Class 2 Device Recall 6.0mm Round Fluted Bur, Super Long

See Related Information [22]

Recall Date	July 14, 2016
Recall Status[1]	Open
Recall Number	Z-2205-2016
Recall Event ID	74562[23]
510(K)Number	K143320[24]
Product Classification	Drills, burrs, trephines & accessories (simple, powered)[25] - **Product Code** HBE[26]
Product	6.0mm Round Fluted Bur, Super Long
Code Information	5190-010-060 Lot Numbers 15231017, 16033017, 16066017
Recalling Firm/ Manufacturer	Stryker Instruments Div. of Stryker Corporation 4100 E Milham Ave Portage MI 49002-9704
For Additional Information Contact	Kara Spath 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 [2]	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 dont 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

Recall 25-7