

Symphion[®] Operative Hysteroscopy System

Prescriptive Information

Refer to the device directions for use for complete instructions on the device.

Intended Use/ Indications for Use

Symphion System with Controller (software version 2.1.1 and prior): 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.

Symphion System with Prime Controller (software version 3.#.#): The Symphion System is intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device by distending the uterus with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and providing fluid management through either the closed loop recirculation of filtered distension fluid or non-recirculating/non-filtered distension fluid.

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

General Warnings

- The Symphion System is only intended for use as outlined in above, 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.
- Use Resection and Coagulation modes 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 electrosurgical 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.

Reuse Warning

- The Symphion Resecting Device and Symphion Fluid Management Accessories are supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Minerva Surgical representative.
- The Symphion Resecting Device and Symphion Fluid Management Accessories are for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection 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 of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy

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
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the Symphion Fluid Deficit Readout,

including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- 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 estimate the fluid deficit using a single 3-liter saline bag:
 - 2500 mL - Remaining volume in bag = total fluid deficit
 - 2700 mL – Remaining volume in saline bag – Volume in recovery bag = total fluid deficit (EXPRESS FMA only)

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

- 1500 mL - Remaining volume in bag = total fluid deficit.
- 1700 mL – Remaining volume in saline bag - Volume in recovery bag = total fluid deficit (EXPRESS FMA only)

*Take notice of the measurement tolerance of the saline bag (+/-10%)
IMPORTANT: 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.

Note: The Symphion System does not allow for more than 2500 mL to be absorbed by the patient when used in accordance with this manual.

- Fluid Intake: Strict monitoring of fluid intake should be maintained. Intrauterine instillation of saline exceeding 2-liter 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 prior to the insertion of the scope into the patient, manually purge via turning on infusion while the scope is outside of the patient until there is no longer air in the infusion tubing. If air remains in the infusion tubing following the manual purge or is noted in the infusion tubing at any point during the procedure after the scope has been inserted into the patient, remove the Endoscope from the uterine cavity and discontinue the procedure.
- To prevent hypo/hyponatremia 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® system permits the operator to select an intrauterine pressure up to 125 mmHg. Clinicians using the Symphion System should be aware of the 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. (Not applicable to EXPRESS FMA)
- Magnetically susceptible medical devices should not be used closer than 15 cm (6 inches) to any part of the Symphion Controller. Otherwise, degradation of the performance of this equipment could result.

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.
- Magnetically susceptible medical devices should not be used closer than 15 cm (6 inches) to any part of the Symphion Controller. Otherwise, degradation of the performance of this equipment could result.

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.*

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

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 electrosurgical 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.
- As with all hysteroscopic procedures, device may come into contact with bloodborne pathogens or other potentially infectious materials. Healthcare professionals should follow standard medical facility procedures to minimize the risk of exposure.
- 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 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.
- 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.
- 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.
- All models of the Fluid Management Accessories are designed for use with a SINGLE 2-liter or 3-liter Irrigation USP saline bag:
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 open the latch of pumps while hysteroscope is in the patient. This may result in a loss of visualization and/or serious patient injury.
- 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.

Potential 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

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. The physician using this device must be trained in diagnostic hysteroscopy and hysteroscopic surgery using powered instruments. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*

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