



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: Dear Abbott Vascular Distributor

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
- The use of devices from these lots should cease immediately.
- Please review your inventory, identify your customers who have received affected units
- Notify all impacted customers of this FSCA and retrieve the unused units
- Where required by Country regulation, notify the Competent Authority of this FSCA
- Return all unused identified products to Abbott Vascular
- Share this notification with other relevant personnel in your organization
- Complete the Effectiveness Check form and Closure Statement at the end of this letter

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.

Sincerely,



Hassan Hamouda
General Manager

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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	60218G1	61123G2	
	60408G1		60303G1	61201G1	
	60408G2		60330G1	61208G1	
	60510G1		60330G2	61214G1	
	60616G1		60406G1	61214G2	
	60721G1		60406G2	61216G1	
	60809G1		60406G3	61216G2	
	60912G1		60406G4	1012449-15	60128G1

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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	1012449-20	60126G1	1012450-15	61209G1	
	60330G2		60223G1		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	1012449-25	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			

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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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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	60301G1
	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		60721G1
	60311G1		60413G1		60819G1
	60712G1		60413G2	60822G1	
	60909G1		60425G1	60909G1	
	61102G1		60425G2	61026G1	
	61122G1		60621G1	61111G1	
	1012452-15		50105G1	60720G1	61121G1
			50115G1	60729G1	1012453-20
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
	60301G1
1012451-12T	60301G1
	60502G1
	60701G1
	61004G1
1012451-15T	60301G1
	60401G1
	60601G1
	60701G1
	60805G1
	61004G1
	50204G1
1012452-08T	50406G1
	50202G1
1012452-12T	50901G1
1012452-15T	50204G1
1012453-08T	60202G1
	60502G1
	60701G1
	61101G1
1012453-12T	60202G1
	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
1013156-15	61209G1
	50919G1
	51210G1
1013157-08	61101G1
	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

Distributor Effectiveness Check Form and Closure Statement

Distributor Account # _____
Account Name _____
Address _____

(Information required for regulatory effectiveness check)

We confirm that;

- All concerned customers of the affected devices, if any, have been identified and notified of this FSCA
- The Competent Authority has been informed, where required by country regulation

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, after signing this form, please return it 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: _____

Distributor Authorised Person

Title (print)

Signature

Date

This form is to be returned to Abbott Vascular

- If returning product, call Abbott Vascular Customer Service to receive RGA number.
- Record RGA number above.
- Scan an e-mail to eva.boruvkova@av.abbott.com and marram.el-maraghy@av.abbott.com.

Return a copy of this completed form with the returned product.