# INSTRUCTIONS FOR USE
# NOVASURE™ DISPOSABLE DEVICE

**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.**

This provides instructions for using the NovaSure™ Disposable Device. Please refer to the Operator's Manual for complete instructions.

**THE NOVASURE™ DISPOSABLE DEVICE IS NOT TO BE USED WITH OTHER CONTROLLERS AND/OR RF GENERATORS, NOR SHOULD THE NOVASURE™ RF CONTROLLER BE USED WITH OTHER DISPOSABLE DEVICES.**

## 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 operator's manual and Instructions For Use, 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 section of this manual to abort, resolve, and/or continue the treatment in the event the system detects a loss of $CO_2$ during the Cavity Integrity Assessment (CIA) test, which indicates a possible uterine perforation.

Adjunct personnel must be familiar with the Operator's Manual and other training materials prior to using the Novasure™ System.

## 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 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 pre-treatment. 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,



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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, is 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™ 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.

## 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 or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean section or transmural myomectomy.
- 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 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 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.**

## UTERINE PERFORATION

- Use caution not to perforate the uterine wall when sounding, dilating, or inserting the Disposable Device.
- The NovaSure™ System performs a Cavity Integrity Assessment (CIA) test to evaluate the integrity of the uterine cavity. Although designed to detect a perforation of the uterine wall, it is an indicator only, and clinical judgment must always be used to assess the integrity of the uterine cavity. **IF A UTERINE PERFORATION IS SUSPECTED, THE PROCEDURE SHOULD BE TERMINATED IMMEDIATELY.**
- **IF THE CAVITY INTEGRITY ASSESSMENT FAILS THREE TIMES FOR ANY REASON OTHER THAN $CO_2$ LEAKAGE AT THE EXTERNAL CERVICAL *OS*, ABORT THE PROCEDURE.**

  **NOTE: $CO_2$ 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 $CO_2$ leakage under either of these conditions.**
- OVERRIDING THE CAVITY INTEGRITY ASSESSMENT SYSTEM MAY RESULT IN SERIOUS PATIENT INJURY. The override feature for the Cavity Integrity Assessment test should be used ONLY if the physician's clinical judgment indicates, WITH ABSOLUTE CERTAINTY, that NO uterine perforation exists. If absolute certainty cannot be achieved, 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.

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 RF Controller starts $CO_2$ flow to purge any air out of the 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 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.

- Do not use in the presence of a flammable anesthetic mixture.

## 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.
- The NovaSure™ System consists of the following components:
  - Single-patient use NovaSure™ Disposable Device with connecting cord;
  - NovaSure™ RF Controller;
  - NovaSure™ $CO_2$ Canister;
  - NovaSure™ Desiccant;
  - NovaSure™ Foot Switch; and
  - Power Cord.

  To ensure proper operation, never use other components with the NovaSure™ System.
- 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 cornu-to-cornu distance less than 2.5 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; or
  - who are post-menopausal.
- Do not attempt to repair the Controller if problems are suspected. Call Novacept Customer Service or a Novacept, Inc. 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.
- Do not use the NovaSure™ Suction Line Desiccant if Desiccant material is pink in color.
- The carbon dioxide canister contains gas under high pressure.
- $CO_2$ 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 $CO_2$ flow and potential risk of embolism, perform the seating procedure immediately after inserting the device and proceed directly from the seating procedure to the CIA test.
- 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 other conductive object, *e.g.* monitors may display false readings.

## 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 plus Rollerball endometrial ablation. Tables 1A through 1D summarize the adverse events reported during the first 1 year of follow-up for all patients entered in this study.

### TABLE 1A – INTRA-OPERATIVE ADVERSE EVENTS

| ADVERSE EVENT | NOVASURE™ n=175 (%) | LOOP RESECTION PLUS ROLLERBALL n=90 (%) |
|---|---|---|
| Bradycardia | 1 (0.6%) | 0 |
| Uterine perforation | 0 | 3 (3.3%) |
| Cervical tear | 0 | 2 (2.2%) |
| Cervical stenosis | 0 | 1 (1.1%) |
| **TOTAL** | **1 (0.6%)** | **6 (6.7%)** |

### 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%) |
| **TOTAL** | **9 (5.1%)*** | **5 (5.6%)**** |

* 9 events reported in 6 (3.4%) patients
** 5 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%) |
| **TOTAL** | **5 (2.9%)*** | **7 (7.8%)**** |

* 5 events reported in 4 (2.3%) patients
** 7 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%) |
| **TOTAL** | **21 (12.0%)*** | **15 (16.7%)**** |

* 21 events in 19 (10.9%) patients
** 15 events in 15 (16.7%) patients

### POTENTIAL ADVERSE EVENTS

The following adverse events were not observed in clinical studies of the NovaSure™ System, but could occur with endometrial ablation:

- Thermal injury
- Electrical burn
- Perforation of the uterine wall
- Post-ablation tubal sterilization syndrome
- Air or gas embolism
- Pregnancy

### ANTICIPATED POST-PROCEDURAL COMPLICATIONS

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

- Cramping/pelvic pain. Post-treatment 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 have been reported in patients immediately following the procedure and can be managed with medication.
- Vaginal discharge.
- Vaginal bleeding/spotting.

## CLINICAL STUDY

**Purpose:** The use of the NovaSure™ System in the treatment of menorrhagia from benign causes in pre-menopausal women was compared to loop resection plus rollerball ablation to evaluate safety and effectiveness.

**Study Endpoints:** The primary effectiveness measure was a validated menstrual diary scoring system developed by Higham (Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart *Br J Obstet Gynaecol* 1990;97:734-9). Patient success was defined as a reduction in menstrual flow at 1 year to a diary score of $\leq$75. Study success was defined as a statistical difference of less than 20% in patient success rates between NovaSure™ Impedance Controlled Endometrial Ablation System and Loop Resection plus Rollerball ablation. Secondary endpoints included responses from a quality-of-life questionnaire. Safety evaluation was based on the adverse events reported during the

study, including device-related complications. The anesthesia regimen used to perform the procedure was also recorded.

**Methods**: A randomized (2:1), prospective study was conducted at 9 clinical sites and included 265 patients diagnosed with menorrhagia. Menstrual diary scores were collected pre-treatment and monthly for 12 months post-treatment. None of the patients received hormonal pre-treatment to thin the endometrial lining. Patients were treated at any time in their menstrual cycle. Control patients received loop resection for pre-treatment 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 1) had at least 3 prior months (documented) failed medical therapy; 2) had a contraindication to medical therapy; or 3) 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
- Symptomatic endometriosis
- Prior uterine surgery (except low segment cesarean section) that interrupts the integrity of the uterine wall e.g. transmural myomectomy or classical cesarean section. Prior endometrial ablations
- Patient on medications that could thin the myometrial muscle, such as long-term steroid use
- Patient on anticoagulants
- 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 2cm) which are likely to be the cause of the patient's menorrhagia.
- Presence of an IUD
- Suspected or confirmed uterine malignancy 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:** 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 9 investigational sites.

**PATIENT ACCOUNTABILITY**

| NUMBER OF PATIENTS | NOVASURE™ | LOOP RESECTION PLUS ROLLERBALL |
|---|---|---|

| | | |
|---|---|---|
| **Entered into Study** | **175** | **90** |
| Aborted procedures* | 4 | 2 |
| **Treated** | **171** | **88** |
| Failed – required additional treatment* | 4 | 2 |
| Failed – hysterectomy performed* | 2 | 2 |
| Lost to follow-up* | 2 | 2 |
| Hodgkin's* | 1 | 0 |
| **6-Month Follow-up** | **162** | **82** |
| Failed – hysterectomy performed* | 1 | 0 |
| Pelvic pain – administered leuprolide* | 1 | 0 |
| Lost to follow-up* | 4 | 0 |
| **12-Month Follow-up** | **156** | **82** |

* Discontinued patients

## Results

***Primary Endpoint: Bleeding Scores***

Patient success was based on a reduction in diary score from ≥ 150 pre-treatment to ≤ 75 at one year post-treatment. Table 2 shows the success rates for all 265 patients entered into the study (Intent-to-Treat Group).

### Table 2 – Effectiveness: Success Rates at One Year

**Intent-to-Treat Patients**

| | **NovaSure™ n=175** | **Loop Resection Plus Rollerball n=90** |
|---|---|---|
| Number of successful patients (diary score ≤75) | 136 | 67 |
| Study success rate (% patients with score ≤75) | 78% | 74% |
| Number of Patients with Amenorrhea (score = 0) | 63 | 29 |
| Amenorrhea rate (% patients with score = 0) | 36% | 32% |

**NOTE:** Data presented in the Table 2 above represent the clinical results based on the total number of 265 patients randomized (Intent-to-Treat Group) for the study. Please note that in the NovaSure™ arm 4 patients were not treated due to unexpected variables identified during patient selection and screening (uterine sound length > 10 cm, etc.). Also, included in this group are patients who were lost to follow-up (n=6) as well as patients that had a successful procedure outcome, but had a hysterectomy or other treatment due to pain (endometriosis, adenomyosis) within the 12-months follow-up interval. All of these discontinued patients (19 NovaSure™; 8 Rollerball) were considered treatment failures for the data analysis presented in Table 2.

***Secondary Endpoint: Patient Satisfaction***

Patient satisfaction was assessed by administering Quality of Life (SF-12 Questionnaire) and Menstrual Impact questionnaires prior to treatment and at 3, 6 and 12 months post-treatment. Table 3 shows the patient responses for both groups 12 months post-treatment.

### Table 3 – Effectiveness: Quality of Life at 1 Year

| | **NOVASURE™ n (%)** | **LOOP RESECTION PLUS ROLLERBALL n (%)** |
|---|---|---|
| Number of Patients Responding | 154 | 82 |



35

| | | | |
|---|---|---|---|
| PMS | pre-treatment | 102 (66%) | 54 (66%) |
| | post-treatment | 56 (36%) | 29 (35%) |
| Dysmenorrhea | pre-treatment | 86 (56%) | 46 (56%) |
| | post-treatment | 32 (21%) | 28 (34%) |
| Satisfied or very satisfied with procedure | | 141 (92%) | 76 (93%) |
| Definitely or probably would recommend procedure to friend | | 146 (95%) | 78 (95%) |

***Secondary Endpoint: Procedure Time***

Procedure time, a secondary end-point, 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 ± 3.5 minutes and 24.2 ± 11.4 minutes, respectively). (See Table 4 above.)

Mean time for application of RF energy was 84.0 ± 25.0 seconds in a subset of monitored patients.

**Table 4 – Operative Procedure Time**

| OPERATIVE PARAMETERS | NOVASURE™ n=175 | LOOP RESECTION PLUS ROLLERBALL n=90 |
|---|---|---|
| Number of treated patients* | 171 | 88 |
| Procedure time minutes** (± SD) | 4.2 ± 3.5 | 24.2 ± 11.4 |

* 6 aborted procedures (4 NovaSure™; 2 loop resection plus rollerball)
** Statistically significant difference between treatment groups (Student's t-test; $p < 0.05$)

***Secondary Endpoint: Anesthesia Regimen***

Anesthesia was delivered at the discretion of the 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.

## Clinical Observations

***Hysterectomy***

Five women had a hysterectomy within the first year after the ablation procedure. Table 5 lists the reasons for hysterectomy.

**Table 5 – Hysterectomy**

| REASON FOR HYSTERECTOMY | NOVASURE™ n=175 | LOOP RESECTION PLUS ROLLERBALL n=90 |
|---|---|---|
| Adenocarcinoma diagnosed at time of procedure | 1 | 1 |
| Pain and bleeding | 2 | 0 |

| | | |
|---|---|---|
| Infection | 0 | 1 |
| **Total** | **3 (1.7%)** | **2 (2.2%)** |

NOTE: The 3 NovaSure™ patient hysterectomies were in women under the age of 40 and the 2 Loop Resection plus Rollerball hysterectomies occurred in women 40 years of age and older.

## 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 pre-treated 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

PICTURE #1

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™ $CO_2$ Canister

Note: Please have available at least one extra Disposable Device, Desiccant assembly and $CO_2$ Canister.

PICTURE 1A

1.2 Prepare the NovaSure™ RF Controller. Place on a small table to one side of the patient within visual field of the surgeon. Attach AC Power Cord to the Controller and plug into AC outlet.

1.3 Screw the $CO_2$ Canister into the regulator on the back panel of the Controller until tightened.

1.4 Open the $CO_2$ regulator.

PICTURES #2 AND #3

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 bee 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.

**DO NOT TREAT A PATIENT WITH A UTERINE CAVITY LENGTH THAT IS LESS THAN 4 CM, AS CERVICAL CANAL DAMAGE MAY OCCUR.**
**NOTE THAT PATIENTS WITH A UTERINE CAVITY LENGTH GREATER THAN 6.0 CM HAD OBSERVED SUCCESS RATES THAT WERE LOWER THAN THE OVERALL STUDY SUCCESS RATES.**

2.11 Open the sterile NovaSure™ Disposable Device package. Place the 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.

PICTURE #4

**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.

PICTURE #5

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) patient before performing STEP 2.15.

2.15 Connect the Disposable Device cord to the appropriate port on the front panel of the Controller.

PICTURE #6

**PLUGGING THE NOVASURE™ DISPOSABLE DEVICE INTO THE NOVASURE™ RF CONTROLLER STARTS $CO_2$ FLOW TO PURGE ANY AIR OUT OF THE DEVICE AND TUBING. THIS 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.**

Note: $CO_2$ 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 $CO_2$ flow and potential risk of embolism, perform the seating procedure immediately after inserting the device and proceed directly from the seating procedure to the CIA test.

## CAVITY LENGTH TABLE (SEE 2.21)

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.

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.

2.16 Deploy the Disposable Device outside of the patient and ensure the Controller "ELECTRODE ARRAY POSITION" LED is extinguished when the array is opened. If the LED is not extinguished, close and open the 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. PICTURE # 7

NOTE: If the WIDTH dial reads less than 4.0 cm close the 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 Novacept Customer Service.

2.18 Completely retract the electrode array by pressing the lock release button, holding the front grip stationary and pulling the rear handle backwards until the Closed Array Indicator reads CLOSED to indicate that the electrode array has been retracted into the sheath of the disposable device.
PICTURE #7A

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.

**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 1 above, 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.
PICTURE #8

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 device in-line with the axis of the uterus as the Disposable Device is inserted transcervically into the uterine cavity. Advance the Disposable Device until the distal end of the sheath touches the fundus. PICTURES #9A and 9B

NOTE: **If the Device is difficult to insert into the cervical canal, use clinical judgement 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 device ~0.5 cm to and from the fundus and rotating the handle of the 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.

PICTURE #10

NOTE: **ONCE THE DISPOSABLE DEVICE HANDLES ARE LOCKED, THE UTERUS SHOULD MOVE IN CONJUNCTION WITH THE DEVICE.**

2.29 Gently move the Disposable Device using anterior, posterior and lateral movements.
PICTUREs #11 and 12

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.
PICTURE # 13

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.

PICTURE # 13A

2.32 Slide the Cervical Collar forward until it forms a seal against the external cervical *os*. Lock in place by depressing the locking tab by applying firm pressure until you hear it click.

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

PICTURE #14

CAUTION: **The efficacy of the NovaSure™ System has not been fully evaluated in patients with a cornu-to-cornu distance less than 2.5 cm.**

**CAUTION: If the Electrode Array Position LED light is illuminated see the troubleshooting section of the Operator's Manual under "Electrode 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.

2.35a **Automatic Mode**
To operate the system in the automatic mode, press the ENABLE button prior to beginning the Cavity Integrity Assessment test. Upon successful completion of the Cavity Integrity Assessment test in Step 2.36 ("CAVITY ASSESSMENT" LED is solid green), the ablation cycle will start automatically.

b **Semi-Automatic Mode** (Step 3.37 below)
To operate the system in the semi-automatic mode, DO NOT press the ENABLE button prior to beginning the Cavity Integrity Assessment test. Upon successful completion of the Cavity Integrity Assessment test in Step 2.36 ("CAVITY ASSESSMENT" LED is solid green), the ablation cycle will not start automatically.

2.36 Begin the Cavity Integrity Assessment (CIA) procedure by stepping on the foot switch once. The Cavity Integrity Assessment LED flashes green in conjunction with an audible beep at a rate of once per second when the system is performing a CIA test. The duration of the test will range between approximately 7 and 30 seconds. A steady green LED appears when the CIA test has passed and the system can deliver RF energy. Power cannot be applied to the disposable device until the Cavity Integrity Assessment LED is a steady green light. PICTURE #15

If the Cavity Integrity Assessment test fails, then the CAVITY INTEGRITY ASSESSMENT LED on the NovaSure™ RF Controller will flash red, and a rapid audible beep will sound at a rate of four times per second.

If the Cavity Integrity Assessment test fails, press the foot switch to stop the sound. Next:

A. IF A PERFORATION IS SUSPECTED, THE PROCEDURE SHOULD BE TERMINATED IMMEDIATELY

B. Unlock the Cervical Collar by releasing the locking tab by applying firm pressure until you hear an audible click. Advance it only to the point where the flange on the collar head contacts the external cervical os. Lock the collar in place by depressing the locking tab. Repeat the Cavity Integrity Assessment test by pressing the foot switch.

C. 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 test by pressing the foot switch.

D. IF THE CAVITY INTEGRITY ASSESSMENT FAILS THREE TIMES FOR ANY REASON OTHER THAN $CO_2$ LEAKAGE AT THE EXTERNAL CERVICAL *OS*, ABORT THE PROCEDURE.

NOTE: $CO_2$ 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 $CO_2$ leakage under either of these conditions.

E. WARNING: OVERRIDING THE CAVITY INTEGRITY ASSESSMENT SYSTEM MAY RESULT IN SERIOUS PATIENT INJURY.

The override feature for the Cavity Integrity Assessment test should be used ONLY if the physician's clinical judgment indicates, WITH ABSOLUTE CERTAINTY, that NO uterine

perforation had occurred. If absolute certainty cannot be achieved, ABORT THE PROCEDURE. To override the CIA Test, press and hold the ENABLE button for 7 seconds.

**NOTE: The Cavity Integrity Assessment Test cannot be overridden until at least one assessment test attempt has failed.**

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

2.37 When operating the system in automatic mode, the ablation cycle will start automatically after the successful completion of the Cavity Integrity Assessment test.

When operating the system in semi-automatic mode, the ablation cycle will not start automatically after the successful completion of the Cavity Integrity Assessment test. Press the ENABLE button, and depress the footswitch a second time to initiate the ablation cycle.

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 anytime by depressing the footswitch.

PICTURE #16

2.38 After automatic termination of the ablation procedure (approximately 90 seconds), unlock the Cervical Collar and slide it to its proximal position.

PICTURE #17A

2.39 Close the Disposable Device by pressing the lock release button, holding the front grip stationary and pulling the rear handles backwards until the Closed Array indicator reads CLOSED to indicate that the Disposable Device is in the closed position. (See Step 2.18 and PICTURE 7A)

PICTURE #17B

2.40 Withdraw the Disposable Device from the uterine cavity. PICTURE #18

2.41 Turn off the RF Controller. Close the $CO_2$ 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.

**NOTE: THE PROCEDURE CAN BE STOPPED AT ANY TIME BY PRESSING THE FOOTSWITCH.**

**SPECIFICATIONS**

**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 maximum diameter = 7.5 mm.



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4. The NovaSure™ Disposable Device overall dimensions: 19" x 6." x 12" (48.3 cm x 15.2 cm x 5 cm).

**Operating, Non-Packaged Conditions**

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

**Non-Operating, Packaged Conditions**

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

**PARTS LIST**

ORDERING INFORMATION AND RELATED PARTS AND ACCESSORIES

| Product Number | Description |
|---|---|
| RFC2007-115 | NovaSure™ RF Controller Model 07, 115 Volts |
| RFC2007-230 | NovaSure™ RF Controller Model 07, 230 Volts |
| 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-$CO_2$-10 | Medical Carbon Dioxide Gas, $CO_2$, Cylinder 10 pack |
| NS2000 | NovaSure™ Impedance Controlled Endometrial Ablation Disposable Device Kit |
| NS2000-BIO | Biohazard Kit |

Contact your distributor for ordering.

Manufactured by: NOVACEPT, INC.

**SERVICE REPRESENTATIVES**

Should the NovaSure™ RF Controller become inoperable, contact Novacept, Inc. Customer Service Department for instructions and a Return Goods Authorization number (RGA #). Clean and repackage the Controller appropriately and return it for repair, servicing, and/or modification 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 Controller.

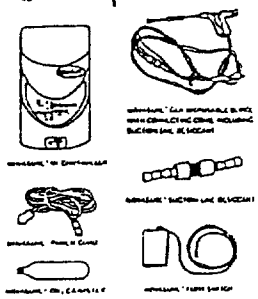
For service, technical support, or reorder information, contact, in the United States:

**Novacept, Inc.**
1047 Elwell Court
Palo Alto, CA 94303
Phone: (650) 428-3668
Fax: (650) 428-3639
www.novacept.com

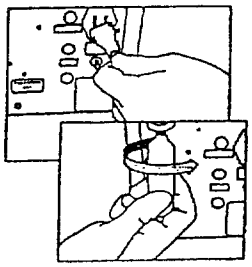
**NOTE: Any device-related incidence or problems, which are believed to represent a safety issue, should be reported to the Novacept, Inc. Customer Service Department or Authorized European Representative.**

Authorized European Representative:
MedPass International Ltd.
Windsor House
Barnett Way
Barnwood
Gloucester GL4 3RT
United Kingdom

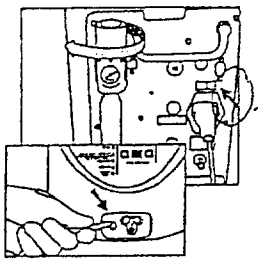
Picture #1
Set-up 1.1
(see also picture #1A step 1.1.



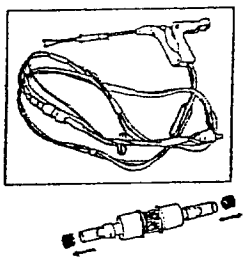
Picture #2
1.2 to 1.3



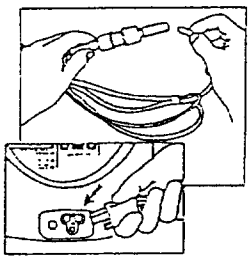
Picture #3
1.4 to 1.6



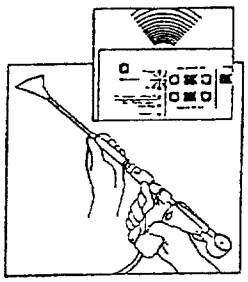

Picture #4
2.11 to 2.12



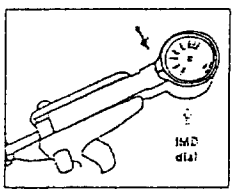
Picture #5
2.13 to 2.15



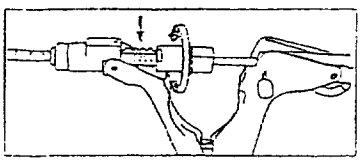
Picture #6
2.15 to 2.16



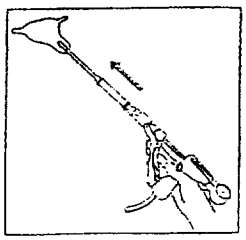
Picture #7 (see also PICTURE 7A (ATTACHED))
2.17 to 2.20



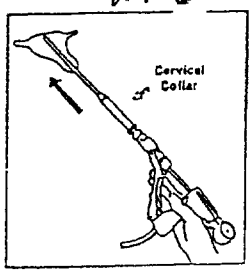
Picture #8
2.23



Picture # 9A
2.26



Picture # 9B
2.26




Picture # 10
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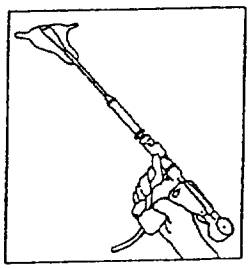

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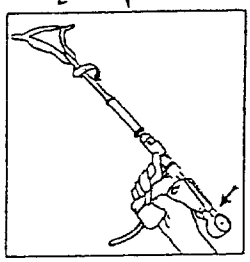
2.29



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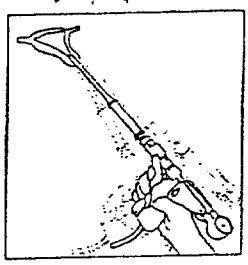
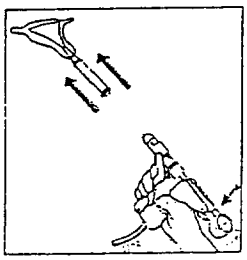
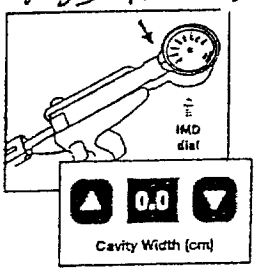


Picture # 13 (see also PICTURE 13 A. ATTACHED)
2.31



Picture # 14
2.33 to 2.34

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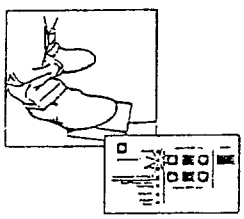
2.36



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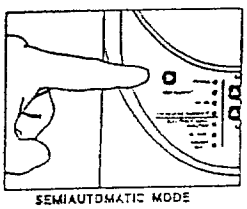
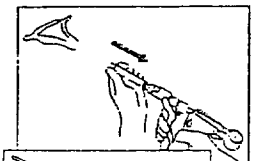
2.37

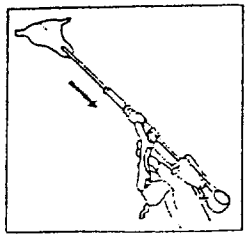


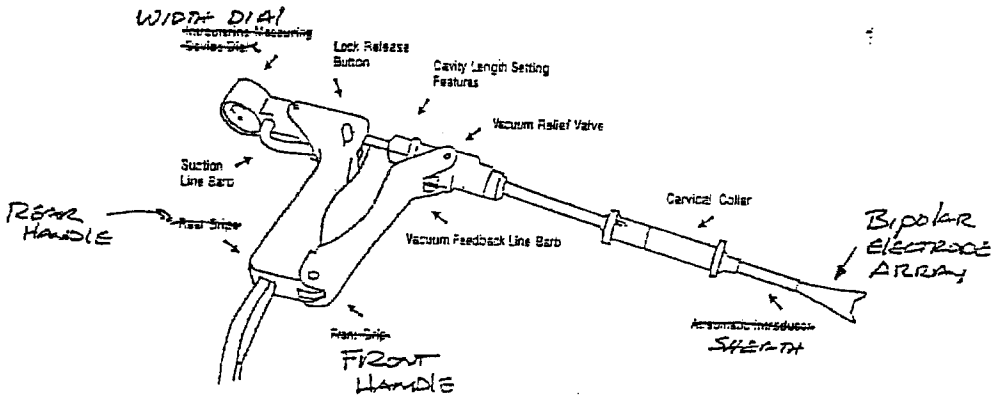

Picture # 17A
2.38



Picture 17B
2.39

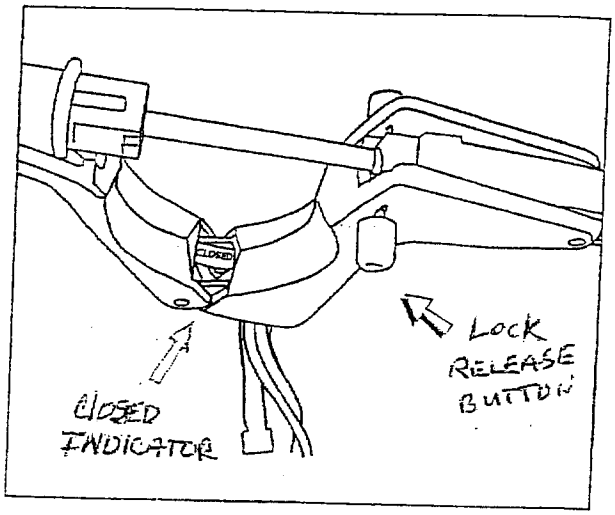
Picture # 18 2.40





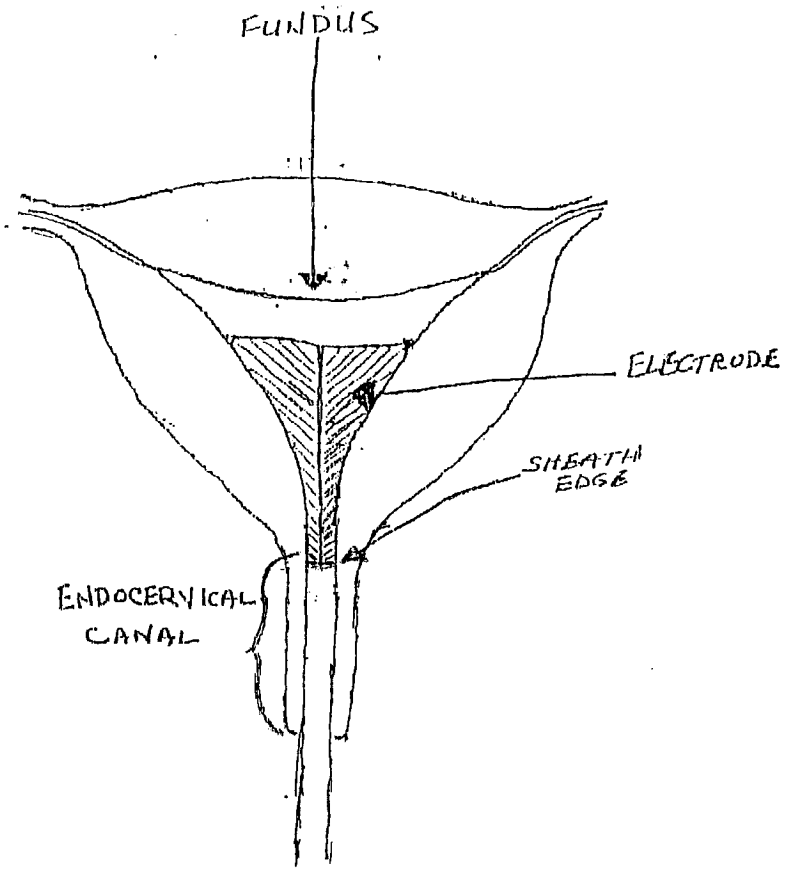

NOVASURE™ DISPOSABLE DEVICE DIAGRAM

PICTURE 1A



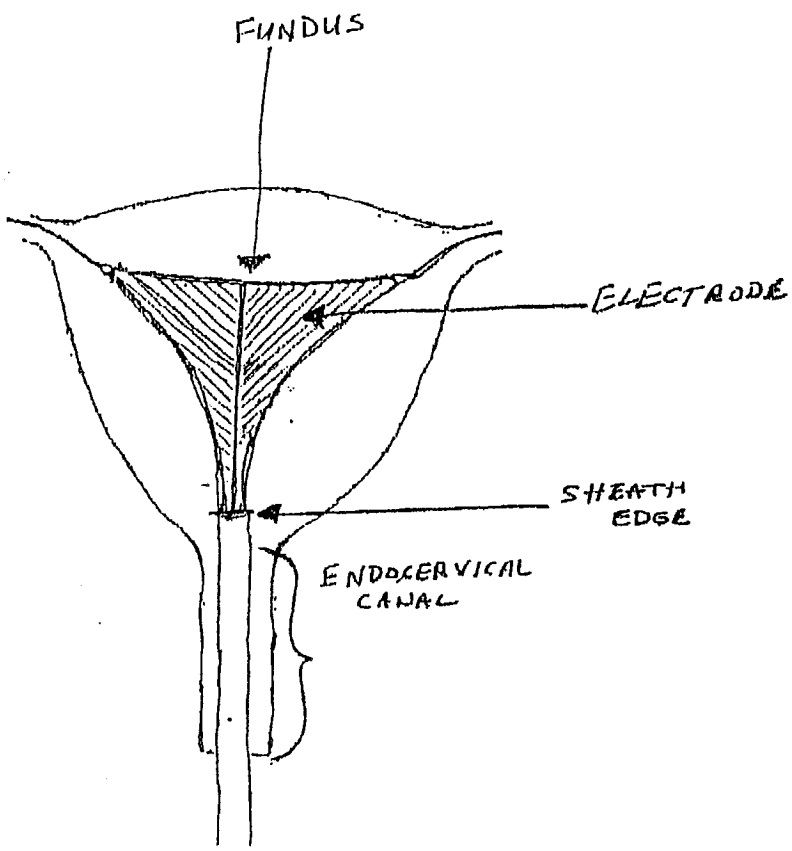

PICTURE 7A

INCORRECT PLACEMENT




SHEATH EDGE RESIDES IN ENDOCERVICAL CANAL

CORRECT PLACEMENT




SHEATH EDGE RESIDES IN LOWER UTERINE SEGMENT

PICTURE 13A

NOVASURE™

***Resolve the bleeding. Restore your life.***

If you experience excessive menstrual bleeding (menorrhagia), you may be interested in a new and effective endometrial ablation technology that is quick, simple, safe and complete. The NovaSure™ Impedance Controlled Endometrial Ablation System briefly applies a precisely controlled dose of energy to remove the endometrial lining of the uterus to reduce and ideally eliminate excessive menstrual bleeding. The NovaSure™ System can be used by your doctor to treat excessive menstrual bleeding (menorrhagia) due to benign causes in pre-menopausal women who have completed childbearing.

## WHAT IS MENORRHAGIA?

Menorrhagia is heavy menstrual bleeding, usually defined as bleeding which lasts seven or more days per cycle or which is so excessive that it requires changing protection nearly every hour.

Women suffering from menorrhagia can experience fatigue, anemia, embarrassing accidents, and restricted activity. It is estimated that approximately 20% of all women suffer from excessive bleeding at some time during their reproductive years.

In the United States, over 2 million women visit their gynecologist each year because of menorrhagia. Of these, approximately 200,000 receive a hysterectomy. The NovaSure™ procedure is one of several procedures that provide less invasive, uterine-sparing treatment options.

## WHAT ARE THE TREATMENT OPTIONS?

### *Drug Therapy*

Drug Therapy is typically the first treatment option, which consists of oral contraceptives or other hormones that treat hormonal imbalances. This therapy is only effective about 50% of the time, and usually must be continued in order to remain effective. Some women have undesirable side effects, including headaches, weight change, and nausea.

### *Dilation and Curettage (D & C)*

Dilation and Curettage is frequently the second option if drug therapy is ineffective. This is a common surgical procedure that involves scraping of the inside of the uterus using a surgical instrument. This may reduce bleeding for a few cycles.

### *Endometrial Ablation*

If you do not plan to have any more children, your doctor may suggest more aggressive surgical treatment options. Several methods are currently available.

- Conventional hysteroscopic endometrial ablation removes the lining of the uterus with an electrosurgical tool or laser. A hysteroscope (instrument to view the inside of the uterus) is used to visualize the areas of treatment. Most women return to work within 3 days. This method effectively reduces or eliminates bleeding in approximately 85% of the patients. Risks include perforation, bleeding, infection, or even heart failure due to fluids used to open up or distend the uterus.

- A new generation of endometrial ablation devices is now available. Some devices destroy the endometrium using heated fluid. Others use freezing temperatures to destroy the tissue. Recently, the NovaSure™ device, which uses a precisely controlled dose of energy, was made available for use in the U.S.

### *Hysterectomy*

Hysterectomy or surgical removal of the uterus is the only definitive treatment for menorrhagia. Hysterectomy is a major procedure, performed in the hospital under general anesthesia, and is accompanied by surgical risks, hospitalization, and, depending on the technique used, a recovery period of up to six weeks.

## WHO IS A CANDIDATE FOR THE NOVASURE™ PROCEDURE?

Women with heavy menstrual bleeding who have completed childbearing may be candidates for the NovaSure™ procedure. There are some exclusion criteria that only an examination by a physician can determine.

## HOW IS THE NOVASURE™ PROCEDURE PERFORMED?

The NovaSure™ procedure is typically performed in an outpatient surgery setting, involving local anesthesia with IV sedation or general anesthesia, depending on the surgeon's recommendation. After slight dilation of the cervix, a slender tube is inserted through the cervix into the uterus, and a triangular gold-plated mesh is expanded out of the tube.

This triangular mesh imitates the shape (both length and width) of the uterine cavity. Next, gentle suction is applied, bringing the uterine tissue into close contact with the mesh triangle. Electrical energy is then delivered to the entire uterine lining (endometrium) for approximately 90 seconds. The triangle is then retracted and the tube removed. This application of energy is intended to permanently remove the lining of the uterus, thereby reducing or eliminating future bleeding.

After the NovaSure™ procedure, the patient may spend approximately 2 hours recovering, before being sent home.

NO MEDICAL DEVICE REMAINS INSIDE THE UTERUS AFTER THE PROCEDURE

## WHAT DISCOMFORTS CAN I EXPECT AFTER HAVING AN ENDOMETRIAL ABLATION PROCEDURE?

The following are some of the post-operative discomforts associated with any endometrial ablation procedure.

Patients may experience some post-operative uterine cramping and pain shortly after the procedure, and can generally be treated with mild pain medication such as Ibuprofen.

Some patients may experience nausea and vomiting as a result of the anesthesia. Watery and/or bloody discharge after an endometrial ablation is also common for several weeks after the procedure.

## ARE THERE ANY POSTPROCEDURE COMPLICATIONS FOR WHICH I SHOULD CALL MY PHYSICIAN AFTER I GET HOME?

You should call your physician if you develop a fever higher than 100.4°F, worsening pelvic pain that is not relieved by ibuprofen (e.g., Advil® or Motrin®) or other medication prescribed by your physician, nausea, vomiting, bowel or bladder problems, and/or a greenish vaginal discharge.

## WHAT RISKS ARE ASSOCIATED WITH THE NOVASURE™ PROCEDURE?

Your physician will explain the surgical risks of all treatment options in detail. Some of the risks of endometrial ablation procedures are perforation of the uterus, bleeding, infection, injury to organs within the abdomen and pelvis, and accumulation of blood within the uterus due to scarring. A possible hazard exists for women with cardiac pacemakers or other active implants.

Another rare, but important, risk of any endometrial ablation procedure is that it may decrease your doctor's ability to make an early diagnosis of cancer of the endometrium. The reason for this is that one of the warning signs of endometrial cancer is bleeding, and endometrial ablation procedures decrease or eliminate bleeding.

## CAN I STILL BECOME PREGNANT AFTER ENDOMETRIAL ABLATION?

It is important to know that, although the chances for pregnancy are reduced following an endometrial ablation procedure, it is still possible to become pregnant. Pregnancy following endometrial ablation is very dangerous for both the mother and the fetus. You should not have endometrial ablation if you think you want to have a baby in the future. You should use some form of birth control or have a sterilization procedure is you decide to have endometrial ablation. Please discuss these options with your physician.