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

<table>
<thead>
<tr>
<th>Catalogue number</th>
<th>Product name</th>
</tr>
</thead>
<tbody>
<tr>
<td>12106450S</td>
<td>GAM Kirschner Wire</td>
</tr>
<tr>
<td>18060050S</td>
<td>T2 K-Wire</td>
</tr>
<tr>
<td>18063030S</td>
<td>T2 K-Wire Recon</td>
</tr>
</tbody>
</table>

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)

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]

Stryker Orthopaedics, 325 Corporate Drive, Mahwah, NJ, 07430

Appendix:
Business Reply Form
## AFFECTED PART AND LOT CODES

<table>
<thead>
<tr>
<th>Manufacturer Part Number</th>
<th>Manufacturer Part Name</th>
<th>Lot Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>12106450S</td>
<td>GAM Kirschner Wire</td>
<td>K081727 K0911F4 K09DS64</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0800BC K09379B K09F026</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0800BD K096A26 K0A1E8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0800BE K096A2A K0A1E8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0800BF K096A2C K0A1E8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0800C0 K098213 K0A63AB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K081720 K098215 K0A63AB</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K081721 K09A1E0 K0A63AC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K081722 K09A1E1 K0A7BC1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K081723 K08E1E1 K098A4F</td>
</tr>
<tr>
<td>18060050S</td>
<td>T2 K-Wire</td>
<td>K084BF K0937A7 K09BA53</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0920A4 K0937C4 K09BA54</td>
</tr>
<tr>
<td></td>
<td></td>
<td>K0A1EFD</td>
</tr>
<tr>
<td>18063030S</td>
<td>T2 K-Wire Recon</td>
<td>K086847 K08E1E9 K09AA8</td>
</tr>
</tbody>
</table>
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: ____________________________________________________