HTA® System
In-Office Global Endometrial Ablation
POTENTIAL PHYSICIAN BENEFITS OF PERFORMING THE HTA® PROCEDURE IN AN OFFICE SETTING

• Time savings and flexibility
  - Schedule on days and times convenient for the physician

• Favorable Reimbursement
  - 2007 Medicare rate of $2,185 with private reimbursement potentially up to $3,600

• Practice Marketing Opportunity
  - Potentially increase profitable practice revenue with or without adding new patients

• Synergy with other office based procedures
  - Set-up and procedure regimen conducive to performing in-office procedures such as hysteroscopy and sterilization

Important – Please Note: Reimbursement information provided by Boston Scientific Corporation (BSC) is gathered from third-party sources and is presented for illustrative purposes only. This information does not constitute reimbursement or legal advice, and BSC makes no representation or warranty regarding this information or its completeness, accuracy or timeliness. Laws, regulations and payer policies concerning reimbursement are complex and change frequently, and service providers are responsible for all decisions relating to coding and reimbursement submissions. Accordingly, BSC strongly recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coding, coverage and reimbursement matters.
POTENTIAL PATIENT BENEFITS OF PERFORMING THE HTA® PROCEDURE IN AN OFFICE SETTING

- **Less anxiety**
  - More comfortable setting than ASC or Hospital

- **Overall shorter time from “admit to discharge”**
  - Less pre-procedure fluid and food intake restriction if anesthesia is not required

- **May reduce risk/effects of general anesthesia**
  - Potential for quicker recovery time if general anesthesia is not required

- **Less out-of-pocket expense for some private insurance plans**
  - Office co-pay fee vs. surgery deductible ($$)
Physician Experience In-office


- 40 of 40 patients treated under paracervical block with oral sedation


- 285 HTA System procedures performed under paracervical block with oral sedation over 5 years without any reports of procedures discontinued because of pain

Interview with Dr. Mark Glasser, January 18, 2007, PDM #90321474.

- 54 Patients treated under paracervical block with oral sedation, including 22 patients with irregular shaped cavities

Phillips R. Practical In-office Experience with the HTA System. Poster Presentation at AAGL. 11-2006

- 55 patient survey respondents reported an average peak pain score of 3.60 on an analog pain scale of 1-10 during the ablation procedure
Clinical Outcomes

Donovan A. Review of 419 Cases of Endometrial Ablation with the Use of the HTA System for the Treatment of Menorrhagia. Podium Presentation at 34th Annual Meeting of AAGL. 11-2005

- 6 to 48 month follow-up of 419 patients from single private practice setting. 77% reported outcomes of amenorrhea or no protection necessary.


- 53% reported amenorrhea (per protocol 72/136) at 3 years from original FDA PMA clinical trial

![Bar chart showing amenorrhea and patient satisfaction at 24 months and 36 months.](chart.png)
SUMMARY OF TECHNIQUE SPOTLIGHT

Authored by

Mark Glasser, MD
Kaiser Health San Rafael, CA
Department of Gynecology

Robert Nadelberg, MD
Newton-Wellesley Hospital, Newton MA
Department of Anesthesia

Authors’ Recommendation for Pre and Post-Procedural Pain Management

1. Ibuprofen 800mg. (Meclomen 100mg, Cataflam® 50mg) - taken night before
2. Diazepam 10mg - taken 1-2 hours prior to procedure
3. Vicodin® 2 tabs - taken 1-2 hours prior to procedure
4. Toradol® 30 mg + Atropine 0.4mg IM - taken 30 minutes pre-procedure
5. Atarax® Sedative 25 mg (2 tabs) or Anzemet® Tablets 100 mg for post-op nausea prevention (give to patient to take at home if necessary)

* Use discretion in prescribing combinations of analgesics and sedatives. The above are recommendations and should be tailored to the individual patient.

Safe anesthesia and successful procedure outcomes are dependent upon:

1. Patient Selection
2. Careful Technique
3. Clinical Vigilance

Patient Selection

To minimize the potential for adverse anesthetic outcomes, any elective medical procedure should be limited to patients with no significant co-morbid conditions who fall into the classification of the American Society of Anesthesiologists Physical Status 1 or 2. In addition, patient selection criteria should also include the patient’s tolerance for pain and/or discomfort, level of anxiety, and preference for the type of setting the procedure will be performed in such as a physician’s office vs. a hospital/outpatient operating room.

This Technique Spotlight was sponsored by Boston Scientific. The opinions expressed in this Technique Spotlight are those of the authors alone. Boston Scientific makes no representations or warranties as to the accuracy or completeness of the information herein.
2 Careful Technique

If choosing to treat patient under local anesthesia, an effective Para Cervical Block will facilitate the introduction of cervical instruments such as the HTA® System’s procedure sheath.

Para Cervical Block Technique

1. 15 cc 1%, Carbocaine®, Anesthetic, Polocaine® Anesthetic at 8 o’clock and 4 o’clock (alternatively the use of 2% chloroprocaine [2% Nesacaine® Anesthetic - MPF 2%] or 1% Xylocaine® [Lidocaine])
2. Give 5 cc intracervical 1cm deep and 10 cc Para Cervical submucosally to raise weal
3. 5-10 cc submucosally between uterosacrals
4. Monitor patient’s BP/Pulse using a patient vital signs monitoring system

3 Clinical Vigilance

Observe patient carefully for progression of sedation beyond anxiolysis. The most common cause of complications in selecting local anesthesia for any procedure relates to the progression of sedation to a level deeper than anticipated and consequent problems resulting in hypoxia and cardiovascular instability.

The definitions of levels of sedation are as follows:

- **Minimal Sedation** (Unsedated)
  - Normal response to verbal stimulation
- **Moderate Sedation/Analgesia**
  - Purposeful response to verbal or tactile stimulation
- **Deep Sedation/Analgesia**
  - Purposeful response following repeated or painful stimulation
- **General Anesthesia**
  - Unresponsive even with painful stimulus

**Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.**

*This Technique Spotlight was sponsored by Boston Scientific. The opinions expressed in this Technique Spotlight are those of the authors alone. Boston Scientific makes no representations or warranties as to the accuracy or completeness of the information herein.*
## Technology Comparison

### Technology Matrix

<table>
<thead>
<tr>
<th>Vision</th>
<th>HTA® System</th>
<th>ThermaChoice® System</th>
<th>Her Option® System</th>
<th>NovaSure® System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct visualization</td>
<td>No direct visualization</td>
<td>No direct visualization</td>
<td>No direct visualization</td>
<td></td>
</tr>
<tr>
<td>Visual confirmation of sheath position before activation</td>
<td>Possible activation in false passage</td>
<td>Possible activation in false passage</td>
<td>Possible activation in false passage</td>
<td></td>
</tr>
<tr>
<td>-</td>
<td>-</td>
<td>Requires concurrent ultrasound</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anatomy</th>
<th>HTA® System</th>
<th>ThermaChoice® System</th>
<th>Her Option® System</th>
<th>NovaSure® System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cavity 6-10.5cm</td>
<td>Cavity 6-10cm</td>
<td>Cavity 6-10cm</td>
<td>Cavity 6-10cm</td>
<td></td>
</tr>
<tr>
<td>Includes irregular shapes and intramural fibroids ≤ 4cm</td>
<td>Includes intramural fibroids ≤ 2cm</td>
<td>Includes intramural fibroids ≤ 2cm</td>
<td>Includes intramural fibroids ≤ 2cm</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pressure &amp; Manipulation</th>
<th>HTA® System</th>
<th>ThermaChoice® System</th>
<th>Her Option® System</th>
<th>NovaSure® System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low pressure and no probe movement is designed to reduce discomfort</td>
<td>High pressure</td>
<td>Probe movement</td>
<td>Probe movement Electro stimulation</td>
<td></td>
</tr>
</tbody>
</table>

Source: Competitive SS&E documents

1. HTA Presentation MVU5450
**GEA TECHNOLOGY REPORTED OUTCOMES**

<table>
<thead>
<tr>
<th></th>
<th>HTA® System</th>
<th>ThermaChoice® System</th>
<th>Her Option® System</th>
<th>NovaSure® System¹</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Postprocedural</strong></td>
<td>3y</td>
<td>3y</td>
<td>1y</td>
<td>3y</td>
</tr>
<tr>
<td><strong>Interval</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Amenorrhea</strong></td>
<td>53%¹</td>
<td>15%</td>
<td>22%</td>
<td>44%</td>
</tr>
<tr>
<td><strong>Satisfactory</strong></td>
<td>41%</td>
<td>53%</td>
<td>45%</td>
<td>43%</td>
</tr>
<tr>
<td><strong>Reduction in Bleeding</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Success (Amenorrhea +</strong></td>
<td>94%</td>
<td>68%</td>
<td>67%</td>
<td>87%</td>
</tr>
<tr>
<td><strong>Reduction in Bleeding)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: No direct comparison can be made due to differences in manufacturer’s clinical study protocol

¹ Per Protocol Patients (72/136)
³ This Data has not been published, however it has been presented during a podium presentation at the 2005 AAGL annual meeting
**HYPOTHETICAL HTA® SYSTEM IN-OFFICE PROFITABILITY**

<table>
<thead>
<tr>
<th>Number of HTA System cases per year</th>
<th>96</th>
</tr>
</thead>
</table>

**HTA System cases done at HOSPITAL:**

| Physician Fee - Reimbursement in-hospital (Medicare $336) CPT® Code 58563-47 | $336.00 |
| Paracervical block - in-hospital (Medicare $40) CPT Code 64435-51 | $40.00 |

**Potential Doctor Profit (per year)** $36,096.00

**HTA System cases done IN-OFFICE:**

| Doctor Fee - Reimbursement in-office (Medicare $2,185) CPT Code 58563-47 | $2,185.00 |
| Paracervical block - in-office (Medicare $78) CPT Code 64435-51 | $78.00 |

**Total annual Revenue from in-office ablations** $217,248.00

| Cost of HTA System disposables per case | $845.00 |
| Cost of other disposables | $100.00 |
| Cost of office time/personnel (may not include all overhead costs) | $100.00 |

**Total annual Cost of in-office ablations** $100,320.00

**Potential Doctor Profit (per year)** $116,928.00

**Potential Lost Income by not doing the procedure in office** $80,832.00

---

Important – Please Note: Reimbursement information provided by Boston Scientific Corporation (BSC) is gathered from third-party sources and is presented for illustrative purposes only. This information does not constitute reimbursement or legal advice, and BSC makes no representation or warranty regarding this information or its completeness, accuracy or timeliness. Laws, regulations and payer policies concerning reimbursement are complex and change frequently, and service providers are responsible for all decisions relating to coding and reimbursement submissions. Accordingly, BSC strongly recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coding, coverage and reimbursement matters.

CPT is a registered trademark of American Medical Association


1 Informational purposes only. Actual results may vary.
# TECHNOLOGY ESTIMATED ROI COMPARISON

<table>
<thead>
<tr>
<th>Current Product</th>
<th>Medicare Average Payment per Procedure</th>
<th>Disposable Cost per Procedure</th>
<th>Net Revenue per Procedure</th>
<th>Cases per Month</th>
<th>Annual Cost</th>
<th>Annualized Net Revenue</th>
<th>HTA System potential ability to treat 25% more patients</th>
<th>Total Annual Revenue and Differential</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA® System</td>
<td>$2,263</td>
<td>$850</td>
<td>$1,413</td>
<td>8</td>
<td>$81,600</td>
<td>$135,648</td>
<td>$33,912</td>
<td>$169,560</td>
</tr>
<tr>
<td>NovaSure® System</td>
<td>$2,263</td>
<td>$950</td>
<td>$1,313</td>
<td>8</td>
<td>$91,200</td>
<td>$126,048</td>
<td>-</td>
<td>-$43,512</td>
</tr>
<tr>
<td>ThermaChoice® System</td>
<td>$2,263</td>
<td>$875</td>
<td>$1,388</td>
<td>8</td>
<td>$84,000</td>
<td>$133,248</td>
<td>-</td>
<td>-$36,312</td>
</tr>
<tr>
<td>Her Option® System2</td>
<td>$2,385</td>
<td>$1,200</td>
<td>$1,185</td>
<td>8</td>
<td>$115,200</td>
<td>$113,760</td>
<td>-</td>
<td>-$55,800</td>
</tr>
</tbody>
</table>

1 Informational purposes only. Actual results may vary.

2 Cost of ultrasound equipment and cost of personnel to operate will vary by practice, so cost is not included in this estimate.

3 Endometrial Ablation and the HTA System, March 2002, MTG Newsletter, Peer Review Network Inc.

4 2007 Medicare rates for CPT® Codes 58563 + 64435
Reimbursement Considerations

BACKGROUND
In 2007, Medicare will increase ASC payment for 58563 to $1,339 from $630, an increase of 113%.
Over 95% of HTA® System patients are non-Medicare. Private payer reimbursement will vary greatly depending on individual provider contracts.

COMMONLY USED ICD-9 DIAGNOSIS CODES
626.2 Excessive/frequent menstruation; heavy periods, menometrorrhagia, menorrhagia, polymenorrhea
626.6 Metrorrhagia; bleeding unrelated to menstrual cycle, irregular inter-menstrual bleeding
626.8 Other; dysfunctional or functional uterine hemorrhage NOS
627.1 Postmenopausal bleeding
627.4 Irregular menstruation cycle
627.0 Premenopausal menorrhagia
626.9 Menstrual disorder, NOS

MEDICARE PHYSICIAN, HOSPITAL OUTPATIENT & ASC PAYMENTS

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Code Description</th>
<th>Physician Payment</th>
<th>Facility Payment</th>
<th>Hospital Outpatient Payment</th>
<th>ASC Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>58563-47</td>
<td>Hysteroscopy, surgical; with endometrial ablation (e.g. endometrial resection, electrosurgical ablation, thermoablation)</td>
<td>$2,185</td>
<td>$336</td>
<td>$2,091</td>
<td>$1,339</td>
</tr>
<tr>
<td>64435-51</td>
<td>Injection, anesthetic agent; paracervical (uterine) nerve block</td>
<td>$78</td>
<td>$40</td>
<td>$139</td>
<td>NA</td>
</tr>
</tbody>
</table>

POSSIBLE CODES FOR BILLING HTA SYSTEM PROCEDURE SET (Private Payers Only)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99070</td>
<td>Supplies and materials (except spectacles), provided by the physician over and above those usually included with the office visit or other services rendered (list drugs, trays, or materials)</td>
</tr>
<tr>
<td>A4649</td>
<td>Surgical supply; misc.</td>
</tr>
<tr>
<td>272</td>
<td>Medical/Surgical sterile supply</td>
</tr>
<tr>
<td>279</td>
<td>Other supplies/devices</td>
</tr>
</tbody>
</table>

¹ MD payments calculated using the 2007 conversion factor of $37.8975 and mandated budget neutrality work adjuster of 0.8994. Source: December 1, 2006 Federal Register.
² Hospital Outpatient payments are 2007 Medicare national averages. Source: November 24, 2006 Federal Register. Actual rates will vary geographically.
³ ASC payments are from the 2007 Update to the Ambulatory Surgical Center Covered Procedures List. Source: November 24, 2006 Federal Register.

Important - Please Note: Reimbursement information provided by Boston Scientific Corporation (BSC) is gathered from third-party sources and is presented for illustrative purposes only. This information does not constitute reimbursement or legal advice, and BSC makes no representation or warranty regarding this information or its completeness, accuracy or timeliness. Laws, regulations and payer policies concerning reimbursement are complex and change frequently, and service providers are responsible for all decisions relating to coding and reimbursement submissions. Accordingly, BSC strongly recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coding, coverage and reimbursement matters.

CPT is a registered trademark of American Medical Association.
CPT Codes © 2007 American Medical Association. All rights reserved.
INFORMATION FOR OFFICE MANAGERS FOR IN-OFFICE ENDOMETRIAL ABLATION

Medicare’s 2005 In-Office MD Rate Change

As of January 1, 2005, Medicare adjusted its non-facility (physician office) physician payment for hysteroscopic endometrial ablation (CPT® code 58563) to account for the office costs (medical supplies, equipment, nursing time, etc) in providing this procedure.

The 2007 Medicare national average rate office-based MD rate for this procedure is $2,185, and $336 for the facility-based MD rate

What Will Private Payers Pay?

Some private payers automatically link their payment systems to Medicare, meaning that they would pay the higher in-office rate as of 1/1/05. However, many others do not, and would pay MDs based largely off the lower facility-based rate. Physicians and office managers should always check with their health plans before performing in-office ablations to confirm that the payment will cover the costs of providing this procedure in the office.

Fee Schedule Inquiries Should go to Network Account Managers

Office managers should contact their Network Account Managers at health plans on adjustments to fee schedules. These health plan reps may also be referred to as Physician Contracting, Provider Relations or Provider Network Services representatives. Because physicians have contracts with the plans, inquiries and requests for rate adjustments are usually at least considered by the plans. Many other plans may change their fee schedules in time based on pressure from physicians and offices.
The HTA System is a potential alternative for treating women with excessive uterine bleeding.

**Features**

- Gravity flow to patient limits maximum fluid pressure to $< 52\text{mm Hg}$.
- Circulating heated saline fully conforms with the entire endometrial lining.
- Procedure performed under hysteroscopic visualization.

**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 $\leq 4\text{cm}$.

**Before and After View of the Uterine Cavity**

Hysteroscopic images showing appearance of uterine cavity immediately before and after treatment with the HTA system.
<table>
<thead>
<tr>
<th>Reorder Number</th>
<th>Product Description</th>
<th>Unit of Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>M00656000K0</td>
<td>HTA® System, 95-135 VAC, 50/60Hz; includes: Compact mobile HTA System 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</td>
<td>1 each</td>
</tr>
<tr>
<td>M006560201</td>
<td>Procedure Set, Sterile, Single Patient Use; includes: 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</td>
<td>1 box</td>
</tr>
<tr>
<td>M006550310</td>
<td>Adapter for Storz Brand Hysteroscope Telescope; Allows 2.9mm /12° or 30° Storz Telescope (#26020FA or #26120BA), to be used with HTA® Procedure Sheath</td>
<td>1 each</td>
</tr>
<tr>
<td>M006550340</td>
<td>Adapter for Wolf Brand Hysteroscope Telescope; Allows 2.7mm /25° Wolf Telescope (#8979.11) to be used with HTA Procedure Sheath</td>
<td>1 each</td>
</tr>
<tr>
<td>M006550350</td>
<td>Adapter for ACMI-Circon Brand Hysteroscope Telescope; Allows 2.7mm /12° or 30° ACMI-Circon Telescope (#G27L-12A or #G27L30WA) to be used with HTA Procedure Flow Sheath</td>
<td>1 each</td>
</tr>
<tr>
<td>M006550360</td>
<td>Adapter for Olympus Brand Hysteroscope Telescope; Allows 3mm /0° or 12° or 30° Olympus Telescope (#A4674A or #A4673A or #A4672A) to be used with HTA Procedure Flow Sheath</td>
<td>1 each</td>
</tr>
</tbody>
</table>
Her Option is a registered trademark of Cit Healthcare LLC
NovaSure is a registered trademark of Cytic Corporation
ThermaChoice and Motrin are registered trademarks of
Johnson & Johnson Corporation
CPT is a registered trademark of American Medical
Association
Essure is a registered trademark of Conceptus, Inc
Carbocaine is a registered trademark of Hospira, Inc
Polocaine is a registered trademark of Abraxis Bioscience, Inc
Valium and Toradol are registered trademarks of Roche
Holdings Inc, or its affiliates
Atarax is a registered trademark of Pfizer Inc
Vicodin is a registered trademark of Abbott Laboratories
Cataflam is a registered trademark of Novartis Corporation

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

INDICATIONS: The HTA System is a hysteroscopic ther-
mal 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 con-
traindicated 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 ade-
nomatous hyperplasia; who has active pelvic inflamma-
tory 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 transmural myomectomy; who has
an intruterine 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; complica-
tions with pregnancy (Note: pregnancy following abla-
tion is dangerous to both the mother and the fetus);
risk 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 diag-
nostic hysteroscopy.

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