

CLEANING AND STERILIZATION PROTOCOL

Minimally Invasive Bunion Plating System



Introduction

This document is intended to establish safe and effective reprocessing procedures in health care facilities for the Minimally Invasive Bunion Plating System.

Warning and Precautions

All non-sterile products must be carefully cleaned promptly prior to sterilization and proper sterilization must be performed prior to use.

Trilliant Surgical instruments within the Minimally Invasive Bunion Plating System are intended to contact normally sterile tissue or body space during use. Due to this intended use it is considered a critical device and must be thoroughly cleaned and sterilized after each use. Do not allow contaminated devices to dry prior to cleaning and reprocessing as subsequent reprocessing steps are facilitated by not allowing blood, bodily fluid, bone and tissue debris, saline, or disinfectants to dry on used instruments.

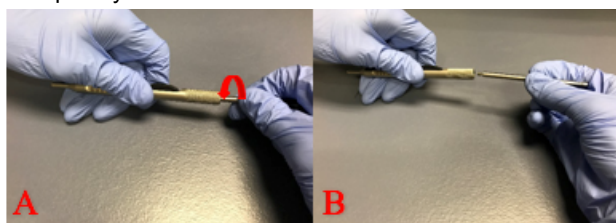
CLEANING

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 Gauge (310-00-010) should be properly disassembled prior to cleaning. The following instructions demonstrate how to properly disassemble the provided Depth Gauge prior to cleaning:

1. While holding the depth gauge, unthread the back slide from the main body in a counter-clockwise motion and remove completely.



2. While holding the depth gauge, remove the thumb slide (black piece) from the depth gauge by pulling the slide up from the slot. DO NOT REMOVE THE ATTACHED WIRE



3. Proceed to provided cleaning instructions.

Cleaning Instructions

Trilliant Surgical recommends the following cleaning instructions for all system components and 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. Thoroughly rinse components using reverse osmosis / deionized (RO/DI) water for at least one minute
11. Allow parts to air dry. A clean lint-free cloth may be used to aid in drying
12. Visibly inspect for remaining soil on part

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

Tray Base and Tray Lid Cleaning Instructions:

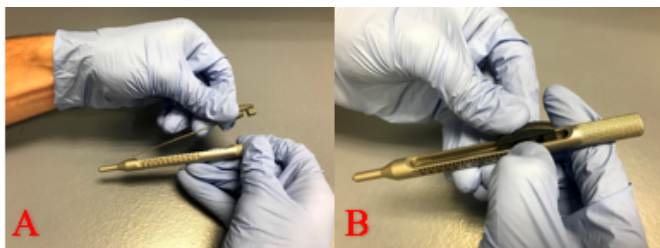
Trilliant Surgical recommends the following cleaning instructions for the system tray and tray lid:

1. Thoroughly clean the tray base and tray lid to remove gross soil.
2. Cycle tray base and tray lid through automated washer (STERIS® Reliance Genfore) for processing using the parameters detailed above.
3. Visibly inspect the tray base and tray lid for remaining soil on components.

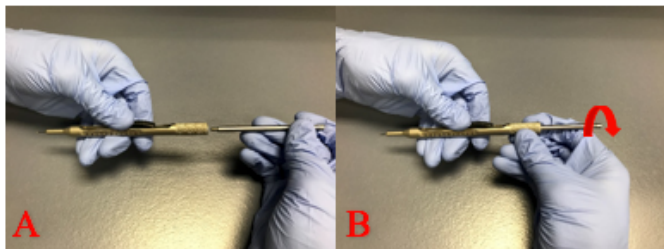
System Instrumentation Assembly Instructions:

Following proper cleaning, reassemble the provided Depth Gauge in the following manner prior to sterilization:

1. While holding the depth gauge insert the wire through the slot into the smaller diameter cannulation. Insert the thumb slide (black piece) into the depth gauge slot by squeezing the underside tabs and pressing firmly on the thumb slide until it “snaps” into place.



2. Thread the back slide into the depth gauge in a clockwise motion until hand tight.



3. Proceed to provided sterilization instructions.

NON-STERILE PRODUCT STERILIZATION

The Minimally Invasive Bunion Plating System 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 clean instruments promptly 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	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	40 minutes
Dry Time	Recommended 50 minutes**	Recommended 50 minutes**

*The system shall be packaged for sterilization by double wrapping in standard central supply wrap (i.e. Bio-Shield® Sterilization Wrap).

**Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.

*** Do not stack trays during sterilization

Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

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