stryker®

URGENT: Field Safety Notice

Date

«ATTENTION»
«ADDRESS1»
«ADDRESS2»
«CITY», «ST» «ZIP»

Field Safety Corrective Action: RA 2008-097

Description:	MRS Cemented Stems
Catalog Number:	6485-3-000, 6485-3-008, 6485-3-009, 6485-3-010, 6485-3-018, 6485-3-019, 6485-3-300, 6485-3-308, 6485-3-309, 6485-3-310, 6485-3-318, and 6485-3-319
Lot Code:	refer to list provided by mfr

Dear xxx

Our manufacturer, Stryker® Orthopaedics Limerick, has initiated a Field Safety Corrective Action concerning all lots of the MRS Cemented Stems referenced above. The intent of this FSN is to list all known hazards potentially associated with the use of the product affected by this action and list the risk mitigation factors associated with the use of the subject devices.

Issue

Stryker® Orthopaedics has become aware that there are no statements or warnings written on the label or in the Instructions for Use, for the MRS Cemented Stems about the proper indication stating that the 8, 9, 10mm diameter MRS Cemented Stems should only be used with GMRS Distal Femoral Components and the GMRS Proximal Tibial Components.

Potential Hazards

Hazard 1

There is no verbiage in the Instructions for Use or on the label stating that the 8, 9, 10mm diameter MRS Cemented Stems are indicated for use only in the GMRS Proximal Tibial and Distal Femoral Components.

1) The hazardous situation is that the stem performance is unknown. Without having performance testing, the smaller diameter stems potentially cannot withstand the physiological loads experienced in vivo over time. This can lead to the following harms:
    - The risk to the patient is revision surgery due to stem failure.

Risk Mitigation Factors

- Reference the surgical protocol which describes the compatibility between components.

Stryker Orthopaedics is 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.

Our records indicate that you have received the above referenced product(s). We therefore request that you take the following actions:

1. Inspect your inventory and quarantine any of the subject devices listed above.
2. Complete the attached customer response form indicating product disposition/quantities to be returned.
3. Complete this form even if you do not have any devices to return. This will preclude the need for Stryker to send any reminder notices.
4. Circulate this notice internally to all affected parties.
5. Display this notice prominently until the action has been completed.
6. If you have further distributed any of the subject devices to other organisations we request that you please provide full details of the new owner. Stryker will then follow up with the new owner directly.
7. Inform Stryker of any adverse events relating to this issue.
8. On completion of the attached customer response form please return to your local Stryker Distributor, contact details given below.
9. On receipt of this form a Stryker representative will contact you to arrange for return of affected devices and replacement or credit of returned products.

Please note that your signature on the customer response form confirms that you received this notification and fulfilled the requested actions. It does not obligate you to take any additional action beyond what is called for in this Field Safety Notice.

We regret any inconvenience this action may cause you and on behalf of Stryker thank you sincerely for your help and support in completing this action swiftly.

Sincerely,