

URGENT FIELD SAFETY NOTICE

Date: March 18, 2022

Dear Valued Customer,

Type of Action: Advisory Notice

LINC Medical Systems Ltd voluntarily issues this Field Safety Notice (FSN) to inform healthcare providers that our Instructions for Use (IFU) document for ALL our silicone foley catheters has been updated and is found included with the products indicated and also located at <https://www.linc-medical.co.uk/wp-content/uploads/2021/10/GB-Catheter-IFU-v7.pdf>. This is to align our instructions with our manufacturers' worldwide distribution network. Clarifying these changes proactively ensures the device is used with its optimized benefits.

The following are the changes to the IFU that are of note:

- Before use, check the catheter and balloon by inflating. Fully deflate the balloon after functional inspection.

Recommended User Action:

- The IFU should be considered when using any LINC foley catheter
- Please review, complete, sign and return the attached Acknowledgement Form
- Forward this notice to anyone in your facility that needs to be informed.
- The IFU should be consulted before product is used

Transmission of this Field Safety Notice:

This notice should be passed on to all persons who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.

Yours Sincerely,



Demetrio Cadiante
Managing Director
LINC Medical Systems LTD
7 Kingsley Street
Leicester
LE2 6DY

Affected Products

Product Code (prefix)	Product Description
0850xxxxx	LINC All Silicon Catheter Round Tip
0845xxxx	LINC All Silicone Open Tipped Standard length
0847xxxx	LINC All Silicone Open Tipped Female length
1007UBxxxx	Uniflo-Xtra All Silicone Foley Tip Catheter with extra drainage hole
1011UBxx	LINC All Silicone Catheter (Tiemann Tip)
0846xxxx	All Silicone foley catheter with guidewire hole
1007UBxxOT	OptiTip All Silicone Open Tip Catheter

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Acknowledgement Form

Please read each question below and check the answer you have chosen		Yes	No
1	Did you read and understand the information that has been provided and will follow the necessary instructions to ensure the proper actions will be taken?		
2	Do you currently have any of the impacted product on hand?		
3	Did you further distribute or forward the impacted product?		
4	Did you notify the impacted customers of this URGENT Field Safety Notice (If yes, please provide a copy of the notification)		

FORWARD RESPONSES ONLY TO:
lincadmin@linc-medical.co.uk

Institution name:	
Institution address:	
Form completed by:	
Signature and date:	