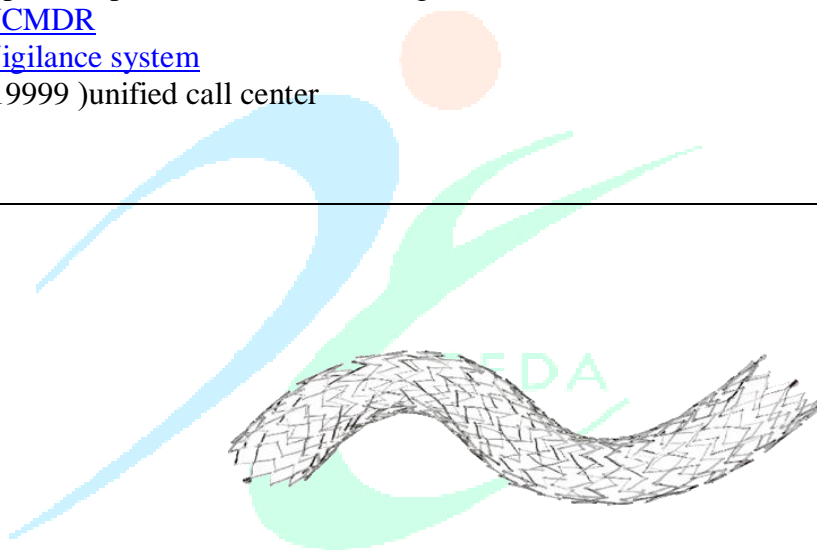


Safety Communication

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.

<p>Recommendation /Actions:</p>	<ul style="list-style-type: none"> - 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. <p>For more information, please click here.</p> <p>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</p>	
<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>Medtronic Saudi Arabia LLC</p>
	<p>Assigned Contact Person:</p>	<p>Faisal Matbuli</p>
	<p>Mobile/Phone:</p>	<p>+(966) 535355500</p>
	<p>Email:</p>	<p>ksa.ra@medtronic.com</p>