Medtronic

URGENT FIELD SAFETY NOTICE
CoreValve EnVeo R Loading System
Model: LS-EnVeoR-23 Lot: 0007332506
Recall

Medtronic reference: FA638

December 2014

Dear Risk Manager:

Medtronic is initiating an Urgent Medical Device Recall for 62 distributed EnVeo R Loading systems (lot number 0007332506) used to load the Evolut R valve on its delivery system. This letter is subsequent to the verbal notification your facility may have received from a Medtronic Representative beginning December 4, 2014. This lot of product is incorrectly labeled as 23mm product on the box and pouch, but actually contains the size 26/29 mm loading system which is not approved for market release. This situation is limited to this single lot of loading systems which Medtronic has recalled. This recall does NOT impact the CoreValve Transcatheter Aortic Valve Implant (TAVI) System.

The loading system is used to load the valve onto the delivery system and does not impact the patient; therefore, the situation presents no additional risk of patient harm or injury. The size of the loading system is documented on the unit itself and is easily identifiable prior to using the product. Through December 15, 2014, Medtronic has received 5 field reports associated with the incorrect loading system, with no adverse patient events reported.

Our records indicate that your facility has received one or more of the affected units. In response to the prior verbal notification, you may have already segregated the affected units. At this time we are requesting that the units be returned to Medtronic. Please review this notification in its entirety, and take the following actions:

- Immediately segregate and remove all affected products that remain in your inventory.
- Return all affected inventory to Medtronic. Your sales representative will assist you with this return as applicable. Returns will be credited.
- Replacement product may be ordered per current ordering processes.

If affected product has been used, no action is necessary. Since there is no patient impact as a result of this situation, no patient management recommendations are necessary.

Please share this notification with others in your organization as appropriate. If product within scope of this recall has been forwarded to another facility, please notify the facility of the issue and assist with the return of affected product.

Medtronic has notified the Competent Authority of your country of this action.

We appreciate your cooperation with this matter and apologize for the inconvenience that it may cause. If you have any questions, please contact your Medtronic sales representative.

Sincerely,