



Urgent Field Safety Notice

Infinity-Lock

21 June 2016

Field Safety Corrective Action

Date: 21 June 2016

Attention: Name of Distributor

Details of affected devices

This Field Safety Notice applies to the Infinity-Lock (part number 102-1088) and disposable instrument set (part number 202-1088), lot numbers VAL 1478, VAL 1479, VAL 1480 and 318320.

Description of the problem

In a small number of cases (2 from approximately 25 implanted to date) it has been reported that the Infinity-Lock has ruptured when the screw was being inserted into the bone tunnel to secure the implant in place. The ruptures have been noted during the surgery, and in each case there was no harm caused to the patient.

It is believed that the issue relates to the very small diameter of the bone tunnel relative to the screw, in combination with patients with very hard bone, resulting in the Infinity-Lock shearing at the sharp bone tunnel edges when the screw was inserted.

To reduce the risks of rupture at this stage in surgery, it has been determined that over-drilling the 4.0mm bone tunnel with a 4.5mm drill still provides sufficient fixation strength (1045N) while at the same time decreasing the force of the screw and tape against the bone tunnel edges. To provide additional strength, which may be required particularly for patients with soft bone, it has been shown that passing the ends of the Infinity Lock underneath the clavicle and securing with a reef knot gives an average UTS of 1203N, well above the required fixation strength.

It is not envisaged that any patients who have already undergone successful surgery with the Infinity-Lock would be at any risk, since to date the failure mode has only been observed at the point of insertion of the screw. If rupture was to occur, it would be apparent at the time of the surgery.

Advice on action to be taken by the distributor

The disposable instrument kit currently supplied with the Infinity-Lock includes a 4.0mm cannulated drill. It is recommended that the cannulated drill is used to make an initial bone tunnel, which is then over-drilled using a 4.5mm drill. This drill will be supplied separately by Xiros, free of charge. The part number for the 4.5mm drill is 202-3021.

Of the stock of Infinity-Locks you have been sent, please inform us how many have already been implanted. Xiros will then supply sufficient 4.5mm drills to cover all as yet unused Infinity-Locks.

Please ensure that a 4.5mm drill is sent to all customers provided with an Infinity-Lock, together with a copy of the Field Safety Notice for users which will describe the use of the 4.5mm drill and the requirement to tie the Infinity-Lock in a reef knot under the clavicle for additional fixation strength.

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 the additional drill and Field Safety Notice for users is supplied to all customers with Infinity-Lock product from the listed batch numbers.

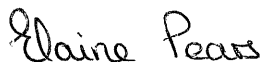
Contact reference person

In case of any questions please contact Elaine Pears, QA Manager, Xiros Ltd, Springfield House, Whitehouse Lane, Leeds, LS19 7UE

Elaine.pears@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 faxing/scanning and e-mailing back the acknowledgment sheet attached.



Elaine Pears

QA Manager

Acknowledgement form

Please complete the following and either fax back (+44 (0)113 238 7201) or scan and e-mail to Elaine Pears, QA Manager, on elaine.pears@xiros.eu.com

I confirm receipt of the Field Safety Notice dated 21 June 2016 in relation to the Infinity-Lock and disposable instrument set provided by Xiros. I confirm that customers with an Infinity-Lock from lot numbers VAL 1478, VAL 1479, VAL 1480 and 318320 will be supplied with an additional 4.5mm drill supplied separately by Xiros together with a copy of the Field Safety Notice for users dated 21 June 2016.

Signed.....

Name.....

Position.....

Company.....

Date.....