

NovaSure®

Instructions for Use and Controller

Operator's Manual

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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 CO₂ 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 CO₂ canister, desiccant, foot switch and power cord, which are designed to be used together as a system.



NovaSure Disposable Device with Connecting Cord, Including Section Line Desiccant

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