IDOMAN
TEORANTA

Urgent Field Safety Notice

Thermablate EAS
FSCA-03
Date : 2018-07-18

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Attention: Users of Thermablate - Gynaecologists Users

Details on affected devices:

Thermablate Treatment Control Unit Kit Product Code: 22101
Thermablate Disposable Cartridge Product Code: 21004
Website: www.idoman-med.com

Description of the problem:
Thermablate EAS IFU is being updated to include the following changes:

1. The IFU and Operators manual will be combined. There will no longer be an IFU in each disposable cartridge, rather, an IFU will be provided with each TCU in the carry case.

2. This new combined IFU has been elaborated to include new information as follows:

* **Added detail on patient selection as follows:**

- Added reference to the FIGO classification system (PALM-COEIN)

*** Added more details on ASSESSMENT OF UTERUS AND CAVITY as follows:**

- **Assessment of the Endometrium**
- Assessment of the Endometrium to be carried out by endometrial biopsy within the last 6 months to exclude endometrial neoplasia (Hyperplasia or Cancer)
- **Assessment of the Endometrial Cavity**
- Assessment of the Endometrial Cavity should be performed by uterine sound, Transvaginal or Transabdominal Ultrasound, Saline / Gel Infusion Sonography (SIS)/(GIS), Hysterosalpingography (HSG) or Hysteroscopy.

*** Added Safety Information**

Warning section was updated as follows:

- Like every surgical intervention, endometrial ablation procedure may require access to emergency surgery premises which should be in proximity to the facility conducting the Thermablate procedure.
- An effective form of contraception is required following Thermablate procedure.
- A hysteroscopy must be performed prior to balloon insertion to ensure uterus has not been perforated during dilation, sounding or curettage
- If you are unable to see the LCD display messages or the unit loses power, turn the power switch to the off position and wait for thirty (30) seconds. After this 30-second period, withdraw the balloon quickly but carefully since some liquid may still be contained in the balloon
- Medical Equipment should not to be placed against exposed flesh during treatment.

Contraindication section was updated as follows to add:

Thermablate EAS™

- A patient who has had hysteroscopic tubal occlusion/sterilization performed in the last 3 months and in whom the 3-month tubal occlusion confirmatory test has not been performed
- Bicornate uterus as a contraindication
- T-incision Caesarean section as a contraindication

*** Added potential adverse event rates**

This section was elaborated to include the following information:

As with all endometrial ablation procedures, serious injury or death can occur.

The following adverse events have been potentially associated with endometrial ablation:

- Pelvic cramping
- Nausea and vomiting
- Perforation of the uterus
- Perforation of the Bowel
- Rupture of the uterus
- Thermal injury to adjacent tissue/organs, resulting in emergency surgery, and patient requiring a colectomy and creation of a stoma
- Heated liquid escaping into the cervix, vagina, or fallopian tubes
- Infection
- Post-ablation tubal sterilization syndrome (PATSS)
- Haematometra.
- Pelvic Abscess
- Peritonitis
- Tubovarian abscess
- Salpingectomy

A table presenting post market surveillance data on the above adverse event rates are inserted into the IFU.

*** Elaborated on Patient Counselling section as follows:**

- Added information in relation to First line treatment for Menorrhagia

*** Added effectiveness data as follows:**

CLINICAL STUDIES

Two studies that have evaluated the safety and effectiveness of the Thermablate are added to the IFU.

Advise on action to be taken by the user:

- Confirmation fax back form to be sent back to the manufacturer to confirm this notification has been read and understood.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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

FAX BACK FORM – ACKNOWLEDGEMENT OF FIELD SAFETY NOTICE

Clinical Lead / Chief of Gynecology :		Distributor:	
Hospital Name:		National Competent Authority:	

This request applies to:

- All users of the Thermablate EAS System
- Distributors of the Thermblate EAS System
- National Competent Authorities for which the Thermablate EAS System is present in that market.

D Yes — I have acknowledged, read and understood the attached Field Safety Notice from Idoman Teoranta.

D Yes — Will assure that all Thermablate users in their hospital will review and follow the new IFU revision E

Signature: _____ Date Signed: _____

Please return this completed form to Idoman Teoranta as follows:

regulatory@idoman-med.com
or
Fax: 353 94 9544725

Please return no later than 25/08/2018