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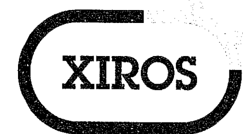

Urgent Field Safety Notice

Infinity-Lock

18 July 2016

Field Safety Corrective Action – follow-up to FSN dated 21 June 2016

Date: 18 July 2016

Attention: New Vision Healthcare, Ireland

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, which had been the subject of FSN dated 21 June 2016, and also to lot number 318500.

Description of the problem

As previously described in FSN dated 21 June 2016, in a small number of cases (2 from approximately 25 implanted to that date) it had been reported that the Infinity-Lock had ruptured when the screw was being inserted into the bone tunnel to secure the implant in place. The ruptures had been noted during the surgery, and in each case there was no harm caused to the patient. FSN dated 21 June 2016 reported the use of a 4.5mm bone tunnel to reduce the potential for rupture whilst maintaining fixation strength. An additional knot was recommended to further ensure the maintenance of fixation strength even in patients with soft bone. Additional 4.5mm drills were provided for those Infinity-Lock sets still in the field, and were included with lot number 318500 which was manufactured subsequently to the FSN.

Further to FSN dated 21 June 2016, additional information has become available from one of the two cases where rupture occurred. This indicated that the case in question was actually a revision case of a previous repair with a competitor product, which meant that the position of the bone tunnel recommended for the Infinity-Lock technique was compromised. In addition, the patient's clavicle was unusually thin. A combination of a more oblique angle than recommended, plus the depth of the clavicle vs the fixation screw could provide an explanation for the rupture. The possibility that the tape was inadvertently severed during the cutting of the lead suture with a scalpel could also not be ruled out.

To reduce the risks of rupture due to accidentally cutting through the tape when removing the lead suture, we have amended the position of the knot on the Infinity-Lock to make it easier to access and remove.

We have also amended the IFU to include an additional contraindication for revision cases where the position of the tunnel may be compromised due to the earlier surgery and where the clavicle is particularly thin.

The other rupture which was investigated as part of FSN dated 21 June 2016 appeared to have occurred when the screw was fully tightened in the clavicle of an individual with particularly hard bone. This failure would only

occur at the point at which the screw was fully inserted and so fixation strength would never be compromised in such a case.

Due to the additional information received, the original precaution of creating a 4.5mm bone tunnel as reported in FSN dated 21 June 2016 is no longer deemed necessary, and following additional clinician input regarding the convenience and practicality of this suggestion, the step is to be removed.

Advice on action to be taken by the distributor

Please recall any kits that are with customers and return these plus any kits which you still have available at your premises to Xiros. This includes the Infinity-Lock implant set (102-1088), Infinity-Lock disposable instrument set (202-1088) plus any 4.5mm drills (202-3021) which were provided under FSN dated 21 June 2016.We will replace these with kits which include the Infinity-Lock with the revised knot position, plus the revised Instruction for Use.

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 Infinity-Lock product from the listed batch numbers is returned to Xiros.

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 18 July 2016 in relation to the Infinity-Lock and disposable instrument set provided by Xiros. I confirm that I will return all remaining Infinity-Lock products plus associated 4.5mm drills at my premises and those of my customers from lot numbers VAL 1478, VAL 1479, VAL 1480, 318320 and 318500 to Xiros for replacement.

Signed……………………………………………………………………………………………

Name……………………………………………………………………………………………

Position…………………………………………………………………………………………

Company………………………………………………………………………………………

Date………………………………………………………………………………………………