12/06/2015

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2015-035

Type of Action: Field Safety Corrective Action: Recall

Description: SERFAS 90o Energy probe

Catalog #: 279-350-101

Lot Code: All non-expired product
(Lot numbers13128AE2 through 14337AE2)

Dear customer:

Please find attached details of a Product Action that has been initiated by Stryker 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.

Incident reported:

Stryker is voluntarily recalling the SERFAS 90o Energy Probe (also known as the 90R probe), part number 279-350-101, all non-expired product (lot numbers 13128AE2 through 14337AE2). Note that this recall is only for this specific probe.

Reason for the Recall: There have been a total of 23 reports of fragments of the probe breaking off into the patient since December 2013.

Risk to Health: There is a potential risk that fragments may be released into the joint space as a result of the probe breaking requiring immediate surgical intervention to remove the fragments. In addition, there is a potential risk the fragments may remain within the joint space, resulting in function impairment.

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 to 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 organizations.

    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. Please comply with any local regulations concerning the notification of adverse events to your National or local Competent Authorities.

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 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.
    On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 2016, January and your timely response will enable us to ensure that we meet this target.

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
Telephone

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 cause. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remaining on the market.

Yours Sincerely,

STRYKER®

FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

June XX, 2015

HOSPITAL

ADDRESS

CITY, STATE ZIP

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Lot Code: All non-expired product
(Lot numbers13128AE2 through 14337AE2)

Type of Action: **Return to Supplier**

I have received the notification from Stryker® Endoscopy dated May XX, 2015 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____

Surgeon (Signature) Date

_____

Surgeon (Print)

Please fax this signed and dated form to XXXX