



## **Guidelines for Sterilizing and Maintaining DENOVO Instruments and Parts**

### **1. General Guidelines**

All instruments and reusable parts are to be cleaned, disinfected, and sterilized prior to each use. In addition, cleaning, disinfection and sterilization is highly recommended for the first-use of an instrument or parts after removal from the product packaging.

The user is solely responsible for the sterility of the instruments and parts. Therefore, please ensure that only validated procedures are used for cleaning, disinfection and sterilization. The sterilization equipment must be maintained and checked regularly to insure the equipment is working properly and within specifications.

Some countries, states and territories have additional requirements not listed below. The user is responsible for incorporating any additional standards that may apply.

### **2 Sterilizing Procedure**

#### **2.1 Cleaning and Disinfection**

If possible, an automatic procedure in a Washer / Disinfector unit should be used cleaning and Disinfection of the instruments. A manual procedure, even in the case of application of a ultrasonic bath, should only be used if an automatic procedure is not available or if such a method is not compatible with specific materials; in this case, the significantly lower efficiency of a manual procedure must be considered. The pre-treatment step is to be performed in both cases.

#### **2.2 Pre-treatment**

Before sterilizing the items, coarse materials must be completely removed immediately after use (within 2 hours).

Use an enzymatic cleaner or a disinfectant solution; the disinfectant should be aldehyde-free, have an approved efficiency (CE mark, DGHM, RKI), and be compatible with the part being disinfected. Make sure to follow the disinfectant manufacturer's instructions.

For manual removal of coarse impurities use only a soft brush (not metallic).

#### **2.3 Automatic Cleaning / Disinfection in a Washer-Disinfector unit**

When using a Washer-Disinfector unit,

- 1) use only an approved unit for such use.
- 2) post rinse only with low contaminated and deionized water
- 3) use filtered air for drying
- 4) perform regular maintenance and calibration.
- 5) use a detergent suitable for the unit and application
- 6) follow the manufacturer's guidelines for using the unit.

Procedure:

- 1) Disassemble any parts that can be disassembled. Open instruments (like scissors and forceps) for maximum exposure.
- 2) Place parts or instruments in a cassette suitable for the application.
- 3) Start the cleaning program per the manufacturer's recommendations.



- 4) Remove the sterilized units promptly (especially those parts that contain iron which could rust).
- 5) Inspect and package (where applicable) sterilized units immediately (but do not package if still wet).

## 2.4 Manual and Ultrasonic Cleaning and Disinfection

### 2.4.1 General Information

When selecting cleaning and disinfection detergents,

- 1) detergents need to be applicable base on the parts to be sterilized.
- 2) use only detergents with approved efficiencies (CE marl, etc.)
- 3) dissolve powder-based detergents completely in de-ionized water before use.
- 4) observe the detergent manufacturer's recommendations.

Combined cleaning/disinfection solutions should only be used in cases of low contamination (no visible impurities).

### 2. 4.2 Manual Cleaning and Disinfection

#### Cleaning

- 1) Disassemble any parts that can be disassembled and open the blades/beaks on instruments to expose the maximum surface area.
- 2) Soak the parts for the recommended soaking time as specified by the manufacturer (makes sure remain completely immersed).
- 3) Remove the parts from the cleaning solution and post rinse them intensively with low-contaminated deionized water.
- 4) Inspect the parts for proper cleaning.

#### Disinfection

- 1) Soak parts completely for the recommended soaking time.
- 2) Post rinse parts with low-contaminated deionized water.
- 3) Inspect parts and perform any maintenance required on instruments. Make sure parts are dry before packaging.
- 4) Package the parts.

### 2.5 Inspection

Inspect all parts after the cleaning and disinfection step for corrosion, damaged surfaces and impurities. Do not use parts or instruments that are damaged. If parts are still dirty, repeat the process.

### 2.6 Maintenance

Hinged instruments should be lubricated with a lubricate suitable for steam sterilization.

### 2.7 Packaging

Parts and instruments should be contained within pouches, wraps or bags that are suitable for steam sterilization (temperature resistant to 141 °C (286 °F)).

### 2.8 Sterilization

Please only use the recommended sterilization procedures listed below. Other sterilization procedures are the

responsibility of the user.

- 1) Fractionated vacuum or gravity procedure (with sufficient drying)
- 2) Steam sterilizer according to EN 13060 and EN 285
- 3) Validated procedure according to ISO/ANSI AAMI.
- 4) Maximum sterilization temperature of 138 °C (280 °F) plus tolerance according to ISO/ANSI AAMI.
- 5) Sterilization time of at least 20 min at 121 °C or 5 minutes at 132 °C (270 °F)

## 2.9 Inspection and Maintenance Recommendations for Steam Sterilizers

- 1) Follow the manufacturer's instructions for care of the machine
- 2) Clean on a regular basis
- 3) Use only deionized water
- 4) Parts must be completely dried after sterilization and before handling. Sterilizers with an auto drying program are recommended.

## 2.10 Restrictions

- 1) Do not use flash sterilization
- 2) DO not use radiation sterilization
- 3) The application of dry heat sterilization is the responsibility of the user,

## 2.11 Storage of Parts and Instruments

Store the sterilized parts in a dry, dust-free location. Sterilization can only be maintained if the parts remain packaged or wrapped – impermeable to micro-organisms. The status of sterilization should be marked on the package or wrap. Keep sterile and non-sterile parts away from each other.

## 2.12 Material Resistance

Detergents of disinfectants containing the following substances must not be used:

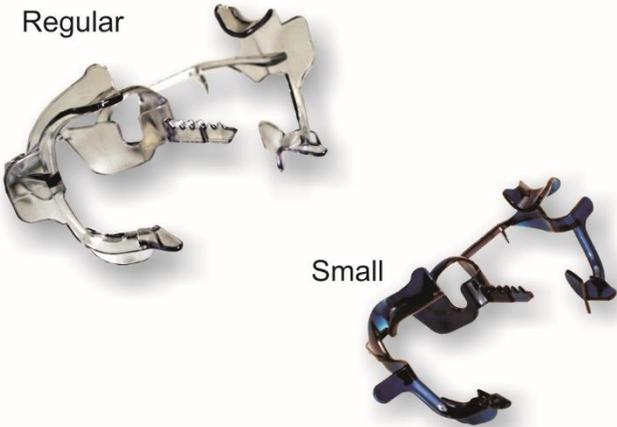
- 1) strong bases (pH > 9)
- 2) strong acids (pH < 4)
- 3) phenols or iodophors
- 4) interhalogenic agents
- 5) strong oxidizing agents
- 6) organic solvents

Do not clean any instruments, sterilization trays or parts using metal brushes or steel wool.

Do not expose instruments or parts to temperatures higher than 141 °C (286 °F).

Water quality may influence the result of cleaning and disinfection. Corrosion and staining could be caused by minerals in the water. Using deionized water will eliminate this problem.

Description	Part #'s	Sterilization Guidelines
<p>DENOVO Wire Shear</p> 	<p>Part #802-020 and #802-026</p>	<p>Due to the carbide blade, these instruments should be hand-wiped only. Other methods of sterilization will pit the carbide blades and will no longer function as designed.</p> <p>Use an intermediate-level surface disinfectant which is effective against TB, HBV, HCV, viruses (hydrophilic and lipophilic), bacteria (including MRSA and VRE) and fungi (Cavicide® or other similar products).</p>
<p>Stainless Steel Hand Instruments</p> 	<p>800-xxx, 805-xxx, 811-003, 813-xxx.</p>	<p>All instruments should be free of all loose material prior to sterilization (either by ultrasonic cleaner, dedicated cleaning device, or manually).</p> <p>Instruments can be sterilized using autoclave, dry heat, or chemical vapor cleaner. Care must be taken to ensure the temperature does not exceed 350 °F (177 °C).</p>
<p>Crown Scissors</p> 	<p>801-201T, 801-202T, 801-203T</p>	<p>All scissors should be free of all loose material prior to sterilization (either by ultrasonic cleaner, dedicated cleaning device, or manually).</p> <p>Instruments can be sterilized using autoclave, dry heat, or chemical vapor cleaner. Care must be taken to ensure the temperature does not exceed 350 °F (177 °C).</p> <p>Make sure the blades of the scissors are OPEN to prevent rust or pitting, and utilize a drying cycle if available on your machine. It is important that the blades be allowed to dry before storage.</p>
<p>Professional Bite Stick</p> 	<p>#811-002</p>	<p>Bite Sticks should be free of all loose material prior to sterilization (either by ultrasonic cleaner, dedicated cleaning device, or manually).</p> <p>Bite Sticks are made from a special liquid-crystal polymer and can be sterilized using autoclave, dry heat, or chemical vapor cleaner. Care must be taken to ensure the temperature does</p>

Description	Part #'s	Sterilization Guidelines
Re-usable Parts	8385-xxx, 8906-xxx, 90x- xxx, 160-xxx	<p>not exceed 350 °F (177 °C).</p> <p>Re-usable parts can be re-used provided they are cleaned and sterilized properly. Extra care should be taken to insure that all biological contaminants are removed during the cleaning process, prior to disinfecting and sterilization.</p>
<p>ClearField Cheek Retractors</p>  <p>Regular</p> <p>Small</p>	430-xxx	<p>This product was designed and priced to be disposable, and DENOVO Dental recommends this; however, for offices that which to re-use the cheek retractors, the following guidelines must be met:</p> <ol style="list-style-type: none"> <li>1) Do NOT use any heat ore pressure sterilization such as autoclaves or chemiclaves.</li> <li>2) Cold sterilization can be used on this product. Please use a cold sterile product classified as glutaraldehydes. These products have a specific use life, typically 28 days, once activated and/or put into use.</li> </ol> <p>Please use the manufacturer's recommendations for the duration of sterilization, which is typically between 3-6 hours. Note that if additional items are added to the solution during a specific time period, the timing must be restarted.</p> <p>There are other, non-glutaraldehyde-containing solutions for chemical disinfection and sterilization. These solutions are ortho-phthaldehydes. Make sure the cleaning solution you use is approved by the FDA for the sterilization of dental products.</p> <p>Dental practices should check with their state environmental protection agency to determine if there are special requirements for the disposal of cold</p>



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Description	Part #'s	Sterilization Guidelines
		sterile solutions. In addition, some products have neutralizers or inactivators that can be added to the solutions prior to disposal (pouring down the drain if allowed).