Urgent Medical Device Notice

Abre™ venous self-expanding stent system

Instructions for Use Updates

November 2021

Dear Healthcare 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 FDA approved updates to the IFU are 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.
- Please complete the enclosed Customer Confirmation Form and email to RS.CFQFCA@medtronic.com.
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA’s MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Medtronic will notify all applicable regulatory agencies of this matter. 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 questions regarding this material, please contact your Medtronic Field Representative.

Sincerely,

Padraic Curran

Senior Director, Quality

Medtronic Peripheral Vascular Health
### Change From

Appropriate stent size selection is crucial. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use Table 11 for guidance in selecting the appropriate stent size.

### Change To

- Avoid placing the cranial end or caudal end of the stent within the common iliac vein at the transition curve to the external iliac vein and internal iliac confluence. Improper placement of the stent may result in tenting or kinking of the vessel. Extending the stent length beyond the transition curve is recommended to minimize risk of migration. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism, and/or the need for surgical intervention, including open surgical removal from the heart.

- Selection of the appropriate stent diameter and length is crucial. An undersized stent can result in stent migration and suboptimal luminal diameter. Stents with a diameter of ≤14mm and/or lengths of ≤80mm should be assessed for applicability as a stand-alone stent because of migration risk, particularly in non-thrombotic iliac vein lesions and in patients that have had a previous DVT, but otherwise have normal veins with an iliac vein compression.

- Ensure that there is appropriate stent apposition to the vessel wall to secure sustained fixation through changing vessel size and shape during the procedure and post-procedural patient movement. Options to ensure appropriate stent apposition include visualization with IVUS during the procedure, confirming that the stent is extended around a curve, that the stent diameter is constrained by the vessel below the stent’s nominal diameter, or that the stent is anchored by a second stent.

### Location

Section 4 Precautions

<table>
<thead>
<tr>
<th>Change From</th>
<th>Change To</th>
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Considering the estimated anatomic vessel diameter, use Table 11 to select the Abre stent diameter size. Choose a stent length that extends beyond both ends of the target lesion, with at least 1 cm on each side of the lesion to reduce the risk of restenosis.

Table 11. Sizing Guide

<table>
<thead>
<tr>
<th>Stent diameter (mm)</th>
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Caution: Appropriate stent size selection is crucial and ensures appropriate stent apposition to the vessel wall. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use Table 11 for guidance in selecting the appropriate stent size.

Considering the estimated anatomic vessel diameter, use Table 11 to select the Abre stent diameter size. A recommended way to calculate the equivalent diameter of an elliptical lumen is to determine the circle with the same perimeter. The root-mean-square of the major and minor axes of the ellipse provides a very good approximation. To achieve good wall apposition, it is recommended that a stent is chosen with a diameter of 2 mm greater than the reference vessel diameter.

Intraprocedural IVUS is encouraged (as a complementary imaging modality to venography) to more accurately determine the reference vessel diameter, the extent of disease, and the degree of stenosis. Considerations should be made for dynamic changes of the veins. Ensure the patient is suitably hydrated because hydration may impact vessel shape and size.

Determine the cranial and caudal placement zones for the stent, with a goal of stenting from “healthy” vessel tissue to “healthy” vessel tissue. Extending the stent length caudally to support fixation in an unaffected vessel is encouraged to prevent stent migration. It is particularly important to extend the stent length caudally in non-thrombotic iliac vein lesions and in patients that have had a previous DVT but have otherwise normal veins with an iliac vein compression.

Caution: Avoid placing the cranial end or caudal end of the stent within the common iliac vein at the transition curve to the external iliac vein and internal iliac confluence. Improper placement of the stent may result in tenting or kinking of the vessel. Extending stent length beyond the transition curve is recommended to minimize risk of migration. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism,
and/or the need for surgical intervention, including open surgical removal from the heart.

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Caution: Ensure that there is appropriate stent apposition to the vessel wall to secure sustained fixation through changing vessel size and shape during the procedure and post-procedural patient movement. Options to ensure appropriate stent apposition include visualization with IVUS during the procedure, confirming that the stent is extended around a curve, that the stent diameter is constrained by the vessel below the stent’s nominal diameter, or that the stent is anchored by a second stent.

Perform post-deployment balloon dilation as needed, using an appropriately sized balloon catheter with conventional dilation techniques.

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Section 11.4 Post Stent Deployment