

Symphion™ Tissue Removal System

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 System is intended to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device.

Refer to Endoscope instructions for use for specific indications for use.

Contraindications

Pregnancy, genital tract infections, and known uterine cancer are contraindications to hysteroscopy.

Use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated. See the operator's manual of your hysteroscope for absolute and relative contraindications.

The Symphion System contains a large amount of metal components. Therefore it is MRI unsafe. Do not use the Symphion System in conjunction with MRI, CT or RFID.

Warnings

Symphion System General Warning

- The Symphion System is only intended for use as outlined in Section 3, Intended Use/Indications For Use.
- Before using the Symphion System, please review all available product information carefully!
- The Symphion System should only be used by physicians trained in hysteroscopy and hysteroscopic surgery using powered instruments. Healthy tissue can be injured, e.g., perforation by improper use of the Resecting Device. Use every available means to avoid such injury.
- Do not use the Symphion System with another fluid management system, endoscope, or controller. Use with another fluid management system, endoscope or controller may result in failure of the device to operate or lead to patient or physician injury.
- **DANGER:** Do not operate the Symphion System in close proximity to volatile solvents such as methanol or alcohol, or in the presence of flammable anesthetics, as explosion may occur.

Controller with Integrated Fluid Management Warnings

Known Risks Associated with use of Electrosurgical Devices:

- EMC issues – interference causes device failure, interference causes other devices to fail, RF interferes with pacemaker, defibrillator
 - Electrical safety issues – shock, burn – device/controller overheats, incorrect power source used, water enters the controller, use of incorrect power source, arcing.
 - Explosion/fire if operated near volatile solvents
 - Tissue damaged during coagulation/resection
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- Fluid Overload: There is a risk of distension fluid reaching the circulatory system of the patient by passing into the capillaries of the body cavity. This can be caused by distension pressure, flow rate, perforation of the body cavity and duration of the endoscopic procedure. It is critical to closely monitor the inflow and outflow of the saline at all times. Vital signs recording, physical examination and pulse oximetry is recommended, as it may reduce the risk of fluid overload.
 - Fluid Deficit: The fluid absorbed by the patient must be monitored. The following equation should be used to calculate the fluid deficit using a single 3-liter saline bag:
3000 ml – (Remaining Volume in bag + 550 ml) = total fluid loss
3000 ml: Total amount of fluid in the saline bag at the start of the procedure*
550 ml: Dead volume (undeliverable volume in the tubing, filter, and tissue catch)

The following equation should be used to calculate the fluid deficit using a single 2-liter saline bag:

$$2000 \text{ ml} - (\text{Remaining Volume in bag} + 550 \text{ ml}) = \text{total fluid loss}$$

2000 ml: Total amount of fluid in the saline bag at the start of the procedure*
550 ml: Dead volume (undeliverable volume in the tubing, filter, and tissue catch)
**Take notice of the measurement tolerance of the saline bag (+/- 10%).*

- Fluid Intake: Strict monitoring of fluid intake should be maintained. Intrauterine instillation of saline exceeding 2 L should be followed with great care due to the possibility of fluid overload.
- Serum Sodium Concentration: As with any normal saline hysteroscopic insufflation, the possibility of fluid intravasation and subsequent electrolyte disturbances may occur. It is important that the physician monitor the patient's electrolytes if significant intravasation occurs. The Symphion™ System does not measure sodium or other electrolyte concentrations.
- Rupture of the Fallopian Tube Secondary to Tubal Obstruction: Distension of the uterus may lead to a tear of the fallopian tube should there be an obstruction or permanent occlusion. The rupture could lead to saline flowing into the patient's peritoneal cavity, resulting in fluid overload. It is critical to closely monitor the input and outflow of saline at all times.
- An air embolism can be the result of air contained in the tubing set or connected instrument reaching the patient. To prevent air from being pumped into the patient ensure that the infusion tubing set is purged prior to start of the procedure and that there is always fluid in the saline bag. If air bubbles are seen in the infusion tubing set remove the Endoscope from the uterine cavity and discontinue the procedure.
- To prevent hypo/hypernatremia assess electrolytes before and after procedure, and observe for signs of significant electrolyte imbalance (e.g., electrocardiogram and physician examination)
- Use of pressures higher than 100 mmHg is strongly discouraged. Intrauterine pressure should be maintained as low as possible so as to allow adequate visualization and minimize the forces

potentially driving fluid, room air and/or gas into circulation. Cavity distension is usually possible with pressure values between 35 to 70 mmHg. A pressure above 75 to 80 mmHg is required only in rare cases or if the patient has unusually high blood pressure.

- While fluids must always be monitored during use, exercise extreme caution and very close fluid monitoring in patients with severe cardiopulmonary disease.
- The Symphion closed-loop system permits the operator to elect intrauterine pressure up to 125 mm Hg. Clinicians using the Symphion System should be aware of the 2013 AAGL practice guidelines regarding uterine cavity distension pressure (i.e. lowest pressure necessary to distend the uterine cavity and ideally should be maintained below the mean arterial pressure) when setting distension pressure on the Symphion System.
- Testing of the Symphion System has not been confirmed in patients with hemoglobinopathies (e.g., Sickle Cell Disease, Beta Thalassemia) and therefore, the possible effects are unknown.
- Hemolysis may occur during recirculation. If significant hemolysis occurs, this may result in electrolyte (e.g., increased serum potassium) changes or decrease in hemoglobin. Hemolysis may reveal red-tinged coloring of the recirculated fluid, but may not be visually apparent. Therefore, assessment of serum electrolytes and hemoglobin level after completion of the procedure is recommended.

Resecting Device Warnings

- Do not operate the Resecting Device without clear visualization. The device resecting window area should be in the field of view while the Resecting Device is operating. If visualization is lost at any point during the procedure, resection/coagulation must be stopped immediately.

Warnings Applicable to Air/Gas Emboli Hazards:

- Gas bubbles are a normal by-product of electrosurgical procedures performed in liquids. When bubbles occur in the uterus, care should be taken to manage the removal of air/gas bubbles to minimize the inherent risk of emboli. Bubbles produced during tissue vaporization may interrupt surgery by temporarily interfering with field of view and may also result in electrode overheating, causing damage to the electrode tip.
- Surgeons should consider the anticipated length of surgery and size of leiomyomata when selecting patients for procedures.
- Operating room personnel must be trained to purge air from fluid lines prior to surgery, avoid entry of air into fluid lines, and provide constant, careful attention to fluid deficits. Avoid situations where the fluid bag is completely emptied.
- Basic equipment should be available to fulfill the requirements for monitoring of fluid deficit, assessment and control of intrauterine pressure, and anesthesia monitoring. Intrauterine pressure should be maintained as low as possible so as to allow adequate visualization and minimize forces potentially driving air and gas into circulation.
- Surgical team must have access to appropriate resuscitative capabilities.
- Patients should be kept in flat or in reverse Trendelenburg position.
- If room air or gas embolism is suspected, surgeon should consider interrupting surgery, deflating the uterus, and removing sources of fluid and gas until the diagnosis and a management plan are clarified.
- Surgeon should avoid entry of air into uterus by:
 - Carefully purging air from fluid inflow lines and hysteroscopic devices prior to use
 - Following cervical dilation, care should be taken to minimize the exposure of the open cervix to room air

- Keeping an effective cervical seal during surgery as much as possible once the cervix is dilated
- Using active fluid outflow to effectively flush the uterus of bubbles and debris
- Minimizing the frequency of removal and reinsertion of hysteroscopic devices

Considerations for anesthesia

- Nitrous oxide anesthesia may enlarge the size of air bubbles and thus should be avoided when possible in operative hysteroscopy.
- Patients at high risk for room air and gas embolism should be managed using controlled ventilation.
- For high-risk patients undergoing operative hysteroscopy, one should consider intra-operative monitoring, such as end-tidal CO₂ monitoring if under general anesthesia and pre-cordial Doppler monitoring to detect room air and gas emboli early.

Adverse Events

Potential complications of continuous flow endoscopic surgery include:

- Anesthesia-related; adverse reaction or over-medication
- Uterine perforation
- Damage to Adjacent Organs
- Cervical tear/injury
- Bleeding
- Endometritis
- Urinary tract infections
- Infection, sepsis
- Nausea, vomiting
- Pelvic cramping, abdominal pain
- Cervical stenosis
- Hematometra
- Dysmenorrhea
- Dyspareunia
- Uterine synechiae (Asherman's syndrome)
- Vaginal discharge
- Fluid overload
- Electrolytic imbalance
- Rupture/obstruction of the fallopian tube
- Hyponatremia
- Hypothermia
- Pulmonary edema
- Cerebral edema
- Idiosyncratic reactions
- Dehydration
- Over-pressurization/over-fill the cavity
- Biohazard exposure to tissue, blood, fluid
- Under-filled cavity
- Loss of visualization

- Incorrect distention media used
- Kinked tubing, leaks in tubing/system
- Cannot create seal with cavity
- Air embolism
- Damage to healthy tissue

Precautions

Symphion System General Precautions

Do not use the Symphion System 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).

Use Resection and COAG with caution in the presence of any active implantable or body worn medical devices such as internal or external pacemakers or neurostimulators. Interference produced by the use of electro-surgical devices can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. The output of the Symphion device might also affect other types of active devices such as implanted neurostimulator devices. Consult the active implantable device manufacturer (for implanted pacemakers and ICDs the hospital cardiology department might also be helpful) for further information when use of myomectomy or tissue coagulation is planned in patients with active implantable devices such as cardiac pacemakers.

If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing myomectomy or tissue coagulation. Electrosurgery or tissue coagulation may cause multiple activations of ICDs.

Small electrical arcs between the resection electrode and the tissue being resected can produce low-frequency currents that may produce local neuromuscular stimulation. Per standard of care, ensure that the patient's legs are supported and secured appropriately.

Prior to use, examine all system components for possible damage and ensure proper function. If any of the system components are damaged, do not use.

Do not use the Resecting Device or the Fluid Management Accessories if the sterile barrier or sterility is compromised prior to or during the procedure. Failure to maintain sterile technique in the operating room could result in infection.

Do not lubricate the Resecting Device or the Fluid Management Accessories.

Do not use the Resecting Device or the Fluid Management Accessories after the expiration date.

The Resecting Device and Fluid Management Accessories are intended for single use only. Discard the Resecting Device and Fluid Management Accessories after use.

Do not re-use or re-sterilize the Resecting Device and Fluid Management Accessories. Use of re-processed, single use device(s) may result in patient or physician injury.

Controller with Integrated Fluid Management Precautions

Verify the Controller is fully operational prior to starting the clinical procedure. Failure of the Controller could result in an unintended increase of output power.

Interference produced by the operation of high-frequency equipment may adversely affect the operation of other electronic medical equipment such as monitors, imaging systems.

Do not operate the Controller in a moist environment, as a shock hazard may exist. If liquids have entered the unit, the Controller must

be returned to the manufacturer for testing prior to use.

Use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the system.

Return Controller to manufacturer for servicing in the event of failure.

In case of Controller failure, remove the Endoscope and Resecting Device from the body cavity immediately. Remove the tubing from the pump heads; switch off/ unplug the power cord to stop Controller operation.

Removing screws and/or opening this device will invalidate the warranty.

To ensure proper grounding reliability, a Hospital Grade Power Cord must be used with a receptacle marked "Hospital Grade".

Do not sterilize the Controller. Sterilization may damage the unit.

Reconditioning, refurbishing, repair, or modification of the Controller is expressly prohibited as it may result in loss of function and/or patient injury.

Do not obstruct openings on the bottom and back of the Controller, as they provide required airflow for cooling.

The Controller needs special precautions regarding EMC and needs to be placed and put into service according to the EMC information provided in this document. Note that portable and mobile RF communication equipment can affect the performance of the Controller (See Appendix G of DFU).

The Controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Controller should be observed to verify normal operation in the configuration in which it will be used.

If electromagnetic interference with other equipment is suspected, re-orient the device and/or remove possible sources of interference (e.g., cellular phones, radios, etc.) from the room.

Needle monitoring electrodes are not recommended.

Patient should not come into contact with grounded metal parts; the use of antistatic sheeting is recommended.

Cables to the surgical electrodes are recommended to be positioned such that contact with patient or other leads is avoided.



The lightning flash with arrowhead symbol, within an equilateral triangle, is intended to alert the user to the presence of un-insulated “dangerous voltage” within the product’s enclosure that may be of sufficient magnitude to constitute a risk of electric shock to persons.

Use only normal saline (sodium chloride (0.9% w/v; 150 mmol/l)) irrigation solution. The performance of the system will be adversely affected by use of any other solution.

The Fluid Management Accessories is designed for use with a SINGLE 2 liter or 3 liter Irrigation USP saline bag:

- 2 liter saline bag such as Hospira part# 0409-7972-07
- 3 liter saline bag such as Baxter part# 2B7477 or Hospira part# 0409-7972-08.

USE A SINGLE 2-LITER or 3-LITER IRRIGATION USP SALINE BAG ONLY. DO NOT USE MULTIPLE SALINE BAGS. USE OF MULTIPLE SALINE BAGS INCREASES THE CHANCE OF FLUID OVERLOAD.

Do not pinch, step on, kink or otherwise occlude the tubing set. Tubing restrictions can result in high pressure or poor device performance.

Do not close the latch of the pump on the indicators installed on tubing. This may result in a failure of the pump.

Continuous, extended RF energy output may cause the Controller to overheat. If this occurs, the Controller must be allowed to cool down before further use.

Resecting Device Precautions

Excessive force on the Resecting Device tip does not improve resection performance and may increase the risk of perforation or device damage.

Do not allow the tip of the Resecting Device to touch any hard object. If such contact does occur, inspect the tip. If there are cracks, fractures, or if there is any other reason to suspect the tip is damaged, replace the Resecting Device immediately.

Any monitoring electrodes are recommended to be placed as far as possible from the Resecting Device when high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient. Monitoring systems incorporating high frequency current-limiting devices are recommended for use.

Excessive force applied during insertion or removal of the Resecting Device may result in device damage or tissue injury including perforation.

Insertion and removal of the Resecting Device should always be under direct visualization.

Do not activate the Resecting Device unless the resecting window and tip are immersed in a saline environment. Electrodes may arc if activated in air, damaging the device.

Do not activate the Resecting Device while the resecting window section is inside the Endoscope. Ensure that the resecting window is outside the Endoscope working channel in the saline environment before activating RF resection or coagulation.

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WH-269901-AB JAN 2018