Benesta® Rod Lens Hysteroscope

Instructions for Use

REF CAL-TR111

℞ ONLY

READ THESE INSTRUCTIONS COMPLETELY PRIOR TO USING THE CALDERA MEDICAL BENESTA® HYSTEROSCOPE

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10-403 Rev D

Symbol Glossary

The following is an explanation of symbols that may be used on Caldera Medical's products and packaging:

Symbol	Title/ Meaning/ Referent	Function/ Description	ISO 7000 Reg. no.	ISO 15223-1 or Other
Manufacture				
	**Manufacturer**	Indicates the medical device manufacturer.	3082	5.1.1
EC REP	**EU Authorized Representative**	Indicates the authorized representative in the European community.	N/A	5.1.2
	**Date of Manufacture**	Indicates the date when the medical device was manufactured.	2497	5.1.3
	**Use by Date**	Indicates the date after which the medical device is not to be used.	2607	5.1.4
LOT	**Batch Code**	Indicates the manufacturer's batch code so that the batch or lot can be identified.	2492	5.1.5
REF	**Catalogue number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.	2493	5.1.6
Sterility				
STERILE EO	**Sterilized Using Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	2501	5.2.3
	**Do Not Re-sterilize**	Indicates a medical device that is not to be re-sterilized.	2608	5.2.6
	**Do Not Use If Package Is Damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.	2606	5.2.8
	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process.	2609	5.2.7
Storage				
	**Keep Dry**	Indicates a medical device that needs to be protected from moisture.	0626	5.3.4
	**Temperature Limit**	Indicates the temperature limits to which the medical device can be safely exposed	0632	5.3.7
	**Humidity Limitation**	Indicates the range of humidity to which the medical device can be safely exposed	2620	5.3.8
Safe Use				
	**Do Not Re-use**	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	1051	5.4.2
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use.	1641	5.4.3
 [IFU URL]	**Consult Instructions for Use, or For Instructions for Use Refer to**	Indicates the need for the user to consult the instructions for use and where the electronic instructions for use (eIFU) and symbols glossary can be found.	1641	5.4.3
	**Follow Instructions for Use**	Refer to Instruction manual/booklet; on medical electrical equipment, Follow Instructions for Use	ISO 7010-M002	N/A
	**Caution**	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	0434A	5.4.4
	**General Warning**	General Warning Sign	N/A	ISO 7010-W012
	**Type BF Applied Part**	Signifies Applied Part Type	N/A	IEC 60517-5840
IPX2	**Ingress Rating**	Signifies that the device is rated to level 2 for water ingress protection, and that water splashing against the enclosure from any direction shall have no harmful effect.	N/A	N/A
	**Non-Ionizing Electromagnetic Radiation**	Indicates generally elevated, potentially hazardous levels of non-ionizing radiation, or to indicates equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	N/A	IEC 60417-5140
Other				
	**Packaging Unit**	Indicates the number of pieces in the package.	2794	N/A
℞ ONLY	**Prescription Only**	Requires prescription in the United States of America.	N/A	21 CFR 801.109

Table 1. Components of the Benesta® Hysteroscope Set (CAL-TR111)

Caldera Medical Catalog Code	Description
CAL-TR113	Benesta® Hysteroscope
CAL-TR112	Benesta® Outflow Channel
CAL-TR121	Benesta® Hysteroscope Light Post Adapter – Large (Storz/Olympus)
CAL-TR122	Benesta® Hysteroscope Light Source Adapter – Small (Dyonics/Wolf)
CAL-TR123	Benesta® Valve Lever and Cap x 3
CAL-TR124	Benesta® Hysteroscope/Outflow Channel End Cap x 2
CAL-TR125	Benesta® Working Channel Brush, 3mm
CAL-TR126	Benesta® Inflow Channel Brush, 2mm

Table 2. Components not provided with the Benesta® Hysteroscope Set

Caldera Medical Catalog Code	Description
CAL-TR1511 CAL-TR1513	Benesta® Tissue Removal Device, 1-pack Benesta® Tissue Removal Device, 3-pack
CAL-TR1415	Benesta® Fluid Pack with Y-Tubing and 2 Single-Use Seals (5 pack)
CAL-TR131	Benesta® Sterilization Tray
N/A*	Fluid Source – either Hanging Fluid Bag or Fluid Management System
N/A*	Standard male Luer connectors for fluid inflow
N/A*	Standard male Luer connectors for fluid Outflow (If outflow channel is used)
N/A*	Light Source
N/A*	Camera / Video System

* Equipment not provided by Caldera Medical.

Device Description

The Benesta® Hysteroscope is intended for use in visualizing the uterine cavity and performing diagnostic and operative hysteroscopy procedures, including use with the Benesta® Tissue Removal Device. Benesta® Hysteroscope system includes the hysteroscope and removable outflow channel. The removable outflow channel provides a fluid outflow lumen when the Benesta® Hysteroscope is being used in a diagnostic mode. The removable outflow channel includes a sealed entry port to permit the introduction of instrumentation.

- The reusable Benesta® Hysteroscope utilizes rod lenses for visualization and fibers for illumination. The Benesta® Hysteroscope includes a working channel designed to accommodate the respective Benesta® Tissue Removal Device. (See Figure 1). The components of the Benesta® Hysteroscope Set are listed in Table 1 and the hysteroscope components are shown in Figure 2.
- The Operative Benesta® Hysteroscopy System can be used with a hanging bag or a fluid management system (FMS) to provide continuous flow of distending media.

NOTE: Selection of a FMS is at the discretion of the user. FMS equipment should be capable of a minimum operating pressure of 40 mmHg to maintain appropriate intrauterine distention and be capable of measuring fluid deficit to monitor fluid absorption by the patient.

NOTE: Prior to initiation of surgical procedure, confirm compatibility with all equipment to be used with the Benesta® Hysteroscope, as not all equipment may be compatible and pose a risk if not used in conjunction with the manufacturer's specifications

- To visualize the endometrial cavity, a remote light source is connected to the hysteroscope light-post adapter via a fiber optic (or similar) cable. The light source is typically coupled to a camera system that allows display of the operative field on a video monitor.

NOTE: Selection of a video monitor and camera cable is at the discretion of the user. To connect with the hysteroscope eyepiece, the camera coupler must be compatible with the 32 mm (1.25 in) diameter eyepiece and provide sufficient brightness/contrast and resolution to accurately visualize the endometrial cavity.

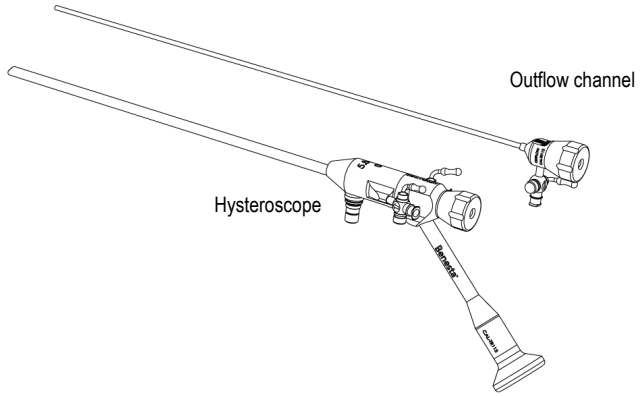

Figure 1. Benesta® Hysteroscope and removable Outflow Channel

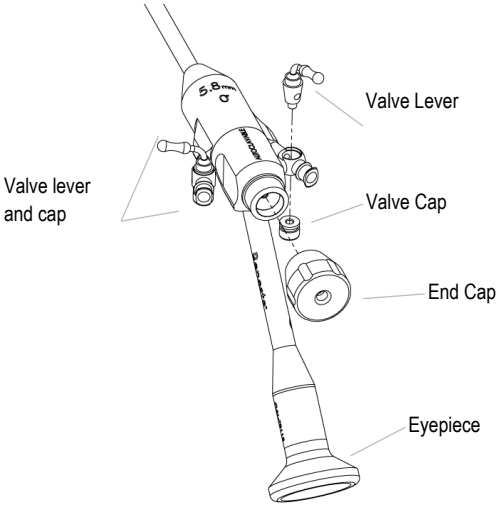

Figure 2. Benesta® Hysteroscope components

Indications for Use

The Benesta® Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and operative/ surgical procedures.

Contraindications

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

- Acute pelvic inflammatory disease
- Inability to distend the uterus
- Cervical stenosis
- Cervical/vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication
- Severe anemia
- Inability to circumnavigate a myoma due to myoma size
- Intolerance to anesthesia

Warnings

- Before using the Benesta® Hysteroscope for the first time, please review all available product information.
- For use only by physicians trained in diagnostic hysteroscopy and hysteroscopic surgery
- Careful pre-operative assessment, including imaging, should be performed on each patient prior to a hysteroscopic procedure to evaluate for conditions which may, depending on their severity or extent, affect the appropriateness of hysteroscopy.
- Hysteroscopic myomectomy should not be undertaken without adequate training, preceptorship, and clinical experience. Patients should be carefully evaluated to determine the presence of clinical conditions that can significantly complicate a hysteroscopic myomectomy.
- A pregnancy test before the performance of hysteroscopy is recommended whenever the possibility of pregnancy exists.
- The Benesta® Hysteroscope is to be used only in conjunction with accessories that comply with the following safety standards: National/Regional versions of IEC 60601-1, the general safety requirements for medical devices; and, as applicable, IEC 60601-2-18 or IEC 60601-2-2. Before using any accessory, be sure to follow the instructions provided with the accessory to determine criteria for safe use.
- For any accessories or electrical equipment intended to be used with the Benesta® Hysteroscope, please consult device instructions for use to determine safety criteria and risk mitigations when used with hysteroscopic equipment.
- Interconnections conditions require the applied parts of other medical electrical equipment used within the configuration for endoscopic application to be Type BF applied parts or Type CF applied parts.
- The Benesta® Hysteroscope is not intended for use with electrosurgical equipment.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- All equipment performance is considered to be safety-related including any degradation of performance caused by reciprocal interference. If the product is not put into service in accordance with the electromagnetic safety requirements in this manual and fails to perform as specified, the procedure should be aborted immediately, and biomedical engineering staff should be alerted to the observed issues.
- The Benesta® Hysteroscope and outflow channel are shipped non-sterile. They must be thoroughly cleaned and sterilized before use.
- After every hysteroscopic procedure, if the hysteroscope light-post adapters have been used, they should be removed from the hysteroscope, appropriately disassembled, and then cleaned and sterilized before subsequent use.
- Uterine perforation can result in injury to bowel, bladder, major blood vessels, and ureters.
- High-energy radiated light emitted from illuminating fibers may give rise to temperatures exceeding 106°F/41°C within 8 mm of the distal end of the hysteroscope. Do not leave tip of hysteroscope in direct contact with the patient tissue or combustible materials, as burns may result. Lower the light source output when working in close proximity to the object.
- A sterile, backup hysteroscope and accessories are recommended in case of device breakage or other accidental loss of function.
- When hysteroscopes are used with laser equipment, appropriate filtering spectacles must be worn by the operating team. In some cases, a specific filter must be put between the hysteroscope and camera head to prevent camera damage by high-power laser radiation. Contact your laser supplier for details. To prevent hysteroscope damage by high-power laser radiation, always ensure that the laser delivery fiber is seen through the hysteroscope and not directed at the hysteroscope before energizing the laser.
  - Not for use in an oxygen-rich environment.
  - No modification of this equipment is allowed.
  - Potential complications of hysteroscopy with fluid media:
    - Hypothermia
    - Pulmonary edema
    - Cerebral edema
    - Hyponatremia (if electrolyte free media are used)

- Uterine perforation resulting in possibly injury to bowel, bladder, major blood vessels, and ureters.

Precautions

- Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.
- If liquid distension media is used, strict fluid intake and output surveillance should be maintained. If a low viscosity isotonic liquid distention medium is used, intrauterine instillation exceeding 2500 mL should be followed with great care to the possibility of fluid overload. Possible complications of continuous flow hysteroscopy:
  - Hyponatremia
  - Hypothermia
  - Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels, and ureter
  - Pulmonary edema
  - Cerebral edema
- To reduce the risk and amount of systemic media absorption, intrauterine distension pressure should be maintained at the lowest pressure necessary to distend the uterine cavity and ideally should be maintained below the mean arterial pressure (MAP).
- Do not use the seals if the sterile package is open or appears compromised. Do not use the device if damage is observed.
- Avoid exposing the Benesta® Hysteroscope to sudden temperature changes. Do not immerse hot hysteroscopes in cold liquids.
- Any mechanical manipulation of the eyepiece may result in seal breakage. Therefore, do not attempt to remove the eyepiece.
- To avoid perforation, do not use the Benesta® Hysteroscope tip as a probe and exercise caution when the hysteroscope is being inserted through the cervix and when the hysteroscope tip is near the uterine wall.

SET-UP

Inspection Prior to Use

Prior to each use, the outer surface of the insertion portion of the Benesta® Hysteroscope should be inspected to ensure there are no unintended rough surfaces, sharp edges or protrusions. Ensure that the single-use seals have been appropriately positioned in both the Benesta® Hysteroscope and the outflow channel.

Before each use or after a change of viewing modes / settings on a camera control unit, check to ensure the observed view provides a live image (rather than a recording) and has the correct image orientation.

Equipment Needed for Indicated Procedures (not provided by Caldera Medical) (Table 2)

- Fluid source or system
- Video / Camera System
- Endoscopic light source (e.g. Metal-Halide or Xenon) with compatible fiber optic light guide (not supplied with this product).
- Standard male Luer connectors for fluid inflow
- Standard male Luer connectors for fluid Outflow (If outflow channel is used)

NOTE: The Benesta® Hysteroscope is compatible with Metal-Halide and Xenon light sources with up to 300 watts of power.

NOTE: It is recommended to have access to another hysteroscope in case of any droppage, contamination, damage and/or malfunction.

Caldera Medical Supplies Needed for Indicated Procedures (Table 2)

- Benesta® Fluid Pack (1 Single-use Y-Tubing and 2 single-use seals)
- Benesta® Tissue Removal Device

Placement of Single-Use Seals

Both the Benesta® Hysteroscope and the outflow channel require installation of single-use seals at the proximal end of their working channels. Figure 3 below illustrates the seal installation process.

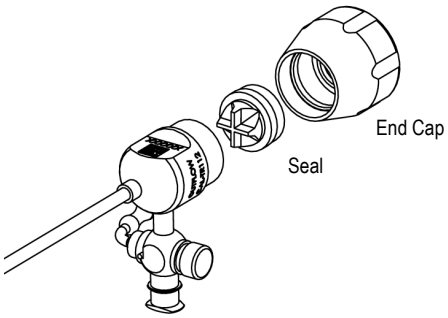

Figure 3. Seal installation

1. Remove end caps from hysteroscope and outflow channel.
2. Place seal within inside end cap in the orientation shown in Figure 3.
3. Screw end caps into place on the hysteroscope and outflow channel.
4. Insert the removable outflow channel into the hysteroscope's working channel. Reverse this process to remove the outflow channel.

Connecting Inflow Tubing

1. The Benesta® Hysteroscope has two ports that accommodate standard male Luer connectors for fluid inflow.
2. Connect the single-use Y-tubing to both male Luer connectors on the hysteroscope, as shown in Figure 4. Single-use Y-tubing is provided separately in the fluid pack.
3. Connect the single arm of the Y-tubing to the fluid inflow source. The Y-tubing can accommodate either a standard male Luer connector or friction connection.

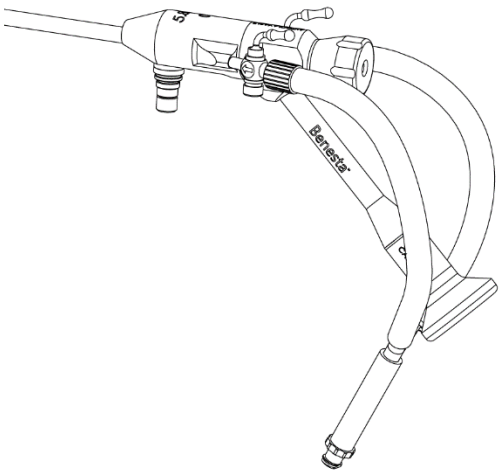

Figure 4. Y-Tubing attachment

Connecting Outflow Tubing (used with outflow channel)

1. The removable outflow channel includes a port that can accommodate a standard male Luer connector or friction connection. A standard male Luer connection is recommended to minimize fluid leakage.
2. Connect outflow tubing (purchased separately) to the port on the outflow channel.

Installing Light-Post Adapter

1. Ensure the light-post adapter installed on the hysteroscope is compatible with the intended light source. Adapters are available for connection to Storz, Olympus, Dyonics, Wolf, and ACMI light sources as shown in Figure 5.
2. Ensure the fiber optic surface remains free of foreign matter. Do not use tools to tighten the light post adapters – hand-tighten only.

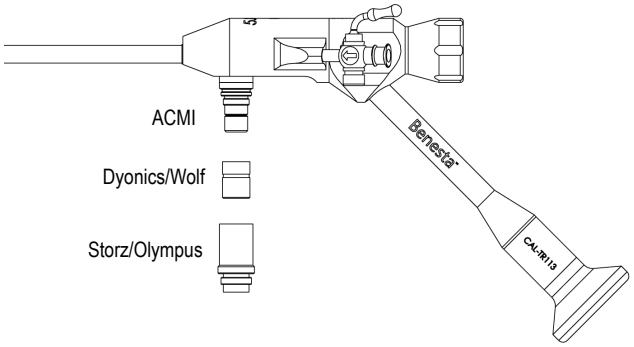

Figure 5. Light-post adapters

Directions for Use

1. The Benesta® Hysteroscope may be used by looking through the eyepiece of the hysteroscope directly, however, it may be more convenient to couple a video system to the eyepiece. If a video system is being connected to the Benesta® Hysteroscope, thread an eyepiece coupler onto the camera head and securely attach the eyepiece coupler onto the Benesta® Hysteroscope eyepiece.
2. Plug the video cable into the camera control unit (CCU).
3. Turn on the power to the monitor, CCU, and light source. Adjust the video system components per the manufacturer's instructions. The system is now ready to use.

NOTE: The inflow of the Benesta® Hysteroscope can be adjusted by opening or closing either of the two inflow valve lever. In order to maintain full fluid inflow, both inflow valve levers must be in the open position. To stop inflow completely, both valve levers must be in the closed position.

CLEANING AND STERILIZATION

A manual or automated cleaning procedure may be used, as described below. Proper cleaning must be performed prior to disinfection or sterilization.

Manual Cleaning

1. Completely remove light-post adapter from the hysteroscope.
2. Remove end caps from the Benesta® Hysteroscope and removable outflow channel and discard all single-use seals.
3. All valve levers and caps on the Benesta® Hysteroscope and removable outflow channel must be disassembled.

WARNING: Failure to remove the single-use seals from the Benesta® Hysteroscope and removable outflow channels will affect proper cleaning and sterilization of the product.

4. Fully immerse the Benesta® Hysteroscope, outflow channel, and accessories in a bath with enzymatic cleaning solution for 5 minutes and flush lumens with enzymatic cleaner using a syringe, a minimum of three times.

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

5. Scrub all crevices using a cleaning brush to remove any visible debris, taking care not to scratch any optical surface. Use cleaning brushes that are suitable to contact the full interior dimensions (diameter and length) of the lumens. The following dimensions for cleaning brushes are recommended:
    - Benesta® Hysteroscope working channel: 3.0mm brush diameter and at least 340mm overall length (REF CAL-TR125, 3mm Working Channel Brush, or equivalent).
    - Benesta® Hysteroscope fluid channels: 2.0mm brush diameter and at least 370mm overall length (REF CAL-TR126, 2mm Inflow Channel Brush, or equivalent).
    - Removable Outflow Channel: 2.0mm brush diameter and at least 370mm overall length (REF CAL-TR126, 2mm Inflow Channel Brush, or equivalent).
6. Flush each lumen with cold water.
7. Brush all inner and outer surfaces with cleaning brush and appropriately sized lumen brushes under cold water until all visible residues are removed.

8. If visible contamination remains on the Benesta® Hysteroscope, outflow channel, or other accessory components, repeat all previous cleaning steps until no visible contamination remains.
9. Make sure to thoroughly rinse the Benesta® Hysteroscope, outflow channel, and accessory components to completely remove the cleaning solution.
10. Ensure the Benesta® Hysteroscope and hysteroscope accessories are completely dry prior to sterilization or storage. A lint-free cloth and/or filtered compressed air may be used for drying.

Automated Cleaning

Manual Pre-Cleaning

1. Fully immerse the Benesta® Hysteroscope, outflow channel, and accessories in a bath with enzymatic cleaning solution for 5 minutes, and flush lumens with enzymatic cleaner using a syringe, a minimum of three times.

NOTE: It is recommended to use a mild enzymatic cleaner with a near-neutral pH, such as Enzol.

2. Flush the inner lumen with cold water using a water jet pistol for at least 20 seconds.
3. Brush inner and outer surfaces with cold water until all visible residues are removed.

Washer/Disinfector Cleaning

4. Place the Benesta® Hysteroscope, outflow channel, and accessories in an instrument basket.
5. Clean using a washer or disinfector and follow manufacturer instructions for suggested cycle parameters.
    - At a minimum, the cycle should consist of two pre-rinses with cold water, one wash at 43°C water, and two final rinses with cold water.
6. Ensure that the Benesta® Hysteroscope and hysteroscope accessories are completely dry prior to sterilization or storage. A lint-free cloth and/or filtered compressed air may be used for drying.

NOTE: Extra care should be taken to ensure that the lens and eyepiece of the Benesta® Hysteroscope are free of cleaning solution or visible residue.

NOTE: Do not use any ultrasonic cleaning methods. The energy transmitted through fluid cavitation will damage seals and optical surfaces and will void the warranty.

NOTE: Foreign matter remaining on the fiber surface of the light-post after cleaning may tend to burn and discolor the surface when exposed to a high intensity light source.

NOTE: If available, filtered or de-ionized water are recommended for all cleaning steps requiring water.

Disinfection

The decision on the reprocessing method must be made in accordance with international and national standards and guidelines. For thermostable equipment, sterilization should be preferred to disinfection.

1. Ensure that the Benesta® Hysteroscope has been cleaned prior to chemical high-level disinfection (HLD).
2. Follow internal safety measure and utilize protective equipment (PPE). At a minimum a gown/apron, mask, eye protection and gloves should be worn at all times during the disinfection process.
3. Follow the manufacturer's or internal validated HLD instructions for use in preparation of the chemical disinfectant solution with an FDA-cleared HLD intended for semi-critical devices.
4. Fully immerse the Benesta® Hysteroscope, outflow channel, end cap and lever components in the disinfectant bath, ensuring all surfaces are fully submerged.
    a. If sterilization with the Benesta® Hysteroscope Sterilization Tray, ensure tray is fully submerged in solution.
    b. Use a syringe to fill the Benesta® Hysteroscope and outflow channel lumens with the solution and ensure that no air bubble exist within the lumens.
5. Follow the HLD manufacturer's instructions for semi-critical device processing, including immersion time, temperature, and quality monitoring parameters.
    a. The devices should be immersed for a minimum of 12 minutes in the solution at a minimum temperature of 20°C.
    b. The processing time begins when the last item is placed into the immersion bath.
    c. Do not add items once the immersion time has begun.
    d. Do not remove items once the immersion time has begun. If items are removed, you will need to restart the cleaning process from page 6 in the IFU.
    e. Ensure that the bath container is covered at times, except when inserting or removing the devices.
6. If you have removed your PPE after the immersion process, you will need to re-dress. At a minimum a gown/apron, mask, eye protection and gloves should be worn at all times during the chemical sterilization process. Follow your internal safety measures for use with chemical process.
7. Remove the devices from the immersion bath and thoroughly rinse with water, preferably sterile. It is recommended that a minimum of 2 gallons of water are used to rinse the devices, and a flushing of all lumens with a syringe of water is completed. Repeat the rinsing process for a total of 3 rinses.
    a. After each use, discard the rinse water per internal processes.
8. Dry the devices with sterile-appropriate, lint-free cloths or sponges.
    a. It is recommended to dry all lumens with forced or compressed air.
9. Dispose of the chemical solution following the manufacturers or internal instructions.
10. Use the devices immediately after HLD or prepare for storage according to facility procedures and national and local laws and guidelines to maintain high level disinfection.

Sterilization

The Benesta® Hysteroscope, outflow channel, light-post adapters, valve levers and end caps can be sterilized in an FDA-cleared autoclave wrap, autoclave pouch or, preferably, sterilized in a container which secures the instruments in place, such as the Benesta® Sterilization Tray (sold separately). Prior to sterilization, ensure that the hysteroscope and components have been thoroughly cleaned.

1. When placing instruments and components into sterilization wrap, pouch or tray, be sure the instruments do not experience any undue forces or stress which might damage the system including the delicate internal optics of the hysteroscope.
    - Prior to sterilization, all components should be disassembled to allow for steam penetration with all levers and values in the open position.
2. If using an FDA-cleared sealable pouch, insert the Benesta® Hysteroscope and disassembled components in an appropriately sized pouch, and process according to the manufacturer's instructions and standard clinic/ hospital procedures.
3. If using an FDA-cleared sterilization wrap or tray, wrap the Benesta® Hysteroscope and components or the outside of the tray. Utilize wrapping techniques according to the wrap manufacturer's instructions and standard clinic/ hospital procedures.
    - It is recommended that the sequential wrapping technique per AAMI ST:79 be used when utilizing a sterilization tray.
4. Follow standard clinic/ hospital procedures to sterilize the wrapped or pouched hysteroscope and components using the settings shown in Table 3.

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.

Table 3. 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 to determine the effectiveness of the sterilization process.

5. After the autoclave door is opened, all contents must be allowed to cool thoroughly. Place wrapped/pouched contents on a wire rack or shelf with linen cover in an area free of traffic and strong air currents for a minimum of 30 minutes, or until cooling is complete. The potential for condensation may increase if the contents are not allowed to cool properly.
6. 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.

Maintenance

We recommend that you inspect the Benesta® Hysteroscope carefully before and after the procedure for possible signs of damage.

1. Check the image quality of the Benesta® Hysteroscope by viewing the monitor. If image quality is impaired:
    – Check the distal and proximal lenses of the Benesta® Hysteroscope for cracked or scratched lenses.
    – Check the surface cleanliness of the distal and proximal lenses. A foggy or cloudy image can be the result of moisture entering the optical system or lack of cleanliness of exterior surfaces. When viewing reflected light, the surfaces should appear smooth and shiny.
2. Check the illumination system of the Benesta® Hysteroscope. Reduced brightness can result from fiber damage:
    – Check for fiber optic damage in the Benesta® Hysteroscope by holding the distal end of the hysteroscope toward a low-power light and observing the light-post on the hub. The center of the light-post should appear clear or white. Noticeable black spots indicate serious damage to the fiber illumination bundle in the hysteroscope. This will affect light transmission and the brightness of the image viewed on the monitor.

WARNING: Do not look directly into distal end of the Benesta® Hysteroscope while it is illuminated as this may damage your eye.

Storage

- The Benesta® Hysteroscope and Removable Outflow Channel should be stored either in their shipping box or in a sterilization tray. In either case, proper care should be taken to ensure that the Benesta® Hysteroscope and outflow channel are immobile to prevent any damage.
- If stored within a wrapped container, inspect wrap prior to usage. If the wrap is open, damaged, or visible moisture is present, do not use the device until it is reprocessed.
- The device should not be stored at temperatures below 40°F or above 120°F, or in conditions where the humidity is below 40% or above 60%.

Service - Accessories

The following are replacement/service parts for the Benesta® Hysteroscope (Table 4).

Table 4. Replacement components

Catalog Code	Description
REF CAL-TR111	Benesta® Hysteroscope Set.
REF CAL-TR112	Benesta® Outflow Channel
REF CAL-TR121	Replacement Hysteroscope Light Post Adapter – Large (Storz/Olympus)
REF CAL-TR122	Replacement Hysteroscope Light Source Adapter – Small (Dyonics/Wolf)
REF CAL-TR123	Replacement Valve Lever and Cap
REF CAL-TR124	Replacement Hysteroscope/Outflow Channel End Cap
REF CAL-TR125	3mm Working Channel Brush
REF CAL-TR126	2mm Inflow Channel Brush

Reuse/Use-Life

For the Benesta® Hysteroscope, end of life is normally determined by wear and damage due to use. Please consult the Maintenance Section of this document for re-use inspection prior to and for continued usage of the Benesta® Hysteroscope. The Benesta® Hysteroscope should be serviced annually or sooner if problems are found during inspection and maintenance.

Warranty, Service, and Repair

Please contact Caldera Medical via email (info@calderamedical.com) or telephone, at 866-422-5337.

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

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