

NEXTSTEP ARTHROPEDIX

Reprocessing of Surgical Instruments

PRODUCT

These instructions were developed to provide reprocessing instructions for NextStep Arthropedix surgical instruments and sterilization cases and trays.

WARNING

Instruments are provided non-sterile and must be properly cleaned and sterilized prior to each use.

INSTRUCTIONS

Preparation at the point of use

Remove excess debris, blood and tissue from instruments with a disposable wipe. Place devices in a container of distilled water or cover with damp towels. If instruments cannot be soaked or maintained damp then they should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.

Note: Soaking in a proteolytic enzyme solution prepared according to the manufacturer will facilitate cleaning especially in instruments with complex features such as lumens, mating surfaces, blind holes and cannulas.

Containment / Transportation

Transport the re-usable instruments to the point where cleaning is to be performed as soon as practical. Follow hospital protocols when handling contaminated instruments and bio-hazard materials. During transportation instruments should be covered or in closed containers.

Preparation for decontamination

Whenever possible, instruments should be reprocessed in a dis-assembled or open state. Refer to specific disassembly instructions for individual instruments. All cleaning solutions should be prepared at the use-dilution and temperature recommended by the manufacturer.

Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated.

Manual cleaning

1. Rinse the instruments under running tap water with a temperature of less than 20⁰ C for a minimum of 2 minutes.
2. Prepare an enzymatic detergent according to the manufacturer's recommendations in tap water with a temperature of less than 20⁰ C.
3. Completely submerge instruments in the enzymatic detergent solution and gently shake to remove trapped bubbles. Actuate all moving parts of the device while submerged to ensure contact with enzymatic cleaning solution. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces.
4. Soak instruments for a minimum of 10 minutes.
5. Scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Particular attention should be given to crevices, roughened surfaces, cutting features, hinged joints, sharp edges, box locks, and areas with small components or springs. Lumens, blind holes and cannulas should be cleaned using a long narrow nylon bristle brush/pipe cleaner. Insert a snug fitting long narrow brush/pipe cleaner into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times.
Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.
6. Remove the instruments from the enzymatic solution and rinse in tap water for a minimum of two (2) minutes. Actuate all moveable and hinged parts while rinsing.
7. Prepare an ultrasonic cleaning bath with neutral pH detergent according to the manufacturer's recommendations in tap water. Completely submerge instruments in the cleaning solution and gently shake them to remove any trapped bubbles. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces. Sonically clean the instruments at the time, temperature and frequency recommended by the equipment manufacturer and optimal for the detergent used. A minimum of ten (10) minutes is recommended.
8. Remove the instruments from the ultrasonic bath and rinse in high purity water (reverse osmosis or distilled) for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.
9. Visually inspect the instruments for any visible soil or contamination and repeat the cleaning steps above if any remaining soil is observed. If the soil or contamination cannot be removed the instrument should be appropriately disposed and not re-used.
10. Dry instruments with a clean, absorbent non-shedding wipe. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas and difficult to access areas.

Combination Manual / Automated Cleaning

1. Rinse the instruments under running tap water with a temperature of less than 20⁰ C for a minimum of 2 minutes.
2. Prepare an enzymatic detergent according to the manufacturer's recommendations in tap water with a temperature of less than 20⁰ C.
3. Completely submerge instruments in the enzymatic detergent solution and gently shake to remove trapped bubbles. Actuate all moving parts of the device while submerged to ensure contact with enzymatic cleaning solution. Lumens, blind holes and cannulations should be flushed with a syringe to remove bubbles and ensure contact of the solution with all instrument surfaces.
4. Soak instruments for a minimum of 10 minutes.
5. Scrub surfaces using a soft nylon-bristled brush until all visible soil has been removed. Particular attention should be given to crevices, roughened surfaces, cutting features, hinged joints, sharp edges, box locks, and areas with small components or springs.

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Lumens, blind holes and cannulas should be cleaned using a long narrow nylon bristle brush/pipe cleaner. Insert a snug fitting long narrow brush/pipe cleaner into the lumen, blind hole or cannula with a twisting motion while pushing in and out multiple times.

Note: All scrubbing should be performed below the surface of the enzyme solution to minimize the potential of aerosolizing contaminated solution.

6. Remove the instruments from the enzymatic solution and rinse in tap water for a minimum of one (1) minute. Actuate all moveable and hinged parts while rinsing.
7. Place instruments in a suitable validated washer. Follow the washer manufacturer's instructions for loading the instruments for maximum cleaning exposure; e.g. open all instruments, place concave instruments on their side or upside down, use baskets and trays designed for washers, place heavier instruments on the bottom of trays and baskets. If the washer is equipped with special racks use them according to the manufacturer's instruction.

| Treatment | Time (MM:SS) | Temperature | Cleaning Solution |
|----------------------|--------------|--|--|
| Pre-wash | 02:00 | Cold Water (< 40 ⁰ C) | N/A |
| Wash 1 | 05:00 | Hot Water (heated to > 60 ⁰ C) | Enzymatic Detergent diluted per manufacturer's instructions |
| Rinse 1 | 02:00 | Cold Water (< 40 ⁰ C) | N/A |
| Wash 2 | 02:00 | Hot Water (heated to > 60 ⁰ C) | Neutral pH Detergent diluted per manufacturer's instructions |
| Rinse 1 | 01:00 | High Purity Water (reverse osmosis or distilled) (heated to > 43 ⁰ C) | N/A |
| Thermal Disinfection | 05:00 | > 90 ⁰ C | N/A |
| Dry | 07:00 | 110 ⁰ C | N/A |

8. Confirm the water supply meets the specifications in Table 1 of AAMI TIR 34. If this cannot be confirmed, then manually final rinse the instruments in high purity water (reverse osmosis or distilled) for a minimum of one (1) minute or until there is no sign of residue detergent or biologic soil. Actuate all moveable and hinged parts while rinsing. Thoroughly and aggressively flush lumens, holes, cannulas and other difficult to access areas.
9. Visually inspect the instruments for any visible soil or contamination and repeat the cleaning steps above if any remaining soil is observed. If the soil or contamination cannot be removed the instrument should be appropriately disposed and not re-used.

Drying

Allow instruments to drain and dry with a clean, absorbent non-shedding wipe. Clean, filtered compressed air may be used to remove moisture from lumens, holes, cannulas, and difficult to access areas.

Product Reuse Life

The useful life of the NextStep Arthropedix instruments depends on many factors including the method and duration of each use, and the handling between uses. Careful visual inspection and functional tests of the instrument is the recommended method to determine the end of serviceable life for an instrument. Check all instruments for smooth function of hinges, ratchets, sleeves, etc. Visually inspect all instruments for any signs of corrosion, pitting, discoloration, cracking, etc. Properly dispose of any instrument not meeting these criteria.

Packaging for Sterilization

Single devices may be packaged in a medical grade sterilization pouch or wrap. Care should be used when packaging so that the pouch or wrap is not torn. Devices should be wrapped using the AAMI double wrap or equivalent method.

Cases and trays should be double wrapped in FDA cleared steam sterilization wrap using AAMI double wrap method or equivalent.

Sterilization

NextStep Arthropedix instruments are recommended to be steam sterilized in a pre-vacuum autoclave cycle at 270° F (132° C) for (4) minutes exposure time and a (30) minute drying time.

For further information, please contact:



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Caution, consult accompanying documents