

NovaSure®

Instructions for Use and Controller

Operator's Manual

Table of Contents

- Physician Checklist..... 1
- System Description..... 1
- Indications..... 3
- Contraindications..... 3
- Warnings..... 3
- Precautions..... 4
- Adverse Events..... 5
- Anticipated Post-Procedural Complications..... 6
- Other Adverse Events..... 6
- Clinical Study..... 6
 - Patient Selection..... 9
 - Patient Counseling..... 9
- Pretreatment Preparation of Patient..... 9
- NovaSure Impedance Controlled Endometrial Ablation System Instructions for Use..... 10
- Periodic Maintenance and Service:
 - Model 08-09 RF Controller..... 16
 - NovaSure Model 08-09 RF Controller LED Descriptions..... 18
 - Troubleshooting Most Common Alarms:
 - Model 08-09 RF Controller..... 18
- Periodic Maintenance and Service:
 - Model 10 RF Controller..... 21
 - NovaSure Model 10 RF Controller Screen Icons..... 21
 - Troubleshooting Most Common Alarms:
 - Model 10 RF Controller..... 22
- Additional Troubleshooting..... 24
- Replacement Instructions..... 24
- Specifications..... 24
- Cleaning and Sanitizing..... 28
- Parts List..... 28
- Warranty..... 28
- Technical Support and Product Return Information..... 29
- Symbol Definitions..... 30

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

Hologic Novasure Service Manual

R Barnett



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Table of Contents Hologic Novasure Service Manual

1. Understanding the eBook Hologic Novasure Service Manual
 - The Rise of Digital Reading Hologic Novasure Service Manual
 - Advantages of eBooks Over Traditional Books
2. Identifying Hologic Novasure Service Manual
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Hologic Novasure Service Manual
 - User-Friendly Interface
4. Exploring eBook Recommendations from Hologic Novasure Service Manual
 - Personalized Recommendations
 - Hologic Novasure Service Manual User Reviews and Ratings
 - Hologic Novasure Service Manual and Bestseller Lists
5. Accessing Hologic Novasure Service Manual Free and Paid eBooks
 - Hologic Novasure Service Manual Public Domain eBooks
 - Hologic Novasure Service Manual eBook Subscription Services
 - Hologic Novasure Service Manual Budget-Friendly Options

6. Navigating Hologic Novasure Service Manual eBook Formats
 - ePub, PDF, MOBI, and More
 - Hologic Novasure Service Manual Compatibility with Devices
 - Hologic Novasure Service Manual Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Hologic Novasure Service Manual
 - Highlighting and Note-Taking Hologic Novasure Service Manual
 - Interactive Elements Hologic Novasure Service Manual
8. Staying Engaged with Hologic Novasure Service Manual
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Hologic Novasure Service Manual
9. Balancing eBooks and Physical Books Hologic Novasure Service Manual
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Hologic Novasure Service Manual
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Hologic Novasure Service Manual
 - Setting Reading Goals Hologic Novasure Service Manual
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Hologic Novasure Service Manual
 - Fact-Checking eBook Content of Hologic Novasure Service Manual
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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