

CLEANING AND STERILIZATION PROTOCOL

Twist Subtalar Implant and Disco Subtalar Implant Systems



CLEANING

Non-sterile products must be carefully 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. Trilliant Surgical recommends the following cleaning and sterilization instructions:

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

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 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	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	15 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.

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