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

stryker

Orthopaedics

URGENT MEDICAL DEVICE REMOVAL

RE: AXSOS CALIBRATED DRILL
ATTENTION: SURGEONS, RISK MANAGER, DIRECTOR or MATERIALS MANAGER

Date 22 March 2013

Product Recalled AxSOS Calibrated Drill Bit ø4.3mmx263mm, flat

Manufacturer Part Number	Manufacturer Part Name	Lot Numbers
703615	AxSOS Calibrated Drill Bit ø4.3mmx263mm, flat	K121854, K225487, K669162

Product Issue Stryker received a report indicating that the scale of the AxSOS Calibrated Drill Bit ø4.3mmx263mm, flat, is incorrect. The scale is used to indicate the correct screw length after the drilling step during surgery, which allows the screw length to be read on the scale and at the end of the drill guide. The incorrect scale could result in the surgeon selecting a screw that is 10mm longer than intended.

Potential Hazards The usage of the incorrect scale could potentially cause the insertion of a screw up to 10 mm longer than intended which in turn might lead to:

- Additional time under anesthesia due to prolongation of surgery;
- Soft tissue damage;
- Pain;
- Motor loss; and
- Sensory loss

Risk Mitigation

1. Fluoroscopy is used during the procedure to verify fracture reduction and position of the implants.
2. Due to the anatomic region and screw insertion procedure, it is likely that the surgeon will recognize the extra screw length and halt the procedure.

Actions Needed

1. Please inform users of this Medical Device Removal and pass 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 Colleen O'Meara, Stryker Orthopaedics
   325 Corporate Drive
   Mahwah, NJ, 07430
   REF: PFA #2013-040

   or

   Contact Stryker customer service and refer to PFA #2013-040 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 Aminah Crawford, Recall Coordinator. (aminah.crawford@stryker.com).
4. Keep a copy of the completed and executed Business Reply Form for your records.

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

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,

Colleen O'Meara
Manager, Regulatory Compliance
Stryker Orthopaedics
325 Corporate Drive
Mahwah, NJ, 07430
Phone: 1-201-972-2100
Email: colleen.omeara@stryker.com

Appendix:
Business Reply Form

CUSTOMER RESPONSE ON RECEIPT

We have received your letter, Ref: 2013-040, dated 22 March 2013 concerning the Urgent Medical Device Field Removal Notification of the AxSOS Calibrated Drill and will follow your instruction.

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

email: aminah.crawford@stryker.com
fax: (877) 648-7114
address: 325 Corporate Drive
Mahwah, NJ 07430

Hospital / Customer Name: _____

Date / Printed Name / Signature: _____