Class 2 Device Recall 5.0mm Round Fluted Bur, Super Long

Recall Date
July 14, 2016

Recall Status
Open

Recall Number
Z-2204-2016

Recall Event ID
74562

510(K)Number
K143320

Product Classification
Drills, burs, trephines & accessories (simple, powered) - Product Code HBE

Product
5.0mm Round Fluted Bur, Super Long

Code Information
5190-010-050 5.0mm Round Fluted Bur, Super Long , Lot Number: 15322017

Recalling Firm/Manufacturer
Stryker Instruments Div. of Stryker Corporation
4100 E Milham Ave
Portage MI 49002-9704

For Additional Information Contact
Kara Speth
269-389-4518

Manufacturer Reason for Recall
Stryker Instruments initiated a voluntary recall of specific lots of Round Fluted Burs, due to tarnishing or corrosion which may be present on the recalled burs and could result in a foreign body reaction (inflammation) necessitating surgical intervention.

FDA Determined Cause
Under Investigation by firm

Action
Stryker initiated a voluntary recall of the Stryker Round Fluted Burs (used with Stryker CORE® System) on June 16, 2016, via certified mail due to the potential for the devices to have tarnishing or corrosion present. Non-responding accounts will be contacted by phone, email, and/or fax as necessary in an effort to obtain signed Business Reply Forms. Affected product will be removed from the field. Further corrective and preventative actions will be determined through the associated CAPA. The existing label will be defaced, packaging will be opened and products will be destroyed. 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. 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.

Quantity in Commerce
25

Distribution
US Distribution to the states of: CA, IL, SD Foreign: Canada, Netherlands

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=147988

7/25/2016