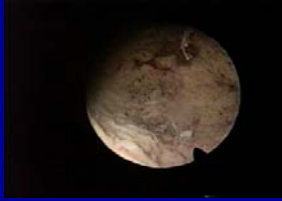
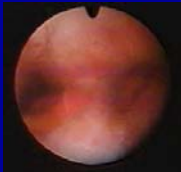


HTA Sheath Withdrawal



Uterine Septum

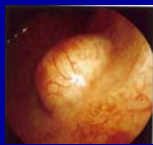


Pre-Treatment



Post-Treatment

Submucous Fibroid



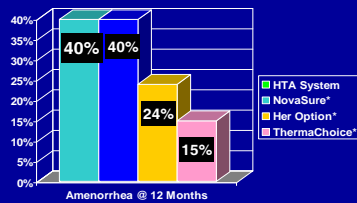
Post-Op Patient Instructions

Patient Expectations

- Cramping may be moderate to severe for 2 days
- Expect vaginal discharge for a few weeks after treatment

Endometrial Ablation Technologies: Second Generation Comparison

Second Generation Comparison Phase III Clinical Trial Results*



* Varying inclusion criteria

Success @ 12 Months

Technology	Subjects Treated		Amenorrhea		Study Success (PBLAC < 75)	
	Thermal n=	REA n=	Thermal %	REA %	Thermal %	REA %
MEA	215	107	55	46	87	83
NovaSure	175	90	36	32	78	74
HTA	187	89	35	47	68	76
Cryogen	193	86	22	46	67	73
ThermaChoice	137	138	12	22	74	70

Hysterectomy Following Ablation

Rates = 21-29%

Cervix Dilatation

	Diameter
MEA	8.0 mm
HTA	7.8 mm
Novasure	7.2 mm
ThermaChoice	5.5 mm
Her Option	4.5 mm

Assessing the Safety of the New Global Endometrial Devices

Complications

Maude

Bea Arthur?

Results for HTA System

Severity of Adverse Events

Class I (Internal/bowel requiring surgery)	2
Class II (Internal/Bowel treated w/o intervention)	0
Class III (Vulva/Vaginal injury; infection)	18
Class IV (Unknown)	1

Results for NovaSure

Severity of Adverse Events

Class I (Internal/bowel requiring surgery)	16
Class II (Internal/Bowel treated w/o intervention)	3
Class III (External/Vaginal Injury, infection)	3
Class IV (Unknown)	3

Recent Complication: 2005-2007

From the Maude Data
www.fda.gov/cdrh/maude.html

Results for NovaSure® 2005-Present

Severity of Adverse Events

Class I (Internal / bowel requiring surgery)	16
Class II (Internal/Bowel treated w/o intervention)	4
Class III (External/Vaginal Injury, infection)	0

Results for Microsulis® 2005-Present

Severity of Adverse Events

Class I (Internal / bowel requiring surgery)	6
Class II (Internal/Bowel treated w/o intervention)	2
Class III (External/Vaginal Injury, infection)	1

Results for HTA System 2005-Present

Severity of Adverse Events

Class I (Internal/bowel requiring surgery)	0
Class II (Internal/Bowel treated w/o intervention)	0
Class III (Vulva/Vaginal injury)	16*

* 5 were MD error

Results for ThermaChoice® 2005-Present

Severity of Adverse Events

Class I (Internal/bowel requiring surgery)	1
Class II (Internal/Bowel treated w/o intervention)	0
Class III (Vulva/Vaginal Injury)	5*

* 1 was MD error

Results for Her Option 2005-Present

Severity of Adverse Events

Class I (Internal/bowel requiring surgery)	1
Class II (Internal/Bowel treated w/o intervention)	0
Class III (Vulva/Vaginal injury)	0

Procedure Code for Endometrial Ablation

- CPT **58563** – “Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)”

NOT:

- CPT **58353** - “Endometrial ablation, thermal, without hysteroscopic guidance”

Device Costs

HTA® System	ThermaChoice® System	NovaSure® System	Microsulis® MEA System
*\$739	\$820	\$850	\$700

What is the CPT® Code for Endometrial Ablation with the HTA® System?

- CPT 58563 –
 - "Hysteroscopy, surgical; with endometrial ablation"
- Medicare Allowable- Hospital/Outpatient
 - \$2,095.00
 - Ambulatory Surgery Center
 - \$ 996.00
 - In Office
 - \$2,301.00

*Estimated private payer MD fee ranges (128-140% of Medicare)

Second Generation Comparison

	HTA® System	ThermaChoice™ System	Her Option™ System	NovaSure™ System
Safety	Visual control	Blind	Blindly Introduced	Blind
	Visual confirmation of proper position before activation		Ultrasound placement	Possible activation/ false passage
Efficacy	Cavity ≤ 10.5cm*	Cavity ≤ 10cm	Cavity ≤ 10cm	Cavity ≤ 10cm
	Includes abnormal shapes and myomas ≤4cm	Includes intramural fibroids ≤2cm	Includes intramural fibroids ≤2cm	Includes intramural fibroids ≤2cm

Second Generation Comparison Published Studies

	HTA®	ThermaChoice™	MEA®	NovaSure™
Fibroids	I/II ? size	II ≤ 3 cm	I/II ≤ 3cm * FDA approved	I/II ≤ 3 cm

Second Generation Comparison

	HTA®	ThermaChoice™	Her Option™	NovaSure™
Patient Comfort	Low pressure (50 mm Hg)	Higher pressure (160-180 mm Hg)	No pressure Probe movement	Negative pressure Probe movement Electro stimulation