URGENT FIELD SAFETY NOTICE: RA2016-080
AutoPlex® System

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

June 20, 2016

Catalogue Numbers: 0605-887-000, 0607-687-000
Product description: AutoPlex® System
Lot Numbers: see below

Dear AutoPlex® System 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 voluntarily recalling the following AutoPlex® System.

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).

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

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.

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

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

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory and quarantine all subject devices pending return to Stryker.
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 concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this 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.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within **XXX** 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 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.

Yours Sincerely,

XXXXXX