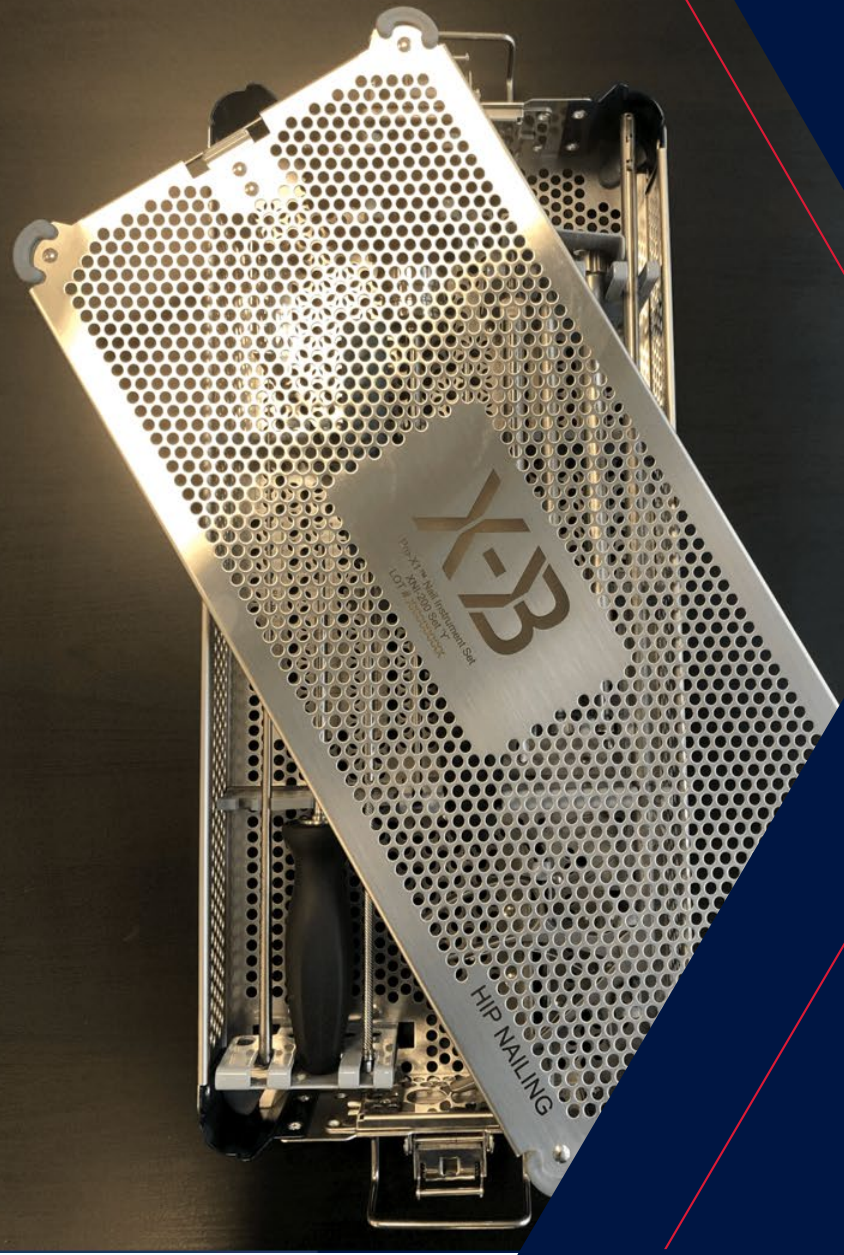
Pro-X1® Trochanteric Nailing System

Instrument Reprocessing Instructions

X-Bolt Trauma Orthopedics



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1. Introduction

This Document is created based on the requirements of EN ISO 17664, Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

These reprocessing instructions apply to the X-Bolt Orthopedics' instrument sets; Set-X and Set-Y. The purpose of these recommendations is to assist both the hospital and central supply management in developing procedures for the safe and effective reprocessing of X-Bolt Orthopedics' reusable instruments.

These recommendations do not apply to sterile single-use implants, such as the Pro-X1® Trochanteric Nailing System, femoral head k-wire, and drill bits.

Warnings and Precautions

- Surgical instruments are used with or on patients who may harbour both recognised and unrecognised infections. To prevent the spread of infection, all reusable instruments must be thoroughly cleaned and sterilised **prior to** initial use **and after** each patient use.
- Devices labelled "for single use"  must not be reprocessed for re-use. Please refer to the device label to identify single or multiple use and/or cleaning and re-sterilisation release.
- Instruments may have sharp edges or features. Caution should be exercised when handling instruments.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment.
- **Metal brushes or scoring pads must not be used during manual cleaning procedures.** These items may damage the surface and finish of the instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.

Decontamination Considerations – Creutzfeldt-Jakob Disease

- The agents for transmission of Creutzfeldt-Jakob Disease (CJD) are believed to be resistant to normal processing methods of disinfection and sterilisation. Therefore, the methods of decontamination and sterilisation outlined below may not be appropriate where CJD transmission is a risk.
- It is outside the scope of this document to describe in detail the precautions that should be taken for transmissible spongiform encephalopathy agents.
- Refer to the World Health Organisation (WHO) guidelines for a detailed listing of appropriate decontamination methods.

Indications for Use

The Pro-X1® Trochanteric Nailing Instrument sets are indicated for use in the implantation of the Pro-X1® Trochanteric Nailing System manufactured by X-Bolt Orthopedics.

Contraindications

The Pro-X1® Trochanteric Nailing Instrument sets supplied by X-Bolt Orthopedics are not designed, sold or intended for use other than indicated. Only use instruments supplied by X-Bolt Orthopedics as the safety and efficacy of other devices cannot be guaranteed.

Limitations on reprocessing

Repeated processing, according to these instruction, has minimal effect on and should not compromise the performance of the re-usable Pro-X1® Trochanteric Nailing Instrument sets. End of life is determined by damage due to use detected during receiving inspection.

Receiving Inspection

- Upon receipt in the hospital, instrument sets should be inspected for completeness.
- Marking on instruments must be legible. These may include gauge markings, angles etc. Notify your X-Bolt Orthopedics' distributor if markings are not legible.
- The graduations on devices with a measuring function are accurate to ±1mm

Damage Inspection

- Inspect the instruments for damage, wear & corrosion at all stages of handling.
- Cutting edges should be free of damage and present a continuous edge.
- Check all instruments with long slender features for distortion.

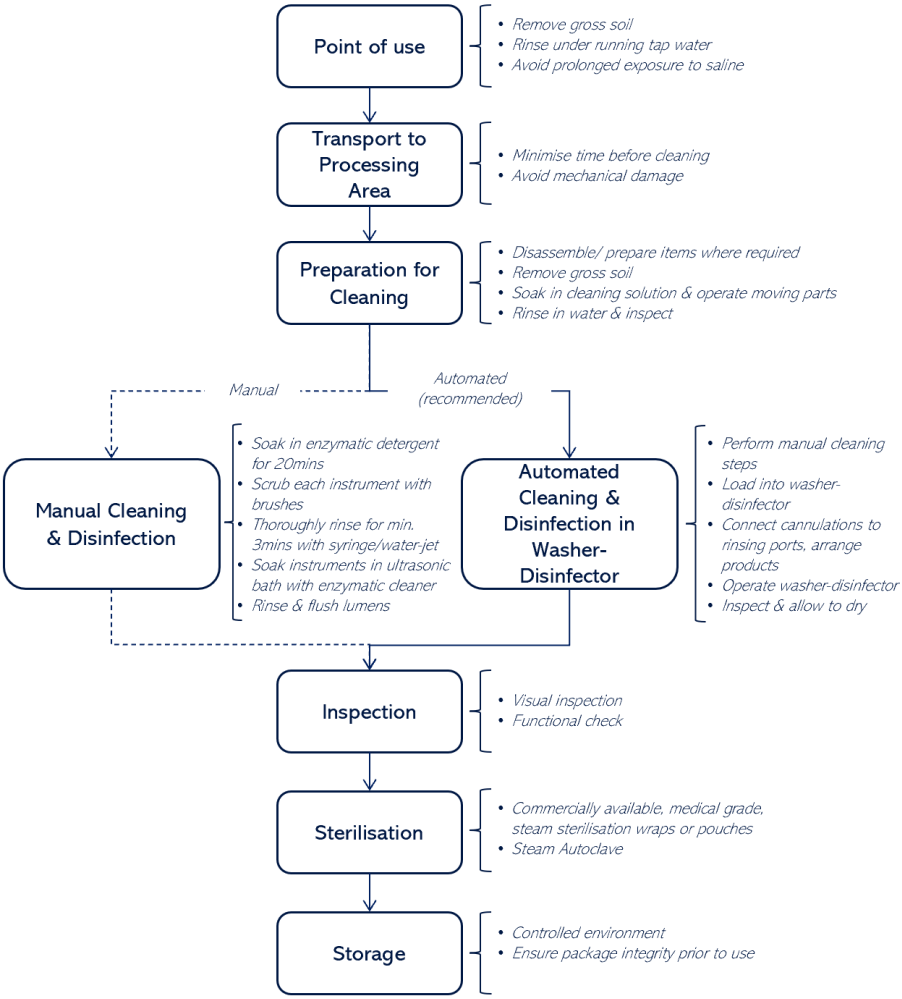
Information for Cleaning and Sterilisation of Surgical Instruments

Most instrument systems include inserts / trays and a container(s). Many instruments are intended for use with a specific implant. It is essential that the surgeon and operation room staff are fully conversant with the appropriate surgical technique for the instruments and associated implant.

These reprocessing instructions apply to the Pro-X1® Trochanteric Nailing System.

2. Reprocessing Instructions

A summary flowchart for the steps required to prepare medical devices for re-use or to prepare new medical devices for initial use is provided below.
More detailed instructions can be found on the following pages.



Point of use

- Clean the device as soon as possible after use.
- Avoid prolonged exposure with saline to minimise risk of corrosion.
- Remove excess soiling with a disposable non-shedding wipe.

Transport

- Observe universal precautions for handling contaminated/bio-hazardous waste.
- Instruments should be cleaned as soon as possible after use to minimise the potential for drying prior to cleaning.

Preparation for Cleaning

- Where applicable, multi-component instruments should be disassembled/fixed in their "open" position using breakaway tabs (or similar).
- Prepare a neutral pH or nearly neutral pH enzymatic detergent at the use-dilution and temperature recommendations of the agent's manufacturer.

Note: *It is important to select enzymatic solutions intended for breakdown of blood, body fluids and tissues. Some enzymatic solutions are specifically for breakdown of faecal matter or other organic contaminants and may not be suitable for use with orthopaedic instruments. The manual pre-cleaning and cleaning instructions within this document were validated using Cidezyme (0.8%) and the automated cleaning instructions using Neodisher (0.5%).*

Manual Cleaning Instructions

1. Remove all instruments from their trays/cases and clean/disinfect separately.
2. Submerge the instruments in enzymatic detergent (Cideyzyme 0.8%) and soak for 20 minutes.
3. While submerged in enzymatic detergent, scrub each instrument with a soft-bristled brush & **operate moving parts**, paying special attention to areas where debris might accumulate (e.g. threads). Lumens and crevices should be cleaned with a long, narrow soft-bristled brush.
4. Remove the instruments from the enzymatic detergent and rinse each instrument thoroughly in purified water (such as distilled or deionized water) for a minimum of three minutes. Thoroughly flush lumens and other difficult to reach areas (e.g. threads and crevices) with jet-washer / syringe.
5. Soak the instruments in an ultrasonic bath for 15 min at 40 °C with 0.8% enzymatic cleaner. After 10 minutes, remove the bone compactor & treat with jet-pistol as described above. Following rinsing, return the bone compactor to the ultrasonic bath for the remaining 5 minutes.
6. Remove the instruments from the Ultrasonic bath and rinse each instrument thoroughly with purified water (such as distilled or deionized water) for at least 3 minutes and until there is no sign of soil in the rinse stream. Thoroughly flush lumens and other difficult to reach areas (e.g. threads and crevices).

Note: *If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as-needed basis.*

Combination Manual/ Automated Cleaning Instructions

1. Remove all instruments from their trays/cases and clean/disinfect separately.
2. Submerge the instruments in enzymatic detergent (Cideyzyme 0.8%) and soak for 20 minutes.
3. While submerged in enzymatic detergent, scrub each instrument with a soft-bristled brush & operate moving parts, paying special attention to areas where debris might accumulate (e.g. threads). Lumens and crevices should be cleaned with a long, narrow soft-bristled brush.
4. Remove the instruments from the enzymatic detergent and rinse each instrument thoroughly in purified water (such as distilled or deionized water) for a minimum of three minutes. Thoroughly flush lumens and other difficult to reach areas (e.g. threads and crevices) with jet-washer / syringe.
5. Soak the instruments in an ultrasonic bath for 15 min at 40°C with 0.8% enzymatic cleaner. After 10 minutes, remove the bone compactor & treat with jet-pistol as described above. Following rinsing, return the bone compactor to the ultrasonic bath for the remaining 5 minutes.
6. Remove the instruments from the Ultrasonic bath and rinse each instrument thoroughly with purified water (such as distilled or deionized water) for at least 3 minutes and until there is no sign of soil in the rinse stream. Thoroughly flush lumens and other difficult to reach areas (e.g. threads and crevices).

Step	Description
NOTE	Connect washer / disinfector's irrigation hose to the bone-compactor's luer port
1	2 min pre-cleaning with cold tap water
2	Drain
3	5 min cleaning with deionized water at 45°C and 0.5% Neodisher Medizyme
4	Drain
5	3 min rinsing and neutralization with deionized water.
6	Drain
7	2 min final rinse with deionized water.
8	Drain

Note: *The washer / disinfector manufacturer's instructions must be strictly adhered to.*

Inspection and Functional Check

- Check each device for signs of visible soil. All exterior surfaces as well as inner lumens should be inspected. The device must be macroscopically clean, i.e., visibly free from protein based residues and other soiling.
- Repeat cleaning processes if soil is visible, and re-inspect.

3. Packaging & Sterilisation

Packaging Individual Instruments and Kits

- Re-assemble the instruments back into the cleaned and disinfected trays.
- Commercially available, medical grade, steam sterilisation wraps or pouches (paper, Tyvek or equivalent) may be used to double package single instruments. Ensure the package is large enough to contain the instrument without stressing the seals.
- Only intact components or instruments should be processed. Functionality must be verified following cleaning and prior to packaging.

Sterilisation

- These sterilisation instructions are consistent with AORN and ANSI / AAMI / ISO guidelines. They should be used for items supplied non sterile (excluding non-sterile sample products provided for demonstration purposes only), for reprocessing reusable devices, or for sterile items that can be re-sterilised.
- Where possible, reusable instruments should be disassembled for sterilisation and all surfaces must be accessible to the sterilising medium.
- Instruments and Instruments sets including tray lids shall be wrapped in medical grade steam sterilization compatible wrap that is FDA cleared and compliant to ISO 11607-1.
- Do not sterilise/re-sterilise devices in the protective bag or container in which they are supplied.
- **Precaution/Warning:** Components should be sterilised loose and not stacked in layers. Follow the steriliser manufacturer instructions for loading patterns.

All reusable instruments and instrument kits should be steam sterilized using these parameters:

Type	Minimum Temperature	Minimum Exposure[6]	Minimum Dry Time[7]
U.K. Pre-Vacuum/ Pulsating Vacuum[1,3,4]	134°C / 273°F	15 minutes	30 minutes
U.S. Pre-Vacuum/ Pulsating Vacuum[2,3,5]	132°C / 270°F	15 minutes	30 Minutes
Gravity Cycle	121°C / 254 °F	30 minutes	

1. *Validated exposure time required to achieve a 10^{-6} sterility assurance level (SAL).*
2. *Validated exposure temperature required to achieve a 10^{-6} sterility assurance level (SAL).*
3. *Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.*
4. *Disinfection / steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is a concern regarding TSE/CJD contamination.*
5. *For universal instruments cases without defined load configurations.*
6. *AAMI/AORN steam sterilization cycles with longer cycle times than those listed are also acceptable.*
7. *Drying times vary according to load size and should be increased for larger loads.*

4. Storage

- Sterilised, packaged instrument trays should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin and temperature/humidity extremes.
- Sterilised instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity. **If the instrument package shows any evidence of tampering or has been exposed to moisture, the instrument set must be repackaged and sterilised.**

5. Additional Information

- Lubrication is recommended for the moving components of the Bone Crusher. Any lubrication must be added prior to sterilisation.
- Discard blunt, damaged, severely corroded or discoloured instruments.

The instructions provided above have been validated by X-Bolt Orthopedics as being CAPABLE of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Appendix I – Dismantling & Assembling Instructions

Bone Crusher (XNI-014)

The Bone Crusher should be reprocessed in the "open" position to ensure that all areas can be thoroughly cleaned prior to sterilization. To keep the device open, a breakaway tab (or similar) can be wrapped around the front & back handles as shown in Figure 1 resulting in the distal arms to remain open (Figure 2).

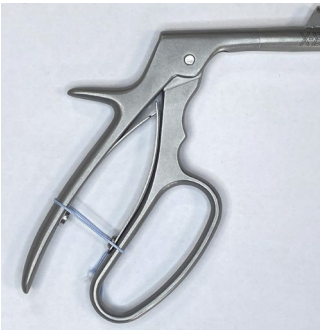


Figure 1: Bone Crusher (XNI-014) with handle locked in "open" position

Figure 2: Distal arms of the Bone Crusher in "open" position.

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The information presented in this brochure is intended as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific X-Bolt products. Always refer to the package insert, product label and instructions for use before using any X-Bolt product. Surgeons must always rely on their own clinical judgement, training and expertise when deciding which products and techniques to use with their patients.

European Patents:
EP 2175790, EP 3496637, EP 2175790
US Patents:
US 9724141B2, US 8911446B2, US 11259854B2

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