URGENT FIELD SAFETY NOTICE UPDATE

Product Field Action	**1570495- UPDATE**
Type of Action:	Field Safety Corrective Action: **Return to Supplier**
Description:	Various Stryker Hip Products
Catalog #:	Various (See Attachment 1)
Lot Code:	Various (See Attachment 1)

Xx, September, 2017

Dear Customer:

On 21st July 2017 Stryker Orthopaedics initiated a voluntary, lot-specific recall for the Stryker hip Products and Lot I.D.s referenced above for a potential packaging issue. This initial communication requested that affected product be quarantined and returned to Stryker and stated that an additional communication would be forwarded upon completion of the internal investigation on this issue.

The intent of this letter is to list all known hazards potentially associated with the use of the Products and list any risk mitigation factors.

Issue:

Stryker has discovered that the packaging of certain sizes and lots of the above-referenced Product contained inner and outer Tyvek sterile barriers that were not fully sealed. Three reports were received of the Tyvek sterile barriers not being fully sealed, and in each case the discrepancy was identified prior to surgery.

Potential Hazards:

1. Device is not utilized during surgery.
2. Non-sterile implant.

The aforementioned potential hazards may result in the following patient harms:

1. Delay in surgery <15 minutes while new device is obtained.
2. Infection.

Risk Mitigation:

According to the Instruction for Use (IFU) provided within each packaged component, the end user is instructed to inspect the package and seal for damage and, if present, to discard the device. As any damage to the packaging will be likely obvious to the end user, inspection and verification prior to transferring the device to the sterile field, that both the outer and inner blister is acceptable, as per the IFU, may mitigate potential risk.

Our records indicate that you have received the above referenced product. Please assist us in meeting our regulatory obligation by:

1. **(As requested previously).** Immediately locate and quarantine subject devices referenced in this notice.

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 associated with the use of the subject devices.

    a. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

6. Complete the attached customer response form and return to the address indicated. *(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)*

On behalf of Stryker we thank you sincerely for your help and support in completing this action 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 and appreciate your assistance in meeting this objective.

Should you have any queries concerning this matter please do not hesitate to contact the undersigned.

Yours Sincerely,

_____

FIELD SAFETY CORRECTIVE

ACTION ACKNOWLEDGMENT FORM

Product Field Action **1570495-UPDATE**
Type of Action: Field Safety Corrective Action: **Return to Supplier**
Product Description: Various Stryker Hip Products
Catalogue Numbers: Various (See Attachment 1)
Lot Code: Various (See Attachment 1)

I acknowledge receipt of the Field Safety Notice for the PFA 1570495-UPDATE from Stryker® Orthopaedics stating that they initiated a Field Safety Corrective Action of the above referenced product (Attachement 1), and I can confirm that

We have not located any of these devices in our inventory:				
We have located the following devices:				
Product description	**Product Reference**	**Lot Number**	**Qty**	**Qty Quarantined**
We have further distributed subject devices to the following organisations:				
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 COMPLETE AND FAX THIS FORM TO X
OR EMAIL TO X.

ATTACHMENT I
PFA 1570495 UPDATE

Please, check carefully within your inventory and organization if any of the following Part Numbers and **affected lot number**. **Please be aware that only these batches are affected.**

Part Number	Lot Number
4845-0103	G5964186E
6720-0837	56211103
4585-0102	G5953064D
6276-1-125	55958705
6720-0837	56211704
6020-2530	55967305
4845-0203	G6013168C
6720-0837	56211401
6720-0535	56241803
6721-0535	57317205
6020-4535	56011205
6021-4535	56132703
6721-0435	57315302
6721-0737	56662106
6021-0740	56011301
6021-0030	55624702
6276-5-216	55959003
6020-4535	56011202
6721-0737	57284004
6020-0740	55852403
6721-0435	57315101
6720-0535	57300703
6021-0230	56019501
4845-7-116	53428604
6276-1-127	55709001
6276-1-127	55709002
6276-1-127	55709003
6276-5-521	55627501
6276-5-526	55709901
6020-4535	56011203
6021-4535	56109304
6276-5-525	55349102
542-11-50E	57319901