

MEDICAL DEVICE DESCRIPTION – The Phoenix Sinus Tarsi Stent Instrument Set is used to insert the Phoenix Sinus Tarsi Implants. The reusable instruments are provided non-sterile and must be cleaned and steam sterilized prior to use.

INTENDED USE – The Phoenix Sinus Tarsi Stent Instrument Set is intended for the insertion and removal of Phoenix Sinus Tarsi Implants. Refer to LBL-20000 for indications and safety information for the Phoenix Sinus Tarsi Stent implants.

WARNINGS & PRECAUTIONS

- The Instrument Set is provided **NON-STERILE**—it must be cleaned and sterilized prior to use, shortly after use, and between uses.
- (US) Federal law restricts this device to sale by or on the order of a physician and the device is intended for use only or under the direction of trained surgeons.
- Guide pins are single use and not intended for reprocessing. Dispose of guide pins after use.
- Do not allow biological soils to dry on contaminated devices.
- Do not place soiled instruments back into the tray before proper cleaning.
- Improper cleaning and sterilization may lead to infection.
- Phoenix Sinus Tarsi Stent Instruments shall not be used for any purpose other than their intended use.
- Do not use it with patients who are allergic or hypersensitive to stainless steel (SST).

INSTRUMENT SET CONTENTS

Quantity	Instrument Description	Catalog No.	Material
1	Phoenix Trial Sizer 05	STS-T05	17-4 PH SST
1	Phoenix Trial Sizer 06	STS-T06	17-4 PH SST
1	Phoenix Trial Sizer 07	STS-T07	17-4 PH SST
1	Phoenix Trial Sizer 08	STS-T08	17-4 PH SST
1	Phoenix Trial Sizer 09	STS-T09	17-4 PH SST
1	Universal Handle	STS-DQC	SST, Medical Grade Silicone
1	Phoenix Driver	STS-D	17-4 PH SST
1	Phoenix Driver Sleeve	STS-DS	17-4 PH SST
3	Guide Pin	STS-GP	304 SST

INSTRUMENT REPROCESSING INSTRUCTIONS

All instruments **must be inspected** before each surgery **and** before sterilization: the tip of the trial sizers & driver should be free of nicks and burrs as these conditions may prevent the guide wire or the implant from sliding through the cannula freely, the positioning sleeve should slide on & off the driver with ease. Guide Wires should be free of burrs, bends, bows, or nicks as these conditions may prevent the implant from sliding through the cannula of the trial sizers or driver freely. These conditions may prevent the implant from being driven into place as intended. **The driver, trial sizers, and positioning sleeve** should be cleaned & sterilized per the instructions below before being returned to the manufacturer. **Defective Guide Wires** should not be used & discarded appropriately. Do not dispose in general waste.

APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT MUST BE WORN DURING HANDLING AND CLEANING. PRECAUTIONS SHOULD BE FOLLOWED WHEN HANDLING CONTAMINATED OR POTENTIALLY CONTAMINATED INSTRUMENTS

STEP ONE: Clean Instrument Set

Following use and prior to cleaning, keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Disassemble all instruments in accordance with the directions below:

- Disengage the driver (STS-D) or trial sizers (STS-T0X) from the universal handle.
- Remove the positioning sleeve (STS-DS) from the driver (STS-D).

Ensure all equipment to be used for reprocessing has been properly maintained and calibrated.

Manual Cleaning Procedure:

1. Rinse under running tap water (10-20°C) for a minimum of 1 minute.
2. Prepare an Enzol (or equivalent enzymatic cleaner) solution in accordance with the enzymatic cleaner manufacturer instructions using Deionized water. Bath temperature to be at least 13.5°C.

Note: Cleaning and disinfection agents containing chloride, iodide, bromide, high alkaline, or high pH can be corrosive to stainless steel instruments and should not be used.

3. Fully immerse devices in prepared detergent bath.
4. Using a soft nylon M16 bristled brush, thoroughly brush the exterior surfaces at least 6 times.

Note: 1 direction accounts for 1 brush.

5. Using a soft nylon lumen brush, thoroughly brush the interior lumen at least 6 times.

Note: 1 direction accounts for 1 brush.

6. Rinse under running tap water (10-20°C) for a minimum of 1 minute.
7. Repeat cleaning steps 1-6.
8. Thoroughly rinse with distilled water for a minimum of 1 minute paying attention to flush lumens, blind holes and difficult to reach areas.
9. Inspect devices under normal lighting conditions to determine if all adherent visible soil has been removed from surfaces, lumens, crevices, and serrations. If visible soil is seen, repeat the cleaning.
10. Dry thoroughly with a clean, lint-free cloth.
11. Place the device back into its appropriate location within the sterilization tray.

STEP TWO: Visually Inspect Instrument Set

All instruments **must be inspected** before each surgery **and** before sterilization: the tip of the trial sizers & driver should be free of nicks and burrs as these conditions may prevent the guide wire or the implant from sliding through the cannula freely, the positioning sleeve should slide on & off the driver with ease. Guide Wires should be free of burrs, bends, bows, or nicks as these conditions may prevent the implant from sliding through the cannula of the trial sizers or driver freely. These conditions may prevent the implant from being driven into place as intended. **The driver, trial sizers, and positioning sleeve** should be cleaned & sterilized per the instructions below before being returned to the manufacturer. **Defective Guide Wires** should not be used & discarded appropriately. Do not dispose in general waste.


STEP THREE: Sterilize Instrument Set

All non-sterile instruments must be cleaned and sterilized prior to use. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled within the instrument tray(s). Instruments should be positioned to allow the steam to come into contact with all surfaces. Do not stack trays during sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be wrapped in an FDA cleared sterilization wrap and steam sterilized.

The following is the recommended sterilization cycle:











- Method: Steam
- Cycle: Pre-Vacuum
- Temperature: 270°F (132°C)
- Exposure Time: 4 minutes
- Drying Time: 30 minutes

LIMITED WARRANTY – Astra OrthoMed, Inc. warrants that this device meets the manufacturer’s specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the device prior to implantation. Astra OrthoMed, Inc. does not warrant the outcome of the surgical procedure

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Any serious incident in relation to the device should be reported to Astra OrthoMed, Inc. and the competent authorities.

Glossary Of Symbols used on the Shelf Box Package Label and / or Instructions for Use

	Batch code		Unique device identifier
	Catalog number		Date of manufacture
	Caution		Manufacturer
	Prescription use only		Medical device
	Consult instructions for use		Non-sterile