Urgent Safety Communication

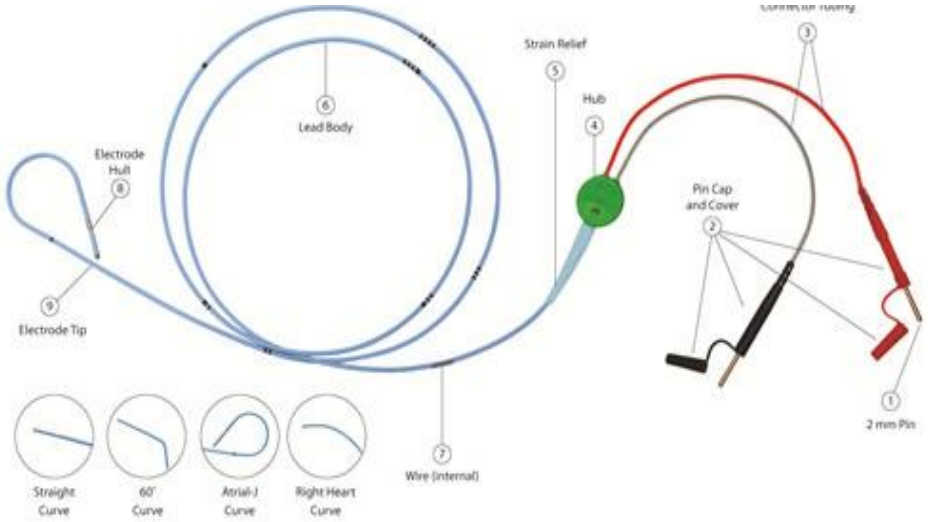
Oscor Inc. Issues Recall of TB – Temporary Bipolar Pacing Lead (Unshrouded 2 mm Pins Models)

Device/ Product Name:	TB Temporary Bipolar Pacing Leads with 2 mm Unshrouded Connectors (Unshrouded 2 mm Pins Models).
Lot numbers/Serials:	**MODEL NUMBERS:**

GTIN	GUDID/Label	TB Specification Description			
	Model Number	Series	French size	Pin	Curve Type
836559009726	20004	TB	4F	Unshrouded	Straight
836559009733	20005	TB	5F	Unshrouded	Straight
836559009740	20006	TB	6F	Unshrouded	Straight
836559009788	20010	TB	4F	Unshrouded	Atrial J
836559009795	20011	TB	5F	Unshrouded	Atrial J
836559009801	20012	TB	6F	Unshrouded	Atrial J
836559009856	20017	TB	5F	Unshrouded	60° Curve
836559009863	20018	TB	6F	Unshrouded	60° Curve
836559009900	20022	TB	4F	Unshrouded	Right Heart
836559009917	20023	TB	5F	Unshrouded	Right Heart
836559009924	20024	TB	6F	Unshrouded	Right Heart
836559009030	TBK04110USG	TB	4F	Unshrouded	Straight
836559009054	TBK05110USG	TB	5F	Unshrouded	Straight
836559009078	TBK06110USG	TB	6F	Unshrouded	Straight
885672007027	TBVK04110USG	TB	4F	Unshrouded	60° Curve
885672007034	TBJK04110USG	TB	4F	Unshrouded	Atrial J
885672004378	TBRHK04110USG	TB	4F	Unshrouded	Right Heart
885672103682	TBRHK06110USG	TB	6F	Unshrouded	Right Heart

Table 1: TB-Temporary Bipolar Pacing Lead with Un-Shrouded Pins Affected Models.

Manufacturer:	**Oscor Inc.**

Problem:	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.
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
	Contact Person:	------
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	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