

Surgical Instruments

Reprocessing Instructions for Reusable Instruments

Document Number: 90-001, Rev H

Introduction

This document is intended to establish safe and effective reprocessing procedures in health care facilities for surgical instruments supplied by Nexxt Spine®. This procedure details the requirements to 1) minimize the organic soil transfer from one patient to another 2) prevent accumulation of residual soil through the product's use life, and 3) allow for successful, subsequent sterilization steps. These instructions encompass the following systems:

- Inertia® Pedicle Screw System
- Blade® Anterior Cervical Plate System
- Honour® Spacer system
- Facet Fixx® System
- Inertia® MIS Pedicle Screw System
- Struxxure® Anterior Cervical Plate System
- NEXXT MATRIX® System
- Saxxony® Posterior Cervical Thoracic System
- NEXXT MATRIX® Stand Alone Cervical System

Warning and Precautions

This instruction is not intended for implants or disposable instruments. Sterilization requirements for implants are contained in the IFU and should be strictly adhered to. Nexxt Spine surgical instruments are provided non-sterile unless it is explicitly labeled sterile. Instruments provided non-sterile must be sterilized prior to use.

Nexxt Spine surgical instruments 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.

Surgical instrumentation of complexity (multiple components, moving components, textured surfaces) requires 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. Sterilization parameters recommended in this document or the device's 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.

Contact Information

Nexxt Spine, LLC.
14425 Bergen Blvd, Suite B
Noblesville, IN 46060
317-436-7801
www.nexxtspine.com

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*.

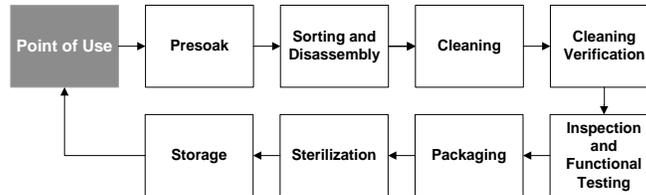


Figure 1

Point of Use

Reprocessing begins at the point of use, which includes initial cleaning measures to prevent drying of the soil and contaminants in and on the device. Prolonged exposure to saline should be avoided to minimize the potential for corrosion.

Presoaking

Presoaking the instruments with an enzymatic solution, such as Enzol® by Advanced Sterilization Products®, for a minimum of 1 minute will moisten and loosen the soil, thus making the cleaning step more efficient. Rinsing thoroughly ensures the removal of any potentially harmful residue from the soaking solution. When presoaking the instruments, personnel should 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, contaminated items should be removed from their transport containers, and prepared for cleaning. All instruments should be checked for damage and corrosion prior to cleaning. If a component is lost, damaged, or corroded then contact Nexxt Spine directly or your local representative.

If the device consists of more than one component, and is designed to be disassembled, the instrument should be disassembled prior to cleaning and disinfection. Noninterchangeable components of assemblies shall be kept together to ensure correct reassembly. Instruments that are complex and/or designed to be disassembled prior to cleaning are provided in Appendix A of this document.

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: quality of water; the quality, concentration, and type of cleaner; washing method; rinsing and drying; preparation of the contaminated devices; the time, temperature, load capacity of the equipment being used; and 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. Ultrasonic cleaning should not exceed temperatures of 140°F (60°C) to prevent coagulation and should be ran 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. They should be cleaned with a brush, cloth, or sponge, and a low foaming, pH neutral detergent solution, such as Renu-Klenz™ by Steris Corporation®, 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 sterilizing 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 and prevents this verification. If a boroscope 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 then 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. Instruments should be removed of any excessive moisture with a clean, absorbent, and non-shedding wipe.

Packaging

Instruments should be loaded in the instruments trays that are provided with the sets. 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.

Sterilization

The recommended autoclave cycle is stated on the product insert, which is supplied with the set, in the individual packaging of the product, or on the company's website at www.nexxtspine.com.

Storage

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

Appendix A

PN# I21-01-01, Honour® PLIF and PN# I54-01-01, NEXXT MATRIX® System TLIF Oblique Inserter



Figure 2



Figure 3



Figure 4

Detailed Instructions:

- Unthread and separate inner shaft from outer body.
- The I.D. and inside corners of the outer shaft in Figure 3 should be thoroughly cleaned with a nylon brush.

- The internal and external threads in Figure 4 should be thoroughly cleaned with a nylon brush. The

PN# I15-01-01, (Honour® & NEXXT MATRIX® System) TLIF Inserter



Figure 5



Figure 6



Figure 7

Detailed Instructions:

- Unthread and separate the inner shaft from outer body.

- The I.D., external grooves of the outer tube, and external thread of the inner shaft, shown in Figure 6, should be thoroughly cleaned with a nylon brush.
- The internal and external threads in Figure 7 should be thoroughly cleaned with a nylon brush. The

PN# I10-33-07, Inertia® Polyaxial Screw Inserter



Figure 8

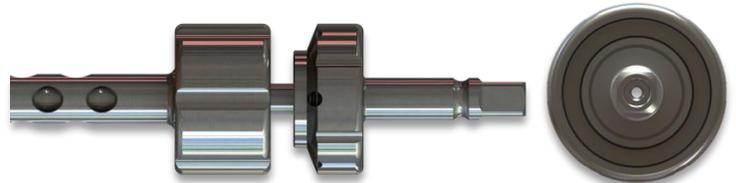


Figure 9



Figure 10



Figure 11

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.
- The cannulation, shown in figure 9, should be thoroughly cleaned with an appropriately sized guide wire, and/or a syringe.

- The external threads and outer sterilization ports, shown in Figure 10, should be thoroughly cleaned with a small nylon brush.
- The locking wheel, threads, and sterilization ports, shown in Figure 11, should be thoroughly cleaned with a nylon brush while moving the lock in alternating positions.

PN# I30-13-02, Blade® Spring-Loaded Awl



Figure 12



Figure 13



Figure 14

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.
- The trocar tip, outer sterilization ports, and inner shaft, shown in Figure 13, should be thoroughly cleaned with a small nylon brush.
- The green handle, outer ports, and inner shaft, shown in Figure 14, should be thoroughly cleaned with a nylon brush and/or a syringe. Special care should be taken to properly flush out the green handle as the internal spring mechanism can act as a cavity and retain blood.

PN# I10-32-02, Inertia® Rod Reducer



Figure 15



Figure 16



Figure 17

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.
- The sliding plunger, linkage, slots, and I.D. shown in Figure 16 should be thoroughly cleaned with a nylon brush and/or syringe while opening and closing the instrument.

- The handle, shown in figure 17, should be cleaned below the exterior surfaces and special attention should be given around the pin areas.

PN# I10-35-01, Inertia® One-Shot® Screw Inserter



Figure 18



Figure 19



Figure 20

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.

- The external threads and outer sterilization ports, shown in Figure 19, should be thoroughly cleaned with a small nylon brush.
- The green locking wheel, threads, and sterilization ports, shown in Figure 20, should be thoroughly cleaned with a nylon brush while moving the lock in alternating positions.

PN# I10-01-11, Inertia® Torque Limiting Handle



Figure 21



Figure 22



Figure 23

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.
- The I.D., shown in Figure 22, should be thoroughly cleaned with a nylon brush and a syringe.
- The locking sleeve, shown in figure 23, should be moved in alternating positions while scrubbing with a nylon brush.

PN# I30-14-03, Blade® DTS Guide



Figure 24



Figure 25



Figure 26

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.

- The articulating attachment fingers, slots, and inside corners, shown in Figure 25, should be thoroughly cleaned with a nylon brush and/or syringe while moving the fingers to alternating positions.
- The holes, shown in figure 26, should be cleaned using a nylon brush.

PN# I14-14-10, Facet Fixx®



Figure 27

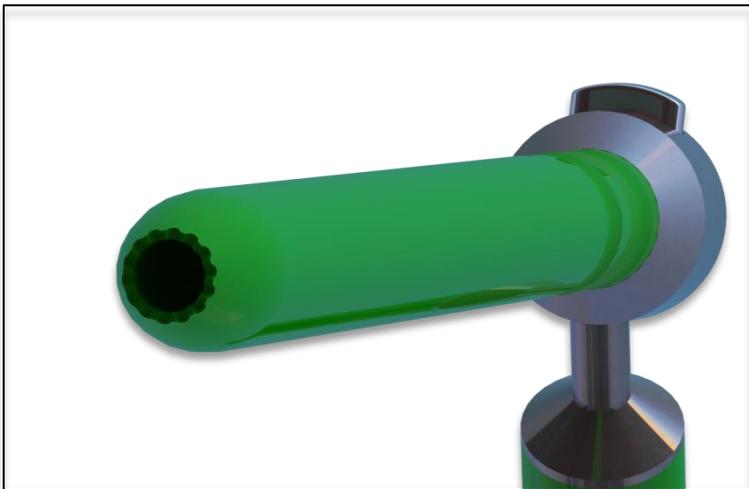


Figure 28



Figure 29

Detailed Instructions:

- Cleaning for this instrument should be completed while the unlock button is immersed in the cleaning solution.
- The serrated teeth located at the tip of the instrument, shown in figure 28, should be carefully cleaned with a nylon brush.
- The internal features of the button, shown in figure 29, should be carefully cleaned with a nylon brush while actuating the button back and forth manually.

PN# I14-01-01, Facet Fixx® Inserter



Figure 30



Figure 31

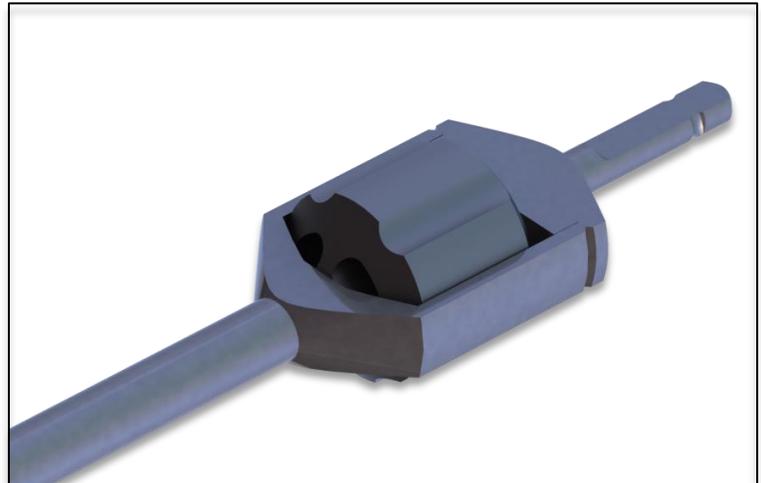


Figure 32

Detailed Instructions:

- Cleaning for this instrument should be completed while immersed in the cleaning solution.

- The external threads and outer sterilization ports, shown in Figure 31 should be thoroughly cleaned with a small nylon brush.
- The thumb wheel, and internal ports, and shaft shown in Figure 32, should be thoroughly cleaned with a nylon brush while moving the thumb wheel in alternating positions.