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enquiries@xiros.co.uk
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Urgent Field Safety Notice

09 February 2021

Reference:	FSN 2021-001
Description:	CC-Hook Left (Neoligaments Branded)
	CC-Hook Right (Neoligaments Branded)
Product Codes:	202-1411 (CC-Hook Left)
	202-1413 (CC-Hook Right)
UDI:	05060267131904 (CC-Hook Left)
	05060267131911 (CC-Hook Right)
LOT Numbers:	331431 (CC-Hook Left)
	331429 (CC-Hook Right)
	331430 (CC-Hook Right)
Summary:	Field Safety Corrective Action - RECALL
Attention	Distributor / Customer

Dear Distributor or Customer,

As part of our ongoing commitment to patient care, Xiros has initiated a voluntary medical device field action for the three affected product LOTS identified above.

Reason for Voluntary Product Field Action:

Xiros has received five complaints regarding difficulty loading the Nitinol Wire into the CC-Hook. This instrument is used to simplify the passing of a tape in ACJ surgery. As a result, Xiros has taken the decision to recall products in the affected LOTS. We can confirm that this does not affect any other LOTS or products that have been placed on the market.

Potential Hazards:

Users may experience difficulty assembling the device due to a slightly higher internal surface roughness within the CC hook. However, as described in the Instructions for Use, the CC-Hook when used as a coracoid passer is optional.

Potential Risk to Patients:

The potential hazard described will be identified prior to any patient contact with the device. While there may be a short delay in completing the procedure, there is no direct risk to the patient. It is possible to complete the surgery using alternative standard instrumentation. This has been confirmed by clinical opinion.

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Potential Risk to Patients Who Have Already Had Surgery Using This Device:

There is no risk to patients with a completed procedure. This is solely an intraoperative assembly issue with the device.

Required Action:

Any remaining items held by you or your customers must be quarantined pending return. Xiros will arrange for these items to be collected and either refunded or replaced in due course.

Transmission of this Field Safety Notice:

This notice needs to be forwarded to all those who need to be aware within your organisation.

Contact Reference Person:

In case of any questions please contact Stephen Curran, Compliance Director, Xiros Ltd, Springfield House, Whitehouse Lane, Leeds, LS19 7UE.

Steve.curran@xiros.co.uk; 0113 238 7200

I confirm that this notice has been notified to the following:

- MHRA
- BSI in the Netherlands
- HPRA in Ireland
- FIMEA in Finland
- MoH in Oman
- TGA in Australia
- SMPA in Sweden
- Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland
- SAHPRA in South Africa
- MCCAA in Malta
- Advena (authorised representative in the EU)

Please confirm receipt of this Field Safety Notice by e-mailing back the acknowledgment sheet attached below to the address above.

On behalf of Xiros we thank you sincerely for your help and support in completing this action and regret the inconvenience this will cause. We would like to reassure you that Xiros is committed to only promoting devices that meet our high internal quality standards and improve patient care.

Stephen Curran
Compliance Director

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Acknowledgement Form – Xiros FSN 2021-001

Please complete the following and scan and email to Stephen Curran at Steve.curran@xiros.co.uk;

I confirm receipt of the Field Safety Notice dated 09 February 2021 in relation to the CC-Hook provided by Xiros. I confirm that any remaining items have been quarantined pending refund or replacement.

Signed: _____

Name: _____

Position: _____

Hospital: _____

Date: _____

Note: We will follow up with any actions to resolve the situation as soon as possible, this form is intended to confirm that you are aware of the issue, not that it is yet resolved.