URGENT MEDICAL DEVICE RECALL NOTIFICATION

Stryker Round Fluted Burs (used with Stryker CORE™ System)

ATTN: RISK MANAGER, OR DIRECTOR, MATERIALS MANAGER

June 16, 2016

The purpose of this letter to advise you that Stryker Instruments is voluntarily recalling specific lots of Round Fluted Burs. These burs are used in conjunction with the Stryker CORE™ System.

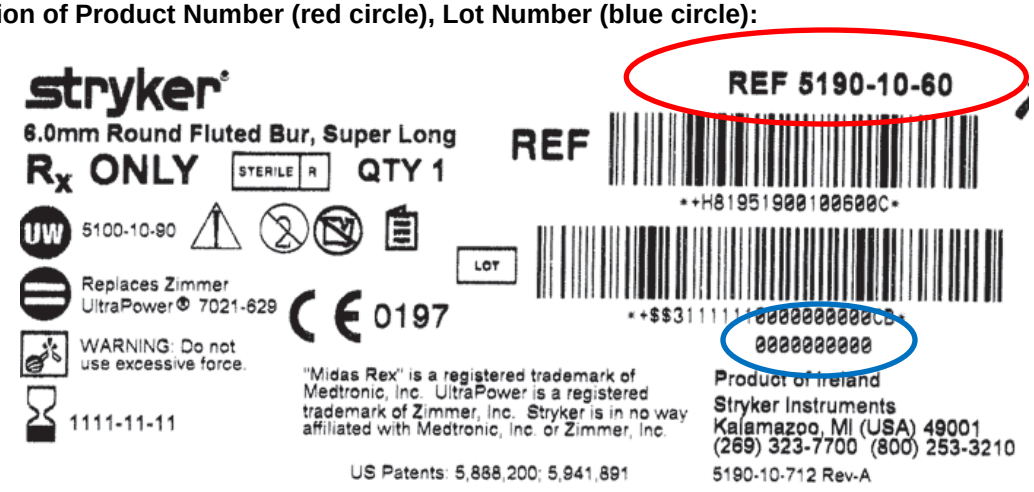
Stryker Product Number	Product Description	Lot Number	Dates of Distribution
5190-010-050 (5190-10-50)	5.0mm Round Fluted Bur, Super Long	15322017	Nov 24, 2015 – Mar 21, 2016
5190-010-060 (5190-10-60)	6.0mm Round Fluted Bur, Super Long	15231017, 16033017, 16066017	Aug 24, 2015 – Mar 21, 2016

Reason for Voluntary Recall:
Tarnishing or corrosion may be present on the recalled burs.

Risk to Health:
Use of a bur with corrosion may lead to a foreign body reaction (inflammation) necessitating surgical intervention.

Product Description:
Round Fluted Burs are single use cutting accessories used for a variety of procedures, including but not limited to Orthopaedic, Neuro, Spine, ENT, Dental and Endoscopic applications. They are intended to be used with the Stryker CORE™ System.

Location of Product Number (red circle), Lot Number (blue circle):



Instruments

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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 affected Round Fluted Burs from the affected lots are at your facility. Quarantine and discontinue use of the recalled Round Fluted Burs.

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 kara.spath@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. Upon receipt of the recalled product, a credit will be issued 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:

Kara Spath
269-389-4518
kara.spath@stryker.com