

# The HTA® System

— components —

## Digital display

Guides operation of the HTA System, digital display provides step-by-step message prompts as well as self diagnostic messages.



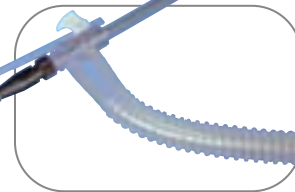
## Fluid Level Reservoir

Provides gravity flow control to achieve approximately 52mm Hg within the patient's uterus and continuous monitoring of circulating fluid volume. Loss of more than 10mls of fluid either cumulatively or at once, fluid flow to the patient is interrupted. In the event of fluid loss, an alarm will sound and an error message will warn the user there has been a fluid loss.



## HTA System Insulated Sheath with Tenaculum Stabilizer

Insulated continuous flow sheath is designed to help protect cervical canal from thermal effect. The Tenaculum Stabilizer feature is designed to prevent accidental withdrawal of the sheath from the cervix while offering improved ease of use.



## Heater Canister

The newly designed disposable heater canister facilitates easier set-up and quicker O.R. turnover before and after each procedure using the HTA System.



# HTA® System

## Endometrial Ablation System

Reorder Number	Product Description	Unit of Measure
M0065600K0	<b>HTA® System, 95-135 VAC, 50/60Hz;</b> <b>Includes:</b> Compact mobile HTA® Control Unit, incorporating microprocessor control and digital display of operational prompts; peristaltic outflow pump; adjustable height fluid reservoir support pole; mobile base with 10cm (4 inch) casters (2 with locks); removable powercord; and users manual	1 each
M006560201	<b>Procedure Set, Sterile, Single Patient Use; includes:</b> Fluid Reservoir with Level Sensing Circuit, Cassette for Peristaltic Pump with Complete Fluid Circuit Tubing Set, Disposable Heater Canister and procedure sheath with Dual Circuit Connecting Tubes and Tenaculum Stabilizer; PACKAGED STERILE; Box of 5	1 box
M006550310	<b>Adapter for Storz Brand Hysteroscope Telescope;</b> Allows 2.9mm /12° or 30° Storz Telescope (#26020FA or #26120BA), to be used with HTA® Procedure Sheath	1 each
M006550340	<b>Adapter for Wolf Brand Hysteroscope Telescope;</b> Allows 2.7mm /25° Wolf Telescope (#8979.11) to be used with HTA Procedure Sheath	1 each
M006550350	<b>Adapter for ACMI-Circon Brand Hysteroscope Telescope;</b> Allows 2.7mm /12° or 30° ACMI-Circon Telescope (#G27L-12A or #G27L30WA) to be used with HTA Procedure Flow Sheath	1 each
M006550360	<b>Adapter for Olympus Brand Hysteroscope Telescope;</b> Allows 3mm /0° or 12° or 30° Olympus Telescope (#A4674A or #A4673A or #A4672A) to be used with HTA Procedure Flow Sheath	1 each

Refer to HTA System User's Manual provided with product for complete instructions for use.

**INDICATIONS:** The 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 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; who has any anatomical or pathologic condition in which weakness of the myometrium could exist, such as, prior classic cesarean section or transmurular 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: 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. **WARNINGS:** NOTE: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury. **CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. The physician using the device must be trained in diagnostic hysteroscopy.**

\*Individuals depicted in this brochure are models and included for illustration purposes only. Models depicted are not users and do not endorse the HTA System.

# HTA® System

## Endometrial Ablation System

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www.bostonscientific.com

Ordering Information  
1.888.272.1001

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# HTA® System

## Endometrial Ablation System

The HTA System is a potential alternative for treating women with excessive uterine bleeding.

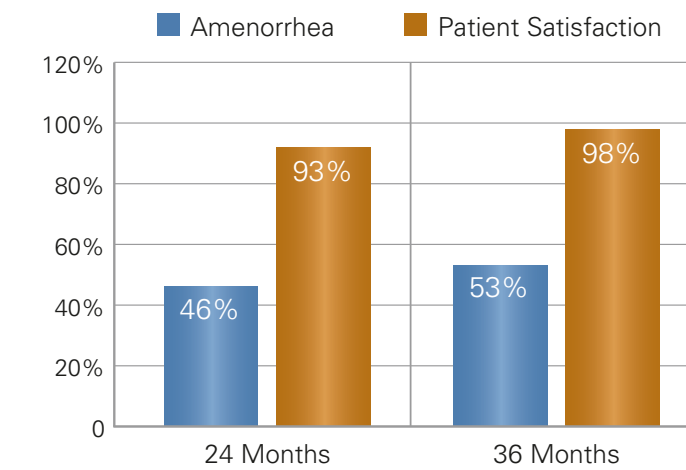
Unlike traditional ablation technologies that rely on the precise direct application of laser or electro-surgical energy to the entire lining of the uterus, the HTA System utilizes circulation of heated saline that fully conforms to the entire endometrial lining – including the cornual areas. As a result, the outcome of an HTA System treatment is less experience-dependent than laser or electro-surgical techniques. Patients with a partial septate uterus or intra-mural fibroids  $\leq 4$ cm, may generally be treated with the HTA System.

## 1 Proven Clinical Outcomes

More than 7 million women suffer from excessive uterine bleeding. Today, women have a choice for a less invasive treatment option that can improve their quality of life. The HTA® System offers both high amenorrhea rates and overall patient satisfaction rates.\*

For Indication, Contraindication, Potential Adverse Effects, and Warnings, please refer to last page of this brochure.

\* November 2003, Vol. 10 NO. 4 The Journal of the American Association of Gynecologic Laparoscopists- Phase III Clinical Data. Per protocol population.



## 2 Versatile

With the HTA System's unique free-floating saline delivery system, a patient with a partial septate uterus, or with intra-mural fibroids  $\leq 4$ cm, may be treated.

## 3 Economical

In today's healthcare environment, the decision to purchase new technology to treat patients isn't simply based on cost. It should also offer broad application and deliver excellent clinical outcomes.

### Histology Tissue Sections

Depth and uniformity of denaturation from pre-hysterectomy, treatment with the HTA System is clearly shown by the absence of active oxidative enzymes in Image A, a section of the cornua. The effectiveness of the insulated sheath is clearly shown by the presence of active oxidative enzymes throughout as dark reactive product in Image B, a section of the cervical canal.



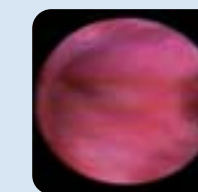
A. Cornua Section



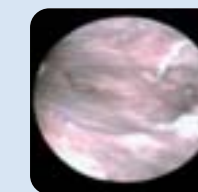
B. Cervical Canal Section

### Before and After View of the Uterine Cavity

Hysteroscopic images showing appearance of uterine cavity immediately before and after treatment with the HTA system.



Before



After

### Features

- Gravity flow to patient limits maximum fluid pressure to  $< 52$ mm Hg.
- Circulating heated saline fully conforms with the entire endometrial lining.
- Procedure performed under hysteroscopic visualization.
- HTA® System Control Panel provides step-by-step prompts.

### Benefits

- Low pressure avoids escape of fluid through fallopian tubes or cervical canal.
- Designed for more efficient uterine coverage.
- Permits treatment of the partial septate uterus.
- Permits treatment in the presence of intra-mural uterine fibroids  $\leq 4$ cm.

