

### Urgent Field Safety Notice

25 May 2023

Reference: FSN 2023-001  
Description: CC-Hook Left CC-Hook Right  
Product Codes: 202-1411 (CC-Hook Left), UDI 05060267131904  
202-1413 (CC-Hook Right), UDI 05060267131911  
LOT Numbers: CC-Hook Left – from expiry date 28 Oct 2024  
CC-Hook Right – from expiry date 13 Oct 2024  
Summary: Field Safety Corrective Action – Field Safety Notice  
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 affected product batches identified above.

#### Reason for Voluntary Product Field Action:

Xiros has received feedback that there have been a small number of instances where the CC-Hook instrument has deformed during use. The hook performs as intended when Instructions for Use are followed but can deform when excessive force is used, or where it is used as a lever to manipulate bone.

#### Potential Hazards May Include:

Users may experience some difficulty in completing the procedure if the instrument has deformed. However, as indicated in the instructions for use, the use of the CC-Hook as a coracoid passer is optional.

#### Potential Risk to Patients:

While there may be a short delay in completing the procedure, it is possible to complete the surgery using standard instrumentation.

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

There is no evidence to suggest any risk to patients as in all cases the procedures were completed successfully.





**Required Action:**

Users should be advised that in order to avoid damaging or deforming the instrument do not impact it, subject it to excessive blunt force or use it for leverage to manipulate bone.

**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](mailto:Steve.curran@xiros.co.uk); 0113 238 7200

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

- MHRA
- BSI in the Netherlands
- TGA in Australia
- EOF in Greece
- HPRA in Ireland
- MoH in Israel
- MoH in Italy
- MMA in Malta
- IGJ in Netherlands
- MoH in Oman
- Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland
- National Authority of Medicines and Medical Devices of Romania - Romania
- SAHPRA in South Africa
- SMPA in Sweden
- FDA in USA
- Advena (authorised representative in the EU)



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www.xiros.co.uk



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



Five Star Occupational  
Health and Safety  
Award 2018



Health &  
Wellbeing  
Award



INVESTORS  
IN PEOPLE | Gold



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Acknowledgement Form – Xiros FSN 2023-001

Please complete the following and scan and email to Stephen Curran at [Steve.curran@xiros.co.uk](mailto:Steve.curran@xiros.co.uk);

I confirm receipt of the Field Safety Notice dated 25 May 2023 in relation to the CC-Hook provided by Xiros.

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Hospital: \_\_\_\_\_

Date: \_\_\_\_\_

