URGENT FIELD SAFETY NOTIFICATION

Type of action:	Recall (RA2018-1657945)
Reference:	**160430**
Description:	Mako Onlay Insert Extractor-
Lot numbers:	19020414, 19090616, 19090915, 19100616, 19100915, 19110317, 19110616, 19110915, 19130315, 19140315, 19451016, 19471016, 19490515, 19500515, 19510515, 19520515, 19530515, 26051212, 26070512, 26080913, 26130512, 26170513, 26201111, 26290412, 26440912, 19461016, 26340312, 19120317
Legal Manufacturer:	MAKO Surgical Corp. 2555 Davie Road. Fort Lauderdale. 33317

January 26, 2018

Dear Customer,

Stryker has initiated a voluntary, lot-specific, recall for the Mako Onlay Insert Extractor (160430). 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 received a report that a hinge pin disassociated from the Mako Onlay Insert Extractor (160430). In the reported case, the disassociated hinge pin was discovered on the back table prior to being used during surgery and a backup device was available and used to complete the procedure.

Potential Hazards

In the event of a disassociated hinge pin, the following potential hazards may occur:

- Disassociated Hinge Pin.
- Foreign Object (i.e. Hinge Pin left in wound)
- Excessive Metal Wear Debris

Potential Harms

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

- Complications associated with extended surgery time of > 30 min.
- Poor implant performance
- Adverse local tissue reaction and/or Inflammatory Response
- Pain and/or poor soft tissue function (i.e., muscle, tendon), potentially necessitating revision surgery

Risk Mitigation

1. Optional Instrument: Because the Mako Onlay Insert Extractor is an optional instrument, risk can be mitigated by not using the extractor. A similar instrument may be utilized to lift up the removal holes at the front of the trial insert for extraction.

2. Functional Inspection: In the event the Mako Onlay Insert Extractor is utilized, risk may be mitigated by performing an inspection of the instrument prior to use, as per Stryker's recommendations in "Instructions for: Cleaning, Sterilization, Inspection and Maintenance of Reusable Medical Devices."

3. Lavage Steps: As part of the routine surgical lavage steps, there exists the potential that these steps could remove an unnoticed Hinge Pin left in the surgical wound. This would mitigate the hazards of foreign object and excessive metal wear debris in the surgical wound.

Actions Needed

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

8. Return the product to Stryker.

We request that you respond to this notice within XX calendar days from the date of receipt. The target date for completion of this action is XXXXXXXX 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: XXXXXXX
Position: XXXXXXX
Telephone: XXXXXXX
Fax: XXXXXXX
E-mail: XXXXXXX

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.

Sincerely,

URGENT FIELD SAFETY NOTIFICATION
ACNOWLEDGEMENT FORM

January 26, 2018

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

I have received the urgent field safety notification from Stryker stating that it has initiated a recall for the Mako Onlay Insert Extractor described above.

We have not located any of these devices in our inventory:				
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 organizations:				
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		Stamp:	
Contact Signature		E-mail Address	
Contact Phone No.		Date	

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