XX Jan 09

URGENT: Field Safety Notice

Affected Product: HA Stems

FSCA identifier: Product Field Action RA 2008-137

Type of Action: Field Safety Corrective Action: Return to Supplier

Description: HA Hip Stem

Product ref: Refer to attachment

«HOSPITAL»
«ADDRESS_1»
«CITY», «ST» «ZIP»

Dear Distributor/ Risk Management/Surgeon:

Stryker® Orthopaedics initiated a voluntary Field Safety Corrective Action for specific lots of the HA coated Hip Stems referenced above. The intent of this letter is to list all known hazards potentially associated with the use of the product affected by the voluntary Field Safety Corrective Action and list the risk mitigation factors associated with the use of the product affected by the voluntary Field Safety Corrective Action.

Stryker® Orthopaedics has become aware that specified lots of sprayed HA hip stems did not meet Stryker's Internal Material Specification for tensile bond strength and crystallinity. Affects of this deviation can lead to accelerated release of HA particles, accelerated release of HA fragments and accelerated Ca (Calcium) and P (Phosphate) release from HA coating. This deviation was identified during testing to qualify batch 260-07205 for production use.

Potential hazards associated with this deviation include accelerated release of HA particles, accelerated release of HA coating fragments and accelerated Calcium/Phosphate release from the HA coating, patient risks associated with these potential hazards are negligible to minimal as described below.

Patient risk associated with the accelerated release of HA particles is negligible. HA particulate from the Stryker coating does not appear to be a cause of three-body wear and this conclusion remains unchanged regardless of any discrepancy – related increase in HA particulate. There is no evidence to support or suggest that any increase in HA particulate represents a potential primary cause of debris-mediated osteolysis, which involves very high concentrations (e.g., tens of billion per gram of tissue) of sub-micron size particles of materials normally considered to be relatively inert in their bulk form.

Patient risk associated with the accelerated release of HA coating fragments is minimal. Coating fragments arising from stress- or strain – related mechanisms would be present at the implant bone interface, which, again, has been shown to greatly inhibit debris migration. Coating adhesion and composition are more important with thicker coatings, e.g., 150-200 microns, which are known to be inherently weaker and less resistant to strain than those in the 50 micron thickness range.

Patient risk associated with accelerated calcium and phosphate release from the HA coating is negligible. Bone response is affected by dissolution kinetics, the stress environment, and the inherent stability of the implant. The dissolution kinetics of a Ca-P coating are a reflection of its entire composition, not just a single phase within the coating, and a marked change in dissolution would be relatively small compared to other Ca-P coatings.

With respect to risk mitigation factors, the only theoretical adverse effect (if any) that could take place is interference of HA-particulate debris with the metal-PE articulation of the implant. Use of ceramic bearings would prevent this potential adverse effect because of the much harder nature of the ceramic-ceramic articulation.

Technical and medical assessments do not show an increased health risk to patients and Stryker® Orthopaedics is therefore not recommending any additional patient follow-up at this time. The implanting and treating physicians are in the best position to exercise medical judgment for their patients and should make the final decision on this point. Please note that your signature on this form only confirms that you received this notification and does not obligate you to take any additional action beyond what is called for in this Field Safety Corrective Action notification letter.

Our records indicate that you have received the above referenced product(s) and we are requesting that you assist us in this voluntary Field Safety Corrective Action by completing the attached Product Field Safety Corrective Action Acknowledgment Form.

In the occurrence that the any of the affected Lots are unused, please follow the below advice:

1. Immediately check your internal inventory and quarantine all subject devices.
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. Please provide contact details so that Stryker can inform the recipients appropriately.
5. Complete the attached customer response form.
   (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)
6. Please inform Stryker of any adverse events
7. Return the completed form and any affected devices to your local Stryker Representative

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients.
We apologize for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

We would like to also inform you that as our national Competent Authority, The Irish Medicines Board (IMB) has been notified of this action.

If you have any further enquiries, Please contact your local Sales Representative.

Yours Sincerely,

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STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

January 6, 2009

SURGEON

ADDRESS

CITY, STATE ZIP

FSCA identifier: Product Field Action RA 2008-137

Description: HA Coated Hip Stems

Catalog Number/Lot Code: See Attached List

I have received the notification from Stryker® Orthopaedics dated January 6, 2009 stating that they initiated a voluntary Field Safety Corrective Action of the above referenced product.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)

Please fax this signed and dated form to XXXX