

URGENT FIELD SAFETY NOTIFICATION

Various Stryker Hip Products

July xx, 2017

FSCA identifier:	Product Field Action # 1570495
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)

Dear Customer:

On July xx 2017 Stryker Orthopaedics voluntarily recalled the Products and Lot I.D.s referenced above for a potential packaging issue.

Technical and medical assessments are currently underway to determine any potential hazards associated with the use of the product. An additional communication will be forwarded upon completion of the internal investigation on this issue.

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

1. 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.
 - a) Please provide contact details so that Stryker can inform the recipients appropriately.
 - b) If you are a Distributor, note that you are responsible for notifying your affected customers.
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***)

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

We request that you respond to this notice within 7 calendar days from the date of receipt.

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:** _____ **email:** _____

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 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,



URGENT FIELD SAFETY NOTIFICATION
Acknowledgement Form

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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 from Stryker® Orthopaedics stating that they initiated a Field Safety Corrective Action of the above referenced product (Attachement 1)

Acct: Account #:

Print Customer Name Customer Title

Contract Phone Number Customer Signature Date

Email Address Fax number

If you have further distributed any affected product, please indicate to whom below (attach additional sheets as necessary):

Name Address City State Zip Contact

Person Product(s)

ATTACHMENT I

PFA 1570495

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
4845-0102	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
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