

July 2018

URGENT Field Safety Notice: RA2018-1802553

FSCA identification: RA2018-1802553

Action type: Field Safety Corrective Action: Recall

Legal Manufacturer: MAKO Surgical Corp. 2555 Davie Road. Fort Lauderdale. 33317

Product Affected:

Catalogue no	Description	Lot no
107120	Vizadisc Knee Procedure Tracking Kit	17097K, 17124K, 17129K, 17136K, 17143K,
107130	Vizadisc Hip Procedure Tracking Kit	17103H

Dear Customer,

Stryker has initiated a lot-specific recall for the Vizadisc Knee Procedure Tracking Kit and Vizadisc Hip Procedure Tracking Kit. The intent of this letter is to list known hazards and harms potentially associated with the aforementioned product and list any risk mitigation factors.

Issue

Stryker has discovered that specific lots of the Vizadisc Knee Procedure Tracking Kit and Vizadisc Hip Procedure Tracking Kit have the potential to be damaged on the Vizadisc reflective material causing an inability to be detected by the camera. The Vizadisc is a small, circular disposable used to provide a reflective surface recognizable to the Mako system camera. The Vizadisc attaches to the arrays to provide constant location and orientation information to the Mako system while the probes can be used to register bone surfaces and instruments throughout a surgical case.

Potential Hazards

In the event of damage to the material on the Vizadisc Tracking Kit, the following potential hazard may occur:

- Inability of the Vizadisc to be detected by the Mako system

Potential Harms

The aforementioned hazards may result in the following potential harm:

- Complications associated with extended surgery time of 20 minutes while retrieving a secondary Vizadisc Tracking Kit

Risk Mitigation

1. Risk may be mitigated by performing a visual inspection of the discs during pre-surgery setup as the defect can be recognized due to apparent discoloration. If the defect was identified the disc could be replaced prior to surgery.
2. In the event that a Vizadisc is damaged, risk may be mitigated by testing the Vizadiscs by attaching to the probes and arrays during pre-surgery setup, as per Stryker's recommendations in "Surgical Technique Guide." This provides an opportunity for the user to show each instrument to the camera after assembly to confirm that all discs are detectable.

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 31 August 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

RA2018-1802553: Acknowledgement Form

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I acknowledge receipt of the Field Safety Notice for RA2018-1802553 and can confirm that:

We have not located any of these devices in our inventory: <i>(please delete if not applicable)</i>				
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