Inability to distend the uterus

Acute pelvic inflammatory disease

Invasive carcinoma of the cervix/endometrial cancer

Recent uterine perforation

Medical contraindication or intolerance to anesthesia

- Cervical stenosis
- Cervical/vaginal/Pelvic infection
- Uterine bleeding or menses
- Known pregnancy
- 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 output 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 Endoscope 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. The Symphion 6.3 Endoscope 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 Endoscope 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 ~8mm 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.

1. DEVICE DESCRIPTION

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

The Symphion 6.3 Endoscope is for use with the Symphion System.

2. INTENDED USE/INDICATIONS FOR USE

The Symphion 6.3 Endoscope 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

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 Endoscope 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 output 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 Endoscope is for procedures outlined in the indications for use statement ONLY. Before using the Symphion 6.3 Endoscope, 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 Endoscope 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 result in damage or loss of function.
- Boston Scientific 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:

- Hypotension
- 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 Endoscope 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 Endoscope 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 Endoscope 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 ~8mm 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 Endoscope is supplied non-sterile. It must be disassembled, cleaned, and sterilized before the first use. It must be disassembled, cleaned, and sterilized before each 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 Endoscope
- 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 ENDOSCOPE
The Symphion 6.3 Endoscope 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 utilized for infusion of distention 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 Endoscope is 333mm. The working length of the Symphion 6.3 Endoscope is 280mm. (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)
- Two layers of central supply wrap (Kimberly Clark, catalog #KC300 or equivalent), or
- Steam Sterilization Tray with Endoscope Basket (Aesculap® tray lid P/N JX220, tray bottom, P/N JN021 and scope basket P/N JF435R or equivalent)
  - Equivalent steam sterilization trays can be used but must be identified and validated by the user facility
- Single-Use Paper Filter (4 in x 10.16cm) x 9 in (22.6cm) for use with tray only
- Follow tray manufacturer’s IFU for inspection, maintenance, cleaning and assembly of tray.

STERRAD® Sterilization:
- STERRAD sterilizer capable of STERRAD 100S, STERRAD Standard Cycle and STERRAD 100NX Standard Cycle
- STERRAD Sterilization Tray with Endoscope Basket (Aesculap tray lid P/N JX220, tray bottom, P/N JN021 and scope basket P/N JF435R or equivalent)
  - Equivalent STERRAD sterilization trays can be used but must be identified and validated by the user facility
  - Single-Use Polypropylene Filter (4 in x 10.16cm) x 9 in (22.6cm) for use with tray only
  - Follow tray manufacturer’s IFU for inspection, maintenance, cleaning and assembly of tray.

IMPORTANT: 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 Endoscope 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
Boston Scientific recommends careful inspection of the endoscope before each use 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. 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.

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 (e.g. 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 brittles 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
11. After cleaning, inspect devices under normal lighting to ensure that all visible debris has been removed.
12. If not visibly clean, repeat cleaning as necessary.
13. 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.

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 1).

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

![Figure 1](image-url)

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.

13.2 STERILIZATION INSTRUCTIONS - ENDOSCOPE
Symphon 6.3 Endoscope must be sterilized using one of the following methods.

Boston Scientific (Master Brand DFU Template 8.2677in x 1.6929in A4, 90105918AW), eDFU, MB, Symphion, EN, 91061524-01E
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 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.
- Central supply wrap should not be used and was not validated for use with the Aesculap sterilization trays.
- Single-Use Paper Filter (4 in (10.16cm) x 9 in (22.8cm)) for use with tray only.

Steam Sterilization Tray
- Steam, pre-vacuum method at 275°F for 3 minutes.
- Drying time 16 minutes
- Steam, pre-vacuum method at 270°F 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 equivalent).
- Equivalent STERRAD sterilization trays can be used but must be identified and validated by the user facility.
- Central supply wrap should not be used and was not validated for use with the Aesculap sterilization trays.
- Single-Use Polypropylene Filter (4 in (10.16cm) x 9 in (22.8cm)) 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

Boston Scientific Corporation (BSC) 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 BSC’s control directly affect the instrument and the results obtained from its use. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

CUSTOMER SERVICE/TECHNICAL SUPPORT

Contact Boston Scientific Customer Service for any customer or technical support.
Call 888-272-1001

Enzol and Sterrad are registered trademarks of Johnson & Johnson.
Aesculap is a registered trademark of Aesculap AG.
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: TROUBLESHOOTING

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible Cause</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Picture cloudy, foggy</td>
<td>• Optical surfaces contaminated</td>
<td>• Clean in accordance with section 12.1</td>
</tr>
<tr>
<td></td>
<td>• Deposits, encrustations on the optical surfaces</td>
<td>• Clean optical surfaces in accordance with instructions section 12.2</td>
</tr>
<tr>
<td></td>
<td>• Leaky, defective lens system</td>
<td>• Return endoscope to manufacturer or authorized representative for repair</td>
</tr>
<tr>
<td>Picture too dark, too small illumination</td>
<td>• Optical surfaces contaminated</td>
<td>• Clean in accordance with section 12.1</td>
</tr>
<tr>
<td></td>
<td>• Deposits, encrustations on the optical surfaces</td>
<td>• Clean optical surfaces in accordance with instructions section 12.2</td>
</tr>
<tr>
<td></td>
<td>• Fiber optic defect</td>
<td>• Check fiber optic according to section 11.2</td>
</tr>
<tr>
<td></td>
<td>• Defect light cable, light source</td>
<td>• Check light cable, light source</td>
</tr>
</tbody>
</table>
| 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                                |