

Update

URGENT: Field Safety Notice

FSCA identifier: RA2018-1802553 **UPDATE**

Type of Action: Field Safety Corrective Action: Recall

Product Affected:

Catalog no	Description	Lot no
107120	Vizadisc Knee Procedure Tracking Kit	Already notified: 17097K, 17124K, 17129K, 17136K, 17143K,
		New batches Affected: 17007K, 17013K, 17024K, 17035K, 17054K
107130	Vizadisc Hip Procedure Tracking Kit	Already notified: 17103H,
		New batches Affected: 16354H

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

December XX, 2018

Dear Customer,

Stryker has initiated **an expansion** to the voluntary, lot-specific recall for the Vizadisc Knee Procedure Tracking Kit and Vizadisc Hip Procedure Tracking Kit (RA2018-1802553), originally initiated in July 2018. 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.

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 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.

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 no 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 the 31 of March of 2019 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,



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FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

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December XX, 2018

I have received the updated medical device removal notification from Stryker initiated on December XX, 2018 stating that it has initiated an expansion to the voluntary, lot-specific recall for the Mako Vizadisc Knee Procedure Tracking Kit and Mako Vizadisc Hip Procedure Tracking Kit (PN: 107120, 107130) described above.

Hospital/Branch/Agency Representative
(Signature)

Date /Stamp

Hospital/Branch/Agency Representative
(Print)

Name of Hospital/Branch/Agency

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:

Fax:

Email: