Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

Urgent Field Safety Notice

EnVeo™ R Loading System

Model Numbers: LS-EnVeoR-23 and LS-EnVeoR-2629

Recall

July 2015

Medtronic reference: FA659

Dear Risk Manager, Health Care Professional:

Medtronic is initiating a voluntary product recall of EnVeo™ R Loading Systems for specific lot numbers (see enclosure) of model numbers listed above due to particulate being observed in a small number of cases. Through 6 July 2015, Medtronic has received eight (8) reports related to this issue out of 7347 potentially affected units. Two (2) were reported as particulate being observed in packaged kits and six (6) were reported as particulate being observed in the loading bath during valve loading. To date, **there have been no reports of any adverse patient effects with this issue.** This issue does not affect other Medtronic devices or other components of the Evolut® R TAV system.

Presence of particulate in the EnVeo R Loading System has the potential to be transferred to the Transcatheter Aortic Valve (TAV) and released into the patient's vasculature after deploying the TAV. If this were to occur, potential harms may include embolism into the bloodstream. While Medtronic has received only 8 reports of particulate identified from the loading system, with no reports of adverse patient effects, bench testing has demonstrated a higher prevalence of particulate and the potential for its transfer to the TAV.

Our records show that your facility has received one or more of these potentially affected devices.

As such, Medtronic requests that you:

- Immediately quarantine unused potentially affected product from your inventory.
- Return all potentially affected product in your inventory to Medtronic. Your Medtronic Representative will assist you with returning affected devices and ordering replacement devices as needed.

Medtronic is not making any special patient management recommendations; patients should continue to be managed in accordance with your standard patient management protocol.

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

Please share this notification with others in your organization as appropriate. If any EnVeo R Loading Systems within scope of this action have been sent to another facility, please notify that facility of this issue and facilitate the retrieval of the devices.

We appreciate your cooperation and apologize for the inconvenience that this issue may cause. Please be assured that patient safety and product quality remain our primary concern.

Please contact your Medtronic Sales Representative directly for any questions that you may have or via Customer Services Tel no 353 1 511 1400.

Sincerely,

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Dr. Thomas Vassiliades, M.D.
Vice President, Medical Affairs
Medtronic Structural Heart

Keith Taverner
Regulatory Affairs Manager UK & Ireland

Enclosure:

EnVeo R Loading System Lot Numbers affected by this Urgent Medical Device Recall dated July, 2015:

0007266413	0007408862	0007456298	0007495694	0007530973	0007579948
0007332504	0007408865	0007462901	0007495696	0007537892	0007579951
0007332506	0007408867	0007462903	0007508883	0007537894	0007592664
0007332508	0007408869	0007462905	0007508885	0007569474	0007592666
0007332510	0007428258	0007476215	0007508891	0007569477	0007592669
0007343321	0007428260	0007476217	0007515698	0007569482	0007592672
0007343324	0007428263	0007476219	0007515700	0007573778	0007598984
0007343327	0007435169	0007482219	0007515703	0007573785	
0007350825	0007439358	0007482222	0007522598	0007573788	
0007350837	0007439360	0007482226	0007522600	0007573791	
0007393098	0007439362	0007492356	0007522603	0007579940	
0007393101	0007456292	0007495691	0007530963	0007579944	