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January 4, 2017

Field Safety Notice
AFX™ Endovascular AAA System
Voluntary withdrawal of AFX with Strata graft material and larger diameter sizes of AFX2

Dear Physician,

In addition to the Field Safety Notice that was sent out by Endologix in December 2016, please find below additional important information related to the AFX® Endovascular AAA System (AFX System):

1. **Voluntary withdrawal of the small remaining quantity of original AFX with Strata graft material**
2. **Voluntary withdrawal of the AFX2 Main Body (28 mm) and/or Iliac Limbs (20 mm)**

Please note the temporary suspension of the CE mark of the AFX System remains in place; therefore, the AFX product remains unavailable in the countries of the European Economic Area, Switzerland and Turkey and any product in your inventory should remain in quarantine until the CE mark suspension is lifted.

Endologix confirms that appropriate notifications to Regulatory Agencies have been completed

1. ***Voluntary Recall of Remaining Product with Strata Graft Material***

   Following the previous FSN, Endologix wants to ensure there are no unused AFX devices with the Strata graft material remaining in hospital and distributor inventories. AFX devices with the Strata graft material can be identified by the finished good product code starting with the letter F (i.e., FXXXXX or FXXXXX-XX). A comprehensive list of affected finished good product codes (F#s) is provided in *Attachment 1*.

   IMMEDIATE ACTION REQUIRED: Please check your current AFX inventory. If you identify any AFX devices with the Strata graft material, please immediately contact your Endologix Representative to arrange a return.

   For guidance on patient follow-up, please refer to the Field Safety Notice distributed by Endologix in December 2016.

2. ***Voluntary Recall of AFX2 Main Body (28 mm) and/or Iliac Limbs (20 mm)***

On December 27, Endologix announced a temporary, global hold on shipments of its AFX and AFX2 Systems to complete an investigation of a manufacturing issue with some sizes of the device, which is related to graft damage caused during **loading the stent graft onto the delivery system**. A hole could be created in the graft material which, if large enough, could result in a Type IIIb endoleak. A Type IIIb endoleak would likely be identified during the initial implant procedure upon completion angiogram. This manufacturing issue was identified through on-going product testing, and it is **not related to clinical experience discussed in the previous FSN.**

Based on upon the investigation, it has been determined the issue is limited to the largest AFX2 sizes. As such, Endologix wants to ensure there are no AFX2 devices in these sizes in hospital and distributor inventories. AFX2 devices with these sizes can be identified by the finished good product code starting with the letter F (i.e., FXXXXX or FXXXXX-XX). A comprehensive list of affected finished good product codes (F#s) is provided in *Attachment 2.*

IMMEDIATE ACTION REQUIRED: Please check your current AFX2 inventory. If you identify any AFX2 devices in these sizes (28 mm Main Body and/or 20 mm Iliac Limbs), please immediately contact your Endologix Representative to arrange a return.

To date, there have been no reported Type IIIb endoleaks and only one Type IIIa endoleak reported in the 4,143 AFX2 units sold worldwide. As such, while the risk has been determined to be low, should a patient present with a Type IIIa or Type IIIb endoleak, please refer to the Field Safety Notice distributed by Endologix in December 2016 for guidance on patient follow-up.

Our Commitment to Safety and Excellent Clinical Outcomes

Endologix, Inc. is deeply committed to patient safety and excellent clinical outcomes. We will continue to develop, manufacture and test devices to the highest quality standards and provide experienced clinical support. Through our on-going clinical research and post-market surveillance programs, we will actively monitor the clinical experience with AFX and all our devices and provide important information to care for your patients. If you have any questions regarding the content of this notification, please contact your Endologix representative.

Yours Sincerely,
Endologix

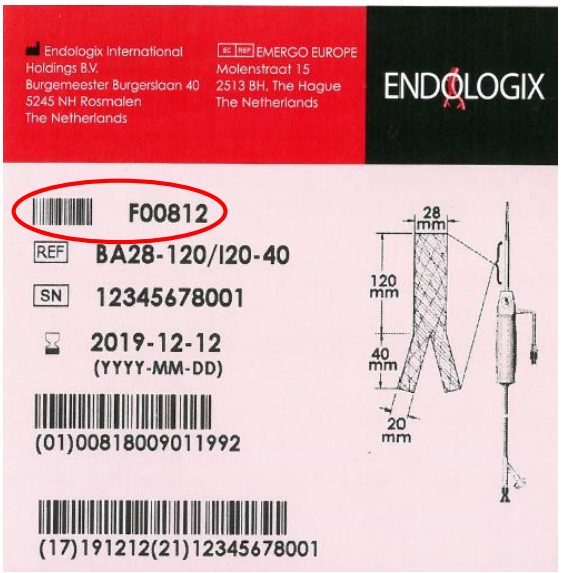
Shari O'Quinn
Vice President, Clinical & Regulatory Affairs

Attachment 1: AFX devices with Strata graft material

AFX STRATA F-Numbers

Model #	F #	Model #	F #	Model #	F #	Model #	F #
BA22-80/I20-40	F00627	BA28-80/I20-40	F00663	A22-22/C95-O20	F00405	A25-25/C95-O20V	F00726-06
BA22-100/I16-40	F00429	BA28-120/I16-40	F00655	A25-25/C55-O20	F00388	A28-28/C55-O20V	F00726-07
BA22-80/I16-40	F00424	BA28-100/I16-40	F00431	A25-25/C75-O20	F00393	A28-28/C75-O20V	F00726-08
BA22-60/I16-40	F00418	BA28-80/I16-40	F00426	A25-25/C95-O20	F00395	A28-28/C95-O20V	F00726-09
BA22-100/I13-40	F00412	BA28-60/I16-40	F00420	A28-28/C55-O20	F00389	A31-31/C80-O20V	F00726-10
BA22-80/I13-40	F00409	BA28-100/I13-40	F00414	A28-28/C75-O20	F00394	A31-31/C100-O20V	F00726-11
BA22-60/I13-40	F00406	BA28-80/I13-40	F00411	A28-28/C95-O20	F00370	A34-34/C80-O20V	F00726-12
BA22-90/I20-30	F00623	BA28-60/I13-40	F00408	A31-31/C80-O20	F00398	A34-34/C100-O20V	F00726-13
BA22-70/I20-30	F00622	BA28-90/I20-30	F00659	A31-31/C100-O20	F00404	I16-16/C55	F00561
BA22-90/I16-30	F00421	BA28-70/I20-30	F00658	A34-34/C80-O20	F00400	I16-16/C55F	F00371
BA22-70/I16-30	F00415	BA28-90/I16-30	F00423	A34-34/C100-O20	F00369	I16-16/C88	F00373
BA25-120/I20-40	F00600	BA28-70/I16-30	F00417	A22-22/C55V	F00703-01	I20-13/C70F	F00566
BA25-80/I20-40	F00645	BA28-100/I16-55	F00368	A22-22/C75V	F00703-02	I20-13/C88F	F00567
BA25-120/I16-40	F00637	BA28-80/I16-55	F00428	A22-22/C95V	F00703-03	I20-20/C55	F00564
BA25-100/I16-40	F00430	A22-22/C55	F00381	A25-25/C55V	F00703-04	I20-20/C55F	F00375
BA25-80/I16-40	F00425	A22-22/C75	F00384	A25-25/C75V	F00703-05	IS20-25/C55	F00378
BA25-60/I16-40	F00419	A22-22/C95	F00442	A25-25/C95V	F00703-06	IF20-25/C65	F00379
BA25-100/I13-40	F00413	A25-25/C55	F00382	A28-28/C55V	F00703-07	IS20-25/C65	F00380
BA25-80/I13-40	F00410	A25-25/C75	F00385	A28-28/C75V	F00703-08	I16-16/C55 SA	F00551
BA25-60/I13-40	F00407	A25-25/C95	F00390	A28-28/C95V	F00703-09	I16-16/C55F SA	F00553
BA25-110/I20-30	F00642	A28-28/C55	F00383	A31-31/C80V	F00703-10	I16-16/C88 SA	F00552
BA25-90/I20-30	F00641	A28-28/C75	F00386	A31-31/C100V	F00703-11	I20-13/C70F SA	F00556
BA25-70/I20-30	F00640	A28-28/C95	F00391	A34-34/C80V	F00703-12	I20-13/C88F SA	F00557
BA25-110/I16-30	F00635	A31-31/C80	F00396	A34-34/C100V	F00703-13	I20-20/C55 SA	F00554
BA25-90/I16-30	F00422	A31-31/C100	F00443	A22-22/C55-O20V	F00726-01	I20-20/C55F SA	F00555
BA25-70/I16-30	F00416	A34-34/C80	F00397	A22-22/C75-O20V	F00726-02	IS20-25/C55 SA	F00558
BA25-100/I16-55	F00432	A34-34/C100	F00399	A22-22/C95-O20V	F00726-03	IF20-25/C65 SA	F00560
BA25-80/I16-55	F00427	A22-22/C55-O20	F00387	A25-25/C55-O20V	F00726-04	IS20-25/C65 SA	F00559
BA28-120/I20-40	F00601	A22-22/C75-O20	F00392	A25-25/C75-O20V	F00726-05		

Example:



Attachment 2: AFX2 devices in 28 mm Main Body and/or 20 mm Iliac Limbs

AFX2 28 mm Main Body and/or 20 mm Iliac Limbs F-Numbers

Generic Model Code	$X^1X^2X^3$-X^4/X^5X^6-X^7						
Example	BEA22-60/I20-40						
Parameter	X^1	X^2	X^3	X^4	X^5	X^6	X^7
Interpretation	B	EA	22	60	I	20	40

X^2 = EA	X^3 = 28mm (Aortic Body Stent Graft Diameter)		X^3 = 25mm (Aortic Body Stent Graft Diameter)		X^3 = 22mm (Aortic Body Stent Graft Diameter)	
	Model #	F #	Model #	F #	Model #	F #
X^6 = 20mm (Iliac Stent Graft Diameter)	BEA28-120/I20-40	F00820-01	BEA25-120/I20-40	F00820-28	BEA22-120/I20-40	F00820-55
	BEA28-100/I20-40	F00820-02	BEA25-100/I20-40	F00820-29	BEA22-100/I20-40	F00820-56
	BEA28-80/I20-40	F00820-03	BEA25-80/I20-40	F00820-30	BEA22-80/I20-40	F00820-57
	BEA28-60/I20-40	F00820-04	BEA25-60/I20-40	F00820-31	BEA22-60/I20-40	F00820-58
	BEA28-110/I20-30	F00820-16	BEA25-110/I20-30	F00820-43	BEA22-110/I20-30	F00820-70
	BEA28-90/I20-30	F00820-17	BEA25-90/I20-30	F00820-44	BEA22-90/I20-30	F00820-71
	BEA28-70/I20-30	F00820-18	BEA25-70/I20-30	F00820-45	BEA22-70/I20-30	F00820-72
	BEA28-50/I20-30	F00820-19	BEA25-50/I20-30	F00820-46	BEA22-50/I20-30	F00820-73
	BEA28-100/I20-55	F00820-24	BEA25-100/I20-55	F00820-51	BEA22-100/I20-55	F00820-78
	BEA28-80/I20-55	F00820-25	BEA25-80/I20-55	F00820-52	BEA22-80/I20-55	F00820-79
X^6 = 16mm (Iliac Stent Graft Diameter)	BEA28-120/I16-40	F00820-06				
	BEA28-100/I16-40	F00820-07				
	BEA28-80/I16-40	F00820-08				
	BEA28-60/I16-40	F00820-09				
	BEA28-110/I16-30	F00820-20				
	BEA28-90/I16-30	F00820-21				
	BEA28-70/I16-30	F00820-22				
	BEA28-50/I16-30	F00820-23				
	BEA28-100/I16-55	F00820-26				
	BEA28-80/I16-55	F00820-27				

Example: