

## Safety Communication

## رسالة سلامة

### Tip breaks and wobble/vibration in this subset of devices

<b>Device/ Product Description:</b>	Sterile Blade Single-Use Accessories
<b>Affected product:</b>	Check the complete list <a href="#">here</a>
<b>Manufacturer:</b>	Medtronic
<b>Problem:</b>	Complaints related to tip breaks and wobble/vibration in this subset of devices. Tip breaks or detachment of fragments may cause harm to the patient, cause lack of oxygenation or foreign body reaction if the fragment were to migrate into the patient's airway or be irretrievable. There is also a chance that the tip may impact critical structures such as nerves and arteries. Blade wobble or vibration may also lead to permanent damage if it causes the blade to impact critical structures.
<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>• Quarantine all unused affected blades listed in Appendix A.</li> <li>• Return all unused affected devices to the authorized representative.</li> </ul> <p>For more information, please click <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>Authorized Representative Details</b>	AR name:	Medtronic Saudi Arabia
	Assigned Contact Person:	Nahar Alsurayi
	Mobile/Phone:	+966 503226812
	Email:	<a href="mailto:nahar.s.alsurayi@medtronic.com">nahar.s.alsurayi@medtronic.com</a>

