



August 20, 2018

URGENT: MEDICAL DEVICE RECALL NOTIFICATION

cc Chairman Medical Board (CMB) and relevant Head of Departments (HoD)

K2M, Inc. has identified a potential for YUKON Polyaxial Screws that are currently in distribution within the US market which could impact the ability of the screw to properly mate with the set screw during final tightening. In order to comply with FDA regulatory requirements, K2M has initiated a Class III recall for these products. Our records indicate that the products listed below have been shipped to the indicated location. Please send all YUKON Polyaxial Screws listed below. If product has already been used/consumed, please indicate in the attached Tracking/Verification Form, sign and return to RCL023@k2m.com.

STEPS FOR PRODUCT RECALL

1. **Locate and Segregate Recalled Product.** A K2M Reverse Logistics Representative will contact you regarding the product to be recalled. Please immediately remove the recalled product from your inventory (regardless of its location) and segregate the product in a secure location for return. The specific catalog numbers, lot numbers and quantities are listed in the table below.
2. **Package and Ship the Returned Goods.** Package the recalled product
 - i. If you received a replacement, you are encouraged to use the same box in which you received the replacement
 - ii. Do not return in the same box as other products
- b. Use the FedEx label that has been provided to you by email
- c. Appropriately seal the box
- d. Send the product **on or before August 8th, 2018** to:

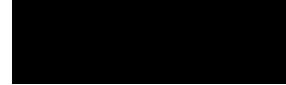
K2M, Inc.
600 Hope Parkway SE
Leesburg, VA 20175
USA

| Agency Name | Transmedic Group | | |
|-------------|------------------|---------------------------------|--------------|
| Catalog # | Lot # | Description | QTY Recalled |
| 7601-03512 | FUVG | Polyaxial Screw Size Ø3.5x12 mm | 154 |
| 7601-03514 | FUVD | Polyaxial Screw Size Ø3.5x14 mm | 34 |
| 7601-03514 | FUVE | Polyaxial Screw Size Ø3.5x14 mm | 22 |
| 7601-03532 | FUWL | Polyaxial Screw Size Ø3.5x32 mm | 55 |
| 7601-03534 | FUWK | Polyaxial Screw Size Ø3.5x34 mm | 56 |
| 7601-04030 | FUWF | Polyaxial Screw Size Ø4.0x30 mm | 46 |
| 7601-05022 | FUWU | Polyaxial Screw Size Ø5.0x22 mm | 58 |
| 7601-05028 | FUWV | Polyaxial Screw Size Ø5.0x28 mm | 46 |
| 7601-05030 | FUWW | Polyaxial Screw Size Ø5.0x30 mm | 27 |



Thank you for your support. Please contact me at **571-919-2000** if (i) you have any questions regarding this effort, (ii) you need assistance locating any of the recalled pieces or (iii) believe that the quantities shown above do not accurately reflect your account's inventory. We regret any inconvenience that this action may cause and appreciate your understanding as we take action to ensure continued patient and customer satisfaction.

Sincerely,



Ed Crown
Senior Director, Quality

