

Scope

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

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

Scope.....	1
Table of Contents.....	1
General Information.....	2
1. General Guidelines	2
Sterilization Procedure Details.....	3
2. Pre-Treatment: Rinse & Disinfect	3
3. Ultrasonic Clean	3
4. Preparation for Sterilization.....	4
5. Sterilization.....	4
6. Storage	5
Sterilization per Product Guidelines.....	7
7. Special Procedures.....	7
7.1. Wire Shear & Instruments with Blades.....	7
7.2. Pediatric Forceps	8
7.3. Non-Standard Instruments.....	8
7.4. Standard Steel Instruments.....	8
Product Index.....	10

General Information

1. General Guidelines

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

Cleaning and sterilization are required for the **first use of instruments** after removal from the protective packaging. 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; up to 20 years. The user is responsible for proper inspection between each use to detect corrosion, damage, warping, or other wear. Immediately remove damaged instruments from use.

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** 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).

1.3. Personal Protection

All used and contaminated Instruments and 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 instruments or abrasive chemicals.

1.4. Reprocessing Stations

Ensure proper locations and procedures are in place to place and identify instruments 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 or instruments before initiating the reprocessing process.

Contaminated instruments and parts must be cleaned as early as possible after use in order to maximize safety. Remove coarse debris, dental materials or other residues from the instruments immediately after application (within a maximum time of 2 hours):

2.1. Rinse Instruments

- 1) Rinse thoroughly with de-ionized water. Check that hinged instruments or part tubes are free of debris.
- 2) Check the instruments for damage: corrosion, warping, breakage or other extensive wear. For manual removal of coarse impurities use only a soft brush or cloth. Never use metal brushes or steel wool.

2.2. Disinfect Instruments

- 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) Remove any final coarse impurities with a soft brush or cloth.
- 5) Proceed to the Ultrasonic cleaning stage immediately. *Do not allow instruments to sit wet.*

2.3. Restrictions

- Do NOT rinse or soak the Denovo Wire Shear (part #802-020).
- The use of a Washer Disinfector or other Automatic washer is NOT recommended.
- 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. Ultrasonic Clean

3.1. Run Ultrasonic Cycle

- 1) Place parts or instruments in a cassette suitable for the application. Open instruments (like scissors and forceps) for maximum exposure. Ensure no parts are touching.
- 2) Load parts into the Ultrasonic cleaner making sure parts are fully immersed and never overload the unit.

Setup and start the ultrasonic cleaning program per the manufacturer's recommendations, 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.

- 3) Check the detergent manufactures guidelines for soaking times (usually at least 16 minutes for cassette systems.).
- 4) 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.
- 5) Allow instruments and parts to dry completely to prevent wicking, cross-contamination or corrosion.
- 6) Proceed to the preparation and packaging phase immediately.

3.2. Ultrasonic Cleaner Validation

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), 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.

3.3. Restrictions

- Do NOT Ultrasonic clean instruments with a cutting blade:
 - Denovo Wire Shear (*part #802-020*)
 - Distal End Cutters (parts #805-550 & #805-551)
 - Pin & Ligature Cutter (*part #805-604*)
 - Crown Scissors (parts #801-201T, #801-202T, #801-203T)
 - The use of a Washer Disinfector or other Automatic washer is NOT recommended.

4. Preparation for Sterilization

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

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

4.3. Preparation & Packing

- 4) 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.
- 5) Pack & label according to manufacturer's instructions.

5. Sterilization

Check individual product restrictions before initiating sterilization.

5.1. Autoclave Cycle (steam)

- 1) Load instruments into pouches individually and seal. Open hinged instruments as much as possible within the pouch.
- 2) Place pouches and/or cassettes (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 steam sterilization				
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>			

5.2. Dry Cycle

- 4) Run the Sterilizer's dry cycle according to the manufacturer's instructions.
- 5) Instruments and parts must be completely dry and cool before handling. **INSPECT for rust immediately after removal from the Autoclave.** If any is found, contact Denovo.
- 6) **Inspect for any moisture immediately after removal from the Autoclave.** Any moisture in the pouch or on the instrument may cause rust during storage.
- 7) Proceed to storage

Skippping the Dry Cycle step and attempting to manually dry instruments usually *does not* fully dry hinge interiors and beveled grips and *can lead* to rusting in these areas. Do not skip the Dry Cycle step.

5.3. 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

5.4. Restrictions

- 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 Chemiclave Sterilization
 - Do NOT use Cold Sterilization methods
 - Do NOT use flash or radiation sterilization.
 - Do NOT use formaldehyde, ethylene oxide, or plasma sterilization.

6. Storage

6.1. Store

- 1) Ensure instruments are completely dry. Any moisture left on the instruments, especially in the hinge or textured grip areas will most likely cause rust.
- 2) Sterile patient care items should be stored in a closed and well-ventilated area that would protect against dust and moisture.
- 3) Store packages or pouches vertically with proper identification labeling
- 4) Do not store sterile packages or pouches on top of or above a sterilizer.

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 NOT use this cleaning or sterilization method on this product

7.1. Wire Shear & Instruments with Blades

DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Rinse & Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
Denovo Wire Shear 	802-020	N	N	N	Y*	N	N	N	N	Due to the carbide blade which will rust after any contact with moisture, Wire Shears should be hand-wiped only. Other methods of sterilization will pit the carbide blades and will no longer function as designed. Pre-trim wires and avoid contact with dirty gloves. 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. Lubricate hinge periodically.
Orthodontic Distal, Pin & Ligature Cutters 	805-550 805-551 805-604	Y*	N	N	Y	Y*	N	N	N	Rinse, Soak and clean cutters prior to sterilization. DO NOT use and Ultrasonic cleaner system as this will dull the blade of the instrument. Steam sterilization is recommended, do not use dry heat sterilization as this will dull the cutting blades. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Dental Scissors 	801-201T 801-202T 801-203T	Y*	N	N	Y	Y*	N	N	N	Rinse, Soak and clean Scissors prior to sterilization. DO NOT use and Ultrasonic cleaner system as this will dull the blade of the instrument. Steam sterilization is recommended, do not use dry heat sterilization as this will dull the cutting blades. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.

7.2. Pediatric Forceps

DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Rinse & Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
Pediatric Forceps 	813-101	Y*	Y*	N	Y	Y*	N	N	N	Take extra care to ensure Forceps are free of all loose material or matter prior to sterilization. Rinse, Soak in an Enzymatic cleaner, rinse again and run through an Ultrasonic Cycle. Forceps are recommended to be steam sterilized. Drying cycle must be run to fully dry hinge, and textured handle grips and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
	813-102									
	813-103									
	813-104									
	813-105									

7.3. Non-Standard Instruments

DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Rinse & Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
Band Removers 	800-202 800-204	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on removers prior to sterilization. Steam sterilization is recommended. Delrin and Aluminum inserts can undergo sterilization. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Lightweight band seater 	811-003	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on the band seater prior to sterilization. Band seater is made with high-strength Aluminum, Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Section 1.2 for restrictions also apply to this instrument.
Molar band seater (bite stick) 	811-002	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on Bite Stick prior to sterilization. Bite Sticks are made from a special liquid-crystal polymer that can withstand high temperatures. Steam sterilization (vacuum or gravity) is recommended. Do <u>NOT</u> use dry heat sterilization. Section 1.2 for restrictions also apply to this instrument.

7.4. Standard Steel Instruments

DEVICE:	PART #	Clean Method				Sterilization				NOTES:
		Rinse & Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chem-clave:	Cold Chemicals:	
Tube Crimping Plier 	800-419	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on pliers prior to sterilization. Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Contouring & other band pliers 	800-108 800-313 805-314	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on pliers prior to sterilization. Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Orthodontic Pliers 	805-306 805-314 800-313 805-303 805-501	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on pliers prior to sterilization. Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Bracket Removers 	805-334 805-335	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on removers prior to sterilization. Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Crown Crimping & Contouring pliers 	800-417 800-421 800-112 800-114	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on pliers prior to sterilization. Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.
Crown Removing Plier 	800-015	Y*	Y*	N	Y	Y*	N	N	N	Properly rinse, disinfect and run an Ultrasonic Cycle on pliers prior to sterilization. Steam sterilization is recommended. Drying cycle must be run to fully dry the instrument and prevent rust. Lubricate hinge periodically. See section 1.2 for material restrictions.

Product Index

SKU/ Part #:	Device Name	Clean Method				Sterilization				Details Page #:
		Rinse & Soak:	Ultrasonic:	Auto Washer:	Manual:	Steam Heat:	Dry Heat:	Chemical:	Cold Chemicals:	
800-015	CROWN REMOVING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
800-108	BAND CONTOURING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
800-112	CROWN CONTOURING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
800-114	CROWN CONTOURING JOHNSON #114	Y*	Y*	N	Y	Y*	N	N	N	8
800-202	POSTERIOR BAND REMOVER	Y*	Y*	N	Y	Y*	N	N	N	7
800-204	POSTERIOR BAND REMOVER LONG	Y*	Y*	N	Y	Y*	N	N	N	7
800-313	THREE JAW PLIER - TO .036 WIRE	Y*	Y*	N	Y	Y*	N	N	N	8
800-417	REGULAR CROWN CRIMPING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
800-419	DENOVO TUBE CRIMPING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
800-421	SMALL CROWN CRIMPING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
801-200	CROWN SCISSORS 3 PC SET	Y*	N	N	Y	Y*	N	N	N	6
801-200T	CROWNS SCISSORS 3 PIECE SET SS	Y*	N	N	Y	Y*	N	N	N	6
801-201T	CROWN SCISSORS STRAIGHT SS	Y*	N	N	Y	Y*	N	N	N	6
801-202T	CROWN SCISSORS CURVED SS	Y*	N	N	Y	Y*	N	N	N	6
801-203T	CROWN SCISSORS CURVED FEST SS	Y*	N	N	Y	Y*	N	N	N	6
802-020	DENOVO WIRE SHEAR 1.0MM - 1.2MM	N	N	N	Y*	N	N	N	N	6
805-303	TWEED ARCH BENDING PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
805-306	HOWE PLIER REGULAR	Y*	Y*	N	Y	Y*	N	N	N	8
805-314	BIRD BEAK PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
805-334	DB BRACKET REMOVING PLIER ANG	Y*	Y*	N	Y	Y*	N	N	N	8
805-335	DB BRACKET REMOVING PLIER STRA	Y*	Y*	N	Y	Y*	N	N	N	8
805-501	WEINGART UTILITY PLIER	Y*	Y*	N	Y	Y*	N	N	N	8
805-550	DISTAL END SAFETY HOLD CUTTER	Y*	N	N	Y	Y*	N	N	N	6
805-551	DIST END SAFETY HOLD CUTR SLIM	Y*	N	N	Y	Y*	N	N	N	6
805-604	PIN & LIGATURE CUTTER	Y*	N	N	Y	Y*	N	N	N	6
805-741	PLIER STAND	Y*	Y*	N	Y	Y*	N	N	N	8
811-002	BITE STICK W/TRIANGLER INSERT	Y*	Y*	N	Y	Y*	N	N	N	7
811-003	LIGHTWEIGHT BAND SEATER	Y*	Y*	N	Y	Y*	N	N	N	7
813-100	PEDO FORCEPS KIT	Y*	Y*	N	Y	Y*	N	N	N	7
813-101	#1 PEDO FORCEP UPPER ANT	Y*	Y*	N	Y	Y*	N	N	N	7
813-102	#44 PEDO FORCEP LOWER ANT	Y*	Y*	N	Y	Y*	N	N	N	7
813-103	#23 LOWER MOLAR COW HORN	Y*	Y*	N	Y	Y*	N	N	N	7
813-104	#10S MLR FORCEP BAYONET	Y*	Y*	N	Y	Y*	N	N	N	7
813-105	#27 MLR FORCEP BD BEAK	Y*	Y*	N	Y	Y*	N	N	N	7

I Amendment History Table:

Revision Date		Description of Change	Made by (initials)
1	2018.01.14	Sterilization document creation	PH
3	2019.01.12	Sterilization document basic updates and corrections	PH
3	2021.02.20	Sterilization document format update	CH
4	2021.03.01	Added approximate sterilization times	CH
5	2021.03.16	Corrected and expanded on sterilization times, temps, pressures and drying time.	CH
6	2024.09.04	Corrections on sterilization processes down to only recommending Steam Sterilization. Removing Auto-washing recommendations. Split documents to instrument specific.	CH
6	2025.01.02	Reviewed	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>