

# Cleaning, Disinfection & Sterilization Instructions

per ISO 17664

Garrison® Dental Solutions, LLC

**Reinigungs-, Desinfektions- und Sterilisationsanleitung** (German/Deutsch)

**Instrucciones de limpieza, desinfección y esterilización** (Spanish/Español)

**Limpeza, Desinfecção & Instruções de esterilização** (Portuguese/Português)

**Istruzioni di pulizia, disinfezione e sterilizzazione** (Italian/Italiano)

**Instructions pour le nettoyage, la désinfection et la stérilisation** (French/Français)

**Instructies voor schoonmaken, desinfecteren en steriliseren** (Dutch/Nederlands)

**Vejledning til rengøring, desinfektion og sterilisation** (Danish/Dansk)

**Instruktioner för rengöring, desinfektion och sterilisering** (Swedish/Svensk)

**Instruksjoner for rengjøring, desinfeksjon og sterilisering** (Norwegian/Norsk)

**Puhdistus-, desinfiointi- ja sterilointiohjeet** (Finnish/Suomi)

**Instrukcja czyszczenia, dezynfekcji oraz sterylizacji** (Polish/Polski)

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. Any use of other reprocessing procedures/methods is at the discretion and sole responsibility of the practitioner.

### **Contact Information:**

For the most current information, visit [www.garrisondental.com/sterilization](http://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: SG400, SG500, SG600, AU400, AU500, G100, G200, FX400, FX500, FX600, 3DXR, 3D500, NTG400, NTG500, Q400L-1, Q400R-1, Q500L-1, Q500R-1	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: SG Series, AN Series, FX Series, FXH Series, SXR Series, M Series, SM Series, AU Series, B Series, NTG Series, SMT Series	B
Wedges: Strata-G™, Fusion™ Anterior, Composi-Tight® 3D Fusion™, Wedge Wands®, G-Wedge™, FenderWedge™, Quad™ Wedge (includes assortment kits)	B
Blue View™ VariStrip™	B
ReelMatrix™ Spools & Matrices	C
ReelMatrix™ Instrument	C
eZr™ Polishing/Adjusting Instruments	D
A+Wedge® (includes assortment kits)	E
Rally™ Polishers	F
Loop™ Curing Light** (EN, fr-CA, IT, DE)	G

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\*\* this product is available only in select countries.

## 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.

### For users employing automated cleaning or disinfection equipment:

- Garrison Dental Solutions' reusable devices are intended for terminal steam sterilization as the validated microbial inactivation step. Automated cleaning or disinfection equipment may be used prior to sterilization, provided it does not alter device materials or intended use. However, no specific automated disinfection process is claimed or validated for these devices.
- The use of automated equipment should always be followed by validated manual cleaning and terminal steam sterilization as described in the Instructions for Use. No additional disinfection validation is required or endorsed under current product claims.
- Any use of other reprocessing procedures/methods is at the discretion and sole responsibility of the practitioner.

### 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 SG400, SG500, SG600, FX400, FX500, FX600, 3D500, 3DXR, Q400L-1, Q400R-1, Q500L-1, & Q500R-1: 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 a minimum of 270°F (132°C) and 30.46 psi (210kPa) for a minimum of 4 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.

- Any use of other reprocessing procedures/methods is at the discretion and sole responsibility of the practitioner.

**Sterilization:**

- Process product through steam autoclave and store only in CE/FDA approved sterilization pouch.
- Steam autoclave sterilization only. Perform one cycle at a minimum of 270°F (132°C) and 30.46 psi (210kPa) for a minimum of 4 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"

**Basic Principles:**

- Ensure equipment used is serviced and checked regularly, and manufacturer's use instructions are followed.
- Please heed regulations applicable to your country.
- Avoid contact of dissimilar metals at any point during the sterilization process.
- Any use of other reprocessing procedures/methods is at the discretion and sole responsibility of the practitioner.

**Spools and Matrices Cleaning and Sterilization:**

- Spools and Matrices are single use disposable items. Do not attempt to sterilize them. Prior to use they may be sprayed with a chemical disinfectant if desired.

**Instrument 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.

**Instrument Sterilization:**

- Sterilize in a steam autoclave using distilled water at a temperature of 134°C (273°F) for 3 minutes.
- 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.

**Instrument 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 proteins resulting from blood and tissue.
- 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 5 minutes full cycle, a sterilization temperature of 134°C (273°F) and a drying time of 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 minutes, 10 minute holding time, detergent – Dr. Weigert neodisher MediClean Dental, rinsing for 3 minutes at 75°C (167°F) with neodisher Z Dental

*Sterilization* – Holding time full cycle 5 minutes, sterilization temperature 134°C (273°F), drying time 10 minutes, 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.

## Procedure “G”

### Cleaning During Use:

- The Loop™ handpiece, charging base and light shield are not autoclavable and no portion can be sterilized. Only use approved disinfecting solutions. Refer to Section “Cleaning After Use.”
- To keep the Loop handpiece clean and functioning properly, a new barrier sleeve should be used for each patient. Only use Loop barrier sleeves that are specifically designed for use with the Loop curing light.
- The supplied Loop lens cleaning cloth should be used exclusively for drying the lens after cleaning.

### Cleaning After Use:

- Only use approved disinfecting solutions. If using a spray, do not spray the disinfecting solution directly on the device. Instead, spray or moisten a gauze or soft cloth with disinfecting solution and use it to wipe down and clean the unit. This ensures that significant amounts of disinfectant solution do not wick into the seams of the unit. When finished, dry any residual disinfectant solution remaining on the surface of the handpiece with a soft cloth. Do not use the supplied Loop lens cleaning cloth for anything other than drying the lens after cleaning.

### Approved disinfectant solutions:

- Lysol® Brand III Disinfectant Spray
- Lysol® disinfectant or Lysol® concentrate (alcohol-based only)
- Cavicide™ non-bleach products
- Isopropyl alcohol
- FD 366 (Durr Dental)
- CAUTION: Do not use a metal edged instrument on the OLED display screen.

### **Cleaning the Lens:**

- Inspect the lens after each cleaning. If contaminants are found on the lens or the OLED Display Screen shows a failure for a Self-Check Dirty Lens Detection, carefully clean with the following method:
- Clean the lens with a dry Loop lens cleaning cloth. If this does not clean the lens, then proceed to the next step.
- Buff the lens surface with your regular disinfectant solution or isopropyl alcohol and a soft cloth using light pressure in a circular motion. If this does not remove the dental material or contaminant, then proceed to the next step.
- Use a metal edged (non-diamond tipped) dental instrument to apply lateral pressure to the side and/or edge of the cured dental material that has bonded to the lens. Take care to not scratch the lens and avoid repeated scraping motions to clear away the cured dental material.
- Repeat Steps 1-2. Surface is not ready for use.

### **Cleaning the Charging Base:**

- Clean every few weeks or as needed. Carefully clean with the following method:
- Temporarily disconnect the charging base from the power supply cord.
- For cleaning, refer to Section "Cleaning After Use."
- Make sure that the charging pins and surrounding area are completely dry when finished. You may use compressed air or gentle use of a dry soft cloth. Take care to not bend the charging pins when drying.
- Reconnect the power supply cord to the charging base.

### **Cleaning the Self-Check & Calibration Surfaces:**

- On the charging base, there are two calibration surfaces that should be cleaned. Clean once per year or if having problems with Calibration.

**Black surface used for Self-Check Dirty Lens Detection:** Clean the Self-Check Dirty Lens Detection surface with air blow-off only. Use sufficiently to remove all dust and debris. In most cases, nothing more will be required to keep the black surface functional. In cases of severe contamination, the use of a mild surface cleaner like Sparkle™ or Windex™ may be gently applied via a cotton swab if followed with a gentle rinse of distilled water and dried with clean compressed air.

**White surface used for Calibration:** Cleaning of the white calibration surface is rarely needed due to its protected location, but the process requires more care:

- Carefully clean the white surface with the supplied Loop lens cleaning cloth. If this does not fully clean the surface, then proceed to the next step.
- Do not use sprays or cleaners other than what is prescribed. Gently wipe with gauze or a towelette saturated with Sparkle™ or Isopropyl Alcohol. Wipe in a gentle circular motion.
- Repeat the above step using distilled water.
- Blow off with compressed air and allow 5 minutes additional dry time. Surface is now ready for use.