



## URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

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

**Part Numbers and Lot Numbers** continued

| <b>Device Identifier/GTIN</b> | <b>Device Description</b>  | <b>Part Number</b> | <b>Lot Number</b> |         |
|-------------------------------|----------------------------|--------------------|-------------------|---------|
| 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](mailto:eva.boruvkova@abbott.com) and [alena.silova@abbott.com](mailto:alena.silova@abbott.com).
- ☐ Return a copy of this completed form with returned product.