

NovaSure®
Endometrial Ablation



NovaSure® Radio Frequency Endometrial Ablation Log Book

Date: _____

HOLOGIC®
www.hologic.com

Personal Details

Surname: _____ Forename: _____

No.	Trainer Name	Hospital	Dates	Signature
1				
2				
3				
4				
5				

NovaSure® Log Book

Introduction

This log book has been designed specifically by Hologic to clearly identify your training needs and track progress. It aims to record experience, understanding and competence of the NovaSure® endometrial ablation system.

The log book has 2 main sections:

1. Theory: Most topics will be covered in the theoretical Training Day. When you have addressed each subject in your reading and tutorials, and feel confident about it, then insert the date in the relevant box.
2. Practical: Levels 1-4 represents the expected levels of competence and are to be interpreted as follows:
 - Level 1:** Observe NovaSure® being carried out
 - Level 2:** Carry out a NovaSure® under direct supervision (your trainer is present throughout)
 - Level 3:** Carry out a NovaSure® under indirect supervision (your trainer need not be scrubbed, but should be immediately available for help and advice)
 - Level 4:** Independent competence - no supervision needed

Practical training should be undertaken at your own hospital with your trainer. Hologic suggests that you undertake:

- 3 observed cases to meet Level 1 criteria
- 5 cases managed under direct supervision to meet Level 2 criteria
- 5 cases managed under indirect supervision to meet Level 3 criteria
- 5 cases that you have managed independently to meet Level 4 criteria

There is also an **OSATS** for performing NovaSure® – please complete regularly to demonstrate progression of training.

Theory

Subject	Date of Completion	Trainer's Signature
Physics of NovaSure®		
Practical Techniques		
Clinical Results		
Indications for use		
Relative Contraindications		
Counselling and Patient Preparation		
Safe Practice		
Infection Control		
NovaSure® Under Local		
Troubleshooting		
How to report a complication to MHRA		

Level 1 – Observed Cases

Case No.	Date	Unit No.	Indication for Novasure®	GA or LA	Complications / Problems Encountered	Trainer's Signature

Additional Cases

Level 2 – Cases Under Direct Supervision

Case No.	Date	Unit No.	Indication for Novasure®	GA or LA	Complications / Problems Encountered	Trainer's Signature

Additional Cases

Level 3 – Cases Under Indirect Supervision

Case No.	Date	Unit No.	Indication for Novasure®	GA or LA	Complications / Problems Encountered	Trainer's Signature

Additional Cases

Trainer's Statement

I can confirm that my trainee _____ is now competent to undertake NovaSure® independently.

Trainer: _____

Title: _____

Signature: _____

Hospital/Facility: _____

Date: _____

Hologic Statement

I can confirm that _____ is now competent to undertake NovaSure® independently.

Name: _____

Signature: _____

Title: _____

Date: _____

Endometrial Ablation Protocol

Trainee Name	Assessor Name	Level of Training: Grade/Year	Post	Date

Clinical details / Complexity of case

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Preparation of the Patient

Done Independently

Needs Help

Consider cervical softening agents when difficult cervical dilatation envisaged

Selects cases appropriately for local or general anaesthetic

Ensures correct positioning of the patient

Pre-device insertion

Familiar with device + troubleshoots problems

Safe cervical dilatation

Check hysteroscopy before device insertion

Operative Procedure	Done Independently	Needs Help
Follow manufacturers instructions re treatment cycle		
Appropriate use of prophylactic antibiotics		
Repeat hysteroscopy post procedure if concerned about cavity integrity		
Immediate post-operative care		
Ensures adequate analgesia		
Arranges appropriate review		

Generic Technical Skills Assessment

Assessor, please tick the candidate's performance for each of the following factors:

Respect for tissue	<input type="checkbox"/> Frequently used unnecessary force on tissue or caused damage by inappropriate use of instruments.	<input type="checkbox"/> Careful handling of tissue but occasionally causes inadvertent damage.	<input type="checkbox"/> Consistently handled tissues appropriately with minimal damage.
Time, motion and flow of operation and forward planning	<input type="checkbox"/> Many unnecessary moves. Frequently stopped operating or needed to discuss next move.	<input type="checkbox"/> Makes reasonable progress but some unnecessary moves. Sound knowledge of operation but slightly disjointed at times.	<input type="checkbox"/> Economy of movement + maximum efficiency. Obviously planned course of operation with effortless flow from one move to the next.
Knowledge and handling of instruments	<input type="checkbox"/> Lack of knowledge of instruments.	<input type="checkbox"/> Competent use of instruments but occasionally awkward or tentative.	<input type="checkbox"/> Obvious familiarity with instruments.
Suturing & Knotting Skills	<input type="checkbox"/> Placed sutures inaccurately or tied knots insecurely, and lacked attention to safety.	<input type="checkbox"/> Knotting and suturing usually reliable but sometimes awkward.	<input type="checkbox"/> Consistently placed sutures accurately with appropriate and secure knots, and with proper attention to safety.
Technical use of assistants. Relations with patient and the surgical team	<input type="checkbox"/> Consistently placed assistants poorly or failed to use assistants. Communicated poorly/frequently showed lack of awareness of the needs of the patient and/or the professional Team.	<input type="checkbox"/> Appropriate use of assistant most of the time. Reasonable communication and awareness of the needs of the patient and/or of the professional team.	<input type="checkbox"/> Strategically used assistants to the best advantage at all times. Consistently communicated and acted with awareness of the needs of the patient and/or of the professional team.
Insight / Attitude	<input type="checkbox"/> Poor understanding of areas of weakness.	<input type="checkbox"/> Some understanding of areas of weakness.	<input type="checkbox"/> Fully understands areas of weakness.
Documentation of Procedures	<input type="checkbox"/> Limited documentation Poorly written	<input type="checkbox"/> Adequate documentation, but with some omissions, or areas that need elaborating.	<input type="checkbox"/> Comprehensive legible documentation, indicating findings, procedure and post-operative management.

Generic Technical Skills Assessment cont.

Based on the checklist and the Generic Technical Skills Assessment, Dr _____

is competent in all areas included in this OSATS is working towards competence

Needs further help with:

Date: _____

Signed (trainer): _____

Signed (trainee): _____

**Competent to perform the entire
procedure without the need for supervision**

Date: _____

Signed: _____

Signed: _____

Equipment Competency Statement

Surname	Forename(s)	Title (Mr/Mrs/Miss/Dr etc)
Job Title	Personal Number (Stated on wage slip)	
Department/Directorate/Ward/Unit	Phone/Extension No.	

Self-Verification of competence is undertaken by assessment against the following statements:

These statements are designed to indicate competence to use this item. Responsibility for the use remains with the user, so if you are in any doubt regarding your competence to use the item, you should seek education to bring about improvement. Various methods including self-directed learning, coaching and formal training may be initiated (consider local resources, product operating manual, discussion with colleagues or the appropriate key person in your area).

Carry out an initial assessment. You must answer yes to all questions before considering yourself to be competent.

If you are not competent, instigate learning and then repeat assessment.

Items to achieve (please circle the appropriate answer)	Initial Assessment Date:	Second Assessment Date:
Are you safe using this Device? Can you / Do you:		
NovaSure Radio Frequency (RF) Controller:		
Visually check the equipment for damage	Yes / No	Yes / No
Demonstrate correct set up of RF Controller	Yes / No	Yes / No
Demonstrate how to switch on the RF Controller and attach foot pedal	Yes / No	Yes / No
Demonstrate how to change the gas on the RF Controller	Yes / No	Yes / No
Demonstrate how to attach a NovaSure Device into the RFC	Yes / No	Yes / No
Demonstrate how you would insert the desiccant filter	Yes / No	Yes / No
Demonstrate how to input the width and length measurements into RF Controller	Yes / No	Yes / No
Demonstrate what action to take if the RFC is alarming continuously once turned on	Yes / No	Yes / No
NovaSure Troubleshooting:		
Vacuum Light:		
Demonstrate what action is needed if a vacuum light appears during the first 10 seconds of the procedure	Yes / No	Yes / No
Identify how you would reset the vacuum alarm	Yes / No	Yes / No
Demonstrate what action would be taken if the vacuum test continued to appear once the procedure has been restarted	Yes / No	Yes / No
Demonstrate what action would be taken if the desiccant filter is completely pink	Yes / No	Yes / No
Understand how long the test will take to produce a result	Yes / No	Yes / No

Items to achieve continued... (please circle the appropriate answer)	Initial Assessment Date:	Second Assessment Date:
CIA Alarm		
Demonstrate what action would be taken with repeated CIA test failures	Yes / No	Yes / No
Demonstrate the steps involved in checking the device for CO2 flow	Yes / No	Yes / No
Demonstrate the steps involved to help the surgeon seal the cervix	Yes / No	Yes / No
Demonstrate the steps involved in testing the device for leaks	Yes / No	Yes / No
System Fault Alarm		
Identify where the System Fault Alarm light is	Yes / No	Yes / No
Demonstrate what action should be taken if a System Fault light appears	Yes / No	Yes / No
Adverse Incidents		
Do you know how to report an adverse incident involving a medical device or piece of equipment?	Yes / No	Yes / No

Statement

I certify that I am aware of my professional responsibility for continuing professional development and I realise that I am accountable for my actions. With this in mind I make the following statement:

I require further training before I can use this product in a competent manner

Signature: _____

Date: _____

Indicate how you plan to meet your learning needs:

I am competent to use this product without further training:

Signature: _____

Date: _____

Keep this form in your personal portfolio or training record. Ensure that your Manager receives a copy of the form and enters details of your competence in their records.

NovaSure[®]

Endometrial Ablation

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