

HERizon™ Medical Endoscope Image Processing System

Prescriptive Information

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

Indications

The Medical Endoscope Image Processing System is intended to be used for viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures.

Recognized indications for diagnostic hysteroscopy include:

- Abnormal uterine bleeding
- Infertility & pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

Contraindications

This product is not suitable for people with the following conditions:

- acute pelvic inflammatory disease
- known or suspected pregnancy

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

- inability to distend the uterus
- cervical stenosis
- cervical/vaginal infection
- uterine bleeding or menses
- invasive carcinoma of the cervix
- recent uterine perforation
- medical contraindication or intolerance to anesthesia

Warnings/Precautions

- Do not attempt to disassemble the hysteroscope or the Image Processor. Do not attempt to open, or gain access into, the Image Processor. Doing so may result in electronic shock.
- Handle the hysteroscope and image processor with care.
- This system cannot be used with high frequency equipment or laser equipment.
- The system does not interfere with other electromagnetic equipment in normal use. If the operating frequency of other equipment is similar to that of the system, it is recommended to maintain a large separation distance.
- During normal use, the medical endoscope image processor does not produce waste or residue. When the product reaches the end of its service life, dispose of the device in accordance with medical device waste regulations. This is to prevent any potential reuse of the materials and to minimize the risk of environmental pollution. The hysteroscope should be disposed of following its single use in accordance with hospital procedures for biohazardous materials.
- If the hysteroscope does not function properly, replace it with another properly functioning hysteroscope.
- The hysteroscope and accessories must be checked for rough surfaces, sharp edges or protrusions that may cause injury before each use.
- The Image Processor may be used together with other medical electronic equipment. To avoid potential safety hazards, it is recommended to follow the surgical operation guidelines, use and precautions for safe use of other medical surgical equipment.
- It is recommended to use read-write protection software when using an external storage device (UDisk, USB flash drive, etc.) to copy data, in order to prevent the external storage device's data from being accessed without consent.
- When the external storage device is used for obtaining data from the image processor, an appropriate antivirus software program should be used to check for and remove any potential software virus prior to use with the Image Processor.
- During normal use, the temperature of the hysteroscope should not exceed 41 C°. If an abnormally high temperature is suspected, dispose of the hysteroscope and replace it with another one.
- Do not look straight into the hysteroscope lens as it may cause eye damage from the light source.
- Before use, perform a white balance and make the proper adjustments to the image on the screen.
- Before each use or after changing the viewing settings, the operator should check to ensure that the view observed through the endoscope provides a real-time image (instead of a stored image) and that the image orientation is correct to prevent potential patient injury.
- Users should maintain and securely position the Medical Endoscope Image Processor in a stable position, while also ensuring proper ventilation and protection against moisture and dampness.
- When not in use, it is recommended to store the Medical Endoscope Image Processor in the original packaging.
- The Medical Endoscope Image Processor should not be subjected to any sharp or blunt force impact.
- Do not place the Medical Endoscope Image Processor in environments with high temperatures, humidity, dust, direct sunlight or corrosive gases and/or fluids.
- Only personnel who have been trained or whose knowledge and practical experience are sufficient to ensure correct operation should operate and use this system.

- Only those who have read the appropriate IFUs and know the correct use of the system and accessories can operate it.
- If this system is to be used with other equipment, the user should consult applicable IFUs and receive appropriate training on the use of the equipment and use it strictly in accordance with its IFU.
- This product is by prescription only.
- The Image Processor is nonsterile and reusable. The disposable electronic hysteroscope is ethylene oxide (EO) sterilized and for single use only.
- This system can only be used with compatible accessories as defined by the manufacturer.
- Do not use the System near or in a Magnetic Resonance (MR) environment.

Potential Adverse Events

Potential complications of continuous flow hysteroscopic 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 the system must be trained in diagnostic hysteroscopy. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.*



Product manufactured and packaged for Minerva Surgical, Inc
by Jiangsu Jiyuan Medical Technology Co, Ltd.
4255 Burton Drive
Santa Clara, CA 95054 USA
Customer Service: 855-464-7874
www.minervasurgical.com