



20-Mar- 2017

## URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

COMMERCIAL NAME: NC Trek RX Coronary Dilatation Catheter  
NC Traveler RX Coronary Dilatation Catheter  
NC Tenku RX PTCA Balloon Catheter

FSCA-Identifier: March 22, 2017

Type of Action: Device Recall

### **Attention: Risk Manager or Healthcare Professional**

Dear Valued Abbott Vascular Customer:

Abbott Vascular has initiated a voluntary field action regarding specific lots of the NC Trek RX Coronary Dilatation Catheter, NC Traveler RX Coronary Dilatation Catheter, and NC Tenku RX PTCA Balloon Catheter. Our records indicate that affected lots have been shipped to your account.

Product from the identified lots may exhibit difficulty in removing the protective balloon sheath which can result in issues with inflating or deflating the balloon. The worldwide frequency of tight sheath removal, inflation and deflation reported events is 0.12%. Potential risks associated with balloon inflation and deflation difficulties include air embolism, additional intervention, thrombosis, and myocardial infarction. In one reported case, failure to deflate the balloon necessitated surgery, leading to multiple post-operative complications and death.

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

#### How does this issue occur?:

If excessive force is required to remove the balloon sheath, the sheath may damage the device causing problems with inflating or deflating the balloon.

#### What action is Abbott Vascular asking you to take?:

- Please reference the attached list of affected part numbers and lot numbers
- Please immediately stop using the devices from these lots.
- Please review your inventory, complete, and return the attached Effectiveness Check Form
- Return all unused identified products to Abbott Vascular
- Share this notification with other relevant personnel in your organization

#### What is Abbott Vascular doing?:

Abbott Vascular has already implemented corrective actions to ensure ongoing product performance. Abbott Vascular will work with you to replace returned units with similar product, 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 Vascular 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 Vascular Representative or Customer Service department on xxx xxxxx.

Sincerely,

Abbott Vascular Deutschland GmbH - Betriebsstätte Wetzlar

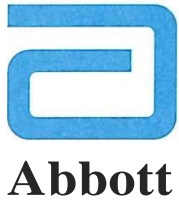


**URGENT FIELD SAFETY NOTICE / DEVICE RECALL**

March 22, 2017

NC Trek RX Coronary Dilatation Catheter

Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
1012448-06	60414G1	1012448-15	61014G1	1012449-12	60408G1
	60721G1		61028G1		60413G1
1012448-08	60208G1		61206G1		60413G2
	60419G1	61206G2	60425G1		
	60420G1	1012448-20	60310G1		60429G1
	60603G1		60421G1		60511G1
	60906G1		60421G2		60512G1
	61121G1		60527G1		60531G1
	61121G2		60716G1		60607G1
1012448-12	60225G1		60819G1		60623G1
	60229G1		61024G2		60713G1
	60318G1	1012449-06	60523G1		60721G1
	60318G2		61026G1		60804G1
	60429G1	1012449-08	60317G1		60805G1
	60429G2		60318G1		60809G1
	60607G1		60412G1		60812G1
	60705G1		60419G1		60816G1
	60804G1		60502G1		60824G1
	60818G1		60502G2		60926G1
	60921G1		60525G1		60929G1
	60921G2		60705G1		61012G1
	61108G1		60801G1		61019G1
	61111G1		60809G1		61019G2
	61128G1		60826G1		61020G1
61128G2	60916G1		61115G1		
61218G1	61018G1		61121G1		
1012448-15	60202G1		61121G1		61122G1
	60310G1	61121G2	61123G1		
	60401G1	1012449-12	61123G2		
	60408G1		60218G1	61201G1	
	60408G2		60303G1	61208G1	
	60510G1		60330G1	61214G1	
	60616G1		60330G2	61214G2	
	60721G1		60406G1	61216G1	
	60809G1		60406G2	61216G2	
60912G1	60406G3		1012449-15	60128G1	
	60406G4				

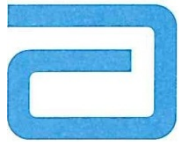


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March 22, 2017

NC Trek RX Coronary Dilatation Catheter (Continued)

Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
1012449-15	60215G1	1012449-15	61122G1	1012450-12	60623G1
	60215G2		61123G1		60831G1
	60224G1		61128G1		60921G1
	60322G1		61130G1		61104G1
	60329G1		61202G1		61207G1
	60330G1	60126G1	61209G1		
	60330G2	60223G1	1012450-15	60315G1	
	60330G3	60225G1		60317G1	
	60401G1	60226G1		60328G1	
	60407G1	60323G1		60414G1	
	60407G2	60331G1		60414G2	
	60427G1	60331G2		60613G1	
	60428G1	60516G1		60718G1	
	60428G2	60519G1		60810G1	
	60428G3	60721G1		60901G1	
	60429G1	60805G1		60922G1	
	60502G1	60824G1		61128G1	
	60603G1	60907G1		61130G1	
	60609G1	61004G1	1012450-20	60318G1	
	60621G1	61116G1		60329G1	
	60718G1	61128G1		60429G1	
	60720G1	61130G1		60613G1	
	60727G1	61206G1		60804G1	
	60801G1	60405G1	60929G1		
	60809G1	60412G1	1012451-06	60603G1	
	60810G1	60805G1		61006G1	
	60816G1	1012450-06	60610G1	1012451-08	60323G1
	60824G1		61101G1		60329G1
	60906G1	1012450-08	60530G1		60329G2
	60919G1		60803G1		60330G1
	60926G1		61014G1		60425G1
	60928G1		61206G1		60428G1
61104G1	1012450-12	60212G1	60526G1		
61107G1		60412G1	60531G1		
61111G1		60414G1	60623G1		
61111G3		60528G1	60713G1		



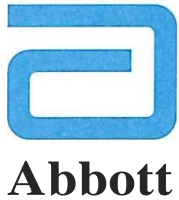
**Abbott**

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March 22, 2017

NC Trek RX Coronary Dilatation Catheter (Continued)

Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number	
1012451-08	60805G1	1012451-12	61108G1	1012451-15	60920G1	
	60819G1		61114G1		61010G1	
	60929G1		61122G1		61024G1	
	61104G1		61123G1		61101G1	
	61204G1		61130G1		61115G1	
	61206G1		61212G1		61118G1	
	61207G1		61212G2		61123G1	
	61208G1		61213G1		61123G2	
1012451-12	60205G1	1012451-15	60210G1		1012451-20	61202G1
	60214G1		60224G1			61204G1
	60215G1		60226G1	61214G1		
	60322G1		60227G1	60128G1		
	60330G1		60229G1	60307G1		
	60408G1		60307G1	60310G1		
	60415G2		60314G1	60318G1		
	60415G3		60329G1	60329G1		
	60415G4		60329G2	60419G1		
	60418G1		60331G1	60419G2		
	60418G2		60401G1	60519G1		
	60502G1		60408G1	60603G1		
	60525G2		60408G2	60824G1		
	60527G1		60505G1	60830G1		
	60527G2		60512G1	60901G1		
	60601G1		60603G1	60927G1		
	60616G1		60607G1	61115G1		
	60629G1		60628G1	61121G1		
	60720G1		60701G1	61201G1		
	60729G1		60720G1	1012451-25	60809G1	
	60805G1		60727G1	1012452-08	50114G1	
	60818G1		60801G1		50316G1	
	60829G1		60818G1		50319G1	
	60907G1		60826G1		50513G1	
	60922G1		60826G2		51022G1	
	61003G1		60909G1		51217G1	
	61010G1		60909G2		60112G1	
	61107G1		60913G1		60603G1	

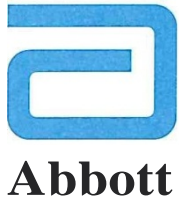


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March 22, 2017

NC Trek RX Coronary Dilatation Catheter (Continued)

Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
1012452-08	60810G1	1012452-15	60718G1	1012453-12	60705G1
	60921G1		60726G1		60722G1
	61007G1		60826G1		60810G1
	61216G1		61115G1		60907G1
1012452-12	50109G1		61128G1		61004G1
	50210G1		61208G1		61012G1
	50306G1	1012452-20	50106G1		61214G1
	50317G1		50120G1		61218G1
	50330G1		50204G1		1012453-15
	50420G1		50206G1	60303G1	
	50817G1		50316G1	60329G1	
	50928G1		50603G1	60331G1	
	51023G1		51110G1	60427G1	
	51029G1		60412G1	60428G1	
	60217G1		60607G1	60613G1	
	60226G1		61018G1	60617G1	
	60308G1		1012453-08	60405G1	
	60311G1			60413G1	60819G1
	60712G1	60413G2		60822G1	
	60909G1	60425G1		60909G1	
	61102G1	60425G2		61026G1	
	61122G1	60621G1		61111G1	
1012452-15	50105G1	60720G1		61121G1	
	50115G1	60729G1		1012453-20	60209G1
	50213G1	60819G1	60226G1		
	50316G1	61026G1	60505G1		
	50319G1	61130G1	60623G1		
	50420G1	61204G1	60810G1		
	50609G1	1012453-12	60926G1		
	50929G1		60302G1	61122G1	
	51103G1		60408G1		
	51109G1		60415G1		
	60224G1		60502G1		
	60331G1		60502G2		
	60405G1		60503G1		
	60505G1		60503G2		
	60621G1				



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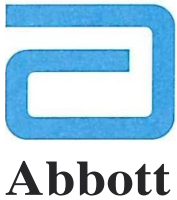
NC Tenku RX PTCA Balloon Catheter

Part Number	Lot Number
1012448-08T	60202G1
	60301G1
	60502G1
1012448-12T	60301G1
	60401G1
	61101G1
1012448-15T	60202G1
	60401G1
	60601G1
	60801G1
	61101G1
1012449-08T	60302G1
	60401G1
	60601G1
	60801G1
1012449-12T	60202G1
	60401G1
	60502G1
	60601G1
	60701G1
	60902G1
	61004G1
	61101G1
1012449-15T	60202G1
	60301G1
	60401G1
	60502G1
	60601G1
	60701G1
	60801G1
	60902G1
	61101G1
1012450-08T	60401G1

Part Number	Lot Number
1012450-08T	60601G1
	60801G1
1012450-12T	60301G1
	60701G1
1012450-15T	60301G1
	60502G1
	60701G1
1012451-08T	60301G1
	60502G1
	60701G1
	60902G1
1012451-12T	60301G1
	60502G1
	60701G1
	61004G1
	60301G1
1012451-15T	60401G1
	60601G1
	60701G1
	60805G1
	61004G1
	50204G1
1012452-08T	50406G1
	50202G1
1012452-12T	50901G1
	50204G1
1012452-15T	50204G1
	60202G1
	60502G1
1012453-08T	60701G1
	61101G1
	60202G1
1012453-12T	60506G1

NC Traveler RX Coronary Dilatation Catheter

Part Number	Lot Number
1013152-12	61209G1
	61209G2
1013152-15	61102G1
1013152-20	61102G1
1013153-08	61012G1
	61209G1
1013153-12	61101G1
1013153-15	60415G1
	61209G1
1013153-20	61102G1
1013154-08	61101G1
1013154-12	61101G1
1013154-15	61102G1
1013154-20	60415G1
1013155-08	61102G1
1013155-12	61101G1
1013155-15	60415G1
	61209G1
1013155-20	61102G1
1013156-12	50415G1
	50919G1
	51110G1
	61209G1
1013156-15	50919G1
	51210G1
	61101G1
1013157-08	61102G1
1013157-12	60415G1
	61102G1
1013157-15	60415G1
	61209G1



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COMMERCIAL NAME: NC Trek RX Coronary Dilatation Catheter  
NC Traveler RX Coronary Dilatation Catheter  
NC Tenku RX PTCA Balloon Catheter  
FSCA-Identifier: March 22, 2017  
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 Coronary Dilatation Catheter, NC Traveler RX Coronary Dilatation Catheter, and NC Tenku RX PTCA Balloon Catheter, please check one box in the section below. If affected inventory was identified, please contact Customer Services to obtain a Returned Goods Authorization (RGA) number. After signing this form, please return the form and any identified products to Abbott Vascular.

- A thorough search for all affected products has been completed and no affected units remain in inventory.  
**No devices will be returned.**
- Affected NC Trek RX Coronary Dilatation Catheter, NC Traveler RX Coronary Dilatation Catheter, and NC Tenku RX PTCA Balloon 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 Vascular

- If returning product, call Abbott Vascular Customer Service XXX XXX XXXX to receive RGA number. Record RGA number above.
- Fax this completed form to XXX XXX XXXX or scan an e-mail to XXXXXXXXXXXX
- Return a copy of this completed form with the returned product.