

FIELD SAFETY NOTICE

April 4th, 2014

Subject:

Update LS2101 Thermablate Endometrial Ablation System (EAS) Multilingual Instructions for Use (IFU) to Revision B

Attention: Gynecologists Users

Products related to Notice:

Thermablate Treatment Control Unit Kit	Product Code : 22101
Thermablate Disposable Cartridge	Product Code : 21004

Description of Issue

Two changes have been made to the Instructions for Use for Thermablate-EAS

Recommendations

Review and follow the updated Instructions for Use for Thermablate EAS

IFU can be downloaded at: www.idoman-med.com

Description of Changes Made to Instructions For Use

Change 1:

In LS2101 Thermablate EAS Multilingual IFU Revision A the sequence of procedures just prior to inserting the Thermablate catheter into the uterus to initiate treatment was:

- Measure length of uterus from external os to fundus using uterine sound.
- Confirm that measurement is between 8-12 cm.
- Use dilators to gradually dilate cervix up to 7 mm. Dilators should pass easily through cervix with minimal discomfort to the patient. Dilators should not be advanced deeper than the predetermined uterine depth.
- Perform hysteroscopy prior to balloon insertion to ensure that uterus has not been perforated or that a false passage has not been created during dilatation, sounding or curettage (if performed)
- Alternatively, use ultrasonic surveillance during the treatment to check for correct balloon position inside the uterine cavity.



In LS2101 Thermablate EAS Multilingual IFU Revision B the sequence of procedures just prior to inserting the Thermablate catheter into the uterus to initiate treatment includes a second sounding of the uterus just after dilation and before performing hysteroscopic examination of the uterus to confirm that perforation of the uterus or the creation of a false passage has not occurred during the dilation and soundings. The additional step is highlighted below:

- Measure length of uterus from external os to fundus using uterine sound.
- Confirm that measurement is between 8-12 cm.
- Use dilators to gradually dilate cervix up to 7 mm. Dilators should pass easily through cervix with minimal discomfort to the patient. Dilators should not be advanced deeper than the predetermined uterine depth.
- ***Measure length of uterus a second time using the uterine sound. Confirm that sounding length of the uterus after dilation is the same as sounding length obtained prior to dilation.***
- ***If there is a discrepancy of more than 0.5cm between the first and second measurements a false passage or perforation of the uterus may have been created during the dilation.***
- Perform hysteroscopy prior to balloon insertion to ensure that uterus has not been perforated or that a false passage has not been created during dilatation, sounding or curettage (if performed).
- Alternatively, use ultrasonic surveillance during the treatment to check for correct balloon position inside the uterine cavity

Change 2:

In LS2101 Thermablate EAS Multilingual IFU Revision A the following was listed as a contraindication for a Thermablate treatment:

A patient with a lower segment C Section scar that has a linear scar thickness of less than 1 cm

In LS2101 Thermablate EAS Multilingual IFU Revision B this contraindication has been changed to:

A patient that has had three or more lower segment C sections and where the linear scar thickness in those patients is less than 8mm

The Irish Medicines Board has been notified of these changes.

Should you have any further questions, please contact: customerservice@idoman-med.com

