

Symphion™ Endoscope

Prescriptive Information

Refer to link below for the device Directions for Use for complete instructions on this device:

<http://www.bostonscientific.com/manuals/manuals/landing-page.html>

Rx ONLY

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

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.

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

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 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 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.

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

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.

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