URGENT Field Safety Notice: RA 2016-169

Date: November 2016

Legal Manufacturer: Stryker Trauma GmbH, Prof.-Kuentscher-Strasse 1-5, 24232 Schoenkirchen/Kiel, Germany

Description: K-Wires

Product Code: 12106450S GAM Kirschner Wire
18060050S T2 K-Wire
18063030S T2 K-Wire Recon

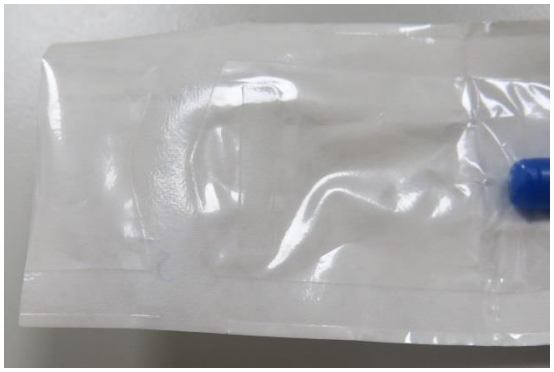
Lot Number: See attached list

Dear Customer,

Please find attached details of a voluntary Field Safety Corrective Action that has been initiated by Stryker Trauma GmbH, Division Trauma and Extremities for sterile packaging of K-Wire(s). It was found through review of packaging that the seal integrity of the pouch may be compromised. More specifically, there is a potential that the sterile pouch is not sealed at one end due to a manufacturing error.

Stryker Trauma GmbH, Division Trauma and Extremities is recalling all unconsumed, non-expired lots of above listed article numbers. Given high turnover for this product and the frequency with which it had been on backorder it is not expected that a significant quantity of units subject to this notice remain in the field. No injury or harm has been reported for this event.

Packaging example – sterile pouch inside (plastic) clear tube


Example of chevron seal - potentially not present

Stryker UK
Stryker House, Hambridge Road, Newbury, Berks. RG14 5AW | P +44 1635 262400 | F +44 1635 580300| stryker.com

Potential Hazards

A missing seal could potentially lead to unsterile product.

Risk Mitigation

The nonconformance is obvious to the user.

Surgical guidelines outline inspection of the sterile barrier (seal) for sterile packed medical devices prior to use.

The pouch itself shows a note: "Contents sterile unless this package has been damaged or opened."

The secondary packaging is a (plastic) clear tube with silicone caps at both ends. While not validated as a sterile barrier, it does provide additional protection to the enclosed pouch package configuration.

Furthermore, it should also be noted that it is standard practice for surgeons to administer antibiotics peri-operatively in order to reduce the risk of potential infection

Actions Needed

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.

4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a) Please provide contact details so that Stryker can inform the recipients appropriately.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

If returning the product would adversely impact your ability to provide necessary medical care to patients, you can consider re-sterilizing the product per Sterilization instructions contained in the Instruction for Use.

We request that you respond to this notice within 7 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
Fax: 01635 262 464
E-mail: nina.goddard@stryker.com

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

RA 2016-169 – Affected product list

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers			
12106450S	GAM Kirschner Wire	K0800BB	K081727	K0911F4	K09D564
		K0800BC	K082C8B	K09379B	K09F026
		K0800BD	K084F89	K096A26	K0A1EF8
		K0800BE	K084F98	K096A2A	K0A1EFA
		K0800BF	K08683D	K096A2C	K0A1EFB
		K0800C0	K08683E	K098213	K0A38FB
		K081720	K086841	K098215	K0A63AB
		K081721	K08820B	K099AA0	K0A63AC
		K081722	K089AF5	K09AD33	K0A7BC1
		K081723	K08E1E1	K09BA4F	
18060050S	T2 K-Wire	K084FBF	K0937A7	K09BA53	K09BA55
		K0920A4	K0937C4	K09BA54	K09BA56
		K0A1EFD			
18063030S	T2 K-Wire Recon	K086847	K08E1E9	K099AA8	

RA 2016-169: PFA Acknowledgement Form

I acknowledge receipt of the Field Safety Notice for RA 2016-169 and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***			
We have located the following devices:			
Product Description	**Product Reference**	**Lot Number**	**Qty**

Please tick one of the two options below:

☐ We would like to return the above items for replacement

☐ We are able to sterilize them as per the IFU and use the items

We have further distributed subject devices to the following organisations:	
Facility Name	
Facility Address	

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO nina.goddard@stryker.com