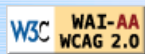


[Home](#)[About Us](#)[What's New](#)[Medical Device Administrative Control System](#)[Search Database](#)[Safety Alerts and Communications](#)[Report Adverse Incidents](#)[Events](#)[Information and Publication](#)[Frequently Asked Questions](#)[Press Release](#)[Download Forms](#)[Useful Sites](#)

Medical Device Control Office

Safety Alerts and Communications

[Home](#) >> [Safety Alerts and Communications](#) >> [Important Safety Alerts](#)

Medical Device Safety Alert: Boston Scientific Imager II Angiographic Catheter

Medical device manufacturer, Boston Scientific, has issued a medical device safety alert concerning its Imager II Angiographic Catheter. The details of the affected device are as follows:-

- Material Number (UPN): M001316581 (5-pack outer package UPN); M001316580 (single unit, inner package UPN);
- Lot/Batch number: 00116127;
- Expiration Date: September 30, 2018]

The manufacturer is initiating a voluntary removal of a single lot of Imager II Angiographic Catheters due to packaging mislabeling. After receiving one complaint from the field, the manufacturer determined that one lot of product was labeled as Imager II Contra 2 curve catheters, when in fact it contained Contra curve catheters. The curve discrepancy is easily detected by users and the device can be readily exchanged resulting in an insignificant prolongation in procedure. There have been no reports of patient injury.

According to the local supplier, the affected products are not distributed in Hong Kong.

If you are in possession of the affected products, please contact your supplier for necessary actions.

Posted on 21 December 2016

[Previous](#)[Back to Top](#)