

NovaSure Endometrial Ablation

NovaSure is a device for endometrial ablation, which is a procedure that removes the endometrium, that the US Food and Drug Administration, or FDA, approved for use on 28 September 2001. Endometrium is the tissue that lines the uterus. NovaSure destroys the endometrium by sending electric beams at the endometrium. Hologic, a medical technology company concerned with women's health, developed NovaSure to treat menorrhagia, or heavy bleeding during menstruation. Menorrhagia is a common symptom of endometriosis. Endometriosis is the growth of the endometrium outside of the uterus. While NovaSure is not a treatment that doctors use to directly treat endometriosis, the procedure may help alleviate heavy bleeding during menstruation, which may improve a patient's quality of life as heavy menstrual bleeding is often associated with high levels of anxiety and low levels of confidence.

There are two main techniques for endometrial ablation. They are balloon therapy and use of radio-frequency, or RF, energy. Doctors in the US first used those techniques during the 1990s. Balloon therapy is an endometrial ablation procedure in which the doctor inserts a thin tube, or a catheter, into the uterus to remove the endometrium. At the end of the catheter is a balloon filled with heated fluid. The heated fluid kills endometrial cells and, therefore, destroys the endometrium. The other procedure uses RF energy. During that endometrial ablation procedure, the doctor inserts an electrical device into the uterus to produce an electrical current that destroys the endometrium. NovaSure uses RF energy and is an instance of the second type of the endometrial ablation procedures.

Researchers developed multiple endometrial devices based on balloon therapy and RF energy techniques, and in 1997, endometrial ablation became a popular procedure for combatting heavy menstrual bleeding. In the US, endometrial ablation gained popularity during the late 1990s. Medical companies marketed endometrial ablation as a safe, less invasive, and cost-effective alternative to hysterectomy, which is the surgical removal of the uterus and another treatment for heavy menstrual bleeding. Hysterectomy has high complication rates after the procedure. Possible complications include infection, bladder and bowel damage, and excessive bleeding.

In response to the growing popularity of endometrial ablation, medical technology company Johnson & Johnson, headquartered in New Brunswick, New Jersey, manufactured ThermaChoice III in the late 1990s. ThermaChoice III is a balloon therapy device. The FDA approved ThermaChoice III in 1997. It remained the primary type of endometrial ablation procedure until medical companies developed devices such as NovaSure, Genesys Hydro-Thermal Ablation System, or HTA, and HerOption. The FDA approved all of those endometrial ablation devices in 2001. In 2015, Johnson & Johnson recalled ThermaChoice III after citing issues with the shelf life of the device.

Hologic, a medical technology company headquartered in Marlborough, Massachusetts, developed NovaSure to improve previous endometrial ablation procedures. The company compared NovaSure to three other devices for endometrial ablation, ThermaChoice III, HTA, and HerOption, to highlight NovaSure's advantages. For instance, the length of the NovaSure procedure is shorter than any of the other three procedures. The average duration of the NovaSure procedure is four minutes, while the average duration of the other procedures is approximately thirty minutes. ThermaChoice III, HTA, and HerOption procedures require hormonal pretreatment and are dependent on the patient's menstrual cycle. According to Hologic, NovaSure does not require hormonal pretreatment and may be performed at any point during the patient's menstrual cycle.

NovaSure is an endometrial ablation device that uses RF energy to destroy the lining of the uterus. NovaSure utilizes two major instruments, Disposable Device and the RF Controller, to complete the procedure. The Disposable Device is a single-use bipolar electrode array that the doctor inserts

into the uterus to emit RF energy. Once the doctor has inserted the Disposable Device, it expands within the uterus. The Disposable Device is connected to the RF Controller, which is a power output generator that provides RF energy to the Disposable Device. The doctor measures the length of the cervix, which is the opening of the uterus, and inputs the measurement into the Disposable Device, which causes the RF Controller to calculate the appropriate electrode array length for the procedure. Further, each NovaSure system contains a carbon dioxide canister, desiccant, foot switch, and power cord.

There are multiple steps to NovaSure endometrial ablation. First, the doctor uses an ultrasound to measure the cervix. Doctors can perform the NovaSure procedure when the length of the cervix is greater than or equal to four centimeters. If the cervix length is appropriate for the procedure, the doctor inputs that measurement into the RF Controller to determine the electrode array length for the procedure. Then, the doctor uses drugs to dilate the cervix to eight millimeters. Once the cervix is dilated and ready for the procedure, the doctor connects the Disposable Device to the RF Controller and inserts the Disposable Device into the uterus. The electrode array, which is a triangular-shaped device, expands within the uterus. Next, the doctor uses the RF Controller to perform a cavity integrity assessment, which detects perforations within the uterus. The RF Controller delivers carbon dioxide to the Disposable Device, and the Disposable Device administers the carbon dioxide into the uterus. If the carbon dioxide remains within the uterus for four seconds, then the cavity integrity assessment is successful and there are no perforations in the uterus. Next, ablation occurs, which is a ninety second process. During the ablation, the Disposable Device emits RF energy to destroy the endometrium cells. Once the RF Controller flashes a green light, which is an indication that the process is complete, the doctor removes the Disposable Device from the uterus.

NovaSure, like other endometrial ablation procedures, combats heavy menstrual bleeding, which is a common symptom of endometriosis. Alleviating heavy menstrual bleeding in women with endometriosis does not cure endometriosis, but may help ease the burden of endometriosis. According to the FDA, women should only receive an endometrial ablation procedure such as NovaSure if they do not plan to become pregnant in the future, as endometrial ablation may cause dangerous complications for the pregnant woman and the fetus. According to the NovaSure website safety page, women with uterine cancer, active urinary tract infection, or pelvic inflammatory disease should not receive an endometrial ablation procedure because further complications may develop.

NovaSure has a high satisfaction rate, as reported by patients. A literature review by Richard J. Gimpelson, a doctor of obstetrics and gynecology, cites multiple studies that found the use of NovaSure was associated with reduced rates of heavy menstrual bleeding in patients. Further, Gimpelson found that NovaSure posed a nonsignificant risk for complications such as an infection after the procedure.

While NovaSure is not a treatment used to directly address endometriosis, the procedure may help alleviate heavy bleeding during menstruation. According to Hologic, approximately 93 percent of patients surveyed in clinical trials reported that they had used NovaSure to improve their quality of life, as heavy menstrual bleeding caused the patients high levels of anxiety and low levels of confidence.

Sources

1. Gimpelson, Richard J. "Ten-year literature review of global endometrial ablation with the NovaSure device." *International Journal of Women's Health* 6 (2014): 269-280.
2. Hologic, Inc. "A Complete Guide to NovaSure Endometrial Ablation." Hologic, Inc. http://www.novasure.com/sites/novasure/files/NovaSure_Physician_Brochure_2015_1.pdf (Accessed July 30, 2018).
3. Hologic, Inc. "What is NovaSure Endometrial Ablation?" Hologic, Inc. <http://www.novasure.com/patients/what-novasure-endometrial-ablation> (Accessed July 30, 2018).
4. Hsu, Albert L., Izabela Khackikyan, and Pamela Stratton. "Invasive and non-invasive methods for the diagnosis of endometriosis." *Clinical Obstetrics and Gynecology* 53 (2010): 413-419.

5. John Hopkins Medicine. "Endometrial Ablation." John Hopkins Medicine. https://www.hopkinsmedicine.org/healthlibrary/test_procedures/gynecology/endometrial_ablation_92,P07774 (Accessed July 30, 2018).
6. MedLine Plus. "Hysterectomy." US National Library of Medicine. <https://medlineplus.gov/hysterectomy.html> (Accessed July 30, 2018).
7. PubMed Health Glossary. "Endometrium." National Institute of Health. <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022606/> (Accessed July 30, 2018).
8. United States Food and Drug Administration. "Class 2 Device Recall Gynecare ThermaChoice III." Food and Drug Administration. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=142341> (Accessed July 30, 2018).
9. United States Food and Drug Administration. "Summary of Safety and Effectiveness Data: NovaSure Impedance Controlled Endometrial Ablation System." Food and Drug Administration. https://www.accessdata.fda.gov/cdrh_docs/pdf/P010013b.pdf (Accessed July 30, 2018).