Urgent Medical Device Recall

DENALI Polyaxial Screw – 6.5 x 45 mm

Date: October 21, 2019

Attention: [redacted]

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

Product Name	Catalog Number	Lot Number
DENALI Polyaxial Screw – 6.5 x 45 mm	101-06545	HNNA (limited to 100 units associated with [redacted] shipped from Leesburg on Feb. 22, 2019)

Important Note: Stryker/K2M, Inc. initiated this recall retrospectively. This notification is for documentation purposes only as your organization previously returned all affected product to Stryker/K2M, Inc. in March 2019.

Initiating Event

On February 22, 2019, Stryker/K2M, Inc. Leesburg shipped 100 DENALI screws to [redacted]. This shipment contained packages with DENALI labeling (101-06545 Lot: HNNA), but included MESA screws (801-05535 Lot: HNKA).

Potential Hazard

The potential hazard is the product has an incorrect label. No adverse events have been reported for this issue. All product was previously returned to Stryker/K2M, Inc. in March 2019.

Product Description

DENALI is a set screw-based thoracolumbar pedicle screw system that is compatible with a 5.5mm diameter connecting rod. The screw is available with a polyaxial or monoaxial head that locks in position when a rod is placed within the saddle and a set screw is tightened into place. The screws are available in a range of diameters and lengths.

Figure 1. DENALI Polyaxial Screw – 6.5 x 45 mm

Spine
600 Hope Pkwy SE, Leesburg, VA 20175| P +1 201 749 8000 | F +1 201 831 3000 | stryker.com

Actions Needed

No additional action for the 100 units of product is required as your organization previously returned all affected product to Stryker/K2M Inc. However, to assist with Stryker/K2M Inc.'s documentation of this matter, please submit a signed **Product Accountability Form** (attached) to Stryker Spine/K2M, Inc. via email: Spine-RegulatoryActions@Stryker.com.

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,

Meriam Gabera
Senior Manager, Regulatory Affairs & Quality Assurance
Stryker Spine
[redacted]