Field Safety Notice RA2017-1575801

10. Aug. 2017

URGENT MEDICAL DEVICE RECALL- REMOVAL

FSCA identifier: Product Field Action RA2017-1575801
Type of Action: RECALL-REMOVAL
Description: AXS Offset - Unit identified with defect within hub
Catalog #: M003DC0501500
Lot #: 19704728, 19704729, 19704730

Dear Customer:

Stryker Neurovascular has initiated a recall and removal for the devices identified above. Our records indicate that you have been supplied with at least one of the subject devices. We therefore request that you read this notice carefully and complete the actions requested by the manufacturer. The intent of this letter is to instruct you to return all impacted product to Stryker.

Issue:
Stryker Neurovascular has become aware that some units of AXS Offset product were not manufactured to specification by 1 product builder. There is a potential defect in the hub section of product which can lead to decreased tensile strength and potential separation of the hub and catheter shaft during use.

Potential Risk
Patients who have previously been treated with this product are not affected by this issue.

For potential patients- The most likely adverse health consequence to the patient from this defect is prolongation of the procedure after introduction into the vasculature due to the need to replace it with another device. There is also a remote potential of air embolism in more severe cases if the catheter body separates from the shaft during the procedure.
However, there are no anticipated long term adverse health consequence to the patient after the catheter is removed from the body if the defect was not observed as part of the procedure.

Risk Mitigation:
Follow the instructions below under Immediate Actions Required.

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

1. Immediately check your internal inventory for impacted Catalog and lot numbers.
2. Segregate the affected units in a secure location for return to Stryker.
3. Circulate this Field Safety Notice internally to all interested/affected parties.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility.

5. 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.*

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

7. 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 the form even if you no longer have any of the subject devices in your physical inventory.

8. Return the completed form to your nominated Stryker Representative or to NVFieldActions@stryker.com.

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 15 Sept 2017 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

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,

STRYKER® NEUROVASCULAR

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ACKNOWLEDGMENT FORM

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Product Disposition				
Product Code/Cat No.	**Lot/ Serial No**	**Qty to be returned**	**Qty Used**	**Qty not located**

I have received the notification from Stryker stating that they have initiated a product field action for the above referenced product.

I acknowledge receipt of the of this **URGENT MEDICAL DEVICE RECALL- REMOVAL**

Form completed by:	
Facility	
Contact address	
Phone	
Date	

Please email this signed and dated form to NVFieldActions@stryker.com