URGENT MEDICAL DEVICE RECALL NOTIFICATION
Sagittal Blade 18.0X.97X90MM

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

August 17, 2016

The purpose of this letter to advise you that Stryker Instruments is voluntarily recalling the Sagittal Blade 18.0X.97X90MM, product number 6118-097-090, lot number 16029017.

Stryker Product Number	Product Description	Lot Number	Dates of Distribution
6118-097-090	Sagittal Blade 18.0X.97X90MM	16029017	March 11, 2016 through July 28, 2016

Reason for Voluntary Recall:

For a small portion of the affected lot, the seal between the top and base rollstock material of the product packaging was not manufactured correctly resulting in a sterile barrier breach.

Risk to Health:

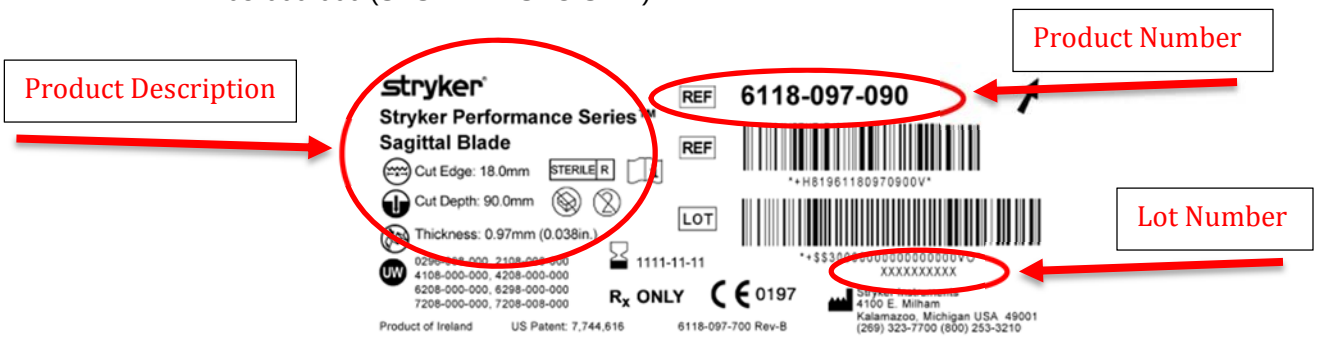
Due to a breach in sterility, there is a potential for a bone or soft tissue infection which may require medical or surgical intervention.

Product Description:

Heavy duty Sagittal Blades are used to cut bone and bone related tissue in a variety of orthopedic procedures. Typical procedures include, total-knee, uni-compartmental knee, hip, shoulder and ankle procedures.

These blades can be used with the following handpieces;

- 4208-000-000 (SYSTEM 5 SAGITTAL SAW)
- 6208-000-000 (SYSTEM 6 SAG SAW)
- 6298-000-000 (ES6 SAGITTAL SAW)
- 7208-000-000 (SYSTEM 7 SAG SAW)



Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification.

2. Check all stock areas and/or operating room storage to determine how many Sagittal Blades from the affected lot (listed above) are at your facility. Quarantine and discontinue use of the recalled Sagittal Blades.

3. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand.
   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 this letter and the attached BRF to all affected locations. Please indicate each location on the BRF.

5. Fax the completed BRF to Stryker Instruments Regulatory Department at 866-521-2762, or scan and email a copy to kellyjo.davis@stryker.com.

6. If the BRF for your facility indicates that recalled product is currently on hand, a FedEx label will be emailed to you. This shipping label should be used to return recalled product.

7. Upon receipt of the recalled product, replacement product will be shipped to your account.

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 online, or by fax or phone.

Online: www.fda.gov/Safety/MedWatch/HowToReport/default.htm
Fax: (800) FDA-0178 Phone: (800) FDA-1088
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.

For questions regarding this recall, please contact Stryker Instruments:

Kelly Jo Davis
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kellyjo.davis@stryker.com