

Cleaning, Disinfection & Sterilization Instructions

per ISO 17664

Garrison Dental Solutions,
LLC

This cleaning, disinfection and sterilization guide has been provided in accordance with ISO 17664, covering the proper techniques necessary to ensure Garrison Dental Solutions' product will be suitable for safe and optimal use.

Failure to follow the stated procedure may result in product failure, premature wear and/or non-optimal performance.

Contact Information:

For the most current information, visit www.garrisondental.com/sterilization

To contact the manufacturer directly:

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How to use this guide:

Identify product requiring cleaning, disinfection or sterilization in the left column of the product matrix. Follow the procedure indicated in the right column of the product matrix.

Product Line	Cleaning, Disinfection & Sterilization Procedure:
Sectional Matrix Kits	A, B, C, E, F (as appropriate to kit contents)
Matrix Ring: AU400, AU500, G100, G200, FX400, FX500, FX600, 3DXR, 3D500, 3D600, C400, C500, NTG400, NTG500	A
Matrix Forceps - All varieties	A
Ring Forceps - All varieties	A
TN Series Composite Instruments	A
FitStrip Interproximal Finishers	A
PerForm Instruments	A
Blue View Cervical Handle	A
Matrix Bands: FX Series, SXR Series, M Series, SM Series, AU Series B Series, MC Series, NTG Series, NTGT Series, SMT Series	B
Metal Pinch	B
Wedges: Composi-Tight 3D Fusion, Wedge Wands, G-Wedges, Soft Wedge (Includes assortment kits)	B
Blue View VariStrip	B
Blue View Pinch	B
Blue View Grip Strips	B
ReelMatrix Spools & Matrices	B
ReelMatrix Instrument	C
eZr Polishing/Adjusting Instruments	D
A+Wedges (includes assortment kits)	E
Rally Polishers	F

Procedure "A"

Basic Principles:

- All products are supplied non-sterile and may be appropriately cleaned, disinfected, and sterilized before use.
- Ensure equipment used is serviced and checked regularly, and manufacturer's use instructions are followed.
- Please heed regulations applicable to your country.
- Repeated reprocessing may affect the product. Decommissioning of the device is normally determined by wear and damage prior to use.
- Avoid contact of dissimilar metals at any point during the cleaning & sterilization process.

Cleaning:

- Products should be cleaned as soon as possible after use to prevent soils from hardening.
- Remove all visible debris after use and prior to sterilization.
- Product can be manually cleaned with IMS® Daily Clean*, following manufacturer's instructions.
- Use a nylon brush or similar soft brush. – For FX400, FX500, FX600, 3D500, 3D600, & 3DXR: Take care not to damage the Soft-Face during cleaning.
- You may optionally pre-soak the contaminated rings with IMS® Daily Clean*, following the manufacturer's instructions, for up to 6 minutes to aid in manual cleaning.
- DO NOT expose product to solutions containing chemicals such as alcohol, acetone, ketone, or other harsh chemical disinfectants.
- Visually inspect product for damage (eg. rust and cracking). Remove from service if damage is present.
- If any visible debris remains, repeat process above as needed.

Sterilization:

- Process product through steam autoclave and store only in CE/FDA approved sterilization pouch.
- Steam autoclave sterilization only. Perform one cycle at 270°F (132°C) and 30.46 psi (210kPa) for 6 minutes, following the autoclave manufacturer's instructions, with a 20-30 minute drying time. Never exceed temperatures of 278.6°F (137°C).
- DO NOT use chemical sterilization techniques.

Storage:

- Store sterilized product in a dry and dust free location.
- Keep product sealed in the sterilization pouch until ready to use.

Procedure "B"

Basic Principles:

- All products are supplied non-sterile and may be appropriately sterilized before use.
- Ensure equipment used is serviced and checked regularly, and manufacturer's use instructions are followed.
- Please heed regulations applicable to your country.
- Products are single use only and cannot be reprocessed.
- Avoid contact of dissimilar metals at any point during the sterilization process.

Sterilization:

- Process product through steam autoclave and store only in CE/FDA approved sterilization pouch.
- Steam autoclave sterilization only. Perform one cycle at 270°F (132°C) and 30.46 psi (210kPa) for 6 minutes, following the autoclave manufacturer's instructions, with a 20-30 minute drying time. Never exceed temperatures

of 278.6°F (137°C).

- DO NOT use chemical sterilization techniques.

Storage:

- Store sterilized product in a dry and dust free location.
- Keep product sealed in the sterilization pouch until ready to use.

Procedure "C"

Cleaning:

- Instrument must be in open position. Take care not to damage tips.
- Remove visible debris or organic matter from the instrument and surface with a disposable wipe or surface brush. This is to be done by scrubbing with warm tap water and soap or detergent.
- Inspect instrument for debris. Repeat cleaning if there is debris left.
- All external surfaces must be wiped with a lint-free cloth or sprayed with a suitable disinfectant.
- Rinse external surfaces with warm tap water.
- Dry instrument.
- Do not immerse the instrument in liquid or place it in an ultrasonic cleaning unit.

Sterilization:

- Sterilize in a steam autoclave using distilled water at a temperature of 134°C (273°F) for 3 min.
- Sterilization is NOT a substitute for proper cleaning. Clean the instrument first then sterilize it.
- Do not use cold sterilization methods that involve soaking the instrument in a liquid.

Storage:

- Store sterilized product in a dry and dust free location.
- Keep product sealed in the sterilization pouch until ready to use.

Procedure "D"

Basic Principles:

- All products are supplied non-sterile and may be appropriately cleaned, disinfected and sterilized before use.
- Ensure equipment used is serviced and checked regularly, and manufacturer's use instructions are followed.
- Please heed regulations applicable to your country.
- Repeated reprocessing may affect the product. Decommissioning of the device is normally determined by inspection for wear and damage prior to use.
- Avoid contact of dissimilar metals at any point during the cleaning & sterilization process to prevent corrosion.

Notices:

- Avoid the use of strong acids and bases as they may oxidize the stainless steel shaft.
- Rinse with distilled water after treatment with cleaning and disinfectant solutions.
- Avoid temperatures >150°C (302°F).
- Ultrasonic bath temperatures must not exceed temperatures of 42°C (107°F) to avoid possible coagulation of albumen.
- The label on the cleaning and/or disinfecting solution MUST specifically say "suitable for rubber polishers or synthetics/silicones".

Point of Use:

- Products should be cleaned as soon as possible after use to prevent soils from hardening.
Pre-clean under running water with a plastic bristle brush.

Manual Cleaning:

- Under running water with a plastic bristle brush.
- Optional – Ultrasonic assisted cleaning with a suitable cleaning agent and disinfectant. Rinse afterwards under running water.

Automatic Cleaning:

- Thermal disinfectant – Manufacturer's specification according to EN ISO 15883 using the cleaning program as indicated by the manufacturer's operating instructions.

Disinfection:

- Use a solution classified suitable for rubber and silicone polishers/synthetics by the manufacturer.
Follow manufacturer's recommendations for exposure times and concentrations.
- Rinse with distilled water after treatment with cleaning and disinfectant solutions.

Drying:

- Dry with fresh, clean, lint-free cellulose tissues.

Inspection:

- Visually check all instruments for cleanliness and safe suitability of use with 5-10X magnification.
Repeat cleaning if necessary. Decommission and dispose of instruments in the event of discernible defects.

Sterilization:

- Steam Autoclave according to manufacturer's operating instructions using a hold time of five (5) minutes full cycle, a sterilization temperature of 134°C (273°F) and a drying time of ten (10) minutes.

Storage:

- Store instruments packed and protected in suitable sterile packaging, cassettes or retainers in dry, clean conditions at ambient temperature.

Validated Materials:

Manual Cleaning – Durr Dental ID 212, 2% concentration, 5 minute holding time

Ultrasonic – Durr Dental ID 212 ready made solution, 2% concentration, 2 minute holding time

Automatic Cleaning – Miele G 7883, Special Program 93°C (199°F) for 10 min, 10 minute holding time, detergent – Dr. Weigert neodisher MediClean Dental, rinsing for 3 min at 75°C (167°F) with neodisher Z Dental

Sterilization – Holding time full cycle 5 min, sterilization temperature 134°C (273°F), Drying time 10 min, threshold values of contents for feed-water and steam condensates

Procedure "E"

Basic Principles:

- Products are single use only and cannot be reprocessed.

Sterilization:

- DO NOT clean or sterilize as this will affect the astringent coating.

Storage:

- Store in original packaging in a cool dry location.
- Do not mix in with similar products.

Procedure "F"

Basic Principles:

- All products are supplied non-sterile and may be appropriately sterilized before use.
- Ensure equipment used is serviced and checked regularly, and manufacturer's use instructions are followed.
- Please heed regulations applicable to your country.
- Products are single use only.

Sterilization:

- Moist heat sterilization with fractional prevacuum. Full cycle, 134°C (273°F) / 3.1 bar (45 psi) for at least 5 minutes, drying time 10 minutes. Do not exceed 135°C (275°F). IMPORTANT: Use suitable packaging for sterilization.
- Warning: not suitable for sterilization with hot air or chemiclave. This procedure was validated by an independent and accredited laboratory.

Storage:

- A dry, dust-free storage at 2 - 28°C (36 - 82°F) is recommended. Improper storage conditions can shorten the shelf life and cause malfunction of the product.



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For additional information:
Call toll free **888.437.0032**
or online at www.garrisondental.com