

Instructions for Use Nordent Tissue Forceps

Intended use

Tissue forceps are hinged instruments that are used to grasp and retract tissue after a flap has been cut.

Do not use on patients with a hypersensitivity to stainless steel.

Inspection

Be sure to inspect the instruments for fissures, cracks, surface damages or other damage prior to each use.

Instruments that show any signs of corrosion, dull or weakened blades, misalignment or defects should be taken out of service immediately.

Processing

Medical devices should not be distorted, bent or overloaded, these can cause loss of function, fracture or destruction of the devices.

Cleaning / Disinfection / Sterilization

The instruments are delivered non-sterile.

Brand-new instruments, as well as instruments returned from repair, must be removed from their transportation packaging before including them in the sterile processing and supply cycle. This also requires removal of all protective devices (such as foils, caps, etc.). Prior to sterilizing such instruments for the first time, they must be thoroughly cleaned. In particular, all oil residues must be carefully removed. If cleaning is done manually, hot water must be used for this purpose, adding a suitable, commonly available washing-up liquid (e.g. Priel). Machine cleaning is possible if a thermal disinfector is available. Instruments should always be stored in a dry room to prevent condensation and consequential corrosion damage. Prior to initial use, such instruments must be sent through the entire processing cycle in the same way as used instruments.

This may only be done by trained personnel and in compliance with the regulations in force at the time.

- O Ensure that all residues (blood, tissue particles, medicines) are carefully removed from the instruments immediately after the surgical intervention.
- O Instruments should never be just "dropped" when disposing of them. Instead, put them down carefully to avoid mechanical damage.
- O Do not immerse instruments in NaCl solutions because this may cause pitting or stress corrosion cracking. Use only an approved detergent-disinfectant solution that has no protein-fixing effect (as regards the mix, be sure to follow the product manufacturer's instructions for use).

- O Never expose stainless steel instruments to products that are not specifically formulated for use with dental instruments or for the purpose of cleaning and sterilizing dental instruments. Do not expose stainless steel dental instruments to the following chemicals. These chemicals will cause an adverse reaction and may destroy your instruments: Chlorine or Chlorinated products, Household Bleach, Tarter and Stain Remover, Aluminum Chloride, Aqua Regia, Barium Chloride, Bichloride of Mercury, Calcium Chloride, Carbolic Acid, Chlorinated Lime, Citric Acid, Dakin's Solution, Ferric Chloride, Ferrous Chloride, Hydrochloric Acid, Iodine, Lysol®, Mercury Chloride, Mercury Salts, Phenol, Potassium Permanganate, Potassium Thiocyanate, Sodium Hypochlorite (bleach), Stannous Chloride, Sulfuric Acid and Tartaric Acid (Tarter & Stain Remover)
- O Water quality may influence the result of the cleaning and disinfection of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. By using completely deionized or distilled water most water quality problems can be avoided beforehand.
- O Avoid overloading instrument and washing trays.
- O Process the instruments immediately after use (do not store them dirty). Jointed instruments must always be processed in open condition.

Cleaning/Disinfection (Manual)

Use only cleaners and disinfectants suitable (approved) for stainless steel instruments.

When manually cleaning or handling contaminated instruments, personnel should wear heavy duty, puncture resistant utility gloves in order to avoid injury or cross contamination. They should also wear a face mask, eye protection or face shield and a gown or jacket because splashing will likely occur.

- 1. Completely disassemble the instruments, if applicable.
- 2. Pre-Treat all contaminated instruments by soaking in an enzymatic cleaning solution. Contaminated instruments should be pre-treated within two hours of use and it is necessary that all instrument surfaces are completely submersed. The instructions of the enzymatic cleaner manufacturer must be observed.
- 3. Remove the instruments from the cleaning solution and remove any remaining debris or deposits using a soft brush. Do not use any brush with metal bristles or steel wool.
- 4. Rinse instruments completely with low contaminated and deionized water, making certain that there is no remaining residue, debris or residual cleaner left on the instruments.
- 5. Inspect the instruments for proper cleaning.
- 6. Thoroughly dry all instruments before packaging the instruments for sterilization.

Ultrasonic Cleaning Procedure

When manually cleaning or handling contaminated instruments, personnel should wear heavy duty, puncture resistant utility gloves in order to avoid injury or cross contamination. They should also wear a face mask, eye protection or face shield and a gown or jacket because splashing will likely occur.

- 1. Completely disassemble the instruments if applicable. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed. Use the processing time recommended by the manufacturer of the detergent and/or the cassette system.
- 2. Do not overload the Ultrasonic Cleaning unit. Use "Sweep modus" if available.

- 3. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water.
- 4. Inspect the instruments to make certain that all residue, debris and residual cleaning solution is removed from the instruments and that the instruments are free of defects and safe to use.
- O 5. Thoroughly dry all instruments before packaging for sterilization.

Sterilization

Steam Autoclave

Steam sterilizer according to or AAMI/ANSI ST55 and AAMI/ANSI ST8 Validated according to or ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification)

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at 121°C (250°F)	Drying times
Wrapped instruments	30 minutes	Minimum 30 minutes

⁻ NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 132°C (270°F)	Drying times
Wrapped instruments	4 minutes	Minimum 30 minutes

 NOTE—This table represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Never exceed temperatures 350° F / 177° C as this will have an adverse effect on the temper of the steel.

Notice: No liability is accepted for reuse instruments which applied to patients with

Creutzfeldt-Jacob or HIV-positive patients.

Storage

Products must be stored in a dry and dust-protected place, avoid humidity and consequential corrosion. Some medical devices are very delicate, should be individually packed or stored in protective containers. Please ensure that instruments are not in contact with chemical substances.

Warranty

Our products are manufactured to the highest quality standards. Please do not hesitate to contact us if there are any problems regarding our products. The user takes full responsibility for proper use and care of these instruments. Damage caused by misuse, neglect, modification, or accidents are not covered by warranty. Nordent Manufacturing, Inc. does not accept liability to results caused by unauthorized repairs.

Reusability

This device is a reusable medical device.

Contraindications: Hypersensitivity to stainless steel.

Material

Medical parts: 440A Stainless steel.

Method: High Gloss Surface

Reference standards: YY/T 0294.1

Nordent Manufacturing, Inc. does not accept liability to results caused by proved non-compliance of this instruction for use

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