



Genesys HTA™ System

Seeing is believing

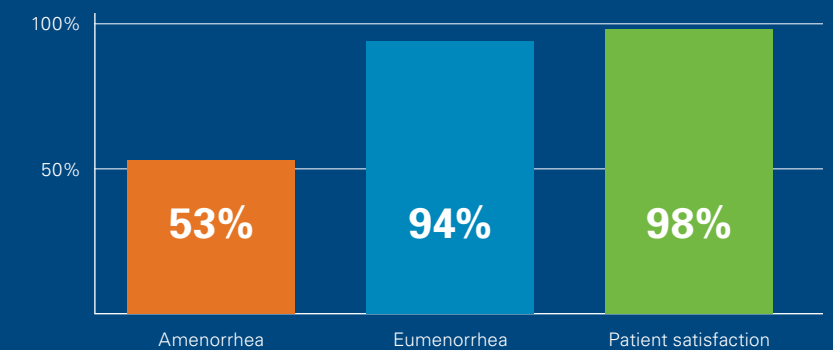
The Genesys HTA™ System

Designed for direct visualization and intuitive operation to deliver a safe, effective and versatile treatment for menorrhagia.

Deliver a visible difference to your patients

The HTA™ System has the highest Phase III clinical amenorrhea rates at three years vs. the NovaSure™ System¹, the ThermaChoice™ Devices, and the HerOption™ System for evaluated patients.²

The HTA System at three year follow up for evaluated patients:



Offers the flexibility to treat a variety of patients in multiple settings



Continuous direct visualization allows potential treatment of a wider range of uterine cavities including those with some abnormalities^{1,3}

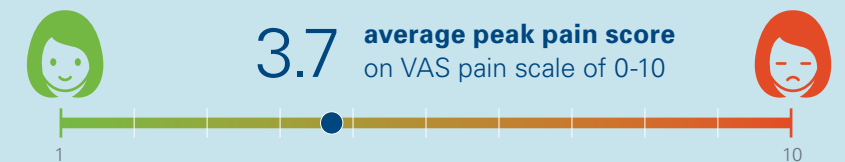


Free-flowing saline conforms to each patient's uterine cavity, providing consistent treatment with intramural fibroids smaller than 4 cm or with a partial septate uterus

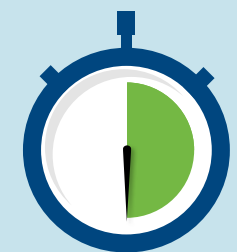


Quiet, compact design and demonstrated tolerability with paracervical block and oral sedation allow potential use in the operating room or the office

Study of 100 patients treated with the system in suburban private practice demonstrated:⁴



67% of patients were discharged within 15 min post procedure



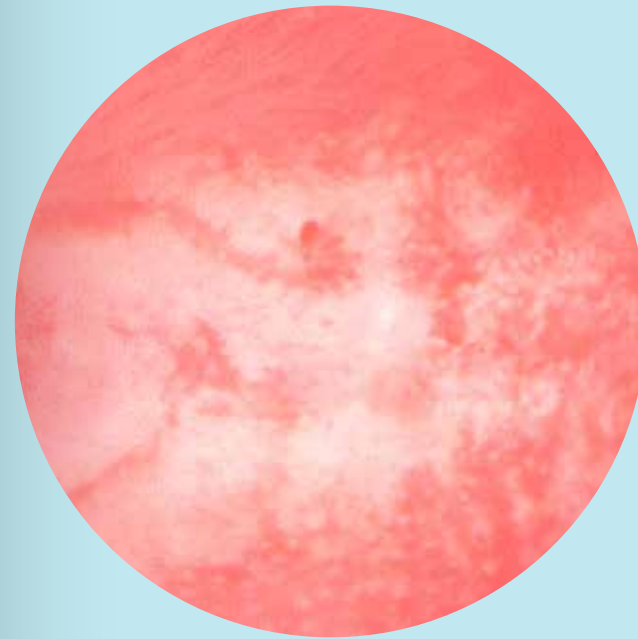
99% of patients were discharged within 30 min post procedure



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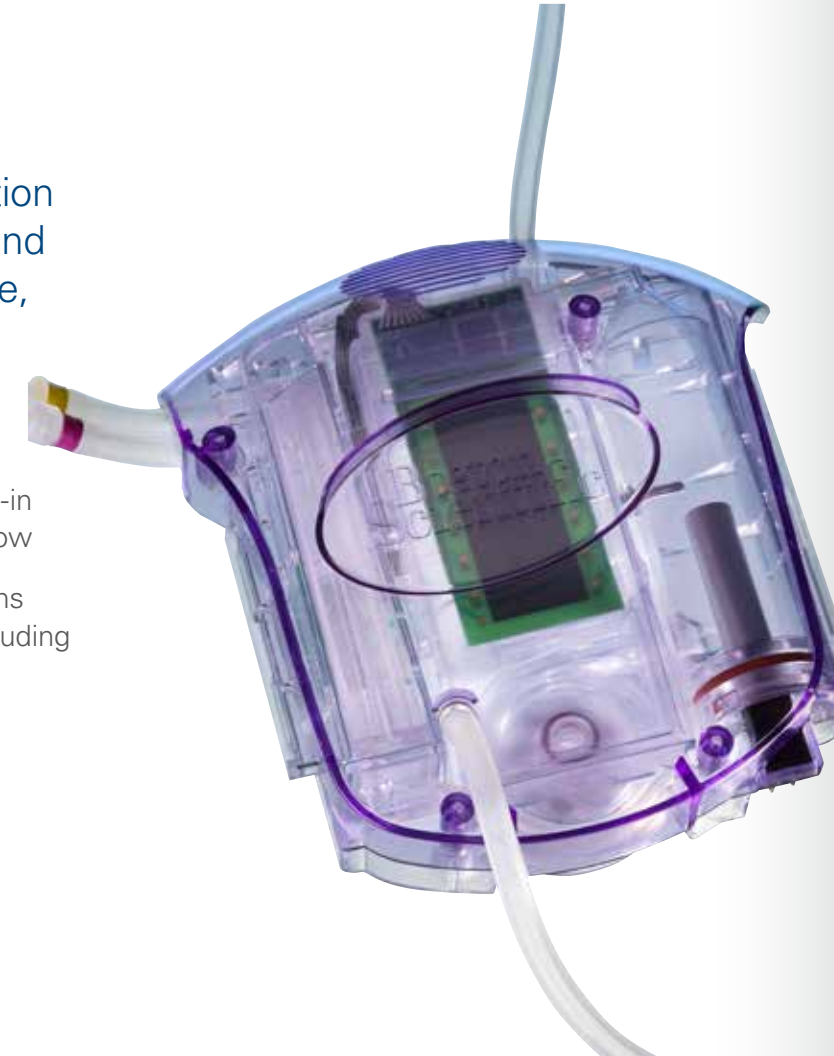
Seeing is believing



Continuous visualization eliminates the need to perform blinded hysteroscopic surgery and gives you the ability to see and treat the uterine cavity during the entire procedure.

Easy set-up and intuitive operation allows for ease of use for you and the entire surgical team – before, during and after the procedure.

- Simple set-up and restart designed for quick case turn around
- Compact, disposable cassette with drop-in loading heats, filters and controls fluid flow
- Console displays step-by-step instructions and real-time procedure information, including time, temperature and fluid monitoring



Over 400,000

women have been treated across the HTA™ and Genesys HTA Systems⁶

Demonstrated safety with the Genesys HTA System

In a multicenter, post market clinical trial, the safety and reliability of the Genesys HTA System were evaluated in 992 women across 18 sites.

Clinically significant thermal burns with Genesys HTA System (p<0.01): 0.1% (1/992)⁵

The entire system is designed for safe use, allowing you to confidently deliver a safe and effective therapy.

- Genesys ProCerva™ Procedure Sheath provides redundant protection to help gain and maintain a cervical seal and Seal Integrity Check verifies cervical seal before procedure initiation
- Tapered “sieve” tip aids in debris handling and helps prevent clogging of device or tubing



Boston Scientific is committed to providing quality products and healthcare solutions in the area of gynecologic surgery so women can lead more fulfilling lives. The innovative Genesys HTA™ System and Symphion™ System were designed with physicians' needs in mind and demonstrate our commitment to advancing care for women. We invite you to partner with us.



Ordering information

Order Number	Product Description	Unit of Measure
M006580010	Genesys HTA System 115V Control Unit Includes: Control unit, User's Manual and power cord	1 each
M006580040	Genesys HTA System Pedestal Includes: Pedestal pole, pedestal base and IV pole. Must be ordered with control unit.	1 each
M006580211	Genesys HTA ProCerva Procedure Set Includes: Cassette, Drain Bag and Procedure Sheath	Box of 5
M006550310	Adaptor for Storz Hysteroscope 2.9mm, 12° or 30° (#23020FA or #26120BA)	1 each
M006550340	Adaptor for Wolf Hysteroscope 2.7mm, 25° or 30° (#8947.401)	1 each
M006550350	Adaptor for ACMI-Circon Hysteroscope 2.7mm, 12° or 30° (#G27L-12A or #G27L30WA)	1 each
M006550360	Adaptor for Olympus Hysteroscope 3mm, 0°, 12° or 30° (#A4674A, #A4673A or #A4672A)	1 each

- 1 Evaluated Population. Carter JF, Endometrial Ablation: More Choices, More Options. The Female Patient. 2005;30(12):35-40
- 2 Evaluated population, treated with the HTA® System (72/136). Goldrath MH, Evaluation of HydroThermAblator and Rollerball Endometrial Ablation for Menorrhagia 3 Years after Treatment. The Journal of the American Association of Gynecologic Laparoscopists. November 2003, Vol. 10, No. 4.
- 3 Reilly GP, Can Endometrial Ablation Technique Effectiveness Be Properly compared without considering the uteruses treated? 2008 AAGL Podium Presentation
- 4 Patients treated with the HTA® System with the HTA Procedure Sheath with Tenaculum Stabilizer. Phillips R, Schultz M, Patient Pain Tolerance of In-Office HydroThermal Ablation. 2007 AAGL Podium presentation
- 5 Berman JM, Analysis of the Safety and Reliability of a Hydrothermal Ablation System - A Multicenter, Prospective Postmarket Study. The Journal of Reproductive Medicine, May-June 2014, Vol 59, Numbers 5-6
- 6 Data on file

Refer to Genesys HTA™ System Installation and Operator's Manual provided with product for complete instructions for use.

INDICATIONS: 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 Genesys HTA 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; hydrosalpinx; in whom a tight cervical seal cannot be established and maintained around the procedure sheath; who has any anatomical or pathologic condition in which weakness of the myometrium could exist, such as, prior classic cesarean section or transmural myomectomy; who has an intrauterine device in place; or who has active genital or urinary tract infection, e.g., cervicitis, endometritis, vaginitis, cystitis, etc., at the time of treatment. **POTENTIAL ADVERSE EFFECTS** that may occur include: pain, cramping, nausea, vomiting, bleeding, infection, laceration, Endometritis, thermal injury to adjacent tissue including cervix, vagina, vulva, and/or perineum; heated saline escaping from the device system into the vascular spaces; hemorrhage; perforation of uterus; complications with pregnancy (Note: pregnancy following ablation is dangerous to both the mother and the fetus); risks associated with hysteroscopy, complications leading to serious injury and death, post-ablation tubal sterilization syndrome, and delayed diagnosis of cancer of the endometrium. **WARNINGS:** NOTE: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury. **CAUTION:** Federal Law (U.S.) restricts this device to sale by or on the order of a physician. The physician using the device must be trained in diagnostic hysteroscopy

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