SYMPHION®
Operative Hysteroscopy System

6.3 HYSTEROSCOPE

PREFACE

This manual provides the information you need to operate and maintain the Symphion® 6.3 Hysteroscope. It is essential that you read and understand all the information in this manual before using or maintaining this device.

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℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

1. DEVICE DESCRIPTION

The Symphion 6.3 Hysteroscope is a reusable instrument for use in visualizing the body cavity during diagnostic and surgical hysteroscopic procedures.

The Symphion 6.3 Hysteroscope is for use with the Symphion® System.

2. INTENDED USE/INDICATIONS FOR USE

The Symphion 6.3 Hysteroscope is intended to provide the physician with a means for endoscopic diagnostic and therapeutic surgical procedures. It is indicated for use in diagnostic examination and surgical hysteroscopic procedures.

3. CONTRAINDICATIONS

- Acute pelvic inflammatory disease
- Inability to distend the uterus
- Cervical stenosis
- Cervical/vaginal/Pelvic infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix/endometrial cancer
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

4. WARNINGS

- In the case of suspected pregnancy, a pregnancy test is necessary before carrying out diagnostic hysteroscopy.
- Do not use the Symphion 6.3 Hysteroscope in patients where anatomy does not support an endoscopic procedure (i.e. cervical stenosis, existence of an IUD, or in conditions that limit access to the target tissue).
- Fluid overload: For continuous flow endoscopic surgery, there is a risk of distention fluid reaching the circulatory system of the patient's soft tissue by passing through the tissue enclosing the treatment site. This can be affected by distention pressure, flow rate, perforation of the cavity and duration of the surgery. It is critical to closely monitor the input and outflow of the distension fluid at all times.
- Excessive force applied during insertion or removal of the device may result in tissue injury including perforation. To avoid perforation, do not use the scope tip as a probe and exercise caution when the scope is being inserted into the body cavity and when the scope tip is near the cavity wall. Perforation can result in possible injury to bowel, bladder, major blood vessels, and ureter.
- High energy radiated light emitted from illuminating fiber at the distal end of the scope may give rise to temperatures exceeding 106°F (41°C) (within 8mm in front of the Endoscope). Do not leave the tip of scope in direct contact with patient tissue or consumable materials, as burns may result. Lower the light source output when working in close proximity to the object.
- The Endoscope light post and adapter may exceed temperatures of 106°F (41°C). The Endoscope should not be placed on the patient or on combustible materials as burns may result.
- When using HF surgical equipment, keep the working part of the active electrode in the field of view to avoid accidental HF burns. Avoid contact with metal parts of the Endoscope and other conductive accessories by ensuring that the active electrode is at a sufficient distance from the tip of the Endoscope before activation of the HF output. Ensure that only medical electrical equipment that complies with IEC 60601-1 and its relative particular standards is connected to, or used in conjunction with, the Endoscope.
- The Symphion 6.3 Hysteroscope is for procedures outlined in the indications for use statement ONLY. Before using the Symphion 6.3 Hysteroscope, please review all available product information and these instructions carefully.
- Endoscopic procedures should only be performed by trained professionals with sufficient knowledge and training. It is the responsibility of the user to be familiar with indications, contraindications, potential complications and risks associated with the endoscopic procedure being performed.
- Endoscope cleaning brushes are for single patient use. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may create a risk of contamination of the device and/or cross infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death.
- After use of cleaning brushes, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

5. PRECAUTIONS

The Symphion 6.3 Hysteroscope is supplied non-sterile. Prior to first use, it must be removed from the protective packaging, cleaned and sterilized. Prior to each subsequent use it must be cleaned and sterilized.

- Prior to each use, inspect the device to ensure it is functioning properly and free of damage. Damage can compromise device function and safety. Do not use a damaged device.
- Avoid exposing the scope to sudden temperature changes. Do not immerse hot scopes into cold water or liquid. Allow the scope to properly cool after autoclave cycles.
- Any mechanical manipulation of the eyepiece may result in seal breakage, therefore do not attempt to remove the eyepiece.
- Between uses the device must be stored in accordance with these instructions. Storing in another manner may results in damage or loss of function.
- Minerva Surgical is not responsible for damage caused by misuse of the scope. Misuse of the scope shall void the warranty.

6. ADVERSE EVENTS

Potential complications of continuous flow endoscopic surgery include:

- Hyponatremia
- Hypothermia
- Perforation
- Perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter
- Pulmonary edema
- Cerebral edema
- Air embolism

7. COMPATIBILITY

Symphion 6.3 Hysteroscope is for use in conjunction with the Symphion System. Refer to Symphion System instructions for directions on use of the scope as part of the Symphion System.

Symphion 6.3 Hysteroscope offers adapters for the Endoscope light post and light cable for connection to Storz, Olympus, Smith & Nephew/Wolf and ACMI light sources (See Appendix A).

Before using Symphion 6.3 Hysteroscope with any other accessory or device, be sure to follow the instructions provided with the accessory or device, including in the case of a HF electrode, the maximum recurring peak voltage rating.

Accessories or other devices may require the use of an endoscopic seal to prevent leakage or aspiration through the working channel of the hysteroscope. Seals should cover the ~9mm proximal end of the working channel and create an adequate opening to allow passage of the device/accessory into the working channel while minimizing leaks.

8. HOW SUPPLIED

IMPORTANT: The Symphion 6.3 Hysteroscope is supplied non-sterile. It must be disassembled, cleaned, and sterilized before the first use. It must be disassembled, cleaned, and sterilized before every subsequent use.

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible

CONTENTS:

- 1 ea Symphion 6.3 Hysteroscope
- 1 ea Wolf Adapter
- 1 ea Storz / Olympus Adapter
- 2 ea Cleaning Brushes
  - 1 ea Working channel brush (See Appendix C)
  - 1 ea Fluid channel brush (See Appendix C)

9. SYMPHION® 6.3 HYSTEROSCOPE

The Symphion 6.3 Hysteroscope is a custom 0° degree ø6.3mm rigid scope with two integrated fluid channels (2x ø1.5mm) and one working channel (ø3.7mm). Used in conjunction with the Symphion System, the Endoscope's fluid channels are used for infusion of distension fluid and direct pressure monitoring of the cavity. The working channel accommodates the Symphion 3.6 Resecting Device. The overall length of the Symphion 6.3 Hysteroscope is 333mm. The working length of the Symphion 6.3 Hysteroscope is 208mm. (See Appendix A).

10. REQUIRED MATERIALS

10.1 MATERIALS USED EACH TIME THE ENDOSCOPE IS BEING REPROCESSED

Cleaning:

- Enzymatic neutral pH cleaner (ENZOL® or equivalent)
- 10mL volume disposable syringe (2ea)
- Working channel brush (see Appendix C)
- Fluid channel brush (see Appendix C)
- Isopropyl alcohol
- Gauze pads
- De-mineralized water (minimum 3 gallons)
- Lukewarm running tap water 72° - 109°F (22°- 43° C)

Steam Sterilization:

- Steam Sterilizer capable of pre-vacuum cycles (dynamic air-removal) for 3 minutes at 275°F(135°C) or 4 minutes at 270°F (132°C)
- Two layers of central supply wrap (Kimberly Clark, catalog #KC300 or equivalent), or
- Steam Sterilization Tray with Endoscope Basket (Aesculap® tray lid P/N JK020, tray bottom, P/N JN021 and scope basket P/N JF435R or equivalent), or
- Steam Sterilization Tray with Lid and Instrument Tray Holders (**Advanced Sterilization Products AptiMax™** tray with lid P/N 13830 and **Advanced Sterilization Products Aptimax™** Instrument Tray Holders P/N 99404 and P/N 99406 or equivalent). See Appendix D for Advanced Sterilization Products AptiMax tray holder placement instructions.
- Equivalent steam sterilization trays can be used but must be identified and validated by the user facility
- Aesculap® Sterilization Tray Only: Single-Use Paper Filter (4 in (10.16cm) x 9 in (22.9cm)) for use with tray only
- Follow Tray and Tray Holders manufacturer's IFU for inspection, maintenance, cleaning and assembly of tray.

STERRAD® Sterilization:

- STERRAD® sterilizer capable of STERRAD® 100S, STERRAD® NX Standard Cycle and STERRAD® 100NX Standard Cycle
- STERRAD® Sterilization Tray with Endoscope Basket (Aesculap® tray lid P/N JK020, tray bottom, P/N JN021 and scope basket P/N JF435R or equivalent), or
- STERRAD® Sterilization Tray with Lid and Instrument Tray Holders (**Advanced Sterilization Products AptiMax™** tray with lid P/N 13830 and **Advanced Sterilization Products Aptimax™** Instrument Tray Holders P/N 99404 and P/N 99406 or equivalent). See Appendix D for **Advanced Sterilization Products AptiMax™** Instrument Tray Holder placement instructions).
- Equivalent STERRAD® sterilization trays can be used but must be identified and validated by the user facility.
- Aesculap® Tray Only: Single-Use Polypropylene Filter (4 in (10.16cm) x 9 in (22.9cm)) for use with tray only
- Follow Tray and Tray Holders manufacturer's IFU for inspection, maintenance, cleaning and assembly of tray.

NOTE: Central supply wrap should not be used and was not validated for use with the Aesculap® sterilization trays.

10.2 MATERIALS USED WHEN CLEANING THE OPTICAL SURFACE OF THE ENDOSCOPE

(Optics should only be cleaned when the image as viewed through the scope is cloudy, and not as part of your routine cleaning procedures.)

- 70% Isopropyl alcohol
- Clean cotton-tipped swab

10.3 MATERIALS MAY BE USED FOR CLEANING VERIFICATION

- 3% hydrogen peroxide

11. INSPECTION, MAINTENANCE AND TESTING

IMPORTANT: The Symphion 6.3 Hysteroscope is supplied non-sterile. It must be disassembled, cleaned, and sterilized before the first use. It must be disassembled, cleaned, and sterilized before every subsequent use.

11.1 INSPECTION PRIOR TO USE

Prior to each use, inspect the outer surface of the scope and the inner surface of the working and fluid channels to ensure there are no unintended rough surfaces, sharp edges, or protrusions.

11.2 MAINTENANCE AND TESTING

Minerva Surgical recommends careful inspection of the endoscope and any accessories before and after each procedure for possible signs of damage. This will allow early detection of minor damage, which if repaired immediately will increase the life of the endoscope.

1. Check the image quality of the scope by viewing the monitor. If image quality is impaired:
   a. Check the distal and proximal lenses of the endoscope for cracked or scratched lenses.
   b. Inspect the shaft of the endoscope for dents. Dents along the shaft might adversely affect fluid flow.
   c. 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. Specific instructions to remove deposits are provided in **Section 12.2, Cleaning Instructions – Optical Surfaces**.

IMPORTANT: Endoscopes with damaged glass surfaces (e.g., chips), impaired image quality or striking surface damage and deformation may no longer be used and should be discarded or sent to the manufacturer or an authorized service specialist to be checked.

IMPORTANT: If deposits are not removable by cleaning, the Endoscope should be sent to the manufacturer or an authorized service specialist to be checked.

2. Check the illumination of the scope by connecting the scope to a light source. Reduced brightness can result from fiber damage. If reduced brightness is encountered:
   a. Check for illumination fiber damage in the scope by holding the distal end of the scope toward a light and observing the light post on the hub. The center of the light post should appear clear or white. Black spots indicate serious damage to the illumination fiber bundle in the scope. This damage affects light transmission to the surgical site and the brightness of the image viewed on the monitor.

IMPORTANT: Endoscopes with damaged fiber optics should be sent to the manufacturer or an authorized service specialist to be checked.

12. REPROCESSING INSTRUCTIONS

IMPORTANT: Concentration levels specified by the manufacturer of the detergent must be strictly adhered to. Contact times specified in these instructions for use must be strictly adhered to. Use only freshly prepared solutions.

IMPORTANT: Do not soak the endoscope in Isopropyl Alcohol or other corrosive liquids that may not be compatible with the scope.

IMPORTANT: Always use fresh volumes of water for rinsing. Do not reuse rinsing water for rinsing or any other purpose.

IMPORTANT: Endoscopes have been validated for reprocessing up to 50 cycles. Post 50 cycles the endoscope may require refurbishment.

12.1 CLEANING INSTRUCTIONS - ENDOSCOPE

- Proper cleaning must be performed prior to sterilization. An effective cleaning process is essential to ensure effective sterilization.
- Clean the Endoscope as soon as possible after use.
- If it is not possible to clean/rinse the Endoscope immediately following a procedure, the instrument should be placed in a basin with clean lukewarm tap water until proper cleaning can be commenced per the instructions below.

Cleaning Agent:

Use ENZOL® or an equivalent neutral pH enzymatic detergent. Enzymatic detergents aid in the removal of organic soil such as blood.

1. Disassemble the instruments as much as possible (i.e. light-guide adapter, See Appendix A).
2. Gently and thoroughly rinse the endoscope with lukewarm running tap water 72-109°F (22°- 43°C) for a minimum of one (1) minute.
3. Prepare the cleaning solution, enzymatic neutral pH cleaner (ENZOL® or equivalent), in accordance with the concentration defined by the manufacturer of the detergent.
4. Place the disassembled instruments in the cleaning solution so that they are completely covered. Ensure that the instruments do not touch. Soak the instruments for a minimum of 10 minutes. Move the parts back and forth several times to ensure that all surfaces are exposed to cleaning solution.
5. Flush the lumens of the instruments five times with minimum 10mL volume of cleaning solution using a disposable syringe.
6. Inspect cleaning brushes prior to use. Do not use if shaft is bent/kinked, or bristles are frayed/missing. Scrub the working channel using the working channel cleaning brush and scrub the fluid channels using the fluid channel cleaning brush (See Appendices B and C). Ensure that all interior surfaces, crevices, lumens, cavities, and holes of the working and fluid channels are scrubbed thoroughly to remove any visible debris, taking care not to scratch any optical surfaces.
7. Scrub the exterior surface of the endoscope and the proximal end of the working channel with a gauze pad soaked in an enzymatic, neutral pH cleaner (ENZOL® or equivalent).
8. Scrub each optical surface with a gauze pad soaked in an enzymatic, neutral pH cleaner (ENZOL® or equivalent).
9. Remove the instruments from the cleaning bath and rinse the device, thoroughly flushing the interior lumens and cavities, for a minimum of two minutes with warm tap water.
10. Scrub each optical surface with a gauze pad soaked in isopropyl alcohol. Rinse thoughtfully with de-mineralized water.

Cleaning Verification

1. After cleaning, inspect devices under normal lighting to ensure that all visible debris has been removed.
2. If not visibly clean, repeat cleaning and re-inspect.
3. For difficult-to-view areas, 3% hydrogen peroxide may be applied (bubbling is evidence of the presence of blood).

Note: Rinse instruments thoroughly with de-mineralized water following any hydrogen peroxide testing.

4. Inspect following the instructions in Section 11.2, **Maintenance and Testing.**

12.2 CLEANING INSTRUCTIONS – OPTICAL SURFACES

Due to insufficient cleaning or foreign matter contamination, deposits may develop on the three optical surfaces of the Endoscope (Figure 3).

These are:

1. The distal tip
2. The proximal window or eyepiece
3. The fiber optic light post

Figure 3.

Remove these deposits using a clean cotton-tipped swab soaked in 70% Isopropyl Alcohol. Gently press the swab onto the optical surface to be cleaned and scrub the surface with a circular motion. Rinse the optical surface with de-mineralized water to remove any remaining alcohol.

IMPORTANT: Optics should only be cleaned when the image as viewed through the scope is cloudy, and not as part of your routine cleaning procedures.

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

IMPORTANT: 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.

12.3 STERILIZATION INSTRUCTIONS - ENDOSCOPE

Symphion 6.3 Hysteroscope must be sterilized using one of the following methods.

12.3.1 Steam Sterilization Instructions

- Sterilization Configuration
- Steam Autoclave Wrapped
- Prior to steam sterilization, devices should be wrapped in two layers of central supply wrap (Kimberly Clark, catalog #KC300 or equivalent)

OR

Steam Sterilization Tray

- Prior to steam sterilization, devices should be loaded into the scope basket and placed inside the steam sterilization tray (Aesculap® tray lid P/N JK020, tray bottom, P/N JN021 and scope basket P/N JF435R or **Advanced Sterilization Products AptiMax™** tray with lid P/N 13830 and **Advanced Sterilization Products Aptimax™** Instrument Tray Holders P/N 99404 and P/N 99406 or equivalent).
- Equivalent steam sterilization trays can be used but must be identified and validated by the user facility.
- Follow tray manufacturer's IFU for inspection, maintenance, cleaning and assembly of tray.
- Aesculap® Tray Only Central supply wrap should not be used and was not validated.
- Aesculap® Tray Only: Single-Use Paper Filter (4 in (10.16cm) x 9 in (22.9cm) for use with tray only.

Sterilization Cycles

- Steam, pre-vacuum method at 275F for 3 minutes. Drying time 16 minutes
- Steam, pre-vacuum method at 270F for 4 minutes. Drying time 30 minutes

12.3.2 STERRAD® Sterilization Instructions

Sterilization Configuration

STERRAD® Sterilization Tray

- Prior to STERRAD® sterilization, devices should be loaded into the scope basket and placed inside the STERRAD® sterilization tray (Aesculap® Tray lid P/N JK020, tray bottom, P/N JN021 and scope basket P/N JF435R or **Advanced Sterilization Products AptiMax™** tray with lid P/N 13830 and **Advanced Sterilization Products Aptimax™** Instrument Tray Holders P/N 99404 and P/N 99406 or equivalent).
- Equivalent STERRAD® sterilization trays can be used but must be identified and validated by the user facility.
- Aesculap® Tray Only: Central supply wrap should not be used and was not validated.
- Aesculap® Tray Only: Single-Use Polypropylene Filter (4 in (10.16cm) x 9 in (22.9cm) for use with tray only

Follow tray manufacturer's IFU for inspection, cleaning, maintenance and assembly of tray.

Sterilization Cycles

- STERRAD® 100S
- STERRAD® NX Standard cycle
- STERRAD® 100NX Standard cycle

IMPORTANT: Never sterilize an endoscope that has not been cleaned. The success of the sterilization process depends on the previous state of cleaning.

IMPORTANT: Sterilization process parameters must be strictly adhered to. If the specified parameters are not met this may result in damage or a reduction in the life-span of the endoscope.

IMPORTANT: After sterilization, hot endoscopes should not be quenched; instead, they should be allowed to cool down to room temperature. Drastic changes in temperature can lead to damage to the endoscope or breakage of the glass components.

13. STORAGE

The endoscope and accessories should be stored either in their shipping box or in a sterilization tray. In either case, ensure that the endoscope is immobile to prevent any damage.

WARRANTY

Minerva Surgical warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Minerva Surgical's control directly affect the instrument and the results obtained from its use. Minerva Surgical's obligation under this warranty is limited to the repair or replacement of this instrument that Minerva Surgical determines is caused by defects in material and workmanship if notice thereof is received within one year plus a 7-day grace period from the date of shipment. Minerva shall not be liable for any incidental or consequential loss, damage Surgical or expense directly or indirectly arising from the use of this instrument. **Minerva Surgical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.** Buyer may, at its sole cost and expense, purchase an extended warranty (CORECare Warranty Agreement) from Minerva Surgical to extend the term of this warranty.

CUSTOMER SERVICE/TECHNICAL SUPPORT

Contact Minerva Surgical Customer Service for customer or technical support.

Call +1 (855) 646-7874

Enzol® and STERRAD® are registered trademarks of Johnson & Johnson.

Aesculap® is a registered trademark of Aesculap AG.

AptiMax™ is a trademark of Advanced Sterilization Products.


Consult Instructions for use on this website: www.minervasurgical.com

Serial Number

Catalog Number

Batch Code Lot Number


Legal Manufacturer


Contents


Date of Manufacture


Store in a cool dry place


Do not use if package is damaged.

Non Sterile


For single use only. do not reuse.


Legal Manufacturer

Manufactured for:
Minerva Surgical, Inc.
4255 Burton Drive,
Santa Clara, CA 95054 USA
Customer Service 855-646-7874

APPENDIX A: FIGURE A1

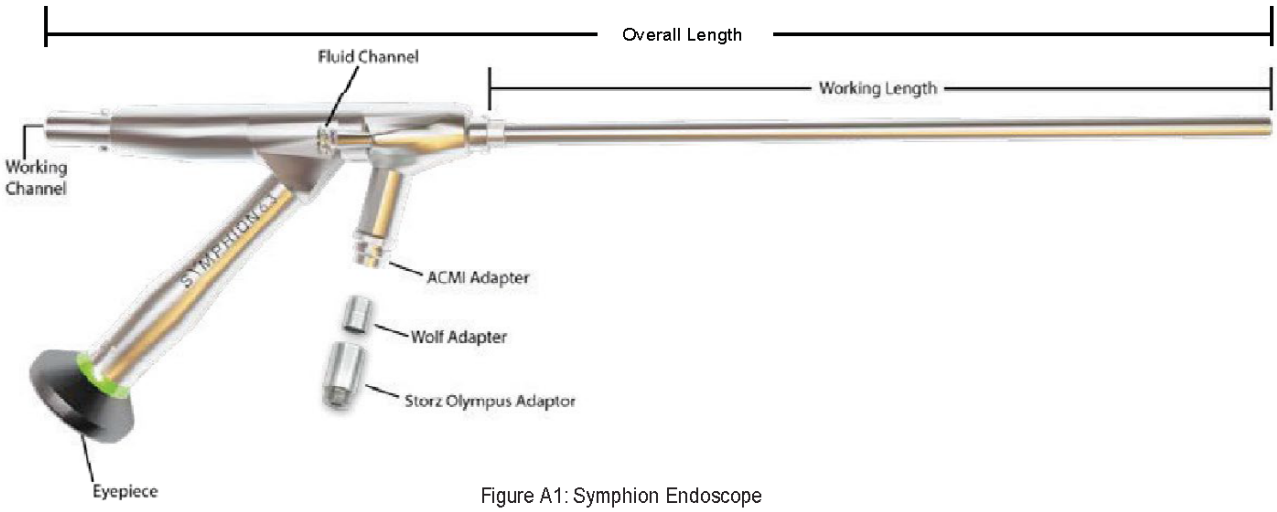
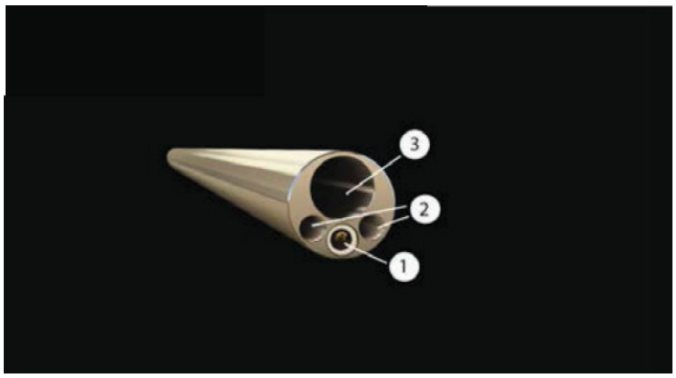


Figure A1: Symphion Endoscope

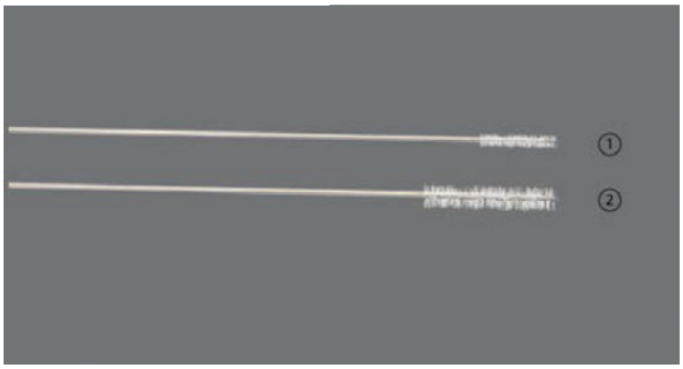
APPENDIX B: FIGURE B1



1. Lens
2. Fluid Channel
3. Working Channel

Figure B1: Endoscope working/fluid channel

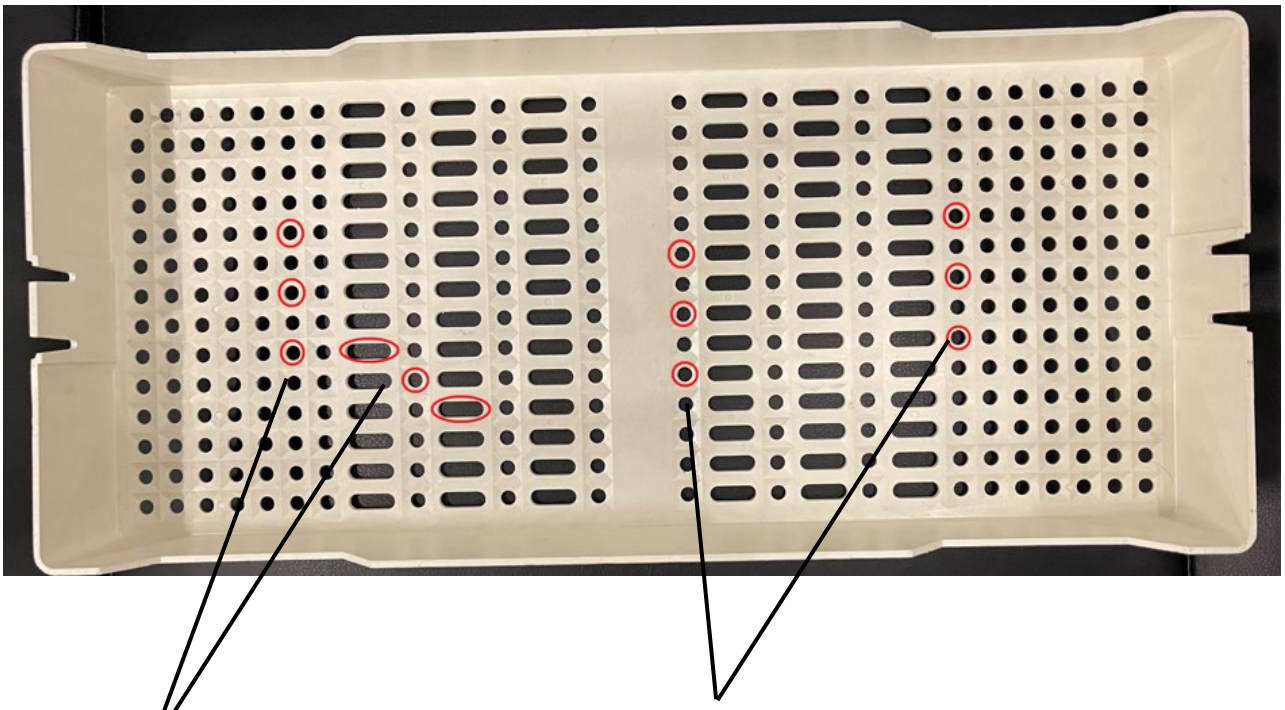
APPENDIX C: FIGURE C1



1. Fluid Channel Brush
2. Working Channel Brush

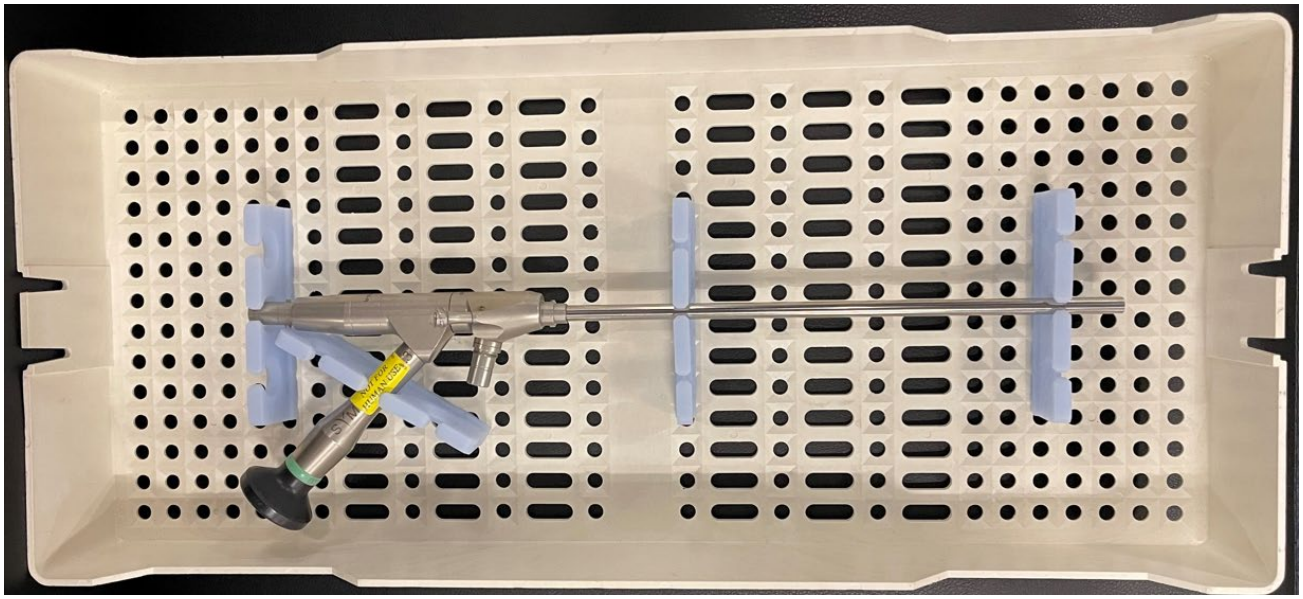
Figure C1: Cleaning Brushes

APPENDIX D: TRAY CONFIGURATION EXAMPLE



ASP AptiMax™ hysteroscope holder
Part Number: 99404

ASP AptiMax™ hysteroscope holder
Part Number: 99406



NOTE: The images above show the recommended Symphion Hysteroscope placement that has been validated by Minerva Surgical under laboratory conditions for sterilization purposes.

APPENDIX E: TROUBLESHOOTING

Problem	Possible Cause	Recommended Action
Picture cloudy, foggy	- Optical surfaces contaminated	- Clean in accordance with section 12.1
	- Deposits, encrustations on the optical surfaces	- Clean optical surfaces in accordance with instructions section 12.2
	- Leaky, defective lens system	- Return endoscope to manufacturer or authorized representative for repair
Picture too dark, too small illumination	- Optical surfaces contaminated	- Clean in accordance with section 12.1
	- Deposits, encrustations on the optical surfaces	- Clean optical surfaces in accordance with instructions section 12.2
	- Fiber optic defect	- Check fiber optic according to section 11.2
	- Defect light cable, light source	- Check light cable, light source
Yellowish lighting	- Dirty fiber optics	- Clean in accordance with section 12.1, if necessary clean optical surfaces in accordance with 12.2. - If optics cannot be cleaned manually return the endoscope to manufacturer or authorized representative for service
	- Dirty, broken fiber optic cable	- Check fiber optic cable (for example, on a white surface light) and replace if necessary
Staining, discoloration	- Inadequate cleaning (for example, remaining protein residues)	- Clean in accordance with section 12.1
	- Cleaning solutions are contaminated or being reused	- Always use freshly prepared solutions - Repeat cleaning in accordance with section 12.1