

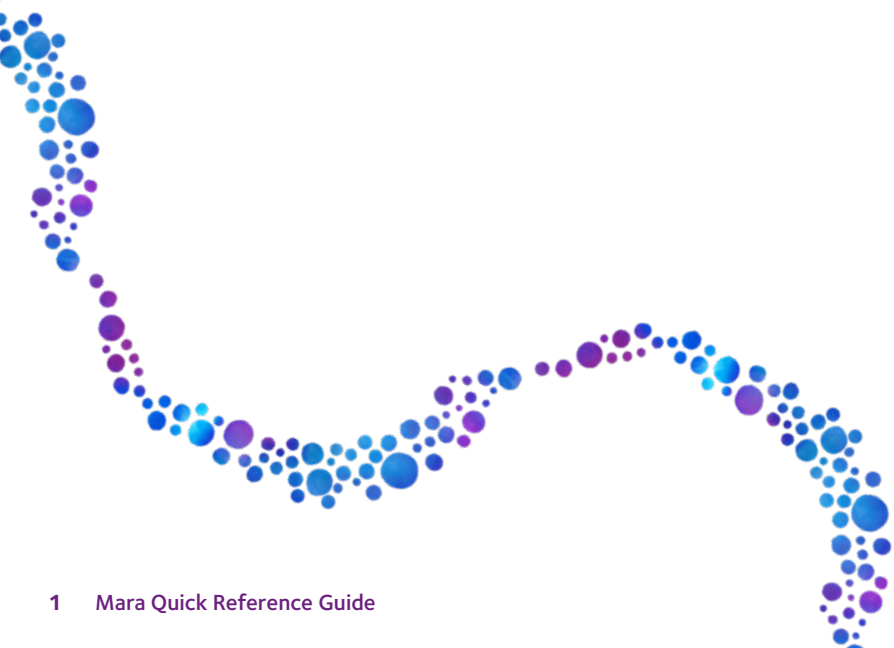
Mara™  
Water Vapor Ablation System

# 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

Indication for Use and Important Safety Information . . . . .	3
Equipment and Materials Checklist . . . . .	4
Mara Setup . . . . .	5
Introduction to Using the System . . . . .	6
Instructions . . . . .	7



## 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.

## Important Safety Information

Mara Water Vapor Ablation System is indicated to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. Pregnancy following the Mara procedure can be dangerous. The Mara procedure is contraindicated for those who have suspected uterine cancer, pre-malignant conditions of the endometrium, endometrial hyperplasia, prior classical cesarean section, transmural myomectomy (including myomectomy performed immediately prior to Mara procedure), taking medications that thin the uterine muscle, uterine length <6cm, prior endometrial ablation, active genital or urinary tract infection, PID, or systemic bacterial infection, IUD currently in place, suspected hydrosalpinx or undiagnosed abnormal vaginal bleeding. Mara is not a sterilization procedure. Rare but serious risks include, but are not limited to, perforation, infection, thermal injury, and serious complications in future pregnancies. Temporary side effects may include cramping, nausea, abdominal pain and distension, vomiting, vaginal infection, and endometritis. Inform patients to contact you if they experience a possible side effect related to Mara. For detailed benefit and risk information, please consult the IFU.

# 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

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- **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.

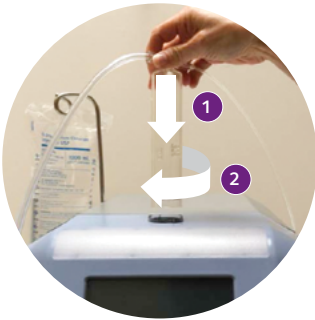
**Note:** Insert the speculum, and measure the length of the uterus from the external cervical ostium to the fundus using a uterine sound.



# 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.



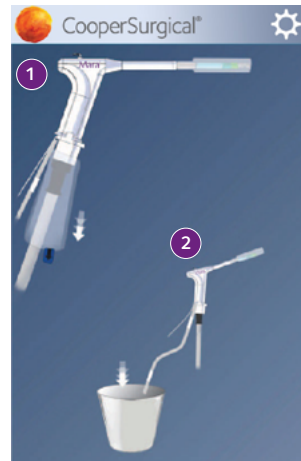
Momentarily Press Button

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

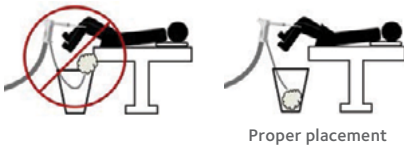
Insert Cartridge

# 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.



- 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.

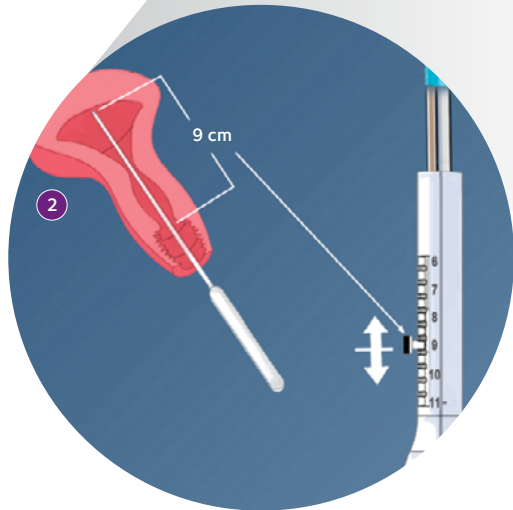
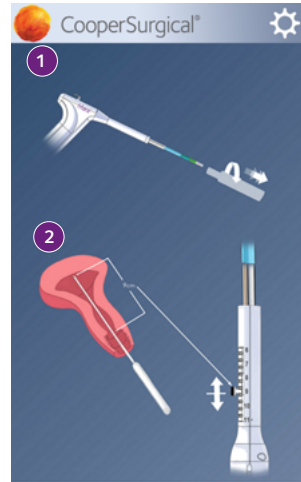
The Water Vapor Probe Test will perform 4 checks, as indicated by the **BLUE PROGRESS BAR** at the bottom of the Console screen. The software will automatically proceed when all 4 checks are complete (progress bar is full).



# 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.



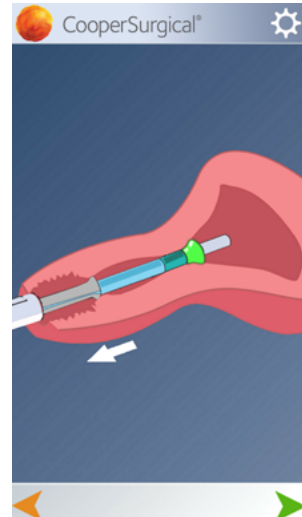
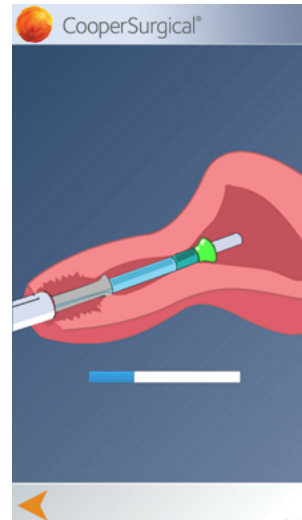


# Internal Balloon Inflation

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.

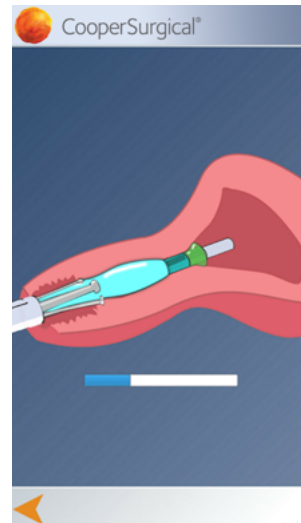


# External and Middle Balloon Inflation

## No Action Needed

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

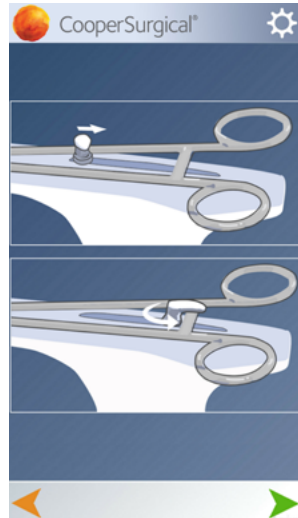
**Note:** **DO NOT** remove the speculum once the Water Vapor Probe is placed and all three balloons are inflated. Removing the speculum at this point could result in unintended movement of the Water Vapor Probe, which may lead to Integrity Test and Patency Test failures.



# 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.

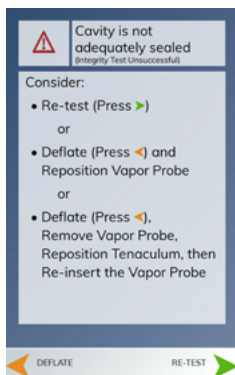


# Integrity Test

## 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:

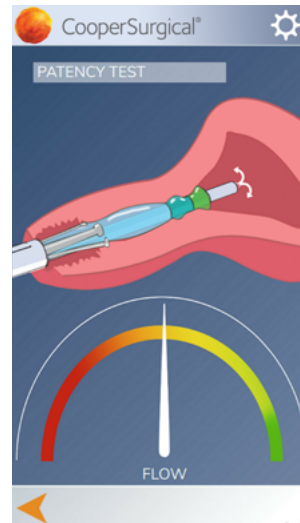
- Retest by pressing the **GREEN ARROW**
- or**
- Press the **ORANGE ARROW** to deflate the balloons and remove and reposition the Water Vapor Probe.


# 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.



**Vapor Probe Tip is Obstructed**  
(Patency Test Unsuccessful)

Consider:

- Re-test (Press ►)
- Adjust position of handle to match uterine version or flexion, then Re-test (Press ►)
- Ensure tip is not pressed into the fundus, then Re-test (Press ►)
- Deflate (Press ◀)
  - Check for tissue or blood on the tip
  - Ensure tip is not in false passage

 DEFLATE  RE-TEST

## Patency Test Failure

If Patency Test does not pass, either:

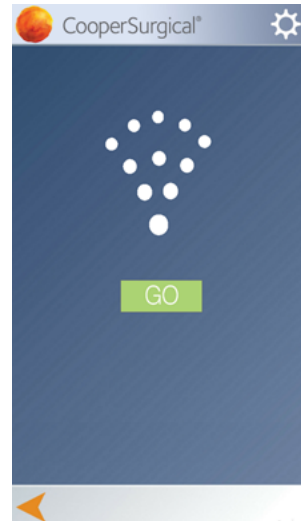
- Retest by pressing the **GREEN ARROW**
- or**
- Press the **ORANGE ARROW** to deflate the balloons and remove and reposition the Water Vapor Probe.

**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.

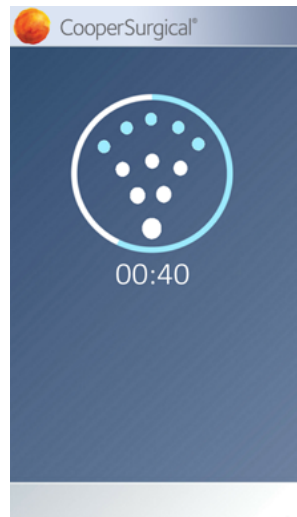
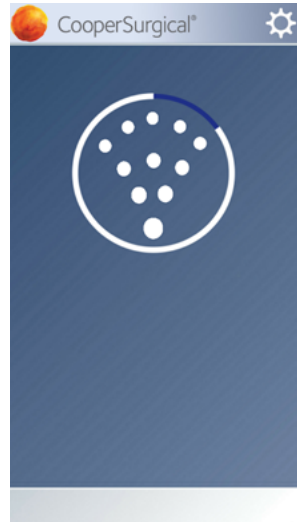


**Note:** The **RED TREATMENT INTERRUPT BUTTON** may be pressed at any time to stop treatment. Once engaged, turn the **RED TREATMENT INTERRUPT BUTTON** clockwise to release. Options to proceed are then given on the screen.

# Water Vapor Treatment Begins

## No Action Needed

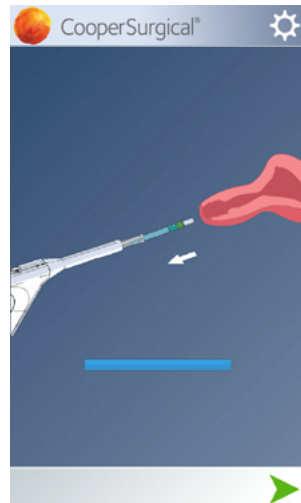
**Note:** The dark blue portion of circle denotes water vapor flush time period. There is an audible sound during water vapor delivery. The circle will fill in slowly with light blue until water vapor delivery is complete. The treatment clock will appear after the flush period.



## 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.





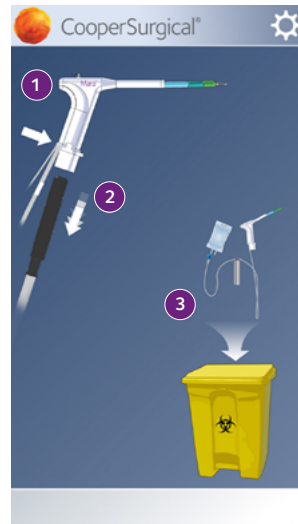
# Disconnect Water Vapor Probe and Syringe

## 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 from 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:**

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

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# Mara<sup>TM</sup>

[maratreatment.com](https://maratreatment.com)