IDOMAN
TEORANTA

Urgent: Field Safety Notice

Device: Thermablate EAS System
FSCA-identifier: Carmel Kelly **Title:** QA & RA Manager
Date: 2015-March 31st
Type of action: The FSCA is required for the following reasons:

- Advice given by MANUFACTURER regarding the use of the Thermablate EAS device

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Attention: EU & Canadian Competent Authorities, SGS Notified Body & End users of the Thermablate EAS System.

Details on affected devices: Thermablate EAS System

Thermablate Treatment Control Unit Kit	Product Code: 22001
Thermablate Disposable Cartridge	Product Code: 21004

Description:
The FSCA is required for the following reason:

1. Additional warning is being added to the IFU as follows:

"Do not perform same day Thermablate EAS procedure and hysteroscopic tubal occlusion/sterilization.
Thermablate EAS procedure can be safely and effectively performed with nickel titanium inserts in place, however the procedure should only be performed after the 3 month tubal occlusion confirmation test."
The IFU can be downloaded at: www.idoman-med.com. In addition a copy is provided with this FSN.

Potential hazard to the patient: There is an increased risk of patient injury (including damage to non targeted tissue) if both Thermablate EAS procedure and hysteroscopic tubal occlusion/sterilization are performed on the same day.

Advise on action to be taken by the user:
"Do not perform same day Thermablate EAS procedure and hysteroscopic tubal occlusion/sterilization.
Thermablate EAS procedure can be safely and effectively performed with nickel titanium inserts in place, however the procedure should only be performed after the 3 month tubal occlusion confirmation test."

Please complete the fax back form attached and return by no later than 22 May 2015.

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who use the Thermablate EAS System.

The HPRA have been notified of these changes. Should you have any further questions, please contact: regulatory@idoman-med.com

Thermablate EAS™

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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.

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

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

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 22/May/2015

Thermablate EAS™