

## Safety Communication

## رسالة سلامة

### Issues with the Trivantage EMG Tubes during use

<b>Device/ Product Description:</b>	NIM Trivantage EMG Endotracheal Tube
<b>Affected product:</b>	Refer to “Table A” and “Attachment 1” in the attached FSN
<b>Manufacturer:</b>	Medtronic SA
<b>Problem:</b>	<ul style="list-style-type: none"> <li>• Experiencing difficulty passing the Electrode Check on the NIM Mainframe immediately after intubating the patient</li> <li>• Losing the connection between the EMG Tube and the Mainframe during a procedure, resulting in an “Electrode Off,” “Lead Off,” or “Channel Not Reading” error message on the NIM console screen and the inability to proceed with nerve monitoring.</li> <li>• Receiving excess signal noise from the NIM console due to lead-off issues.</li> </ul>
<b>Recommendation /Actions:</b>	<p>If any of these issues are identified during surgery, the risks associated with a non-conforming Trivantage EMG Tube could potentially result in:</p> <ul style="list-style-type: none"> <li>○ A case being cancelled after the patient is anesthetized</li> <li>○ Possible nerve damage, Therefore, the required actions are:</li> </ul> <ul style="list-style-type: none"> <li>• Do NOT use any impacted product, Remove and quarantine all unused impacted product(s) in your inventory.</li> <li>• Return the impacted product(s) to Medtronic, if an alternative product is needed, your Medtronic representative can assist you with identifying a suitable replacement product.</li> </ul> <p>For more information, please click <a href="#">here</a></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	
<b>Authorized Representative Details</b>	AR name:	Medtronic Saudi Arabia
	Assigned Contact Person:	Alsurayi, Nahar
	Mobile/Phone:	0555066900
	Email:	<a href="mailto:nahar.s.alsurayi@medtronic.com">nahar.s.alsurayi@medtronic.com</a> <a href="mailto:ksa.ra@medtronic.com">ksa.ra@medtronic.com</a>

