

**“奧斯卡”暫時型心律調節器導線
回收警訊
(國內無進口受影響產品)**

許可證字號：衛署醫器輸字第 023510 號

產品英文名稱：“Oscor”TB Temporary Bipolar Pacing Lead

受影響規格/型號/批號：

名稱描述	型號	批號
TB LEAD, 4F UN-SHROUDED	020004	詳見附件 (國內無 進口受影 響產品)
TB LEAD, 5F UN-SHROUDED	020005	
TB LEAD, 6F UN-SHROUDED	020006	
TB LEAD, 4F UN-SHROUDED ATRIAL J-TIP	020010	
TB LEAD, 5F UN-SHROUDED ATRIAL J-TIP	020011	
TB LEAD, 6F UN-SHROUDED ATRIAL J-TIP	020012	
TB LEAD, 4F UN-SHROUDED 60 DEG CURVE	020016	
TB LEAD, 5F UN-SHROUDED 60 DEG CURVE	020017	
TB LEAD, 6F UN-SHROUDED 60 DEG CURVE	020018	
TB LEAD, 4F UNSHROUDED RIGHT HEART CURVE	020022	
TB LEAD, 5F UN-SHROUDED RIGHT HEART CURVE	020023	
TB LEAD, 6F UN-SHROUDED RIGHT HEART CURVE	020024	
TB LEAD 5F UNSHROUDED CONVENIENCE KIT	TBK05110USG	
TB 6F U CONVENIENCE KIT ADELANTE SIGMA PLUS 6F S10CM D15CM	TBK06110USG	
TBRH 6F RT HEART CURVE U CONV. KIT ADELANTE SIGMA PLUS 6F S10CM D15CM	TBRHK-06110USG	

發布對象：醫療從業人員/醫療器材專業人員

警訊說明：(回收/矯正原因描述)

在使用某些 2mm 無遮蓋連接器的 TB (暫時型雙極心律調節器導線) 時，連接器的蓋子可能會滑開，且可能造成連結電線暴露。在某些情況下，這可能會導致電線失去連結性，或在移動導線時造成斷裂，而影響整個心律調節器的運作。

國內矯正措施：

經查，國內無進口受影響型號/批號產品，故傳永有限公司無須執行回收行動。

廠商聯絡資訊：

公司名稱：傳永有限公司

聯絡電話：(02)2985-3632 ext.212

聯絡人電子郵件：michelle.chou@transmedic.com.tw

相關警訊來源(網址)：

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=167175>

附件

名稱描述	型號	批號	
TB LEAD, 4F UN-SHROUDED	020004	C1-06951	C1-09166
		C1-06993	D1-02633
		C1-06994	D1-02883
		C1-07016	DP-01395
		C1-07017	OR-03868
		C1-07018	OR-03874
		C1-09074	OR-04404
TB LEAD, 5F UN-SHROUDED	020005	C1-06923	C1-08497
		C1-06945	C1-08498
		C1-06946	C1-08499
		C1-06947	C1-08676
		C1-06995	C1-08677
		C1-06996	C1-08678
		C1-06997	C1-08679
		C1-07012	C1-08685
		C1-07013	C1-08686
		C1-07014	C1-08687
		C1-07015	C1-08688
		C1-08486	C1-08689
		C1-08487	C1-08691
		C1-08488	C1-08692
		C1-08494	C1-08693
		C1-08495	C1-08694
		C1-08496	C1-09046
		C1-09047	DP-01259
		C1-09048	DP-01455
		C1-09251	DP-01554
		C1-09252	DP-02161
		C1-09253	DP-02766
		D1-02542	DP-02790
		D1-02805	DP-02844
		D2-01795	OR-04380
		D2-01939	OR-04407
TB LEAD, 6F UN-SHROUDED	020006	C1-06953	C1-08666
		C1-06954	C1-08667
		C1-06955	C1-08668
		C1-06956	C1-08669
		C1-07079	C1-08670
		C1-07080	C1-08671

		C1-07081	C1-08672
		C1-07082	C1-08673
		C1-07945	C1-08674
		C1-07946	C1-08675
		C1-07955	C1-08680
		C1-07956	C1-08681
		C1-07957	C1-08682
		C1-07958	C1-08683
		C1-07959	C1-08701
		C1-07960	C1-08702
		C1-07961	C1-08703
		C1-07962	C1-08704
		C1-07963	C1-08705
		C1-07964	C1-08706
		C1-07965	C1-08707
		C1-07966	C1-08708
		C1-08396	C1-08709
		C1-08398	C1-08710
		C1-08407	C1-08711
		C1-08409	C1-08712
		C1-08410	C1-08713
		C1-08411	C1-08714
		C1-08412	C1-08715
		C1-08716	DP-01214
		C1-08717	DP-01374
		C1-08718	DP-01492
		C1-08719	DP-01553
		C1-08720	DP-01569
		C1-08721	DP-01601
		C1-08722	DP-02162
		C1-08723	DP-02793
		C1-08724	DP-02932
		C1-08731	DP-02942
		C1-08732	DP-03114
		C1-08733	DP-03115
		C1-08734	DP-03116
		C1-08735	DP-03117
		C1-08753	DP-03118
		C1-08754	DP-03123
		C1-08755	DP-03144
		C1-08756	DP-03229
		C1-08757	OR-03853

		C1-08758	OR-03878
		C1-08759	OR-03939
		C1-08760	OR-03961
		C1-08761	OR-04060
		C1-08762	OR-04100
		C1-08763	OR-04278
		C1-09444	OR-04329
		D1-02562	OR-04330
		D1-02806	OR-04366
		D2-01691	OR-04367
		D2-01775	OR-04368
		DP-01003	OR-04369
		DP-01004	OR-04399
		DP-01082	OR-04408
TB LEAD, 4F UN-SHROUDED ATRIAL J-TIP	020010	C1-06957	DP-01059
TB LEAD, 5F UN-SHROUDED ATRIAL J-TIP	020011	C1-06940	D1-02916
		D1-02559	OR-04406
TB LEAD, 6F UN-SHROUDED ATRIAL J-TIP	020012	D1-02565	OR-04370
TB LEAD, 4F UN-SHROUDED 60 DEG CURVE	020016	C1-06952	DP-01058
TB LEAD, 5F UN-SHROUDED 60 DEG CURVE	020017	DP-03054	OR-04416
TB LEAD, 6F UN-SHROUDED 60 DEG CURVE	020018	D1-02490	DP-01490
		D1-02567	OR-03879
		D2-01777	OR-04277
		D2-01991	OR-04280
		DP-01105	OR-04371
		DP-01357	OR-04383
		DP-01359	
TB LEAD, 4F UNSHROUDED RIGHT HEART CURVE	020022	DP-02185	
TB LEAD, 5F UN-SHROUDED RIGHT HEART CURVE	020023	C1-08091	C1-08121
		C1-08092	C1-08122
		C1-08093	C1-08123
		C1-08094	C1-08124
		C1-08095	C1-08126
		C1-08096	C1-08127
		C1-08097	C1-08128
		C1-08098	C1-08129
		C1-08099	C1-08130
		C1-08100	C1-08131
		C1-08101	C1-08132

		C1-08102	C1-08133
		C1-08103	C1-08134
		C1-08104	C1-08135
		C1-08105	C1-08136
		C1-08106	C1-08137
		C1-08107	D1 02817
		C1-08108	D1-02817
		C1-08109	D1-02822
		C1-08110	D1-02924
		C1-08111	DP-01116
		C1-08112	DP-01372
		C1-08113	DP-01434
		C1-08114	DP-01596
		C1-08115	DP-02792
		C1-08117	DP-02933
		C1-08118	DP-02940
		C1-08119	DP-02949
		C1-08120	OR-04381
		OR-04382	OR-04600
		OR-04405	OR-04609
		OR-04579	OR-04625
TB LEAD, 6F UN-SHROUDED RIGHT HEART CURVE	020024	C1-07890	C1-08618
		C1-07891	C1-08622
		C1-07892	C1-08623
		C1-07893	C1-08624
		C1-07894	C1-08625
		C1-07895	C1-08626
		C1-07896	C1-08628
		C1-07897	C1-08629
		C1-07898	C1-08630
		C1-07918	C1-08631
		C1-07919	C1-08653
		C1-07920	C1-08654
		C1-07921	C2-07889
		C1-07922	D1-02749
		C1-07923	D1-02818
		C1-07924	D2-01776
		C1-07925	D2-01793
		C1-07926	DP 01042
		C1-07927	DP-01042
		C1-07928	DP-01044
		C1-07929	DP-01155

		C1-07930	DP-01375
		C1-07931	DP-01438
		C1-07932	DP-01573
		C1-07933	DP-01584
		C1-07934	DP-01597
		C1-07935	DP-01677
		C1-07936	DP-01683
		C1-07937	OR-04124
		C1-07938	OR-04226
		C1-07943	OR-04274
		C1-07944	OR-04325
		C1-08599	OR-04374
		C1-08600	OR-04375
		C1-08617	OR-04376
		OR-04377	OR-04379
		OR-04378	OR-04401
TB LEAD 5F UNSHROUDED CONVENIENCE KIT	TBK05110USG	DP-01161	DP-02435
		DP-02004	DP-02884
		DP-02009	
TB 6F U CONVENIENCE KIT ADELANTE SIGMA PLUS 6F S10CM D15CM	TBK06110USG	D1-02232	DP-02083
		D1-02520	DP-02408
		D1-02833	DP-02885
		DP-01376	
TBRH 6F RT HEART CURVE U CONV. KIT ADELANTE SIGMA PLUS 6F S10CM D15CM	TBRHK-06110USG	C1-08813	FP-54291
		DP-02166	FP-55411
		FP-054291	