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stryker®
UK

URGENT Field Safety Notice: RA2016-080

27 June 2016

Product Code	Lot Numbers	Description
0605-887-000 0607-687-000	Various – Please refer to page 4	AutoPlex® System

Dear Customer,

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

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. The purpose of this letter is to advise you that Stryker Instruments is recalling the following AutoPlex® System.

Reason for Voluntary Recall:
The valve on the AutoPlex® System's injection assembly may become blocked, resulting in a cement backflow towards the injector handle.

Risk to Health:
There is a potential for a delay in surgery if additional cement needs to be prepared for the injection procedure.

Product Description:
The AutoPlex® System is used for mixing bone cement and delivering the bone cement percutaneously.

For purposes of being able to readily locate recalled product within your inventory, we are providing two methods for identifying the affected AutoPlex® Systems: 1. By Sterilization Lot Number listed on the corrugated shipper and plastic bag (See Fig. 1) and/or 2. By Manufacturing Lot Number listed on the individual blister packs (See Fig. 2).

bsi.
RS11877

Fig. 1 Corrogated shipper & plastic bag label. Part and lot numbers are circled.

Fig. 2 Blister pack label. Part and lot numbers are circled.

Actions Required:

1. Immediately check your internal inventory and quarantine any subject devices that are located.

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.

5. Complete the attached customer response form and return to Mark Fielding by fax (01635 262 464) or by e-mail (nina.goddard@stryker.com).

   a) Please complete this form even if you do not have any affected product. This will preclude the need for Stryker to send any reminder notice.

6. Upon receipt of a completed response form, a Stryker Representative will contact your facility to arrange collection of any affected devices that have been located on site and to arrange any replacements that are required.

7. Please inform Stryker of any adverse events concerning the use of the subject devices.

8. Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

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 the target 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.

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

Yours faithfully,

Nina Goddard
Quality Assurance and Regulatory Affairs

RA2016-080 Affected Lot Numbers

Product Number	Product Description	Sterilization Lot Numbers	Manufacturing Lot Numbers
0605-887- 000	AUTOPLEX W/O NDL. INTL	Please refer to the manufacturing lot number.	16022012, 16040012, 16050012, 16057012, 16069012, 16078012, 16104012, 16112012, 16124012
0607-687- 000	AUTOPLEX W/VERTAPLEX HV	16021012, 16022012, 16025012, 16025022, 16026012, 16026022, 16027012, 16027022, 16028012, 16028022, 16033012, 16041012, 16048012, 16048022, 16049012, 16049022, 16049032, 16053012, 16056012, 16056022, 16060012, 16061012, 16063012, 16063022, 16070012, 16070022, 16074012, 16088012, 16092012, 16098012, 16100012, 16104012, 16104022, 16105012, 16106012, 16107012, 16109012, 16109022, 16113022, 16113032, 16118012, 16118022	16015012, 16016012, 16017012, 16018012, 16019012, 16020012, 16021012, 16022012, 16025012, 16036012, 16039012, 16041012, 16042012, 16043012, 16047012, 16048012, 16049012, 16053012, 16054012, 16055012, 16056012, 16062012, 16063012, 16064012, 16077012, 16081012, 16095012, 16096012, 16097012, 16098012, 16099012, 16100012, 16103012, 16106012, 16109012, 16110012

RA 2016-080: PFA Acknowledgement Form

Product Code	Lot Numbers	Description
0605-887-000 0607-687-000	Various – Please refer to page 4	AutoPlex® System

I acknowledge receipt of the Field Safety Notice for RA2016-080 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**
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO NINA.GODDARD@STRYKER.COM.