



URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

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

The appropriate regulatory agencies have been notified of this action.

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.

Sincerely,

<signature of country manager>
<printed name>
<title>

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

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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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 to receive RGA number. Record RGA number above.
- Scan and email this form to eva.boruvkova@abbott.com and alena.silova@abbott.com.
- Return a copy of this completed form with returned product.