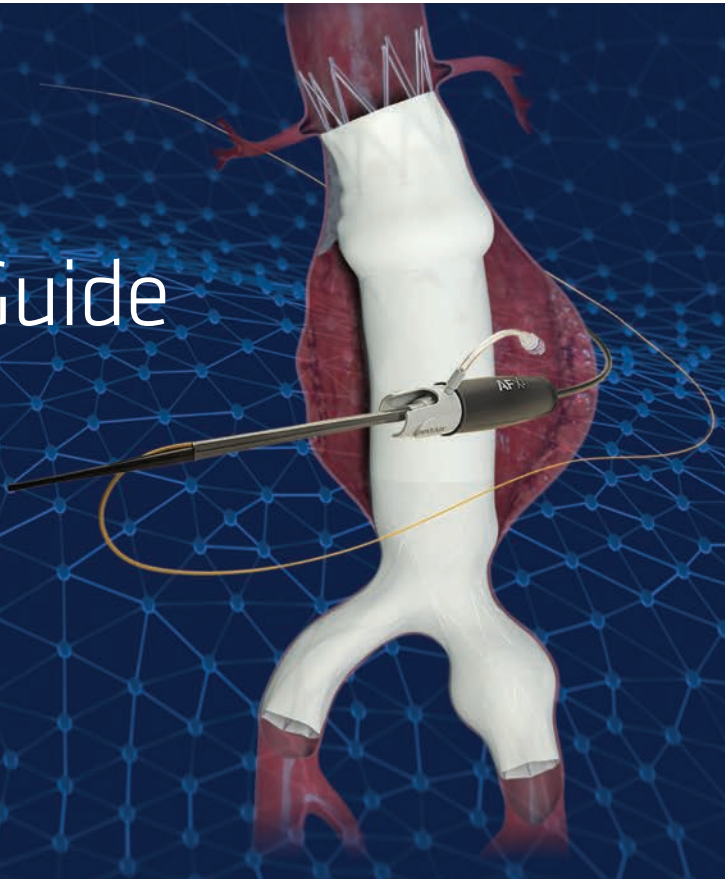
Endologix

Quick Reference Guide



AFX®2

Bifurcated Endograft System

Indications for Use

The AFX® Endovascular AAA System is indicated for endovascular treatment in patients with AAA. The devices are indicated for patients with suitable aneurysm morphology for endovascular repair, including:

- Adequate iliac/femoral access compatible with the required delivery systems (diameter ≥ 6.5mm)

- Non-aneurysmal aortic neck between the renal arteries and the aneurysm
  - With a length of ≥ 15mm
  - With a diameter of ≥ 18mm and ≤ 32mm
  - With neck angle of ≤ 60° to the body of the aneurysm
  - Aortic length ≥ 1.0cm longer than the body portion of the chosen bifurcated model.

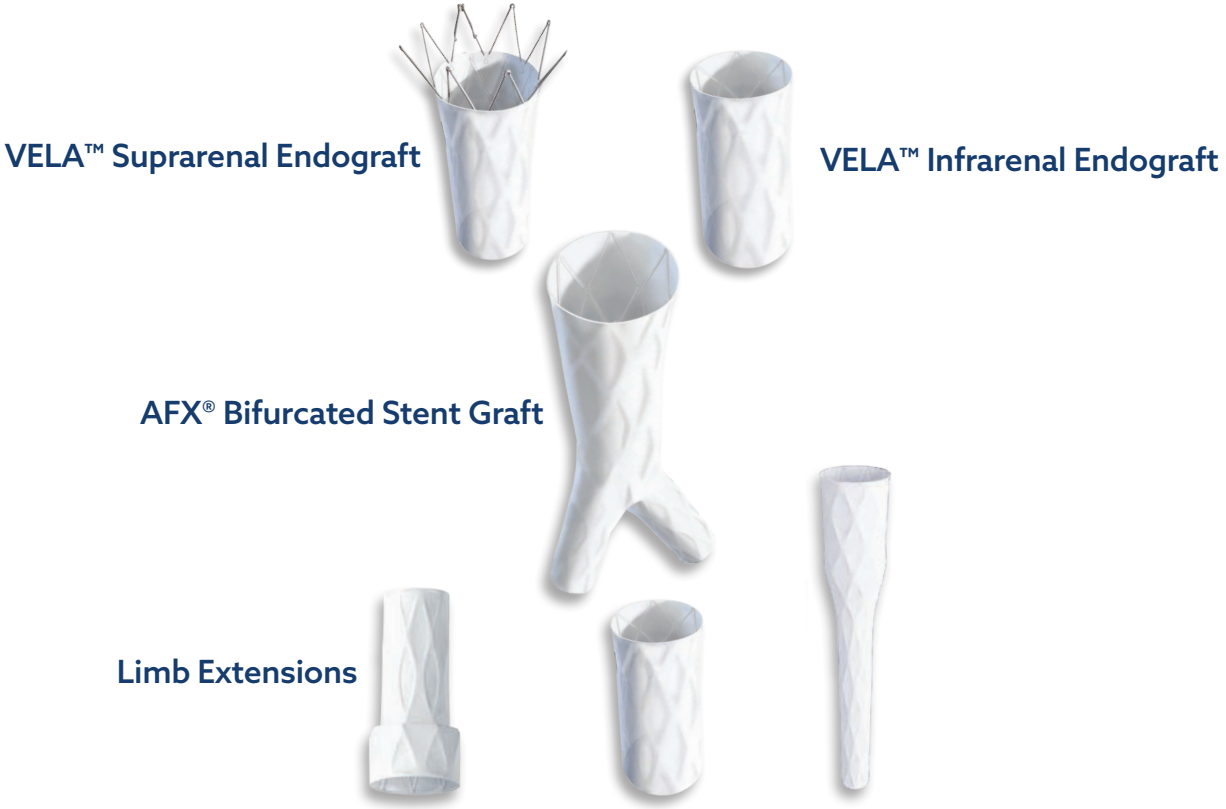
- Common iliac artery distal fixation site
  - With a distal fixation length of ≥ 15mm
  - With ability to preserve at least one hypogastric artery
  - With a diameter of ≥ 10mm and ≤ 23mm
  - With an iliac angle of ≤ 90° to the aortic bifurcation

- Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally.

Contraindications

The AFX Endovascular AAA System is contraindicated in:
Patients who have a condition that threatens to infect the stent graft.
Patients with sensitivities or allergies to the device materials.

AFX System Components



AFX2 Procedure: Materials Required

ENDOLOGIX PRODUCTS*

- ☐ AFX® Introducer System- S17-45
- ☐ AFX®2 Bifurcated Delivery System- BEAXX-XX/IXX-XX
- ☐ VELA™ Suprarenal Endografts- AXX-XX/CXX-O20-V (as required)
- ☐ VELA™ Infrarenal Endografts- AXX-XX/CXX-V (as required)
- ☐ Limb extensions- ISXX-XX/CXX-SA or IXX-XX/CXX-F-SA (as required)
- ☐ Endovascular Snare
- ☐ 0.035" Stiff Wire

EQUIPMENT

- ☐ Power injector
- ☐ Ultrasound (e.g. Sonosite) (optional)
- ☐ IVUS (optional)

OR SUPPLIES

Sheaths:

- ☐ 7F Contralateral
- ☐ 6-8F sheath for ipsilateral percutaneous access

*All medical devices and tools are to be selected and utilized at the discretion of the medical professional.

Additional Wires:

- ☐ 0.035" Standard Guidewire x2
- ☐ 0.035" Stiff Wire (e.g. Luderquist, Meier)

Catheters:

- ☐ 0.035" compatible hard tip 5F angiographic pigtail catheter (adequate length)
- ☐ Exchange catheters (e.g. Berenstein, Kumpe, etc.)

Balloons:

- ☐ Compliant Aortic balloon (e.g. Coda, Reliant, etc.)
- ☐ PTA balloons

Other:

- ☐ Access needles
- ☐ Micro puncture
- ☐ Standard syringes
- ☐ Radiopaque contrast media
- ☐ Radiopaque (ruler) in millimeter increments
- ☐ Heparinized solution and sterile saline solution

If Percutaneous:

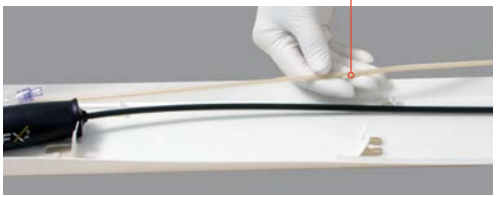
- ☐ Ipsilateral "pre-close" device (Abbott Vascular, Inc. Perclose ProGlide closure device)
- ☐ Contralateral–Doctor preference for 7F Sheath

Sterile Transfer: Best Practices

Preloaded wire straightener

Sterile tray

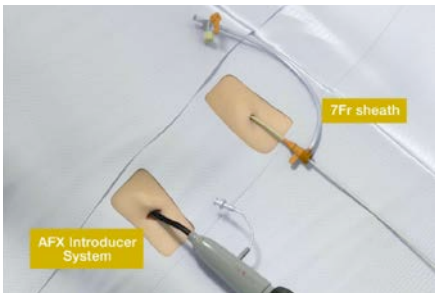
Removal of sheathed wire from the tray



Sterile transfer of device and sheathed wire with preloaded straightener

Best Practice: Hold contralateral wire with both hands when removing device from tray.

AFX System Set Up



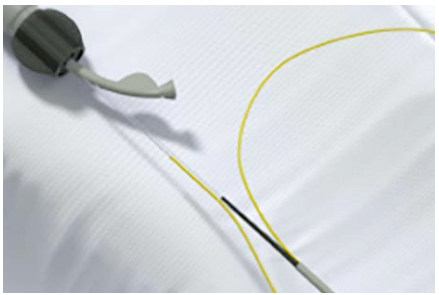
1. System Set Up

Flush side port and guidewire lumen.

Position the AFX introducer and the 7F contralateral sheath in place. Position the snare wire above the bifurcation.

Advance the AFX2 delivery system over the stiff guidewire and up to the hemostasis valve of the AFX introducer.

Align the snareable tip of the contralateral wire with the end of the wire straightener.



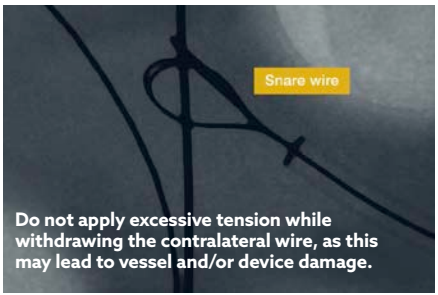
2. Contralateral Wire Insertion

As a unit, insert the wire with the straightener into the lumen of the AFX introducer and slightly tighten the hemostasis valve.

Advance the contralateral wire into the AFX introducer, loosen the hemostasis valve and peel off the wire straightener.

Best Practices:

- **Always keep a hand on the wire while inserting into valve.**
- **Yellow portion of wire must enter wire straightener to create hemostasis.**



3. Contralateral Wire Snaring

While advancing the contralateral wire from the ipsilateral side, snare the floppy end of the wire at the aortic bifurcation.

Withdraw the contralateral wire and snare out of the 7F contralateral sheath while simultaneously advancing the contralateral wire up the ipsilateral side.

Advance the AFX2 delivery system until the handle docks into the hemostasis valve of the AFX introducer.

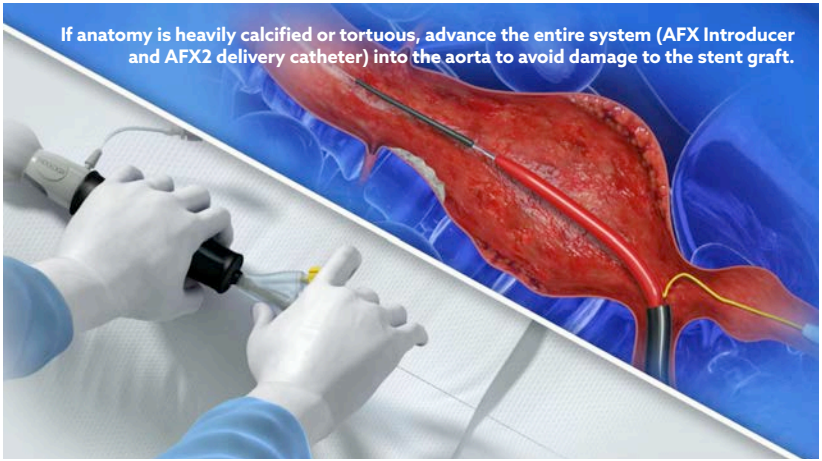
Ensure the side port is pointing medially to maintain alignment of the contralateral limb.

Best Practice:

- **Upon snaring the contralateral wire, advance the wire up through the ipsilateral side and withdraw the wire out of the contralateral sheath at the same rate.**

Refer to the IFU for full instructions.

AFX System Set Up



Visually verify that the stent graft is seated on the aortic bifurcation, and that the proximal end is not covering the lowest renal artery.

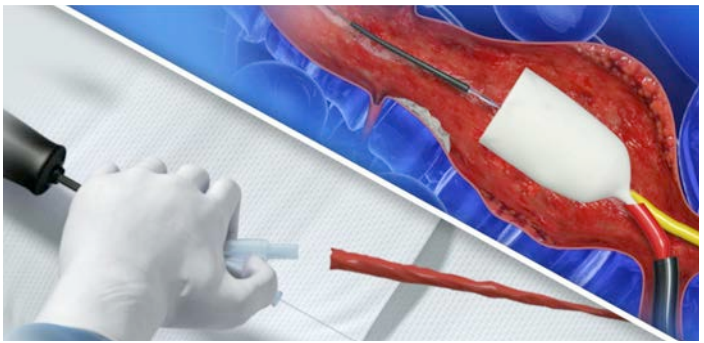
Best Practices:

- **Ensure delivery system remains parallel to direction of transfer.**
- **Once at the transfer stop pin the introducer sheath and inner core and twist to resolve wire orientation if misaligned.**
- **Use a dry sponge to enhance grip to aid in graft transfer.**

4. Stent Graft Transfer

- Pin the AFX introducer handle and advance the inner core.
- Continue until the transfer stop is aligned with the device handle then remove the transfer stop.
- Advance the inner core in 50mm increments until the stent graft fully exits the end of the AFX introducer.
- Orient the contralateral limb by pinning the AFX introducer handle and rotating the inner core.
- Pin the AFX2 delivery system handle and gently pull down on the contralateral wire and inner core simultaneously to guide each limb into its respective iliac artery.

AFX2 Deployment



1. AFX2 Main Body Deployment

- Hold the inner core Y-connector, and twist the control cord cap to disengage it.
- Slowly pull the cap to deploy the main body of the stent graft.
- Continue to pull on the control cord until the main body cover material exits through the Y-connector.
- If necessary, cap the port with a standard luer cap.

The yellow marker on the control cord indicates that the main body cover is fully withdrawn into the inner core.

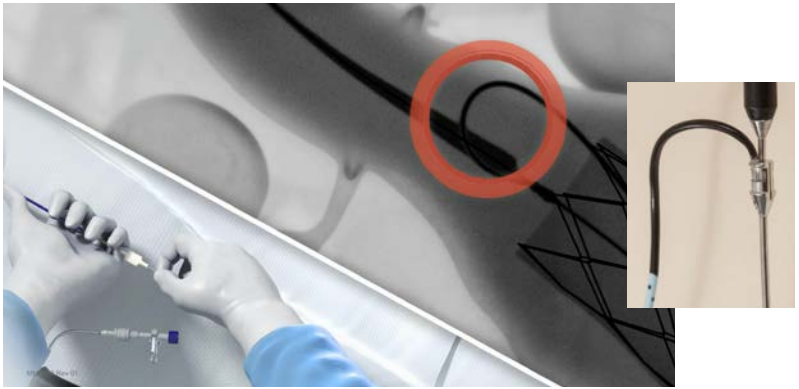
2. Contralateral Limb Deployment

- **Hold the AFX2 delivery system steady by pinning the inner core.**
- Slowly pull the yellow contralateral wire cover to deploy the contralateral limb.
- Continue pulling until the yellow contralateral wire cover is fully removed.

Failure to pin the inner core during contralateral limb deployment may result in premature ipsilateral limb deployment.

Benign deflection of the welded wire may occur upon limb deployment.

AFX2 Deployment



3. Contralateral Wire Release

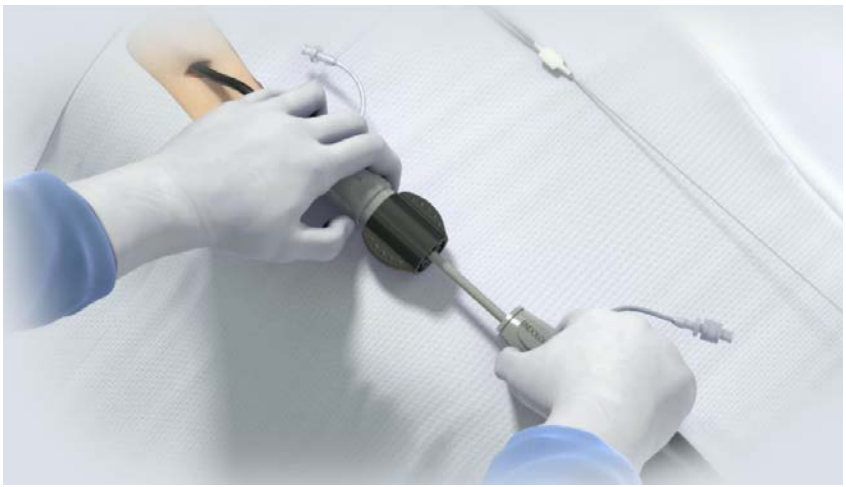
- Advance a pigtail catheter over the contralateral wire until the tip is in contact with the wire lock.
- Advance the pigtail and wire together until an arch is formed above the wire lock.
- Hold the pigtail catheter in place and pull on the contralateral wire to release it from the wire lock.

4. Ipsilateral Limb Deployment

- Hold the AFX2 delivery system steady by pinning the device handle.
- Pull on the inner core slightly to deploy the ipsilateral limb inside the AFX introducer.
- Pin the inner core and retract the AFX introducer slightly to release the deployed ipsilateral limb.

Best Practice: Pull on the inner core until the wire lock is just above the aortic bifurcation to deploy the ipsilateral limb inside the AFX Introducer sheath.

AFX2 System Removal



If resistance is encountered during withdrawal of the AFX2 delivery catheter through the bifurcated stent graft, rotate the inner core 90 degrees and proceed with withdrawal.

Do not advance the inner core as this may disturb the bifurcated stent graft positioning.

- Retract the inner core until it reaches a positive stop.
- Squeeze the handle snap cap to undock the AFX2 delivery system from the AFX introducer.
- Remove the AFX2 delivery system from the aortic guidewire.

AFX2 Troubleshooting

Contralateral Wire

Issue	Solution
• Lock Wire prematurely deploys	• Deploy the contralateral limb and re-cannulate through the deployed limb
• Contralateral wire fails to release	• Retract the pigtail from the tip of the wire to the level of the bifurcation. • Retract the inner core to deploy the ipsilateral limb while simultaneously retracting the contralateral until the locking mechanism is positioned above the bifurcation. • Retract AFX Introducer to deploy limb before retracting system. • While advancing the contralateral wire, continue retracting the inner core until the tip retracts into the AFX Introducer and a stop is felt. • Detach the bifurcated delivery system from the AFX Introducer and disconnect the contralateral wire from the locking mechanism. • Re-advance the pigtail catheter while ensuring proper cannulation of thebifurcated device and position at or above the renal arteries.

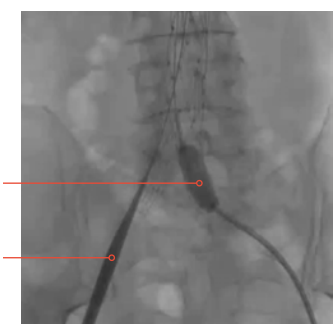
AFX2 Troubleshooting

Tethering

Issue	Solutions
Anchoring of the bifurcated device may be required if movement occurs during Aortic Extension System advancement.	Position and inflate an appropriately sized PTA balloon, from the contralateral side, to anchor the AFX2 Bifurcated device, during advancement of the Aortic Extension. Depending on balloon size it may be necessary to use a contralateral sheath larger than 7F. The appropriate size PTA balloon should be based upon the diameter of the contralateral common iliac artery.

CAUTION: *If a balloon is used to stabilize the stent graft when introducing extension stent graft delivery catheter, care should be taken to avoid over-inflation of the balloon and/or disturbance of the bifurcated graft positioning.*

Do not exceed the manufacturer's recommended maximum balloon inflation diameter. Rupture of the balloon may occur. Adhere to balloon inflation parameters as described in this booklet. Over-inflation beyond the nominal diameter of the stent graft may result in damage to the vessel wall and/or vessel rupture, or damage to the stent graft.



Best Practice: Determine whether balloon tethering may be required prior to the case. Should there be a likelihood balloon tethering will be required, have the appropriate aortic balloon size and model on hand.

AFX2 Troubleshooting

Device Removal

Issue	Solution
Resistance is encountered during withdrawal of the AFX2 delivery catheter through the bifurcated stent graft.	Rotate the inner core 90 degrees to reposition the wing on the delivery system, and proceed with withdrawal.

Control Cord

Issue	Solution
Control cord will not deploy the bifurcated main body.	Confirm the device is not deployed. Hold the AFX Introducer in place and start retracting inner core. This will restart the deployment of the graft by popping sutures as inner core passes through main body. DO NOT cut the control cord handle. 

AFX Graft Selection

Step 1

Choose Proximal Endograft

Measure aortic neck diameter and renal to bifurcation distance to select the proximal aortic extension.

Aortic Vessel Diameter (mm)	Proximal Extension Diameter (mm)
18-23	25
20-26	28
23-32	34

AFX Graft Selection

Step 2

Select Iliac Limb Dimensions

Measure common iliac artery diameters and lengths to select iliac limb dimensions for the bifurcated stent graft.* Consider iliac extensions, if applicable (Step 4).

Iliac Vessel Diameter (mm)	Bifurcated Limb Diameter (mm)	Available Limb Lengths (mm)
10-11	13	40
10-14	16	30, 40, 55
14-18	20	30, 40

*Limb lengths dependent on specific bifurcated device. See specifications under Model Numbers.

AFX Graft Selection

Step 3

Select Bifurcated Stent Graft

Use the renal to bifurcation length determined in Step 1 to choose the length of the main body. Ensure appropriate overlap with the proximal extension.** For main body diameter, use one diameter size smaller than the proximal aortic diameter.

Proximal Endograft Diameter (mm)	Main Body Diameter (mm)	Main Body Lengths (mm)	Proximal Endograft Covered Lengths (mm)
25	22	40, 60, 70, 80, 90	55, 75, 95
28	25	60, 70, 80, 90, 100, 110, 120	55, 75, 95
34	28	60, 70, 80, 90, 100, 110, 120	80, 100

**Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally.

AFX Graft Selection

Step 4

Choose Iliac Extensions, if applicable

Ensure appropriate overlap with iliac limbs of the bifurcated stent graft.**

Straight

Proximal Diameter (mm)	Distal Diameter (mm)	Length (mm)
16	16	55
16	16	88
20	20	55

Shaped (Tapered or Stepped†)

Proximal Diameter (mm)	Distal Diameter (mm)	Length (mm)
20	25	55†
20	25	65†
20	13	70
20	13	88

**Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally.

AFX Model Numbers

AFX®2 Bifurcated Stent Grafts

Bifurcated	Aortic Dimensions	Diameter (mm)		Length (mm)		Iliac Dimensions	Diameter (mm)	Length (mm)
BE	A	22	-	40	/	I	13	40
BE	A	22	-	60	/	I	13	40
BE	A	22	-	60	/	I	16	40
BE	A	22	-	70	/	I	16	30
BE	A	22	-	70	/	I	20	30
BE	A	22	-	80	/	I	16	40
BE	A	22	-	80	/	I	20	40
BE	A	22	-	90	/	I	16	30
BE	A	22	-	90	/	I	20	30
BE	A	25	-	60	/	I	16	40
BE	A	25	-	70	/	I	16	30
BE	A	25	-	70	/	I	20	30
BE	A	25	-	80	/	I	13	40
BE	A	25	-	80	/	I	16	40
BE	A	25	-	80	/	I	16	55
BE	A	25	-	80	/	I	20	40
BE	A	25	-	90	/	I	16	30
BE	A	25	-	90	/	I	20	30

Bifurcated	Aortic Dimensions	Diameter (mm)		Length (mm)		Iliac Dimensions	Diameter (mm)	Length (mm)
BE	A	25	-	100	/	I	16	40
BE	A	25	-	100	/	I	20	40
BE	A	25	-	110	/	I	16	30
BE	A	25	-	110	/	I	20	30
BE	A	25	-	120	/	I	16	40
BE	A	25	-	120	/	I	20	40
BE	A	28	-	60	/	I	16	40
BE	A	28	-	70	/	I	16	30
BE	A	28	-	70	/	I	20	30
BE	A	28	-	80	/	I	16	40
BE	A	28	-	80	/	I	20	40
BE	A	28	-	90	/	I	16	30
BE	A	28	-	90	/	I	20	30
BE	A	28	-	100	/	I	16	40
BE	A	28	-	100	/	I	20	40
BE	A	28	-	110	/	I	16	30
BE	A	28	-	110	/	I	20	30
BE	A	28	-	120	/	I	16	40
BE	A	28	-	120	/	I	20	40

AFX Model Numbers

VELA™ Suprarenal Endografts

Aortic Dimensions	Proximal Diameter (mm)		Distal Diameter (mm)		Covered	Length (mm)		Open	Length (mm)	VELA™ Radiopaque Marker
A	25	-	25	/	C	75	-	O	20	V
A	25	-	25	/	C	95	-	O	20	V
A	28	-	28	/	C	75	-	O	20	V
A	28	-	28	/	C	95	-	O	20	V
A	34	-	34	/	C	80	-	O	20	V
A	34	-	34	/	C	100	-	O	20	V

VELA™ Infrarenal Endografts

Aortic Dimensions	Proximal Diameter (mm)		Distal Diameter (mm)		Covered	Length (mm)	VELA™ Radiopaque Marker
A	25	-	25	/	C	75	V
A	25	-	25	/	C	95	V
A	28	-	28	/	C	75	V
A	28	-	28	/	C	95	V
A	34	-	34	/	C	80	V
A	34	-	34	/	C	100	V

Standard Infrarenal Aortic Extensions

Aortic Dimensions	Proximal Diameter (mm)		Distal Diameter (mm)		Covered	Length (mm)
A	25	-	25	/	C	55
A	28	-	28	/	C	55

AFX Model Numbers

Flexible Limb Extensions

Iliac Dimensions	Proximal Diameter (mm)		Distal Diameter (mm)		Covered	Length (mm)	Design	Stand Alone
I	16	-	16	/	C	55	F	SA
I	20	-	13	/	C	70	F	SA
I	20	-	13	/	C	88	F	SA
I	20	-	20	/	C	55	F	SA

Limb Extensions with Spine

Iliac Dimensions	Proximal Diameter (mm)	Distal Diameter (mm)			Covered	Length (mm)	Design	Stand Alone
I		16	-	16	/ C	88		SA
I	S*	20	-	25	/ C	55		SA
I	S*	20	-	25	/ C	65		SA

*Stepped

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INDICATIONS FOR USE: The Endologix AFX/AFX2 Endovascular AAA Systems are indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair using a surgical vascular access technique or a bilateral percutaneous technique; adequate iliac/femoral access compatible with the required delivery systems (diameter ≥ 6.5mm); a non-aneurysmal aortic neck between the renal arteries and the aneurysm: with length of ≥ 15mm, diameter ≥ 18 to ≤ 32mm and neck angle of 60° to the body of the aneurysm; aortic length ≥ 1.0cm longer than the body portion of the chosen bifurcated model; common iliac artery distal fixation site with length ≥ 15mm, diameter of ≥ 10 to ≤ 23mm, and with ability to preserve at least one hypogastric artery; and with an iliac angle of 90° to the aortic bifurcation. Extension stent grafts must have the ability to overlap the bifurcated stent graft by at least 30 to 40mm proximally and at least 15 to 20mm distally.

CONTRAINDICATIONS: The Endologix AFX/AFX2 Endovascular AAA Systems are contraindicated for use in patents who have a condition that threatens to infect the graft and in patients with sensitivities or allergies to the device materials.

Refer to the Instructions for Use for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

NOTE: The AFX® Endovascular AAA System and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability.

CE marked. Please refer to current product instructions for use.

Endologix