

ALERTA

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una Alerta asociada a:

NOMBRE DEL DISPOSITIVO MÉDICO	Catéter de Dilatación Coronaria ABBOTT VASCULAR
NO. IDENTIFICACIÓN RISARH	A1704-129
REFERENCIAS DEL DISPOSITIVO MEDICO	1012448-06, 1012448-12, 1012448-15, 1012448-20, 1012449-06, 1012449-08, 1012449-12, 1012449-15, 1012449-20, 1012449-25, 1012450-06, 1012450-08, 1012450-12, 1012450-15, 1012450-20, 1012451-06, 1012451-08, 1012451-12, 1012451-15, 1012451-20, 102451-25, 102452-08, 1012452-12, 1012452-15, 1012452-20, 1012453-08, 1012453-12, 1012453-15, 1012453-20, 1012448-08T, 1012448-12T, 1012448-15T, 1012449-08T, 1012449-12T, 1012449-15T, 1012450-08T, 1012450-12T, 1012450-15T, 1012451-08T, 1012451-12T, 1012451-15T, 1012452-08T, 1012452-12T, 1012452-15T, 1012453-08T, 1012453-12T, 1013152-12, 1013152-15, 1013152-20, 1013153-08, 1013153-12, 1013153-15, 1013153-20, 1013154-08, 1013154-12, 1013154-15, 1013154-20, 1013155-08, 1013155-12, 1013155-15, 1013155-20, 1013156-12, 1013156-15, 1013157-08, 1013157-12, 1013157-15, lotes específicos.
REGISTRO SANITARIO	2017DM-0015991
INDICACIONES Y USO ESTABLECIDOS	Los catéteres para dilatación coronaria se emplean para: 1. La dilatación con balón de la porción estenótica de una arteria coronaria o de la estenosis de un injerto de derivación con el fin de mejorar la perfusión del miocardio. 2. La dilatación con balón de una oclusión en una arteria coronaria, con objeto de restablecer el flujo coronario en los casos de infarto de miocardio con elevación del segmento ST. 3. La dilatación con balón de un stent después de implantarlo (modelos de balón de 2,00 mm a 5,00 mm solamente).
NOMBRE DEL FABRICANTE	Abbott Vascular

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DESCRIPCIÓN DEL PROBLEMA El fabricante informa que las vainas de los globos protectores de los catéteres anteriores pueden ser difíciles de eliminar, causando dificultades con inflar o desinflar el balón, lo cual podría conllevar a que se presenten potencialmente eventos adversos serios sobre los pacientes.

FUENTE ANEXO 1

FECHA DE NOTIFICACION 04 de Abril de 2017

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

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ANEXO 1

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[Critical Priority] - A28295 : Abbott Vascular—NC Trek and NC Traveler Dilatation Catheters and NC Tenku RX PTCA Balloon Catheters: Protective Balloon Sheath May Be Difficult to Remove Medical Device Ongoing Action

Published: Wednesday, March 29, 2017
Last Updated: Friday, March 31, 2017

UMDNS Terms:

- Catheters, Vascular, Angioplasty, Balloon [17184]
- Catheters, Vascular, Angioplasty, Balloon, Coronary [34313]

Product Identifier:

Catheters:	Part No.	Lot Nos.:
NC Trek RX Coronary Dilatation	1012448-06	60414G1, 60721G1
NC Trek RX Coronary Dilatation	1012448-08	60208G1, 60419G1, 60420G1, 60603G1, 60906G1, 61121G1, 61121G2
NC Trek RX Coronary Dilatation	1012448-12	60225G1, 60229G1, 60318G1, 60318G2, 60429G1, 60429G2, 60607G1, 60705G1, 60804G1, 60818G1, 60921G1, 60921G2, 61108G1, 61111G1, 61128G1, 61128G2, 61218G1
NC Trek RX Coronary Dilatation	1012448-15	60202G1, 60310G1, 60401G1, 60408G1, 60408G2, 60510G1, 60616G1, 60721G1, 60809G1, 60912G1, 61014G1, 61028G1, 61206G1, 61206G2
NC Trek RX Coronary Dilatation	1012448-20	60310G1, 60421G1, 60421G2, 60527G1, 60716G1, 60819G1, 61024G2
NC Trek RX Coronary Dilatation	1012449-06	60523G1, 61026G1
NC Trek RX Coronary Dilatation	1012449-08	60317G1, 60318G1, 60412G1, 60419G1, 60502G1, 60502G2, 60525G1, 60705G1, 60801G1, 60809G1, 60826G1, 60916G1, 61018G1, 61121G1, 61121G2
NC Trek RX Coronary Dilatation	1012449-12	60218G1, 60303G1, 60330G1, 60330G2, 60406G1, 60406G2, 60406G3, 60406G4, 60408G1, 60413G1, 60413G2, 60425G1, 60429G1, 60511G1, 60512G1, 60531G1, 60607G1, 60623G1, 60713G1, 60721G1, 60804G1, 60805G1, 60809G1, 60812G1, 60816G1, 60824G1, 60926G1, 60929G1, 61012G1, 61019G1, 61019G2, 61020G1, 61115G1, 61121G1, 61122G1, 61123G1, 61123G2, 61201G1, 61208G1, 61214G1, 61214G2, 61216G1, 61216G2
NC Trek RX Coronary Dilatation	1012449-15	60128G1, 60215G1, 60215G2, 60224G1, 60322G1, 60329G1, 60330G1, 60330G2, 60330G3, 60401G1, 60407G1, 60407G2, 60427G1, 60428G1, 60428G2, 60428G3, 60429G1, 60502G1, 60603G1, 60609G1, 60621G1, 60718G1, 60720G1, 60727G1, 60801G1, 60809G1, 60810G1, 60816G1, 60824G1, 60906G1, 60919G1, 60926G1, 60928G1, 61104G1, 61107G1, 61111G1

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NC Trek RX Coronary Dilatation	1012449-20	60126G1, 60223G1, 60225G1, 60226G1, 60323G1, 60331G1, 60331G2, 60516G1, 60519G1, 60721G1, 60805G1, 60824G1, 60907G1, 61004G1, 61116G1, 61128G1, 61130G1, 61206G1
NC Trek RX Coronary Dilatation	1012449-25	60405G1, 60412G1, 60805G1
NC Trek RX Coronary Dilatation	1012450-06	60610G1, 611101G1
NC Trek RX Coronary Dilatation	1012450-08	60530G1, 60803G1, 61014G1, 61206G1
NC Trek RX Coronary Dilatation	1012450-12	60212G1, 60412G1, 60414G1, 60528G1, 60623G1, 60831G1, 60921G1, 61104G1, 61207G1, 61209G1
NC Trek RX Coronary Dilatation	1012450-15	60315G1, 60317G1, 60328G1, 60414G1, 60414G2, 60613G1, 60718G1, 60810G1, 60901G1, 60922G1, 61128G1, 61130G1
NC Trek RX Coronary Dilatation	1012450-20	60318G1, 60329G1, 60429G1, 60613G1, 60804G1, 60929G1
NC Trek RX Coronary Dilatation	1012451-06	60603G1, 61006G1
NC Trek RX Coronary Dilatation	1012451-08	60323G1, 60329G1, 60329G2, 60330G1, 60425G1, 60428G1, 60526G1, 60531G1, 60623G1, 60713G1, 60805G1, 60819G1, 60929G1, 61104G1, 61204G1, 61206G1, 61207G1, 61208G1
NC Trek RX Coronary Dilatation	1012451-12	60205G1, 60214G1, 60215G1, 60322G1, 60330G1, 60408G1, 60415G2, 60415G3, 60415G4, 60418G1, 60418G2, 60502G1, 60525G2, 60527G1, 60527G2, 60601G1, 60616G1, 60629G1, 60720G1, 60729G1, 60805G1, 60818G1, 60829G1, 60907G1, 60922G1, 61003G1, 61010G1, 61107G1, 61108G1, 61114G1, 61122G1, 61123G1, 61130G1, 61212G1, 61212G2, 61213G1
NC Trek RX Coronary Dilatation	1012451-15	60210G1, 60224G1, 60226G1, 60227G1, 60229G1, 60307G1, 60314G1, 60329G1, 60329G2, 60331G1, 60401G1, 60408G1, 60408G2, 60505G1, 60512G1, 60603G1, 60607G1, 60628G1, 60701G1, 60720G1, 60727G1, 60801G1, 60818G1, 60826G1, 60826G2, 60909G1, 60909G2, 60913G1, 60920G1, 61010G1, 61024G1, 61101G1, 61115G1, 61118G1, 61123G1, 61123G2, 61202G1, 61204G1, 61214G1
NC Trek RX Coronary Dilatation	1012451-20	60128G1, 60307G1, 60310G1, 60318G1, 60329G1, 60419G1, 60419G2, 60519G1, 60603G1, 60824G1, 60830G1, 60901G1, 60927G1, 61115G1, 61121G1, 61201G1

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NC Trek RX Coronary Dilatation	102451-25	60809G1
NC Trek RX Coronary Dilatation	102452-08	50114G1, 50316G1, 50319G1, 50513G1, 51022G1, 51217G1, 60112G1, 60603G1, 60810G1, 60921G1, 61007G1, 61216G1
NC Trek RX Coronary Dilatation	1012452-12	50109G1, 50210G1, 50306G1, 50317G1, 50330G1, 50420G1, 50817G1, 50928G1, 51023G1, 51029G1, 60217G1, 60226G1, 60308G1, 60311G1, 60712G1, 60909G1, 61102G1, 61122G1
NC Trek RX Coronary Dilatation	1012452-15	50105G1, 50115G1, 50213G1, 50316G1, 50319G1, 50420G1, 50609G1, 50929G1, 51103G1, 51109G1, 60224G1, 60331G1, 60405G1, 60505G1, 60718G1, 60726G1, 60826G1, 61115G1, 61128G1, 61208G1
NC Trek RX Coronary Dilatation	1012452-20	50106G1, 50120G1, 50204G1, 50206G1, 50316G1, 50603G1, 51110G1, 60412G1, 60607G1, 61018G1
NC Trek RX Coronary Dilatation	1012453-08	60405G1, 60413G1, 60413G2, 60425G1, 60425G2, 60621G1, 60720G1, 60729G1, 60819G1, 61026G1, 61130G1, 61204G1
NC Trek RX Coronary Dilatation	1012453-12	60302G1, 60408G1, 60415G1, 60502G1, 60502G2, 60503G1, 60503G2, 60621G1, 60705G1, 60722G1, 60810G1, 60907G1, 61004G1, 61012G1, 61214G1, 61218G1
NC Trek RX Coronary Dilatation	1012453-15	60301G1, 60303G1, 60329G1, 60331G1, 60427G1, 60428G1, 60613G1, 60617G1, 60721G1, 60819G1, 60822G1, 60909G1, 61026G1, 61111G1, 61121G1
NC Trek RX Coronary Dilatation	1012453-20	60209G1, 60226G1, 60505G1, 60623G1, 60810G1, 60926G1, 61122G1
NC Tenku RX Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon	1012448-08T	60202G1, 60301G1, 60502G1
NC Tenku RX PTCA Balloon	1012448-12T	60301G1, 60401G1, 61101G1
NC Tenku RX PTCA Balloon	1012448-15T	60202G1, 60401G1, 60601G1, 60801G1, 61101G1
NC Tenku RX PTCA Balloon	1012449-08T	60302G1, 60401G1, 60601G1, 60801G1
NC Tenku RX PTCA Balloon	1012449-12T	60202G1, 60401G1, 60502G1, 60601G1, 60701G1, 60902G1, 61004G1, 61101G1
NC Tenku RX PTCA Balloon	1012449-15T	60202G1, 60301G1, 60401G1, 60502G1, 60601G1, 60701G1, 60801G1, 60902G1, 61101G1
NC Tenku RX PTCA Balloon	1012450-08T	60401G1, 60601G1, 60801G1
NC Tenku RX PTCA Balloon	1012450-12T	60301G1, 60701G1
NC Tenku RX PTCA Balloon	1012450-15T	60301G1, 60502G1, 60701G1
NC Tenku RX PTCA Balloon	1012451-08T	60301G1, 60502G1, 60701G1, 60902G1

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NC Tenku RX PTCA Balloon	1012451-12T	60301G1, 60502G1, 60701G1, 61004G1
NC Tenku RX PTCA Balloon	1012451-15T	60301G1, 60401G1, 60601G1, 60701G1, 60805G1, 61004G1
NC Tenku RX PTCA Balloon	1012452-08T	50204G1, 50406G1
NC Tenku RX PTCA Balloon	1012452-12T	50202G1, 50901G1
NC Tenku RX PTCA Balloon	1012452-15T	50204G1
NC Tenku RX PTCA Balloon	1012453-08T	60202G1, 60502G1, 60701G1, 61101G1
NC Tenku RX PTCA Balloon	1012453-12T	60202G1, 60506G1
NC Traveler RX Coronary Dilatation	1013152-12	61209G1, 61209G2
NC Traveler RX Coronary Dilatation	1013152-15	61102G1
NC Traveler RX Coronary Dilatation	1013152-20	61102G1
NC Traveler RX Coronary Dilatation	1013153-08	61012G1, 61209G1
NC Traveler RX Coronary Dilatation	1013153-12	61101G1
NC Traveler RX Coronary Dilatation	1013153-15	60415G1, 61209G1
NC Traveler RX Coronary Dilatation	1013153-20	61102G1
NC Traveler RX Coronary Dilatation	1013154-08	61101G1
NC Traveler RX Coronary Dilatation	1013154-12	61101G1
NC Traveler RX Coronary Dilatation	1013154-15	61102G1
NC Traveler RX Coronary Dilatation	1013154-20	60415G1
NC Traveler RX Coronary Dilatation	1013155-08	61102G1
NC Traveler RX Coronary Dilatation	1013155-12	61101G1
NC Traveler RX Coronary Dilatation	1013155-15	60415G1, 61209G1
NC Traveler RX Coronary Dilatation	1013155-20	61102G1
NC Traveler RX Coronary Dilatation	1013156-12	50415G1, 50919G1, 51110G1, 61209G1
NC Traveler RX Coronary Dilatation	1013156-15	50919G1, 51210G1, 61101G1
NC Traveler RX Coronary Dilatation	1013157-08	61102G1
NC Traveler RX Coronary Dilatation	1013157-12	60415G1, 61102G1
NC Traveler RX Coronary Dilatation	1013157-15	60415G1, 61209G1

Geographic Regions: Worldwide

Manufacturer(s): Abbott Vascular Devices Div Abbott Laboratories Inc 3200 Lakeside Drive, Santa Clara, CA 95054, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Nursing, OR/Surgery, Vascular Laboratory, Materials Management

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Problem: In a March 22, 2017, Urgent Field Safety Notice /Device Recall letter submitted by ECRI Institute member hospitals and posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA), Abbott Vascular states that the protective balloon sheaths of the above catheters may be difficult to remove, which could cause difficulties with inflating or deflating the balloon. Abbott Vascular also states that potential risks associated with balloon inflation and deflation difficulties include air embolism, the need for additional intervention, thrombosis, and myocardial infarction. Abbott Vascular further states that it has received one report in which failure to deflate the balloon necessitated surgery, leading to multiple postoperative complications and death.

Action Needed: Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product, verify that you have received the March 22, 2017, Urgent Field Safety Notice Device Recall letter and Effectiveness Check Form from Abbott Vascular. Complete the Effectiveness Check Form, and return it to Abbott Vascular using the instructions on the form. Return unused affected product to Abbott Vascular. Abbott Vascular will work with your facility to replace returned units with similar product, pending availability. Notify all relevant personnel at your facility of the information in the letter, and forward a copy of the letter to any facility to which you have further distributed affected product.

For Further Information:

Abbott Vascular

Tel.: (800) 227-9902 (U.S.) or (0800) 973246 (U.K.)

Website: [Click here](#)

References:

- Great Britain. Medicines and Healthcare Products Regulatory Agency. Abbott: NC Trek RX coronary dilatation catheter, NC Traveler RX coronary dilatation catheter and NC Tenku RX PTCA balloon catheter [online]. London: Department of Health; 2017 Mar 27 [cited 2017 Mar 27]. (Field safety notice; reference no. 2017/003/021/291/006). Available from Internet: [Click here](#) .

Comments:

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our [HDA Format Guide](#) .

Source(s):

- 2017 Mar 24. Member Hospital. March 22, 2017 Abbott letter submitted by ECRI Institute member hospitals (includes reply form) [Download](#)
- 2017 Mar 28. MHRA FSN. 2017/003/021/291/006 [Download](#)
- 2017 Mar 28. MHRA FSN. March 22, 2017 Abbott letter posted by MHRA (includes reply form) [Download](#)
- 2017 Mar 29. Manufacturer. Manufacturer confirmed information.