Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	ANGIOGUARD™ RX / XP Emboli Capture Guidewire System
Device Model	

ITEM_NUMBER	LOT_NUMBER
401814RM	35265339
	35265670
401814RMC	35262517
	35263334
	35264204
	35264222
	35265345
	35265669
501814RE	35264217
	35264226
	35265330
	35265344
	35265381
	35265639
	35265641
	35265652
	35265655
	35265662
	35265664

ITEM_NUMBER	LOT_NUMBER
501814REC	35264223
501814RMC	35264208
	35264212
	35265329
	35265649
	35265654
	35265667
601814RE	35264218
	35264224
	35264806
	35265342
	35265343
	35265382
	35265383
	35265646
	35265656
601814RM	35265658

ITEM_NUMBER	LOT_NUMBER
601814RMC	35263328
	35264207
	35264213
	35264216
	35265393
	35265648
	35265659
603014MC	35265492
701814RE	35264219
	35265391
	35265392
	35265399
	35265668
701814RMC	35265661
801814RMC	35264202
	35265335

Manufacturer	Cordis
Country of Origin	USA
Reference	Link

For more information please contact Medical_Devices@nhra.bh

Reason of Recall	NHRA initiates this FSN due to a potential for the inability to safely deploy and capture the filter basket of the ANGIOGUARDTM RX / XP delivery system due to deployment sheath peeling difficulty and/or separation, capture sheath separation and difficulty exiting the guidewire RX port. The potential impacts include but are not limited to situations of an intra-procedural delay; unplanned percutaneous or surgical intervention; or stroke.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh