



URGENT FIELD SAFETY NOTICE: RA2017-1668701

Product: Stryker Instruments various disposable products

ATTN: Risk Manager, Operating Room Director, Materials Manager

November, 2017

FSCA identification: Product recall RA2017-1668701

Action type: Field Safety Corrective Action

Catalogue Numbers: 0206-530-000

0605-887-000

0607-687-000

Product description: refer to the tables below

Lot Number: refer to the tables below

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling select disposable products that were distributed between October 16, 2017 and November 14, 2017. Please refer to the specific product numbers and descriptions listed in the tables below.

Product Description:

Product #	Product Description	Lot Number(s)
0605-887-000	AutoPlex System	17278012
0206-530-000	180-Gram Cement Cartridge with Breakaway Femoral Nozzle	17277012, 17283012

For the purpose 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 and/or 2. By Manufacturing Lot Number listed on the individual blister packs.

Product #	Product Description	Sterilization Lot Number(s)	Manufacturing Lot Number(s)
0607-687-000	AutoPlex System: w/ VertaPlex HV	17278012, 17278022, 17279022, 17282012, 17282022, 17291012, 17291022	17237012, 17240012, 17242012, 17243012, 17244012, 17259012, 17259012

Reason for the Voluntary Recall:

During routine testing, it was found that bioburden levels were higher than internally acceptable rates; therefore, this voluntary recall is being initiated since the sterility of the products cannot be confirmed.

Risk to Health:

In addition to the normal risk of infection that any procedure carries, there is an additional potential risk that if an affected product is used in a procedure, an infection may occur which may require medical treatment.

Stryker Instruments

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Actions to be taken by the Customer/User:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

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 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

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