Medical Device Safety Alert: Boston Scientific Express LD Biliary Stent

Medical device manufacturer, Boston Scientific, has issued a medical device safety alert concerning its Express LD Biliary Stent. The details of the affected device are as follows:-

- Material Number (UPN): A) H74938046520750; B) H74938046530750; C) H74938046540750; D) H74938046560750
- Batch: A) 18032682, 19472345, 19544802, 19808367, 19394085; B) 18032680, 18068984, 17922271; C) 19200184; D) 19321955
- Batch Expiration Date Range: 23 April 2018 to 6 October 2019

The manufacturer is implementing this Medical Device Correction on certain lots of the Express LD Biliary Stent due to incorrect electronic directions for use (e-DFU), impacting Canada only. The e-DFU card included with these products refers to the United States e-DFU on the Boston Scientific e-labeling website, which currently contains indications that are not approved by Health Canada. No adverse health consequence is reasonably expected to occur and no complaints have been received to date.

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 22 December 2016

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