Instructions for Cleaning, Sterilization, Inspection and Storage of CrossRoads® Screw System Non-Sterile Instruments

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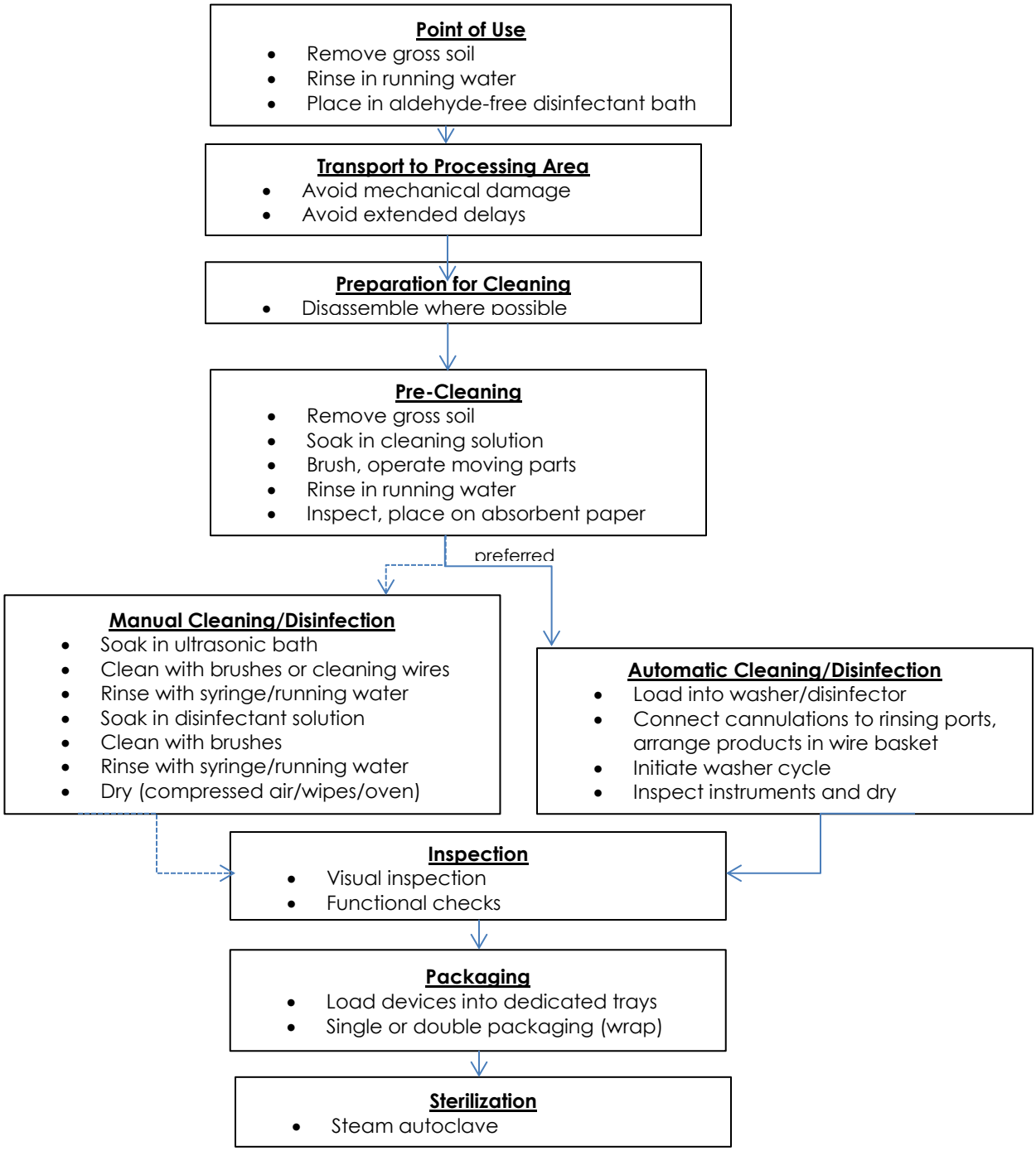
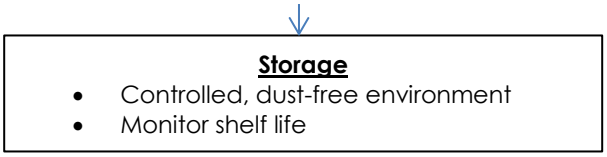
Introduction

This document is intended to give general guidance on how surgical instruments supplied by CrossRoads Extremity System may be processed to prepare them for use. It also gives instructions for inspection to determine when an instrument has reached the end of its serviceable life and must be replaced.

Processing Instructions

The sequence of steps required to prepare surgical instruments for re-use or to prepare new devices for initial use are summarized in the chart below. More detailed instructions for each step are given on the following pages.





Cleaning

Two methods of cleaning CrossRoads Extremity Systems instruments are provided in these instructions, a **manual method** and a method using an **automated washer disinfector**. Whenever possible the automated method should be used. The automated cleaning process is more reproducible and therefore more reliable, and staff are less exposed to the contaminated devices and the cleaning agents used.

Whichever method is used, staff should use suitable **protective clothing and equipment** at all times. In particular take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.

The guidance concentrations and **times for device immersion** in the cleaning solutions and/or disinfectants given by the detergent manufacturers shall be observed. If these concentrations and times are exceeded significantly, discoloration or corrosion could occur with some materials. This could also happen if rinsing after cleaning and/or disinfecting is insufficient.

For cleaning or disinfecting surgical instruments only specifically formulated **cleaning agents** and/or disinfectants (detergents) should be used.

CrossRoads Extremity Systems does not recommend any specific cleaning and/or disinfection agent.

The **quality of the water** used for diluting cleaning agents and/or disinfectants and for rinsing surgical instruments should be carefully considered.

Application of freshly prepared purified water/highly purified water or sterile water for rinsing purposes (according to the pharmacopeias) with less than 10 cfu/ml and 0.25 EU/ml is highly recommended.

Mineral residues from hard water as well as higher contamination with microorganisms and endotoxins can result in staining of the device or prevent effective cleaning and decontamination.

Caution:

CrossRoads Extremity Systems trays are intended for sterilization, transport and storage of surgical instruments. They are not designed for cleaning and disinfection in the fully loaded state. The devices must be removed from the tray for adequate cleaning results.

Point of Use

Directly after application (within a maximum of 2 hours postoperatively) remove gross soil using absorbent paper wipes. Additionally, intensive rinsing of the surgical instruments with fluent water or transfer of the surgical instruments into a bath with an aldehyde free disinfectant solution is highly recommended.

Transport to processing area

Avoid mechanical damage, e.g. do not mix heavy devices with delicate ones. Pay particular attention to cutting edges, both to avoid injury and damage to the surgical instrument. Get the surgical instruments to the point where cleaning is to be performed as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the surgical instruments with a damp cloth or store the surgical instruments in closed boxes to avoid drying of soil.

Preparation for cleaning

Disassemble the device where possible. See instructions provided in "Disassembly Instructions" section

Pre-Cleaning

The pre-cleaning step can be omitted in case of direct subsequent manual cleaning and disinfection. In case of highly contaminated surgical instruments to be subjected

to an automatic cleaning process, pre-cleaning in an ultrasonic bath is recommended.

Equipment required:

- Cleaning bath or vessel large enough to allow complete immersion of the instruments.
- Freshly prepared cleaning solution using a cleaning agent intended for manual cleaning see section "Cleaning Agents", with concentration, temperature, and soaking time not less than 10 minutes(but temperature not exceeding 50 °C)
- Brushes – soft and firm, bottle brushes or cleaning wires for cannulations etc.
- Personal protective equipment as recommended by the cleaning agent supplier (minimum overalls, gloves, face/eye shield)
- Absorbent paper
- Syringes (volumes 1 to 50 ml depending on the size of the cannulations to be rinsed)

Caution:
Never use metal brushes or steel wool for (pre-) cleaning.

Procedure

- Remove gross soil using paper wipes and solution of cleaning agent.
- Immerse surgical instrument in solution of cleaning agent.
- Ensure that all surfaces are thoroughly wetted; using a syringe to ensure that solution reaches all parts of cannulations etc. Ensure that air is not trapped within features of the device when immersing in the solution.

- Soak for a minimum of 10 minutes.
- Using suitable brushes (only soft brushes, never metal brushes or steel wool) or cleaning wires clean the surgical instrument thoroughly paying particular attention to rough surfaces and features where soil may be shielded from the brushing.
- Use a firm bristle brush for cleaning bone-cutting features such as drill tips and reamer flutes.
- Use a bottle brush of appropriate diameter for cannulations. Ensure that the brush passes the whole length of each cannulation at least three times.
- Operate articulating devices and those with moving parts.
    - Rinse in running water for at least 1 minute until all traces of cleaning solution are removed.
    - Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Completely rinse at least three times using a syringe (volume 1-50 ml).
    - Visually inspect for any remaining soil and repeat the steps above if necessary.
    - Allow to drain on absorbent paper or transfer immediately to cleaning step.

Manual Cleaning and Disinfection

Caution:

Combined cleaning and disinfection procedures are only recommended in case of surgical instruments which are only slightly contaminated.

<u>Manual Cleaning</u>

Equipment required:

• Ultrasonic bath large enough to allow complete immersion of the surgical instrument. Frequency 25 – 50 kHz, temperature according to detergent manufacturer`s instructions.

• Cleaning agent intended for manual cleaning and suitable for ultrasonic treatment; concentration as specified in detergent manufacturer's instructions.

• Suitable brushes (only soft brushes, **never metal brushes or steel wool**) or cleaning wires (for small channels) to reach all parts of the device.

• Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed)

• Freshly prepared purified water/ highly purified water or sterile water for rinsing purposes.

Manual Cleaning Procedure:

• Prepare an ultrasonic bath with a cleaning solution at the concentration and temperature specified in the detergent manufacturer´s instructions.

• Immerse the device completely and activate the bath for at least 10 minutes.

• Using suitable brushes (only soft brushes, never metal brushes or steel wool) or cleaning wires (for small channels) clean the device paying particular attention to rough surfaces and features that may be shielded from the brushing action. Additionally, pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse cannulations at least three times with a syringe.

• Rinse for at least 1 minute in running water of the specified quality until all traces of cleaning solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse cannulations at least three times with a syringe.

• If, after completion of the cleaning step in the ultrasonic bath, encrusted soil remained on the device which had to be removed with the brush, the cleaning step must be repeated as described above.

• Operate articulating devices and those with moving parts.

• Rinse in running water for at least 1 minute until all traces of cleaning solution are removed.

• Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Completely rinse at least three times using a syringe.

• Visually inspect for any remaining soil and repeat the steps above if necessary.

• Allow to drain on absorbent paper or transfer immediately to cleaning step.

Disinfection Equipment required:

• Bath large enough to allow complete immersion of the surgical instrument, temperature according to detergent manufacturer`s instructions.

• Disinfectant intended for manual disinfection and compatible with the applied cleaning detergent; concentration according to the detergent manufacturer's instructions.

• Syringes (volumes 1 to 50 ml depending on the size of the channels to be rinsed).

• Freshly prepared purified water/ highly purified water or sterile water for rinsing purposes.

• Filtered medical compressed air (if available) or clean and lint-free single use wipes.

Disinfection Procedure:

• Prepare a bath with a disinfectant solution at the concentration and temperature specified in the detergent manufacturer´s instructions.

• Immerse the device completely for at least the time specified in the detergent manufacturer´s instructions.

• Rinse cannulations at least three times with a syringe.

• Rinse for at least 1 minute in running water of the specified quality until all traces of disinfectant solution are removed. Pay particular attention to cannulations and blind holes as well as hinges and joints between mating parts. Rinse at least five times with a syringe (volume 1-50ml).

• Dry the surgical instrument using medical compressed air and clean, lint-free single use wipes or by heating in an oven below 110°C.

• Visually inspect and repeat complete manual cleaning and disinfection if necessary.

Automated Cleaning and Disinfection using washer-disinfector (recommended)

Equipment required:

• Washer-disinfector with fundamentally approved efficiency (e.g. CE mark or FDA approval according to ISO 15883), properly installed, qualified and regularly subjected to maintenance and testing

• Approved thermal disinfection program (Ao value > 3000 or – in case of older devices – application of at least 5 min at 90 °C; chemical disinfection program not recommended due to danger of remnants of the disinfectant on the instruments) with sufficient rinsing steps and filtered air for an active drying program (application of rinsing aids not recommended, danger of remnants)

• Final rinsing/disinfection only with freshly prepared purified water/ highly purified water

• Cleaning agent intended for automated cleaning concentration as specified in the detergent manufacturer's instructions.

Procedure:

• Arrange the surgical instruments into wire baskets (i.e., NOT in CrossRoads Extremity trays) and load the surgical instruments into the washer-disinfector.

• Connect cannulations to the rinsing ports of the washer-disinfector. If no direct connection is possible, locate the cannulations directly on injector jets or in injector sleeves of the injector basket.

• Avoid contact between devices (movement during washing could cause damage, and washing action could be obstructed).

• Arrange surgical instruments so that cannulations are not horizontal and blind holes incline downwards (to assist drainage).

• Articulating devices should be in the open position.

• Operate the washer-disinfector cycle.

• On completion unload the washer-disinfector. Visually inspect each device for remaining soil and dryness. If soil remains repeat the cleaning process including the pre-cleaning stage. Remaining wetness may be removed with medical grade compressed air and clean, lint-free single use wipes or by heating in an oven below 110°C.

Inspection

Before preparing for sterilization, all surgical instruments should be inspected. Generally un-magnified **visual inspection** under good light conditions is sufficient. All parts of the devices should be checked for visible soil and/ or corrosion.

Particular attention should be paid to:

• Soil "traps" such as mating surfaces, hinges, and cutting flutes.

• Recessed features (holes, cannulations).

• Features where soil may be pressed into contact with the device, e.g. drill flutes adjacent to the cutting tip, sides of teeth cutting instruments.

• Cutting edges should be checked for sharpness and damage.

• For devices that may be impacted check that the device is not damaged to the extent that it malfunctions or that burrs have been produced that could damage tissues or surgical gloves.

Functional checks should be performed where possible:

• Mating devices should be checked for proper assembly.

• Surgical instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).

• Rotating instruments (e.g. multiple use drill bits, reamers) should be checked for straightness (this can be achieved by simply rolling the instrument on a flat surface).

Note:

CrossRoads Extremity Systems does not define the maximum number of uses appropriate for re-usable surgical instruments. The useful life of these devices depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method of determining the end of serviceable life for the surgical instrument.

Packaging

Where appropriate the cleaned, disinfected, and checked surgical instruments should be assembled into the dedicated trays provided. When performing a **pre-vac sterilization cycle** – CrossRoads Extremity Systems cases/trays should be double wrapped according to AAMI/CSR technique.

The packaging for terminally sterilized surgical instruments should fulfill the following requirements:

• EN ISO 11607

• Suitable for steam sterilization (temperature resistance up to at least 141 °C, sufficient steam permeability)

• Sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage

Sterilization

Prior to sterilization, place all CrossRoads Screw Systems surgical instruments into their respective places in the trays provided and shown below:

or

Steam autoclave (moist heat) sterilization using a pre-vacuum (forced air removal) cycle is recommended. Autoclaves should comply with the requirements of, and be validated, maintained and checked in accordance with EN 285/EN 13060, EN ISO 17665, and ANSI AAMI ST79.

Steam Sterilization – Pre-Vac Method:

Method	Moist heat sterilization according to EN ISO 17665
Cycle	**Saturated steam with fractional forced air removal**
Exposure Time	4 minutes
Temperature	132°C (270°F)
Drying Time	Recommended: 30 minutes (minimum in chamber)

Please note that according to EN ISO 17665 the final responsibility for validation of sterilization techniques and equipment lies directly with the hospital. To ensure optimal processing all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

Storage before use

After sterilization, please store the surgical instruments in the sterilization packaging in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental and handling conditions. A maximum shelf life for sterilized surgical instruments before use should be defined by each health care facility.

Cleaning Agents

In all cases

• follow the indications, instructions and warnings provided by the supplier of the cleaning agent and/ or disinfectant,

• select only detergents intended for cleaning and/or disinfection of surgical instruments made of metals and plastics, and

• select only disinfectants with approved efficiency (VAH/DGHM or FDA approval or CE mark). Ensure that the substances listed below are not ingredients of the cleaning or disinfection detergent chosen:

- Organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- Strong lye (maximum admitted pH-value 10.9*)
- Organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxides, hypochloride)
- Halogens (chlorine, jodine, bromine)
- aromated, halogenated hydrocarbons.

The table below lists cleaning agents which have been shown to be effective for the specified use:

Use	Supplier	Designation
Pre-Cleaning/Manual Cleaning	Johnson and Johnson	Cidezyme/Enzol
Manual Disinfection	Johnson and Johnson	Cidex OPA
Automatic Cleaning/Disinfection in a washer disinfector	Dr. Weigert	Neodisher Mediclean forte

Revision History

Rev	DCO No.	Nature of Change	Release Date
A	0054	Initial Release	02/13/2015
B	0135	Removed gravity displacement method of steam sterilization	09/16/2015