COOK

Cook Medical Europe
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Urgent Field Safety Notice

Commercial name of the affected product: EchoTip® Ultra Endobronchial High Definition Ultrasound Needles
Manufacturer : Cook Ireland Ltd.
FSCA-identifier: 2015FA0009
Type of action: IFU update

Date: 25 November 2015

Attention: Risk Management/Recall Administration

Details on affected devices:

Part Numbers:

ECHO-HD-22-EBUS-O (EchoTip® Ultra Endobronchial High Definition Ultrasound Needles)
ECHO-HD-25-EBUS-O (EchoTip® Ultra Endobronchial High Definition Ultrasound Needles)

Affected Lot Numbers:

Lot Number	Lot Number	Lot Number	Lot Number	Lot Number	Lot Number
C1116535	C1125439	C1140105	C1152274	C1161960	C1169919
C1116538	C1126058	C1140105	C1152468	C1162430	C1169920
C1116541	C1127370	C1140598	C1152469	C1163388	C1170082
C1117061	C1130174	C1143273	C1152641	C1163713	C1170084
C1117086	C1130179	C1143851	C1152642	C1164362	C1170086
C1117651	C1130185	C1144715	C1152643	C1164365	C1170087
C1119784	C1131652	C1146104	C1152990	C1164392	C1172089
C1119788	C1135485	C1146107	C1154442	C1164420	C1173025
C1119789	C1135487	C1146456	C1155266	C1164827	C1174704
C1120397	C1138250	C1148260	C1156256	C1167098	C1174705
C1120638	C1138252	C1149128	C1156856	C1167549	C1174705
C1121308	C1139574	C1149808	C1156857	C1167549	
C1121816	C1139576	C1150868	C1157014	C1167931	
C1122234	C1139577	C1152269	C1158248	C1169098	
C1124514	C1139585	C1152271	C1159099	C1169697	
C1124521	C1139585	C1152272	C1159609	C1169698	
C1125439	C1139596	C1152273	C1160628	C1169699	

Description of the problem:

Cook Ireland Ltd is updating the Instructions for Use (IFU) IFU0051 from revision 5 to revision 6 for the EchoTip® Ultra Endobronchial High Definition Ultrasound Needles to **re-insert the following text "*This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease"* due to an omission of this text from Revision 5 of this IFU.** This statement was included in the previous revision of the IFU, this notice is for customers who had not previously received the device and therefore may not be aware of the risks of re-use of this device as required by the MDD 93/42/EC.

This Field Safety Corrective Action is to correct the IFU; the IFU is being updated to reflect these changes. Neither device nor IFU need to be returned to Cook Medical.

Modifications made to the IFU are as follows:

The IFU is being updated to re-insert the following text:

"This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease"

Action to be taken by the user:

1. Please review the the attached list of affected products and lot numbers that were shipped to your account and identify any devices you still have in stock.

2. Please affix a copy of this Field Safety Notice to each of the affected products still in stock at your facility to ensure all users of these products are aware of the IFU updates.

3. **Please note this it to inform you of the updates to the IFU of the affected products and <u>there is no need</u> to return any affected devices or IFUs.**

4. Please complete the enclosed Customer Response Form and send via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61334441).

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 or patient 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:

Sinead Burke
Director of Regulatory Affairs
COOK Ireland Ltd.
O'Halloran Road, National Technology Park, Limerick, IRELAND

Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.

Signature

Annemarie Beglin
Quality Systems Manager

COOK®

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FIELD ACTION CUSTOMER RESPONSE FORM

Field Action reference no.: 2015FA0009

Affected device: EchoTip® Ultra Endobronchial High Definition Ultrasound Needles, Reference attached list of impacted Lots.

Please indicate the following:

Customer Number (As Indicated on the attached product list): _____

Customer Name: _____

Street Address: _____

City, ZIP: _____

Completed by: _____

Department: _____

Phone Number: _____

(Please Print)

Please indicate which of the following applies to your facility:

We have received the Urgent Field Safety Notice ref. 2015FA0009 and understand the modifications to the IFU ☐ Yes ☐ No

Distributors:

Have your customers been notified of this Field Safety Corrective Action? ☐ Yes ☐ No

Signed: _____ Date: _____

Please return the completed Customer Response Form by e-mail to European.FieldAction@cookmedical.com or by fax to + 353 61 334441.