Urgent Medical Device Voluntary Customer Communication

Immediate Action Required

This is a Customer Communication Packet.
Please read this entire packet carefully and follow each step.

Urgent Medical Device Voluntary Customer Communication

Immediate Action Required

Table of Contents

This packet contains the necessary items to provide a customer communication of the RA2018-1724696 - Wingspan Field Action. They are as follows:

Urgent Medical Device Voluntary Customer Communication

Immediate Action Required

22 May 2018

URGENT MEDICAL DEVICE CUSTOMER COMMUNICATION

FSCA identifier: RA2018-1724696

Type of Action: CUSTOMER COMMUNICATION

Description: WINGSPAN DELIVERY CATHETER COATING DAMAGE

Catalog #:

M003WE0250090	M003WE0300090	M003WE0350090	M003WE0400090	M003WE0450090
M003WE0250150	M003WE0300150	M003WE0350150	M003WE0400150	M003WE0450150
M003WE0250200	M003WE0300200	M003WE0350200	M003WE0400200	M003WE0450200

Lot Codes:
All Lots of Wingspan Stent System used in China

Dear Customer:

Stryker Neurovascular has initiated a voluntary customer communication regarding 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 on proper use of the device per the DFU provided with the device to prevent damage to the device during the procedure and avoid potential harm to the patient.

Issue:
Stryker Neurovascular has identified Seven (7) Wingspan Delivery Catheters with coating damage occurring on the delivery catheter shaft. The resulting investigation has determined that the damage was use-related, all units were manufactured to specification and no manufacturing issue was identified. All devices are associated with complaints that relate to the user experiencing excessive resistance due to factors encountered during the clinical procedure.

Potential Risk
The lowest risk severity associated with high friction encountered during the procedure is potential for prolongation of the procedure time.

The maximum risk severity associated with high friction is the potential for vessel perforation/dissection/ trauma that could result in hemorrhage or damage to perforator rich circulation which can result in permanent impairment to the patient.

Regulatory Actions
Affected worldwide regulatory authorities are being notified of this communication as required.

Urgent Medical Device Voluntary Customer Communication

Immediate Action Required

Risk Mitigation:

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

Please note that NO product will be returned as a result of this action.

1. Review the Communication and ensure full understanding of the contents.

2. Review the Directions for Use (DFU) and ensure full compliance to the recommendations present, especially to the excerpts below:

   "If excessive resistance is encountered during the use of the Wingspan Stent System or with the Gateway PTA Balloon Catheter at any time during the procedure, discontinue use of the System. Movement of the System against resistance may result in damage to the vessel, a System component, or the patient."

   "Follow the Wingspan Stent System preparation and use instructions carefully…
   1. *Open the pouch to remove the packaging tray, and inspect for compromised packaging.*
   2. *Flush the dispenser hoop with sterile heparinized saline, carefully pull out the proximal hub assemblies from tray, tighten the rotating hemostasis valve onto the Inner Body and remove the Delivery System. Inspect Delivery System for damage, such as kinks. The Stent should be preloaded into the distal tip of the Delivery System.*
      Note: Do not use excessive force when tightening the Outer Body rotating hemostasis valve onto the Inner Body.
   3. *Connect a rotating hemostasis valve to the hub of the Inner Body and flush the lumen of the Delivery System Inner Body with sterile, heparinized saline.*
   4. *Loosen the Delivery System Outer Body rotating hemostasis valve, flush the Delivery System Outer Body with heparinized saline and tighten the hemostasis valve onto the Delivery System Inner Body.*
   5. *Continue to flush the Delivery System Outer Body to purge air from the system.*
   6. *Connect the hemostasis valve side port of the Delivery System Outer Body and Delivery System Inner Body to a pressurized sterile heparinized saline flush.*
   7. *Loosen the hemostasis valve on the Delivery System Outer Body that is locked onto the Delivery System Inner Body, and gently retract the Delivery System Inner Body so that there is a 1-2 mm gap between the proximal end of the dual tapered tip and the distal end of the Outer Body. This should result in a rapid saline drip from the Outer Body tip.*
      Note: Do not use excessive force or lodge the Inner Body tip inside the Delivery System.
   8. *Tighten the Delivery System Outer Body hemostasis valve around the Delivery System Inner Body to hold the Delivery System Inner Body in place during advancement of the Wingspan Stent System."*

3. The affected items may continue to be used in accordance with the DFU accompanying the product.

4. If resistance is observed during advancement of the Wingspan Catheter and the source cannot be determined in accordance with the DFU, withdraw the catheter and use a replacement device to continue with the procedure.

5. Circulate this Customer Communication internally to all interested/affected parties.

6. Maintain awareness of this communication internally until all required actions have been completed within your facility.

7. Inform Stryker if any of the subject devices have been distributed to other organizations.

8. Please provide contact details so that Stryker can inform the recipients appropriately.

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

10. Return the completed form to your nominated Sales 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 31 July 2018 and your timely response will enable us to ensure that we meet this target.

On behalf of Stryker we thank you sincerely for your help and support in completing this action by the target date.

Yours Sincerely,

Darren Coughlan
Complaints Team Lead

Urgent Medical Device Voluntary Customer Communication

Immediate Action Required

STRYKER® NEUROVASCULAR

URGENT MEDICAL DEVICE RECALL- REMOVAL

ACKNOWLEDGMENT FORM

FSCA identifier: RA2018-1724696

Type of Action: CUSTOMER COMMUNICATION

Description: WINGSPAN DELIVERY CATHETER COATING DAMAGE

I have received the notification from Stryker stating that they have initiated a product field action for the above referenced product and I acknowledge receipt and review of the of this **URGENT MEDICAL DEVICE CUSTOMER COMMUNICATION**

I acknowledge receipt of this **URGENT CUSTOMER COMMUNICATION.**

Comments: _____

Form completed by:			
Contact Name		**Facility**	
Contact address		**Signature**	
		Phone	
Date		**Email**	

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