May 2018

URGENT Field Safety Notice: RA2018-1749458

FSCA identification: Product recall RA2018-1749458

Action type: Field Safety Corrective Action: Recall

Description: Mako RIO System Irrigation Clip (Partial Knee Application only)

Catalogue Numbers: 111690

Lot Number: 176364, 178346, 181337, 185213, 186561, 189709, 190559, 193643, 195763A1

Dear Customer,

Stryker has initiated a lot-specific recall for the Mako RIO System Irrigation Clip (Partial Knee Application only). The intent of this letter is to list known hazards and harms potentially associated with the above mentioned product and list any risk mitigation factors.

Issue

Stryker has discovered that specific lots of the Mako RIO System Irrigation Clip have the potential to fracture. The RIO System Irrigation Clip is a sterile disposable, used to direct saline flow for the burring tool during a Mako Partial Knee surgery

Potential Hazards

In the event of a break in the Mako RIO System Irrigation Clip, the following potential hazards may occur:

- Fractured device
- Foreign object (i.e. inert particulate left in wound)

Potential Harms

The above mentioned hazards may result in one or more of the following potential harms:

- Complications associated with extended surgery time of > 15 min:

While retrieving a secondary RIO System Irrigation Clip; or
While attempting to irrigate inert particulate from wound site

- Poor implant performance

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- Inflammatory response
- Pain and/or poor soft tissue function

Risk Mitigation

1. Inert Particulates: The Mako RIO System Irrigation Clip is made from a surgical grade liquid crystal polymer. Particulates of this polymer would be inert if left in the surgical wound.

2. Lavage Steps: As part of either an intentional attempt to remove any possible Mako RIO System Irrigation Clip particulates or during routine surgical lavage steps, there exists the potential that these efforts could remove a fragment of the Mako RIO System Irrigation Clip from the surgical wound. This would mitigate the hazards of foreign inert particulates in the surgical wound.

Immediate Action

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 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.

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

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 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 (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 07 calendar days from the date of receipt. The target date for completion of this action is 29 June 2018 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: Nina Goddard
Position: RAQA Specialist
Telephone: 01635 262 476
E-mail: nina.goddard@stryker.com

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 faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

RA2018-1749458: Acknowledgement Form

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I acknowledge receipt of the Field Safety Notice for RA2018-1749458 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*				
We have located the following devices:				
Product Description	Product Reference	Lot Number	Qty implanted	Qty to return
			NA	
			NA	
			NA	
We have further distributed subject devices to the following organisations:				
Facility Name				
Facility Address				

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 580300
OR EMAIL TO nina.goddard@stryker.com