NovaSure®
Endometrial Ablation

Quick Reference Guide to Performing the Procedure

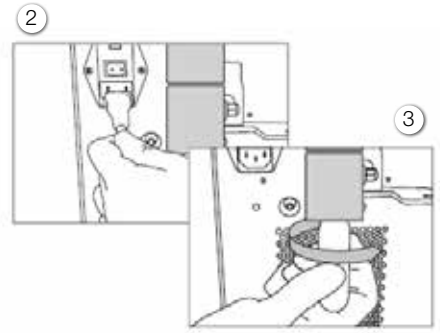
This Quick Reference Guide is designed to be used in conjunction with, but not replace, the NovaSure Instructions for Use and Controller Operators Manual. Prior to performing the procedure, the physician must review, and be familiar with, the full operating instructions for the Controller and Disposable Device, as well as any warnings, contraindications, and safety information.

Required System Components:

A. One sterile, single-patient use, NovaSure Disposable Device
B. Connecting cord (attached to Disposable Device)
C. NovaSure Radiofrequency Controller
D. NovaSure footswitch
E. NovaSure AC power cord
F. One NovaSure non-sterile suction line desiccant assembly
G. One NovaSure CO_2 canister

Preparing the NovaSure RF Controller:

1. Place it on a small sturdy table to one side of the patient within the visual field of the surgeon.
2. Attach the AC power cord to the controller and plug it into the outlet.
3. Screw the CO_2 canister into the regulator on the back panel of the controller until tightened.
4. If equipped with a CO_2 knob, fully rotate to the "HI" position.
5. Press the toggle switch on the back panel of the controller into the "ON" position.
6. Connect the footswitch to the appropriate port on the front panel of the controller.

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Steps of the NovaSure® Procedure

For the Staff

Step 1: After the physician measures the cavity length and determines the length is ≥ 4 cm, open the sterile NovaSure disposable device package.

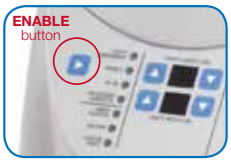

Desiccant Filter

Step 2: Place the disposable device with the connecting cord into the sterile field while keeping the non-sterile suction line desiccant box out of the sterile field.

Step 3: Open the non-sterile suction line desiccant box and pouch. Remove the red caps. (If the desiccant is pink, replace it prior to initiating the ablation.)

Step 4: Connect the barbs on the desiccant to the suction tubing of the disposable device.

Step 5: Connect the disposable device cord to the appropriate port on the front of the controller.



Step 6: Key in the value obtained for length, as dictated by the physician, into the NovaSure RF controller length LED by depressing the UP/DOWN arrows.

Step 7: Key in the width indicated on the WIDTH dial, as dictated by the physician, into the NovaSure RF controller width LED by depressing the UP/DOWN arrows.

Step 8: After the physician steps on the foot pedal and the cavity integrity test assessment is complete, press the ENABLE button on the controller.

Step 9: Once the procedure is complete and the physician removes the disposable device from the patient, turn off the NovaSure controller and close the CO_2 regulator (if equipped).

For the Physician

Step 1: Insert a speculum into the vagina and grasp the cervix with a tenaculum.

Step 2: Sound the uterus and measure the cervix to determine the cavity length. (Use the SureSound® device to determine uterine cavity measurement, if available.) Ensure, the cavity length is ≥ 4 cm.

Step 3: Once the staff connects the disposable device to the controller, squeeze the handles of the disposable device until they lock to ensure the controller ARRAY POSITION LED extinguishes and the WIDTH dial reads ≥ 2.5 cm. Once ensured, press the lock release button and separate the device handles to retract the array.


Lock Release Button

Step 4: Adjust and lock the cavity length setting feature on the disposable device to the cavity length value obtained. The staff will input the length value into the controller.


Cavity Length Setting

Step 5: Confirm that the cervix is dilated to 8.0 mm.

Step 6: Maintaining a slight traction on the tenaculum, hold the front handle of the device to insert the device in line with the axis of the uterus until the distal end reaches the fundus.

Step 7: Withdraw the disposable device approximately 0.5 cm from the fundus. Slowly squeeze handles up to the point of increased resistance (DO NOT LOCK). The width dial should read approximately 0.5 cm.

Step 8: Slowly squeeze the device handles together while gently moving the device ~0.5 cm to and from the fundus and rotating the handle of the disposable device 45° clockwise and counterclockwise from the vertical plane until the handles lock.

Step 9: Once locked, gently move the device using anterior, posterior and lateral movements. To complete placement, slightly pull back the device until the WIDTH dial reading reduces 0.2-0.5 cm.

Step 10: Holding the tenaculum, advance the disposable device slowly and gently to the fundus. The width should read greater than or equal to the previous measurement.

Step 11: Slide the cervical collar to the cervix using the thumb tab.

Step 12: Determine the width value from the width gauge. Ensure that the cavity width is ≥ 2.5 cm. Ask the staff person to input the width value into the controller.


Thumb Tab

Step 13: Press the foot pedal to begin the cavity integrity assessment.

Step 14: Once the cavity integrity assessment is complete and the staff presses the ENABLE button on the controller, press the foot pedal to initiate the ablation cycle.

Step 15: Once the ablation is complete (indicated by a solid green PROCEDURE COMPLETE LED), fully retract the cervical collar by sliding it to its proximal position.

Step 16: Unlock the disposable device by pressing the lock release button. Close the disposable device by holding the front handle stationary and gently pulling the rear handle backwards.

Step 17: Remove the disposable device from the patient.