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**CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN TRAINED IN THE USE OF THE DEVICE.**

Read all instructions, cautions and warnings prior to use. Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.

**NOTE:** The manual that accompanied the disposable device may contain a more recent revision of the NovaSure® system instructions than the manual provided with the controller.

The NovaSure® disposable device is not to be used with other controllers and/or RF generators, and the NovaSure RF® controller is not to be used with other disposable devices.

The NovaSure disposable device does not contain latex.

## Physician Checklist

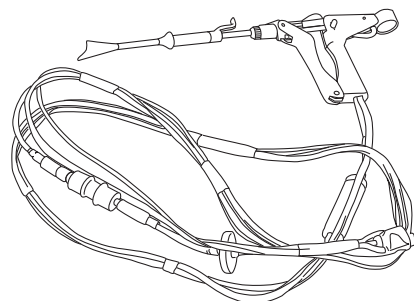
The physician must:

- have sufficient experience in performing procedures within the uterine cavity, such as IUD insertion or dilation and curettage (D&C) and with adequate training, knowledge and familiarity using the NovaSure system;
- review and be familiar with the instructions and complete either NovaSure training or be trained by a qualified physician;
- be aware of the appropriate sequence of actions detailed in the Instructions for Use and Troubleshooting sections of this manual to abort, resolve and/or continue the treatment in the event the system detects a loss of CO<sub>2</sub> during the cavity integrity assessment (CIA), which indicates a possible uterine perforation.

Adjunct personnel must be familiar with these instructions and other training materials prior to using the NovaSure system.

## System Description

The NovaSure® impedance controlled endometrial ablation system consists of the NovaSure disposable device with connecting cord, NovaSure RF controller (controller), NovaSure® CO<sub>2</sub> canister, desiccant, foot switch and power cord, which are designed to be used together as a system.



**NovaSure Disposable Device with Connecting Cord, Including Suction Line Desiccant**

## NovaSure Disposable Device Description

The NovaSure disposable device consists of a single-patient use, conformable bipolar electrode array mounted on an expandable frame that can create a confluent lesion on the entire interior surface area of the uterine cavity. The disposable device is inserted transcervically

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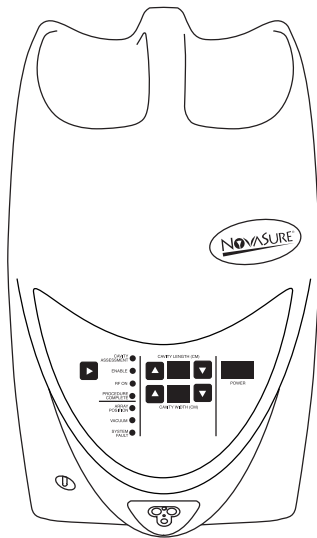
into the uterine cavity, and the sheath is retracted to allow the bipolar electrode array to be deployed and conform to the uterine cavity.

The bipolar electrode array is formed from a metalized, porous fabric through which steam and moisture are continuously suctioned from the desiccated tissue. The disposable device works in conjunction with a dedicated NovaSure RF controller to perform customized, global endometrial ablation in an average of approximately 90 seconds without the need for concomitant hysteroscopic visualization or endometrial pretreatment. The specific configuration of the bipolar electrode array and the predetermined power of the controller create a controlled depth of ablation in uteri sounding less than or equal to 10 cm and having a minimum cornu-to-cornu distance of 2.5 cm.

During the ablation process, the flow of radio frequency (RF) energy vaporizes and/or coagulates the endometrium regardless of its thickness and desiccates and coagulates the underlying, superficial myometrium.

The controller automatically calculates the optimal power level (W) required for the treatment of the uterine cavity, based on uterine size. As tissue destruction reaches an optimal depth, increasing tissue impedance causes the controller to automatically terminate power delivery, thereby providing a self-regulating process. Blood, saline and other liquid present in the uterine cavity at the time of the procedure, as well as vapor liberated from the desiccated tissue, are evacuated by continuous, automatic suctioning.

The disposable device is connected to the controller via a cord containing the RF cable, suction tubing used for pressure monitoring during the cavity integrity assessment cycle and for suction during the ablation cycle, and vacuum feedback tubing used for carbon dioxide delivery during the cavity integrity assessment cycle and vacuum monitoring during the ablation cycle.



**NovaSure RF Controller**

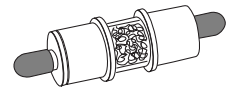
### **NovaSure RF Controller Description**

The NovaSure RF controller is a constant power output generator with a nominal maximum power delivery capability of 180 watts. The controller automatically calculates the power output based on the uterine cavity length (sound measurement minus the length of the endocervical canal) and width measurements that the user key-enters into the controller. Monitoring tissue impedance during the ablation process automatically controls the depth of endo-myometrial ablation. The NovaSure® procedure self-terminates once endometrial vaporization and superficial

myometrial desiccation have reached 50 ohms of impedance at the tissue-electrode interface, or when the treatment timer reaches two minutes. Integral to the controller is the cavity integrity assessment system (CIA) which is designed to determine whether there is a defect or perforation in the wall of the uterus. After the disposable device is placed into the uterine cavity, CO<sub>2</sub> is delivered through the central lumen of the disposable device into the cavity, via the vacuum feedback tubing, at a safe flow rate and pressure. If the CO<sub>2</sub> pressure in the cavity is maintained for a short period of time, indicating that the uterine cavity is intact, then the CIA will allow the NovaSure RF controller to be enabled and proceed with the treatment phase. A vacuum pump contained within the NovaSure RF controller creates and maintains a vacuum in the uterine cavity throughout the endometrial ablation procedure. Once the vacuum is stabilized, the vacuum level is monitored throughout the remainder of the ablation process.

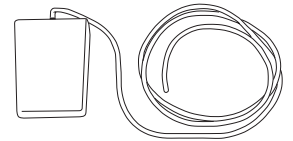
### **NovaSure® Suction Line Desiccant Description**

The NovaSure suction line desiccant is a non-sterile, single-patient use component that the user attaches in-line with the suction tubing, prior to connecting the disposable device to the NovaSure RF controller. The desiccant absorbs the moisture removed from the uterine cavity via the suction tubing during the ablation procedure.



### **NovaSure® Foot Switch Description**

The NovaSure foot switch is a pneumatic switch that connects to the NovaSure RF controller front panel. It is used to activate the NovaSure RF controller and does not contain any electrical components.



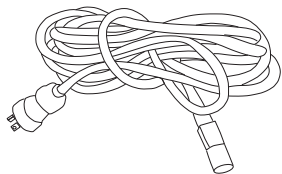
### **NovaSure CO<sub>2</sub> Canister Description**

The NovaSure CO<sub>2</sub> canister is a 16-gram, medical grade CO<sub>2</sub> canister. It is attached to the regulator located on the back panel of the NovaSure RF controller prior to applying line voltage to the NovaSure RF controller. The CO<sub>2</sub> is used by the cavity integrity assessment system to pressurize the uterine cavity.



### NovaSure® AC Power Cord Description

The NovaSure AC power cord, a medical grade cord, connects the NovaSure RF controller to the appropriate line voltage. The receptacle for the power cord, the power input module, is located on the back panel of the NovaSure RF controller.



### INDICATIONS

The NovaSure system is intended to ablate the endometrial lining of the uterus in pre-menopausal women with menorrhagia (excessive bleeding) due to benign causes for whom childbearing is complete.

### CONTRAINDICATIONS

The NovaSure impedance controlled endometrial 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 endometrial carcinoma (uterine cancer) or pre-malignant conditions of the endometrium, such as unresolved adenomatous hyperplasia.
- a patient with any anatomic condition (e.g., history of previous classical cesarean section or transmural myomectomy) or pathologic condition (e.g., long-term medical therapy) that could lead to weakening of the myometrium.
- a patient with active genital or urinary tract infection at the time of the procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis or cystitis).
- a patient with an intrauterine device (IUD) currently in place.
- a patient with a thermally conductive object (e.g., metal implant) present in the uterus or in the uterine cavity, where the object could potentially come in direct contact with or close proximity to the heat generating portion of the endometrial ablation device. If this occurs, heat will be drawn away from the intended treatment area toward other tissue and/or organs in contact with the conductive object, which may be sufficient to cause localized burns.
- a patient with a uterine cavity length less than 4 cm. The minimum length of the electrode array is 4 cm. Treatment of a uterine cavity with a length less than 4 cm will result in thermal injury to the endocervical canal.
- a patient with a uterine cavity width less than 2.5 cm, as determined by the WIDTH dial of the disposable device following device deployment.
- a patient with active pelvic inflammatory disease.

### WARNINGS

**FAILURE TO FOLLOW ANY INSTRUCTIONS OR FAILURE TO HEED ANY WARNINGS OR CAUTIONS COULD RESULT IN SERIOUS PATIENT INJURY.**

**THE NOVASURE DISPOSABLE DEVICE MUST BE USED ONLY IN CONJUNCTION WITH THE NOVASURE RF CONTROLLER.**

**THE NOVASURE PROCEDURE IS INTENDED TO BE PERFORMED ONLY ONCE DURING A SINGLE OPERATIVE VISIT. THERMAL INJURY TO THE BOWEL MAY OCCUR WHEN MULTIPLE NOVASURE THERAPY CYCLES ARE PERFORMED DURING THE SAME OPERATIVE VISIT.**

### Uterine Perforation

- Use caution not to perforate the uterine wall when sounding, dilating or inserting the disposable device.
- If the disposable device is difficult to insert into the cervical canal, use clinical judgment to determine whether or not further dilation is required.
- The NovaSure system performs a cavity integrity assessment (CIA) to evaluate the integrity of the uterine cavity and sounds an alarm warning of a possible perforation prior to treatment (Step 2.36). **(Although designed to detect a perforation of the uterine wall, it is an indicator only and it might not detect all perforations under all possible circumstances. Clinical judgement must always be used.)**
- **If a uterine perforation is suspected, the procedure should be terminated immediately.**
- **If the cavity integrity assessment fails after reasonable attempts implement the troubleshooting procedures (step 2.36), abort the procedure.**
- For patients in whom the procedure was aborted due to a suspected uterine wall perforation, a work-up for perforation should be considered prior to discharge.

### General

- Endometrial ablation using the NovaSure® system is not a sterilization procedure. Therefore, the patient should be advised of appropriate birth control methods.
- Endometrial ablation does not eliminate the potential for endometrial hyperplasia or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- Endometrial ablation is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following the procedure. Pregnancy following ablation may be dangerous for both mother and fetus.
- Patients who undergo endometrial ablation procedures who have previously undergone tubal ligation are at increased risk of developing post ablation tubal sterilization syndrome which can require hysterectomy. This can occur as late as 10 years post procedure.

### Technical

- Do not use the sterile, single-patient use disposable device if the packaging appears to be damaged or there is evidence of tampering.
- The disposable device is for single-patient use only. Do not reuse or re-sterilize the disposable device.
- If any hysteroscopy procedure is performed with hypotonic solution immediately prior to 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.
- Plugging the disposable device into the controller starts CO<sub>2</sub> flow to purge any air out of the disposable device and tubing. This purging operation takes approximately 10 seconds and **must be performed with the disposable device external to the patient to eliminate the risk of air or gas embolism.** The NovaSure® RF controller CAVITY ASSESSMENT LED flashes red and an audible pulsed tone sounds

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throughout the purge procedure. When the tone stops it is safe to insert the disposable device.

- For patients with cardiac pacemakers or other active implants, a possible hazard exists due to interference with the action of the pacemaker that may occur and may damage the pacemaker. Consult the pacemaker manufacturer for further information when use of the NovaSure system is planned in patients with cardiac pacemakers.
- **Danger: explosion hazard.** Do not use in the presence of a flammable anesthetic mixture.
- Failure of the NovaSure® RF controller could result in an unintended increase in output power.

## PRECAUTIONS

- It has been reported in the literature that patients with a severely anteverted, retroflexed or laterally displaced uterus are at greater risk of uterine wall perforation during any intrauterine manipulation.
- A false passage can occur during any procedure in which the uterus is instrumented, especially in cases of severe anteverted retroflexed or a laterally displaced uterus. Use caution to ensure that the device is properly positioned in the uterine cavity.
- The NovaSure system consists of the following components:
  - single-patient use NovaSure® disposable device with connecting cord
  - NovaSure RF controller
  - NovaSure CO<sub>2</sub> canister
  - NovaSure desiccant
  - NovaSure foot switch
  - power cord

To ensure proper operation, never use other components with the NovaSure system. The use of any cables or accessories other than those specified in these instructions may result in increased emissions or decreased immunity of the RF controller.

- The RF controller must be installed and put into service according to the guidance provided in these instructions to ensure its electromagnetic compatibility. Refer to the electromagnetic emissions and immunity tables in the Specifications section.
- The RF controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the RF controller should be observed to verify normal operation in the configuration in which it will be used.
- Portable and mobile RF communications equipment can affect the RF controller. Refer to the electromagnetic immunity tables in the Specifications section for recommended separation distances.
- Patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their medication regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the NovaSure system has not been fully evaluated in patients:
  - with a uterine sound measurement greater than 10 cm;
  - with submucosal fibroids that distort the uterine cavity;
  - with bicornuate, septate or sub-septate uteri;
  - with medical (e.g. GnRH agonist) or surgical pretreatment;
  - who have undergone a previous endometrial ablation including the NovaSure® endometrial ablation procedure; or,
  - who are post-menopausal.

- Do not attempt to repair the controller if problems are suspected. Call Hologic technical support or a Hologic sales representative for instructions.
- Cables to the disposable device should be positioned such that contact with patient or other leads is avoided.
- The user should inspect the disposable device for damage prior to use.
- The suction line desiccant is non-sterile, and the packaging should not be placed in the sterile field.
- **If the ARRAY POSITION LED light is illuminated, see the Troubleshooting section under “ARRAY POSITION LED illuminated.”**
- Do not use the NovaSure suction line desiccant if desiccant material is pink in color.
- The disposable device must be external to (outside of) the patient before connecting the cord to the appropriate port on the front panel of the controller (step 2.15).
- The carbon dioxide canister contains gas under high pressure.
- CO<sub>2</sub> continuously flows from the time that the disposable device is plugged into the controller until the CIA portion of the procedure is complete. To minimize the duration of CO<sub>2</sub> flow and potential risk of embolism, perform the seating procedure immediately after inserting the disposable device and proceed directly from the seating procedure to the CIA.
- Electrically conductive objects (e.g. monitoring electrodes from other devices) that are in direct contact with the electrode array of the disposable device or in close proximity to the electrode array may draw current away from the array. This may result in localized burns to the patient or physician or in distortion of the electrical field of the array, which would change the therapeutic effect (under-treatment or over-treatment). It may also result in distortion of the current in the conductive object, e.g. monitors may display false readings.
- Grounding reliability is only achieved when equipment is connected to a receptacle marked “hospital grade”.
- The cervical collar must be fully retracted to its proximal position in order to minimize the potential for damage to the sheath when closing the array.

## NovaSure® 3-Year Clinical Data

### Adverse Events

The NovaSure® system was evaluated in a randomized, prospective, multi-center clinical study of 265 patients with abnormal uterine bleeding comparing the NovaSure system to a control arm of wire loop resection of the endometrium followed by rollerball ablation.

**Table 1A. Intra-Operative Adverse Events**

	<b>NovaSure</b>	<b>Loop Resection Plus Rollerball</b>
<b>Adverse Event</b>	<b>n=175 (%)</b>	<b>n=90 (%)</b>
Bradycardia	1 (0.6%)	0
Uterine perforation	0	3 (3.3%)
Cervical tear	0	2 (2.2%)
Cervical stenosis	0	1 (1.1%)
<b>TOTAL</b>	<b>1 (0.6%)</b>	<b>6 (6.7%)</b>

**Table 1B. Post-Operative Adverse Events < 24 Hours**

Adverse Event	NovaSure n=175 (%)	Loop Resection Plus Rollerball n=90 (%)
Pelvic pain/cramping	6 (3.4%)	4 (4.4%)
Nausea and/or vomiting	3 (1.7%)	1 (1.1%)
<b>TOTAL</b>	<b>9 (5.1%)*</b>	<b>5 (5.6%)**</b>

\* Nine events reported in 6 (3.4%) patients

\*\* Five events reported in 4 (4.4%) patients

**Table 1C. Post-Operative Adverse Events > 24 Hours – 2 Weeks**

Adverse Event	NovaSure n=175 (%)	Loop Resection Plus Rollerball n=90 (%)
Hematometra	1 (0.6%)	0
Urinary tract infection	1 (0.6%)	1 (1.1%)
Vaginal infection	1 (0.6%)	0
Endometritis	0	2 (2.2%)
Pelvic inflammatory disease	0	1 (1.1%)
Hemorrhage	0	1 (1.1%)
Pelvic pain/cramping	1 (0.6%)	1 (1.1%)
Nausea and/or vomiting	1 (0.6%)	1 (1.1%)
<b>TOTAL</b>	<b>5 (2.9%)*</b>	<b>7 (7.8%)**</b>

\* Five events reported in 4 (2.3%) patients

\*\* Seven events reported in 6 (6.7%) patients

**Table 1D. Post-Operative Adverse Events > 2 Weeks – 1 Year**

Adverse Event	NovaSure n=175(%)	Loop Resection Plus Rollerball n=90 (%)
Hysterectomy	3 (1.7%)	2 (2.2%)
Hematometra	1 (0.6%)	2 (2.2%)
Urinary tract infection	2 (1.1%)	2 (2.2%)
Vaginal infection	5 (2.9%)	2 (2.2%)
Endometritis	2 (1.1%)	1 (1.1%)
Pelvic inflammatory disease	2 (1.1%)	0
Hemorrhage	1 (0.6%)	0
Pelvic pain/cramping	5 (2.9%)	6 (6.7%)
<b>TOTAL</b>	<b>21 (12.0%)*</b>	<b>15 (16.17%)**</b>

\* 21 events in 19 (10.9%) patients

\*\* 15 events in 15 (16.7%) patients

**Anticipated Post-Procedural Complications**

For any endometrial ablation procedure, commonly reported post-operative events include the following:

- Cramping/pelvic pain was reported for 3.4% of the NovaSure patients and 4.4% of the wire resection loop plus rollerball-treated patients within 24 hours of the procedure. Postoperative cramping can range from mild to severe. This cramping will typically last a few hours and rarely continues beyond the first day following the procedure.
- Nausea and vomiting were reported for 1.7% of the NovaSure patients and 1.1% of the wire loop resection plus rollerball patients within 24 hours of the procedure. When present, nausea and vomiting typically occur immediately following the procedure, are associated with anesthesia and can be managed with medication.

- Vaginal discharge
- Vaginal bleeding/spotting

**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 the NovaSure system:

- post-ablation tubal sterilization syndrome
- **pregnancy-related complications (NOTE: PREGNANCY FOLLOWING ENDOMETRIAL ABLATION IS VERY DANGEROUS FOR BOTH THE MOTHER AND THE FETUS.)**
- thermal injury to adjacent tissue
- perforation of the uterine wall
- difficulty with defecation or micturition
- uterine necrosis
- air or gas embolism
- infection or sepsis
- complications leading to serious injury or death

**Clinical Study**

**Purpose:** Safety and effectiveness of the use of the NovaSure system was compared to wire loop resection of the endometrium followed by rollerball ablation in premenopausal women suffering from menorrhagia secondary to benign causes.

**Pretreatment:** Patients randomized into the NovaSure arm received no endometrial pretreatment (e.g. hormone, D&C or patient timing). Patients randomized into the control arm received wire loop resection as an endometrial pretreatment.

**Study endpoints:** The primary effectiveness measure was a validated menstrual diary scoring system developed by Higham (Higham JM, O'Brien PMS, Shaw RW *Br J Obstet Gynaecol* 1990; 97:734-9). Assessment of menstrual blood loss was performed using a pictorial blood loss assessment chart (PBLAC). Patient success was defined as a reduction in menstrual flow at 1 year post-procedure to a diary score of <75. Study success was defined as a statistical difference of less than 20% in patient success rates between the NovaSure impedance controlled endometrial ablation system and wire loop resection plus rollerball ablation. Patients were contacted at two and three years and asked a series of questions regarding their bleeding over the previous 12 months. Each patient's menstrual bleeding status was determined at two and three years using the one-year PBLAC score and bleeding pattern as a reference. Thus, it was possible to directly compare a patient's bleeding pattern or menstrual status at one year to the bleeding pattern at two and three years.

Secondary endpoints included anesthesia regimen, length of procedure and responses from a quality-of-life questionnaire. Safety evaluation was based on the adverse events reported during the study.

**Methods:** A randomized (2:1), prospective clinical study was conducted at 9 clinical sites and included 265 patients diagnosed with menorrhagia. Menstrual diary scores were collected pre-operatively and monthly for 12 months post-procedure. Patients were treated at any time in their menstrual cycle. None of the patients received hormonal pretreatment to thin the endometrial lining. Control patients received hysteroscopic wire loop resection of the endometrium as a mechanical means of endometrial pretreatment followed by rollerball ablation. Study subjects were required to meet the following key patient selection criteria:

**Inclusion criteria**

- Refractory menorrhagia with no definable organic cause (dysfunctional uterine bleeding)
- Ages 25 to 50 years of age
- Uterine sound measurement of 6.0–10.0 cm (external os to internal fundus)
- Minimum PBLAC score of >150 for 3 months prior to study enrollment; or PBLAC score >150 for one month for women who:
  - had at least 3 prior months (documented) failed medical therapy;
  - had a contraindication to medical therapy; or
  - refused medical therapy.

**Exclusion criteria**

- Presence of bacteremia, sepsis or other active systemic infection
- Active or recurrent chronic pelvic inflammatory disease
- Patient with documented coagulopathies or on anticoagulants
- Symptomatic endometriosis
- Prior uterine surgery (except low segment cesarean section) that interrupts the integrity of the uterine wall e.g. transmurular myomectomy or classical cesarean section
- Prior endometrial ablation
- Patient on medications that could thin the myometrial muscle, such as long-term steroid use
- Patient desire to have children or to preserve fertility
- Patient currently on hormonal birth control therapy or unwilling to use a non-hormonal birth control post-ablation
- Abnormal/obstructed cavity as confirmed by hysteroscopy, SIS or HSG. Specifically:
  - septate or bicornuate uterus or other congenital malformation of the uterine cavity
  - pedunculated, submucous leiomyomata or other leiomyomata which distort the cavity; polyps (larger than 2 cm) which are likely to be the cause of the patient's menorrhagia
  - presence of an IUD
- Suspected or confirmed uterine malignancy within the last five years as confirmed by histology
- Endometrial hyperplasia as confirmed by histology
- Unaddressed cervical dysplasia
- Elevated FSH levels consistent with ovarian failure >40 IU/ml
- Pregnancy
- Active sexually transmitted disease

**Patient population:** A total of 265 patients were enrolled in this study. Patients were between the ages of 25 to 50 with 46% under the age of 40 and 54% 40 years of age or older. There were no differences in demographic or gynecological history parameters between the treatment groups, between the age groupings or among the nine investigational sites.

Table 2. Patient Accountability		
Number of Patients	NovaSure	Wire Loop Resection Plus Rollerball
Entered into Study (Intent-to-Treat population)	175	90
Aborted procedures <sup>*1</sup>	-4	-2
Treated	171	88

Additional treatment*	-4	-2
Hysterectomy <sup>*2</sup>	-3	-2
Lost to follow-up*	-5	-2
Hodgkin's disease*	-1	0
Pelvic Pain - administered leuprolide*	-1	0
<b>12-Month follow-up data available</b>	<b>157</b>	<b>82</b>
Additional treatment*	-2	-1
Hysterectomy <sup>*2</sup>	-3	-1
Lost to follow-up*	-2	-5
Missed visit	-1	-1
Declined to participate*	-1	0
Pregnancy*	-1	0
<b>24-Month follow-up data available</b>	<b>147</b>	<b>74</b>
Additional treatment*	0	-4
Hysterectomy <sup>*2</sup>	-5	-1
Lost to follow-up*	-4	-2
<b>36-Month follow-up</b>	<b>138</b>	<b>67</b>
Subject lost to follow-up at 24 mos., returned at 36 mos.	+1	+1
<b>36-Month follow-up data available</b>	<b>139</b>	<b>68</b>

\* Discontinued patients

<sup>1</sup> Four NovaSure did not meet protocol Inclusion Criteria; Two Rollerball had uterine perforation

<sup>2</sup> For hysterectomy, see Table 7

**Results****Primary effectiveness endpoint: bleeding score**

Patient success at 12-months post-procedure is defined as a reduction in diary score from >150 pre-operatively to <75 post-procedure. Amenorrhea is defined as a score of 0. Success at 24 and 36 months, based on telephone questionnaires, is defined as elimination of bleeding or reduction to light or normal flow. Data presented in Table 3 (below) represent the clinical results based on the total number of 265 patients randomized (Intent-to-Treat group (ITT)) for the study. The worst-case scenario is presented whereby each of the discontinued patients (described in Table 2 for patient accountability) is counted as a "failure" for calculating the values listed in the table.

Table 3. Effectiveness: Success Rates–Intent-To-Treat Patients						
	NovaSure (n=175)			Wire Loop Resection Plus Rollerball (n=90)		
Months post ablation	12*	24**	36**	12*	24**	36**
Number of successful patients	136	143	134	67	68	63
Study success rate	77.7%	81.7%	76.6%	74.4%	75.6%	70.0%
# of patients with Amenorrhea	63	64	58	29	26	23
Amenorrhea rate	36.0%	36.6%	33.1%	32.2%	28.9%	25.6%

\* Based on diary scores

\*\* Based on telephone questionnaires

**Secondary effectiveness endpoint: quality of life**

Patient quality of life (QOL) was assessed by administering the quality of life questionnaire (SF-12) and the menstrual impact questionnaire prior to treatment and at 3, 6, 12, 24 and 36 months post-procedure. Table 4 shows the patient responses for both groups pre-operatively, where appropriate, and at 12, 24 and 36 months post-procedure.

<b>Table 4. Effectiveness: Quality of Life (QOL)</b>		
	<b>NovaSure</b>	<b>Wire Loop Resection Plus Rollerball</b>
<b>Number of Patients Responding to Quality of Life Questionnaire<sup>#</sup></b>		
Pre-operatively	175	90
12 Months	154	82
24 Months	143	73
36 Months	139	67
<b>Percent of Patients Satisfied Or Very Satisfied</b>		
12 Months	92.8%	93.9%
24 Months	93.9%	89.1%
36 Months	96.3%	89.7%
<b>Percent of Patients Who Probably Or Definitely Would Recommend This Procedure</b>		
12 Months	96.7%	95.9%
24 Months	96.6%	94.5%
36 Months	97.8%	92.6%
<b>Percent of Patients with Dysmenorrhea</b>		
Pre-operatively	57.1%	55.6%
12 Months	20.8% <sup>&amp;</sup>	34.2% <sup>*,&amp;</sup>
24 Months	20.3% <sup>*</sup>	30.1% <sup>*</sup>
36 Months	17.3% <sup>*</sup>	28.4% <sup>*</sup>
<b>Percent of Patients with PMS</b>		
Pre-operatively	65.1%	66.7%
12 Months	36.4% <sup>*</sup>	35.4% <sup>*</sup>
24 Months	44.0% <sup>*</sup>	46.6% <sup>*</sup>
36 Months	34.5% <sup>*</sup>	41.2% <sup>*</sup>
<b>Percent of Patients Reporting Sometimes, Frequently Or Always Have Difficulty Performing Work Or Other Activities Due to Menses</b>		
Pre-operatively	66.3%	65.5%
12 Months	9.9% <sup>*</sup>	8.6% <sup>*</sup>
24 Months	14.5% <sup>*</sup>	15.0% <sup>*</sup>
36 Months	16.3% <sup>*</sup>	13.3% <sup>*</sup>
<b>Percent of Patients Reporting Sometimes, Frequently Or Always Feel Anxious Due to Menses</b>		
Pre-operatively	74.7%	68.9%
12 Months	23.6% <sup>*</sup>	18.5% <sup>*</sup>
24 Months	24.2% <sup>*</sup>	19.2% <sup>*</sup>
36 Months	18.7% <sup>*</sup>	19.1% <sup>*</sup>
<b>Percent of Patients Reporting Sometimes, Frequently Or Always Miss Social Activities Due to Menses</b>		
Pre-operatively	63.3%	62.2%
12 Months	8.5% <sup>*</sup>	8.6% <sup>*</sup>
24 Months	9.0% <sup>*</sup>	11.1% <sup>*</sup>
36 Months	8.1% <sup>*</sup>	10.8% <sup>*</sup>

<sup>#</sup> Not all patients completed questionnaire

<sup>\*</sup> Statistically significant difference from pre-operative response (Chi-Square;  $p < 0.05$ )

<sup>&</sup> Statistically significant difference between NovaSure and Rollerball Groups (Chi-Square;  $p = 0.02$ )

**Safety endpoint**

Adverse event information is described in the “Adverse Events” section of this manual.

**Secondary endpoint: procedure time**

Procedure time, a secondary endpoint, was determined for each patient by recording the time of device insertion and the time of device removal. The mean procedure time for the NovaSure patients was significantly less than the procedure time for the rollerball group, ( $4.2 \pm 3.5$  minutes and  $24.2 \pm 11.4$  minutes, respectively). Mean time for application of RF energy was  $84.0 \pm 25.0$  seconds in a subset of monitored NovaSure patients (Table 5).

<b>Table 5. Operative Procedure Time</b>		
	<b>NovaSure n=175</b>	<b>Wire Loop Resection Plus Rollerball n=90</b>
<b>Operative Parameters</b>		
Number of treated patients*	171	88
Procedure time minutes ( $\pm$ SD) (Device insertion to device removal)	$4.2 \pm 3.5^{**}$	$24.2 \pm 11.4^{**}$
Procedure time in seconds ( $\pm$ SD) (Time of energy delivery)	$84.0 \pm 25.0$	ND <sup>#</sup>

\* See Table 2 for patient accountability

\*\* Statistically significant difference between treatment groups (Student's t-test;  $p < 0.05$ )

<sup>#</sup> Not determined

**Secondary endpoint: anesthesia regimen**

Anesthesia was left to the discretion of each patient, clinical investigator and attending anesthesiologist. For the NovaSure patients, 27.0% (47/174) had the procedure performed under general anesthesia or epidural and 73.0% (127/174) under local and/or IV sedation. One patient did not have a reported anesthesia regimen in this group. In the rollerball group, 82.2% (74/90) of the patients were treated under general anesthesia or epidural and 17.8% (16/90) under local and/or IV sedation (Table 6).

<b>Table 6. Anesthesia Regimen</b>		
	<b>NovaSure n=175<sup>*</sup></b>	<b>Wire Loop Resection Plus Rollerball n=90</b>
General or epidural	27.0%	82.2%
Local and/or IV sedation	73.0%	17.8%

\* One patient did not have a reported anesthesia regimen.

**Clinical observations****Hysterectomy**

Fifteen women had a hysterectomy within the three years following the ablation procedure. Table 7 lists the reasons for hysterectomy.

**Table 7. Hysterectomy**

Reason For Hysterectomy	NovaSure n=175	Wire Loop Resection Plus Rollerball n=90
Adenocarcinoma diagnosed at time of ablation procedure	1	1
Fibroids	2	0
Pelvic abscess	1	1
Endometriosis	3	0
Adenomyosis	4	0
Hematometra	0	1
Menorrhagia	0	1
<b>TOTAL</b>	<b>11 (6.3%)</b>	<b>4 (4.4%)</b>

7 Hysterectomies were in patients <40 years (7 NovaSure) and 8 hysterectomies were in patients >40 years (4 NovaSure; 4 Rollerball).

### Patient Selection

Menorrhagia can be caused by a variety of underlying problems, including, but not limited to; endometrial cancer, myomas, polyps, drugs and dysfunctional uterine bleeding (anovulatory bleeding). Patients always should be screened and evaluated to determine the cause of excessive uterine bleeding before any treatment option is initiated. Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications and hazards prior to the performance of any endometrial ablation procedure.

### Patient Counseling

As with any procedure, the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation. Patient's expectations should be set in a way that the patient understands that the aim of the treatment is the reduction in bleeding to normal levels.

The disposable device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following the procedure. Patients of childbearing capacity should be cautioned of potential complications, which may ensue if they should become pregnant. This counseling should include the need for post-procedure contraception where indicated. This procedure is not a sterilization procedure and subsequent pregnancies may be dangerous for the mother and fetus.

Vaginal discharge is typically experienced during the first few weeks following ablation and may last as long as a month. Generally, the discharge is described as bloody during the first few days; serosanguineous by approximately one week; then profuse and watery thereafter. Any unusual or foul-smelling discharge should be reported to the physician immediately. Other common post-procedural complications include cramping/pelvic pain, nausea and vomiting.

Uterine perforation should be considered in the differential diagnosis of any post-operative patient complaining of acute abdominal pain, fever, shortness of breath, dizziness, hypotension or any other symptom that may be associated with uterine perforation with or without damage to the adjacent organs of the abdominal cavity. Patients should be counseled that any such symptoms should be immediately reported to their physician.

### Pretreatment Preparation of Patient

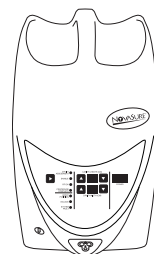
The NovaSure® impedance controlled endometrial ablation system successfully treats a uterine cavity over a range of endometrium thickness. The lining of the uterus does not have to be thinned prior to the procedure, and the procedure may be performed during either the proliferative or the secretory phase of the cycle. Although the safety and effectiveness of the NovaSure system has not been fully-evaluated in patients with medical or surgical pretreatment, it has been evaluated in a limited number of patients who had been pretreated with GnRH agonists with no complications or adverse events.

Active bleeding was not found to be a limiting factor when using the NovaSure system. It is recommended that a nonsteroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued postoperatively to reduce intraoperative and postoperative uterine cramping.

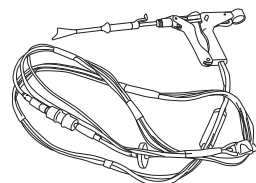
### NovaSure Impedance Controlled Endometrial Ablation System Instructions For Use

Please read all instructions, cautions and warnings prior to use.

#### 1.0 Set-up



**NOVASURE® RF CONTROLLER**



**NOVASURE® DISPOSABLE DEVICE WITH CONNECTING CORD, INCLUDING SUCTION LINE DESICCANT**



**NOVASURE® POWER CORD**



**NOVASURE® SUCTION LINE DESICCANT**



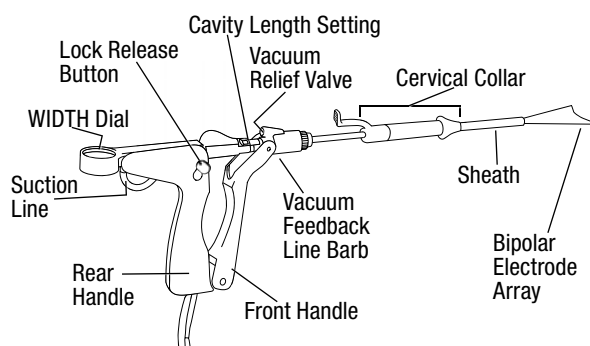
**NOVASURE® CO<sub>2</sub> CANISTER**



**NOVASURE® FOOT SWITCH**

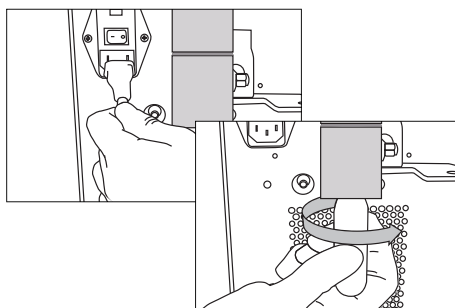
1.1 The following items are required when using the NovaSure system:

- one sterile, single-patient use NovaSure disposable device with
- connecting cord
- one NovaSure RF controller
- one NovaSure foot switch
- one NovaSure AC power cord
- one NovaSure non-sterile suction line desiccant assembly
- one NovaSure CO<sub>2</sub> canister.



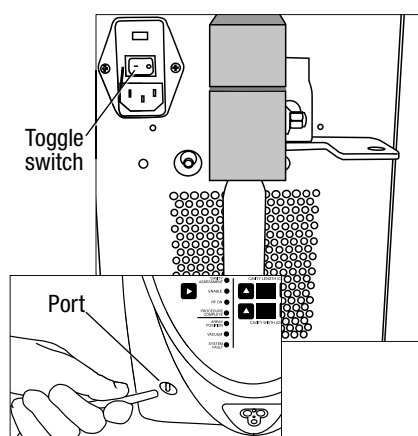
**NOTE:** Please have available at least one extra disposable device, desiccant assembly and CO<sub>2</sub> canister.

- 1.2 Prepare the NovaSure RF controller. Place it on a small table to one side of the patient within visual field of the surgeon. Attach the AC power cord to the controller and plug it into the AC outlet.
- 1.3 Screw the CO<sub>2</sub> canister into the regulator on the back panel of the controller until tightened.



- 1.4 Fully rotate the CO<sub>2</sub> regulator knob to the HI position.

**NOTE:** Newer model controllers are not equipped with a knob on the regulator, thus allowing the CO<sub>2</sub> flow to be automatically regulated. If your controller is not equipped with a regulator knob, proceed to step 1.5.



- 1.5 Press the toggle switch on the back panel of the controller into the "on" position.
- 1.6 Connect the foot switch to the appropriate port on the front panel of the controller.

## 2.0 Procedure

- 2.1 Prepare the patient for the anesthesia.
- 2.2 Place patient in dorsal lithotomy position.
- 2.3 Induce anesthesia according to standard practice.
- 2.4 Perform bimanual examination. Evaluate for severe anteversion or retroversion.
- 2.5 Prepare and drape patient similar to prep for D&C.
- 2.6 Insert a speculum into the vagina.
- 2.7 Grasp the cervix with a tenaculum.
- 2.8 Take a sound measurement of the uterus to measure the length from fundus to external cervical os. **The efficacy of the NovaSure system has not been fully evaluated in patients with a uterine sound measurement greater than 10 cm.**
- 2.9 **Determine the length of the cervical canal and dilate canal to 8.0 mm.**
- 2.10 Using the uterine sound and cervical canal measurements, consult the cavity length table (below) to obtain the appropriate cavity length settings. On the upper end of the table, dimensions have been adjusted to reflect the disposable device electrode length. Correct determination of the cavity length is important for safe and effective treatment. Overestimating the cavity length may result in thermal injury to the endocervical canal.

**WARNING:** Use caution not to perforate the uterine wall when sounding, dilating or inserting the disposable device.

TABLE 8. CAVITY LENGTH									
Uterine Sound (cm)									
Cervix Length (cm)	10	9.5	9	8.5	8	7.5	7	6.5	6
2	6.5*	6.5*	6.5*	6.5	6	5.5	5	4.5	4
2.5	6.5*	6.5*	6.5	6	5.5	5	4.5	4	
3	6.5*	6.5	6	5.5	5	4.5	4		
3.5	6.5	6	5.5	5	4.5	4			
4	6	5.5	5	4.5	4				
4.5	5.5	5	4.5	4					
5	5	4.5	4						
5.5	4.5	4							
6	4								

\* The value of 6.5 is not intended to reflect the numerical difference between the sound length and the length of the cervical canal.

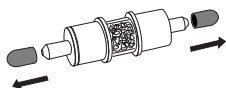
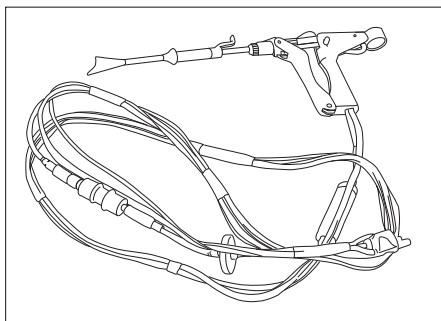
The value 6.5 was entered because it represents the maximum length that the NovaSure array can be extended.

**CONTRAINDICATION:** Do not treat a patient with a uterine cavity length that is less than 4 cm, as cervical canal damage may occur.

**NOTE:** Patients with a uterine cavity length greater than 6.0 cm had observed success rates that were lower than overall study success rates.

- 2.11 Open the sterile NovaSure disposable device package. Place the disposable device with the connecting cord into the sterile field while being careful to keep the non-sterile suction line desiccant box out of the sterile field.

**WARNING:** Do not use the sterile single-patient use disposable device if the packaging appears to be damaged or there is evidence of tampering.



2.12 Open the non-sterile suction line desiccant box and pouch. Remove the red caps.

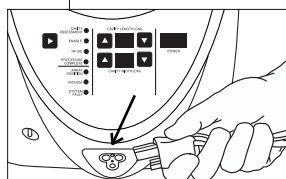
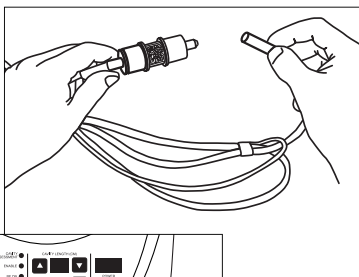
**CAUTION:** The suction line desiccant is non-sterile and the packaging should not be placed in the sterile field.

**CAUTION:** If the suction line desiccant is pink, then replace it prior to initiating the ablation procedure.

2.13 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.

2.14 **CAUTION:** Disposable device must be external to (outside of) the patient before performing step 2.15.

2.15 Connect the disposable device cord to the appropriate port on the front panel of the controller.

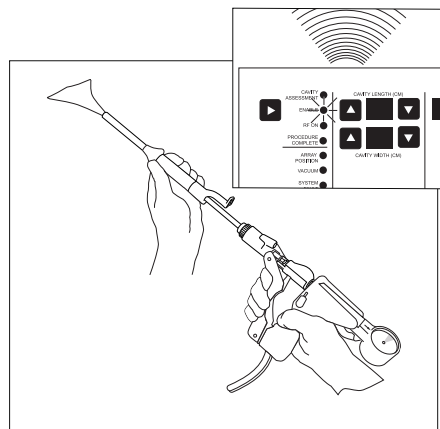


**WARNING:** Plugging the NovaSure disposable device into the NovaSure RF controller starts CO<sub>2</sub> flow to purge any air out of the disposable device and tubing. The purging operation takes approximately 10 seconds and must be performed with the disposable device external to the patient. The NovaSure RF controller CAVITY ASSESSMENT LED flashes red and an audible pulsed tone sounds throughout the purge procedure. When the tone and the LED stop, it is safe to insert the NovaSure disposable device.

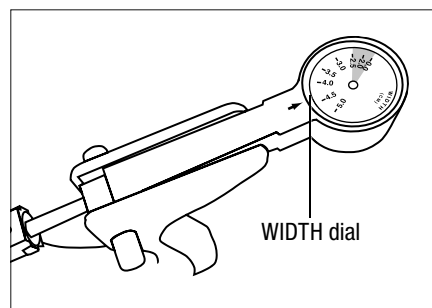
**CAUTION:** CO<sub>2</sub> continuously flows from the time that the disposable device is plugged into the controller until the CIA portion of the procedure is complete. To minimize the duration of CO<sub>2</sub> flow and potential risk of embolism, perform the seating procedure immediately after inserting the disposable device and proceed directly from the seating procedure to the CIA.

**WARNING:** Use caution not to perforate the uterine wall when sounding, dilating or inserting the disposable device.

2.16 Deploy the disposable device outside of the patient and ensure the controller ARRAY POSITION LED is extinguished when the array is opened. If the LED is not extinguished, close and open the disposable device again. If this does not resolve the problem, replace the disposable device.

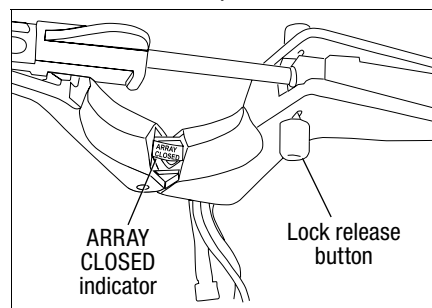


2.17 Be certain the WIDTH dial reads greater than or equal to 4.0 cm.



**NOTE:** If the WIDTH dial reads less than 4.0 cm, close the disposable device and repeat step 2.16 above. If the WIDTH dial still reads less than 4.0 cm, open a new disposable device and return the old disposable device to Hologic technical support.

2.18 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 until the closed array indicator, located at the hinge of the front and rear handles, reads, "ARRAY CLOSED". This indicates that the array has been retracted into the sheath and the disposable device is in the closed position.



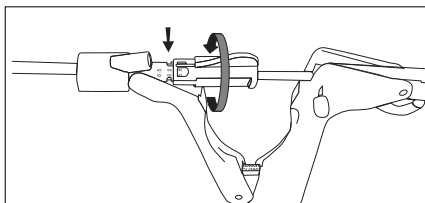
2.19 Make sure the array is completely enclosed by the external sheath.

2.20 Check that the WIDTH dial reads approximately 0.5 cm.

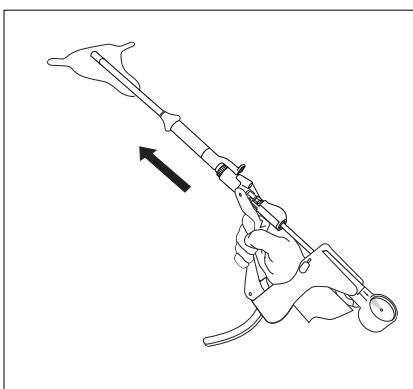
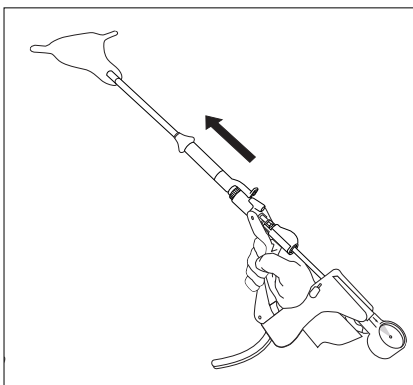
2.21 Using the uterine sound measurement and cervical canal measurements, consult the cavity length table (above) to obtain the appropriate cavity length settings as described in step 2.10 above.

**CONTRAINDICATION:** Do not treat a patient with a uterine cavity length that is less than 4 cm, as cervical canal damage may occur.

- 2.22 Using the cavity length table in section 2.10, key in the value obtained for length into the NovaSure RF controller length LED by depressing the UP/DOWN arrows.
- 2.23 Adjust and lock the cavity length setting feature on the disposable device to the value obtained above. (See step 2.21.) Ensure that the cervical collar is fully retracted to its proximal position.

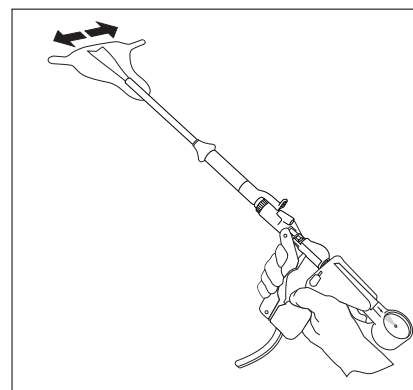


- 2.24 Confirm that the cervix is dilated to 8.0 mm.
- 2.25 Maintain a slight traction on the tenaculum to minimize the angle of the uterus.
- 2.26 Angle the disposable device in-line with the axis of the uterus as the disposable device is inserted transcervically into the uterine cavity. By holding the front handle, advance the disposable device until the distal end of the sheath touches the fundus.



**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.

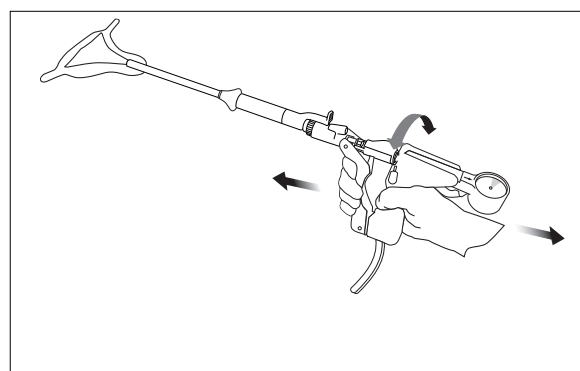
- 2.27 Maintain a reference point at the fundus. Slowly squeeze the handles (DO NOT LOCK) up to the point of increased resistance. DO NOT pull the disposable device back from the fundus. The WIDTH dial should read approximately 0.5 cm. At this point, the external sheath has been retracted.



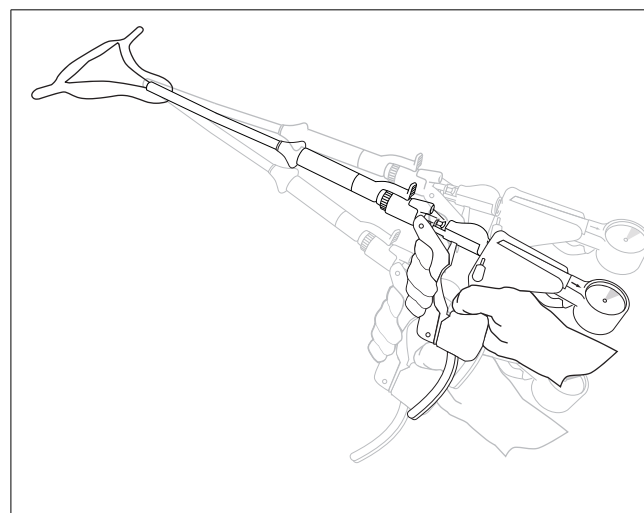
- 2.28 Continue to slowly squeeze the disposable device handles together while gently moving the disposable device ~0.5 cm to and from the fundus and rotating the handle of the disposable device 45° counterclockwise from the vertical plane and 45° clockwise from the vertical plane until the handles lock.

The WIDTH dial should read greater than 2.5 cm.

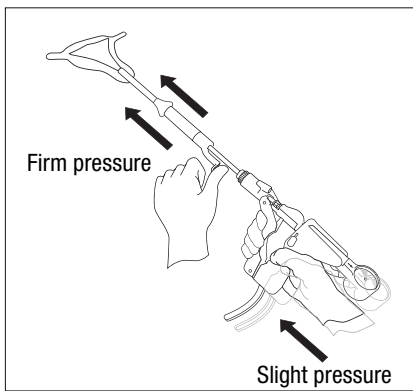
**NOTE:** Once the disposable device handles are locked, the uterus should move in conjunction with the disposable device.



- 2.29 Gently move the disposable device using anterior, posterior and lateral movements.

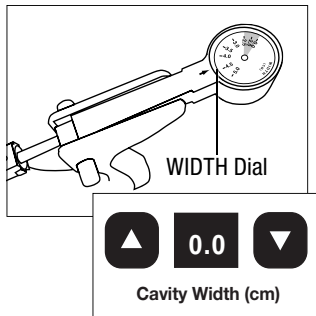


- 2.30 To complete placement, slightly pull back the disposable device until the WIDTH dial reading reduces by approximately 0.2–0.5 cm.
- 2.31 Hold the tenaculum, advance the disposable device firmly to the fundus, maintaining slight forward pressure. The WIDTH dial should read greater than or equal to the previous measurement.



2.32 Slide the cervical collar forward using firm pressure on the tab on the cervical collar, until the cervical collar forms a seal against the external cervical os.

2.33 Read the cornu-to-cornu measurement (2.5 cm minimum) on the WIDTH dial indicator.



**CONTRAINDICATION:** Do not treat a patient with a uterine cavity width less than 2.5 cm, as determined by the WIDTH dial of the disposable device following device deployment.

**CAUTION:** If the ARRAY POSITION LED light is illuminated, see the Troubleshooting section under “ARRAY POSITION LED illuminated.”

2.34 Key in the value indicated on the WIDTH dial into the NovaSure RF controller width LED by depressing the UP/DOWN arrows.

2.35 The system can be operated in either automatic mode or semi-automatic mode. In automatic mode the ablation cycle will start automatically upon successful completion of the cavity integrity assessment (CIA). In semi-automatic mode the ablation cycle will not start automatically following a successful CIA.

**NOTE:** 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.

#### A. Automatic mode

To operate the system in automatic mode, press the ENABLE button prior to beginning the CIA. Proceed to step 2.36. But do not follow step 2.37 if operating the system in automatic mode.

#### B. Semi-automatic mode

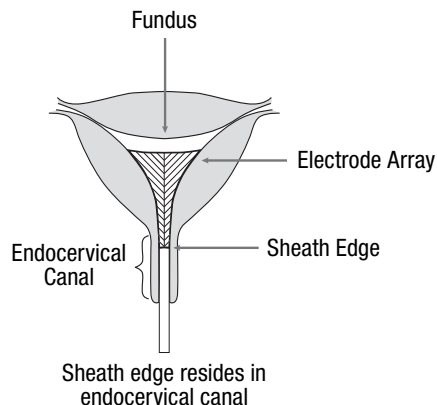
To operate the system in the semi-automatic mode, do not press the ENABLE button prior to beginning the CIA. Follow steps 2.36 and 2.37.

2.36 Begin the cavity integrity assessment (CIA) procedure by stepping on the foot switch once. The CAVITY ASSESSMENT LED flashes green in conjunction with an audible tone at a rate of once per second when the system is performing a CIA. The duration of the test will range between approximately 7 and 30 seconds. A steady green LED appears when the CIA has passed and the system can deliver RF energy. Power cannot be applied to the disposable device until the CAVITY ASSESSMENT LED is a steady green light.

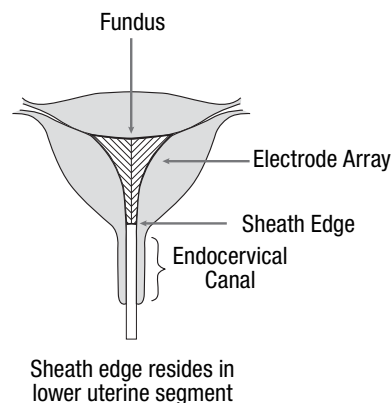
If the cavity integrity assessment fails, then the CAVITY ASSESSMENT LED on the NovaSure RF controller will flash red, and a rapid audible tone will sound at a rate of four times per second.

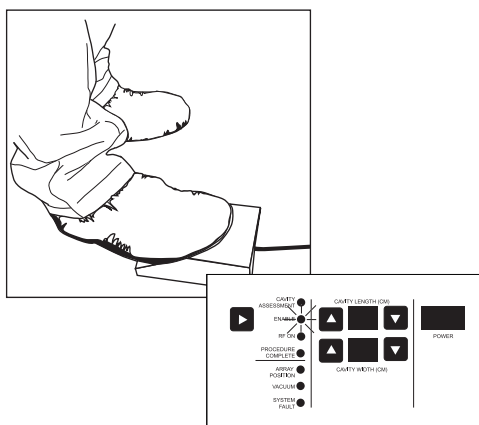
**NOTE:** Correct placement of the electrode array against the fundus is important to safe and effective treatment. If part of the electrode array or the distal edge of the external sheath is seated in the endocervical canal during treatment, there is an increased risk of endocervical thermal injury.

#### INCORRECT PLACEMENT



#### CORRECT PLACEMENT





If the cavity integrity assessment fails, press the foot switch to stop the sound. Next:

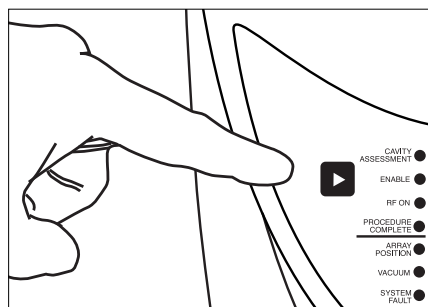
- A. If a perforation is suspected, the procedure should be terminated immediately.
- B. If the test fails again, check for leaks in the system, and between the cervix and cervical collar. Be sure to check all tubing and luer connections, and ensure that a suction line desiccant has been installed. If the leak appears to be at the cervix and cannot be resolved by using the cervical collar, use another tenaculum to grasp the cervix around the sheath. Repeat the cavity integrity assessment by pressing the foot switch.

**NOTE:** CO<sub>2</sub> leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the “hissing” sound of escaping gas may accompany CO<sub>2</sub> leakage under either of these conditions.

- C. If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedures (step 2.36), abort the procedure.

**NOTE:** Removing the disposable device from the uterine cavity after completing a cavity integrity assessment will require an additional test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

#### 2.37 Semi-automatic mode only



#### SEMI-AUTOMATIC MODE

When operating the system in semi-automatic mode, the ablation cycle will not start automatically after the successful completion of the CIA. Once a successful CIA has been completed, press the ENABLE button and depress the foot switch a second time to initiate the ablation cycle.

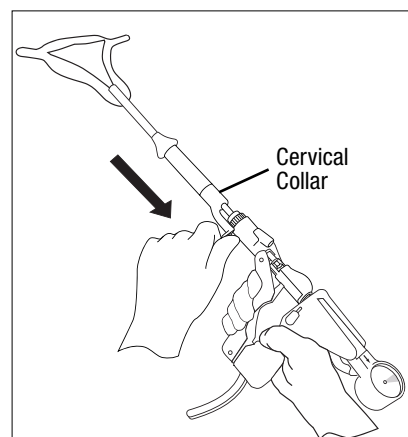
**NOTE:** In some Model 09 RF controllers, a vacuum pre-check occurs automatically prior to initiation of the ablation cycle. The VACUUM LED will flash and an audible tone will be heard for up to 10 seconds during the vacuum pre-check.

During the ablation cycle, a blue RF ON LED will illuminate. At the completion of the ablation cycle, the RF power delivery (RF ON LED), as well as suction, will switch off automatically. The physician can stop the progress of the procedure at any time by depressing the foot switch.

**NOTE:** RF power delivery can be stopped at any time by pressing the foot switch

- 2.38 After automatic termination of the ablation cycle (approximately 90 seconds), fully retract the cervical collar by using the tab on the cervical collar. Fully retract the cervical collar by sliding it to its proximal position.

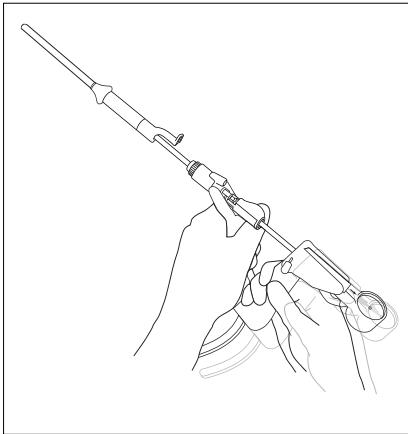
**CAUTION:** The cervical collar must be fully retracted to its proximal position in order to minimize the potential for damage to the sheath when closing the array.



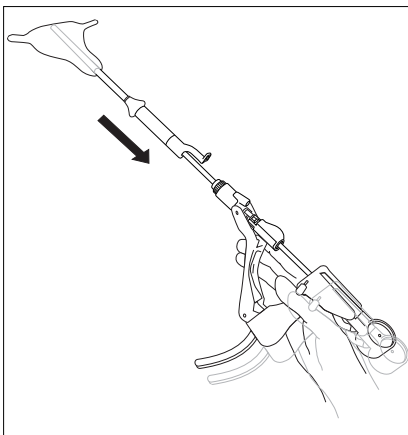
- 2.39 Unlock the disposable device by pressing the lock release button. Close the disposable device by holding the front handle stationary and gently pulling the rear handle backwards until the closed array indicator, located at the hinge of the front and rear handles, reads “ARRAY CLOSED”. This indicates that the array has been retracted into the sheath and the disposable device is in the closed position. (See step 2.18.)

**NOTE:** If it is difficult to close and remove the disposable device, see the Troubleshooting section, “Difficulty closing and removing the disposable device post-ablation.”

**CAUTION:** To avoid damaging the device, employ gentle technique when retracting the array.



2.40 Withdraw the disposable device from the patient.



2.41 Turn off the NovaSure RF controller. Close the CO<sub>2</sub> regulator.

2.42 Perform postoperative patient care according to standard procedures. The used disposable device must be treated as biohazardous waste and disposed of according to standard practices of the hospital or clinic where the treatment is performed.

2.43 Discharge the patient from the hospital or office as indicated by the managing physician.

### Periodic Maintenance and Service

There is no service manual for the NovaSure RF controller since there are no field serviceable components within the unit.

### Periodic maintenance

NovaSure RF controller Model 09: Recommended periodic maintenance includes RF power output testing and standard safety tests such as leakage current in accordance with UL 60601-1, along with regular cleanings, described in the “Cleaning and Sanitizing” section.

### RF power output test

The NovaSure RF controller Model 09 integrates automatic power output testing into a power on self test (POST). During the POST the controller’s power output (Pc) is delivered into a shunt resistor (Rs) located inside the controller. Pc is targeted to be 180 watts and Rs is nominally 25 ohms. During the POST, no power is delivered to the disposable device connector at the front of the controller.

**NOTE:** If a NovaSure disposable device is connected at the time the controller is powered up, the POST will not be performed and the controller will return to normal operation. If a device is connected during the POST sequence, the POST will terminate and the controller will return to normal operation.

The following procedure is used to execute the POST and display the actual value of Pc and Rs determined:

1. With the switch on the power input module in the off position, check to make sure a disposable device is not connected to the RF controller.
2. Depress and hold the length UP and length DOWN arrows simultaneously, then toggle the power switch at the power input module while continuing to depress the arrows. This step initiates the POST, which proceeds automatically.
3. Upon the completion of the POST (approximately 5 seconds), the RF controller will generate one audible tone, and then display the actual value of Pc for two seconds on the power set LED.
4. After two seconds elapse, the power set LED will change to display the actual value of Rs for two seconds.
5. The power set LED will then change to 00, and the RF controller will return to normal operation without further input from the user.

The acceptable limits on  $P_c = 180\text{ W} \pm 10\%$ . If Pc is not within specification, a system fault will occur. The actual value of Rs is for reference only.

**NOTE:** If a system fault occurs during the POST, toggle off the power at the power input module and repeat the POST. If a system fault occurs a second time, remove the RF controller from service and contact Hologic customer service.

**CAUTION:** Do not attempt to repair the controller if problems are suspected. Follow the troubleshooting guide in this manual. If problems persist, call Hologic technical support for instructions.

Sterile NovaSure disposable device: No maintenance is necessary. Single-patient use only. Do not reuse or re-sterilize the NovaSure disposable device.

### NovaSure RF Controller LED Descriptions

The following is a description of the alert LEDs on the NovaSure RF controller.

**CAVITY ASSESSMENT LED:** illuminates in four modes:

1. Flashes red in conjunction with an audible tone at a rate of once per second for the first 10 seconds when the system is purging air out of the disposable device. After 10 seconds, the LED and audible tone will cease, although CO<sub>2</sub> will continue to flow out of the vacuum feedback line.
2. Flashes green in conjunction with an audible tone at a rate of once per second when the system is performing a cavity integrity assessment.
3. Steady green light appears when the cavity integrity assessment has passed and the system can deliver RF energy. Power cannot be applied to the disposable device until the CAVITY ASSESSMENT LED is a steady green.
4. Steady red lights and an audible tone at a rate of four times per second occur when the cavity integrity assessment has failed. The test may be tried again.

**ENABLE LED:** illuminates amber when the user presses the ENABLE button. Acts as a safety so that the NovaSure disposable device will not

accidentally activate when the foot switch is touched. The ENABLE LED will not illuminate when the ARRAY POSITION LED is on.

**RF ON LED:** illuminates blue when the ablation is proceeding (the foot switch has been depressed to activate the NovaSure RF controller with the NovaSure disposable device array in place in the uterus).

**PROCEDURE COMPLETE LED:** illuminates when the tissue impedance reaches 50 ohms and the ablation procedure runs a minimum of 30 seconds.

**ARRAY POSITION LED:** illuminates red when one pole of the electrode array may be in contact with another. This LED should be illuminated when the array is not fully deployed. The ENABLE LED cannot be toggled on, nor can power be delivered to the array when the ARRAY POSITION LED is illuminated.

**VACUUM LED:** illuminates in two conditions:

1. Flashes red accompanied by an audible tone while the system is stabilizing the vacuum level for up to 10 seconds before energy delivery commences (only for Model 09 controllers with a vacuum pre-check function).
2. Illuminates red when the vacuum relief valve is stuck in the closed position, when a blockage is detected in the disposable device or the connection tubing or when the system has a leak. Such a situation might be created by:
  - an over-dilated cervix with poor contact between the cervical collar and the external os;
  - a poor luer connection at the vacuum feedback or suction flush port;
  - a poor attachment of the desiccant tube to the suction tubing;
  - an obstruction in the disposable device tubing; or
  - an obstruction in the disposable device.

**SYSTEM FAULT LED:** illuminates red if the system faults or if there is a self-diagnostic check failure with the system clock or power delivery. If this event occurs, terminate the procedure immediately and contact an authorized Hologic service representative for instructions.

## Troubleshooting Most Common Alarms

### CAVITY ASSESSMENT LED illuminated red

If the CAVITY ASSESSMENT LED is steady red, the cavity integrity assessment has failed. If the cavity integrity assessment fails, then the CAVITY ASSESSMENT LED on the NovaSure RF controller will flash red, and a rapid audible tone will sound at a rate of four times per second. The test may be tried again.

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

If the cavity integrity assessment fails, press the foot switch to stop the sound. The cause of the cavity integrity assessment failure is the inability to pressurize the cavity. It may be caused by:

1. Device leak: ensure that the suction line desiccant filter has been installed. Check all tubing and luer connections to ensure that they are tightly connected.
2. Leak at the external os of the cervix: Look for visible bubbles or a “hissing” sound at the external os of the cervix.  
Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure there is a tight seal. Test again. If the test fails again, use a second tenaculum to grasp the cervix around the sheath of the NovaSure disposable device. Test again.

3. Uterine perforation: **If a uterine perforation is suspected, the procedure should be terminated immediately.**

**NOTE:** CO<sub>2</sub> leakage may occur at the external cervical os due to the presence of an over-dilated cervix. Visible bubbles or the “hissing” sound of escaping gas may accompany CO<sub>2</sub> leakage under either of these conditions.

If the cavity integrity assessment fails after reasonable attempts to implement the troubleshooting procedures (step 2.36), abort the procedure.

**NOTE:** Removing the disposable device from the uterine cavity after completing a cavity integrity assessment will require an additional test to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.

### VACUUM LED illuminated

The VACUUM LED illuminates when the vacuum level is outside its specified range. This can occur as a result of one or more of the following:

- an over-dilated cervix;
- poor contact between the cervical collar and the external cervical os;
- the vacuum relief valve is in the closed position;
- a poor connection in the luer below the disposable device handle;
- an obstruction in the disposable device filter(s) (two) or desiccant; or
- an obstruction within the disposable device.

To eliminate this condition, perform the following:

- Gently press a 2–3.5 mm uterine dilator or sound inside the vacuum relief valve.
- Check the cervical collar position, and reposition it if necessary. Use the tab on the cervical collar to advance the cervical collar towards the external os of the cervix to ensure there is a tight seal. Verify that air is not being drawn through the cervix by a loose fit between the cervical collar and the entrance to the cervical canal. If air is being drawn in through the cervical canal, try to reposition the cervical collar and disposable device shaft to prevent air ingress.
- Ensure the suction canister on the disposable device is vertical and the device tubing is not draped over the patient's leg.
- Check all tubing and luer connections to ensure that they are tightly connected. Check the luer connections used to flush the disposable device on both the vacuum feedback and suction lines. These are located near the disposable device handles. Check the push-on tubing connectors at the desiccant tube. Replace the dessicant if it is pink. Ensure that the filter located near the disposable connection on the vacuum feedback line is tightened.
- Reattempt ablation.

If the problem persists, remove the disposable device from the patient. Deploy the disposable device. Disconnect the luer on the vacuum feedback line (the small diameter tubing). Flush the vacuum feedback line using 40 cc of saline followed by 40–60 cc of air. Repeat this same flushing procedure on the suction line. After performing the above troubleshooting steps, reinsert the disposable device, press the ENABLE button twice and step on the foot switch to reattempt the ablation.

If the VACUUM LED illuminates again:

- Disconnect the disposable device from the RF controller.
- Remove the disposable device from the patient, then;
- Exchange the disposable device with a new disposable device.
- Reattempt the ablation with the new device.

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If a vacuum alarm occurs with the new device, abort the procedure:

**NOTE: Removing the disposable device from the uterine cavity after completing a CIA will require an additional CIA to be performed upon disposable device re-insertion (whether or not the CIA previously passed) prior to initiating an ablation.**

### CO<sub>2</sub> canister low or empty

The NovaSure RF controller will generate an audible tone at a rate of four times per second during this alarm condition. LEDs that were illuminated prior to the alarm will remain in the same state during the low CO<sub>2</sub> event. Pressing the foot switch will not turn off the audible alarm.

1. Replace the CO<sub>2</sub> canister to stop the audible tone.

**NOTE: It is not necessary to remove the disposable device from the patient prior to replacing the canister.**

2. Continue with the procedure.

### ARRAY POSITION LED illuminated

1. Gently move the proximal end of the disposable device and observe if the ARRAY POSITION LED extinguishes. If it does not, proceed with the following:
2. Attempt gentle reseating of the NovaSure disposable device:
  - A. Partially retract the array into the sheath by releasing the disposable device handle lock release button;
  - B. Pull the disposable device back slightly from fundus;
  - C. Slowly redeploy the disposable device array while gently rocking the disposable device back and forth and locking the disposable device handles; and
  - D. Reseat the disposable device against fundus using the seating procedure described in section 2.0.
3. If the uterus is retroverted, take special care to avoid perforation. Apply gentle caudad traction to the cervix with the tenaculum, and elevate the disposable device handle upward toward the ceiling (in-line with the axis of the uterus) while performing the seating procedure.
4. If the ARRAY POSITION LED is still illuminated, fully retract the disposable device array and remove the disposable device from the patient.
5. Deploy the disposable device outside the patient's body; ensure the electrode array is undamaged and that the ARRAY POSITION LED extinguishes.
6. Attempt reinsertion, redeployment and reseating of the disposable device using the seating procedure described in section 2.0.
7. If the ARRAY POSITION LED remains illuminated, replace with a new disposable device.
8. If the ARRAY POSITION LED remains illuminated with a new disposable device, terminate the procedure.

### Additional Troubleshooting

#### Suspected uterine perforation

Prior to Application of Energy:	During or after Application of Energy:
---------------------------------	--

- |   |   |
|---|---|
| 1. Terminate the procedure              | 1. Terminate the procedure              |
| 2. Assure patient stability             | 2. Assure patient stability             |
| 3. Consider work-up for perforation     | 3. Rule out visceral injury             |
| 4. Reschedule procedure, if appropriate | 4. Reschedule procedure, if appropriate |

### Array does not fully deploy and lock in uterus

1. Partially retract array into sheath (hold the front handle stationary and pull the rear handle back and away from the patient);
2. Reposition the disposable device in the cavity;
3. Redeploy the array in cavity;
4. If the disposable device does not lock, remove it from the uterus;
5. Inspect the disposable device for damage;
6. Attempt to open the disposable device and lock it outside the patient;
7. If damaged, the replace disposable device;
8. If the disposable device is not damaged, reinsert it into the patient's uterine cavity and attempt deployment; and
9. If unable to deploy the disposable device to a minimum 2.5 cm cornu-to-cornu distance, terminate the procedure.
10. Consider uterine perforation as a possible cause for not deploying.

### Difficulty closing and removing the disposable device post-ablation

Confirm that the lock release button is depressed:

- If so, gradually withdraw the disposable device from the patient.
- If not, press the lock release button and reattempt to close the disposable device. If it is still difficult to close, gradually withdraw the disposable device from the patient.

### ENABLE LED will not illuminate

Be sure:

1. The ENABLE button is firmly depressed;
2. The NovaSure RF controller is plugged in;
3. The toggle switch at the back of the controller is on; and
4. The ARRAY POSITION LED is not illuminated.

### PROCEDURE COMPLETE LED not illuminated at the end of a procedure

1. If power has not been applied for at least 30 seconds, the LED will not illuminate. Remove the NovaSure disposable device from the uterus after fully retracting the disposable device array into the sheath:
  - A. Release the disposable device lock release button;
  - B. Hold the disposable device front handle steady; and
  - C. Pull the disposable device rear handle backward.
2. Inspect the disposable device for any damage. Fully deploy the electrode array outside the patient, demonstrating that the ARRAY POSITION LED does not illuminate.
3. If the disposable device is not damaged and the ARRAY POSITION LED extinguishes, reinsert, redeploy and reattempt treatment.
4. If the problem persists, replace the disposable device with a new disposable device.
5. Reattempt the procedure. If the problem persists, terminate the procedure.

### RF ON LED will not illuminate

1. If the NovaSure RF controller is plugged in, switched on, the ENABLE LED is on and no power is delivered from the controller when the foot switch is depressed, check the foot switch connection. Also make sure the CAVITY ASSESSMENT LED is green.
2. If the problem persists, terminate the procedure.

## UP/DOWN values will not illuminate when pressing the appropriate keys

Make sure that the disposable device is connected to the controller. The values will not illuminate unless the disposable device is properly connected to the controller.

## Replacement Instructions

The NovaSure RF controller uses a pair of fuses that are located on a fuse carrier in the power input module. Type T5A, 250 V fuses are used. The module can be accessed by using a slotted screwdriver to pop open the fuse carrier door. If required, the fuse carrier may then be removed and the fuses changed. Assembly is the reverse of these steps. Any potentially defective NovaSure product must be returned to Hologic for evaluation. Follow the instructions at the end of this manual in the Service Returns section, for obtaining a returned materials authorization number (RMA #). Do not discard the NovaSure disposable device.

## Specifications

The NovaSure disposable device does not contain latex.

### NovaSure disposable device

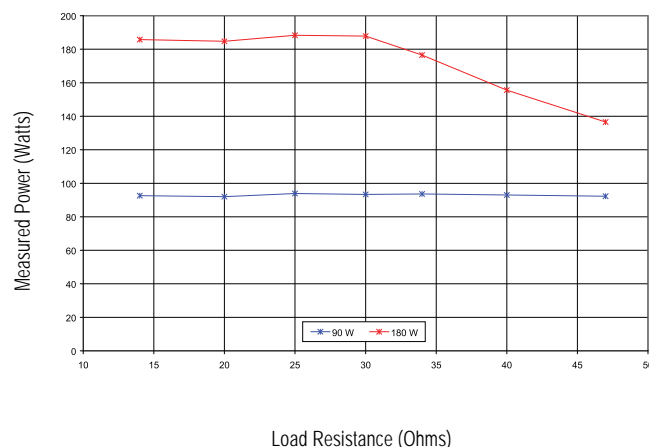
1. The NovaSure disposable device is a Class III device by FDA regulation.
2. The NovaSure disposable device is a Class IIB device according to the MDD 93/42/EEC.
3. The NovaSure disposable device tip nominal diameter: 7.5 mm.
4. The NovaSure disposable device overall dimensions: 19" x 6" x 12" (48.3 cm x 15.2 cm x 5 cm).

### NovaSure RF controller

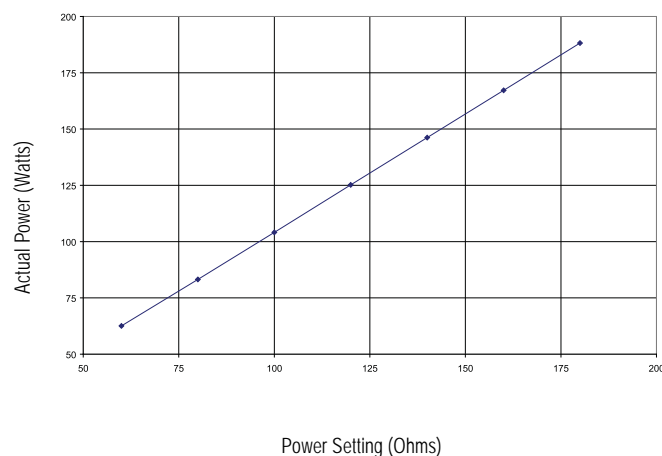
1. The NovaSure RF controller is a Class I, defibrillator-proof Type BF instrument, according to IEC 60601-1.
2. The NovaSure RF controller is a Class III device by FDA regulation.
3. The NovaSure RF controller is a Class IIB device according to the MDD 93/42/EEC.
4. The RF controller has been tested and found to comply with the limits for medical devices according to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Re-orient or relocate the receiving device
  - Increase the separation between equipment
  - Connect the equipment into an outlet on a circuit different from that to which the other device(s) is/are connected.
  - Contact Hologic technical support (or the manufacturer of the other equipment) for assistance.
5. The controller meets the requirements of IEC 60601-1/UL 60601-1, IEC 60601-2-2 and CSA C22.2 No.601.1.
6. Shipment of the controller should be done only in the original Hologic packaging. Environmental requirements for use, shipping and storage are indicated below.

7. The absolute maximum peak voltage generated by the NovaSure RF controller is 153 volts.
8. The absolute maximum peak power generated by the NovaSure RF controller is 216 watts.
9. NovaSure RF controller weight: 24 lbs (11 kg), unpacked.
10. Height: 12.5"; Width: 7.5"; Depth: 14.5" (32 cm x 19 cm x 35.5 cm).
11. The maximum pressure of CO<sub>2</sub> delivered from the NovaSure RF controller and disposable device shall be 90 ± 10 mmHg. The maximum flow rate of CO<sub>2</sub> from the NovaSure RF controller connected to the disposable device shall be 95 ± 15 ml/min. (The maximum flow rate of CO<sub>2</sub> from the NovaSure RF controller without a NovaSure disposable device attached is 117 ± 13 ml/min.)

Power vs. Resistance



Actual Power vs. Power Setting into a 20 Ohm Load



### Operating, non-packaged conditions

Altitude	0 to 10,000 ft	(0 to 3,030 m)
Temperature	10° C to 40° C	(50° F to 104° F)
Humidity	15 to 85% RH at 40° C (non-condensing)	

**Non-operating, packaged conditions**

Altitude	0 to 40,000 ft	(0 to 12,120 m)
Temperature	–30° C to 60° C	(–22° F to 140° F)
Humidity	85% RH, 72 hr, at 38° C (non-condensing)	

**Guidance and manufacturer's declaration – electromagnetic emissions and immunity**

The NovaSure RF controller with cavity integrity assessment is intended for use in the electromagnetic environment specified below. The customer or user of the NovaSure RF controller with cavity integrity assessment should ensure that it is used in such an environment.


**Electromagnetic emissions**

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 2	The NovaSure RF controller with cavity integrity assessment must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The NovaSure RF controller with cavity integrity assessment is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
<b>WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the NovaSure RF controller or shielding the location.</b>		

**Electromagnetic immunity**

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2	±6 kV Contact  ±8 kV Air	±6 kV Contact  ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN/IEC 61000-4-4	±2 kV for power supply lines  ±1 kV for input/output lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Surge EN/IEC 61000-4-5	±1 kV line(s) to line(s)  ±2 kV line(s) to earth	±1 kV line(s) to line(s)  ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout EN/IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds  This condition causes the RF controller to shut down and then return to standby mode.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NovaSure RF controller with cavity integrity assessment requires continued operation during power mains interruptions, it is recommended that the NovaSure RF controller with cavity integrity assessment be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RF generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <u>Recommended separation distance</u>  $d = 1.2\sqrt{P}$

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Radiated RF IEC 61000-4-3	3 Vrms 80 MHz to 2.5 GHz	3 Vrms	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
<b>NOTE 1:</b> At 80 MHz and 800 MHz, the higher frequency range applies. <b>NOTE 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RF generator is used exceeds the applicable RF compliance level above, the RF generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RF generator. <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

### Recommended separation distances between portable and mobile RF communications equipment and the NovaSure RF controller

The NovaSure RF controller with cavity integrity assessment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NovaSure RF controller can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NovaSure RF controller as recommended in the following table, according to the maximum output power of the communications device.

### Recommended separation distance

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. <b>NOTE 1:</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. <b>NOTE 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

### Cleaning and Sanitizing

The use of nonflammable agents for cleaning and sanitizing is recommended. Flammable agents or solvents for cleaning or sanitizing should be allowed to evaporate before use of the NovaSure system.

The NovaSure RF controller is not sterile. Cleaning should be done using a mild detergent and water solution to wipe surface areas only. Do not immerse unit in liquid or introduce liquid into the cooling vents or RF cable areas.

The NovaSure disposable device is a sterile disposable device for single-patient use only.

- Do not use if the packaging is opened or damaged.
- Do not reuse or re-sterilize the disposable device.

Do not sterilize any component of the NovaSure impedance controlled endometrial ablation system.

## ENGLISH

### Parts List

Ordering information and related parts and accessories

Product Number	Description
RFC2009-115	NovaSure® RF Controller, Model 09
RFC2009-230	NovaSure® RF Controller, Model 09
RFC-PC115	Power Cord, 115 Volts, North America
RFC-PC230	Power Cord, 230 Volts, Europe
RFC-PC230UK	Power Cord, 230 Volts, United Kingdom/Ireland
RFC-PC230SZ	Power Cord, 230 Volts, Switzerland
RFC-PC230IT	Power Cord, 230 Volts, Italy
RFC-PC230DEN	Power Cord, 230 Volts, Denmark
RFC2000-FS	Foot Switch
RFC2000- CO <sub>2</sub> -10	Medical Carbon Dioxide Gas, CO <sub>2</sub> , Cylinder 10 Pack
RFC2000- CO <sub>2</sub> -5	Medical Carbon Dioxide Gas, CO <sub>2</sub> , Cylinder 5 Pack
NS2000	NovaSure® Impedance Controlled Endometrial Ablation Disposable Device Kit
NS2007	NovaSure® Kit: 3 NovaSure Impedance Controlled Endometrial Ablation Disposable Devices packaged with 3 SureSound devices (available in USA only)
SOUND12	SureSound: 12 devices (available in USA only)
300001	Biohazard Kit

### Warranty

Hologic warrants the original purchase of the NovaSure® RF controller shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use and maintenance instructions. The obligation of Hologic under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Hologic within one year from the date of purchase, if examination shall disclose to the satisfaction of Hologic, that the NovaSure RF controller does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF HOLOGIC. HOLOGIC NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF A NOVASURE RF CONTROLLER. THIS WARRANTY SHALL NOT APPLY TO A NOVASURE RF CONTROLLER OR ANY OTHER PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY NOVASURE RF CONTROLLER THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED HOLOGIC SERVICE PERSON, MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE NOVASURE RF CONTROLLER AND NOT SUPPLIED AND MANUFACTURED BY HOLOGIC. THE TERM "ORIGINAL PURCHASER", AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE NOVASURE RF CONTROLLER WAS SOLD BY HOLOGIC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

Should any NovaSure RF controller become inoperable after the one year period of this warranty or should damage occur which is not covered under the terms of this warranty, Hologic will upon request, repair the NovaSure RF controller, if possible, for an appropriate handling and repair charge.

**WARNING: Dropping the RF controller voids the warranty and could damage the controller beyond repair. We strongly recommend a stable cart which includes strapping or stabilizing the controller to reduce the risk of being dropped. Please use extra care if transporting the RF controller to an off-site facility. If you have any questions regarding the RF controller, please call 1-800-442-9892 or (508) 263-2900.**

### Technical Support and Product Return Information

#### Service representatives

Should the NovaSure RF controller become inoperable, contact Hologic technical support for instructions and a return materials authorization number (RMA #). Clean and repackage the controller appropriately and return it for repair or servicing to the authorized locations listed below. If the controller is not under warranty, an appropriate handling and repair charge will be established at receipt and examination of the NovaSure RF controller.

For service, technical support or reorder information, contact, in the United States:



Hologic, Inc.  
250 Campus Drive  
Marlborough, MA 01752 USA  
Phone: 800-442-9892 (toll-free)  
or 508-263-2900  
Fax: 508-229-2795  
www.hologic.com

**NOTE: Any disposable device-related incident or problem, which is believed to represent a safety issue, should be reported to Hologic technical support or the Authorized European Representative.**



Hologic UK Ltd.  
Link 10, Napier Way  
Crawley, West Sussex RH10 9 RA UK  
Phone: +44 (0) 1293 522 080  
Fax: +44 (0) 1293 528 010

Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training.

## Service returns

**Read these instructions prior to returning any used/unused potentially defective product to Hologic.**

Contact Hologic Technical Support if the NovaSure disposable device or RF controller fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable.

Return RF controllers according to the instructions provided by Technical Support. Be sure to clean the RF controller before returning it and include all accessories in the box with the returned unit.

Return used or opened disposable devices according to the instructions provided with the Hologic-supplied biohazard kit.

Hologic and its distributors and customers in the European Community are required to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC). Hologic is dedicated to meeting country specific requirements related to the environmentally sound treatment of its products. Hologic's objective is to reduce the waste resulting from the disposal of its electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE to potential reuse, treatment, recycling or recovery to minimize the amount of hazardous substances entering the environment. Hologic customers in the European Community are responsible for ensuring that medical devices marked with the following symbol, indicating that the WEEE Directive applies, are not placed into a municipal waste system unless authorized to do so by local authorities.



Contact Hologic Technical Support to arrange for proper disposal of the RF controller in accordance with the WEEE Directive.

## Symbol Definitions

Alternating current (AC)	
Authorized Representative in the European Community	
Batch code	
Carbon dioxide	
Catalog number	
Category non-AP equipment	
Caution, consult accompanying documents	
CE marking of conformity with notified body identification number	
Dangerous voltage	
Date of manufacture	
Defibrillator-proof Type BF equipment	
Do not re-sterilize	
Do not reuse	
Do not stack above "n" high	
Do not use if package is damaged	
Equipotential ground	
European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC	
Foot switch	
Fragile	
Fuse	
High pressure	
Keep dry	
Latex-free	
Manufacturer	
No oil	
Protect from heat	
Radio frequency (RF) energy (non-ionizing radiation)	
Serial number	
Sterilized using ethylene oxide	
Sterilized by irradiation	
This side up	
Use by	

## ENGLISH

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