Urgent Safety Communication

Oscor Inc. Issues Recall of TB – Temporary Bipolar Pacing Lead (Unshrouded 2 mm Pins Models) [Update]

<table>
<tr><td>Device/ Product Name:</td><td>- 4 Fr TB Temporary Bipolar Pacing Leads with Unshrouded Connectors.
- 6 Fr TB Temporary Bipolar Pacing Leads with Unshrouded Connectors.
- 5 Fr TB Temporary Bipolar Pacing Leads with Unshrouded Convenience Kits.</td></tr>
<tr><td>Updated Lot Numbers/Serials:</td><td>PRODUCT & MODEL NUMBERS:
<table>
<tr><th>Product</th><th>Oscor Inc Model No.</th><th>GTIN</th></tr>
<tr><td>4 Fr TB Temporary Bipolar Pacing Leads</td><td>020016</td><td>00836559009849</td></tr>
<tr><td>6 Fr TB Temporary Bipolar Pacing Leads with Unshrouded Convenience Kits</td><td>TBVK06110USG</td><td>00885672004354</td></tr>
<tr><td>5 Fr TB Temporary Bipolar Pacing Leads with Unshrouded Convenience Kits</td><td>TBRHK05110USG</td><td>00885672004392</td></tr>
</table></td></tr>
<tr><td>Manufacturer:</td><td>Oscor Inc.</td></tr>
<tr><td>Updated Reason:</td><td>Update Reason: Recall expansion to include expired inventory. Oscor states that the recall scope is being expanded to include expired inventory for devices distributed between December 21, 2011, and May 17, 2018. For the previously listed product, see safety communication concerning the same problem which has been issued by SFDA.</td></tr>
<tr><td>Problem:</td><td>Saudi FDA would like to bring your attention that Oscor Inc. Issues Recall of TB – Temporary Bipolar Pacing Lead (Unshrouded 2 mm Pins Models). During the use of some TB - Temporary Bipolar Pacing Leads, featuring the 2mm unshrouded connectors, the connector cap housing (see Picture 1, No. 2 Pin Cap and Cover) may slide and potentially expose the connection wire. In some instances, this may cause the wire to be more susceptible to loss of connectivity or breakage during movement of the cables causing interruption of the pacing system.
The analysis of the returned devices attributed the failure to a design change of the cap housing of the pins. In the last six years, a total of four serious injuries were reported to Oscor which were attributed to a connector cap malfunction causing the lead connector to separate during use potentially leading to an interruption of the pacing system. No deaths were reported; however, the risk for possible injury is a concern if the connectors separate during use.</td></tr>
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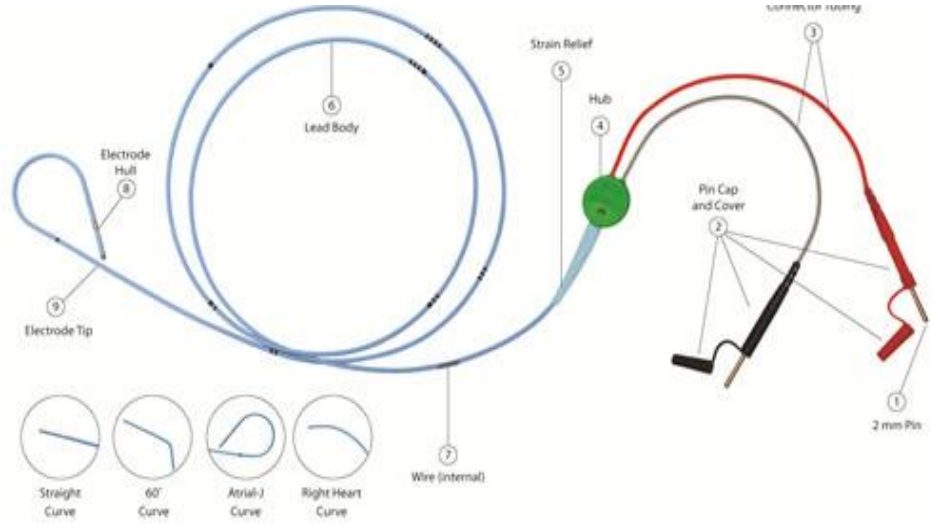
Recommendation/ Actions:	- Identify, isolate, and discontinue use of any affected product in your inventory. - Healthcare professionals are encouraged to report any malfunction and/or adverse events related to the use of these products to the SFDA's National Center for Medical Devices Reporting.
Devices/Products photo:	 **Picture 1**

Authorized Representative Details:		
	Company name:	**Medical Technology Trading Company**
	Phone:	**+966 (11) 4769696**
	Email:	Info@medicaltechnology.com.sa

Healthcare Professionals should report any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406
Fax: +966 (11) 2757245
Or

Saudi Vigilance
https://ade.sfda.gov.sa/Home/Report

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team