The Highest Quality Dental Instruments Manufacturer
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Instructions For Use & Sterilization Best Practices

PDU Dental Hand Instruments and Accessories

Instructions for Use:

All instruments are to be cleaned and sterilized prior to each use. In addition, testing, cleaning, and sterilization is also required for the first use of non-sterile instruments after removal from the protective packaging. Effective cleaning is an indispensable requirement for proper instrument sterilization.

The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning and sterilization cycle.

Instructions contained in this guide have been validated by Power Dental Group.

All instruments are latex free and require no additional special handling.

Cleaning:

Ultrasonic cleaning is the most effective way to clean the instrument.

It is required that the instrument is pre-washed prior to being fully submerged in an open position, if applicable, using low contaminated, deionized water (i.e. distilled water) and an ultrasonic cleaning solution.

Avoid using the following detergents or disinfectant solutions:

- strong alkalines (> pH 9)
- strong acids (< pH 4)
- phenols or iodophors
- interhalogenic agents/halogenic hydrocarbons
- strong oxidizing agents/peroxides
- organic solvents.

Always rinse ultrasonic cleaning solution from the instrument with distilled water prior to sterilization.

An additional way to clean besides ultrasonic would be to manually clean the instrument with Nylon or stainless-steel brushes using a mild or low PH surgical detergent.

We recommend strongly to not use the following to avoid damaging the finish of the instrument: steel wool, steel brushes or scouring pads.

Always rinse any cleaning solution from the instrument with low contaminated, deionized water prior to sterilization.

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Sterilization Best Practices:

Use only the recommended sterilization procedure and guidelines listed below. Other sterilization procedures and or guidelines are the responsibility of the user. Power Dental Group recommends a minimum 30-minute dry time; however, defer to the sterilizing manufacturer's instructions for the equipment used.

Note that the entire instrument is fully autoclavable and sterilizable up to 320°F/160°C. Do not expose instruments to above temperatures, which is possible along the sides and bottom of autoclave units.

General Sterilization Procedure:

1.) With puncture-resistant utility gloves, completely disassemble the instrument, if applicable.
2.) Place all contaminated waste in a biohazardous waste container.
3.) Disassemble instrument if applicable.
4.) Rinse the instrument under running water to remove large debris.
5.) Allow the instrument to soak as needed for the recommended soaking time in the cleaning solution of choice and ensure instrument is sufficiently immersed.
6.) Place the instrument into an ultrasonic cleaner. Note: Do not overload the ultrasonic cleaning unit. There should not be any contact between the instruments if sterilizing multiple instruments at a time.
7.) Remove the instrument from the ultrasonic cleaner and post rinse instrument intensively with low contaminated, deionized water.
    a. Additionally, you can use a clean brush to get in between cracks and crevices while rinsing.
8.) Place the instrument on a dry, clean towel and gently pat to dry the instrument.
9.) Inspect the instrument for a good cleaning result and ensure it is completely dry.
10.) Place the instrument into heat-resistant sterilization bag(s). Note: Thoroughly dry instrument prior to packaging.
11.) Place the bags into the autoclave, ensuring minimal overlap of instruments, and finalize the sterilization process.

Additional Guidelines:

<u>Automated Washer Unit</u> (CANADA)

- Follow steps 1-9 of the general sterilization procedure.
- Place disassembled instrument in a cassette or any other tray system suitable for the instrument and place it in the automated washer unit (no contact between instruments) and finalize sterilization process. If applicable: Connect the instruments to the rinsing port of the washer-disinfector unit, e.g. stainless high volume suction tips.
- Remove the instrument from the automated washer unit after end of the cycle.
- Inspect and package the instruments immediately after removal.

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Steam Sterilization

Use fractionated vacuum or gravity procedure sterilizers.

- Sufficient product drying must be ensured after sterilization and before handling; see below for recommendations.
- Must follow AAMI/ANSI ST55 and AAMI/ANSI ST8
- Must use ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ)

Minimum Cycle Times for Wrapped Instruments
(Gravity-displacement steam sterilization)

- Exposure time (at 121°C / 250°F): 30 minutes Drying time: Minimum 30 minutes.
- Fractionated vacuum/dynamic-air-removal steam sterilization*: Exposure time (at 132°C / 270°F): 4 minutes Drying time: Minimum 30 minutes.
- Sufficient product drying must be ensured after sterilization and before handling.
- Must follow AAMI/ANSI ST55 and AAMI/ANSI ST8
- Must use ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ)

Restrictions:

- Use of flash sterilization, radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization is not permitted.
- The application of dry heat sterilization is the responsibility of the user. For some products, the dry heat sterilization procedure has been explicitly excluded.

Inspection:
Inspect the instrument after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. If the instrument is still visibly soiled, repeat the sterilization process as needed.

Only low contaminated, deionized water should be used.

Anything sterilized must be completely dried after sterilization and before handling.

Do not further use the instrument if damaged.

Maintenance:

The manufacturers' instructions with respect to routine inspection and the regular maintenance of the sterilizer must be observed.

Follow the equipment manufacturer's recommendations for load/weight capacity.

Cassettes and/or instrument packs are not recommended to be stacked on top of one another. Use appropriate racks as recommended by the equipment manufacturer.

Light corrosion on the surface can develop with use and after sterilizing, especially with more aggressive sterilization machines. It is most often mistaken for rust. The common causes for light corrosion/staining and our suggestions on how to avoid staining of the instrument are as follows:

- *Orange/brown stain*: The problem is most often a phosphate layer (brown to light orange) on the instrument, which can from water sources, detergents used to wash and clean the instrument, surgical wrappings, cold sterilization solutions, or dried blood.
- *Black stain*: Black stains are commonly due to an acid reaction. Black stains may result from detergents used to clean the instrument; similar to brown stains caused by high PH in detergents. The black acid type stain can be caused by low PH (less than six) during autoclaving.
- *Dark brown stain*: Dark brown stains are usually a result of dried blood left on an instrument. Blood should be removed from the surface of the instrument immediately. It will break down the surface of the instrument with a chemical reaction.

If the corrosion cannot be eliminated, the instrument should be removed from use. Otherwise, such corrosion could damage other instruments. Note: Hinged instruments must be lubricated with a lubricant suitable for steam sterilization.

Defects must be reported within 30 days of the purchase date. Any Power Dental Group instrument that does not function due to poor workmanship or defects in the material will be repaired or replaced at no additional cost. Any modification, alteration, or sharpening made to Power Dental Group tips/instrument outside of Power Dental Group will render the warranty void. The instrument must be properly sterilized per OSHA and State Health regulations within a sterilizing bag/pouch before sending the product back to Power Dental Group. Failure to comply with these terms will deem the warranty void.

Storage:

Please store the instrument after sterilization in a dry and dust-free place in the clean section of the instrument processing area. Sterilization can only be maintained, if the instrument remains packaged or wrapped - impermeable to micro-organisms - following validated standards. The status of the sterilization must be clearly indicated on the wrapped packaging. For safety, keep sterile and non-sterile instruments strictly apart.

Reusability:

The instrument is manufactured to be reused. The lifetime of the instrument depends on the frequency of use, the care of the user and proper reprocessing methods. The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments (no liability in case of disregard). Re-sharpen the instrument as needed, if necessary. In case sharpening or any repair is performed, repeat the cleaning and sterilization process. Note: Remove any residues from the sharpening process, such as metal residue or sharpening oil.