

**URGENT FIELD SAFETY NOTICE**  
**AFX EndoVascular AAA System, with STRATA graft material**

June 2017

Dear Physician,

This letter provides an update related to the AFX Endovascular AAA System (AFX System). In December 2016, January 2017 and March 2017, we provided guidance on the AFX System that related to Type III endoleaks. As a reminder, the first-generation AFX System was introduced in 2011 and included ePTFE graft material known as STRATA. The STRATA graft material was discontinued in July 2014 and replaced with a more durable ePTFE graft material process known as DURAPLY.

We are committed to providing you with regular updates on all our products. This update provides current information on important recommendations for surveillance of patients implanted with AFX STRATA only. It does not apply to the AFX System (AFX DURAPLY) and AFX2 (also with DURAPLY).

### **Surveillance of Patients Implanted with AFX STRATA**

We wish to provide additional important recommendations for surveillance of patients implanted with AFX STRATA, and to reinforce previously communicated guidance. Given the cumulative Type III endoleak rate with AFX STRATA was higher than expected at 2.9% through 5 years, Endologix convened a physician conference in January 2017 which asked a number of experienced AFX users to review evidence and provide consensus on a number of issues pertaining to the AFX STRATA graft. Following are the consensus recommendations:

- Continued awareness of the possibility of Type IIIb endoleaks in patients implanted with AFX Strata and the importance of surveillance. The main issue being not the occurrence of fabric holes, as all sutured endografts have these, but the potential of “hole propagation”.
- That some patients may be at increased risk of Type IIIb endoleaks – particularly those who have undergone endovascular procedures necessitating passage of wires and sheaths through the existing endograft.
- That patients with Type IIIb endoleaks should be urgently considered for a relining procedure.
- There was consensus that it was not possible to identify patients at high risk of Type IIIb endoleaks, and therefore, they would not warrant prophylactic re-intervention.



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Recently, Endologix communicated with additional physicians and regulatory agencies regarding the optimum follow up interval for surveillance of patients implanted with AFX STRATA, and Endologix reiterates the recommendations in the Instructions for Use (IFU) that high-resolution CT scan (contrast-enhanced and non-contrast) imaging follow-up be performed at one month, six months, one year, and annually thereafter for examination of:

- 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

In addition to the IFU and Consensus recommendations above, Endologix recommends a semi-annual clinical follow up of patients implanted with AFX STRATA and appropriate patient-tailored imaging, if needed, commensurate with patient status and co-morbidities between annual CT scans. Any patient not compliant with the recommended surveillance might benefit from an invitation for endograft assessment. AFX STRATA devices can be identified by the finished good product code starting with the letter F (i.e., FXXXXX or FXXXXX-XX). A comprehensive list of AFX STRATA finished good product codes (F#s) is provided in *Attachment 1*.

Endologix, Inc. is deeply committed to patient safety and good clinical outcomes. As always, we will continue to provide clinical support and will actively monitor the clinical experience with the AFX System and all of our other devices. Through our post-market surveillance and product development programs, we will continuously seek your feedback and update you with any 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**

A handwritten signature in blue ink that reads "Shari O'Quinn".

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:

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