



URGENT FIELD SAFETY NOTICE

EVEREST SPINAL SYSTEM FSCA-RCL-019 CORRECTIVE ACTION

Date: December 1, 2017

Attention: FIELD SAFETY CORRECTIVE ACTION NOTIFICATION

Details on affected devices:

<i>Brand Name</i>	<i>Catalog#</i>	<i>Device Description</i>	<i>Type of Device</i>	<i>Lot#</i>
Everest Spinal System	5101-90254	Cannulated Reamer, Everest MI Spinal System	Class I Reusable Instrument	FXTW

Description of the problem:

K2M, Inc. has identified a potential for breakage in EVEREST MI Reamer due to a manufacturing method that did not meet K2M specification. As a precautionary measure, a field safety corrective action has been initiated since the device does not meet the established product specifications. The field safety corrective action plan includes notifying all distributors/user facilities possessing the subject device to return the subject device and providing the distributors/user facilities replacement parts. The subject device will be disposed upon return at K2M. The potential hazard associated with the continued use of the subject device is that the subject device could break/dissociate during its usage. The associated risk to the patient or the user in the event the subject device breaks during its use is momentary delay in the surgery, where the surgical delay would be due to the retrieval of the disassociated/broken parts. The delay is defined as 'momentary' because the shape and size of the subject device allows easy retrieval of the broken/disassociated parts. Thus, the hazard associated with the continued use of the subject device is deemed "Negligible" which we define as Limited (transient, minor impairment) or no adverse health consequences.

Advise on action to be taken by the user:

- Please review this letter with your Medical Director (if applicable)
- **Locate and segregate Subject Product:** Please immediately remove the subject product from the inventory (regardless of its location) and segregate the product in a secure location for return.
- **Package and Ship the Returned Goods:** Package the subject product in the same box in which the replacement device was received. Send the box using FedEx label provided to:

**K2M Inc.
600 Hope Parkway SE,
Leesburg, VA 20175**

Please retain this letter, and forward this letter to those who may have received the subject device.



Transmission of this Field Safety Notice:

Notification letters have been issued to the respective distributors/user facilities possessing the subject device. Daily follow-ups regarding the status of the product returning will be conducted.

Contact Reference Person:

Ed Crown
K2M Inc.
600 Hope Parkway SE, Leesburg, VA 20175
Phone: (571) 919-2071 Fax (866) 466-6109
Email: ecrown@k2m.com

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Thank you for your support. Please contact me at (+1) 571-919-2000 if you have any questions regarding this effort. We regret any inconvenience that this action may cause and appreciate your understanding as we take action to ensure continued patient and customer satisfaction.

A handwritten signature in black ink, appearing to read 'Ed Crown', written in a cursive style.

Sincerely,
Ed Crown
Senior Director, Quality
ecrown@k2m.com

It is important that your organization takes the actions detailed in the UFSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to this UFSN. Your organizations reply is evidence which, K2M, and subsequently the CA, needs to monitor the progress of the UFSN. Without your reply K2M cannot verify the completeness of the UFSN and the CA may need to issue a Medical Device Alert.



FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed K2M Urgent Field Safety Notice RCL-019 dated December, 2017. Please read the question and indicate the appropriate answer. Return this completed form to K2M at the contact details provided at the bottom of this page.

I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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Name of the person completing questionnaire:	
Title:	
Institution:	RMA(if applicable):
Street:	
City:	Post Code:
Phone:	Email:
Signed:	Date:

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Contact Details:
Fax: (866) 466 6109
Email: ecrown@k2m.com