Medtronic

Medtronic Ireland Limited
Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47

Tel: 01 511 1400
Fax: 01 807 7220

www.medtronic.ie

URGENT FIELD SAFETY NOTICE

Abre™ venous self-expanding stent system

Instructions for Use Updates

November 2021

Medtronic Reference: FA1197

Dear Health Care Professional,

Please provide this letter to your physician implanters.

Medtronic is writing to inform you of upcoming updates to the Instructions for Use (IFU) for the Abre™ venous self-expanding stent system. These updates will provide new information to help mitigate the risk of possible stent migration. Through 31 October 2021 there have been four (4) complaints of stent migration (a failure rate of .0157%) resulting in three (3) endovascular stent retrievals and one (1) open surgical stent retrieval. Three (3) stent migrations occurred to the heart and one (1) to the inferior vena cava. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism, and/or need for surgical intervention. Stent migration to the central vasculature can result in permanent impairment or death. There are no reports of any manufacturing related device failures for the complaints referenced above and no product retrieval is necessary or requested.

Medtronic, in consultation with an Independent Physician Panel, concluded that some modification of use may help to reduce the risk of possible stent migration and is updating the Abre IFU to provide new information for users. The proposed content to be included in the IFU is included in this letter under Attachment A. Medtronic is working to release this updated IFU as soon as possible. The content within this letter is intended to bridge the time until the new IFU is available.

Customer Instructions:

Medtronic records indicate that your practice may be impacted by these Instructions For Use changes. As a result, Medtronic requests that you take the following actions:

- Please review the upcoming updates to the IFU included in Attachment A
- Please share this notice with all those who need to be aware within your organization
- Patients should continue to be monitored per your practice's normal follow-up procedures.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action. This letter serves as a notification for your records regarding the upcoming updates to the Abre™ venous self-expanding stent system Instructions for Use; no further actions are needed.

If you have any questions regarding this material, please contact your Medtronic representative at 01 511 1400.

Sincerely,

Samantha Baxter
Regulatory Affairs
UK and Ireland

Enclosure:

Attachment A, Instructions for Use (IFU) Updates