Indications for use
The Symphion System (formerly known as the IOGYN 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.

Contraindications
- Pregnancy, genital tract infections, and known uterine cancer. Use of this device for intrauterine distension is contraindicated whenever hysteroscopy is contraindicated.
- Do not use the Symphion System in conjunction with MRI, CT or RFID. It is MRI unsafe.

Warnings
- 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. 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.
- Care should be taken to manage the removal of air/gas bubbles to minimize the inherent risk of emboli. 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 reinserion of hysteroscopic devices
- 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.
- 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.
- If significant hemolysis occurs during recirculation, this may result in electrolyte changes or decrease in hemoglobin. Assessment of serum electrolytes and hemoglobin level after completion of the procedure is recommended.

Benefit/risk determination
- The risks of the Symphion System are based on clinical and nonclinical laboratory studies. The risks associated with the use of the device include uterine perforation, fluid overload, embolism, infection and introduction of filtrate into that patient’s circulation through venous sinuses.
- The probable benefits of the Symphion System are also based on clinical and nonclinical laboratory studies.
- The benefits of the device include an upper limit on the maximum volume of saline that may be absorbed by the patient due to the closed loop design of the distension fluid. This maximum is below the currently accepted clinical limits and therefore reduces the risk of fluid overload.
- The Symphion System also offers the benefit of an integrated fluid management and tissue resection device. This integration addresses visualization problems through the use of a controlled vacuum aspiration during active tissue resecting.
- The use of the bipolar resection device allows for coagulation which minimizes blood loss and reduces the risk of perforation from multiple device insertion/removals. It also allows for the use with saline which matches physiological sodium levels.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.