

# CLEANING AND STERILIZATION PROTOCOL

## Arsenal Plating System



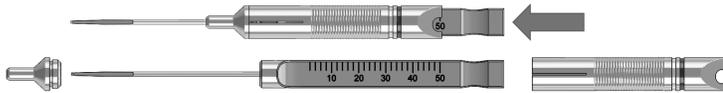
### CLEANING

Non-sterile products must be carefully and thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents.

#### System Instrumentation Disassembly Instructions:

The provided Depth Gauges (330-22-005, 330-27-005) should be properly disassembled prior to cleaning. The following instructions demonstrate how to properly disassemble the provided Depth Gauges prior to cleaning and then reassemble:

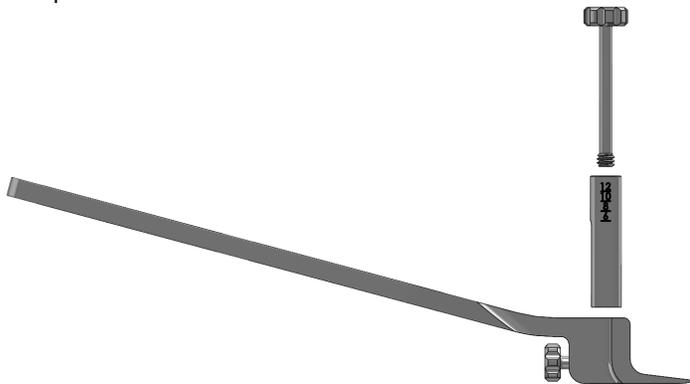
- To remove the cone piece without wire damage, tap the back of the depth gauge firmly on a table. **DO NOT REMOVE THE ATTACHED WIRE.**



- To reassemble after cleaning, pull the slide back through the body to protect the wire and snap the cone piece onto the body.
- Proceed to Calcaneal Slide Plate Placement Guide disassembly instructions.

The provided Calc Slide Plate Placement Guide (330-86-001) should be properly disassembled prior to cleaning. The following instructions demonstrate how to properly disassemble the provided Calc Slide Plate Placement Guide prior to cleaning:

- Unthread the two screws by rotating counterclockwise to separate as shown:



- Proceed to Cleaning Instructions.

#### Instrumentation Cleaning Instructions

Trilliant Surgical recommends the following cleaning and sterilization instructions:

#### Recommended Automatic Cleaning Instructions:

- Rinse with tap water to remove gross soil
- Inject water (60mL) into cannulation to remove gross soil
- Prepare enzymatic detergent (Enzol®) at manufacturer recommendation (1oz/gal) using lukewarm tap water and fully immerse parts
- Use a soft bristled brush (Spectrum M16 or equivalent) and appropriately sized lumen brush to brush all surfaces
- Use syringe to inject detergent (60mL) into cannulation
- Allow articles to dwell in detergent bath for 1 minute

- Remove parts from bath and rinse using reverse osmosis/deionized (RO/DI) water
- Fill syringe with RO/DI water (60mL) and flush part cannulation, where applicable
- Transfer parts into automated washer (STERIS® Reliance Genfore) for processing using the following parameters:

| Phase       | Recirculation Time | Temperature    | Detergent Type and Concentration     |
|-------------|--------------------|----------------|--------------------------------------|
| Pre-wash 1  | 02:00              | Cold tap water | N/A                                  |
| Enzyme Wash | 02:00              | Hot tap water  | Enzol®<br>1 oz/gal                   |
| Wash 1      | 02:00              | 65.5°C         | Prolystica® 2X Neutral<br>1/8 oz/gal |
| Rinse 1     | 01:00              | Hot tap water  | N/A                                  |
| Drying      | 15:00              | 90°C           | N/A                                  |

- Visibly inspect for remaining soil on part
- If the part is not visibly clean, repeat steps 1-10

#### Recommended Manual Cleaning Instructions:

- Rinse with tap water to remove gross soil
- Inject water (60mL) into cannulation to remove gross soil
- Prepare enzymatic detergent (Enzol®) at manufacturer recommendation (1oz/gal) using lukewarm tap water and fully immerse parts
- Use a soft bristled brush (Spectrum M16 or equivalent) and appropriately sized lumen brush to brush all surfaces
- Use syringe to inject detergent (60mL) into cannulation
- Allow articles to dwell in detergent bath for 1 minute
- Remove parts from bath and rinse using reverse osmosis/deionized (RO/DI) water
- Fill syringe with RO/DI water (60mL) and flush part cannulation, where applicable
- Allow parts to air dry. A clean lint-free cloth may be used to aid in drying
- Visibly inspect for remaining soil on part

#### NON-STERILE PRODUCT STERILIZATION

Trilliant Surgical Implant Systems can be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer's user instructions. The user facility must thoroughly clean and disinfect instruments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed:

| Sterilization Method | Pre-Vacuum Steam |
|----------------------|------------------|
| Condition            | Wrapped*         |
| Temperature          | 270°F (132°C)    |
| Time                 | 4 minutes        |
| Recommended Dry Time | 60 minutes       |

\* The system shall be packaged for sterilization by double wrapping in an FDA cleared wrap and wrapping techniques outlined per ANSI/AAMI ST79, then adhered with FDA cleared chemical indicator autoclave tape.  
Note: Do not stack trays during sterilization.

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