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	Sistema Endovascular AAA y Sistema Introductor AFX ENDOLOGIX
NO. IDENTIFICACIÓN RISARH	A1702-36
REFERENCIAS DEL DISPOSITIVO MEDICO	AFX y AFX2, lotes específicos.
REGISTRO SANITARIO	2012DM-0009133
INDICACIONES Y USO ESTABLECIDOS	Establecer el acceso vascular a la arteria femoral o iliaca para insertar el injerto de stent precargado de manera endoluminal sobre un alambre guía.
NOMBRE DEL FABRICANTE	Endologix Inc.
DESCRIPCION DEL PROBLEMA	El fabricante afirma que en enero de 2013 llevó a cabo una investigación sobre los informes de tipo IIIA endofugas (separación de injertos de stent bifurcados y extensión en el punto de solapamiento) con los sistemas anteriores, que fue seguido por una investigación sobre las endofugas tipo IIIb (interrupción del material de injerto de stent) en septiembre de 2013, donde concluyo que ese tipo de fugas internas pueden causar aumento de la presión en el saco del aneurisma, lo que podría potencialmente aumentar el riesgo de rotura del aneurisma y la muerte del paciente, igualmente durante el tiempo de las investigaciones, se llevaron a cabo una serie de cambios a las instrucciones de uso (IFU) del producto, con el fin de evitar que se presenten este tipos de complicaciones y eventos serios sobre los pacientes.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	10 de Febrero de 2017

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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

[High Priority] - A27814 : Endologix—AFX and AFX2 AAA Endovascular Systems: Manufacturer Provides Information Regarding Type III Endoleaks; Manufacturer Recalls Certain AFX and AFX2 Devices
Medical Device Ongoing Action

Published: Monday, January 16, 2017

UMDNS Terms:

- Catheters, Vascular, Guiding [17846]

Product Identifier:
Endovascular Abdominal Aortic Aneurysm (AAA) Systems: (1) AFX, (2) AFX2 *[Consumable]*
Recalled AFX Devices with Strata Graft Material:

Model Nos.:	Product ("F") Nos.:
A22-22/C55	F00381
A22-22/C55-O20	F00387
A22-22/C55-O20V	F00726-01
A22-22/C55V	F00703-01
A22-22/C75-O20	F00392
A22-22/C75-O20V	F00726-02
A22-22/C75V	F00703-02
A22-22/C95	F00442
A22-22/C95-O20	F00405
A22-22/C95-O20V	F00726-03
A22-22/C95V	F00703-03
A25-25/C55	F00382
A25-25/C55-O20	F00388
A25-25/C55-O20V	F00726-04
A25-25/C55V	F00703-04
A25-25/C75-O20	F00393
A25-25/C75	F00385
A25-25/C75-O20V	F00726-05
A25-25/C75V	F00703-05
A25-25/C95	F00390
A25-25/C95-O20	F00395
A25-25/C95-O20V	F00726-06
A25-25/C95V	F00703-06
A28-28/C55	F00383
A28-28/C55-O20	F00389
A28-28/C55-O20V	F00726-07
A28-28/C55V	F00703-07
A28-28/C75	F00386
A28-28/C75-O20	F00394
A28-28/C75-O20V	F00726-08
A28-28/C75V	F00703-08
A28-28/C95	F00391
A28-28/C95-O20	F00370
A28-28/C95-O20V	F00726-09
A28-28/C95V	F00703-09
A22-22/C75	F00384
A31-31/C80-O20V	F00726-10
A31-31/C100	F00443
A31-31/C100-O20V	F00726-11
A31-31/C100V	F00703-11
A31-31/C80	F00396
A31-31/C80-O20	F00398
A31-31/C80V	F00703-10
A31-31/C100-O20	F00404
A34-34/C100-O20	F00369
A34-34/C100-O20V	F00726-13

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A34-34/C100	F00399
A34-34/C100V	F00703-13
A34-34/C80	F00397
A34-34/C80-020	F00400
A34-34/C80-020V	F00726-12
A34-34/C80V	F00703-12
BA22-100/I13-40	F00412
BA22-100/I16-40	F00429
BA22-40/I13-40	F00611
BA22-60/I13-40	F00406
BA22-60/I16-40	F00418
BA22-70/I16-30	F00415
BA22-70/I20-30	F00622
BA22-80/I13-40	F00409
BA22-80/I16-40	F00424
BA22-80/I20-40	F00627
BA22-90/I16-30	F00421
BA22-90/I20-30	F00623
BA25-100/I16-40	F00430
BA25-100/I16-55	F00432
BA25-100/I13-40	F00413
BA25-110/I16-30	F00635
BA25-110/I20-30	F00642'
BA25-120/I16-40	F00637
BA25-120/I20-40	F00600
BA25-60/I13-40	F00407
BA25-60/I16-40	F00419
BA25-70/I16-30	F00416
BA25-70/I20-30	F00640
BA25-80/I13-40	F00410
BA25-80/I16-55	F00427
BA25-80/I20-40	F00645
BA25-80/II 6-40	F00425
BA25-90/I20-30	F00641
BA25-90/I16-30	F00422
BA28-100/I13-40	F00414
BA28-100/I16-40	F00431
BA28-100/I16-55	F00368
BA28-120/I16-40	F00655
BA28-120/I20-40	F00601
BA28-60/I13-40	F00408
BA28-60/I16-40	F00420
BA28-70/I20-30	F00658
BA28-70/I16-30	F00417
BA28-80/I13-40	F00411
BA28-80/I16-40	F00426
BA28-80/I16-55	F00428
BA28-80/I20-40	F00663
BA28-90/I16-30	F00423
BA28-90/I20-30	F00659
I16-16/C55	F00561
I16-16/C55 SA	F00551
I16-16/C55F	F00371
I16-16/C55F SA	F00553
I16-16/C88	F00373
I16-16/C88 SA	F00552
I20-13/C70F SA	F00556

I20-13/C88F	F00567
I20-20/C55	F00564
I20-20/C55 SA	F00554
I20-20/C55F	F00375
I20-20/C55F SA	F00555
I20-13/C70F	F00566
I20-13/C88F SA	F00557
IF20-25/C65	F00379
IF20-25/C65 SA	F00560
IS20-25/C55	F00378
IS20-25/C55 SA	F00558
IS20-25/C65	F00380
IS20-25/C65 SA	F00559

Recalled AFX2 28 mm Main Body and/or 20 mm Iliac Limbs:

Main Body (Aortic Body Stent Graft Diameter):	Iliac Limbs (Iliac Stent Graft Diameter):	Model Nos.:	Product ("F") Nos.:
22 mm	20 mm	BEA22-40/I20-40	F00820-59
22 mm	20 mm	BEA22-50/I20-30	F00820-73
22 mm	20 mm	BEA22-60/I20-40	F00820-58
22 mm	20 mm	BEA22-70/I20-30	F00820-72
22 mm	20 mm	BEA22-80/I20-40	F00820-57
22 mm	20 mm	BEA22-80/I20-55	F00820-79
22 mm	20 mm	BEA22-90/I20-30	F00820-71
22 mm	20 mm	BEA22-100/I20-40	F00820-56
22 mm	20 mm	BEA22-100/I20-55	F00820-78
22 mm	20 mm	BEA22-110/I20-30	F00820-70
22 mm	20 mm	BEA22-120/I20-40	F00820-55
25 mm	20 mm	BEA25-40/I20-40	F00820-32
25 mm	20 mm	BEA25-50/I20-30	F00820-46
25 mm	20 mm	BEA25-60/I20-40	F00820-31
25 mm	20 mm	BEA25-70/I20-30	F00820-45
25 mm	20 mm	BEA25-80/I20-40	F00820-30
25 mm	20 mm	BEA25-80/I20-55	F00820-52
25 mm	20 mm	BEA25-90/I20-30	F00820-44
25 mm	20 mm	BEA25-100/I20-40	F00820-29
25 mm	20 mm	BEA25-100/I20-55	F00820-51
25 mm	20 mm	BEA25-110/I20-30	F00820-43
25 mm	20 mm	BEA25-120/I20-40	F00820-28
28 mm	16 mm	BEA28-40/I16-40	F00820-10
28 mm	16 mm	BEA28-50/I16-30	F00820-23
28 mm	16 mm	BEA28-60/I16-40	F00820-09
28 mm	16 mm	BEA28-70/I16-30	F00820-22
28 mm	16 mm	BEA28-80/I16-40	F00820-08
28 mm	16 mm	BEA28-80/I16-55	F00820-27
28 mm	16 mm	BEA28-90/I16-30	F00820-21
28 mm	16 mm	BEA28-100/I16-40	F00820-07
28 mm	16 mm	BEA28-100/I16-55	F00820-26
28 mm	16 mm	BEA28-110/I16-30	F00820-20
28 mm	16 mm	BEA28-120/I16-40	F00820-06
28 mm	20 mm	BEA28-40/I20-40	F00820-05
28 mm	20 mm	BEA28-50/I20-30	F00820-19
28 mm	20 mm	BEA28-60/I20-40	F00820-04
28 mm	20 mm	BEA28-70/I20-30	F00820-18
28 mm	20 mm	BEA28-80/I20-40	F00820-03

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28 mm	20 mm	BEA28-80/I20-55	F00820-25
28 mm	20 mm	BEA28-90/I20-30	F00820-17
28 mm	20 mm	BEA28-110/I20-30	F00820-16
28 mm	20 mm	BEA28-100/I20-40	F00820-02
28 mm	20 mm	BEA28-100/I20-55	F00820-24
28 mm	20 mm	BEA28-120/I20-40	F00820-01

Geographic Regions: Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Europe, Japan, Malaysia, Mexico, Panama, Peru, Singapore, Thailand, U.S.

Manufacturer(s): Endologix International BVBurgemeester Burgerslaan 40, Rosmalen, Noord-Holland 5245, The Netherlands

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

Problem:
In a December 30, 2016, Important Safety Update letter submitted by ECRI Institute member hospitals and a December 2016 Field Safety Notice letter posted by the German Federal Institute for Drugs and Medical Devices (BfArM), Endologix states that in January 2013 it conducted an investigation into reports of Type IIIa endoleaks (separation of bifurcated and extension stent grafts at the point of overlap) with the above systems, which was followed by an investigation into Type IIIb endoleaks (disruption of the stent graft material) in September 2013. Endologix also states that Type III endoleaks may cause increased pressure in the aneurysm sac, which could increase the risk of aneurysm rupture and patient death. Endologix further states that, during the time of its investigations, a series of updates to the instructions for use (IFU) and modifications to the product were implemented, including the introduction of the following:

- A graft material processing improvement known as Duraply
- Longer lengths of bifurcated devices to maximize component overlap
- AFX2 Bifurcated Endograft System (AFX2 System)

Endologix also states that at the time of the submission of these modifications to FDA, they were part of the firm's ongoing product improvement efforts and not identified as measures intended to address Type III endoleaks; however, the firm's ongoing investigation has determined that these changes may help prevent the occurrence of Type III endoleaks reported with the above devices. For a detailed discussion of the investigation of Type III endoleaks, see Attachment 1 of the letter . Endologix further states that it appears that the rate of Type III endoleaks may be decreasing since the 2014 introduction of the AFX with Duraply and AFX2 systems. The time to event may exceed the amount of follow-up currently available; therefore, the firm does not have clinical data on the effectiveness of these changes longer term. In addition, the rates are calculated based on voluntary reporting and units sold instead of implanted, which may underestimate the true event rate occurring on a per-patient basis. This underestimate may be greater for the more recent versions (i.e., AFX with Duraply, AFX2 system), which may have a larger number of units sold with implants pending as compared to the AFX with Strata. Endologix further states that the Type IIIb endoleak rates in implants that occurred before these modifications increase over time and that the increase may be associated with the Strata graft material, which has not been manufactured since July 2014. Endologix states that GMED, the Notified Body for Endologix, has temporarily suspended the CE mark certification for the above systems as of December 13, 2016, and that the CE mark suspension is related to GMED's concerns about reports of Type III endoleak with a former version of the device (Strata). Endologix also states that the AFX product is not currently available in the European Union (EU).

Endologix states that, separately, on December 27, 2016, the firm announced a temporary hold on shipments of its AFX and AFX2 systems to complete an investigation of a manufacturing problem with some sizes of the devices which is related to loading the stent graft onto the delivery system. Endologix also states that this manufacturing problem was identified through ongoing product testing and is not related to clinical experience. Endologix further states that it has received no reports of Type IIIb endoleaks and one Type IIIa endoleak out of the 4,143 AFX2 units sold. Endologix states that it has lifted the hold on all AFX devices and on all AFX2 devices except for AFX2 devices with the largest size Main Body (28 mm) and/or Iliac Limbs (20 mm).

Action Needed:
Identify any affected product in your inventory and any patients implanted with affected product. If you have affected product and/or patients, verify that you have received the December 30, 2016, Important Safety Update letter and/or the December 2016 Field Safety Notice letter from Endologix. Facilities in the EU should isolate any AFX and AFX2 devices until the CE mark suspension is lifted. All facilities should isolate and discontinue use of any unused AFX devices with Strata graft material and any AFX2 28 mm Main Body and/or 20 mm Iliac Limbs, and contact your Endologix representative to arrange for product return. Because Type III endoleaks may cause increased pressure in the aneurysm sac that could increase the risk of aneurysm rupture and patient death, Endologix recommends that high-resolution computed tomography (CT) (contrast-enhanced and non-contrast) imaging follow-up be performed on patients implanted with all AFX and AFX2 devices at 1 month, 6 months, 1 year, and annually thereafter for examination of the following:

- Device integrity (e.g., absence of stent fracture)
- Maintained overlap between bifurcated and extension stent grafts
- Absence of clinically relevant migration or lateral movement
- Aneurysm enlargement, perigraft flow, loss of patency, increased tortuosity, or progressive disease.

If renal complications or other factors preclude the use of image contrast medium, abdominal radiographs and duplex ultrasound may provide similar information. Plain x-rays may provide information on stent integrity and maintained component overlap. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, changes in the structure or position of the endovascular graft, reduced overlap of stent graft components) warrant a thorough clinical evaluation and assessment of further follow-up. If any evidence of therapy failure (e.g., enlarging aneurysm, Type I or III endoleak, graft occlusion) is observed, the patient's condition and prognosis should be reassessed, along with potential reintervention to re-establish aneurysm exclusion and/or graft patency. Endologix states that postmarket surveillance and review of literature suggest that Type III endoleaks are most commonly treated with a secondary intervention involving placement of an additional device component and that the firm is collaborating with regulatory agencies on recommendations for treatment of patients presenting with a Type III endoleak in an AFX implant. If a secondary endovascular procedure is not appropriate, open surgical repair can be performed to correct a Type III endoleak; however, there is a significantly higher risk of morbidity and mortality.

For Further Information:

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DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

Endologix
Website: 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 Jan 12. Member Hospital. Endologix letter submitted by ECRI Institute member hospitals Download
- 2017 Jan 12. BfArM (Germany). 11413/16 Download
- 2017 Jan 12. BfArM (Germany). Download
- 2017 Jan 16. Manufacturer. Endologix confirmed the information provided in the source material.