

Genesys HTA™ System

Prescriptive Information

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

Intended Use/Indications for Use

The Genesys HTA System is a hysteroscopic thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

Contraindications

The system is contraindicated for use in a patient:

- who is pregnant or wants to be pregnant in the future, as pregnancy after ablation can be dangerous to both mother and fetus;
- who has known or suspected endometrial carcinoma or premalignant change of the endometrium, such as adenomatous hyperplasia;
- who has active pelvic inflammatory disease or pyosalpinx;
- who has hydrosalpinx;
- in whom a tight cervical seal cannot be established and maintained around the procedure sheath;
- who has any anatomical condition (e.g., history of previous classical cesarean section or transmural myomectomy) or pathologic condition (e.g., long term medical therapy) that could lead to weakening of the myometrium;
- who has an intrauterine device in place; or
- who has an active genital or urinary tract infection (e.g., cervicitis, endometritis, vaginitis, cystitis, etc.), at the time of treatment.

Warnings

- For single use only. Do not reuse, reprocess or resterilize.
- Although endometrial ablation with the Genesys HTA System significantly decreases the likelihood of pregnancy, it is not a sterilization procedure. The patient should be advised of appropriate birth control methods.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation may be at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post-procedure.

- DO NOT perform same day HTA procedure and hysteroscopic tubal occlusion/sterilization. Ablation may cause intrauterine synechiae which can compromise (i.e. prevent) the 3-month confirmation test (HSG) for the tubal occlusion device. Women who have inadequate 3-month confirmation tests cannot rely on the tubal occlusion device for contraception.
- Bench and clinical studies have been conducted which demonstrate that the HTA procedure can be safely and effectively performed with nickel titanium tubal micro-inserts in place. However, the HTA procedure should only be performed after the 3-month tubal occlusion confirmation test.
- Warnings can be found in the product labeling supplied with each device.

Potential Adverse Events

As with all endometrial ablation procedures, serious injury or death can occur. The following adverse events could occur or have been reported:

- Thermal injury to adjacent tissue, including cervix, vagina, vulva and/or perineum
- Heated saline escaping from the system into the vascular spaces
- Hemorrhage
- Perforation of uterus
- Complications with pregnancy (Note: Pregnancy following any endometrial ablation procedure is dangerous to both the mother and the fetus.)
- Risks associated with hysteroscopy
- Post ablation tubal sterilization syndrome
- Infection or sepsis
- Complications leading to serious injury or death
- Potential Adverse Events can be found in the product labeling supplied with each device

Cautions/Precautions

- Endometrial ablation procedures using the Genesys HTA System should be performed only by physicians trained in diagnostic hysteroscopy procedures. Follow all Genesys HTA System instructions to reduce the possibility of compromised safety, malfunction, and/or injury to the patient and/or the user.
- To avoid the risk of electric shock, ensure that the selected electrical supply outlet has a proper ground connection and complies with the information listed on the label located on the rear of the control unit.
- To reduce the risk of explosion, do not operate the Genesys HTA System in the presence of flammable anesthetics or a flammable gas mixture with air, oxygen, or nitrous oxide.
- Never use the Genesys HTA System with equipment that has not been safety tested for excessive leakage current.
- Exercise care when handling liquids around electrical equipment. Do not attempt to operate the Genesys HTA System if liquid has spilled onto the unit.
- The Genesys HTA System must be used only with the procedure sheath provided in the Genesys HTA ProCerva Procedure Set. Use of any other hysteroscopic procedure sheath sets will lead to compromised safety for the patient and user.

- Do not hang more than three liters of saline from the hook on the IV pole.
- Confirm that the vaginal speculum is an adequate size (width and length) to assure full separation of vaginal and vulvar tissue away from the procedure sheath, to avoid inadvertent thermal injury, and to provide visibility of the cervix. The temperature of the sheath at this location could be up to 65 °C.
- Do not rest the procedure sheath on the vaginal speculum during the procedure.
- Leave the vaginal speculum in place throughout the procedure.
- Confirm that the height of the control unit handle is properly adjusted to the height of the patient's uterus to allow proper fluid flow and pressure, during the procedure. The laser aiming beam can be used as a secondary means to assist with proper height adjustment.
- Ensure that the height of the control unit handle is no higher than the height of the patient's uterus or fluid leakage into the peritoneal cavity and vagina may occur during the procedure.
- Do not grasp the procedure sheath with the tenaculum as doing so may damage the procedure sheath which could result in thermal injury.
- Throughout the procedure, carefully observe the junction of the procedure sheath with the external cervical os to confirm a tight cervical seal and that there is no fluid leakage.
- Be Aware: The fluid loss alarm signals a loss of at least 10 mL of fluid. Fluid losses in excess of 10 mL may occur in cases when the alarm is triggered.
- Use caution when handling the fluid in the drainage bag after treatment, as the fluid at this stage may still be hot.
- Follow hospital procedures for handling contaminated fluids and disposables.
- Do not attempt to repair or alter any components/parts of the Genesys HTA™ System. All repairs and servicing are to be performed only by authorized Boston Scientific service personnel. See the Warranty.
- Patients who have undergone endometrial ablation, who are later placed on hormone replacement therapy, should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy irrespective of whether total amenorrhea has been achieved after ablation.
- Use Caution when performing the Genesys HTA System procedure on patients with nickel sensitivity, as the Genesys HTA ProCerva™ Procedure Set contains nickel.
- Precautions can be found in the product labeling supplied with each device.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. The physician using the system must be trained in diagnostic hysteroscopy.

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