zethon

Zethon Ltd
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URGENT FIELD SAFETY NOTICE

Zethon Reference	**ZFSN-001**
Date of Notice	16th June 2015
ATTENTION TO	All
Affected products	**REM-DF02, REM-DF04, REM-DF06, REM-DF07 – ALL BATCHES**
Manufacturer	**Zethon Limited** 2 Halton Brook Business Park, Weston Road, Aston Clinton, Bucks HP22 5WF, UK
Pre Feb 2015 Manufacturer formerly known as	**Ross Electro Medical Limited** Units K1-K3, Quarry Field Industrial Estate, Mere, BA12 6LA, UK
Intended device use	The above listed product is designed to be used as a fibrillation cable
Event description	Zethon has advised that all batches of the product listed above have the incorrect supporting regulatory documentation required to be placed on the market.
Patient Risk	There have been no reported safety incidences from using the product.

Advise on action to be taken immediately

1. Immediately inform hospital staff, product users, sales representatives, distributors and any other personnel who may be in contact with the above listed to quarantine products.

2. Please complete, print, sign date and return the attached Customer Response Form to confirm the effectiveness of the resulting action and to assist with stock accountability

3. Return all stock to the manufacturer for the above address. Each shipment must be clearly labelled with the following details:
   Attn. Zethon Vigilance – FSN001

MHRA have been informed of this recall. We would be grateful if you could return all above mentioned products to either Zethon Limited or the distributor you originally purchased the product from by the 6th July 2015. Should you have any queries or would like further assistance with the issue please contact:

Email: vigilance@zethon.com
Telephone: +44 (0) 1296 634 090

Thank you in advance for your cooperation.

Yours faithfully

W. Desoutter

Will Desoutter
Director

zethon

URGENT FIELD SAFETY NOTICE

Customer Response Form

Regulatory Action	Field Safety Notice
Description	Fibrillation Cable

Please complete this page to confirm which product(s) you hold in stock that are listed in the above letter.

Product Code	Batch Number	Quantity

Representative/Distributor/ Hospital Name and Address at location for the above listed batches	
Contact Name	
Contact Title	
Contact Signature	
Contact Telephone Number	
Contact Email Address	
Date of form completion	