Class 1 Device Recall CareFusion, SnowdenPencer, DiamondFlex

See Related Information [22]

Recall Date	July 22, 2016
Recall Status[1]	Open
Recall Number	Z-2212-2016
Recall Event ID	74465[23]
510(K)Number	K092684[24]
Product Classification	Laparoscope, general & plastic surgery[25] - **Product Code** GCJ[26]
Product	DIAMOND-FLEX CIRCULAR RETRACTOR, ANGLED, 40MM 5MM, Product Code 89-6114, Lot Code(s): 878971; 879366; 879404, and Date Code: C16. Designed to retract or elevate organs and tissue to provide better visualization access.
Code Information	Product Code 89-6114, Lot Code(s): 878971; 879366; 879404, and Date Code: C16
Recalling Firm/ Manufacturer	Carefusion 2200 Inc 75 N Fairway Dr Vernon Hills IL 60061-1845
For Additional Information Contact	Customer Advocacy 800-323-9088
Manufacturer Reason for Recall	BD, formerly CareFusion, has identified a potential risk associated with a weld failure which could result in the wire protruding thru the tip of the instrument when articulated. If this failure were to occur while in use in a procedure it has the potential to damages tissue or organs
FDA Determined Cause [2]	Under Investigation by firm
Action	BD, sent an "URGENT: Medical Device/ Safety Alert/Recall Notification" letter dated 6/30/2016 to its customers. The letter describes the product, problem and actions to be taken. The customers were instructed to return the affected units, along with the enclosed CUSTOMER RESPONSE FORM to: BD formerly CareFusion, 75 North Fairway Drive, Vernon Hills, Illinois, 60061 Attn: Customer Advocacy; to expedite the correction process and acknowledge receipt of the notification. The firm will issue a credit upon receipt of the returned affected product. For questions and support 1-800-323-9088 Prompt 3 or email: GMB-US-Complaint-Intake@carefusion.com.
Quantity in Commerce	10
Distribution	Worldwide Distribution - US, including the states of WA and MD; and, the country of Japan.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = GCJ and Original Applicant = CARDINAL HEALTH, INC.[29]