REPROCESSING INSTRUCTIONS FOR REUSABLE INSTRUMENTS

INTRODUCTION

This document is intended to establish safe and effective reprocessing procedures in health care facilities for the Field Orthopaedics (FO) reusable extremity trauma products, including the NX Extremity Nail System and Micro Screw System.

This procedure details the requirements to:

- Minimise the organic soil transfer from one patient to another.
- Prevent accumulation of residual soil through the product's use life.
- Allow for successful, subsequent sterilisation steps.

WARNING AND PRECAUTIONS

This instruction is not intended for implants, tissue products, or disposable instruments. Sterilisation requirements for implants are contained in the Instructions for Use (IFU) for the FO device and should be strictly adhered to. FO surgical instruments are provided NON-STERILE, unless explicitly labelled STERILE. Instruments provided non-sterile must be sterilised prior to use.

FO surgical instruments are intended to contact normally sterile tissue or body space during use. Due to this intended use, they are considered critical devices and must be thoroughly cleaned and sterilised 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.

Surgical instrumentation of complexity (multiple components, moving components, textured surfaces, cannulations) require special attention and must be manually cleaned prior to processing through an ultrasonic cleaner. Avoid highly alkaline conditions and hypochlorite solutions as they can damage and corrode surgical instruments.

Please treat instruments that may have been exposed to Creutzfeldt-Jakob Disease (CJD) according to the health care facility's standard operating procedure. Sterilisation parameters recommended in this document or the device IFU are not intended and not suitable for inactivation of prions. Contact World Health Organization (WHO) or local regulatory authorities for further information on special CJD inactivation processing procedures

LIMITATIONS AND RESTRICTIONS OF REPROCESSING

Surgical instruments are designed for their durability and ability for reuse. FO reusable instruments are typically manufactured from stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments. End of functional life is normally determined by wear and damage due to use.

Devices labelled for single use only should never be reused. Reuse of these devices may potentially result in serious patient harm.

Examples of hazards related to the reuse of these devices include, but are not limited to:

- Significant degradation in device performance.
- Cross-infection.
- Contamination.

CLEANING AND DECONTAMINATION

To assist health care personnel in the decontamination processes and procedures for various types of reusable surgical instruments, this section provides guidelines for the selection and use of available cleaning and microbicidal processes.

The cleaning process must be thorough, as residual organic matter or large numbers of microorganisms can significantly reduce the effectiveness of the subsequent microbicidal process. An outline of the reprocessing procedures is shown below in Figure 1.

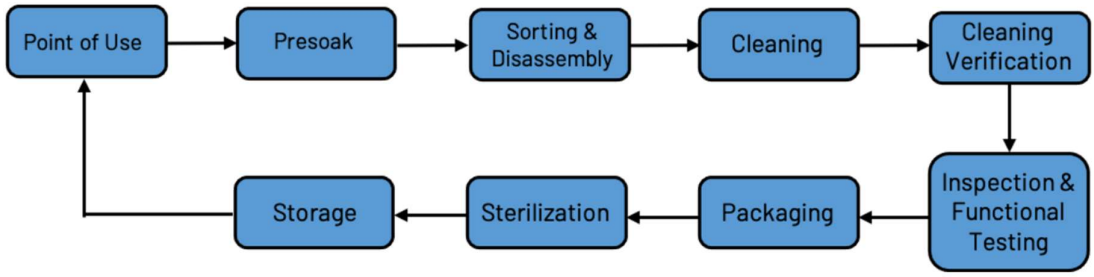

Figure 1: Reprocessing procedure flow chart

POINT OF USE

The cleaning of instruments should begin at the point of use, during the surgical procedure, to prevent drying of blood, soil and debris on the surface and within lumens. The instruments should be kept free of debris and blood during the surgical procedure. If possible, the instruments should be wiped clean using a sterile, water-moistened sponge. Care must be taken that the sponge is not used on the tissues of the patient.

Instruments with lumens should be cleared using the FO cleaning stylet and flushed with a sterile, water-filled syringe to remove blood and debris and prevent drying of the gross soil.

Instruments that may not be used for the remainder of procedure must be immediately soaked in a basin containing sterile water.

Prolonged exposure to saline should be avoided to minimise the potential for corrosion.

PRE-SOAKING

Pre-soak the instruments with an enzymatic solution, such as Enzol® by Advanced Sterilization Products®, for a minimum of 1 minute to moisten and loosen the soil, thus making the cleaning step more efficient.

Rinse thoroughly to ensure the removal of any potentially harmful residue from the soaking solution.

When pre-soaking the instruments, refer to the solution manufacturer's written instructions for the correct dilution, temperature, and soak time.

SORTING AND DISASSEMBLING

Upon arrival in the decontamination area, remove the contaminated items from their transport containers, and prepare for cleaning. Check all instruments for damage and corrosion prior to cleaning. If a component is lost, damaged, or corroded then contact FO directly or your local representative for a replacement.

If the device consists of more than one component, and designed to be disassembled, this device must be disassembled prior to cleaning and disinfection. Keep non-interchangeable components of assemblies together to ensure correct reassembly.

CLEANING

For reusable medical devices, the most important step in decontamination is thorough cleaning and rinsing. Cleaning primarily removes rather than kills microorganisms.

The factors that contribute to cleanliness are:

- The quality of water.
- The quality, concentration of and type of cleaner.
- Washing method.
- Rinsing and drying.
- The time, temperature and load capacity of the equipment being used.
- Preparation of the contaminated devices.
- Operator performance.

Many types of soil could be present on a device, but dried blood is especially difficult to remove. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to clean. It must be rehydrated and then washed.

When using ultrasonic cleaning, to prevent coagulation, do not exceed temperatures of 140°F (60°C) and conduct for a period of 10 minutes. Instruments are optimally cleaned in water and detergent solutions at temperatures between 80°F and 110°F (27° to 44°C), but not to exceed 140°F (60°C).

When cleaning instruments, use a brush, cloth, or sponge, and a low foaming, pH neutral detergent solution, such as Renu-Klenz™, or equivalent. Use a soft bristle brush to

remove all traces of blood and debris; pay close attention to textured areas, crevices, blind holes, hinges, joints, and cannulated parts.

When cleaning an articulating instrument, fully immerse the instrument in the detergent and remove traces of blood and debris with a soft bristle brush. If the instrument can be articulated, retract and open the instrument in the detergent repeatedly.

Heavy instruments should not be placed on top of delicate instruments and small components should be placed in baskets.

Rinse components under warm or hot flowing water for at least one minute, with direct contact of each surface for a minimum of 10 seconds. Repeat this step using purified water.

Dry the internal areas of instruments using compressed air. When drying instruments with concave features, place the concave surface down to facilitate draining.

CLEANING VERIFICATION

Inspect all instruments before sterilising to ensure the complete removal of all soil from surfaces, tubes, holes, and moveable parts. The ANSI/AAMI ST79 acceptance standard for cleanliness is visibly clean.

Some surfaces of an instrument can be visually obstructed which prevents this verification. If a borescope is not available for inspection, checking for blood can be accomplished by immersing or flushing the instrument in a 3% hydrogen peroxide solution.

If bubbling is observed, blood is present, and cleaning must be repeated. Rinse instruments thoroughly after using hydrogen peroxide solution.

INSPECTION AND FUNCTIONAL TESTING

Instruments should be inspected for damage and wear. Check for smooth movement of assemblies without excessive play. Locking mechanisms should attach and detach easily. Cutting edges should be free of nicks and have a continuous edge. Long slender instruments should be straight and free of distortion.

Remove any excessive moisture on instruments with a clean, absorbent, and non-shedding wipe.

PACKAGING

Load instruments in the FO instruments trays that are provided with the kits. When possible, instruments should be placed in the holders in an open position.

If packaged individually, a standard packaging material may be used and packed in accordance with local packaging procedures or ANSI/AAMI ST46-1993.

STERILISATION

The recommended autoclave cycle is stated on the FO product insert and IFU which is available for download on the FO website (www.fieldorthopaedics.com/brochures).

STORAGE

Store sterile packaged instruments in a manner that provides protection from dust, moisture, insects, vermin, and extreme temperature or humidity.

Store away from moisture and direct heat. Please DO NOT stack the FO carry trays.

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