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URGENT
MEDICAL DEVICE RECALL / NC TREK RX & NC Traveler RX

COMMERCIAL NAME: NC Trek RX Coronary Dilatation Catheter
NC Traveler RX Coronary Dilatation Catheter

FSCA-Identifier: January 29, 2020
Type of Action: Device Recall

Attention: Risk Manager or Healthcare Professional

Dear Valued Abbott Customer:

Abbott has initiated a field action regarding specific lots of the NC Trek RX Coronary Dilatation Catheter and NC Traveler RX Coronary Dilatation Catheters, balloon diameters 4.0mm, 4.5mm and 5.0mm. Our records indicate that affected devices have been shipped to your account.

This action does not affect patients having successfully undergone cardiac procedures using these devices.

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. The reported frequency of difficulty or inability to deflate the balloon for the affected population of lots is 0.09%. Potential risks include air embolism, thrombosis, myocardial infarction and additional intervention. There have been no reports of patient death associated with this issue. However, additional intervention such as surgery could lead to post-operative complications which include death.

What action is Abbott requiring from your institution?	• Reference the attached list of affected part numbers and lot numbers • Immediately stop using affected devices from these lots • Review your inventory, complete and return the attached Effectiveness Check Form • Return all unused affected product to Abbott • Share this notification with other relevant personnel in your organization
What action is Abbott taking?	• Abbott has stopped shipping affected lots • Abbott will implement appropriate corrective actions to ensure product performance • Abbott field representative can assist in identifying and returning affected devices • Abbott will work with you to replace returned units with similar devices, pending availability

FDA has been notified of this action. Report any adverse reactions or quality problems experienced with the use of this product to Abbott at (800) 227-9902. Reports may also be sent to the FDA's MedWatch Adverse Event Reporting program by completing Form FDA 3500 online at www.FDA.gov or calling 1-800-FDA-1088.

We regret any inconvenience this may cause you and appreciate your patience. Abbott is committed to providing high quality products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your local Abbott Representative or Customer Service department on (800) 227-9902.

Sincerely,

Steve Eldridge
Divisional Vice President, AV Global Quality and Compliance

Part Numbers and Lot Numbers

Device Identifier/GTIN	Device Description	Part Number	Lot Number	
08717648152054	NC TREK RX 4.00 X 8MM BDC	1012453-08	90731G1	90921G1
			90808G1	90928G1
			90826G1	91003G1
			90906G1	91017G1
				91106G1
08717648152061	NC TREK RX 4.00 X 12MM BDC	1012453-12	90730G1	90919G1
			90731G1	90927G1
			90818G1	91001G1
			90822G1	91015G1
			90905G1	91025G1
			90918G1	91101G1
08717648152078	NC TREK RX 4.00 X 15MM BDC	1012453-15	90815G1	91008G1
			90816G1	91009G1
			90828G1	91020G1
			90904G1	91026G1
			90920G1	91109G1
			90926G1	91117G1
08717648152085	NC TREK RX 4.00 X 20MM BDC	1012453-20	90727G1	91004G1
			90830G1	91028G1
			90923G1	
08717648152092	NC TREK RX 4.50 X 8MM BDC	1012454-08	90801G1	90925G1
			90812G1	91010G2
			90818G1	91022G1
			90818G2	91025G1
			90904G1	91101G1
			90912G1	
08717648152108	NC TREK RX 4.50 X 12MM BDC	1012454-12	90731G1	90912G1
			90805G1	90922G1
			90817G1	91015G1
			90818G1	91016G1
			90904G1	91105G1
			90906G1	
08717648152115	NC TREK RX 4.50 X 15MM BDC	1012454-15	90819G1	90927G1
			90819G2	90930G1
			90916G1	91031G1
			90916G2	
08717648152122	NC TREK RX 4.50 X 20MM BDC	1012454-20	90801G1	91018G1
			90809G1	91021G1
08717648152139	NC TREK RX 5.00 X 8MM BDC	1012455-08	90918G1	91001G1
			90930G1	

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Part Numbers and Lot Numbers continued

Device Identifier/GTIN	Device Description	Part Number	Lot Number	
08717648152146	NC TREK RX 5.00 X 12MM BDC	1012455-12	90918G1	90930G1
			90926G1	91031G1
08717648152153	NC TREK RX 5.00 X 15MM BDC	1012455-15	90806G1	91022G1
			90806G2	91025G1
08717648152160	NC TREK RX 5.00 X 20MM BDC	1012455-20	91010G1	91026G1
08717648195983	NC Traveler RX 4.0 X 8MM	1013157-08	91010G1	
08717648195990	NC Traveler RX 4.0 X 12MM	1013157-12	90812G1	
08717648196003	NC Traveler RX 4.0 X 15MM	1013157-15	91102G1	
08717648196027	NC Traveler RX 4.5 X 8MM	1013158-08	90812G1	
08717648196034	NC Traveler RX 4.5 X 12MM	1013158-12	90813G1	

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NC Traveler RX Coronary Dilatation Catheter

FSCA-Identifier: January 29, 2020
Type of Action: Device Recall

Effectiveness Check Form

Customer Account #_____
Account Name _____
Address _____
_____
(Information required for regulatory effectiveness check)

After reviewing your inventory of NC Trek RX and NC Traveler RX Coronary Dilatation Catheters, please check one box in the section below. If affected inventory was identified, contact Customer Services to obtain a Returned Goods Authorization (RGA) number. After signing this form, return the form and any identified products to Abbott.

☐ A thorough search for all affected devices has been completed confirming all have been consumed and no affected devices remain in inventory.
No devices will be returned.

☐ Affected NC Trek RX and/or NC Traveler RX Coronary Dilatation Catheter devices have been identified and are being returned.

RGA Number: _____

_____ _____ _____
Customer Name/ Title (print) ***Signature*** ***Date***

This form is to be returned to Abbott

- If returning product, call Abbott Customer Service (800) 227-9902 to receive RGA number. Record RGA number above.
- Fax this completed form to 1-951-914-4951 or send a scanned copy via e-mail to AVRegulatoryCompliance@av.abbott.com
- Return a copy of this completed form with the returned product.

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