ARKEO®

Processing Instructions

Auxano® Wedge Fixation System

INTRODUCTION: This document prescribes the cleaning, inspection, sterilization and storage processes required for the Auxano® Wedge Fixation System (WFS) kit contents to be ready for surgical use. The Auxano® WFS 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 Auxano® WFS 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 reprocessing procedure.
- Devices should only be used and reprocessed by qualified and trained healthcare staff. Caution should be exercised when handling devices with sharps 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. Within the Auxano® WFS tray, this applies to the inserter, which consists of a handle and draw rod. These components exist separately within the tray, but may be engaged during surgery for implant placement. In the event that they are used for implant placement, the handle and draw rod will need to be disassembled at the point of use. Do NOT attempt to disassemble components of draw rod at any point.

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 appropriate sized bottle-brush 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 4 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 critical water, meeting relevant standards definition, such as ANSI/AAMI ST108, for a minimum of 2 minutes. Use a syringe, pipette or water jet to flush a minimum of 10ml of critical 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, ensure the devices are thoroughly cleaned. 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. Threaded features on draw rod should have a fully intact thread profile. If damage is detected that compromises device function, do not use the device. Reassemble device, if applicable.

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PACKAGING:

- The cleaned and inspected devices should be assembled into their appropriate location within the Auxano® WFS caddies & trays. Place the inserter handle and draw rod in their appropriate locations within the tray. Inserter handle and draw rod should not be assembled in the sterilization tray.
- Prior to sterilization, the Auxano® WFS 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*
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	Minimum 40 Minutes

*Outside of standard sterilization cycle timing. Requires manual cycle & process modification.

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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