Mara™

Water Vapor Ablation System

Quick Reference Guide

CooperSurgical®

For complete instructions, please refer to the Mara Water Vapor Ablation System Instructions for Use and the Mara Console Operator's Manual.

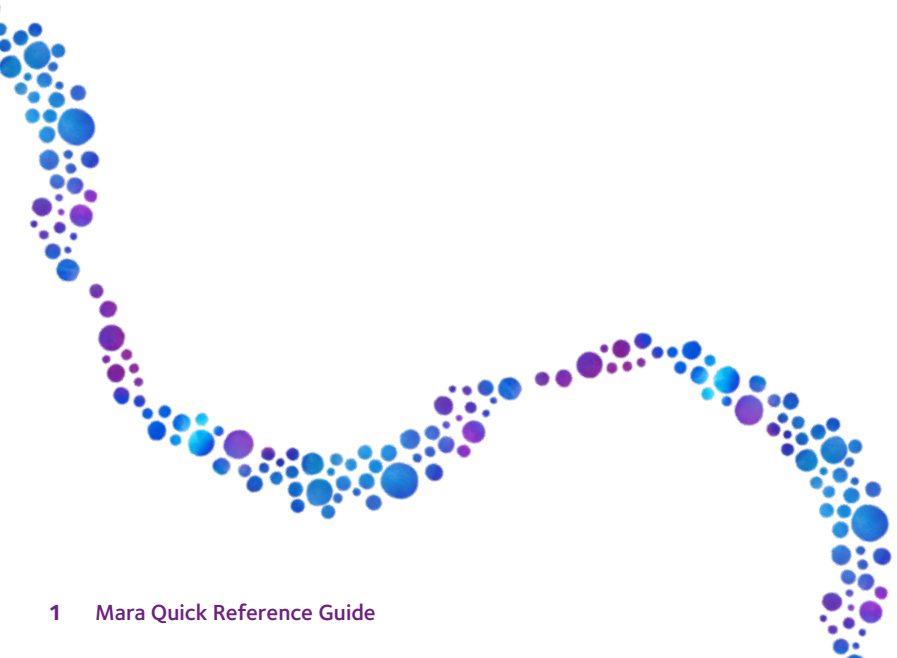


Table of Contents

Indications for Use

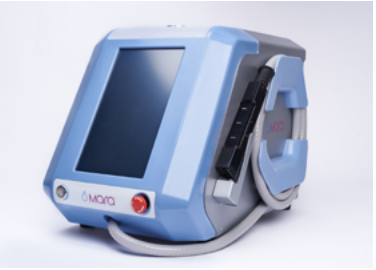
The Mara Water Vapor Ablation System is indicated to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

Important Safety Information

Pregnancy following the Mara procedure can be dangerous. The Mara procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. As with all surgical procedures, there are risks and considerations associated with the use of the Mara Water Vapor Ablation System. Please refer to the device labeling for a detailed discussion of the device's intended use, relevant warnings, precautions, side effects, and contraindications.

Equipment and Materials Checklist

Mara Water Vapor Ablation System Components



Mara Console (non-sterile) includes:

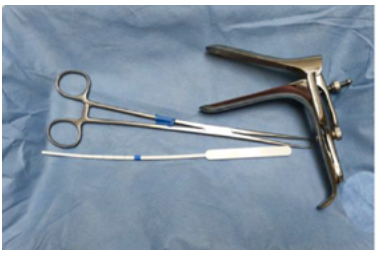
1. Cartridge
2. Cartridge Cable
3. AC power cord

Single Use, Mara Water Vapor Probe Kit (sterile) includes:

1. Mara Water Vapor Probe
2. Saline Delivery Conduit
3. Syringe
4. Saline Supply Line with spiked end

Medical Supplies

1. 1L bag of 0.9% Normal Saline*
2. Patient fluid/waste collection container
3. Uterine sound
4. 10 inch tenaculum, straight-arm with ratchet
5. Speculum



*It is recommended that Normal Saline should be supplied at body temperature.

Mara Setup

- Place the Mara Console on a steady surface next to the patient within sight of the physician.
- Attach the power cord to a grounded wall receptacle.
- Press the Front Panel Power Button on the Console to turn on the system.
- Lock the Saline Supply Hook for the saline bag in the upright position by raising and then rotating the Saline Supply Hook 180 degrees. Hang the saline bag on the Saline Supply Hook once it is locked in the upright position.
- When ready to use the Water Vapor Probe, remove it from its packaging using aseptic technique. **The numbers on the tray are provided as a guide for the removal order.**

Introduction to Using the System

Follow the Touchscreen Prompts on Console

GREEN ARROW in lower right-hand corner—displayed when system is ready to advance to the next step. Touch to proceed to the next step. For certain steps, the screen will automatically advance without the need to press the green arrow.

ORANGE ARROW in lower left-hand corner—available when the balloon inflation process has initiated prior to water vapor delivery. Touch if the physician wishes to deflate the balloons and remove the Water Vapor Probe from the patient to restart the insertion process.

Messages will display options for the user when:

- Tests do not pass
- System errors occur

Instructions

Turn on Console

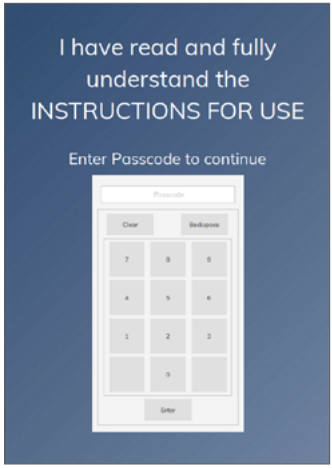
Screen indicates system is on.
No action needed.

System is self-testing.
No action needed.

Read Instructions for Use

Enter the device-specific passcode and press to confirm user has read and understands IFU.

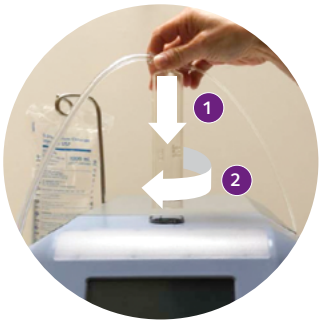
Note: Insert the speculum, and measure the length of the uterus from the external cervical ostium to the fundus using a uterine sound.



Insert Syringe into Console

Firmly insert, then rotate the Syringe clockwise to engage it in the Syringe Port on the top of the Console.

Note: The Syringe will illuminate **GREEN** to indicate proper insertion.



Firmly insert

Rotate clockwise

Connect Water Vapor Probe

1. Spike the Saline Bag with the Saline Supply Line.

Note: Ensure the Saline Supply Hook for the saline bag is locked in the upright position prior to hanging the saline bag.

2. Firmly insert the Cartridge into the Water Vapor Probe handle.

Tip: Momentarily press the Cartridge Release Button at the base of the Water Vapor Probe handle to facilitate insertion.

Note: Screen will automatically advance when Cartridge is connected properly.

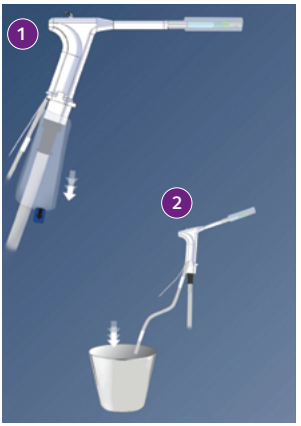
Momentarily Press Button

Cartridge is non-sterile. Handle separately from Water Vapor Probe to maintain sterility.

Insert Cartridge

Prep Cables and Tubes

1. Pull down on the Blue Tab at the base of the Water Vapor Probe handle to pull the Sterile Sheath over the Cartridge Cable.



2. Place the end of the Outflow Tube into a waste collection container. Be sure the distal tip of the Outflow Tube remains in the waste collection container for the remainder of the procedure.

Proper placement

Press **GREEN ARROW** when ready to proceed.

WARNING: Do not place the outlet end of the Water Vapor Outflow Tube into the upper portion of an under-buttock drape due to the risk of burn to the patient. Ensure the outlet end of the Water Vapor Outflow Tube is not submerged in fluid at any time during the procedure. The Outflow Tube carries water condensate and water vapor and could cause thermal injury. The perforated end section of the outflow tubing discharges water condensate and water vapor.

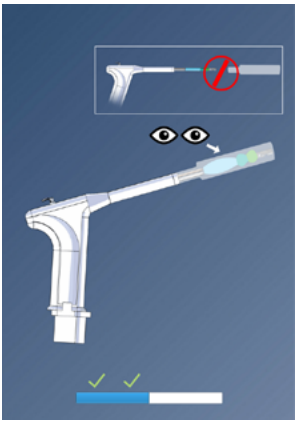
Water Vapor Probe Test

Visually confirm the inflation of all three balloons sequentially.

DO NOT remove the Water Vapor Probe tip cover.

Note: If one of the balloons does not inflate, **DO NOT** proceed. Press the **RED Treatment Interrupt Button** to disconnect and replace the Water Vapor Probe.

Note: The Water Vapor Probe tip, distal tip of the Water Vapor Probe and Water Vapor Probe Outflow Tube cover may feel warm to the touch as a result of the Water Vapor Probe Test.



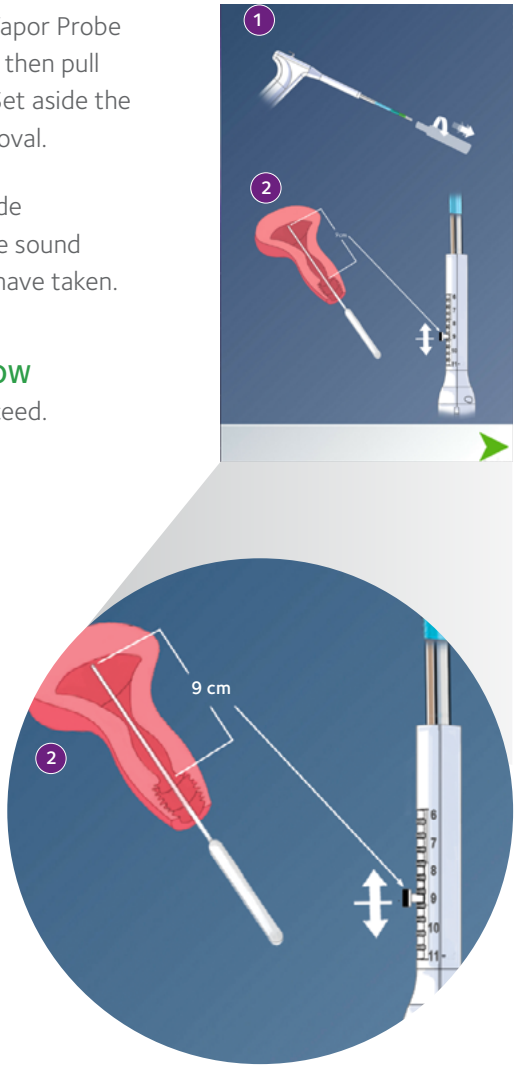
The Water Vapor Probe Test will perform 4 checks, as indicated by the **BLUE PROGRESS BAR** at the bottom of the Console screen. The software will automatically proceed when all 4 checks are complete (progress bar is full).

Set Uterine Measurement

1. Rotate the Water Vapor Probe tip cover clockwise then pull gently to remove. Set aside the tip cover upon removal.

2. Set the Cervical Slide Collar to the uterine sound measurement you have taken.

➤ Press **GREEN ARROW** when ready to proceed.



Insert Water Vapor Probe into Uterus

Note: Saline will begin flowing through the Water Vapor Probe and flow out of the Water Vapor Probe tip.

When saline is flowing insert the Water Vapor Probe into the uterus until the Cervical Collar reaches the exocervix.

WARNING: If a uterine perforation is suspected, the procedure should be terminated immediately. The patient should be evaluated for perforation prior to discharge.

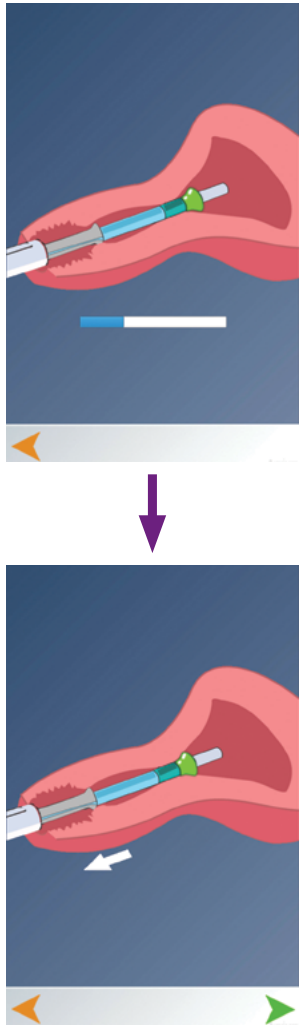
➤ Press **GREEN ARROW** when ready to proceed and start balloon inflation.

Internal Balloon Inflation

Once the internal balloon has inflated, gently pull back the Water Vapor Probe to confirm the internal balloon is seated at the internal cervical ostium.

Note: The **BLUE PROGRESS BAR** indicates the progress of balloon inflation.

➤ Press **GREEN ARROW** when ready to proceed.

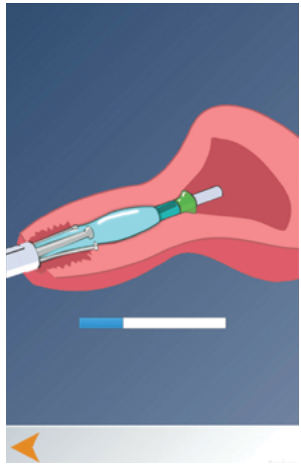


External and Middle Balloon Inflation

No Action Needed

Note: The **BLUE PROGRESS BAR** indicates the progress of balloon inflation.

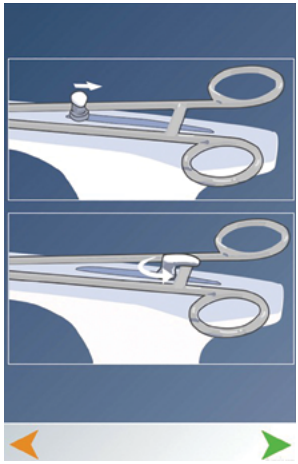
Note: **DO NOT** remove the speculum once the Water Vapor Probe is placed and all three balloons are inflated. Removing the speculum at this point could result in unintended movement of the Water Vapor Probe, which may lead to Integrity Test and Patency Test failures.



Place Tenaculum

- Place the tenaculum onto the Tenaculum Stabilizer.
- Slide the Tenaculum Stabilizer post backward until it touches the horizontal ratchet of the tenaculum.
- Rotate the Tenaculum Stabilizer over the horizontal ratchet of the tenaculum to lock in place.

Press **GREEN ARROW** when ready to proceed.

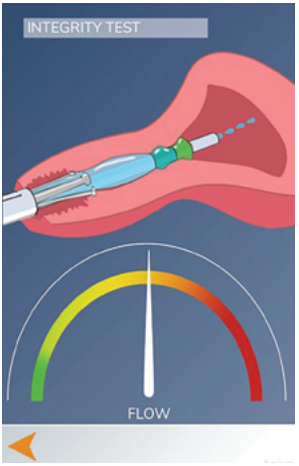


Integrity Test

No Action Needed

DO NOT move the Water Vapor Probe during this test.

Note: The pointer in the flow display will be pointing toward green when the saline flow is low and red when saline flow is too high to pass the test. The test successfully passes when the pointer remains in the green zone.



Integrity Test Failure

If Integrity Test does not pass, either:

- Retest by pressing the **GREEN ARROW**

or

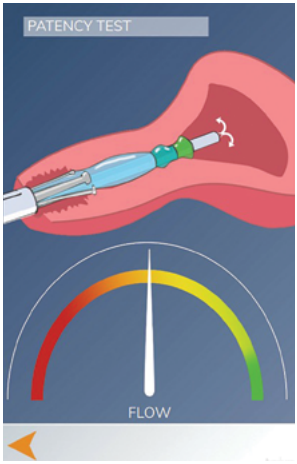
- Press the **ORANGE ARROW** to deflate the balloons and remove and reposition the Water Vapor Probe.

Patency Test

No Action Needed

DO NOT move the Water Vapor Probe during this test.

Note: The pointer in the flow display will be pointing toward green when saline flow is at appropriate level and red when saline flow is too low to pass the test. The test successfully passes when the pointer remains in the green zone.



Patency Test Failure

If Patency Test does not pass, either:

- Retest by pressing the **GREEN ARROW**

or

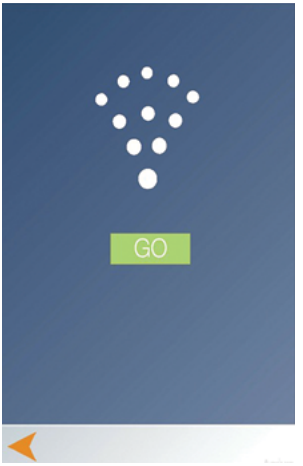
- Press the **ORANGE ARROW** to deflate the balloons and remove and reposition the Water Vapor Probe.

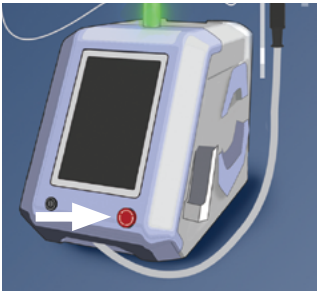
Note: If Retest is chosen, the Integrity Test will be automatically repeated prior to the Patency Test.

Start Water Vapor Treatment

Press “GO” to begin treatment and water vapor delivery. **DO NOT move the Water Vapor Probe during water vapor treatment to avoid injury.**

Note: The Outflow Tube carries water condensate and water vapor and could cause thermal injury. The perforated end section of the outflow tubing discharges water condensate and water vapor.



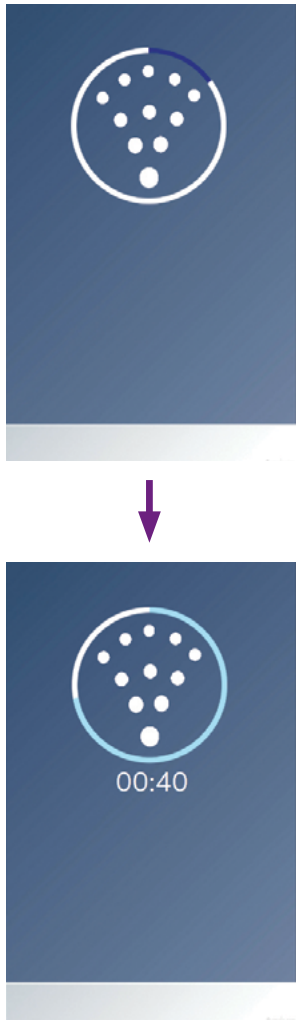


Note: The **RED TREATMENT INTERRUPT BUTTON** may be pressed at any time to stop treatment. Once engaged, turn the **RED TREATMENT INTERRUPT BUTTON** clockwise to release. Options to proceed are then given on the screen.

Water Vapor Treatment Begins

No Action Needed

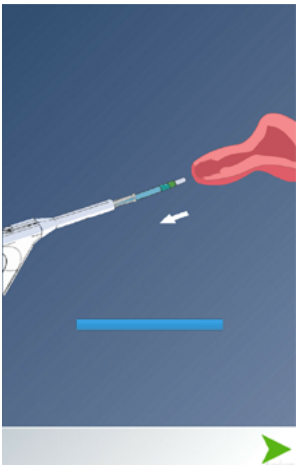
Note: The dark blue portion of circle denotes water vapor flush time period. There is an audible sound during water vapor delivery. The circle will fill in slowly with light blue until water vapor delivery is complete. The treatment clock will appear after the flush period.



Remove Water Vapor Probe

- Wait until the progress bar is all blue to indicate that the balloons have fully deflated.
- Detach the tenaculum from the Tenaculum Stabilizer.
- Remove the Water Vapor Probe from the uterus.

Press **GREEN ARROW** when ready to proceed.



Disconnect Water Vapor Probe and Syringe

Disconnect Water Vapor Probe

1. Gather the Sterile Sheath to expose the Cartridge.
2. While pressing the Cartridge Release Button at the base of the Water Vapor Probe handle, pull the black Cartridge from the handle to separate. Place the Cartridge back into the cradle on the side of the Console.

Press button to release

Disconnect Syringe

3. Rotate the Syringe counter clockwise to disconnect form the Syringe Port. Remove the saline bag with spiked Saline Supply Line from the Saline Supply Hook. Dispose per your institution's guidelines.

Turn Off Console

Press the Front Panel Power Button on the front of the Console to turn the unit off.

Rx Only

INDICATION FOR USE: The Mara Water Vapor Ablation System is indicated 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.

Summary of IMPORTANT SAFETY INFORMATION of the Mara Water Vapor Ablation System (Model GEN-16-050)

CONTRAINDICATIONS: The Mara Water Vapor Ablation System is contraindicated for use in: A patient who is pregnant or who wants to become pregnant in the future. PREGNANCIES FOLLOWING ABLATION CAN BE DANGEROUS FOR BOTH MOTHER AND FETUS; A patient with known or suspected uterine cancer or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia; A patient with endometrial hyperplasia as confirmed by histology; A patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy, including hysteroscopic and/or laparoscopic myomectomy performed immediately prior to the Mara Water Vapor Ablation System procedure); A patient currently on medications that could thin the myometrial muscle, such as long-term steroid use (except for inhaler or nasal therapy for asthma); A patient with a uterine length < 6cm (external cervical ostium to internal fundus); A patient with a history of a prior completed endometrial ablation procedure and/or endometrial resection (including endometrial ablation/resection performed immediately prior to the Mara Water Vapor Ablation System procedure) regardless of the modality by which it was performed; REPEAT ABLATION MAY RESULT IN SERIOUS PATIENT INJURY; A patient with active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis) at the time of treatment; A patient with bacteremia, sepsis or systemic infection; A patient with an intrauterine device (IUD) currently in place; A patient with active pelvic inflammatory disease or known or suspected hydrosalpinx based on history or ultrasound at screening; A patient with undiagnosed vaginal bleeding.

WARNINGS: Uterine perforation can occur during any procedure in which the uterus is instrumented. Use caution not to perforate the uterine wall when sounding, performing any hysteroscopic visualization of the uterus or dilatation of the endocervical canal if required, or inserting the Vapor Probe. Post-treatment, any patient-reported signs/symptoms that could indicate a serious complication, e.g., bowel injury, should be thoroughly evaluated without delay. For a detailed list of Warnings, please refer to the full Instructions for Use at www.maratreatment.com. Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

GENERAL WARNINGS: Endometrial ablation using the Mara Water Vapor Ablation System is not a sterilization procedure. Therefore, the patient should be advised of appropriate birth control methods. For a detailed list of General Warnings, please refer to the full Instructions for Use at www.maratreatment.com. Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

TECHNICAL WARNINGS: For a detailed list of Technical Warnings, please refer to the full Instructions for Use at www.maratreatment.com. Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

PRECAUTIONS: The structure of the endometrial cavity and uterine wall should be thoroughly evaluated to ensure suitability for thermal endometrial ablation. The Mara Water Vapor Ablation System procedure is intended to be performed only once during a single operative visit. For more details on Precautions, please refer to the full Instructions for Use at www.maratreatment.com. Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

ADVERSE EVENTS: The following device and procedure-related adverse events have been reported with use of the Mara Water Vapor Ablation System. The most common procedure-related complications for the Pivotal subjects within 1 year include: Uterine cramping (40%); Nausea (6.5%); Vomiting (3.2%); Vaginal infection (2.6%); Abdominal pain (2.6%); Abdominal Distention (1.9%); Endometritis (1.3%); Other events were limited to single occurrences (0.6%). For a detailed list of Adverse Events and Potential Adverse Events, please refer to the full Instructions for Use at www.maratreatment.com.

Other Adverse Events: As with ***all*** endometrial ablation procedures, serious injury or death can occur. The following adverse events could occur or have been reported in association with the use of other endometrial ablation systems and may occur when the Mara Water Vapor Ablation System is used: Post-ablation tubal sterilization syndrome; Pregnancy-related complications **Note: Pregnancy following any endometrial ablation procedure is dangerous to both the mother and the fetus;** Thermal injury to adjacent tissue including bowel, bladder, cervix, vagina, vulva and/or perineum, fallopian tubes, ureter; Perforation of uterine wall; Hemorrhage; Uterine necrosis; Air embolism; Infection or sepsis; Complications leading to serious injury or death; Cervical or vaginal laceration; Transient change in appearance of the cervical epithelium; Thermal injury to extremity; Mechanical bowel injury; Diarrhea; Headache.

For detailed information on the relevant Safety and Events information for the Mara Water Vapor Ablation System, please refer to the Instructions for Use at www.maratreatment.com.

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