Date

URGENT FIELD SAFETY NOTICE: RA2012-168

Dear Customer

Description:	**Bioabsorbable ACL Screws, BioZip Anchors, XCEL Anchors**
Catalogue #	**234-010-061; 234-010-062; 234-010-064; 234-010-065; 234-010-066 234-010-079; 3910-200-025; 3910-300-015**
Lot #	**87747, 90900, 91705, 92769, 94556, 94558, 95085, 95087, 97275 02J1100445, 02H1102435, 02H1102436, 02H1101959**

Dear Customer

Please find attached details of a Product Action that has been initiated by Stryker Orthopaedics concerning the above referenced subject devices. This action has been taken to ensure that users are aware of important Information concerning the device listed above.

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. You are required only to read the attached Field Safety Notice and then sign and return the Customer Response Form confirming that you have completed the actions requested by the manufacturer. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is 28th April 2013 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position:

Tel: Fax: E-mail:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is

committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours....

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Stryker® Orthopaedics initiated a lot specific Product Field Action for the recall of the subject devices referenced above.

ISSUE:
The Design Examination certificate for the subject devices expired on 12 Oct 2010. The lots listed above were manufactured following the expiry of the design examination certificate, and therefore bear an invalid CE Mark. As such, the products referenced above should not have been distributed to countries having CE Marking requirements.

Potential Hazards
There are no potential hazards associated with this Product Field Action.

Our records indicate that you may have received one or more of the subject devices. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.

Immediate actions
We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
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. Please inform Stryker of any adverse events.
   Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. 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 for Stryker to send any unnecessary reminder notices.
7. Return the completed form to your nominated Stryker Representative.
   On receipt of the form a Stryker representative will contact you to arrange for the collection of any remaining inventory.

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 Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours ……

RA2012-168: FSN ACKNOWLEDGMENT FORM

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I acknowledge receipt of the Field Safety Notice for RA2012-168 and can confirm that:

We have not located any of these devices in our inventory: ***(please delete if not applicable)***	

We have located the following devices:

Product description	Product Reference	Lot Number	Qty	Qty Quarantined

We have further distributed subject devices to the following organizations:

Facility Name		
Facility Address		

Form completed by:

Contact Name		**Contact Facility**	
Contact address		**Contact Position**	
		Contact Tel No	
		Contact Fax No	
		Contact e-mail	

Please return the completed form to: