PDT INSTRUMENT AND ACCESSORY REPROCESSING GUIDE

All PDT, Inc. products are shipped non-sterile. Office practitioners are responsible for proper sterilization prior to the first patient use. It is the responsibility of the office to ensure that employees are trained and qualified to perform the reprocessing and understand all local laws and requirements. Products must be reprocessed after each patient use. It is the practitioner's responsibility to use validated processes for cleaning and sterilizing products. All PDT, Inc. products are designed for trained dental professionals and are to be used in accordance with industry standard dental practices for the instrument's intended purpose. Refer to the PDT website for updates or changes to this reprocessing guide.
A cleaning and sterilization process that meets ADA and CDC guidelines is vital to an effective infection control program. All local regulatory requirements must be followed. Use of a complete system that encompasses and fulfills all critical cleaning and sterilizing elements minimizes risk to patients and staff.

Terminology:
Reprocessing: A validated process used to render a medical device, which has been previously used or contaminated, fit for a subsequent single use.

Cleaning: Physically removing all visible organic and inorganic contamination, either by processing through an ultrasonic instrument washer or by utilizing hand scrubbing with a surfactant or detergent and water once automatic means have been prioritized. Clean does not mean the instruments are sterile.

Disinfecting: A cleaning process that destroys pathogens and other microorganisms. Disinfecting should be an intermediate level disinfection using a product with an EPA-registered claim for activity against hepatitis B, HIV and tuberculosis. Disinfecting is not a substitute for sterilization as it does not kill all microorganisms on an instrument.

Sterilizing: A process that, when performed properly, kills all microorganisms – bacteria, fungi, viruses and highly resistant bacterial endospores on instrument surfaces.

Storage: Holding sterilized items in a controlled environment until disbursed for patient use.

Staff Safety:
Instruments used on patients should be considered contaminated and hazardous to office staff responsible for reprocessing. Personal Protective Equipment (PPE) should be used to ensure staff protection. Staff responsible for reprocessing should wear non-puncture gloves, protective eye shields, masks/protective face shield and clothing protection (gown).

Equipment Maintenance and Verification:
All cleaning and sterilizing equipment must be properly maintained according to the manufacturer's instructions. Sterilization failures can and do occur. Without proper monitoring, these failures may be overlooked, resulting in serious consequences to patients, and potentially, to staff. Common reasons for sterilization failure include:

- Unit malfunction
- Improper packaging
- Improper cleaning of instruments
- Improper timing and temperature
- Overloading the sterilization unit
- Incorrect maintenance of sterilizer

Monitoring and Verification:
Sterilizing units should be monitored by the operator several times a week to ensure the unit is operating properly. Thermometers, timers, pressure levels, and other indicators should be visually monitored to ensure the unit is operating within parameters. In addition to physically monitoring, chemical and biological monitoring should be used according to industry standards. Chemical indicators should be placed inside each instrument pack, if the packaging does not have an external indicator to verify sterilization was completed. Chemical indicators should not be the sole source of verification as the chemicals/dyes used can present false readings of complete sterilization. Biological (spore) monitoring should be performed weekly. Spore testing is the only process that meets all sterilization verification parameters.

Cleaning/Sterilizing Process:
Cleaning instruments provides an opportunity to examine, replace or remove damaged instruments, as well as prepare the instruments for sterilization. Instruments should be properly staged through each cycle to ensure proper sterilization can be completed. The following basic considerations should be observed:

1. As appropriate, instruments must be disassembled, opened or unclamped for reprocessing.
2. Instruments should be cleaned or placed in a soaking solution immediately after use to keep solid debris from hardening on the device surface.
3. All cleaning solutions/detergents must be pH neutral. Avoid cleaning agents containing the following:
    a. Phenols - petroleum based or petroleum derivative types of products
    b. Iodophors (Iodine complex) – or similar types of products
    c. Tartaric acid, bleach, peroxide, other teeth whitening or tartar removal agents or byproducts, or other strong oxidizing agents
    d. Alkaline (> pH 9) or acidic (< pH 5) based products
    e. Esters – acid-based products (chemical names often ending in ‘oate’)
    f. Ketones – chemical names often end in ‘anone’ or ‘one’
    g. Temperatures above 193°C/380°F –which are possible along the sides and bottom of steam sterilizing units.
4. Manufacturer’s recommendations for solution/detergent concentrations, soak time, and water temperature must be observed.
5. Powder-based cleaners must be dissolved completely before instruments are immersed.
6. Filtered or distilled water should be used for all processes to eliminate the possibility of corrosion, staining or bacterial contamination from chemicals and pathogens found in most water systems.
7. Like metals should be processed together. Rusting instruments can cross contaminate other instruments during reprocessing and should be removed from use.

Cleaning Process:

1. Hand Cleaning:
    a. Due to safety issues, hand cleaning should be performed only if no other options are available.
    b. Personal protective equipment should be used (gown, mask and eye protection).
    c. Contaminated instruments should be moved to the cleaning area immediately after patient use.
    d. A soft bristle brush or cloth should be used to remove contamination. Never use abrasive scrubbing pads, wire bristle brushes or steel wool.

e. Minimize the risk of puncture injury by cleaning only one instrument at a time, keeping it low in the sink to minimize splatter.
f. Use pH neutral cleaners – follow all manufacturer instructions.
g. All cleaning solutions must be thoroughly rinsed from the instruments for a minimum of 20 seconds under clean, running water – preferably filtered or distilled.
h. Inspect all instruments to ensure that all contaminants have been removed, paying critical attention to hinges, joints, cavities, bore holes and serrations. Failure to remove all contamination may result in a failure in sterilization.
i. Visually inspect the instruments for any damage, corrosion, or other issues that may result in them being unsuitable for patient use. Remove these instruments from use.
j. Allow instruments to thoroughly dry in a clean, uncontaminated area.
k. Hand cleaning is not a substitute for sterilization.

2. Ultrasonic Cleaning:

a. Ultrasonic units must be inspected and tested according to the unit manufacturer's recommended schedule to ensure proper function.
b. Contaminated instruments should be moved to the cleaning area immediately after patient use.
c. Personal protective equipment should be used (gloves, gown, eye protection).
d. Use pH neutral cleaners – follow all manufacturer instructions.
e. Do not use household cleaners as they may cause pitting, corrosion, rust and other damage to instruments. There is also the risk of damaging the ultrasonic by using these types of cleaner.
f. Follow the unit manufacturer's recommendations for loading - avoid overloading. Overloading the ultrasonic can result in improper cleaning.
g. Use cassettes or baskets as recommended by the unit manufacturer to ensure the instruments are not touching or overlapping.
h. Do not lay instruments on the bottom of the ultrasonic, as this can interfere with cleaning and cause damage to the instruments or the ultrasonic unit.
i. Follow the unit manufacturer's instructions for cycle time based on the immersion method you are using.
j. Once the ultrasonic is activated, the lid or cover should be kept on to reduce the release of spatter or aerosol into the area.
k. All cleaning solutions must be thoroughly rinsed from the instruments for a minimum of 20 seconds under clean, running water – preferably filtered or distilled.
l. Inspect all instruments to ensure that all contaminants have been removed, paying critical attention to hinges, joints, cavities, bore holes and serrations. Failure to remove all contamination may result in a failure in sterilization.
m. Visually inspect the instruments for any damage, corrosion, or other issues that may result in them being unsuitable for patient use. Remove these instruments from use.
n. Allow instruments to thoroughly dry in a clean, uncontaminated area.
o. Ultrasonic processing is not a substitute for sterilization.

3. Automated Washer Unit:

a. Automated washing units must be inspected and tested according to the unit manufacturer's recommended schedule to ensure they function properly.
b. Contaminated instruments should be moved to the cleaning area immediately after patient use.
c. Personal protective equipment should be used (gown, mask and eye protection).

d. Use pH neutral cleaners – follow all manufacturer instructions.
e. Do not use household cleaners as they may cause pitting, corrosion, rust and other damage to instruments.
f. Follow the manufacturer's recommendations for loading - avoid overloading the unit. Overloading the washer can result in improper cleaning.
g. Ensure water flow is adequate for the method of instrument packaging used in the unit.
h. Inspect all instruments to ensure that all contaminants have been removed, paying critical attention to hinges, joints, cavities, bore holes and serrations. Failure to remove all contamination may result in a failure in sterilization.
i. Visually inspect the instruments for any damage, corrosion, or other issues that may result in them being unsuitable for patient use. Remove these instruments from use.
j. Allow instruments to thoroughly dry in a clean, uncontaminated area if the washer does not have a cycle for drying the instruments. Commercial or home level washers are not suitable for cleaning medical instruments.
k. Automated washer processing is not a substitute for sterilization. Some automatic washers can be used as a disinfector.

Prior to Final Sterilization:

1. Inspect all instruments for proper operation and function.
2. Oil hinges and joints using oils designated by local regulations. Test all hinges and joints (as needed) to ensure smooth operations.
3. Ensure all hinged, jointed or clamped instruments are sterilized in the open or loose position.

Sterilizing Process:

1. Only FDA-approved dry or steam heat sterilizers should be used.
2. Monitor the sterilizer's mechanics (thermometer, timers, pressure levels, etc.) to ensure proper functioning.
3. Spore test heat sterilizers on a weekly basis.
4. Follow the manufacturer's maintenance instructions to ensure proper functioning.
5. Follow the manufacturer's instructions for cycle time and temperature, loading and monitoring.
6. Make sure packaging materials are compatible with the sterilizer being used. Improper packaging can cause sterilization to fail. Unless otherwise noted, packaging is single use only.
7. Items must be arranged to allow for free circulation of the sterilizing agent.
8. If the packaging does not have an indicator to verify sterilization was completed, place a chemical indicator inside each instrument pack.
9. Instrument packs must be allowed to dry completely in the sterilizing unit before handling to reduce contamination to the instruments. Instruments must remain in packages until use.
10. Use filtered or distilled water. Follow the unit manufacturer's instructions for types and amounts of water.

The following charts are a guideline for sterilization processing. Follow your local regulatory requirements or the unit manufacturer's instructions if they differ from these guidelines.

Cycle Times for Gravity-Displacement Steam Sterilization

Item	Exposure Time at 121°C (250°F)	Exposure Time at 132°C (270°F)	Exposure Time at 135°C (275°F)	Minimum Drying Time
Wrapped Instruments	30 minutes	15 minutes		15-30 minutes
			10 minutes	30 minutes
Textile Packs	30 minutes	25 minutes		15 minutes
			10 minutes	30 minutes
Wrapped Utensils	30 minutes	15 minutes		15-30 minutes
			10 minutes	30 minutes

Cycle Times for Dynamic-Air-Removal Steam Sterilization

Item	Exposure Time at 132°C (270°F)	Exposure Time at 135°C (275°F)	Minimum Drying Time
Wrapped Instruments	4 minutes		20-30 minutes
		3 minutes	16 minutes
Textile Packs	4 minutes		5-20 minutes
		3 minutes	3 minutes
Wrapped Utensils	4 minutes		20 minutes
		3 minutes	16 minutes

Cycle Times for Dry Air Sterilization - Follow Manufacturer's packaging requirements

Exposure Time at 150°C (300°F)	Exposure Time at 160°C (320°F)	Exposure Time at 170°C (340°F)	Exposure Time at 180°C (356°F)
150 minutes	120 minutes	60 minutes	30 minutes

Cycle Times for High Velocity Hot Air (HVHA) - Follow Manufacturer's packaging requirements

Exposure Time at 190°C (375°F)
12 minutes

Steam Flush-Pressure Pulsing Steam Sterilization (SFPP) – Follow Manufacturer's packaging requirements

Exposure Temperature	Exposure Time
Refer to manufacturer's DFU/CDC Guidelines	Refer to manufacturer's DFU/CDC Guidelines

Storage:
Instrument packs must be completely dry before being moved to storage. Instrument storage should be in the clean area of the instrument reprocessing area and contain enclosed, dust free storage for sterile items.

Special Considerations:
All PDT, Inc. instruments, cassettes and sharpening systems can be sterilized using the preceding instructions. Proper reprocessing has no effect on the life of an instrument. The life of the instrument is determined by use, care in handling, resharpening and proper reprocessing with non-destructive cleaners and detergents. Etched probes should not be left in solution for prolonged periods of time. Soaking or ultrasonic baths may remove the sharpness of markings on etched instruments over time.

Other Considerations:

-Hand tighten mirrors to handles (instrument damage will result if over tightened).
-Periotomes should only be used to saw fibrous attachment away from the tooth. These are not manufactured to be used in elevating the tooth. Please note that these serrated periotomes are quite thin and should only be used to saw through the periodontal ligament. They are precision instruments and any lateral bending force may cause the instrument to fracture.

Sharpening:

-Resharpen only when the tips are dull. Check for sharpness before resharpening by using a Ping Ring.
-For best sharpening results, use the Gleason Guide™ with the appropriate stone.
-Use gentle pressure to resharpen so as not to remove too much material from the tip.
-Check sharpness after a few strokes on the stone to determine if more sharpening is needed.

Disposal of Instruments:
When instruments are determined to have reached the end of their useful life, they must be cleaned and sterilized prior to disposal. Instruments should be disposed of in the manner approved for other sharp implements, such as needles and blades, to ensure protection of subsequent handlers.