

## Safety Communication

## رسالة سلامة

### The Pushwire may fracture

<b>Device/ Product Description:</b>	Pipeline Flex Embolization Device and Pipeline Flex Embolization Device with Shield Technology.
<b>Affected product:</b>	All product models
<b>Manufacturer:</b>	Medtronic SA
<b>Problem:</b>	During delivery, retrieval, or maneuvering of the Pipeline delivery system, the guidewire may be subjected to repeated manipulations and/or excessive force which can lead to hypotube fracture (also referred to as hypotube tensile failure).
<b>Recommendation /Actions:</b>	<ul style="list-style-type: none"> <li>• Make sure that this document is reached to the end-users.</li> <li>• Ensure that all devices affected are identified.</li> <li>• Customers are advised to NOT use any impacted product.</li> <li>• Customers should remove and quarantine all unused impacted products in their inventory.</li> <li>• Affected product should be returned to Medtronic.</li> <li>• If alternative product is needed, Medtronic will assist customers to identifying suitable replacement product.</li> </ul> <p>For more information, please click <a href="#">here</a> &amp; <a href="#">here</a>.</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:  <a href="#">NCMDR</a>  <a href="#">Vigilance system</a>  (19999 )unified call center</p>

<b>Image:</b>			
<b>Authorized Representative Details</b>	AR name:	Medtronic Saudi Arabia LLC	
	Assigned Contact Person:	Faisal Mansour Matbuli	
	Mobile/Phone:	+(966) 535355500	
	Email:	<a href="mailto:ksa.ra@medtronic.com">ksa.ra@medtronic.com</a> ; <a href="mailto:rs.saudira@medtronic.com">rs.saudira@medtronic.com</a>	

