


Safety Communication

رسالة سلامة

Potential risks due to difficulty or inability to deflate the balloon

Device/ Product Description:	Coronary Dilatation Catheter				
Brand:	NC Trek RX; NC Traveler RX				
Affected product:	Device Identifier/GTIN	Device Description	Part Number	Lot Number	
	8717648152054	NC TREK RX 4.00 X 8MM BDC	1012453-08	90731G1 90808G1 90826G1 90906G1	90921G1 90928G1 91003G1 91017G1 91106G1
	8717648152061	NC TREK RX 4.00 X 12MM BDC	1012453-12	90730G1 90731G1 90818G1 90822G1 90905G1 90918G1	90919G1 90927G1 91001G1 91015G1 91025G1 91101G1
	8717648152078	NC TREK RX 4.00 X 15MM BDC	1012453-15	90815G1 90816G1 90828G1 90904G1 90920G1 90926G1	91008G1 91009G1 91020G1 91026G1 91109G1 91117G1
	8717648152085	NC TREK RX 4.00 X 20MM BDC	1012453-20	90727G1 90830G1 90923G1	91004G1 91028G1
	8717648152092	NC TREK RX 4.50 X 8MM BDC	1012454-08	90801G1 90812G1 90818G1 90818G2	90925G1 91010G2 91022G1 91025G1

				90904G1 90912G1	91101G1
	8717648152108	NC TREK RX 4.50 X 12MM BDC	1012454-12	90731G1 90805G1 90817G1 90818G1 90904G1 90906G1	90912G1 90922G1 91015G1 91016G1 91105G1
	8717648152115	NC TREK RX 4.50 X 15MM BDC	1012454-15	90819G1 90819G2 90916G1 90916G2	90927G1 90930G1 91031G1
	8717648152122	NC TREK RX 4.50 X 20MM BDC	1012454-20	90801G1 90809G1	91018G1 91021G1
	8717648152139	NC TREK RX 5.00 X 8MM BDC	1012455-08	90918G1 90930G1	91001G1
	8717648152146	NC TREK RX 5.00 X 12MM BDC	1012455-12	90918G1 90926G1	90930G1 91031G1
	8717648152153	NC TREK RX 5.00 X 15MM BDC	1012455-15	90806G1 90806G2	91022G1 91025G1
	8717648152160	NC TREK RX 5.00 X 20MM BDC	1012455-20	91010G1	91026G1
	8717648195983	NC Traveler RX 4.0 X 8MM	1013157-08	91010G1	
	8717648195990	NC Traveler RX 4.0 X 12MM	1013157-12	90812G1	
	8717648196003	NC Traveler RX 4.0 X 15MM	1013157-15	91102G1	
	8717648196027	NC Traveler RX 4.5 X 8MM	1013158-08	90812G1	
	8717648196034	NC Traveler RX 4.5 X 12MM	1013158-12	90813G1	
Manufacturer:	Abbott				
Problem:	Devices from the identified lots may exhibit difficulty or inability to deflate the balloon due to weaker material proximal to the balloon bond resulting from excess heat exposure during manufacturing. Potential risks include air embolism, thrombosis, myocardial infarction and additional intervention. Additional intervention such as surgery could lead to post-operative complications which include death.				
Recommendation/ Actions:	<ol style="list-style-type: none"> 1. Review this notice and ensure that affected personnel are aware of the contents. 2. Immediately stop using affected devices from these lots 3. Contact the authorized representative for required correction. 				

	<p>For more information, Please click here.</p> <p>If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>	
Devices/Products photo:	 <p>The image shows two boxes of Abbott coronary dilatation catheters. The left box is for the 'NC Traveler' model, featuring a yellow label at the bottom. The right box is for the 'NC TREK' model, featuring a grey label at the bottom. Both boxes are blue with white text and graphics of the catheter.</p>	
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