Cc: Chairman Medical Board and relevant Head of Department

URGENT MEDICAL DEVICE RECALL NOTIFICATION

PRODUCT: Stryker® Performance Series® Sagittal Blade

ATTENTION: OR DIRECTOR, RISK MANAGER, MATERIALS MANAGER

Cc: Chairman Medical Board and relevant Head of Department

March 19, 2019

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling one lot of Performance Series Sagittal Blades.

Product Number	Description	GTIN	Affected Lot	Distribution Dates
6125-127-100	Performance Series Sagittal Blade	[redacted]	18247037	Oct 30, 2018 – Nov 5, 2018

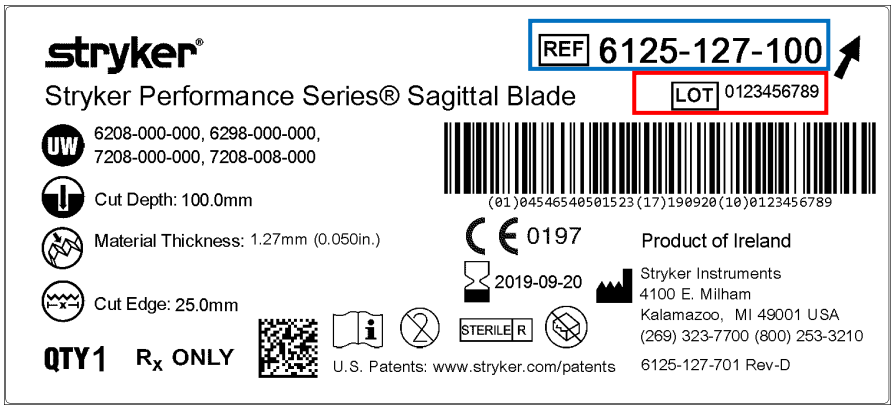
Risk to Health:
Use of a product with a breach in sterility could potentially lead to an infection requiring medical intervention.

Reason for the Voluntary Recall:
During manufacture, packaging materials for a small portion of the lot may not have been properly positioned, resulting in a potential breach in sterility.

Product Description:
Performance Series Sagittal Blades are used in the cutting and shaping of bone and other bone related tissue in various orthopedic procedures. They are intended for use with System 6 Sagittal Saw, Electric System 6 Sagittal Saw, System 7 Sagittal Saw, System 7 Stryker V-Notch Sagittal Saw, System 8 Sagittal Saw.

Location of Product Number (blue) and Lot Number (red) on the label:

Stryker Instruments
4100 E Milham Ave, Kalamazoo, MI 49001 USA | P 269 389 4518| F 866 521 2762



Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification and the Business Reply Form.

2. Immediately check all stock areas and/or operating room storage for affected products. Quarantine and discontinue use of any Performance Series Sagittal Blades from lot 18247037.

3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this Notification and identify how many affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand. Fax the completed BRF to Stryker Instruments at 866-521-2762, or email to kara.spath@stryker.com.

   Note: Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.

4. If you have further distributed this product, please forward copies of this Notification and the BRF to all affected locations, for each location to complete and return. Even if you have distributed all product to another location, please complete a BRF and indicate each location that received product.

5. If the BRF for your facility indicates that recalled product is currently on hand, a FedEx label will be emailed to you and should be used to return recalled product. Upon receipt of the recalled product, replacement product will be shipped to your facility.

We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

Report any serious adverse events or product quality problems to Stryker Instruments: 1-800-253-3210

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to the FDA's MedWatch Adverse Event Reporting program either by fax or phone, or online. Fax: (800) FDA-0178 Phone: (800) FDA-1088
Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm

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