

CLEANING AND STERILIZATION PROTOCOL



Arsenal Plating System

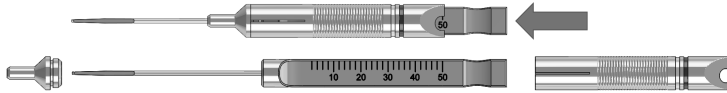
CLEANING

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:

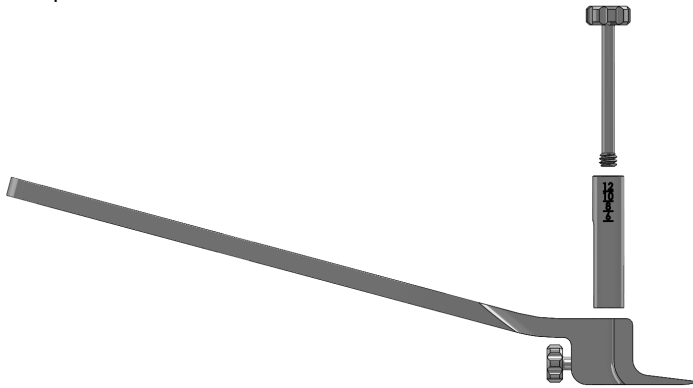
1. To remove the cone piece without wire damage, tap the back of the depth gauge firmly on a table. **DO NOT REMOVE THE ATTACHED WIRE.**



2. To reassemble after cleaning, pull the slide back through the body to protect the wire and snap the cone piece onto the body.
3. 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:

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



2. Proceed to Cleaning Instructions.

Instrumentation Cleaning Instructions

Trilliant Surgical recommends the following cleaning instructions for reusable instrumentation:

Recommended Automatic Cleaning Instructions:

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

7. Remove parts from bath and rinse using reverse osmosis/deionized (RO/DI) water
8. Fill syringe with RO/DI water (60mL) and flush part cannulation, where applicable
9. 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® 1 oz/gal
Wash 1	02:00	65.5°C	Prolystica® 2X Neutral 1/8 oz/gal
Rinse 1	01:00	Hot tap water	N/A
Drying	15:00	90°C	N/A

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

Recommended Manual Cleaning Instructions:

1. Rinse with tap water to remove gross soil
2. Inject water (60mL) into cannulation to remove gross soil
3. Prepare enzymatic detergent (Enzol®) at manufacturer recommendation (1oz/gal) using lukewarm tap water and fully immerse parts
4. Use a soft bristled brush (Spectrum M16 or equivalent) and appropriately sized lumen brush to brush all surfaces
5. Use syringe to inject detergent (60mL) into cannulation
6. Allow articles to dwell in detergent bath for 1 minute
7. Remove parts from bath and rinse using reverse osmosis/deionized (RO/DI) water
8. Fill syringe with RO/DI water (60mL) and flush part cannulation, where applicable
9. Allow parts to air dry. A clean lint-free cloth may be used to aid in drying
10. 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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