

## Scope

This Document outlines the manufacturer’s (Denovo) instructions for cleaning and sterilization procedures for Denovo products.

*This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200*

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

## Table of Contents

<b>Scope .....</b>	<b>1</b>
<b>General Information.....</b>	<b>2</b>
1. General Guidelines .....	2
<b>Sterilization Procedure Details.....</b>	<b>3</b>
2. Pre-Treatment: Rinse & Disinfect.....	3
3. Preparation for Sterilization.....	3
4. Sterilization.....	3
5. Storage .....	4
<b>Sterilization per Product Guidelines.....</b>	<b>4</b>
6. Special Procedures.....	4
<b>Product Index.....</b>	<b>6</b>

## General Information

### 1. General Guidelines

The user is solely responsible for the sterility of the parts and Denovo products. Therefore, please ensure that only validated procedures and products are used for cleaning and sterilization. We highly recommend staying up to date with the current sterilization recommendations and guidelines defined by the AAPD, CDC and OSHA, as well as country, state and local regulatory boards or agencies and equipment manufacturers (as applicable).

The sterilization and cleaning equipment must also be maintained and checked regularly, as well as the parameters applied to each cleaning and sterilization cycle. Cleaning solutions must be verified as compatible with the products being cleaned, and validated for use with dental products. **Refer to section 7 Special Procedures for exceptions and specific specifications per product.** Additionally, consider the legal provisions valid for your country, state or territory as well as to the hygienic instructions of the doctor’s practice or hospital. The user is responsible for incorporating any additional standards that may apply.

#### 1.1. Space Maintainer Bands, wires and other parts

All parts (SM bands, crowns, etc.) are supplied clean but not sterile. Parts are composed of stainless steel 304 or 305, which proves virtually impossible to harbor contaminants, however cleaning and sterilization are recommended for the first use of Denovo parts.

Parts that are sampled for size & fit, but are not used, **can be cleaned, disinfected, and sterilized for re-use.** Parts that are crimped, altered in any way or cemented CANNOT be re-used.

#### 1.2. Material Resistance

Do NOT use Detergents or disinfectants that contain the following substances:

- strong acids (pH < 4)
- strong bases (pH > 9)
- Sodium Hypochlorite
- Povidone-Iodine
- Formaldehyde
- Phenols or iodophors
- Chlorhexidine Gluconate
- Benzalkonium or Benzathonium Chloride
- Interhalogenic agents
- strong oxidizing agents
- organic solvents
- Household Detergents

Do NOT use tap water during cleaning & sterilization processes. Use deionized (max. 10 germs/ml) and low-contaminated (max. 0.25 endotoxin units/ml) water only.

Do NOT expose parts to temperatures higher than 270 °F (132 °C).

#### 1.3. Personal Protection

All used and contaminated parts must be handled with properly protection:

- **Use proper PPE** for handling of soiled products (utility gloves, protective gown, eye protection, etc.)
- Proper care should be taken when handling sharp materials or abrasive chemicals.

#### 1.4. Reprocessing Stations

Ensure proper locations and procedures are in place to place and identify parts at different stages during the sterilization process, and to prevent cross-contamination. The CDC recommends setting up a dedicated reprocessing area that is divided into 4 sections to control quality and ensure safety:

**1. Receiving, Cleaning & Decontamination**

**2. Preparation & Packaging**

**3. Sterilization**

**4. Storage**

## Sterilization Procedure Details

### 2. Pre-Treatment: Rinse & Disinfect

Check section 7 for restrictions on specific parts before initiating the reprocessing process.

#### 2.1. Rinse parts

- 1) Rinse with de-ionized water, being careful not to crush or distort the steel parts.
- 2) Check the part for any distortion, tearing, breakage or other damage.

#### 2.2. Disinfect

- 3) Immediately after rinse, immerse in an enzymatic cleaner or other disinfectant solution (*see section 1.2 on page 2 for restricted solutions*). soak 3–10 minutes at 89.6°F (32°C) as required by the manufacturer’s instructions of the chosen cleaning agent.
- 4) Proceed to the next stage immediately. *Do not allow parts to sit wet.*

#### 2.3. Restrictions

1. The use of a Washer Disinfector or other Automatic washer is NOT recommended.
2. Do NOT use Detergents or disinfectants that contain the following substances:
 

○ strong acids (pH < 4)	○ Formaldehyde	○ Interhalogens
○ strong bases (pH > 9)	○ Phenols or iodophors	○ strong oxidizing agents
○ Sodium Hypochlorite	○ Chlorhexidine Gluconate	○ organic solvents
○ Povidone	○ Benzalkonium Chloride	○ Household Detergents
○ Lodine	○ Benzethonium Chloride	

### 3. Preparation for Sterilization

#### 3.1. Inspection

- 1) Inspect for corrosion, damaged surfaces, distortion, tearing, breakage or other damage. Do not use parts that are damaged.
- 2) Confirm that product is completely dry and free from debris. If parts are visibly soiled, repeat the cleaning process.

#### 3.2. Preparation & Packing

- 3) Parts should be contained within pouches, or loaded into/onto another container that are suitable for steam sterilization (temperature resistant to 286 °F (141 °C)).
- 4) Pack & label according to autoclave manufacturer’s instructions.

### 4. Sterilization

#### 4.1. Autoclave Cycle (steam)

- 1) Load the sterilizer according to manufacturer instruction.

- 2) Run the sterilization program according to the instructions and recommendations of the manufacturer of the sterilizer used. The cycle specifications listed below are minimum requirements for Denovo products:

Cycle times for <b>steam sterilization</b>				
TEMPERATURE (CELCIUS):	TEMPERATURE:	STERILIZATION TIME:	PRESSURE:	DRYING CYCLE:
115°C – 118°C	240°F – 245°F	<i>At least 30 minutes</i>	14-16 psi	30 minutes
121°C – 124°C	250°F – 255°F	<i>At least 15 minutes</i>	14-16 psi	30 minutes
126°C – 135°C	260°F – 275°F	<i>At least 10 minutes</i>	14-16 psi	30 minutes
<i>DO NOT Exceed 143°C</i>	<i>DO NOT Exceed 290°F</i>			

**4.2. Dry Cycle**

- 3) Run the Sterilizer’s dry cycle according to the manufacturer’s instructions.
- 4) Parts must be completely dry and cool before handling. **INSPECT for rust immediately after removal from the Autoclave.**
- 5) **Inspect for any moisture immediately after removal from the Autoclave.** Any moisture on the parts may cause rust during storage.

**4.3. Autoclave Validation**

Prior to use, ensure proper function of your Autoclave system:

- Follow the manufacturer’s instructions for the proper use, setup and maintenance.
- Clean frequently according to manufacturer’s instructions
- Use only deionized water

**4.4. Restrictions**

3. Only use sterilizers with an automatic dry program. Manual drying risks rusting of improperly dried areas and will not be covered by the product warranty.  
Do NOT Use the following methods of sterilization:
  - Do NOT use Dry Heat Sterilization
  - Do NOT use flash or radiation sterilization.
  - Do NOT use Chemiclave Sterilization
  - Do NOT use formaldehyde, ethylene oxide, or plasma sterilization.

**5. Storage**

**5.1. Store**

- 1) Ensure parts are completely dry.
- 2) For Denovo space maintainer bands, wires and other multi-sized parts, remove from sterilization pouch or wrap with clean gloves and add back into the Denovo kit inserts, being careful to match the size/width/type of part to the identified well. Parts are made with stainless steel 304 or 305 and are highly unlikely to harbor any contaminants.
- 3) Store the Denovo kit box in a closed and well-ventilated area that would protect against dust and moisture.








**Sterilization per Product Guidelines**


**6. Special Procedures**

KEY:



Y*	The recommended cleaning or sterilization method for this product
Y	This cleaning or sterilization method is approved for use on this product
Y	This cleaning or sterilization method can be used on this product, but is not recommended and is at the discretion of the user
N	Do <b>NOT</b> use this cleaning or sterilization method on this product

### 6.1. SM bands & wires, SS crowns, matrix & molar bands

DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Rinse & Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemt-clave:	Cold Chemicals:	
	8385-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
	8906-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
	380-xxx 381-xxx 383-xxx 384-xxx 385-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
	170-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Take extra care to not distort parts or cut fingers on the sharp edges. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
	177-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
	160-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Disinfect:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemt-clave:	Cold Chem.:	
	900-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.

<b>SS Anterior Crowns</b> 	907-xxx	Y*	N	N	Y	Y*	N	N	Y	Properly rinse and disinfect prior to sterilization. Steam sterilization is recommended. Ensure part is fully dry before storage. Store in Denovo inserts and kits in a cool, dry, dust-free area. See section 1.2 for material restrictions.
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### 6.2. Clearfield, impression trays

DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Disinfect:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chem.:	
Clearfield Cheek Retractors 	430-300 430-400	Y*	N	N	Y	Y*	N	N	Y	This product is designed and priced to be disposable, but can be cold sterilized if necessary. Ensure device is free of loose material prior to sterilization. <b>Do NOT use any heat or pressure sterilization</b> such as autoclaves or chemiclaves. <b>Cold sterilization can be used.</b> Chemicals used must be classified as either <b>glutaraldehyde</b> or <b>orthophthalaldehyde</b> . These products have a specific use life, typically 28 days, once activated and/or put into use. Verify the manufacturer's recommendations for the proper sterilization. Denovo recommends a duration of 10 hours. Note that if additional items are added to the solution during a specific time period, the timing must be restarted.
All Impression Trays 	730-xxx	Y*	N	N	Y	Y*	N	N	Y	This product is designed and priced to be disposable, but can be cold sterilized if necessary. Ensure device is free of loose material prior to sterilization. <b>Do NOT use any heat or pressure sterilization</b> such as autoclaves or chemiclaves. <b>Cold sterilization can be used.</b> Chemicals used must be classified as either <b>glutaraldehyde</b> or <b>orthophthalaldehyde</b> . These products have a specific use life, typically 28 days, once activated and/or put into use. Verify the manufacturer's recommendations for the proper sterilization. Denovo recommends a duration of 10 hours. Note that if additional items are added to the solution during a specific time period, the timing must be restarted.

### Product Index

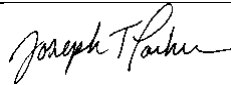

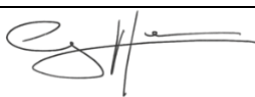
SKU/ Part #:	Device Name	Clean Method				Sterilization			
		Disinfect Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:
160-146 – 160-184	Pedo Molar Maxillary Bands	Y*	N	N	Y	Y*	N	N	Y
160-246 – 160-284	Pedo Molar Mandibular Bands	Y*	N	N	Y	Y*	N	N	Y
161-100 – 161-102	Pedo Molar Band Kits	Y*	N	N	Y	Y*	N	N	Y
170-301 – 170-315	Preformed Matrix Band 3/16 Pedo	Y*	N	N	Y	Y*	N	N	Y
170-401 – 170-415	Preformed Matrix Band ¼ Adult	Y*	N	N	Y	Y*	N	N	Y
171-300 – 171-600	Preformed Matrix Band Kits	Y*	N	N	Y	Y*	N	N	Y
177-101 – 177-301	Strip-T Matrices	Y*	N	N	Y	Y*	N	N	Y

177-101 – 177-417	Woody Wedges	Y*	N	N	Y	Y*	N	N	Y
190-213 – 190-448	Open Crowns	Y*	N	N	Y	Y*	N	N	Y
380-001 – 385-003	Space Maintainer Wires	Y*	N	N	Y	Y*	N	N	Y
387-012 – 387-365	Space Maintainer Kits	Y*	N	N	Y	Y*	N	N	Y
430-300 – 430-400	Clearfield Cheek Retractors	Y*	N	N	Y	Y*	N	N	Y
730-100 – 730-340	Impression Trays	Y*	N	N	Y	Y*	N	N	Y
8385-131 – 8385-197	Space Maintainer Maxillary Bands	Y*	N	N	Y	Y*	N	N	Y
8385-231 – 8385-297	Space Maintainer Mandibular Bands	Y*	N	N	Y	Y*	N	N	Y
8906-111 – 8906-147	Space Maintainer 1 <sup>st</sup> Primary Crowns	Y*	N	N	Y	Y*	N	N	Y
8906-211 – 8906-247	Space Maintainer 2 <sup>nd</sup> Primary Crowns	Y*	N	N	Y	Y*	N	N	Y
900-111 – 900-147	1 <sup>st</sup> Primary Crowns	Y*	N	N	Y	Y*	N	N	Y
900-211 – 900-247	2 <sup>nd</sup> Primary Crowns	Y*	N	N	Y	Y*	N	N	Y
900-311 – 900-348	1 <sup>st</sup> Permanent Crowns	Y*	N	N	Y	Y*	N	N	Y
902-100 – 902-300	Crown Kits	Y*	N	N	Y	Y*	N	N	Y
907-001 – 907-100	Anterior Crowns	Y*	N	N	Y	Y*	N	N	Y
930-106 – 930-301	Space Maintainer Crown Kits	Y*	N	N	Y	Y*	N	N	Y

### I Amendment History Table:

	Revision Date	Description of Change	Made by (initials)
1	2018.01.14	Sterilization document creation	PH
2	2021.02.20	Sterilization document format update	CH
3	2021.03.01	Added approximate sterilization times	CH
4	2021.03.16	Corrected and expanded on sterilization times, temps, pressures and drying time.	CH
5	2024.09.04	Corrections on sterilization processes down to only recommending Steam Sterilization. Removing Auto-washing recommendations. Split documents to instrument specific.	CH

### II Management Approval:

Approved by:	 Joseph Parker, <i>President</i>
Approved by:	 Phil Horton, <i>Service Manager</i>
Approved by:	 Chaz Hanna, <i>Regulatory Manager</i>