

# NovaSure<sup>®</sup> Endometrial Ablation

## Summary of Risks and Considerations

All treatment options for heavy menstrual bleeding have benefits, warnings, precautions, and risks. Before making a final decision, you should discuss these with your doctor.

### **Not all women are candidates for NovaSure endometrial ablation.**

Your doctor will explain the risks of all treatment options. NovaSure<sup>®</sup> endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous. NovaSure endometrial ablation is not for those who have or suspect uterine cancer, have an active genital, urinary or pelvic infection, an IUD. NovaSure endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting.

### **What is NovaSure endometrial ablation?**

NovaSure endometrial ablation is a one-time, 5-minute procedure that gently removes the lining of the uterus—the part that causes the bleeding. The NovaSure procedure can reduce or stop bleeding altogether.

### **Is the NovaSure procedure right for me?**

Women with heavy or long-lasting periods who do not wish to have children in the future may be candidates for the NovaSure procedure. Your doctor can decide if the NovaSure procedure is right for you. If you're sure you don't want any children in the future, and your doctor rules out more serious causes of heavy bleeding, you may be a good candidate for the NovaSure procedure.

### **Can I still become pregnant after the NovaSure procedure?**

It's still possible to get pregnant after the NovaSure procedure. A pregnancy after an ablation is very dangerous for both the mother and the fetus, since the uterine lining would not be able to properly support fetal development. It's very important to talk to your doctor about what birth control you will use after the NovaSure procedure.

### **What can I expect after the NovaSure procedure?**

Immediately after the NovaSure procedure, some women may experience some cramping, mild pain, nausea and/or vomiting. Most women can resume normal activities within a day or so. Be sure to follow any instructions from your doctor, no matter how good you're feeling. A watery and/or bloody discharge following the NovaSure procedure is normal. It could start immediately following the procedure or a couple of weeks afterward. The discharge may only last briefly, or may last up to a couple of months. It could even come and go, increasing after certain activities. This is quite normal and can be expected with any endometrial ablation procedure.

Very few patients experience complications following the NovaSure procedure. However, you should call your doctor right away if you develop:

- A fever higher than 100.4°F
- Worsening pelvic pain that is not relieved by ibuprofen or other prescribed medicine
- Nausea, vomiting, shortness of breath, dizziness
- Bowel or bladder problems
- A greenish vaginal discharge (reddish, yellowish, or brownish is normal)

### **When will I know what my periods will be like after the NovaSure procedure?**

Every woman is different. Plan to give your body about 3 months to fully heal on the inside and resume its normal cycle. Then, you and your doctor should be able to tell what your cycle and your periods will be like.

### Other considerations

Anesthetics are medicines that may be used to prevent pain during the procedure. There are risks associated with the use of any medicines, even local anesthetics. Talk to your doctor about the risks of the particular anesthetic recommended for you.

### Additional warnings, precautions, and risks.

- Endometrial ablation using the NovaSure system is not a sterilization procedure. Talk to your doctor about 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.

### Anticipated post-procedural complications

For any endometrial ablation procedure, commonly reported postoperative events include the following:

- Cramping/pelvic pain was reported for 3.4% of the NovaSure 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 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

**Important Safety Information:** NovaSure endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the NovaSure procedure can be dangerous. The NovaSure procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. NovaSure endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. If you, or someone you know, have possibly experienced a side effect when using our product, please contact your physician.

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### 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