1. **Introduction**

Pulpdent instruments are supplied non-sterile and must be cleaned and sterilized before the first use and before each subsequent use. It is important that instruments be well cleaned before the sterilization process.

1. **Cleaning**
	1. **Recommendations**
		1. An automatic cleaning procedure is preferred for cleaning dental instruments prior to sterilization.
		2. All assembled instruments should be disassembled before reprocessing.
		3. Staff members should wear protective utility gloves when handling used and contaminated instruments.
	2. **Pretreatment**
		1. Never hold contaminated instruments in a dry container.
		2. Dissimilar metal instruments should be separated.
		3. Use an enzymatic cleaner or other detergent according to the manufacturer’s instructions to presoak the instruments.
		4. Before processing instruments, remove gross impurities by rinsing under warm water. This should be performed within two hours of contamination.
		5. If necessary, use a soft brush to remove debris.
	3. **Automatic Cleaning** in an automated washer unit
		1. Follow the manufacturer’s instructions
		2. Completely disassemble instruments, if applicable
		3. A cassette system may be recommended.
		4. Use detergent compatible with the automated washer.
		5. Use low contaminated and deionized water for final rinse.
		6. Use filtered air for drying
		7. Remove the instruments from the washer unit at the end of the cycle.
		8. Inspect and package the instruments immediately after removal.
		9. Inspect and maintain the unit regularly
	4. **Manual And Ultrasonic Cleaning**
		1. Choose a suitable detergent compatible with the instruments to be cleaned.
		2. Powdered detergents must be dissolved completely in water before immersing the instruments in the solution.
		3. Follow the manufacturer’s instructions as to concentration of the solution, time of exposure, and temperature.
		4. Use only freshly prepared solution, low contaminated and deionized water and filtered air for drying.
	5. **Manual Cleaning***:*
		1. Soak the disassembled/open instruments for the recommended soaking time.
		2. Use a stiff nylon cleaning brush (no steel wool or metal brushes) so that surfaces are visibly clean and free from stains and tissue.
		3. Remove the instruments from the cleaning solution and rinse well with low contaminated and deionized water.
		4. Inspect for proper cleaning and function, i.e., scissors blades open and close smoothly, forceps tips are aligned, etc.
	6. **Ultrasonic Cleaning**
		1. Be sure that there is no contact between instruments.
		2. All instruments must be fully submerged in an open position.
		3. Soak the disassembled instruments for the recommended soaking time according to the detergent manufacturer.
		4. Process the instruments for the time required by the detergent manufacturer.
		5. Remove the instruments from the cleaning solution and rinse well with low contaminated and deionized water.
		6. Inspect for proper cleaning

1. **Inspection**

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces and impurities. Remove damaged instruments. If instruments are still dirty, clean again.

1. **Packaging:** Sterilization pouches or containers must:
	1. Be FDA approved
	2. Be suitable for steam sterilization: temperature resistance >141oC/286oF; sufficient steam permeability.
	3. Provide sufficient protection of the instrument and the sterilization packaging against mechanical damage.
	4. Accommodate open instruments (scissors, forceps, needle holders, etc.)
2. **Sterilization**

**Note:** Lubricate all hinged instruments which have any metal to metal contact at the screw or box lock, using a non-silicone, water-soluble, surgical lubricant. Do not use industrial oils or lubricants. All instruments must be sterilized in an open position and/or disassembled.

* 1. **Steam Sterilization**

According to the CDC, steam sterilization (under pressure) is the process of choice for sterilizing instruments. It is considered safe, fast and cost-effective for health care facilities.

* + 1. Fractionated vacuum or gravity procedure
		2. Steam sterilizer according to AAMI/ANSI ST55 and AAMI/ANSI ST8
		3. Validated according to AAMI/ANSI ST 79 and product specific performance qualification (PQ)
		4. Steam sterilizers must be cleaned, inspected and maintained regularly.
		5. Only low contaminated and deionized water should be used.
		6. Sufficient drying time after sterilization and before handling according to the following tables.

**Minimum cycle times for gravity-displacement steam sterilization cycles**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Exposure time at 121oC (250oF)** | **Exposure time at 132oC (270oF)** | **Drying Times** |
| Wrapped Instruments | 30 minutes  | 15 minutes | 15-30 minutes |

**Note:** For a specific sterilizer, consult the manufacturer’s recommendations.

**Minimum cycle times for dynamic-air-removal steam sterilization cycles**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | **Exposure time at 132oC (270oF)** | **Exposure time at 135oC (275oF)** | **Drying Times** |
| Wrapped Instruments | 4 minutes  | --- | 20-30 minutes |
|  | --- | 3 minutes | 16 minutes |

**Note:** For a specific sterilizer, consult the manufacturer’s recommendations.

* 1. **EO Sterilization**

|  |  |  |  |
| --- | --- | --- | --- |
| **EO Concentration** | **Exposure time** | **Temperature** | **Relative humidity** |
| 450-750 mg/L | 1-5 hours | 37.8oC to 60oC (100oF to 140oF) | 40-80% |

**Note:** For a specific sterilizer, consult the manufacturer’s recommendations.

1. **Restrictions**
	1. Do not use detergents or disinfectants containing the following substances:
		1. Strong alkaline pH > 9
		2. Strong acid pH < 4
		3. Phenols or iodophors
		4. Halogenic hydrocarbons
		5. Organic solvents
	2. Do not clean any instrument, sterilization tray or sterilization container using metal brushes or steel wool.
	3. Do not expose instruments, cassettes, trays or sterilization containers to temperatures >141oC/286oF.
2. **Storage**

Store sterilized instruments in a dry, dust-free place away from instrument processing areas. Keep all sterilized instruments packaged or wrapped. The status of the sterilization must be clearly indicated on the wrapping or container.

1. **Reusability**

Instruments, not marked as single-use, can be reused unless inspection has revealed defects or wear that cannot be repaired. The lifetime of instruments depends on the frequency of use, 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 or dirty instruments.

1. **Special considerations**
	1. Amalgam carriers
		1. After use, fully depress the lever repeatedly while rotating the barrel, expelling unused amalgam. All amalgam residue must be removed.
		2. Never apply any part of the carrier into a flame as this distorts the alignment of the instrument, tempers the metal and releases small amounts of mercury vapor into the atmosphere.
		3. Automated cleaning is recommended.
		4. Sterilize by steam sterilization.
	2. E-Z Kleen Carriers (with plastic barrel)
		1. Remove the white plastic barrel
		2. Clean and sterilize the handle as above.
		3. Use a ‘high level disinfectant’ (registered with the US EPA) to sterilize the barrel. A 10-hour immersion is recommended
	3. Pressure syringe
		1. Clean immediately after use.
		2. Remove and discard the needle.
		3. Empty the Pressure Syringe by turning the screw post clockwise as far as it can go.
		4. Wipe off the excess Root Canal Sealer and separate the screw post from the barrel by turning the screw post counterclockwise.
		5. Use Wonder Orange Cleaning Solution to clean the screw post and barrel. A pipe cleaner can be used to help clean the inside of the barrel.
		6. Clean and then sterilize by steam sterilization.
	4. Dam Frame
		1. Clean and sterilize as above.
		2. Use a sterilizer bag.
		3. Do not put objects on top of the Dam Frame in the sterilizer as it will distort it.