Stryker Spine
Zone Industrielle de Marticot
Cestas France 33610

URGENT: FIELD SAFETY NOTICE

Our manufacturer has notified us of a Product Field Action concerning the Medical Devices referenced below. Our records indicate that you have been supplied with some of the subject devices. We would request therefore that you read this notice carefully and follow the instructions provided by the manufacturer.

We would like to reassure you that only the devices listed are affected by this action.

On behalf of Stryker we would like to thank you in advance for your cooperation and support in this matter.

Please note that in accordance with the Medical Device Directive and the Meddev Vigilance Guidance Document this Field Safety Corrective Action has been notified to the National Competent Authority of all countries where subject devices have been distributed.
This Field Safety Notice has been issued in accordance with the European Competent Authority detailed below.

Type of Action	**Recall**
Date of report	2011-10-06
Stryker Internal Reference Number	2009-415
Name of Manufacturer	Stryker Spine Bordeaux
Website address	0
National Competent Authority	if appropriate - please delete if not
Regulatory Agency Reference No	if appropriate - please delete if not

Local Contact Information

Contact Person	
Contact tel number:	
Contact e-mail	

Product Information

Product Description	CERVICORE CHISEL GUIDE
Product Code/Catalogue No:	48290110
Lot Numbers	07G781
Software version (if applicable)	NA
Quantities distributed to your facility	
Expiration date of product	NA
Expected shelf life/product life	0

Issue

Description of problem

Stryker Spine received a report of an inability to insert the guide over the fixation pin. Upon inspection it was discovered that the hole was too narrow to accommodate the fixation pin.

Population concerned

Patients

Potential Hazards associated with use of device

1. The bone cut is suboptimal and may prevent correct implant positioning. This may compromise the construct stablity
2. The surgeon is unable to use the Chisel Guide and must alter his technique and convert to a standard fusion. Prolongation of the surgery of > 30min.
3. The surgeon is unable to complete the Chiseling step of the surgical technique and skips to the broach step

Mitigating circumstances/precautionary measures

NA

Specific advice for surgeons regarding patients with implanted devices

NA

Communications/Attachments

Customer response form	Indicate number of pages
IFU/User manual/Operative Technique	Indicate number of pages
Upgrade kit	indicate nature of kit
Distribution list	
Labels	
etc	

Immediate Actions

1. **Immediately locate and quarantine all subject devices**
2. **Circulate this list internally to all interested/affected parties**
3. **Maintain awareness of this 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. **Immediately inform Stryker of any adverse events concerning use/attempted use of subject devices.**

Product Return Information

1. **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 notices
2. **Return the completed form to:**
3. **A Stryker representative will then contact you to organise return of subject devices**

Name

Position

Signature