stryker
Orthopaedics

January 2012

URGENT FIELD NOTICE: RA2011-161

Dear Customer

Description: Accolade Rasp Handle Assembly
Catalog No.: 1020-1400
Lot Code: P5E93

Please find attached details of a Product Field Action that has been initiated by Stryker Orthopaedics concerning the above referenced devices. Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site. In this case you are receiving the notice because you have potentially received subject devices in the past and we have no record of the device being returned to Stryker or destroyed. As a responsible manufacturer we feel that it is our duty to ensure that you are therefore made aware of the information contained within the manufacturer's Field Notice.

The reason for this action is that the manufacturer has determined that there is potential for the impaction pad of subject devices to detach from the rasp handle, which may consequently cause a delay in the procedure. It is routine for there to be at least two of these devices within the standard instrument kit configuration. Therefore the delay would be less than thirty minutes and would not present any additional risk of serious injury to the patient.

This action requires only that you inspect your physical inventory, locate and remove from service any of the lots identified above. Then complete and return the attached customer response for to your local Stryker Distributor. Please note that your signature on the following form only confirms that you have received this notification and does not obligate you to take any additional action beyond what is called for in this notification letter. Completing the Customer Response 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 23rd March 2012 and your timely response will enable us to ensure that we meet this target and ensure that non conforming devices are removed from the market as quickly as possible.

Should you have any physical inventory, then on receipt of the returned customer Response Form a Stryker Representative will contact you to arrange for the return of subject devices and product replacement. If you have indicated that you do not have any physical inventory then we will update our files and no further communication will be sent. 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: E-mail: Tel: Fax:

Although the manufacturer has identified that there are not any additional patient risks associated with this issue, and therefore in accordance with the Vigilance Guidance document Ref 2.12-1, no obligation to report, Stryker has decided to make a voluntary report to all affected European Competent Authorities. Therefore this action has been notified to your National Competent Authority.

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 and thank you sincerely for your help and support in completing this action in a timely manner.

Yours....

URGENT FIELD NOTICE: RA2011-161

Dear customer

Description: Accolade Rasp Handle Assembly
Catalog No.: 1020-1400
Lot Code: P5E93

Stryker® Orthopaedics has initiated a Product Field Action concerning the above referenced devices

Issue
Stryker ® Orthopaedics has become aware of the potential for the above note Accolade Rasp Handle Assembly to fracture upon use.

Potential Hazards
The potential associated hazard is that the impaction pad may detach from the rasp handle and result in a non-functioning instrument. The following possible sequence of events may occur as a result:
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- Impaction forces may fracture the welds holding the striker plate to the rasp handle.
- This may lead to fatigue stress, fractures and disassociation of the strike plate from the rasp handle.
- The surgeon may proceed with the surgery by removing and replacing the broken rasp handle with a second handle available in the instrument kit.

The hazardous situation is the potential loss of function of the rasp handle with the user being unable to impact the broach during a surgical procedure. The potential resulting harm is an extension of surgery time of less than thirty minutes whilst the surgeon replaces the handle.

Risk Mitigation
Replacement devices are easily available. It is routine for there to be at least two of these devices within the standard instrument kit configuration for this system.

Patient Follow up
There is no requirement for additional patient follow up or monitoring. Should a device break intra-operatively the surgeon would be immediately aware and replace the handle in order to continue the procedure. The risk assessment has indicated that there are not any additional risks for patients associated with this type of event.

Usage
Devices may continue to be used pending availability of replacement devices. Inspect devices prior to and after each procedure. Remove any devices that show evidence of fracturing. Always ensure that two devices are available at the start of the procedure.

Immediate Actions Required

1. Immediately check your internal inventory. Locate and quarantine all subject devices pending return to your local Stryker Distributor.
2. Circulate this Field 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 associated with the use of the subject devices.
   - Please comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.
7. Complete the attached customer response form and return to the address indicated.

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We thank you sincerely for your help and support in ensuring that only conforming devices meeting Stryker's high internal standards remain on the market and apologize for any inconvenience this Field Corrective Action may create.

If you have any further enquiries, please contact the undersigned in the first instance.

Yours faithfully,

RA2011-161: PFA ACKNOWLEDGMENT FORM

Description: Accolade Rasp Handle Assembly
Catalogue No: 1020-1400
Lot No: P5E93

I acknowledge receipt of the Field Notice for RA2011-161 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: