

NovaSure®

Customized Treatment. Proven Outcomes.



Quick Reference Guide

This Quick Reference Guide is designed to be used in conjunction with, 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.

Pre-Procedure Set-up Reference

Required System Components



- > One sterile, single-patient use, NovaSure Disposable Device.
- > One NovaSure RF Controller.
- > One NovaSure Footswitch.
- > One NovaSure AC Power Cord.
- > One NovaSure Non-Sterile Suction Line Desiccant Assembly.
- > One NovaSure CO₂ Canister.

Prepare the Novasure RF Controller.

- > Prepare the NovaSure RF Controller. Place it on a small table to one side of the patient within the visual field of the surgeon.



- > Attach AC Power Cord to the RF Controller and plug into AC outlet.



- > Screw the CO₂ Canister into the regulator on the back panel of RF Controller until tightened.



- > If RF Controller is equipped with a regulator knob, fully rotate the CO₂ regulator knob into the HI position. If not equipped, continue set-up.



- > Press the toggle switch on the back panel of the RF Controller into the "ON" position.



- > Connect the foot switch to the appropriate port on the front panel of the RF Controller.

Prepare the Disposable Device.

- > Open the sterile Novasure Disposable Device package.
- > Place the Disposable Device with the connecting cord into the sterile field.
****Keep the Non-Sterile Suction line Desiccant box out of the sterile field.****
- > Open the Non-Sterile Suction line Desiccant pouch and remove the red caps.
- > **CAUTION:** If the Desiccant is pink, then replace it prior to initiating the ablation procedure.
- > Connect the Desiccant to the barbs on the suction tubing of Disposable Device.
- > Ensure the barbs are fully inserted into the tubing on the Desiccant.
- > Connect the Disposable Device cord to the appropriate port on the front panel of the RF Controller.



Enter uterine cavity measurements.



- > Key in uterine cavity length to Cavity Length LED by depressing the Up/Down Arrows.
- > Key in uterine cavity width to Cavity Width LED by depressing the Up/Down Arrows.

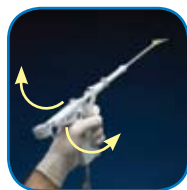
Procedure Initiation.



- > After successful completion of the Cavity Integrity Assessment, press the ENABLE button.
- > The surgeon may now depress the footswitch to initiate the ablation cycle.

Seating Technique

WARNING: If the Disposable Device is difficult to insert into the cervical canal, use clinical judgment to determine whether or not further dilation is required.



Rotate Handle



- > 1. Insert the Disposable Device transcervically at the angle of the uterus, into the uterine cavity. Advance Disposable Device until distal end of sheath touches the fundus.
- > 2. Maintain a reference point at the fundus. Slowly squeeze the handles (DO NOT LOCK) up to the point of increased resistance. DO NOT pull the Disposable Device back from the fundus. The WIDTH dial should read approximately 0.5cm. At this point the external sheath has been retracted.
- > 3. Continue to slowly squeeze the Disposable Device handles together while gently moving the Disposable Device 0.5cm to and from the fundus and rotating the handle of the Disposable Device 45° counterclockwise from the vertical plane and 45° clockwise from the vertical plane until the handles lock. The WIDTH dial should read greater than 2.5cm.
- > Once the Disposable Device handles are locked, the uterus should move in conjunction with the Disposable Device.
- > 4. Gently move the Disposable Device using anterior, posterior and lateral movements.
- > 5. To complete placement, slightly pull back the Disposable Device until the WIDTH dial reading reduces by approximately 0.2-0.5cm.



- > 6. Hold the tenaculum, advance the Disposable Device firmly to the fundus, maintaining slight forward pressure. The WIDTH dial should read greater than or equal to the previous measurement.
- > 7. Slide the Cervical Collar forward until it forms a seal against the external cervical os. Lock in place by depressing the locking tab by applying firm pressure until you hear it click.
- > 8. Read the cornu-to-cornu measurement (2.5cm minimum) on the WIDTH dial indicator. **If device cannot be seated to achieve a width gauge reading greater than 2.5cm, abort procedure.**
- > 9. At this point the CIA can be initiated by depressing the footswitch.

Cavity Integrity Assessment

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Cavity Integrity Assessment (CIA) failure is identified by an audible alarm, coupled with a steady red illumination of the CAVITY ASSESSMENT LED.



If a perforation is suspected, the procedure should be terminated immediately.



- > Press footswitch to silence alarm.
- > Unlock the Cervical Collar by releasing the locking tab by applying firm pressure until you hear an audible click.
- > Advance the Cervical Collar only to the point where the flange on the collar head meets the external cervical os.



- > Lock the collar in place by depressing the locking tab.



- > Repeat assessment test by pressing footswitch.



- > CIA LED steady Green = **Go to ablation cycle.**



- > CIA LED steady Red = **Continue Troubleshooting steps.**

Note: CO₂ leakage may occur at the external cervical os due to an over-dilated cervix. Visible bubbles or the audible sounds of escaping gas may accompany CO₂ leakage under these conditions.



- > Check for leaks in the system, and between the cervix and Cervical Collar.
- > Be sure to check all tubing and luer connections, and ensure that a suction line Desiccant has been installed.
- > If CO₂ leak appears to be at the cervix and cannot be resolved by using the Cervical Collar, use a 2nd tenaculum to grasp the cervix around the sheath.
- > Repeat assessment test by pressing footswitch.

IF THE CAVITY INTEGRITY ASSESSMENT FAILS AFTER REASONABLE ATTEMPTS TO IMPLEMENT THE TROUBLESHOOTING PROCEDURES, ABORT THE PROCEDURE.

Vacuum LED Illuminated

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Vacuum alert is identified by a steady red illumination of the VACUUM LED. No audible tone will occur with a Vacuum alert*



*In some Model 09 RF Controllers, a vacuum pre-check occurs automatically prior to initiation of the ablation cycle. The VACUUM LED will flash and an audible tone will be heard for up to 10 seconds during the vacuum pre-check.



- > Gently actuate vacuum relief valve using a 2-3.5mm uterine sound.



- > Advance and hold the Cervical Collar against the cervix.
- > Ensure the suction canister on the Disposable Device is vertical and the device tubing is not draped over the patient's leg.



- > Tighten the two luer locks below the Disposable Device handle.

Vacuum LED
Illuminated



- > Clear VACUUM LED illumination by pressing the ENABLE button.



- > **Press the ENABLE button and reattempt ablation.**

- > If problem persists Vacuum LED = **Steady Red:**



- > Disconnect Disposable Device from the RF Controller

- > Remove Disposable Device from the patient.



- > Disconnect the luer locks on both lines below the handle.

- > Deploy the Disposable Device in the air and flush the lines in the direction of the handles using 40cc of saline, followed by 40cc of air.

- > Reconnect the Disposable Device to the RF Controller.

- > Reinsert the Disposable Device and **reattempt ablation.**

- > If problem persists, exchange Disposable Device for a new Disposable Device.

- > If Suction line Desiccant is saturated with fluid, and white circular filter is wet, exchange Disposable Device for a new Disposable Device.

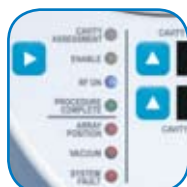
- > Repeat the procedure. If the VACUUM LED illuminates a third time, remove the Disposable Device and abort the procedure.

Array Position LED Illuminated

Electrode Array Position alert is identified by a steady red illumination of the ARRAY POSITION LED. No audible tone will occur with an Electrode Array Position alert.



If Width Dial reading on Disposable Device is less than 2.5cm:



> Gently move the proximal end of the Disposable Device and observe if ARRAY POSITION LED extinguishes. If it does not, proceed with the following:



> Attempt gently reseating of the NovaSure Disposable Device.

> Partially retract the array into the sheath by releasing the Disposable Device handle lock release button.



> Pull the Disposable Device back slightly from fundus.

> Slowly redeploy the Disposable Device while gently rocking the Disposable Device back and forth and locking the Disposable Device handles.



> Reseat the Disposable Device.

- > Use caution with a retroverted uterus. Apply gentle caudad traction to the cervix with the tenaculum, and elevate the Disposable Device handle upward, in-line with the axis of the uterus, while performing seating technique.



- > Proceed with ablation.
- > **If device cannot be resealed to achieve a width gauge reading greater than 2.5cm, abort procedure.**

If Width Dial reading on Disposable Device is greater than 2.5cm:



- > Fully retract the array and remove the Disposable Device from the patient.
- > External to patient, deploy Array and ensure the electrode array is undamaged and that ARRAY POSITION LED extinguishes.
- > Attempt reinsertion, redeployment, and reseating of Disposable Device.
- > If ARRAY POSITION LED remains illuminated, replace with a new Disposable Device.
- > If ARRAY POSITION LED remains illuminated with new Disposable Device, terminate the procedure.



Additional Reference

CO₂ canister Low or Empty.

NovaSure RF Controller will generate an audible alarm when the CO₂ canister is low or empty.

LEDs illuminated prior to alarm will remain in the same state during the CO₂ event.

Pressing the footswitch will not turn off the audible alarm.



- > Replace the CO₂ canister to stop the audible alarm.

Note: It is not necessary to remove the Disposable Device from the patient prior to replacing the canister.

- > Continue with procedure.

Enable LED will not illuminate.

Be sure:



- > The Enable button is firmly depressed.

- > The RF Controller is plugged in.



- > The toggle switch at the back of the RF Controller is on.



- > The ARRAY POSITION LED is not illuminated.

System Fault



- > System Fault LED illuminates Red if the system faults, or if there is a self-diagnostic failure with the system clock or power delivery.
- > If this event occurs, terminate the procedure immediately and contact an authorized Hologic Sales Representative for instructions.

Replacement Instructions

- > Any potentially defective NovaSure product must be returned to Hologic for evaluation.
- > Follow the instructions in the NovaSure Instructions For Use and Controller Operators Manual for obtaining a Returned Materials Authorization number (RMA#). Do not discard the NovaSure Disposable Device.

Procedural Information

- > If any hysteroscopy procedure is performed with hypotonic solution immediately prior to the NovaSure treatment, then the uterine cavity must be flushed with normal saline prior to treatment with the NovaSure System. The presence of hypotonic fluid may reduce the efficiency of the NovaSure System.

RF Controller Information

- > RF power delivery can be stopped at any time by pressing the footswitch.

Disposable Device Information

- > The NovaSure Disposable Device does not contain latex.

