



## Urgent Field Safety Notice

### Medtronic 23mm Engager™ Transcatheter Aortic Bioprosthesis

#### Model: ME-TA2-B23

#### Patient Management Recommendations and Recall

July 2015

Medtronic reference: FA657

Dear Customer,

Medtronic is initiating a voluntary Urgent Medical Device Recall regarding the 23mm Engager™ Bioprosthesis. A review of the 2-year follow-up data of Engager European Pivotal Trial has shown that 16 of 32 subjects implanted with a 23mm device have a mean gradient of  $\geq 20$  mmHg at some point after the implant (average mean gradient at 2-year follow up:  $22.0 \pm 7.5$  mmHg). Gradient is a measure of the resistance to flow through the valve. A mean gradient of 20-40 mmHg is associated with mild stenosis (narrowing of the valve) per the Valve Academic Research Consortium (VARC) -2 guideline.<sup>1</sup> No interventions, balloon valvuloplasty, or surgical replacement were performed related to the elevated gradient on the 16 study patients.

As a result of these data, Medtronic has made the decision to voluntarily discontinue sales and distribution of the 23mm Bioprosthesis permanently. In addition, we are requesting any unused valves be returned to Medtronic. This recall affects only the 23mm Engager bioprosthesis. For the 26mm Bioprosthesis, the 2-year mean gradient data in the Engager European Pivotal Trial remained stable over time (average mean gradient at 2-year follow up:  $13.6 \pm 4.2$  mmHg). No action is required for the 26mm Engager Bioprosthesis or for the Engager Transcatheter Delivery System.

#### Action Required for Health Care Professionals:

Based on current Medtronic training records, you are identified as an implanting physician or a lead physician associated with a facility using the Engager product. Patient management recommendations are provided below:

- Any 23mm Engager patients who are experiencing recurrent aortic stenosis symptoms (such as shortness of breath) or worsening NYHA functional class should undergo a transthoracic echo to assess valve hemodynamics (transvalvular gradient and effective orifice area calculation).
- Asymptomatic patients do not require any additional tests, however it is recommended they are contacted to confirm they are in fact asymptomatic and there has not been any worsening of their NYHA class. If after contact they are confirmed to be asymptomatic, it is recommended follow-up visits occur as part of routine standard care e.g. physician visit and serial transthoracic echos. Commonly, cardiology follow-ups occur at 30 days, 6 months, 12 months, and then yearly for patients without symptoms. The type and interval of follow-up should be determined on the basis of the initial examination.

For those centers participating in one of the Medtronic-sponsored Engager clinical studies, additional information regarding the implications of this recall on the ongoing studies will be provided to the center's Principal Investigator by means of a separate letter.

#### Action Required for Risk/Inventory Manager:

Medtronic is requesting that you take the following actions:

<sup>1</sup> Kappetein AP, Head S, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *European Heart Journal* 2012; 33: 2403–2418.



1. Immediately identify and quarantine all unused model ME-TA2-B23 product in your inventory.
2. Return the units in your inventory to Medtronic. Your Medtronic sales representative will assist you with the return of the product as necessary.

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

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.

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

Sincerely,

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<sup>1</sup> Kappetein AP, Head S, Genereux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2consensus document. *European Heart Journal* 2012; 33: 2403–2418.