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#### Section I: Instrument Care & Reprocessing Guide

## It's important to remember:

While Surgical Stainless Steel is known for its resistance to wear, corrosion, and discoloration, just like any other impermanent material, it is still susceptible to harm when not cared for or maintained properly. Following all manufacturer recommendations for sterilization and reprocessing is imperative to ensure you get the longest lifespan from your instruments.

## An Overview:

ProDentUSA instruments are best maintained if they are cleaned and sterilized immediately after they have performed their intended uses. Reprocessing steps are as follows:

- I. Cleaning & Disinfecting
- II. Lubricating
- III. Sterilizing
- IV. Storing

## Before You Get Started:

- It is important to make sure all staff are properly trained in using the chemicals and equipment necessary to reprocess instruments. All staff must wear protective gear including non-puncture gloves, eye shields, and gowns to protect clothing.
- All instruments should be handled with care throughout the reprocessing cycle to avoid both personal injury and damage caused to instruments from mishandling.
- **Distilled water** must be used in all cleaning and sterilization processes. Minerals, salts, and high chloride content in tap and drinking water will cause discoloration, corrosion and pitting on instrument surfaces when the water dries. Distilled water is free of any impurities and additives and will not tarnish instrument surfaces when used properly.\*

# • A note on disinfectants:

Use only pH neutral chemicals to disinfect<sup>+</sup>. Do not use corrosive chemicals. Detergents or disinfectants containing the following substances must be **avoided**:

- alkalines (> pH 9)
- acids (< pH 4)
- phenols or iodophors (petroleum based/derived chemicals)
- interhalogenic agents/halogenic hydrocarbons/iodophors
- strong oxidizing agents/peroxides/bleach
- organic solvents
- All new instruments must be cleaned, lubricated, and sterilized before use.
- **Titanium coated instruments:** Some ProDentUSA stainless steel instruments are coated with Titanium to add hardness to the working ends. These instruments can be cleaned and sterilized

<sup>\*</sup>Discoloration or tarnish on instrument surfaces happens when the incorrect water or chemical type is used in any step of the reprocessing cycle. See "A note on disinfectants" for a list of chemicals to avoid.

<sup>\*</sup>Low pH detergents may cause pits and stains on instruments. High pH detergents can interfere with the smooth operation of instruments.

using the same methods and parameters as the stainless steel instruments. **Note**: abrasive materials should never be used to clean any part of Titanium-coated instruments.

- **I. CLEANING & DISINFECTING:** All instruments must be cleaned and disinfected prior to sterilization. This step must not be skipped.
  - A. MANUAL CLEANING: Manual cleaning presents many hazards, as there is a greater risk of exposure to potentially dangerous materials. If no other cleaning method is available, staff should wear extra protective gear to manually clean instruments. Washing should be done low in a sink to ensure substances and contaminants do not splash.
    - 1) Immediately after use, remove organic materials by rinsing instruments with distilled water. Rinse should remove most blood, fluids, tissue, and debris.
    - 2) Immerse instruments completely in a disinfectant<sup>\*</sup> for 10-15 minutes, ensuring all hinged, jointed and clamped instruments are in an open position. Then rinse again.
    - 3) Using a stiff nylon brush, gently scrub instruments with a neutral detergent (pH7). Do not use steel wool or wire brushes, as these may cause instruments to corrode from metal to metal contact. Brush delicate instruments separately from general instruments. Make sure all serrated areas, grooves, hinges, joints, and hard to reach areas have been cleaned thoroughly.
    - 4) Check that all instrument surfaces are visibly clean and free from stains and organic materials.
    - 5) After scrubbing, rinse instruments thoroughly using distilled water<sup>\*</sup>. While rinsing, open and close hinged instruments, to make sure hinged areas are rinsed out.
    - 6) Dry instruments immediately and thoroughly, and inspect for functionality.
  - **B. ULTRASONIC CLEANING:** Ultrasonic cleaning is not only safer but also more effective than manual cleaning, particularly for those instruments with hinges and moving parts. Protective gear must be worn throughout the ultrasonic cleaning process.
    - 1) Immediately after use, move contaminated instruments to the cleaning area. For best results, remove all materials like cements, composites, etc. at chairside before processing in the ultrasonic unit.
    - 2) Load instruments with hinges, joints, and clamps in the open position into sterilizing cassette or basket. Take care that instruments, particularly sharp blades and cutting edges, do not overlap or touch. Do not overload cassette, basket, or ultrasonic unit as this will result in improper cleaning.
    - 3) Fill the ultrasonic unit with rust inhibiting, general-purpose solution to the level indicated on the unit. This fluid *must* be prepared and changed daily to ensure your instruments' longevity is not compromised.
    - 4) Fully submerge prepared cassette or basket into fluid. Do not exceed a temperature of 40°C or 104°F, and keep the frequency of the unit at 35-60kHz. Wash instruments for full recommended cleaning cycle.
    - 5) Remove instruments from ultrasonic and rinse thoroughly with distilled water for at least 20 seconds per instrument.
    - 6) Dry instruments immediately and thoroughly and allow to cool.
  - C. AUTOMATIC CLEANING: Of the three methods, automatic washing units are most efficient in cleaning and disinfecting. Protective gear must be worn throughout the automatic cleaning process.
    1) Immediately after use, move contaminated instruments to the cleaning area. For best results,

<sup>\*</sup>Discoloration or tarnish on instrument surfaces happens when the incorrect water or chemical type is used in any step of the reprocessing cycle. See "A note on disinfectants" (pg. 1) for a list of chemicals to avoid.

remove all materials like cements, composites, etc. at chairside before processing in the washer unit.

- 2) Load instruments with hinges, joints, and clamps in the open position into sterilizing cassette or basket. Take care that instruments, particularly sharp blades and cutting edges, do not overlap or touch. Do not overload cassette, basket, or washer unit as this will result in improper cleaning.
- 3) Ensure that correct cleaning solution is being used and begin the washing cycle. The recommended temperature for cleaning/disinfecting instruments in the automatic washer is 105°C or 221°F. Let the whole cycle run before removing instruments.
- 4) Remove instruments from washer unit and allow to cool.
- **D. RESIDUE:** All remaining residue *must* be wiped thoroughly before lubricating and sterilizing, as trapped residue will cause improper sterilization, discoloration, staining, or all of these.
- **II. LUBRICATING:** All hinged, jointed, and box-locked instruments with moving parts must be lubricated prior to sterilization.
  - A. LUBRICANTS: It is important to choose a lubricant that is water-soluble so as to allow steam to permeate for sterilization. Lubricants must be free of mineral and silicone oil as these oils trap microorganisms, preventing proper sterilization. The film created by these oils also adversely affects instruments' functionality. Thermally stable, synthetic lubricants with anti-corrosion agents are recommended.

## **B. LUBRICATING AND FUNCTIONALITY CHECK:**

- 1) After instruments have cooled completely, apply lubricant to hinges and joints with care, opening and closing the joints and hinges as necessary to ensure the lubricant has properly coated the area.
- 2) Check for functionality at this time\*. Open and close all hinged, jointed, and clamped instruments to ensure they are working properly.
- 3) No rinsing is necessary after application. (Except in cold sterilization processes. See Section III.C.2.)
- **C. LUBRICATING IN AN AUTOMATIC WASHER:** Some automatic washers have a lubrication cycle built in. Be sure to choose the correct type of lubricant to use in the washer.
- **III. STERILIZING:** After instruments have been cleaned, disinfected, lubricated, and checked, they are ready to be sterilized. This step kills all microorganisms on instrument surfaces and, when performed properly, renders instruments ready to be used again.
  - A. AUTOCLAVING: The sterilizer for autoclaving or steam sterilizing instruments (either Gravity-Displacement or Dynamic-Air-Removal) must comply with German Standard DIN EN 13060 Type B for wrapped, packaged, solid, hollow, and porous instruments.
    - 1) Use only distilled water in sterilizer. Dirty or impure water will create dirty steam resulting in staining and improper sterilization.
    - 2) Before loading instruments into sterilizer, ensure that all hinged, jointed, and clamped

<sup>\*</sup>Do not perform functionality check until instruments are **completely cool** so as to avoid metal wear and abrasion, which can lead to corrosion.

instruments are wrapped or packaged in the open position. Sterilizing closed instruments will result in cracked hinges due to heat expansion and improper sterilization as steam will not be able to permeate all surfaces of the instrument.

- 3) Place heavy instruments on the bottom of sets and position sets such that steam penetration is not hindered in any way. Do not overload cassette, tray, or sterilizer, as this will not allow full circulation of steam.
- 4) Follow sterilizer manufacturer instructions for cycle time and temperature. See table below for general sterilization parameters for the two types of steam sterilization. Follow all specified routine checks and maintenance regulations.

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Gravity-Displacement Steam Sterilization			
Exposure time at 127°C (260°F)	Drying times		
30 minutes	Minimum 30 minutes		
Dynamic-Air-Removal Steam Sterilization			
Exposure time at 132°C (269.6°F)	Drying times		
5 minutes	Minimum 30 minutes		

#### Table 1: Autoclave Exposure Times and Drying Times

5) Do not remove instruments from autoclave until they are completely dry.

B. DRY HEAT STERILIZATION: Dry heat sterilization is the recommended method of sterilization for ProDentUSA Siberian Stone<sup>™</sup> Pliers and Cutters. This method of sterilization uses oven-type heat to remove microorganisms from instrument surfaces. All dry heat sterilizer manufacturer instructions should be followed closely to ensure your instruments' longevity is not compromised.

- 1) Follow manufacturer's packaging requirements for sterilization cycle. Instruments must be completely dry before dry heat sterilization, as water will interfere with the sterilization process.
- 2) Make sure to load instruments into sterilizer properly.
- 3) Maintain, but **do not** exceed 180°C or 356°F. Exceeding this temperature for even a brief time will compromise your instruments' hardness and functionality. See table below for general dry heat sterilization parameters.

#### Table 2: Dry Heat Temperature and Exposure Times

Temperature	Exposure Time
160°C (320°F)	120 minutes
170°C (338°F)	60 minutes

4) Never open the sterilizer unit during the sterilization cycle. Allow instruments to cool completely before removing them from the unit.

C. COLD STERILIZATION: Cold sterilization is the least efficient way to sterilize instruments because of how long the process takes and because of the chemicals that are used. It should only be used if instruments are not compatible with steam or dry heat sterilization. Cold sterilization **should not** be used for ProDentUSA *Siberian Stone™* pliers, but may be used for non-metal parts of instruments such as rubber tips and/or instruments with non-metal parts, such as luxators with silicon handles.

1) Ensure that all staff follow safety regulations for handling high-level disinfectants/sterilants. These solutions *must* be cleared by the FDA for use in dental settings. Staff should not handle high-level disinfectants without chemical-resistant utility gloves and protective glasses. Cold sterilization should only take place in well-ventilated areas. The container with the solution must always be closed tightly to prevent environmental hazards. Evaporation also decreases the effectiveness of the solution. Follow high-level disinfectant manufacturer instructions closely for changing solution and monitoring germicide.

- 2) Wipe instruments clean of all lubricants, as lubricants interfere with the cold sterilization process.
- 3) Follow high-level disinfectant manufacturer instructions for submerging instruments. Instruments are typically disinfected in 15 to 30 minutes, but, depending on the solution, sterilization occurs only after at least six hours of immersion.
- 4) Be sure to follow state and local guidelines for disposal of high-level disinfectants.

IV. STORING: Storing instruments for future use is an integral part of reprocessing.

- A. All instruments must be completely dry before being stored.
- B. Separate sterile and non-sterile instruments strictly.
- **C.** Store all sterile instruments in a dust-free environment, away from any cleaning areas or equipment.
- D. Do not open instruments' sterile packaging prior to use. Opened instruments are no longer sterile.

## Section II: Revolve<sup>™</sup> Handpiece Care & Reprocessing

Our state of the art *Revolve™* handpieces are guaranteed against any manufacturer defects for a minimum of the first year after purchase. Just like any equipment, **daily** maintenance is essential to the smooth operation of this product. Follow the below instructions to ensure you get the most out of your handpiece:

I. CLEANING: All handpieces must be cleaned and disinfected prior to sterilization. This step must not be skipped.

**A. PREPARATION:** Remove the bur from the handpiece and immediately wipe with a disinfectant wipe or alcohol-soaked cloth. Run the handpiece for about 20 seconds to clear the water line. Disconnect the handpiece from the dental unit and proceed to the next section.

## **B. EXTERNAL CLEANING:**

- 1. Clean the casing: Using a soft cloth, clean the outside of the handpiece with an enzymatic solution or neutral detergent, ensuring you do not spray the detergent onto the handpiece directly. A soft-bristled brush may be used if required. Rinse with water.
- 2. Clean the chuck: Using a small brush, clean inside the chuck.
- 3. Clean the spray port: Remove the head cap and the cartridges. Carefully insert the cleaning wire straight into the spray nozzle. Do not force the wire into the port, as this may damage the functionality. Ensure that the cleaning wire reaches the deepest groove, then remove. Brush off the debris from the spray nozzle and the brush. Rinse with water.

**II. LUBRICATION:** All handpieces must be lubricated prior to autoclaving **after each use** to ensure proper functionality of the handpiece. Follow the steps below for lubrication:

- 1. Place oil spray on a level working area. Take your clean handpiece and position the spray nozzle onto the back end of the handpiece.
- 2. Spray for 1-2 seconds or until you see clear fluid discharging from the working end.

**III. STERILIZATION:** The recommended method of sterilization for  $Revolve^{M}$  handpieces is autoclave or steam sterilization.

1. After the handpiece is cleaned and lubricated, insert the handpiece into a sterilization pouch.

2. Sterilize in an FDA-approved autoclave as per the parameters below:

Gravity-Displacement Steam Sterilization		
Exposure time at 132°C (269.6°F)	Drying times	
15 minutes	Minimum 30 minutes	
Dynamic-Air-Removal Steam Sterilization		
Exposure time at 132°C (269.6°F)	Drying times	
4 minutes	Minimum 30 minutes	

3. Remove the handpieces from the autoclave once the cycle is complete and store in a cool, dry place.

## Section III: The ProDentUSA Repair Shop

All ProDentUSA Signature Siberian Stone<sup>™</sup> Cutters come with a 1-Year Free Sharpening Warranty. Wire cutters, orthodontic pliers, and handpieces of all makes and brands can also be repaired at our repair shop. Download our repair form for further instructions:



## Section IV: Instruments for Change: Our Instrument Recycling Program

At ProDentUSA, we love the earth and everyone in it. That's why we've created a recycling program where we refurbish instruments that can be salvaged and donate them to organizations and doctors around the globe who provide free dental care to communities in need. For instruments that cannot be salvaged, we recycle the materials and donate them to industries that can use it.

You can be a part of ProDentUSA's *Instruments for Change* initiative! Send us any seven used instruments, regardless of manufacturer, and we will send you one instrument for free. Simply sterilize and package the instruments and send them to our headquarters in East Brunswick, New Jersey. Once we receive the instruments, we will send out your free gift. Download and send our recycling program form to get started.

Together, we can close the gap on dental healthcare and spread smiles, one instrument at a time.

For all further questions, do not hesitate to contact us. We are here to help.