

Urgent Field Safety Notice – RA2163119

MESA Rail Cutters

FSCA identifier: 2163119
Type of Action: Field Safety Corrective Action: Recall
Legal Manufacturer: K2M, Inc., now a part of Stryker
Product Affected:

Product Name	Catalog Number	Lot Numbers
MESA Rail Cutter	801-90132	JAKB, HRXB

Date: August XX, 2019

Initiating Event

Stryker has received reports of cutting blades on two lots of MESA Rail Cutters deforming and/or breaking during cutting (Refer to Figure 1). It was subsequently confirmed the blades on these lots of Rail Cutters do not meet the Stryker specified material hardness requirements.

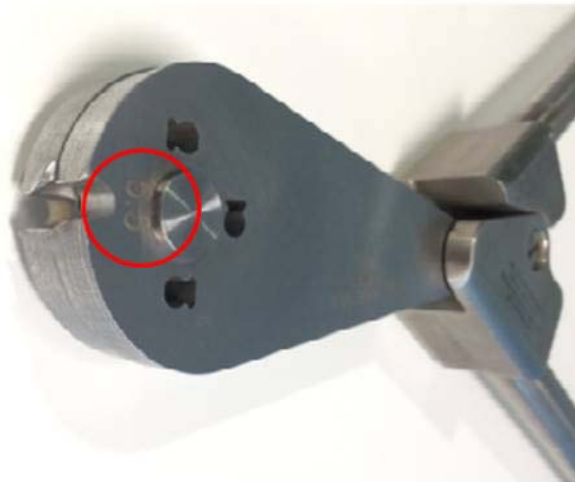


Figure 1. MESA Rail Cutter with damaged blade (see circled area)

Potential Hazard

The potential hazard is the cutting blades on the Rail Cutter fail to cut the rail. However, the Rail Cutter has alternate cutting locations that can be used to cut the rails. (Refer to Figure 2). Therefore, there are no harms identified. Additionally, no adverse events have been reported for this issue.

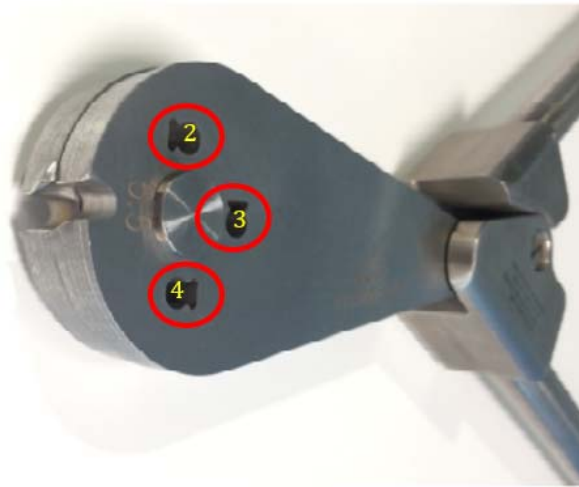


Figure 2: MESA Rail Cutter alternate cutting locations 2 – 4.

Product Description

Telescoping Mesa Rail Cutter (Refer to Figure 3) – The Rail Cutter has a pair of cutting blades with rail shaped slots used to cut the rail to length and a slotted end to cut rails or rods depending on surgeon preference. The Rail Cutter has telescoping handles in order to provide more leverage to cut the rail if necessary.



Figure 3. MESA Rail Cutter

Actions Needed:

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 organizations.
 - 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 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 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.
 - a) 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.

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:
Telephone:
E-mail:

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,



URGENT FIELD SAFETY NOTICE: RA2163119
Acknowledgment form

FSCA identifier: 2163119
Type of Action: Field Safety Corrective Action: Recall
Legal Manufacturer: K2M, Inc., now a part of Stryker
Product Affected:

Product Name	Catalog Number	Lot Numbers
MESA Rail Cutter	801-90132	JAKB, HRXB

I acknowledge receipt of the Field Safety Notice for RA2163119 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:			
Catalog number	Description	Lot number	Qty
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			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

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