

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.

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General Information

1. General Guidelines

The user is solely responsible for the sterility of the parts, instruments 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 validated 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. Denovo Instruments

Cleaning and sterilization are required for the first use of instruments after removal from the protective packaging. Additionally, instruments are to be cleaned and sterilized prior to each use. Instruments can be re-used and their lifetime is dependent on user care, proper use, proper cleaning, sterilization, and frequency of use. The user is responsible for proper inspection between each use to detect corrosion, damage, warping, or other wear. Immediately remove instruments with these problems from use.

1.2. 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 virtual 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.

1.3. Material Resistance

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

- strong acids (pH < 4)
- strong bases (pH > 9)
- phenols or iodophors
- interhalogenic agents
- strong oxidizing agents
- organic solvents

Do NOT clean any instruments or parts using metal brushes or steel wool.

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 instruments or parts to temperatures higher than 290 °F (143 °C).

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

Sterilization Procedure Details

2. Pre-Treatment

2.1. Basics

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

Contaminated instruments and parts must be cleaned as early as possible in the reprocessing process, in order to maximize safety for staff members and more easily remove debris.

Ensure solutions used are compatible with the part being treated.

Process Location & Procedures:

Ensure proper locations and procedures are in place to identify instruments and 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:

- Receiving, Cleaning & Decontamination
- Preparation & Packaging
- Sterilization
- Storage

Protection:

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

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

2.2. Pre-treatment

Prep instruments and units and transport:

- 1) disassemble instruments (if possible) before starting pre-treatment
- 2) Remove coarse debris, dental or other materials from the instruments or parts immediately after application (within a maximum time of 2 hours). Check that hinged instruments or part tubes are free of debris.
- 3) Use a pre-cleaner spray or soak 3–5 minutes at 89.6°F (32°C) as required by the intended cleaning agent used in step 3
- 4) Using an enzymatic cleaner or other solution, pre-clean parts as directed by the disinfectant manufacturer's instructions.
- 5) For manual removal of coarse impurities use only a soft brush or a long handled soft brush. Never use metal brushes or steel wool.
- 6) Prep and pack parts as required by the manufacturer of the device used to clean in section 3.

3. Clean

3.1. Basics

If possible, an ultrasonic bath should be used for Denovo instruments. The ultrasonic bath should be used for Denovo parts. A manual procedure, such as hand scrubbing, should only be used if an automatic procedure is not available, if debris is remaining after automated cleaning or if such a method is not compatible with specific materials or product (see section 7); in this case, the significantly lower efficiency of a manual procedure might be considered.

Protection:

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

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

3.2. Ultrasonic Cleaner guidelines (recommended)

Ensure proper function of your Ultrasonic Cleaner:

- Follow the manufacturer's instructions for the proper use and setup of the ultrasonic cleaner, the type of water to be used (usually deionized (max. 10 germs/ml) and low-contaminated (max. 0.25 endotoxin units/ml)), and proper dilution of detergents.
- Consider the compatibility of the detergents used with parts. Ensure powder-based cleaners are fully dissolved before use.
- Denovo recommends the use of a dual enzyme detergent with corrosion inhibitors and collating agents to remove proteins and starches while protecting the instruments and parts.
- Change solution frequently; at least as often as recommended by the manufacturer.
- Perform regular maintenance.

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. Ensure no parts are touching.
- 3) Setup and start the ultrasonic cleaning program per the manufacturer's recommendations, making sure parts are fully immersed and never overload the unit.
- 4) Check the detergent manufactures guidelines for soaking times (usually at least 16 minutes for cassette systems.).
- 5) Remove the decontaminated units promptly and rinse thoroughly with low contaminated and deionized warm to hot water (to promote faster drying). Inspect parts for cleanliness.
- 6) Allow instruments and parts to dry completely to prevent wicking, cross-contamination or corrosion.
- 7) Proceed to the preparation and packaging phase immediately.

3.3. Automated washer guidelines

In some cases, an office can use an automated washer or disinfectant. Ensure proper function of your Ultrasonic Cleaner:

- Perform a water quality test before implementing a washer/disinfectant. Only rinse deionized (max. 10 germs/ml) and low-contaminated (max. 0.25 endotoxin units/ml) water.
- Ensure that the washer is approved for use in a dental practice. Follow the manufacturer's instructions for the proper use and setup of the washer & perform regular maintenance.
- Use only filtered air for drying.

- Consider the compatibility of the detergents used with parts.
- Do not use an automatic washer for Denovo parts. The washer can be used for Denovo instruments; however an ultrasonic cleaner is preferred.

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 or tray system suitable for the washer application.
- 3) Setup and start the automatic washer program per the manufacturer's recommendations.
- 4) No manual rinsing is needed, but confirm that product is completely dry after cycle is complete to prevent corrosion.
- 5) Proceed to the preparation and packaging phase immediately.

3.4. Manual Guidelines

Manual cleaning is not recommended for instruments, and is at the responsibility of the user:

- Selected detergents need to be applicable base on the parts to be sterilized.
- dissolve powder-based detergents completely in de-ionized water before use.
- observe the detergent manufacturer's recommendations. Combined cleaning/disinfection solutions should only be used in cases of low contamination (no visible impurities).

Procedure:

- 1) Soak the parts for the recommended soaking time as specified by the manufacturer (making sure instruments remain completely immersed).
- 2) Remove the parts from the cleaning solution and post rinse them with low-contaminated deionized water.
- 3) Thoroughly inspect the parts for proper cleaning, repeating soak as necessary.
- 4) dry them by patting them or using an instrument dryer
- 5) Proceed to the preparation and packaging phase immediately.

4. Inspection, Preparation & Packaging

4.1. Inspection

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

4.2. Maintenance

- 1) Apply lubricant suitable for steam sterilization to all hinged instruments.

4.3. Preparation & Packing

- 1) Parts and instruments should be contained within pouches, wrapped cassettes or bags that are suitable for steam sterilization (temperature resistant to 286 °F (141 °C)) along with an indicator or integrator strip.
- 2) Pack & label according to manufacturer's instructions.

5. Sterilization

5.1. Basics

Only use the sterilization methods listed; other forms of sterilization are at the responsibility of the user. Denovo recommends steam sterilization for most stainless-steel parts. Denovo recommends sterilizers with an automatic dry program. Check individual product restrictions before initiating sterilization.

Restrictions:

Do **NOT** use flash or radiation sterilization. Do **NOT** use formaldehyde, ethylene oxide, or plasma sterilization. Use of dry heat sterilization is at the responsibility of the user.

Protection:

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

- 1) Proper PPE is still required at this stage (utility gloves, protective gown, eye protection, etc.)
- 2) Proper care should be taken when handling sharp instruments, sharp materials or chemicals.

5.2. Autoclave (steam)

Denovo recommends fractioned vacuum or gravity steam sterilization.

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

Procedure:

- 1) Place cassettes or pouches (do not stack) into 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 displacement steam sterilization				
ITEM:	TEMPERATURE:	STERILIZATION TIME:	PRESSURE:	DRYING TIME:
Packed Instruments	250°F (121°C)	30 minutes	15 psi	30 minutes
Packed Parts	250°F (121°C)	30 minutes	15 psi	30 minutes

Cycle times for dynamic air removal steam sterilization				
ITEM:	TEMPERATURE:	STERILIZATION TIME:	PRESSURE:	DRYING TIME:
Packed Instruments	270°F (132°C)	4 minutes	1.0 – 2.0 psia	30 minutes
Packed Parts	270°F (132°C)	4 minutes	1.0 – 2.0 psia	30 minutes

Cycle times for chemiclave (chemical vapor) sterilization				
ITEM:	TEMPERATURE:	STERILIZATION TIME:	PRESSURE:	DRYING TIME:
Packed Instruments	270°F (132°C)	20 minutes	20 — 40psi	30 minutes
Packed Parts	270°F (132°C)	20 minutes	20 — 40psi	30 minutes

- 3) Instruments and parts must be completely dry and cool before handling. Sterilizers with auto-drying functions are highly recommended.
- 4) Proceed to storage

5.3. Cold Chemical

Ensure proper function of your chemical sterilization system:

- Ensure chemicals used are approved for use with dental products and are compatible with products

- Follow the manufacturer’s instructions for the proper protections, use, setup and disposal.
- Dental practices should check with their state environmental protection agency to determine if there are special requirements for the use or disposal of cold sterile or other 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).
- Use proper gloves and PPE while handling and working with chemicals.

Procedure:

- 1) Setup chemical bath according to manufacturer instruction.
- 2) Follow instruction’s provided by the manufacturer of the detergent or chemical being used for submersion times, sterile fields, removal and drying (specs listed below are minimum requirements):

Soak cycle times for cold chemical bath sterilization				
ITEM:	TEMPERATURE:	STERILIZATION TIME:	PRESSURE:	DRYING TIME:
Clearfield Retractors	68°F (20°C)	10 Hours	-	Manual
Impression Trays	68°F (20°C)	10 Hours	-	Manual

- 3) If additional items are added to the chemical bath, time must be restarted
- 4) Instruments and parts must be rinsed and completely dried before proceeding to storage

5.4. Dry Heat

Dry heat sterilization is at the responsibility of the user.

Ensure proper function of your dry heat system:

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

Procedure:

- 1) Lubricate hinged instruments thoroughly for dry heat processing.
- 2) Place pouches (do not stack) into the sterilizer according to manufacturer instruction.
- 3) 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 dry heat sterilization				
ITEM:	TEMPERATURE:	STERILIZATION TIME:	PRESSURE:	DRYING TIME:
Stainless Steel Instruments	320°F (160°C)	60 - 120 Minutes	15 psi	-

- 4) Instruments and parts must be completely cool before handling.
- 5) Proceed to storage

6. Storage

6.1. Storage Area

Sterile patient care items should be stored in a closed and well-ventilated area that would protect against dust and moisture.

Do not store sterile packages or pouches on top of or above a sterilizer.

Store packages or pouches vertically with proper identification labeling

6.2. Storage Guidelines for parts

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.





Store the Denovo kit box in a closed and well-ventilated area that would protect against dust and moisture.

Sterilization per Product Guidelines

7. 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
N	Do <u>NOT</u> use this cleaning or sterilization method on this product

7.1. SM bands & wires, SS crowns, matrix & molar bands







DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemt-dlave	Cold Chemicals:	
	8385-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use.</p> <p>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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>
	8906-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use. 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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>
	380-xxx 381-xxx 383-xxx 384-xxx 385-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use. 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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>
	170-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use. 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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>

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DEVICE:	PART #	Clean Method	Sterilization	NOTES:
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		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
Strip-T Matrices 	177-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use.</p> <p>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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>
SS Molar Crowns 	900-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use. 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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>
SS Anterior Crowns 	907-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use. 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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>
Molar Bands 	160-xxx	Y*	N	Y	Y*	N	Y	N	<p>All parts are supplied clean but not sterile, and are recommended to be sterilized before use. 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 <u>cannot</u> be re-used.</p> <p>Remove all biological or other contaminants during the cleaning process.</p> <p>Steam sterilization (vacuum or gravity) is recommended.</p>




7.2. Band instruments

DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemt-clave:	Cold Chemicals:	
Denovo Wire Shear 	802-020 802-026	N	N	Y*	N	N	N	N	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. Use an intermediate-level surface disinfectant (Cavicide® or other similar products) which is effective against TB, HBV, HCV, viruses (hydrophilic and lipophilic), bacteria (including MRSA and VRE) and fungi.
Tube Crimping Plier 	800-419	Y*	Y	Y	Y*	Y	Y	N	Properly clean pliers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.
Band Removers 	800-202 800-204	Y*	Y	Y	Y*	Y	Y	N	Properly clean band removers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended for the instrument and inserts. See section 1.3 for stainless-steel material restrictions (applies to insert as well).
Contouring & other band pliers 	800-108 800-313 805-314	Y*	Y	Y	Y*	Y	Y	N	Properly clean pliers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.
Lightweight band seater 	811-003	Y*	Y	Y	Y*	Y	Y	N	Properly clean seater prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. Section 1.3 for restrictions that apply to stainless steel also apply to this instrument.
Molar band seater (bite stick) 	811-002	Y*	Y	Y	Y*	N	Y	N	Properly clean bite stick prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Bite Sticks are made from a special liquid-crystal polymer that can withstand high temperatures. Steam sterilization (vacuum or gravity) is recommended. Section 1.3 for restrictions that apply to stainless steel also apply to this instrument. Do NOT use dry heat sterilization.






7.3. Forceps

DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
 <p>Pediatric Forceps</p>	813-101 813-102 813-103 813-104 813-105	Y*	Y	Y	Y*	Y	Y	N	<p>Take extra care to ensure Forceps are free of all loose material or matter prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used).</p> <p>Forceps are recommended to be steam (vacuum or gravity) sterilized. See section 1.3 for stainless steel material restrictions.</p>


7.4. Crown instruments

DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
 <p>Crown Crimping pliers</p>	800-417 800-421	Y*	Y	Y	Y*	Y	Y	N	<p>Properly clean pliers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.</p>
 <p>Crown Contouring Pliers</p>	800-112 800-114	Y*	Y	Y	Y*	Y	Y	N	<p>Properly clean pliers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.</p>
 <p>Crown Removing Plier</p>	800-015	Y*	Y	Y	Y*	Y	Y	N	<p>Properly clean pliers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.</p>



7.5. Orthodontic instruments

DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemt-clave:	Cold Chemicals:	
 <p>Orthodontic Pliers</p>	805-xxx	Y*	Y	Y	Y*	Y	Y	N	Properly clean pliers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.
 <p>Orthodontic Cutters</p>	805-550 805-551	Y*	Y	Y	Y*	N	Y	N	Properly clean cutters prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended, do NOT use dry heat sterilization as this will dull the cutting blades. See section 1.3 for stainless-steel material restrictions.
 <p>Bracket Removers</p>	805-334 805-335	Y*	Y	Y	Y*	Y	Y	N	Properly clean removers prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.
 <p>Ligature Directors</p>	805-816 805-818	Y*	Y	Y	Y*	Y	Y	N	Properly clean directors prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.
 <p>Matthieu Needle Holder</p>	805-501	Y*	Y	Y	Y*	Y	Y	N	Properly clean holders prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended. See section 1.3 for stainless-steel material restrictions.

7.6. Dental scissors

DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemi-clave:	Cold Chemicals:	
 <p>Dental Scissors</p>	801-xxx	Y*	Y	Y	Y*	N	Y	N	<p>Properly clean scissors prior to sterilization (ultrasonic cleaner systems are recommended, an automatic washer can be used). Steam sterilization (vacuum or gravity) is recommended, do NOT use dry heat sterilization as this will dull the cutting blades. See section 1.3 for stainless-steel material restrictions.</p>

7.7. Clearfield, impression trays

DEVICE:	PART #	Clean Method			Sterilization				NOTES:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemi-clave:	Cold Chemicals:	
 <p>Clearfield Cheek Retractors</p>	430-300 430-400	N	N	Y	N	N	N	Y*	<p>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.</p> <p>Do NOT use any heat or pressure sterilization such as autoclaves or chemiclaves. Cold sterilization can be used. Chemicals used must be classified as either glutaraldehyde or orthophthalaldehyde. 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.</p>
 <p>All Impression Trays</p>	730-xxx	N	N	Y	N	N	N	Y*	<p>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.</p> <p>Do NOT use any heat or pressure sterilization such as autoclaves or chemiclaves. Cold sterilization can be used. Chemicals used must be classified as either glutaraldehyde or orthophthalaldehyde. 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.</p>

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SKU/ Part #:	Device Name	Clean Method			Sterilization				Details Page #:
		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
160-146 — 160-184	Pedo Molar Maxillary Bands	Y*	N	Y	Y*	N	Y	N	10
160-246 — 160-284	Pedo Molar Mandibular Bands	Y*	N	Y	Y*	N	Y	N	10
161-100 — 161-102	Pedo Molar Band Kits	Y*	N	Y	Y*	N	Y	N	10
170-301 — 170-315	Preformed Matrix Band 3/16 Pedo	Y*	N	Y	Y*	N	Y	N	9
170-401 — 170-415	Preformed Matrix Band ¼ Adult	Y*	N	Y	Y*	N	Y	N	9
171-300 — 171-600	Preformed Matrix Band Kits	Y*	N	Y	Y*	N	Y	N	9
177-101 — 177-301	Strip-T Matrices	Y*	N	Y	Y*	N	Y	N	9
177-101 — 177-417	Woody Wedges	N	N	N	N	N	N	N	-
190-213 — 190-448	Open Crowns	Y*	N	Y	Y*	N	Y	N	10
380-001 — 385-003	Space Maintainer Wires	Y*	N	Y	Y*	N	Y	N	9
387-012 — 387-365	Space Maintainer Kits	Y*	N	Y	Y*	N	Y	N	9
430-300 — 430-400	Clearfield Cheek Retractors	N	N	Y*	N	N	N	Y*	14
730-100 — 730-340	Impression Trays	N	N	Y*	N	N	N	Y*	14
800-015	CROWN REMOVING PLIER	Y*	Y	Y	Y*	Y	Y	N	12
800-108	BAND CONTOURING PLIER	Y*	Y	Y	Y*	Y	Y	N	9
800-112	CROWN CONTOURING PLIER	Y*	Y	Y	Y*	Y	Y	N	12
800-114	CROWN CONTOURING JOHNSON #114	Y*	Y	Y	Y*	Y	Y	N	12
800-202	POSTERIOR BAND REMOVER	Y*	Y	Y	Y*	Y	Y	N	9
800-204	POSTERIOR BAND REMOVER LONG	Y*	Y	Y	Y*	Y	Y	N	9
800-313	THREE JAW PLIER - TO .036 WIRE	Y*	Y	Y	Y*	Y	Y	N	9
800-417	REGULAR CROWN CRIMPING PLIER	Y*	Y	Y	Y*	Y	Y	N	12
800-419	DENOVO TUBE CRIMPING PLIER	Y*	Y	Y	Y*	Y	Y	N	9
800-421	SMALL CROWN CRIMPING PLIER	Y*	Y	Y	Y*	Y	Y	N	12
800-704	DELIN INSERTS FOR PST BND REM	Y*	Y	Y	Y*	Y	Y	N	9
801-200	CROWN SCISSORS 3 PC SET CHROME	Y*	Y	Y	Y*	N	Y	N	14
801-200T	CROWNS SCISSORS 3 PIECE SET SS	Y*	Y	Y	Y*	N	Y	N	14
801-201T	CROWN SCISSORS STRAIGHT SS	Y*	Y	Y	Y*	N	Y	N	14
801-202T	CROWN SCISSORS CURVED SS	Y*	Y	Y	Y*	N	Y	N	14
801-203T	CROWN SCISSORS CURVED FEST SS	Y*	Y	Y	Y*	N	Y	N	14
802-020	1.0MM - 1.2MM WIRE SHEAR	N	N	Y*	N	N	N	N	9
802-026	BAR CUTTER	N	N	Y*	N	N	N	N	9
805-215	MATHIEU NEEDLE HOLDER	Y*	Y	Y	Y*	Y	Y	N	13
805-303	TWEED ARCH BENDING PLIER	Y*	Y	Y	Y*	Y	Y	N	13
805-306	HOWE PLIER REGULAR	Y*	Y	Y	Y*	Y	Y	N	13
805-314	BIRD BEAK PLIER	Y*	Y	Y	Y*	Y	Y	N	13
805-334	DB BRACKET REMOVING PLIER ANG	Y*	Y	Y	Y*	Y	Y	N	13
805-335	DB BRACKET REMOVING PLIER STRA	Y*	Y	Y	Y*	Y	Y	N	13
805-501	WEINGART UTILITY PLIER	Y*	Y	Y	Y*	Y	Y	N	13
805-550	DISTAL END SAFETY HOLD CUTTER	Y*	Y	Y	Y*	N	Y	N	13
805-551	DIST END SAFETY HOLD CUTR SLIM	Y*	Y	Y	Y*	N	Y	N	13
805-604	PIN & LIGATURE CUTTER	Y*	Y	Y	Y*	N	Y	N	13
805-741	PLIER STAND	Y*	N	Y	Y*	N	Y	N	13




SKU/ Part #:	Device Name	Clean Method	Sterilization	Details Page #:
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		Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
805-816	LIGATURE DIRECTOR	Y*	Y	Y	Y*	Y	Y	N	13
805-818	LIGATURE DIRECTOR - DOUBLE END	Y*	Y	Y	Y*	Y	Y	N	13
811-002	BITE STICK W/TRIANGLER INSERT	Y*	Y	Y	Y*	N	Y	N	11
811-003	LIGHTWEIGHT BAND SEATER	Y*	Y	Y	Y*	Y	Y	N	11
813-100	PEDO FORCEPS KIT	Y*	Y	Y	Y*	Y	Y	N	12
813-101	#1 PEDO FORCEP UPPER ANT	Y*	Y	Y	Y*	Y	Y	N	12
813-102	#44 PEDO FORCEP LOWER ANT	Y*	Y	Y	Y*	Y	Y	N	12
813-103	#23 LOWER MOLAR COW HORN	Y*	Y	Y	Y*	Y	Y	N	12
813-104	#10S MLR FORCEP BAYONET	Y*	Y	Y	Y*	Y	Y	N	12
813-105	#27 MLR FORCEP BD BEAK	Y*	Y	Y	Y*	Y	Y	N	12
8385-131 — 8385-197	Space Maintainer Maxillary Bands	Y*	N	Y	Y*	N	Y	N	9
8385-231 — 8385-297	Space Maintainer Mandibular Bands	Y*	N	Y	Y*	N	Y	N	9
8906-111 — 8906-147	Space Maintainer 1 st Primary Crowns	Y*	N	Y	Y*	N	Y	N	9
8906-211 — 8906-247	Space Maintainer 2 nd Primary Crowns	Y*	N	Y	Y*	N	Y	N	9
900-111 — 900-147	1 st Primary Crowns	Y*	N	Y	Y*	N	Y	N	10
900-211 — 900-247	2 nd Primary Crowns	Y*	N	Y	Y*	N	Y	N	10
900-311 — 900-348	1 st Permanent Crowns	Y*	N	Y	Y*	N	Y	N	10
902-100 — 902-300	Crown Kits	Y*	N	Y	Y*	N	Y	N	10
907-001 — 907-100	Anterior Crowns	Y*	N	Y	Y*	N	Y	N	10
930-106 — 930-301	Space Maintainer Crown Kits	Y*	N	Y	Y*	N	Y	N	9

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

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>