

Minerva[®] Surgical Quick Reference Guide

This Quick Reference Guide does not replace Instructions For Use (IFU) or Operators Manual. Refer to the Instructions For Use (IFU) and Operators Manual for complete description of set-up, operation, and a complete list of Warnings, Cautions, and Contraindications.



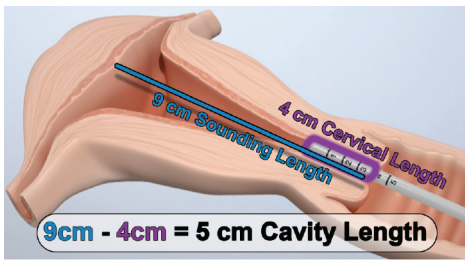
Doctor Instructions



Assistant Instructions



1.



Use caution not to perforate uterus when sounding and dilating. Confirm cervix is dilated to at least 7.0 mm.

DETERMINE CAVITY LENGTH to set the PFA (Plasma Formation Array) length: Obtain the uterine sound length (fundus to external cervical os). Then, use the Minerva Dilator or Hegar Dilator to measure the cervical canal length (internal cervical os to external cervical os). Calculate the length of the uterine cavity (Sound length – Canal length = Cavity length).



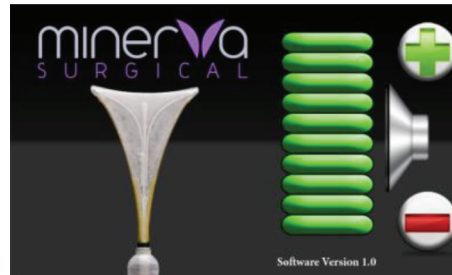
2.



CONNECT DESICCANT to the two ports on the tubing of the Minerva Disposable Handpiece until you feel or hear a click.



3.



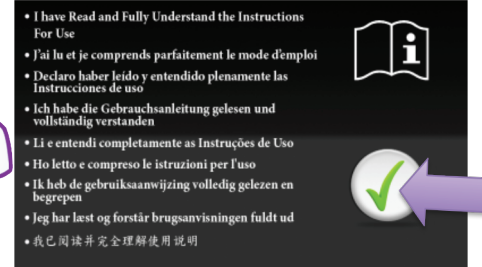
TURN ON CONTROLLER and adjust volume according to preference.

Volume Up Button.

Volume Down Button.



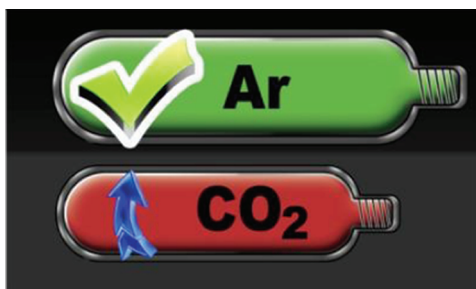
4.



PRESS THE GREEN CHECK MARK confirming your familiarity with the Minerva Operator's Manual and IFU.



5.



You have enough Argon.

Replace CO2 gas canister.

CONFIRM CANISTERS ARE FULL If either one or both gas canister icons appear red, remove and replace with a new canister(s) until both canisters icons are green.



6.



CONNECT HANDPIECE & FOOTSWITCH to the appropriate port on the front panel of the Minerva RF Controller.

7.



Minerva Handpiece Test Successful.

AUTOMATIC HANDPIECE TEST is performed by the Minerva RF Controller. If test fails disconnect and re-connect handpiece to re-start test. NOTE: Steps 7 & 8 must be performed with device outside of patient.



8.



Press toggle switch to set the PFA Length using cavity length calculated in step 1.

SET THE PFA LENGTH according to the uterine cavity length (Step 1) before inserting device.



9.

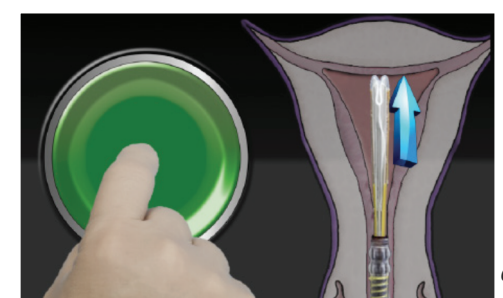


Vacuum minimizes PFA for transcervical insertion.

PRESS & HOLD GREEN BUTTON on Display when doctor is ready to insert the device transcervically. If difficult to insert, consider if further dilation is required for safe insertion. Use caution not to perforate the uterine wall.



10.

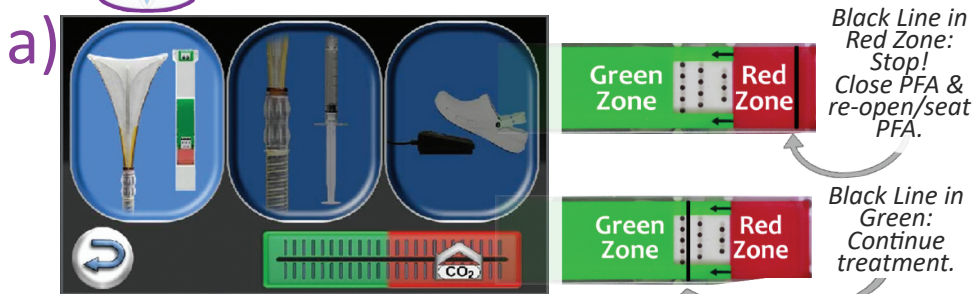


Release green button after the device is inserted and before the surgeon opens the PFA.

RELEASE GREEN BUTTON on the Display after the device is inserted and distal tip of the PFA touches the Fundus.



11. COMPLETE THE THREE STEPS:



OPEN AND SEAT PFA by gently moving the handpiece 0.5cm to and from the fundus until handles lock. Confirm Black line on the Array Opening Indicator is in green zone. DO NOT TREAT IF IN RED ZONE.

INFLATE CERVICAL SEALING BALLOON. Confirm the CO2 arrow icon has moved into the green zone.

TAP THE FOOTSWITCH to begin uterine integrity test (UIT). Upon passing, 120 second ablation countdown begins on display. If UIT fails, see the troubleshooting guide on reverse side.

12.



PROCEDURE COMPLETE:

A) Deflate Cervical Sealing Balloon - by pulling back syringe plunger.

B) Unlock Device Handles and slowly withdraw the Minerva Disposable Handpiece from the patient.

Troubleshooting

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SCENARIOS

Muscle Stimulation

If a muscle stimulation is observed anytime during the procedure, replace the handpiece.

Note: Muscle stimulation can sometimes occur when there is a change in the RF current path. This stimulation is transient.



Missing Desiccant

If the desiccant is missing, or has not been attached properly, this image will appear on the touch screen display shortly after the Minerva Disposable Handpiece is connected to the Minerva RF Controller. Securely attach both ends of the desiccant to the Minerva Disposable Handpiece cord. When properly connected you will feel or hear a click.



Plasma Formation Error or Membrane Defect Detected

If 002 Error Code appears, replace the handpiece.



Failed Uterine Integrity Test

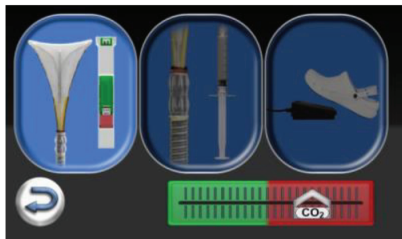
The Uterine Integrity Test will check for possible uterine perforations. If the UIT fails, a brief tone will sound and this image will appear on the touch screen display. If a perforation is suspected, the procedure should be terminated immediately. To rule out a perforation, it may include device removal and hysteroscopic assessment of the uterine cavity for presence of defects, and observation of adequacy of uterine distention.

After ruling out the perforation, trouble shoot using the following steps:

Return to the Minerva Disposable Handpiece deployment screen by pressing the "return" button in the lower left hand corner of the image on the touch screen display.



Return Button



Re-check for leaks between the cervix and Cervical Sealing Balloon by monitoring the CO₂ Flow Rate Indicator image on bottom edge of the touch screen display.



CO₂ Flow Rate Indicator

Remove the Minerva Disposable Handpiece from uterus and verify Cervical Sealing Balloon integrity by inflating the Cervical Sealing Balloon and checking for leaks. If the Cervical Sealing Balloon does not remain inflated, replace Minerva Disposable Handpiece. If the leak appears to be at the cervix and cannot be resolved by using the Cervical Balloon, add one more syringe of air to the balloon, and/or use another tenaculum to grasp and tighten the cervix around the sheath. Repeat the UIT by tapping and releasing the foot switch once the CO₂ indicator is in the green zone.

Always use good clinical judgment and consider terminating the procedure if the Uterine Integrity Test continues to fail after a reasonable number of attempts to prevent serious patient injury.

Complete Error Message List

Error	Description	Required Action
001, 005, 011	Handpiece Defect Error	Replace with new Disposable Handpiece
002	If error occurs after start of 120 second ablation countdown: Membrane Defect Detected	Replace with new Disposable Handpiece
003, 004, 007, 008, 009, 010, 012, 016	Argon Flow Related Error	Replace with new Disposable Handpiece
006	Plasma Formation Error	Disconnect Disposable Handpiece, remove the device from the patient, re-connect the same device, re-insert, re-position, and re-attempt the start of ablation. If error recurs, replace with new Disposable Handpiece.
013, 014	Gas Canister Error	Disconnect Disposable Handpiece, remove the device from the patient, re-connect the same device, re-insert, re-position, and re-attempt the start of ablation.
015	Pause Time Expired Error	Disconnect Disposable Handpiece, remove the device from the patient, re-connect the same device, re-insert, re-position, and re-attempt the start of ablation.
101- 403	System Errors	Stop the treatment and turn the power off using the toggle switch on the back of the controller. Disconnect Disposable Handpiece and remove the device from the patient. Turn the power back on. When the error code clears, proceed with treatment. If the error code does not clear: <ul style="list-style-type: none"> - Note the error code displayed - Call Minerva Surgical at 1-855-646-7874