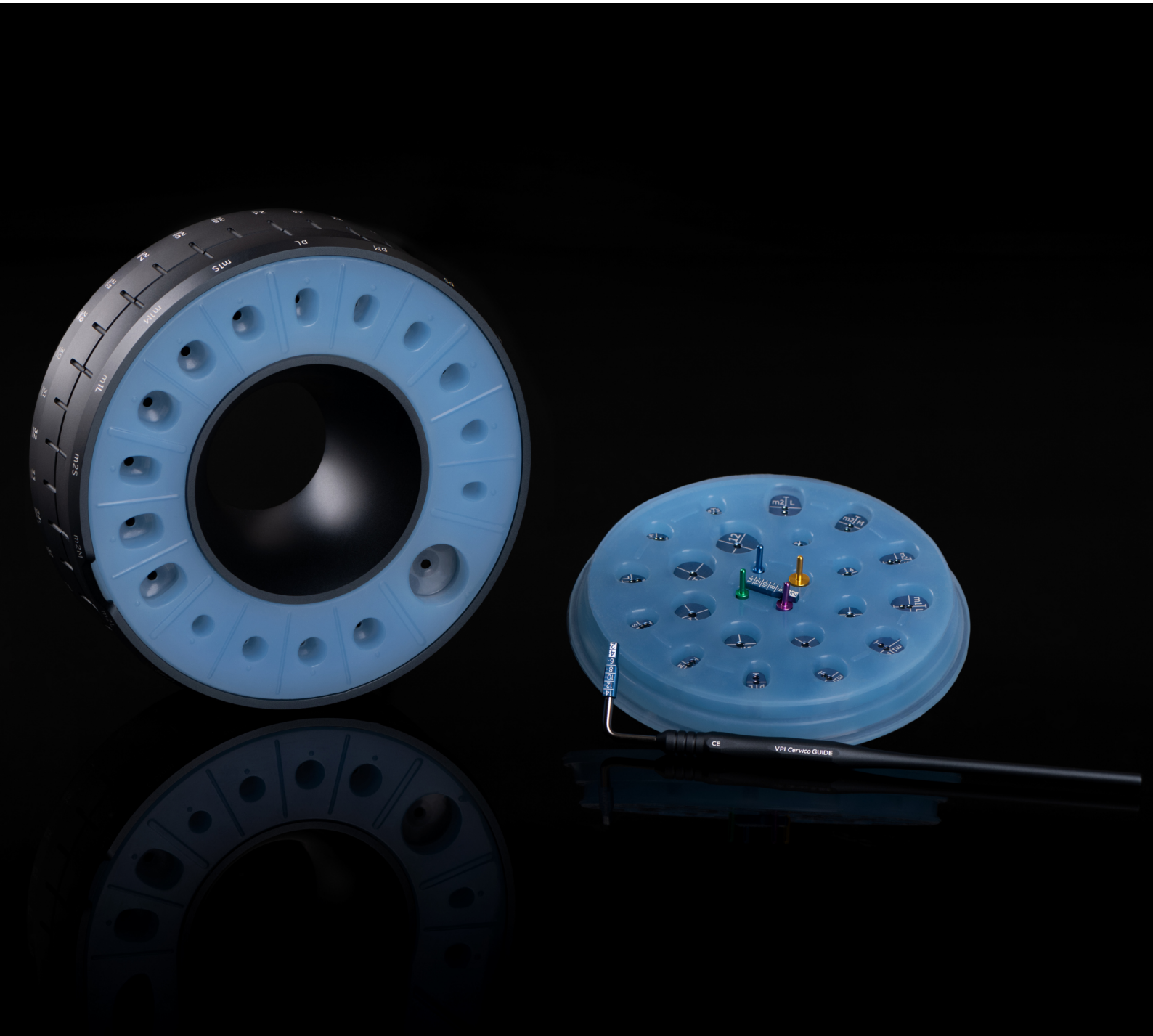
VP INNOVATO HOLDINGS

Cervico System

Sterilization and disinfection guide



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Important Notice

All instruments require cleaning and sterilization before each use, including the first use once they are removed from their packaging. Thorough cleaning is essential for effective sterilization. Users must ensure that they follow verified cleaning and sterilization procedures. Additionally, it is crucial to regularly maintain and check sterilization equipment, ensuring that established parameters for cleaning and sterilization are consistently applied. This guide offers instructions based on standard practices for such devices. **Always comply with the legal and hygiene standards applicable in your location and the guidelines of your medical facility.**

Pre-treatment

Use a dental instrument washer for cleaning instruments. If an automated method is unavailable or if residues persist following automated cleaning, resort to hand scrubbing. Be aware that hand cleaning is considerably less efficient. Regardless of the method, a pre-treatment step should always be completed.

When utilizing an automated washer disinfector, please consider the following:

- Verify the efficacy and approval status of the washer disinfector.
- Ensure the program is appropriate for the instruments and includes adequate rinsing cycles.
- Use only water with minimal contamination and deionization (maximum 10 germs/ml, 0.25 endotoxin units/ml), such as purified water, for post-rinsing.
- Employ filtered air exclusively for the drying process.
- Conduct regular servicing, inspection, and calibration of the washer disinfector.

Choosing detergents for the automated washer disinfector:

- Confirm the detergent's appropriateness for instrument cleaning and any additional uses.

- Ensure detergent compatibility with the instruments.

Detergents or disinfectants containing the following substances must not be used:

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

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool.

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Manual Cleaning

1. Completely disassemble the instruments,

2. Soak the disassembled instruments for the recommended soaking time in the cleaning solution and make sure that the instruments are sufficiently immersed.

3. Remove the instruments from the cleaning solution and post rinse them extensively with low contaminated and deionized water (i.e. purified water).

4. Inspect the instruments for proper cleaning.

5. Thoroughly dry prior to packaging for sterilization.

Inspection

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. Do not further use damaged instruments. If instruments are still visibly soiled, clean again.

Maintenance

Minor surface corrosion may be addressed with a lubricating oil that is appropriate for dental instruments. Should the corrosion remain after treatment, it is imperative to discontinue the use of these instruments to prevent potential harm to others. Once an instrument has undergone lubrication, it necessitates an additional cycle of cleaning and sterilization

Packaging

- It is advised to employ a cassette system and sterilization pouches that meet the following criteria for effective sterilization:

- Compliance with local medical device standards.

- Compatibility with steam sterilization, able to withstand temperatures up to at least 141°C (286°F) with adequate steam penetration.

- Ample protection for both the instruments and the sterilization packaging to prevent mechanical damage.

Ensure that the instruments are fully dried prior to packaging.

Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.

A 30-minute dry time is recommended.

Steam Sterilization

- fractionated vacuum or gravity procedure

- sufficient product drying must be ensured after sterilization and before handling, see table below for recommendations.

- steam sterilizer according to or AAMI/ANSI ST55 and AAMI/ANSI ST8

- validated according to or ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at **250°F (121°C)**	Drying times
Cervico Guide	30 minutes	Minimum 30 minutes
Cervico Premium Mold	30 minutes	Minimum 30 minutes
Cervico Essential Mold	30 minutes	Minimum 30 minutes
VPI Pilot drill kit	30 minutes	Minimum 30 minutes

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

Item	Exposure time at **270°F (132°C) or 273°F (134°C)**	Drying times
Cervico Guide	4 minutes	Minimum 30 minutes
Cervico Premium Mold	4 minutes	Minimum 30 minutes
Cervico Essential Mold	4 minutes	Minimum 30 minutes
VPI Pilot drill kit	4 minutes	Minimum 30 minutes

Do not expose the retention handle of the Cervico Guide to temperatures above 145°C.

Inspection and Maintenance Recommendations for Steam Sterilizers

- The manufacturer´s instructions with respect to routine inspection and the regular maintenance of the Sterilizer must be observed.

- The sterilizer must be cleaned on a regular basis.

- Only low contaminated and deionized water (i.e. purified water) should be used.

- The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

Restrictions

- Immediate use sterilization (flash sterilization) should not be a facility's primary source of sterilization. When used follow manufacturer's instructions for use.

- Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization.

- The application of dry heat sterilization is the responsibility of the user.

Storage

Post-sterilization, ensure that instruments are stored in an area that is both dry and free of dust, within the designated clean zone of the instrument processing space. To preserve sterility, instruments must remain sealed or wrapped in material that blocks microorganisms, in line with established standards. The sterilization status should be clearly indicated on the wrapped packaging or containers. As a precaution, maintain a clear separation between sterile and non-sterile instruments.

Reusability

The instruments can be reused, unless indicated otherwise on the packaging of the item. The lifetime of instruments 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.

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