Safety Communication رسالة سلامة

Possibility of stent migration

Device/ Product Description:	Abre venous self-expanding stent system
Affected product:	All Abre venous self-expanding stent systems
Manufacturer:	Medtronic Saudi Arabia
Problem:	New 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.

<table>
<tr><td>Recommendation /Actions:</td><td colspan="2">

Please review the upcoming updates to the IFU included in Attachment A in the below link.
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.

For more information, please click here.

If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:
NCMDR
Vigilance system
(19999)unified call center
</td></tr>
<tr><td>Devices/Products photo:</td><td colspan="2">  </td></tr>
<tr><td rowspan="4">Authorized Representative Details</td><td>AR name:</td><td>Medtronic Saudi Arabia LLC</td></tr>
<tr><td>Assigned Contact Person:</td><td>Faisal Matbuli</td></tr>
<tr><td>Mobile/Phone:</td><td>+(966) 535355500</td></tr>
<tr><td>Email:</td><td>ksa.ra@medtronic.com</td></tr>
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