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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating room manager

11 June 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
292.001S	Kirschner Wire Ø 2.6 mm with spade point tip, length 500 mm, sterile	3176205; 3272976; 3302529; 3354855; 3579627; 3643508; 3674215; 3706670; 3709906; 3776426; 7574156; 7680618; 7748660; 7995655; 8109294; 8144980; 8218047

Dear Sir/Madam

Synthes is initiating a medical device removal regarding the above mentioned lots of the Kirschner Wire Ø 2.6 mm with spade point tip, length 500 mm, sterile. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Using the current approved packaging configuration for the product and during the qualification, three of thirty (10%) inner pouches failed the integrity test as they exhibited pin holes as a result of being perforated by the tip of the K-Wire which protruded through the protective tip sheath. All outer pouches passed. Additional evaluation was performed after the product was contained. Only six items were in the distribution warehouse at containment. All six items were returned to determine the extent of the failures. It was reported that the six items returned did not have a protective tip sheath, and that three of the six inner (50%) pouches failed the integrity test as they exhibited pin holes as a result of being perforated by the tip of the K-Wire during transit. All outer pouches passed.

Patient risk:

If a breach in sterility is not detected there is the potential that a patient could be exposed to a contaminated device and an infection could result.
If the breach in sterility is detected there is the potential for a surgical delay to occur while additional K-wires are located. However, the delay is not likely to be significant.

Although no known complaints have been filed against this part, unprotected sharp tips of K-wires have been known to cause injury to operative staff.

Customer immediate actions:

1. Please remove and return the above mentioned articles / lots from your inventory immediately.

2. Complete the attached reply form indicating your receipt of this letter. Return the completed form by fax or email to your local Synthes sales organisation.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH

[redacted]
Field Action Manager

[redacted]
Director Quality Assurance Operations

Cc:

NOTICE: MEDICAL DEVICE REMOVAL

Kirschner Wire Ø 2.6 mm with spade point tip, length 500 mm, sterile

292.001S

Verification Section

☐ We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.

☐ We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____