



Benesta™ Hysteroscope Sterilization Tray
Instructions for Use

REF CAL-TR131

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Instructions available electronically

**READ THESE INSTRUCTIONS COMPLETELY PRIOR TO USING
THE CALDERA MEDICAL BENESTA™ HYSTEROSCOPE STERILIZATION TRAY.**



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10-419 Rev B

Device Description

The Caldera Medical Benesta™ Hysteroscope Sterilization Tray is a rectangular case with internal brackets designed to hold the Caldera Medical Benesta™ Hysteroscope and disassembled components during sterilization. The tray may have a removeable internal caddy to securely hold smaller components from the disassembled hysteroscope.

The Benesta™ Sterilization Tray is compatible with the Benesta™ Hysteroscope and accessories, including the components listed in Table 1.

Table 1. Devices and components compatible with the Benesta™ Sterilization Tray

REF CAL-TR131	Benesta™ Hysteroscope Sterilization Tray
REF CAL-TR113	Benesta™ Hysteroscope
REF CAL-TR112	Benesta™ Outflow Channel
REF CAL-TR121	Light Post Adapter, Storz/Olympus
REF CAL-TR122	Light Post Adapter, Dyonics/Wolf
REF CAL-TR123	Valve Lever and Valve Cap
REF CAL-TR124	End Cap
REF CAL-TR125	Working Channel Brush
REF CAL-TR126	Inflow Channel Brush

Indications for Use

The Caldera Medical Benesta™ Sterilization Tray is intended to enclose, protect, and organize the Caldera Medical Benesta Rod Lens Hysteroscope and accessories during sterilization and storage.

The Caldera Medical Benesta™ Sterilization Tray must be used in conjunction with a sterilization wrap that is cleared by the FDA for the indicated sterilization cycles.

Contraindications

- Stacking of trays and overloading of the units will adversely affect sterilization and drying effectiveness. Do not stack trays in the sterilization chamber or on drying racks.
- Contents of the sterilization tray should be limited to devices, components and/or accessories that have been designed to fit within the tray brackets, posts, and caddy.

Reuse Life

End of life for the tray is determined by wear and damage due to use. Refer to Inspection and Maintenance for additional information.

Inspection and Maintenance

Proper care and maintenance are important for the efficient and safe operation of medical/surgical equipment. We recommend careful inspection of all equipment upon receipt and prior to each use, as a safeguard against possible injury to patient and/or operator.

- Visually inspect the sterilization tray prior to and after cleaning for damage, excessive wear and/or corrosion.
- Visually inspect the sterilization tray and its components for chips, cracks, dents or any other signs of damage or degradation prior to use.
- Ensure that any latches, handles and hinges function as intended.
- Ensure that all posts, brackets and the caddy are mounted in the tray.
- Labeling should be legible.

If any defects are observed, contact Caldera Medical. Refer to contact information on the final page of this IFU.

Cleaning Procedure

Proper cleaning must be performed prior to sterilization.

Caution: Do not use solvents, abrasive cleaners, metal brushes, or abrasive pads to clean or dry the tray.

Caution: Inspect the sterilization tray and its components for cleanliness prior to use.

1. Remove lid from the sterilization tray base, remove and if utilized, open the caddy latch/door.
2. Rinse all tray components under running water to remove excess soil.

NOTE: For all cleaning steps requiring water, filtered or de-ionized water is recommended, if available.

3. Immerse entirety the tray base and tray lid in a bath with enzymatic cleaning solution and soak for 5 minutes. (Ensure all components are fully immersed.)

NOTE: A mild enzymatic cleaner with near-neutral pH is recommended, such as Enzol. Follow the cleaning solution manufacturer's recommended processing instructions or facility-validated processing instructions.

4. While tray components are still immersed, scrub all crevices using a soft-bristled cleaning brush to remove any remaining visible debris.
5. If visible contamination of any tray components remains, repeat steps 3-5.
6. Once cleaning is complete, thoroughly rinse the entirety of the tray base and tray lid with cold water to completely remove the cleaning solution.
7. Complete the cleaning process by wiping the entirety of the tray base and tray lid using a soft sponge or lint-free cloth.
8. Ensure that the entirety of the tray base and tray lid are completely dry prior to sterilization or storage.

Sterilization Procedure

The Benesta™ Sterilization Tray can be sterilized with or without hysteroscope components placed inside.

1. If using the tray to sterilize a hysteroscope and disassembled components, ensure hysteroscope and components have been cleaned according to the device Instructions For Use.

Note: The sterilization tray should be cleaned prior to inserting any contents for sterilization processing.

2. Place and arrange the hysteroscope and tray contents in accordance with laser-markings on the bottom of the tray to facilitate sterility contact with all objects in the tray.

Caution: If using a sterilization tray with an internal caddy, ensure that the caddy is closed, locked, and placed correctly in the tray prior to sterilization. The caddy is designed to house small components that may become lost or damaged if the caddy is not closed and secured properly.

3. Place lid on sterilization tray and close latches on each side. Ensure lid is securely attached to the tray base.

Caution: Do not overload trays. The maximum load of the tray is 20 lbs.

4. Wrap tray in FDA-cleared sterilization wrap according to the wrap manufacturer's instructions.
5. Follow standard hospital procedures to sterilize the tray and contents using the settings shown in Table 2.

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Note: Variables that may affect sterilization and drying times include: loading density of the case/tray, instrument configuration, total contents of the sterilizer, steam quality, equipment maintenance, and others. Refer to manufacturer instructions for use (IFU) for any contents to be sterilized within the tray.

Caution: Do not load trays into sterilizer on sides or upside-down. Load trays on cart or shelf with lid always facing upward. This allows proper drying. The Caldera Medical Benesta™ Sterilization Tray is designed to drain in this position (facing upward).

Table 2. Sterilization parameters

	Steam Sterilization, Pre-Vacuum	Steam Sterilization, Gravity
Temperature	132 °C	132 °C
Exposure Time	4 minutes	15 minutes
Dry Time	45 minutes	45 minutes

Important: It is recommended that the institution employ procedures which include the use of biological indicators in order to determine the effectiveness of the sterilization process.

Caution: After the autoclave door is opened, all trays must be allowed to cool thoroughly. Place trays on a wire rack or shelf with linen cover for a minimum of 30 minutes, or until cooling is complete. The potential for condensation may increase if the tray is not allowed to cool properly.

- If condensation is observed, verify that the steam which is being used for sterilization processing, has a quality of more than 97%. Also confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer’s recommendations.

Performance of the Caldera Medical Benesta™ Sterilization Tray has been validated in the following steam autoclave:

Validated Device Contents	(1) Benesta™ Hysteroscope (1) Benesta™ Outflow Channel (2) Light post adapters (2) Valve Cap (2) Valve Insert (2) End Cap
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TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

For technical support and product return information, please contact Caldera Medical via email (info@calderamedical.com) or telephone, at 866-422-5337.

The most current version of the Labeling Symbols Glossary is available for viewing or download here:
www.calderamedical.com/medical-professionals/product-instructions-for-use

All Caldera Medical Instruction for Use (IFU) documents are available in print form at no additional cost upon request. If you would like to request a copy please contact us at 818.879.6555, fax 818.879.6556, or email info@calderamedical.com.

To learn more about Caldera Medical, other products for incontinence, product evaluations, and training opportunities, contact Caldera Medical at 866.422.5337 or visit our website at www.calderamedical.com.

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