Urgent Medical Device Recall

MESA Rail Cutters

Date: August 15th, 2019

Attention: Direct Distributor or Agency Principal and Quality / Inventory Contacts

Affected Product: K2M, Inc., now a part of Stryker, is initiating a voluntary recall for the following affected products:

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

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.

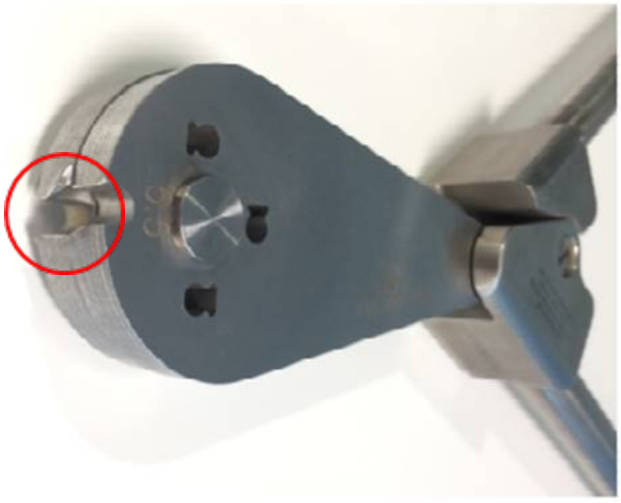

Figure 1. MESA Rail Cutter with damaged blade (see circled area)

Spine
2 Pearl Ct., Allendale, NJ 07470 USA | P +1 201 749 8000 | F +1 201 831 3000 | stryker.com

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.

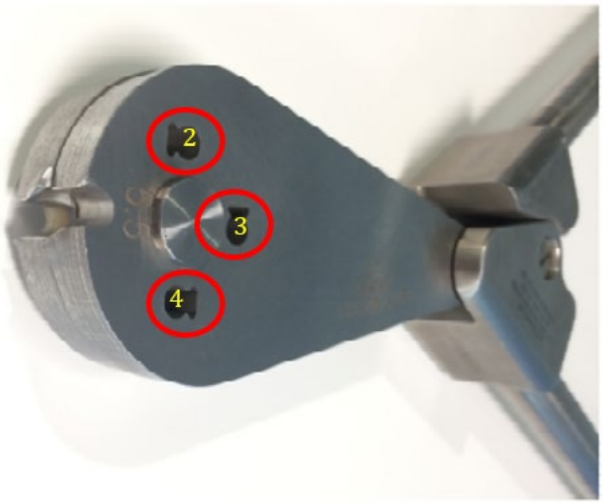

Figure 2: MESA Rail Cutter alternate cutting locations 2 – 4.

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

Direct Distributors and Agency Principals are responsible for the following:

1. Examine **your inventory and identify** any MESA Rail Cutters with the catalog number and lot numbers referenced above.
2. Use the Product Accountability Form to reconcile any affected product.
   - **Complete the Product Accountability Form even if there is no affected product identified.**
3. Within **5 days of receipt of this notice,** the direct distributor/agency personnel responsible for executing the recall must send completed and signed **Product Accountability Form** to Stryker Spine via email: Spine-RegulatoryActions@Stryker.com
4. **All forms must be filled out completely and all information must be reconciled accurately.**
5. Within **5 days of receipt of this notice, mail any affected product** to:

   K2M, Inc.
   610 Hope Parkway SE
   Leesburg, VA 20175

   a. A red return box will be sent to your specified address.
   b. Please place the returning part in the red box and return the red box inside of the Fed Ex box provided. Pack only the product listed above.
   c. Use the FedEx label that has been provided to you by Reverse Logistics.
   d. Appropriately seal the box.

Please share this notification with others in your organization as appropriate.

If you have any questions, please contact Matt Kelleher or Christa Joisil from the Regulatory Compliance Team: Spine-RegulatoryActions@Stryker.com or 201.749.8090.

Sincerely,

[redacted]

Meriam Gabera
Senior Manager, Regulatory Affairs & Quality Assurance
Stryker Spine
P 201 749 8043
[redacted]