



## **Urgent Field Safety Notice**

**22 November 2016**

**Reference:** ILFSN 3

**Description:** Infinity-Lock and disposable instrument set

**Product Code:** Part numbers 102-1088 and 202-1088

**Lot Number:** All lots of these part numbers

**Summary:** Field Safety Corrective Action – return of medical device to manufacturer

**Attention:** Hospital user

Dear Customer,

As part of our ongoing post market surveillance Xiros has initiated a voluntary medical device field action for the above product.

### **Reason for voluntary Product Field action:**

Xiros has received higher than anticipated intra- and post-operative implant and / or instrumentation failures associated with these devices. Although these incidents currently represent a small percentage of cases, given Xiros' commitment to quality and patient care, we feel that a field action is warranted at this time.

The issues observed include: Shearing of disposable hex driver head whilst applying torque in harder bone; cutting of tape implant by the screw during insertion in harder bone; and post-operative loss of reduction due to incorrect surgical procedure, loosening of screw due to poor bone quality and damage to the tape due to a cause yet to be established.

In all intra-operative cases it was possible to complete the surgery either because sufficient interference had already been achieved to securely hold the tape in place prior to its cutting/failure of the hex driver, or by using a replacement tape/driver which the surgeon had available. Two of the three cases of post-operative failure were not as a direct result of a failure of the Infinity-Lock, and the third has not yet been established.

### **Potential Hazards may include:**

- Extended operative time whilst any intra-operative issues are overcome
- An additional procedure to correct any post-operative issue





### Possible risks to patients already implanted with the device

We do not believe that there is any risk to patients who have already undergone successful implantation with the Infinity-Lock. Issues with the hex driver would have been detectable at the point of surgery. We believe that rupture of the Infinity-Lock intra-operatively would also have been detectable at the point of surgery. To the best of our knowledge, once the tape has been fixed within the bone tunnel by the screw, following the correct surgical technique and with no underlying patient condition affecting bone quality/screw fixation, the implantation should be secure and we do not expect post-operative failure.

### Required action

- Any remaining items must be quarantined for return to Xiros. This includes the Infinity-Lock implant set (102-1088) and Infinity-Lock disposable instrument set (202-1088).
- You will be contacted by our Sales team to arrange collection and re-imbusement or exchange for the Infinity-Lock button system, which is not affected by this action.

### Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation to ensure that any of the affected Infinity-Lock product is returned to Xiros.

### Contact reference person

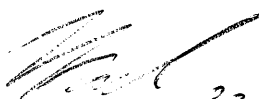
In case of any questions please contact Stephen Seed, Compliance Director, Xiros Ltd, Springfield House, Whitehouse Lane, Leeds, LS19 7UE

**Stephen.seed@xiros.eu.com**; 0113 238 7200

I confirm that this notice has been notified to the MHRA and BSI in the UK, and to the Health Products Regulatory Authority in Ireland.

Please confirm receipt of this Field Safety Notice by handing to our sales rep, faxing or scanning and e-mailing back the acknowledgment sheet attached.

On behalf of Xiros we thank you sincerely for your help and support in completing this action and regret any inconvenience this may 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.

  
22 NOV 2016

Stephen Seed

Compliance Director





**Acknowledgement form**

Please complete the following and either fax back (+44 (0)113 238 7201) or scan and e-mail to Heather Thomas , on heather.thomas@xiros.eu.com

I confirm receipt of the Field Safety Notice dated 22 November 2016 in relation to the Infinity-Lock and disposable instrument set provided by Xiros. I confirm that any remaining Infinity-Lock products at my premises have been returned to Xiros.

Signed.....

Name.....

Position.....

Hospital.....

Date.....