INTREPED®

Processing Instructions

Intraosseous Fusion Device

INTRODUCTION: This document prescribes the cleaning, inspection, sterilization, and storage processes required for the IFD kit contents to be ready for surgical use. The IFD kit is comprised of implants (single-use) and instruments (both reusable and single-use) that are supplied non-sterile and must be fully processed prior to use. The IFD caddies and tray are intended for sterilization, transport, and storage of medical devices. They are not designed or validated for automated cleaning in the fully equipped state. Following surgical use, any used or soiled (contaminated), reusable instruments must be removed from the caddies/tray for cleaning and then, following inspection, returned to the caddies/tray for sterilization. Used single-use instruments and soiled implants must be discarded according to facility guidelines.

PRECAUTIONS:

- Do not use metal brushes/sponges or abrasive cleaners.
- Do not allow contaminated devices to dry prior to cleaning and reprocessing.
- Do not use highly alkaline or hypochlorite salt solutions because of pitting and corrosion risk.
- Extra cleaning attention is required for features such as moving assemblies, textured surfaces, cannulations, and blind holes. Users must check that cavities and cannulations are clear of debris throughout the reprocessing procedure.
- Devices should only be used and reprocessed by qualified and trained healthcare staff. Caution should be exercised when handling devices with sharp points or cutting edges.

CLEANING:

POINT OF USE PREPARATION:

- Separate soiled instruments from clean instruments.
- Wipe excess blood and/or debris from device.
- Flush cannulated devices with sterile or purified water.
- To prevent material drying, store devices under dampened towel or in water bath.
- Reprocess as soon as is reasonably practical following use.

DISASSEMBLE: Disassemble the device, if applicable, prior to cleaning. Do NOT attempt to disassemble ratcheting driver handles.

RINSE: Rinse soiled device under cool running tap water for a minimum of 2 minutes. Use a syringe, pipette, or water jet to flush a minimum of 10ml of water through any cannulation in the device. Use a soft-bristled brush to remove gross soil and debris.

SOAK: Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions. Immerse and soak the device in the cleaning solution for a minimum of 10 minutes.

SCRUB: Manually clean the device for a minimum of 1 minute within the soak solution. Use a soft-bristled brush to remove soil from the outside of the device. Use an appropriately sized bottlebrush or pipe cleaner to remove soil from any cannulation in the device by fully inserting and twisting the brush through the entire passage (3 times minimum). Fully actuate any moving components (3 times minimum).

RINSE: Rinse device under cool running tap water for a minimum of 2 minutes. Use a syringe, pipette, or water jet to flush a minimum of 10ml of water through any cannulation in the device.

INSPECT: Inspect the device for any appearance of soil or detergent residue. If soil or detergent is detected, repeat the previous four steps.

ULTRASONIC CLEANING: Prepare a fresh cleaning solution and place within ultrasonic cleaner. Clean device ultrasonically for a minimum of 15 minutes using a minimum frequency of 40kHz.

FINAL RINSE: Rinse device with deionized (DI) or purified (PURW) water for a minimum of 2 minutes. (Final rinse water should meet Critical Water specifications according to AAMI TIR34.) Use a syringe, pipette, or water jet to flush a minimum of 10ml of (DI or PURW) water through any cannulation in the device.

DRY: Dry the device using a clean, lint-free cloth or clean compressed air. Dry any cannulation with clean compressed air (or syringe).

INSPECTION: After cleaning and prior to sterilization, the devices should be inspected for cleanliness, damage, function, and markings. Damage can include but is not limited to corrosion, discoloration, excessive scratches, cracks, and wear. Cutting edges should be free of nicks and have a continuous edge. Driving features should be free of wear and deformation and have a continuous surface along the drive feature profile. If damage is detected that compromises device function, do not use the device. Reassemble device, if applicable.

HANDLE CARE:

- Functionally inspect ratcheting driver handles to ensure that they connect to mating driver components and function in both clockwise and counterclockwise drive directions. If damage is detected that compromises handle function, do not use the handle.
- Prior to sterilization, lubricate moving parts with a water-based surgical-grade instrument lubricant that is compatible with steam sterilization. Follow lubricant manufacturer's instructions.

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PACKAGING:

- The cleaned and inspected devices should be assembled into their appropriate location within the IFD caddies & trays.
- Prior to sterilization, the IFD tray should be double-wrapped with an FDA cleared sterilization wrap according to the ANSI/AAMI ST79 method.

STERILIZATION:

- Steam sterilize according to the following validated sterilization cycle:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME*	COOL DOWN TIME*
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	50 Minutes	30 Minutes (Wire Rack)

*This sterilization cycle 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).

STORAGE:

- Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes in temperature and humidity.

Date of Manufacture
Manufacturer
REF Catalog Number
Non-Sterile
LOT Batch Code
Do NOT Re-use
Consult Instructions for Use

For product inquiries, cleaning instructions, surgical techniques, or to report any adverse event, please visit us at **www.AuxanoMedical.net**

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AUXANO MEDICAL

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