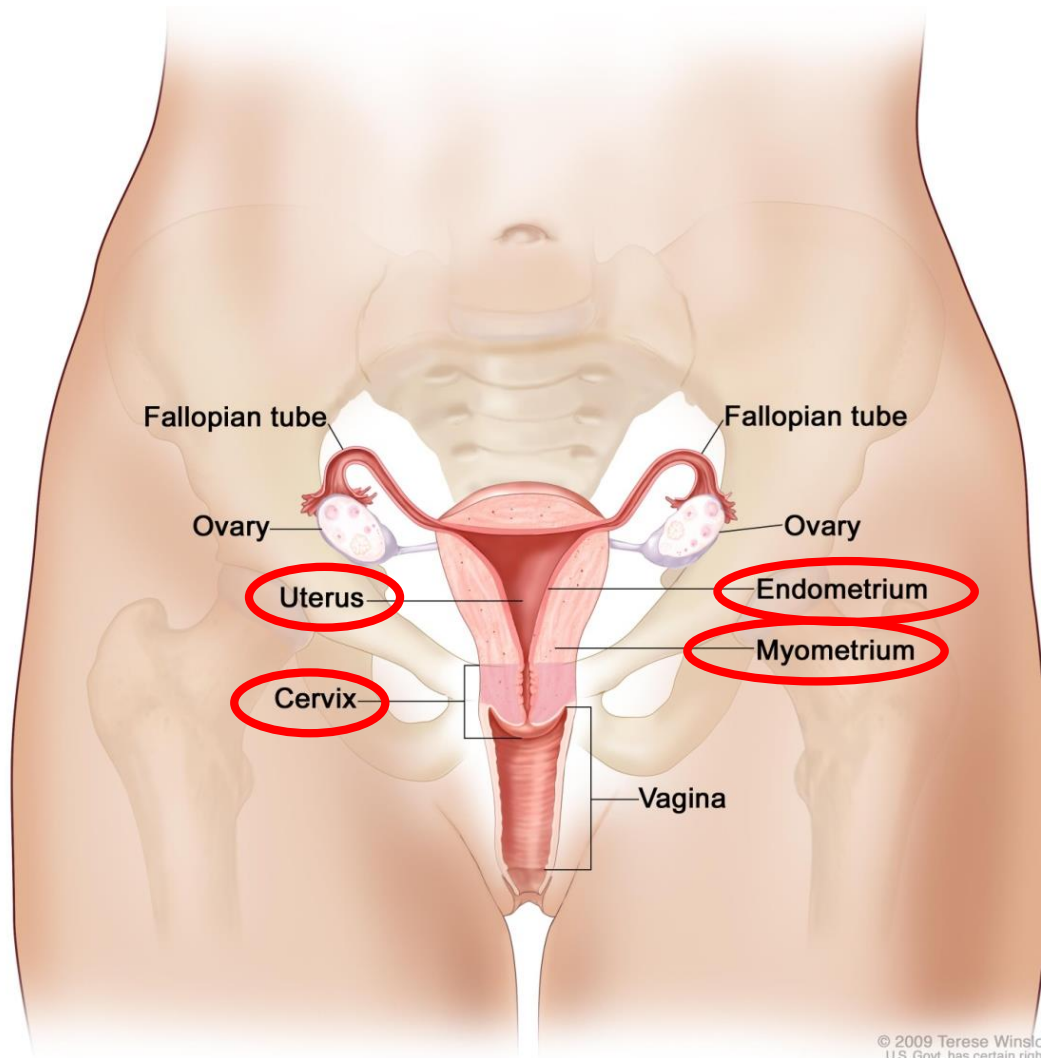
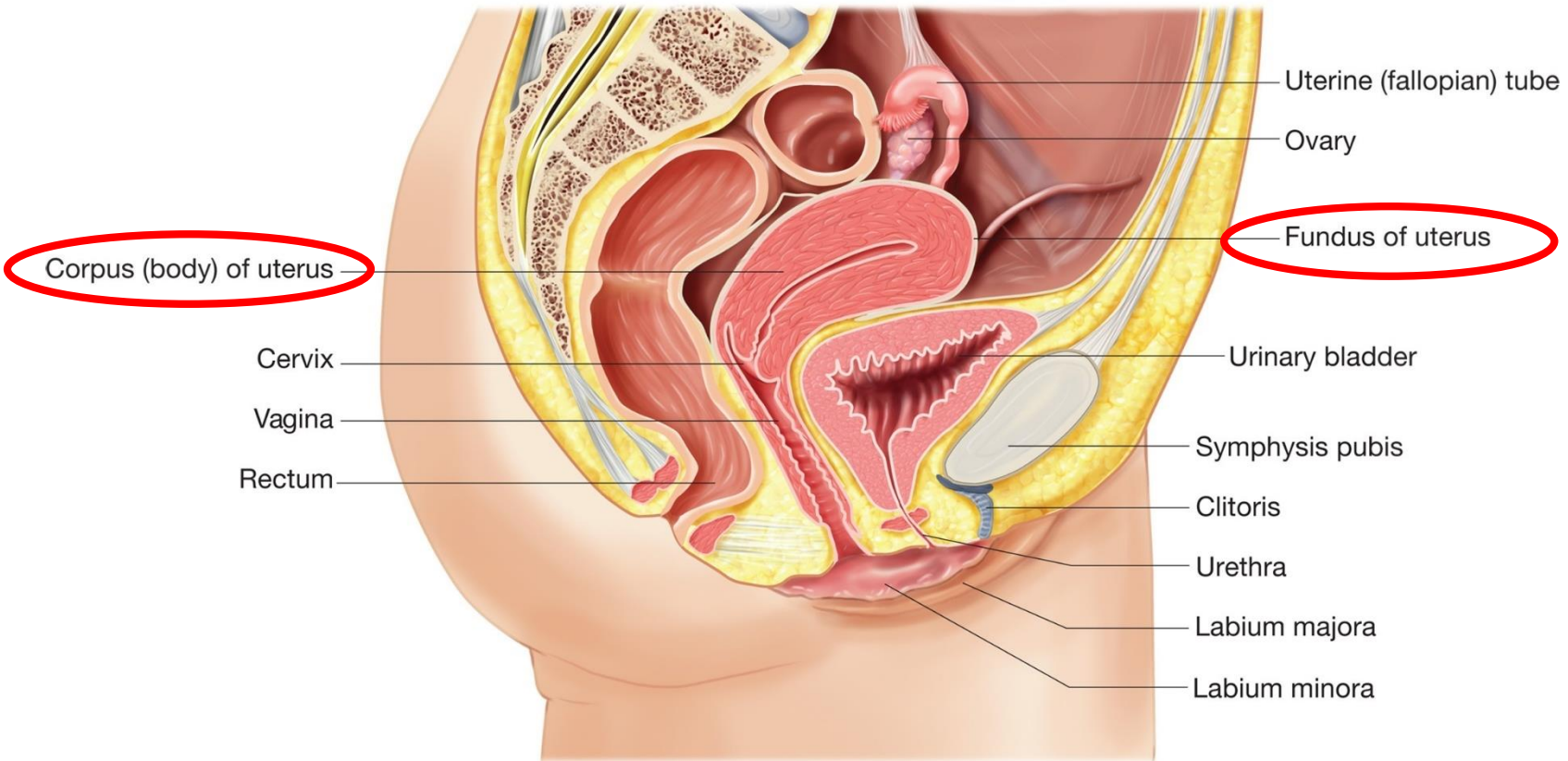


Endometrial
RFA

Basic Female reproductive system anatomy



Basic Female reproductive system anatomy



Important terminology

- ▶ **Menorrhagia:** A blood loss of greater than 80ml or lasting longer than 7days per menstrual cycle constitutes menorrhagia (also called hypermenorrhea)
- ▶ **Endometrium:** the inner tissue part of the uterus that the body peels off and sheds during menstrual period. Endometrium has 2 layers, the basal and the functional (thickens and then sheds during the menstrual cycle)

When this lining spreads in places it shouldn't, a woman can face similar but different conditions:

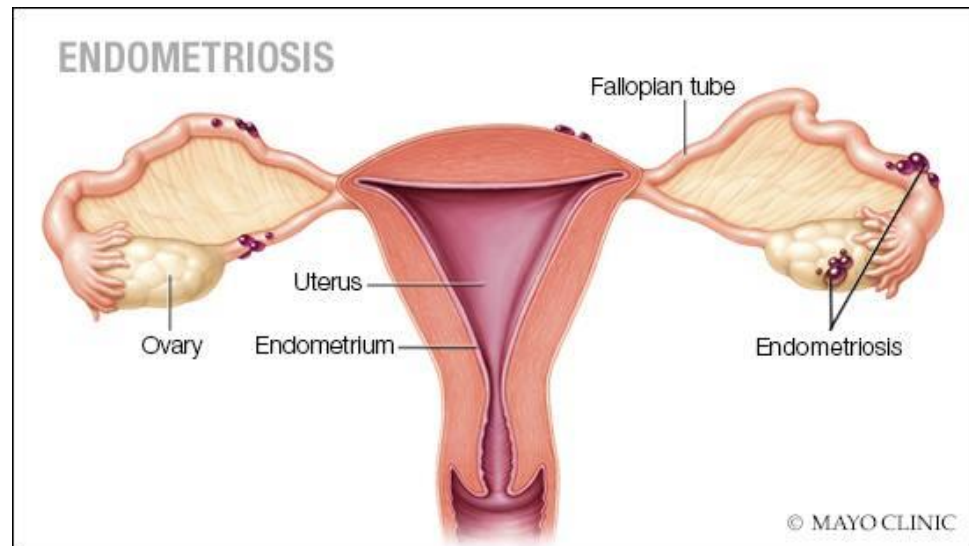
- ▶ **Endometriosis:** the lining of the uterus spreads outside of it. The growth can breach nearby organs, like ovaries, fallopian tubes and bladder
- ▶ **Adenomyosis:** the lining of the uterus grows deep into the muscle wall of the uterus and thickens it. Sometimes it is called *internal endometriosis*



Important terminology



Adenomyosis



Causes & Symptoms of menorrhagia

► Causes:

- Hormonal imbalance
- Polycystic ovary syndrome
- Dysfunction of the ovaries
- Inherited disorder
- Medications
- Myomas - Uterine fibroids
- Adenomyosis

► Symptoms:

- Anemia
- Severe Pain – painful menstrual cramps (dysmenorrhea)
- Reduced athletic performance
- Social life
- May lead to moodiness and depression symptoms



Indications

Endometrial Radiofrequency ablation is used to treat pre-menopausal women with **Menorrhagia** (excessive bleeding) due to benign causes for whom childbearing is complete.

If the cause of menorrhagia is a myoma or multiple myomas, then it is the myoma or myomas that need to be treated.

- ▶ The goal of endometrial ablation is to reduce or even stop blood loss (amenorrhea)
- ▶ **The target is to ablate the basal layer of the endometrium.** At the beginning of menstrual cycle when the functional layer of the endometrium is at its thinnest, this will be the easiest time for ablating basal layer of the endometrium. A high definition ultrasound can distinguish between the functional and basal layer



Treatments

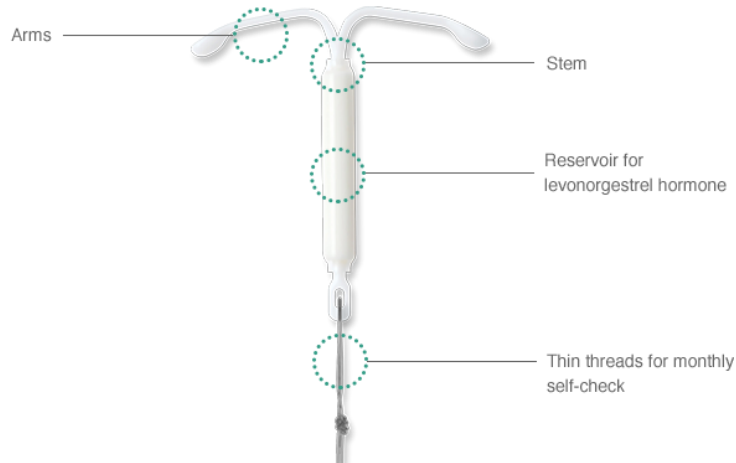
The **current treatments** for menorrhagia are:

- Oral regiments
 - ▶ NSAIDs – mainly helps with dysmenorrhea
 - ▶ Tranexamic acid
 - ▶ Contraceptives
 - ▶ Progesterone
- Implantable Intra Uterine Devices (IUD's) that gradually release hormones
- Surgery - Hysterectomy
- Endometrial Ablation systems



Main competition – minimally invasive

IUD devices



Novasure



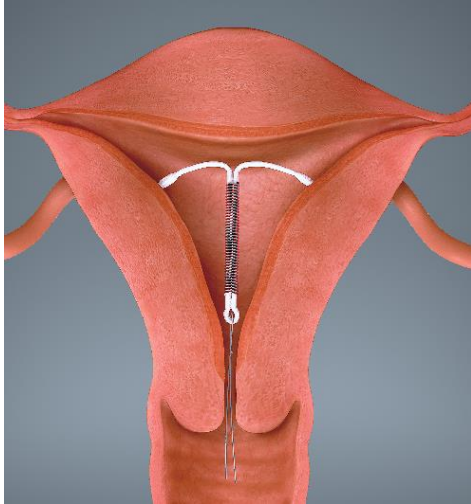
Boston Scientific Genesys HTA



Minerva Surgical



Hormonal Implantable Intra Uterine Devices (IUD's)



- The three well know brands of hormonal IUDs available are **Liletta** and **Skyla** (work up to 3 years) and **Mirena** (up to 5 years)
- Once placed in the uterus, this type of IUD slowly releases small amounts of a progestin hormone called levonorgestrel. They are mainly used for birth control but also lightens the period

▶ Hormonal IUDs can cause side effects similar to those of birth control pills, including:

- Breast soreness and/or tenderness
- Headaches
- Nausea
- Mood changes
- Weight gain
- Acne



Surgery - Hysterectomy

- ▶ A hysterectomy is a surgical procedure that removes the uterus. There are several types of hysterectomy, depending on what's removed:
 - A partial hysterectomy removes the uterus but leaves the cervix intact
 - A standard hysterectomy removes both uterus and cervix
 - A total hysterectomy removes the uterus, cervix, and one or both ovaries and fallopian tubes
- ▶ Hysterectomies are performed through either the abdomen or the vagina. Some can be done laparoscopically or with robot-assisted technology.



Endometrial Ablation Systems

minerva
SURGICAL



- ▶ Manufacturer: Minerva Surgical
- ▶ 3 Mechanisms of Ablation: Electrical current to Ionize argon gas, which turns in to plasma
- ▶ Plasma releases thermal energy in the form of heat which ablates surrounding endometrial tissue that is in direct contact with the silicone array membrane.

NovaSure®
Endometrial Ablation



- ▶ Manufacturer: Hologic
- ▶ Radiofrequency Impedance Controlled Endometrial Ablation System
- ▶ **No ultrasound guidance: good and bad!!**

Genesys HTA™ System



- ▶ Manufacturer: Boston Scientific
- ▶ Perfuses hot saline
- ▶ When the saline temperature reaches 80°C, the treatment period of 10 minutes starts



Endometrial Ablation Systems

cerene®



- ▶ Manufacturer: Channel Medsystems
- ▶ Portable **cryo**ablation device

AEGEA
MEDICAL



- ▶ Manufacturer: Aegea Medical
- ▶ Mara Water Vapor Ablation Treatment
- ▶ They advertise it as designed to be used in doctor's office
- ▶ It has a cervical seal and extra safety check

Cavaterm™



- ▶ Manufacturer: Cavaterm
- ▶ Consists of an adjustable, flexible silicone balloon catheter and the generator
- ▶ Fast circulation of hot fluid inside the balloon with a target temperature of 78C

RF MEDICAL



Endometrial Ablation Systems



- ▶ Manufacturer: June Medical
- ▶ Portable device
- ▶ Balloon circulating hot fluid
- ▶ 2 minutes under local anesthesia



Endometrial Ablation Systems

Cost-Effectiveness of Global Endometrial Ablation vs. Hysterectomy for Treatment of Abnormal Uterine Bleeding: US Commercial and Medicaid Payer Perspectives

Jeffrey D. Miller, MS,¹ Gregory M. Lenhart, MS,¹ Machaon M. Bonafede, PhD, MPH,¹
Andrea S. Lukes, MD, MHSc,² and Shannon K. Laughlin-Tommaso, MD, MPH³



EA is half the cost of hysterectomy

EA is cheaper than hysterectomy in direct & indirect costs



Economic Evaluation of Global Endometrial Ablation Versus Inpatient and Outpatient Hysterectomy for Treatment of Abnormal Uterine Bleeding: US Commercial and Medicaid Payer Perspectives

Jeffrey D. Miller, MS,¹ Machaon M. Bonafede, PhD, MPH,¹ Qian Cai, MS, MSPH,¹ Scott K. Pohlman, MS,²
Kathleen A. Troeger, MPH,² and Aarathi Cholkeri-Singh, MD³



Disadvantages of other treatments

- ▶ Oral regiments
 - Low success rate; rely on patient's compliance; not cost effective
- ▶ Implantable Intra Uterine Devices (IUD's) that gradually release hormones
 - They need to be replaced after 3-5 years; periods in the beginning may get heavier, longer and more painful; some risks of rejection / expulsion by the body; can be uncomfortable; may perforate the uterus (severe complication!) and all the disadvantages of oral contraceptives (depression, weight gain, fear of cancer)
- ▶ Surgery - Hysterectomy
 - Surgery is invasive and requires general anaesthesia.
- ▶ All other ablation systems:
 - Universally ablate the uterus – see next slide “partial endometrial ablation”



Partial endometrial ablation

- ▶ It has been reported that “universal” endometrial ablation devices that ablate the whole endometrium (e.g. hot water balloon or Novasure) cause long term pain and complications.
- ▶ The theory behind this is that all other endometrial ablation systems (hot balloons or other RF systems) ablate all walls of the uterus indiscreetly. The exposed myometrium on both sides then “fuses” to each itself, sealing the uterus shut. Any remaining functional endometrium will bleed slightly. If the blood cannot escape, haematomas, retrograde flow and pain will occur.
- ▶ It should also be noted that the uterus cannot be examined for cancer in the future thereby leading to prophylactic hysterectomies.
- ▶ **The EMT electrode allows for the user to decide how much of the uterus he wishes to ablate in order to achieve the desired outcome (e.g. amenorrhea or eumenorrhea). Ablating less and achieving more “natural” results like eumenorrhea has a lower complication rate and may be the preferable treatment for most patients.**



Advantages of using EMT electrode

- ▶ Minimally invasive and quick procedure
 - Our EMT electrode is inserted trans-vaginally and the ablation procedure takes place under direct ultrasound visualization
- ▶ The doctors may choose what areas of the endometrium to ablate and to what extent.
 - They can choose the desired outcome, eumenorrhea or amenorrhea
 - In other endometrial ablation systems the doctor can only ablate the whole uterus
 - With EMT the non-universal ablation leaves the uterus open, therefore if there is any remaining functional endometrium there can be free blood flow (thereby preventing haematomas and retrograde bleeding and of course allows future examination for cervical cancer)



What you need to perform Endometrial RFA

- ▶ RF Generator (M-3004 or V-1000)



- ▶ Disposable electrode kit

- EMT electrode
- Neutral electrodes (grounding pads)



EMT protocol

- ▶ Sedation, local or total anesthesia
- ▶ Cervix dilatation is usually NOT required as probe is very thin
- ▶ Measure the length of the uterus (done by US examination before the procedure)
- ▶ Hysteroscopy check-up is optional prior to the ablation. The hysteroscope is then removed
- ▶ Endometrium biopsy is strongly recommended to exclude uterine cancer cases. This can be done the same day prior to the RF procedure using hysteroscope or just a curette (possibly with the assistance of endometrial biopsy pipeline system)
- ▶ Insert the EMT electrode
- ▶ Choose the EMT application
 - set the temperature at 80 degrees Celsius
 - time at 1:30
- ▶ Do 3 sessions of 1:30 minute each (2 sessions laterally, one on each side, and 1 session on the midline). First do the 2 sides and last the midline
- ▶ Repeat as necessary depending on the length of the uterus, i.e. if the uterus is 6cm long i.e. retract and repeat as necessary in each position (laterally and in the midline).

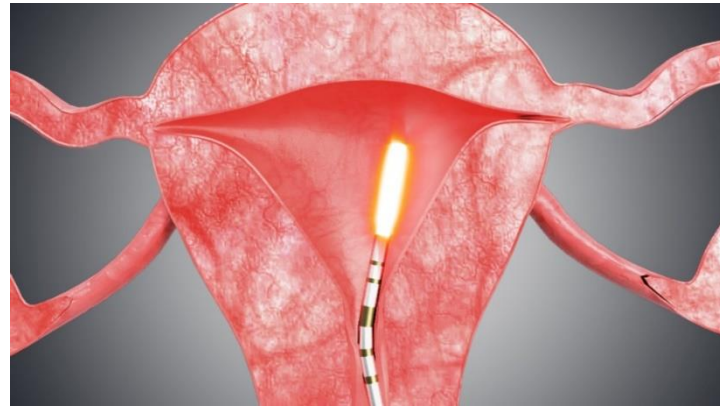
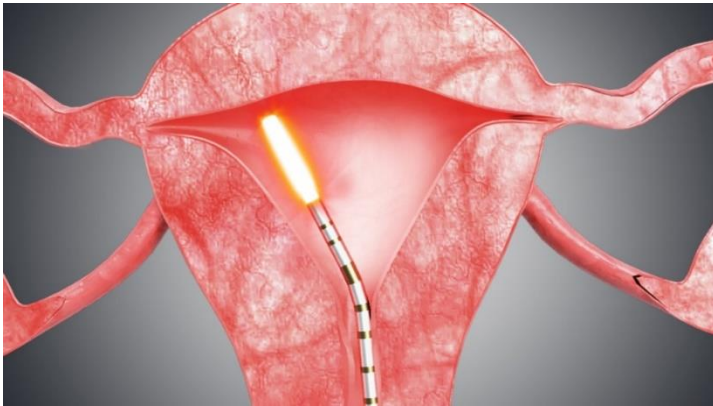
Prof. MUDr. Martin Huser, Ph.D., MBA

University Hospital Brno, Czech Republic, Department of Obstetrics and Gynecology



How to use

- ▶ Do 3 sessions of 1:30 minute each (2 sessions laterally, one on each side, and 1 session on the midline). First do the 2 sides and last the midline



- ▶ Physician can choose amenorrhea or eumenorrhea by controlling the ablation zone



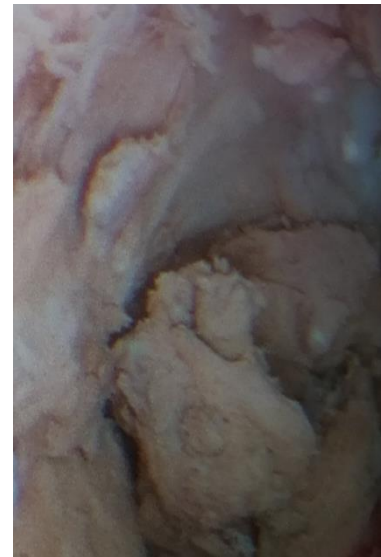
EMT protocol

- ▶ Ablation of the basal layer should ideally be confirmed with an ultrasound.
- ▶ After the ablation it is optional that you enter the uterus with the hysteroscope to check that ablation was satisfactory. In rare cases if ablation is not satisfactory then some additional session might be applied

Prior RFA



Post RFA



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University Hospital Brno, Czech Republic, Department of Obstetrics and Gynecology



Follow up

- ▶ Over the counter pain killers may be given to the patient as necessary
- ▶ Follow up recommended at 1, 6 and 12 months
- ▶ Check for menstrual flow and pain / discomfort scores



The Competition

Feature	RF Medical	Hysterectomy	Universal Ablation Systems	IUD's
Minimally Invasive	✓	✗	✓	✓
Possibility to retain menstrual cycle	✓	✗	✗	✓ (can return to normal cycle after removal of the IUD)
Non-universal ablation so fewer complications	✓	✗	✗	✗
Doctor can decide how much to ablate depending on the desired outcome e.g. eumorrhea or amenorrhea	✓	✗	✗	✗
Can be used in the presence of polyps, myomas or abnormal uterine anatomies (e.g. retroflexed uteri)	✓	✓	✗	?



RF Medical's strong points

- ▶ Multi purpose generators with a dedicated algorithm for endometrial ablation
- ▶ Easy to use touch-screen generators
- ▶ Large ablations in the shortest time possible
- ▶ The EMT electrode allows for the non-universal ablation of the uterus, reducing complication rates and allowing the user to decide on the extend of the ablation and the results.
- ▶ Predictability & reproducibility
- ▶ Quality
- ▶ Price

