



Do not use Striking Cap with Mallet. Strike Introducer And tamp directly

Working Channel Removal

Remove the Ghost Tube from the incision. Assess graft placement in AP oblique and lateral fluoroscopic views.



Instructions for Use

THIS PRODUCT IS MANUFACTURED FROM DONATED HUMAN TISSUE, RECOVERED FROM A SINGLE HUMAN DONOR WITH DOCUMENTED AUTHORIZATION FOR DONATION AND RECOVERY AS DEFINED IN US FDA TITLE 21 CFR PART 1271. THE TISSUE IS RECOVERED AND SUPPLIED FROM U.S. TISSUE BANKS ONLY. THE RECOVERY, PROCESSING AND PACKAGING WERE PERFORMED USING ASEPTIC TECHNIQUES. THE ALLOGRAFT IS TERMINALLY STERILIZED IN ITS FINAL PACKAGING AND IS INTENDED FOR USE IN ONE PATIENT ON A SINGLE OCCASION ONLY. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS TISSUE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR HOSPITAL AND USE TO SPECIFIC HEALTH PROFESSIONALS.

DESCRIPTION AND INDICATION FOR USE

SiLO is a machined cortical bone allograft intended for transplant in small bone fusion procedures. SiLO allografts are manufactured aseptically using Computer Numerically Controlled (CNC) machining technology for dimensional reproducibility and conforming fit within the bone space. The finished allograft is freeze-dried (lyophilized) and terminally sterilized. SiLO is a Human Cellular and Tissue Based Product (HCT/P) per 21 CFR Part 1271. Each allograft is restricted to homologous use for transplant in procedures on a single occasion by a licensed physician or surgeon.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

SiLO was prepared from a donor determined to be eligible by the Medical Director of Aziyo or physician designee based on the results of screening and testing. Donors are screened for high risk behavior and contraindications to transplant through medical/social history interview, review of medical records, physical assessment, and review of post mortem-examination results (when applicable). Tissue from this donor has passed bacteriological testing by a CLIA Certified Laboratory. Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens 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) and found to be negative or non-reactive for a minimum of:

- HIV type 1 and 2 antibody (HIV-1 & 2 Ab)

- HIV type 1 nucleic acid test using PCR and/or TMA format (HIV-1 NAT)
- Hepatitis B virus (HBsAg and HBV NAT)

DONOR SCREENING AND TESTING (continued)

- Hepatitis B core antibody total (HBcAb IgG/IgM or total)
 - Hepatitis C virus (HCV Ab and HCV NAT)
 - Syphilis by rapid plasma reagin (RPR) or other serological tests
- Additional tests, including Human T-cell lymphotropic virus I/II, may have been performed at the time of screening, and results were found acceptable for transplantation. Any additional test(s) performed can be provided upon request. Donor eligibility determination was made by Aziyo Biologics in compliance with U.S. FDA regulations (21 CFR Part 1271) and American Association of Tissue Banks® (AATB®) Standards.

WARNINGS

An allograft may not elicit proper response from the recipient (e.g. fusion/union with adjacent tissue). The allograft is not to provide mechanical support and may collapse if load bearing. It is possible for a host site to become infected or may cause an inflammatory response. Current technologies may not preclude the transmission of infectious agents or disease, including hepatitis and HIV. SiLO may contain trace amounts of one or more processing agents including povidone iodine, hydrogen peroxide, gentamicin and/or vancomycin. It should not be used in patients with sensitivities to these processing agents.

CONTRAINDICATIONS AND PRECAUTIONS

Do not use this allograft material where any contraindica-

Instructions for Use Continued

tion may exist. The allograft is contraindicated where the allograft is intended as a structural support in the skeletal system. Other conditions representing relative contraindications include:

- Severe vascular or neurological disease
- Uncontrolled diabetes
- Severe degenerative disease
- Pregnancy
- Uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs or alcohol.
- Hypercalcemia, or abnormal calcium metabolism
- Existing acute or chronic infections, specially at the operative site
- Inflammatory bone disease such as osteomyelitis
- Malignant tumors
- Severely impaired renal function

SiLO™ machined, cortical bone allografts should not be used if:

- the expiration date shown on the labeling has passed,
- the packaging is damaged or compromised, or
- the recommended storage conditions have not been maintained. Do not resterilize. Do not reuse.

Preparation for Cleaning

Where instruments interface with other devices, disassemble prior to cleaning. Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.

Cleaning (Automated)

Equipment: Automated washer, soft bristle brush, enzymatic detergent¹, and neutral pH detergent².

- Pre-clean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- After pre-cleaning, place in the automated washer, making sure the samples do not touch each other. Load instruments in such a way that the parts can drain.
- Use a standard instruments cycle with the following parameters (at a minimum):

Enzyme Wash	Hot (40-65°C) (104-149°F) for 3 min.
Neutral pH Wash	60°C (140°F) for 3 min.
Rinse	Ambient Temperature for 1.5 min.
Thermal Rinse	90°C (194°F) for 1 min.
Dry	82°C (180°F) for 6 min.

- Determine if the instruments are dry. If they are not dry, dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning.

Cleaning (Manual)

Warning: Movable components and blind holes require particular attention during cleaning.

Preparation of Cleaning Agents (Recommended):

- Add 60 mL of Endozyme® AW Plus to 3.8 L water, (1:64 dilution).

Manual Cleaning Instructions:

- Pre-clean the instruments by placing under running water and scrubbing with a soft bristle brush to remove major debris. Rinse and scrub each instrument for at least one minute.
- Bathe the instruments in the enzymatic solution for 5 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution
- Scrub the instruments with a soft bristle brush while submerged in the detergent.
- Rinse the instruments in cold water.
- Rinse the instruments in deionized water.
- Pat dry with a soft, clean, lint free cloth.
- After drying, check instruments for complete removal of any debris. If necessary, repeat manual cleaning.

Sterilization

For components provided Sterile, the sterilization method is noted on label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile packaged components are supplied in a protective sterile barrier packaging. Inspect package for punctures or other damage prior to surgery. If sterile barrier has been broken, return component to Aurora Spine.

If not specifically labeled STERILE, components are supplied non-sterile and must be cleaned and sterilized prior to surgery.

Warning: Aurora Spine does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10⁻⁶, Aurora Spine recommends the following parameters:

Sterilizer Type	Pre-Vacuum	Gravity
Minimum Temperature	132° C (270° F)	132° C (270° F)
Exposure*	4 minutes	15 minutes
Dry Time	20 minutes	15 minutes

*Aurora Spine has verified the above sterilization cycles and

1 ENZOL®, a trademark of Advanced Sterilization Products, was used in the cleaning validation.

2 Polystica™ Ultra Concentrate neutral detergent, a trademark of Steris Corporation, was used in the cleaning validation.

Instructions for Use Continued

has the validation data on file. The validated sterilization parameters meet the minimum requirements per ISO 17665-1. 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.

Aurora Spine recommends following ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, which includes: physical monitoring of the cycle, inclusion of a chemical indicator internal and external to the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.

TRANSPORTATION, STORAGE AND HANDLING

SiLO machined, cortical bone allografts are supplied freeze-dried (lyophilized) and must be stored at 2°C - 40°C until prepared for use. It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation under the appropriate recommended storage conditions prior to transplant. **DO NOT FREEZE. DO NOT EXPOSE TO EXCESSIVE HEAT.**

HOW SUPPLIED

SiLO machined, cortical bone allograft is supplied terminally sterilized and freeze-dried (lyophilized). The allograft is packaged in a labeled sterile inner peel pouch which is then enclosed in a labeled secondary outer peel pouch. The outer pouch is then contained inside a labeled box.

STERILITY

SiLO machined, cortical bone allografts are provided sterile following an internationally recognized validation method and a proprietary irradiation system using gamma radiation to a Sterility Assurance Level (SAL) of 10⁻⁶.

SHELF LIFE AND DISPOSAL

The expiration date is printed on the label. **DO NOT USE AFTER THE EXPIRATION DATE.** This allograft is sterile in an unopened, undamaged package. Once the inner pouch has been compromised, the tissue shall be transplanted, if applicable, or discarded. Residual materials may be dispensed with other medical waste.

PREOPERATIVE PROCEDURE

In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated, and sepsis eradicated prior to the allograft procedure. Use prophylactic antibiotic coverage as appropriate.

INSTRUCTIONS FOR USE

The inner pouch and allograft are sterile. The exterior of the outer peel pouch is not sterile. It is important to utilize aseptic techniques when unpacking the allograft. The allograft is machined from donated human bone tissue. As such, it may contain minor surface irregularities that result from normal bone structure. These should not affect the ability of the allograft to perform as intended.

1. Examine outer peel pouch. Do not use if there is evidence that the integrity of the outer pouch has been compromised.
2. Aseptically present the inner pouch onto a sterile field.
3. Remove the allograft from the inner pouch and place into a sterile basin or similar.
4. The allograft must be used during the surgical procedure once opened. If opened and not implanted, the allograft must not be resterilized and must be discarded. Customer Service at AURORA SPINE must be notified. Document the reason for non-use of the allograft and indicate the disposition of the tissue on the Allograft Usage Report Record and return the record to AZIYO BIOLOGICS.

TRACEABILITY

It is the responsibility of the user surgeon to complete recipient transplant records for the purpose of tracking the tissue post-transplant. Complete the enclosed Allograft Usage Report (AUR) in detail and return as indicated.

ADVERSE REACTION

All adverse outcomes potentially attributable to the tissue must be promptly reported to Aurora Spine at +1 (760) 424-2004.

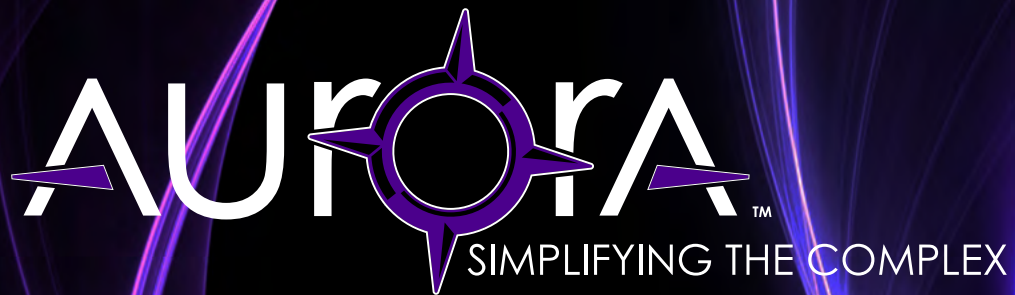
Donor eligibility determined and product manufactured by:



Aziyo Biologics
880 Harbour Way South
STE 100
Richmond, CA 94804, USA
TEL: +1 (800) 922-3100

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