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Urgent Field Safety Notice

Medtronic EnVeo™ R Delivery Catheter System

Model number: ENVEOR-L

August 2016

Medtronic reference: FA729

Dear Physician or Healthcare Professional:

This notification is to provide you with important information regarding the potential for vascular trauma with the use of the Medtronic EnVeo™ R Delivery Catheter System (DCS). While the reports of vascular trauma received by Medtronic have been infrequent (0.136%; 39 events)[1], they have included serious outcomes, including patient death (0.078%; 19 events)[2].

Medtronic's observed rate of 0.136% for vascular trauma is lower than the Transcatheter Valve Therapy (TVT) registry reports in the Journal of the American College of Cardiology (Holmes, et al)[3], which highlighted annular dissection and aortic disruption rates of 0.2% and 0.4% respectively. However, due to the potential severity of these types of events Medtronic conducted a thorough investigation and identified the following recommendations to reduce the rate of vascular trauma events.

1) **Patient Anatomy Considerations:** Physicians should consider that complex anatomical configurations, including combinations of two or more of the following features increase the risk of vascular trauma.
    i) The plane of the aortic annulus (extent of the aortic arch curvature or horizontal heart).
    ii) Combined anterior-posterior and lateral thoracic and abdominal aortic tortuosity.
    iii) Tight curvature of the aortic arch (severe bends).
    iv) Presence of an aneurysmal ascending aorta
    v) Significant calcification in the aortic arch (consider the level, orientation, and size).

2) **Procedural Use:** During advancement of the delivery system, magnify images sufficiently to enable visualization of the capsule tip relative to the patient's vasculature. If the delivery system tip is observed to bend in a different direction relative to the delivery system capsule, do not force passage. Instead, retract the delivery system into a straight portion of the descending aorta, re-orient it by rotating the delivery system 90 degrees, and carefully re-initiate passage.

3) **Procedural Use:** If significant resistance is encountered during advancement of the delivery system, do not force passage. Use increased fluoroscopic magnification to

assess the vasculature. If no damage is identified, retract the delivery system into a straight portion of the descending aorta and consider the following actions:

a) Re-orient the delivery system and carefully re-initiate passage.
b) Consider use of a stiffer guide wire (e.g. Lunderquist).
c) Consider using an alternative commercially available device.
d) Consider a non-transfemoral alternate access route.

[1]Rate based on units sold worldwide.
[2]Rate based on 19 reported deaths out of total units sold worldwide.
[3]Holmes, D. R., Jr., et al. (2015). "Clinical outcomes at 1 year following transcatheter aortic valve replacement." JAMA 313(10): 1019-1028.

The Evolut R System Instructions for Use (IFU) will also be updated appropriately consistent with this communication.

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

We appreciate your review of this notification. If you have any questions regarding this notification, please contact your Medtronic Representative Directly or via Tel No: +353 1 5111 400

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland.