325 Corporate Drive
Mahwah, NJ 07430
201-831-5000

stryker®

Orthopaedics

URGENT MEDICAL DEVICE REMOVAL

RE: sterile packaging of K-Wire(s)
ATTENTION: SURGEONS, RISK MANAGER, DIRECTOR or MATERIALS MANAGER

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

Product Recalled

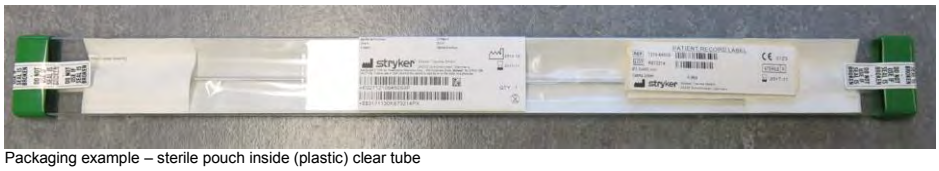
Catalogue number	Product name
12106450S	GAM Kirschner Wire
18060050S	T2 K-Wire
18063030S	T2 K-Wire Recon

Lot #s: 51 specific lots as per attached Affected Product List.

Product Issue

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

Urgent Medical Device Recall – sterile packaging of K-Wire(s)


Example of chevron seal - potentially not present

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

1. Please inform users of this Medical Device Removal and forward this notice to all those individuals who need to be aware within your organization.
2. Return all affected products available at your location to
   Stryker Osteosynthesis
   c/o Christie Samsa, Stryker Orthopaedics
   325 Corporate Drive
   Mahwah, NJ, 07430
   REF: PFA #2015-068
   or
   Contact Stryker customer service and refer to PFA #2016-169 for returning the product to us.
3. Complete and sign the enclosed Business Reply Form and fax a copy to: 1-865-252-3635 or email a copy to yet to be defined, Recall Coordinator, mailto:(xxxxxx@stryker.com).
4. Keep a copy of the completed and executed Business Reply Form for your records.

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.

Report any adverse events or product quality problems to Stryker Orthopaedics: 1-866-OR-ASSIST. (1-866-627-7747).

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to:

MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787

Fax: (800) FDA-0178 Phone: (800) FDA-1088

Urgent Medical Device Recall – sterile packaging of K-Wire(s)

We regret any inconvenience associated with this issue.

As we strive for products that meet your expectations for quality and reliability, please do not hesitate to contact us, in case you have any further questions.

Sincerely,

[redacted]
[redacted]
Stryker Orthopaedics, 325 Corporate Drive, Mahwah, NJ, 07430
[redacted]
[redacted]

Appendix:
Business Reply Form

AFFECTED PART AND LOT CODES

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	

CUSTOMER RESPONSE ON RECEIPT

We have received your letter, Ref: 2016-169, dated DD October 2016 concerning the Urgent Medical Device Field Removal Notification of sterile packaging of Guide Wire(s) and K-Wire(s) and will follow your instruction.

We return this page after completion to Name, Recall Coordinator, at Stryker Orthopaedics by email, fax or letter:

email: name.surname@stryker.com
fax: +1 201 831 XXXX
address: 325 Corporate Drive
Mahwah, NJ 07430

Hospital / Customer Name: _____

Date / Printed Name / Signature: _____