URGENT FIELD SAFETY NOTICE

CASCADIA INTERBODY SYSTEM
FSCA-RCL-021
CORRECTIVE ACTION

Date: April 20, 2018

Attention: *FIELD SAFETY CORRECTIVE ACTION NOTIFICATION*

Description of the problem:
K2M, Inc. has identified a potential for CASCADIA sterile products that are currently in distribution within the European Union market to be missing CE mark on their labels. In order to comply with EU regulatory requirements, K2M has initiated a field safety corrective action for these products. The field safety corrective action plan includes notifying all distributors/user facilities possessing the subject devices to return the subject devices and providing replacement parts to the distributors/user facilities. The subject devices will be relabeled upon return at K2M. The CE mark does not present a direct risk to patient health.

Details on affected devices:

Affected Market	***Germany***		
Catalog #	***Lot #***	***Brand Name/Device Description***	***QTY Recalled***
6101-2852412NL6-G2	FKTD-28193	Cascadia AN Interbody, 8.5x24x12 mm, 6°	1
6101-2225512LL12-G2 (HL6128-7)	FWAP-29393	Cascadia Lateral Interbody, 22x55x12 mm, 12°	2
6101-2225014LL15-G2 (HL6128-7)	FMNA-28524	Cascadia Lateral Interbody, 22x50x14 mm, 15°	2
6101-2131612CL7-G2	FWXD-29938	Cascadia Cervical Interbody, 13x16x12 mm, 7°	2
6101-2131611CL7-G2	FWWL-29392	Cascadia Cervical Interbody, 13x16x11 mm, 7°	1
6101-2131610CL7-G2	GBPD-30105	Cascadia Cervical Interbody, 13x16x10 mm, 7°	2
6101-2131609CL7-G2	GBPH-30003	Cascadia Cervical Interbody, 13x16x9 mm, 7°	2
6101-2131607CL7-G2	FYBX-29938	Cascadia Cervical Interbody, 13x16x7 mm, 7°	1
6101-2131606CL7-G2	FVXH-30200	Cascadia Cervical Interbody, 13x16x6 mm, 7°	1

6101-2131606CL7-G2	FNEW-28652	Cascadia Cervical Interbody, 13x16x6 mm, 7°	1
6101-2131605CL7-G2	FVXG-29938	Cascadia Cervical Interbody, 13x16x5 mm, 7°	2
6101-2121412CL7-G2	FWWN-29761	Cascadia Cervical Interbody, 12x14x12 mm, 7°	1
6101-2121412CL7-G2	FTJP-29938	Cascadia Cervical Interbody, 12x14x12 mm, 7°	1
6101-2121411CL7-G2	FWWP-29638	Cascadia Cervical Interbody, 12x14x11 mm, 7°	1
6101-2121411CL7-G2	FMPW-28653	Cascadia Cervical Interbody, 12x14x11 mm, 7°	1
6101-2121410CL7-G2	GBPE-29938	Cascadia Cervical Interbody, 12x14x10 mm, 7°	1
6101-2121410CL7-G2	FWXB-29470	Cascadia Cervical Interbody, 12x14x10 mm, 7°	1
6101-2121409CL7-G2	FWWW-29761	Cascadia Cervical Interbody, 12x14x9 mm, 7°	1
6101-2121408CL7-G2	GBPN-30004	Cascadia Cervical Interbody, 12x14x8 mm, 7°	1
6101-2121407CL7-G2	FVXC-30107	Cascadia Cervical Interbody, 12x14x7 mm, 7°	2
6101-2121406CL7-G2	FWWV-29637	Cascadia Cervical Interbody, 12x14x6 mm, 7°	2
6101-2121405CL7-G2	GBPG-30004	Cascadia Cervical Interbody, 12x14x5 mm, 7°	1
6101-2121405CL7-G2	FWWX-29470	Cascadia Cervical Interbody, 12x14x5 mm, 7°	1
6101-2131612CL7-G2	GDKL-30503	Cascadia Cervical Interbody, 13x16x12 mm, 7°	1
6101-2131612CL7-G2	FWWM-29638	Cascadia Cervical Interbody, 13x16x12 mm, 7°	1
6101-2131611CL7-G2	FWWL-29392	Cascadia Cervical Interbody, 13x16x11 mm, 7°	2
6101-2131610CL7-G2	GBPD-30105	Cascadia Cervical Interbody, 13x16x10 mm, 7°	2
6101-2131609CL7-G2	FVXN-29938	Cascadia Cervical Interbody, 13x16x9 mm, 7°	2
6101-2131608CL7-G2	FVXM-30003	Cascadia Cervical Interbody, 13x16x8 mm, 7°	1
6101-2131607CL7-G2	FNCV-28652	Cascadia Cervical Interbody, 13x16x7 mm, 7°	2
6101-2131606CL7-G2	FMRC-28652	Cascadia Cervical Interbody, 13x16x6 mm, 7°	2
6101-2131605CL7-G2	FWWY-29637	Cascadia Cervical Interbody, 13x16x5 mm, 7°	2
6101-	FWWN-29761	Cascadia Cervical Interbody, 12x14x12	2

2121412CL7-G2		mm, 7°	
6101-2121411CL7-G2	FWWP-29638	Cascadia Cervical Interbody, 12x14x11 mm, 7°	1
6101-2121411CL7-G2	FMPW-28653	Cascadia Cervical Interbody, 12x14x11 mm, 7°	1
6101-2121410CL7-G2	FWWK-29392	Cascadia Cervical Interbody, 12x14x10 mm, 7°	2
6101-2121407CL7-G2	FRAF-29092	Cascadia Cervical Interbody, 12x14x7 mm, 7°	1
6101-2121406CL7-G2	GBPM-30003	Cascadia Cervical Interbody, 12x14x6 mm, 7°	1
6101-2121405CL7-G2	FWWH-29392	Cascadia Cervical Interbody, 12x14x5 mm, 7°	1

Advise on action to be taken by the user:

1. Please review this letter with your Medical Director (if applicable)
2. **Locate and Segregate Recalled Product**
    - Please immediately remove the recalled products from your inventory (regardless of its location) and segregate the products in a secure location for return. The specific catalog numbers, lot numbers and quantities are listed in the table above.
3. **Complete Documentation**
    - Please complete and submit the attached FIELD CORRECTION EFFECTIVENESS CHECK to RCL021@k2m.com. Your organizations reply is evidence which, K2M, and subsequently the Competent Authority, needs to monitor the progress of the Urgent Field Safety Notice.
    - If you will not be returning all requested product because it has been consumed or is no longer in your possession, please indicate in the attached Tracking/Verification Form, sign and return to RCL021@k2m.com.

4. **Package and Ship the Returned Goods**

- If you received a replacement, you are encouraged to use the same box in which you received the replacement for the return.
- Do not return in the same box as other products.
- Use the return label that has been provided to you by email.
- Appropriately seal the box.
- Send the product on or before **April 27, 2018** to:

K2M UK Ltd.
Ground Floor
1 Roundwood Avenue
Stockley Park, Uxbridge UB11 1FG, UK

Transmission of this Field Safety Notice:
Notification letters have been issued to the respective distributors/user facilities possessing the subject device. Periodic 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 provided to 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.

FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed K2M Urgent Field Safety Notice RCL-021 dated April, 2018. 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 ☐	No ☐

Name of the person completing questionnaire:	
Title:	
Institution:	IMA (if applicable):
Street:	
City:	Post Code:
Phone:	Email:
Signed:	Date:

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

Contact Details:
Fax: (866) 466 6109
Email: RCL021@k2m.com

Tracking/Verification Form

PLEASE FILL OUT AND RETURN TO RCL021@k2m.com

Account Name					
Catalog Number	*Lot Number*	*Description*	*QTY Requested*	*QTY Used as of 2018-04-20*	*Additional QTY to be returned*

By signing my name below, I certify that **I no longer have in my possession** the recalled product listed in the table above as used.

Name **Signature** **Date**