INFORME DE SEGURIDAD

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 un Informe de Seguridad asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Catéteres Centrales para Inserción Periférica ARROW
NO. IDENTIFICACIÓN RISARH	I1702-35
REFERENCIAS DEL DISPOSITIVO MEDICO	ASK-01663-MST, ASK-04001-DU4, ASK-04001-DU5, PH-01351-LS, PI-01351-LS5, PI-01351-SS, PI-01451-LS, PI-01451-LS5, PI-01451-SS, PI-01552-LS, PI-01552-LS5, PI-01552-SS, PL-05041, PL-05052, PR-05041, PR-05041-T, PR-05042, PR-05052, PR-05052-MW, UK-25004-ANHS, UK-25005-ANHS y UK-25006-ANHS, lotes específicos.
REGISTRO SANITARIO	2011DM-0000097-R1
INDICACIONES Y USO ESTABLECIDOS	Indicada para acceso periférico a corto y largo plazo al sistema venoso central para terapia intravenosa, toma de muestras sanguíneas, infusión, inyección energizada o medios de contraste y monitoreo de la presión venosa central (CVP).
NOMBRE DEL FABRICANTE	Arrow Internacional De Chihuahua S.A. De C.V. Arrow International Inc. Arrow.
DESCRIPCION DEL PROBLEMA	El fabricante indica que ha recibido informes donde los componentes de la vaina de desprendimiento en los dispositivos referenciados pueden estallar, también ha detectado que las instrucciones de uso (IFU) incluidas, no informan al usuario de que una incisión en la piel o un método de ampliación alternativa pueden ser necesarios en casos de inserciones difíciles, conllevando a que se presenten posibles eventos adversos serios sobre el paciente y retrasos en el procedimiento quirúrgico.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	10 de Febrero de 2017

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

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

INFORME DE SEGURIDAD

DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

ANEXO 1

[High Priority] - A27930 : Teleflex—Arrow PICC Kits with Peel-Away Sheath Component: Peel-Away Sheath May Flare
Medical Device Ongoing Action

Published: Thursday, January 19, 2017

UMDNS Terms:

- Catheters, Vascular, Infusion, Central Venous, Peripherally-Inserted [18017]

Product Identifier:
Arrow Peripherally-Inserted Central Catheter (PICC) Kits with Peel-Away Sheath Component *[Consumable]*

Material Nos.:	Batch Nos.:
ASK-01663-MST	13F15G0480, 13F15J0148, 13F15K0270, 13F16B0162, 13F16A0227, 13F16F0072, 13F16J0290, 23F14C0035, 23F14C0991, 23F14D0293, 23F14K0013, 23F14M0271, 23F14M1344, 23F15C0653
ASK-04001-DU4	23F14M0791
ASK-04001-DU5	23F15A1551
PH-01351-LS	14F15L0237, 14F16G0236, 23F14A1014, 23F14K1387, 23F15A1156, 23F15D0462, 23F15E1503, 23F15F1353, 23F15F1354, RF1128391, RF2045491, RF2071833, RF2095680, RF2111193
PI-01351-LS5	23F15G0169
PI-01351-SS	14F16C0692, 23F14A1682, 23F14F1527, 23F15D0169, 23F15D1498, 23F15B0290, 23F15C1538, RF1106042, RF2046039, RF2068985, RF2072255, RF2083178, RF2121617, RF3041213, RF3065253
PI-01451-LS	14F15G0383, 14F15H0007, 14F15H0150, 14F15L0001, 14F15L0083, 14F15M0351, 14F16B0490, 14F16C0647, 14F16D0430, 23F14B0935, 23F14H1535, 23F14J0437, 23F14K0406, 23F15A0278, 23F15C0879, 23F15D0302, 23F15D0907, 23F15F0203, 23F15F1270, RF2010466, RF2056533, RF2071225, RF2083179
PI-01451-LS5	14F15L0257, 14F16C0405, 23F14F0326, 23F14G1587, 23F14K1016, 23F15A1813, 23F15F0508, RF2022459, RF2060059
PI-01451-SS	14F15L0346, 14F15M0189, 14F16A0564, 23F13M0611, 23F14D1388, 23F14H1258, 23F14K0710, RF2033296, RF2046451, RF2121618, RF3054225

	14F15G0206, 14F15G0207, 14F15G0208, 14F15G0209, 14F15H0018, 14F15H0154, 14F15K0117, 14F15K0409,
PI-01552-LS	14F15L0002, 14F15L0166, 14F15L0348, 14F16B0094, 14F16B0492, 14F16C0543, 14F16D0580, 14F16F0059, 14F16F0302, 14R15G0206, 14R15G0207, 14R15G0208, 14R15G0209, 23F14A1208, 23F14A1624, 23F14B0780, 23F14B1051, 23F14C0951, 23F14D0649, 23F14E0278, 23F14F0391, 23F14H0291, 23F14J0403, 23F14J0634, 23F14K0032, 23F14K1364, 23F15A0280, 23F15A0814, 23F15A1477, 23F15D0047, 23F15D0908, 23F15F0509, 23F15F0884, RF2019389, RF2022082, RF2045175, RF2069107, RF2084861, RF2108228
PI-01552-LS5	14F15H0053, 14F15L0081, 14F16B0099, 14F16D0054, 14F16E0298, 23F14H1259, 23F14K0711, 23F15A0283, 23F15C0802, 23F15E1402, RF2021185, RF2058413, RF2082779, RF2119502
PI-01552-SS	14F15L0181, 14F15M0326, 23F13H0153, 23F13M0083, 23F14D0265, 23F14D0937, 23F14K0461, 23F14K1388, 23F15B0291, 23F15E0342, RF1117965, RF2044699, RF2057554, RF2096720, RF3013607, RF3039168
PL-05041	23F13H0424, 23F13J0462, 23F14G1310, 23F14H0905, 23F14J0192, 23F15D1811, RF3026385, RF3039521
PL-05052	13F15F0006, 13F15M0096, 13F16B0150, 13F16E0030, 13F16K0041, 23F13L0686, 23F14F0045, 23F14K1132, 23F14M0231, 23F15B1326, 23F15D1393, RF2010122, RF2032944, RF2046123, RF2083835, RF2108991, RF2110308, RF2123072, RF3026372, RF3039532, RF3064828
PR-05041	23F13L0220, 23F14A1661, 23F14B0516, 23F14B0788, 23F14C0659, 23F14E0077,

	23F14E0280, 23F14G1209, 23F14G1300, 23F14H1260, 23F14K1262, 23F14K1389, 23F14M0379, 23F15A0247, 23F15A1721, 23F15C0479, 23F15C1540, 23F15D0168, 23F15D0560, 23F15H0957, 23F15K0529, RF2069980, RF2083226, RF2110045, RF2110992
PR-05041-T	23F14K0179, 23F15B0207, RF2071835
PR-05042	14F15H0104, 14F15K0605, 14F15L0028, 14F16B0096, 14F16C0048, 14F16C0344, 14R16B0096, 23F14A1658, 23F14E0159, 23F14H1334, 23F14K0268, 23F14K0948, 23F15A0110, 23F15B1491, 23F15C2142, 23F15D0163, 23F15D0986, 23F15F1950, 23F15G0343, 23F15H0890, 23F15J0701, 23F15J0922, 23F15L0219, 23F16D0169, RF2060744, RF2107370
PR-05052	23F13K1019, 23F13M0035, 23F14B1049, 23F14A1644, 23F14B0043, 23F14B0604, 23F14D0133, 23F14J1296, 23F14J1437, 23F14K0520, 23F14L0390, 23F14L0780, 23F14M0034, 23F14M0732, 23F14M1087, 23F15A1164, 23F15A1722, 23F15B0296, 23F15B1497, 23F15C0453, 23F15D0988, 23F15D1865, 23F15E0355, 23F15F0904, 23F15M0138, 23F16A0552, 23F16B0598, 23F16D0676, 23F16E0887, RF2069098, RF2072200, RF2096576
PR-05052-MW	14F15H0365, 14F15K0566, 14F15L0003, 14F15L0562, 14F16A0080, 14F16B0243, 14F16D0251, 23F14F0631, 23F14F1536, 23F14L0783, 23F14M0656, 23F15A1297, 23F15A1725, 23F15B1908, 23F15D1867, 23F15E1694, 23F15M0548, 23F16C0107, 23F16C0704, 23F16D0677
UK-25004-ANHS	71F16C1748, 71F16E1175, 71F16F0721, 71F16G0428
UK-25005-ANHS	71F16C1862, 71F16D0984, 71F16F0719, 71F16F2061
UK-25006-ANHS	71F16C1749, 71F16F0717

Geographic Regions: Argentina, Australia, Belgium, Canada, Chile, Colombia, Costa Rica, Dominican Republic, Guatemala, Ireland, India, Mexico, Malaysia, New Zealand, Peru, Saudi Arabia, Singapore, Taiwan, U.S.

Manufacturer(s): Arrow International Inc, a Teleflex company2400 Bernville Rd, Reading, PA 19605, United States

Suggested Distribution: Cardiology/Cardiac Catheterization Laboratory, Critical Care, Nursing, OR/Surgery, IV Therapy, Materials Management

Problem:
In a January 13, 2017, Urgent Medical Device Notification letter submitted by ECRI Institute member hospitals, Teleflex states that it has received reports that the peel-away sheath components in the above kits may flare. Teleflex also states that the instructions for use (IFU) included in the kits do not inform the user that a skin nick or alternative enlargement method may be required for difficult insertions. Teleflex further states that the use of a skin nick reduces the probability of a sheath flare and subsequent complications. Teleflex states that there is a remote possibility of this problem causing a delay in treatment or minor vessel wall trauma and bleeding.

Action Needed:
Identify any affected kits in your inventory. If you have affected kits, verify that you have received the January 13, 2017, Urgent Medical Device Notification letter from Teleflex. No further action is required.

For Further Information:
Teleflex customer service department
Tel.: (866) 246-6990

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 Jan 19. Member Hospital. Teleflex letter submitted by an ECRI Institute member hospital Download
- 2017 Jan 19. Manufacturer. Teleflex confirmed the information provided in the source material.