Medtronic

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 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.

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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.

Sincerely,

Local / BU Manager

Enclosure:

Attachment A, Instructions for Use (IFU) Updates

Attachment A: Instructions for Use (IFU) Updates

<table>
<tr><th>Change From</th><th>Change To</th><th>Location</th></tr>
<tr><td>Appropriate stent size selection is crucial. Stent undersizing can lead to stent migration and suboptimal luminal diameter. Use Table 1 for guidance in selecting the appropriate stent size.</td><td>• Avoid landing in the cranial or caudal end of the stent within the common iliac vein at the transition curve to the external iliac vein and internal iliac vein confluence, as it may result in tenting or kinking of the vessel. Extending stent length beyond the curve should be considered to minimize risk of migration. Stent migration can potentially lead to vessel occlusion, thrombus formation, vessel damage, embolism, and/or need for surgical intervention, including potential for 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</td><td>Section 4 Precautions</td></tr>
<tr><td>Considering the estimated anatomic vessel diameter, use Table 1 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 1. Sizing Guide
<table>
<tr><th>Stent diameter (mm)</th><th>Estimated anatomic vessel diameter (mm)</th><th>Stent length (mm)</th></tr>
<tr><td>10</td><td>7.5-9.5</td><td>40, 60, 80, 100, 120, 150</td></tr>
<tr><td>12</td><td>9.5-11.5</td><td>60, 80, 100, 120, 150</td></tr>
<tr><td>14</td><td>11.5-13.5</td><td>60, 80, 100, 120, 150</td></tr>
</table></td><td>Considering the estimated anatomic vessel diameter, use Table 1 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 2mm 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</td><td>Section 7 Stent Size Selection</td></tr>
</table>

16	13.5-15.5	60, 80, 100, 120, 150
18	15.5-17.5	60, 80, 100, 120, 150
20	17.5-19.0	60, 80, 100, 120, 150

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.

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.

Table 1. Sizing Guide

Stent diameter (mm)	Estimated anatomic vessel diameter (mm)	Stent length (mm)
10	7.5-9.5	40, 60, 80, 100, 120, 150
12	9.5-11.5	60, 80, 100, 120, 150
14	11.5-13.5	60, 80, 100, 120, 150
16	13.5-15.5	60, 80, 100, 120, 150
18	15.5-17.5	60, 80, 100, 120, 150
20	17.5-19.0	60, 80, 100, 120, 150

Caution: Selection of the appropriate stent diameter and length is crucial. An undersized stent can lead to 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.

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.	Perform post-deployment balloon dilation, using an appropriately sized balloon catheter with conventional dilation techniques.	Section 10.4 Post Stent Deployment