

CLEANING AND STERILIZATION PROTOCOL

Two-Step Hammer Toe Implant System



Introduction

This document is intended to establish safe and effective reprocessing procedures in health care facilities for the Two-Step Hammer Toe Implant 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 Two-Step Hammer Toe Implant 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. No system components or instrumentation require disassembly prior to cleaning.

Cleaning Instructions

Trilliant Surgical recommends the following cleaning and sterilization 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	Polystica® 2X Neutral 1/8 oz/gal
Rinse 1	01:00	Hot tap water	N/A
Drying	15:00	90°C	N/A

NOTE: References to "tap water" shall be considered equivalent to "Utility Water" per AAMI TIR34

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) detergent 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 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 components

NON-STERILE PRODUCT STERILIZATION

Two-Step Hammer Toe 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 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	30 minutes
Recommended Dry Time	50 minutes**	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.
**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.
NOTE: Do not stack trays during sterilization.

The proposed sterilization cycle (Gravity - 132°C exposure time 30 min.) is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. 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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