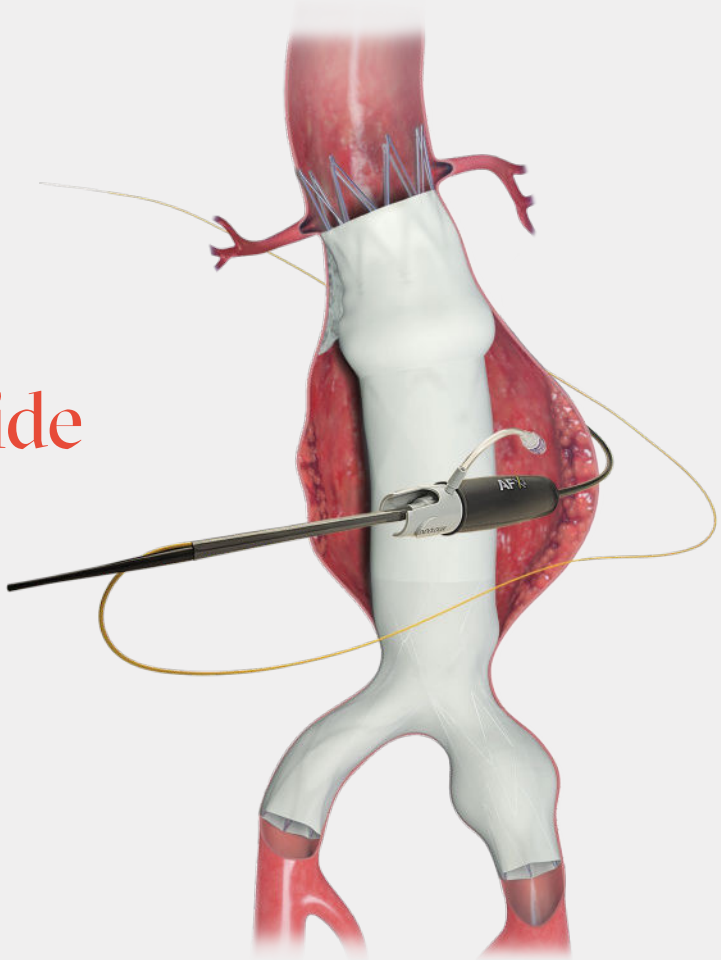
Endologix

Quick Reference Guide



AFX®2
Endovascular
AAA System
with ActiveSeal™

Indications for Use – US

The AFX2 Endovascular AAA System is indicated for endovascular treatment in patients with AAA using a surgical vascular access technique or a bilateral percutaneous technique. 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 AFX2 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

Indications for Use – EU

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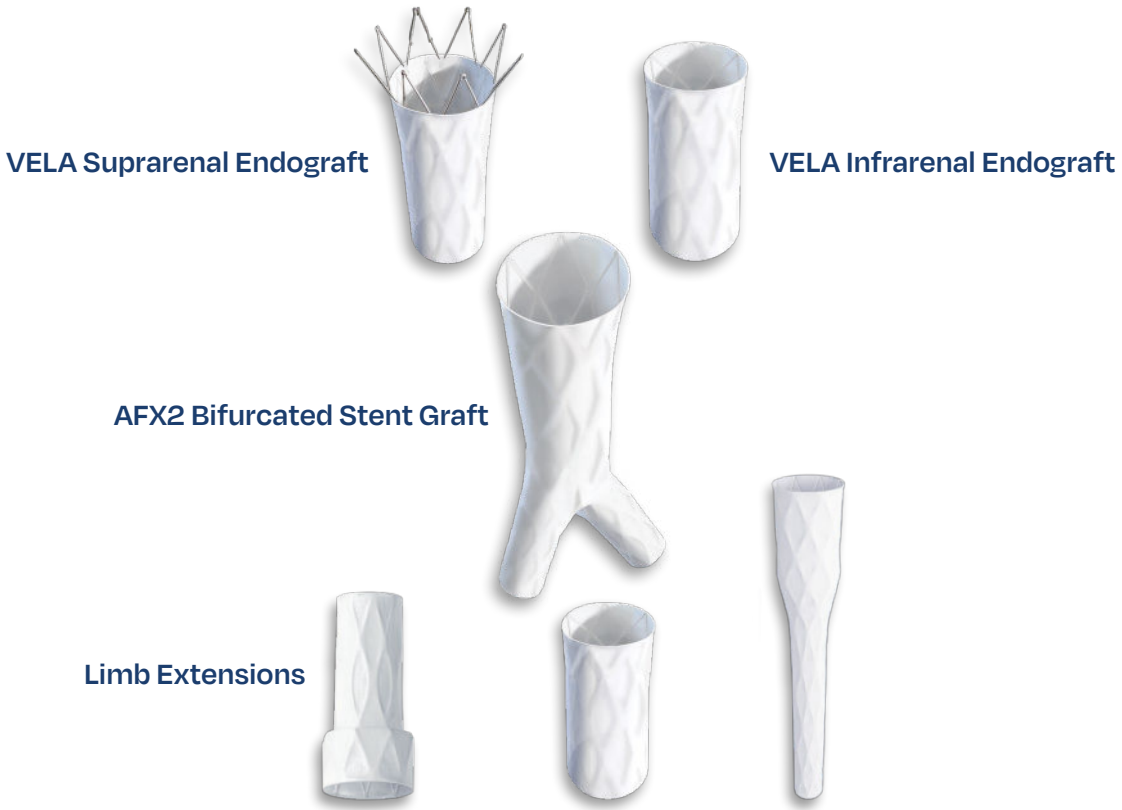
AFX2 System Components



AFX2 Procedure: Materials Required

Products*

- ☐ AFX Introducer system - S17-45
- ☐ AFX2 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
- ☐ HVA-100 ensnare hemostatis valve adapter

Equipment

- ☐ Power injector
- ☐ Ultrasound (optional)
- ☐ IVUS (optional)
- ☐ Compliant aortic balloon

OR Supplies

Sheaths:

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

Additional Wires:

- ☐ 0.035" standard guidewire x2
- ☐ 0.035" stiff wire

Catheters:

- ☐ 0.035" compatible hard tip 5F angiographic pigtail catheter (adequate length)
- ☐ Exchange catheters

Additional Balloons:

- ☐ Compliant aortic balloon
- ☐ PTA balloons

Other:

- ☐ Access needles
- ☐ Micro puncture kit
- ☐ Standard syringes
- ☐ Radiopaque contrast media
- ☐ Heparinized solution and sterile saline solution

If Percutaneous (not indicated in all countries):

- ☐ Ipsilateral percutaneous closure device
- ☐ Contralateral – Physician preference for 7F Sheath

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

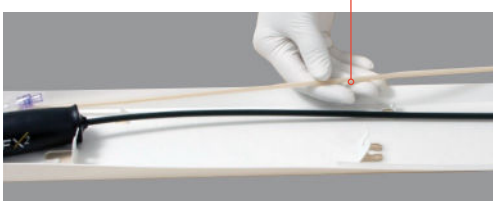
Materials Required

Sterile Transfer: Best Practices

Preloaded wire straightener

Sterile tray

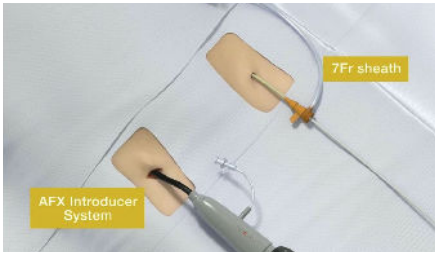
Removal of sheathed wire from the tray



Sterile transfer of device and sheathed wire with preloaded straightener

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

AFX2 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

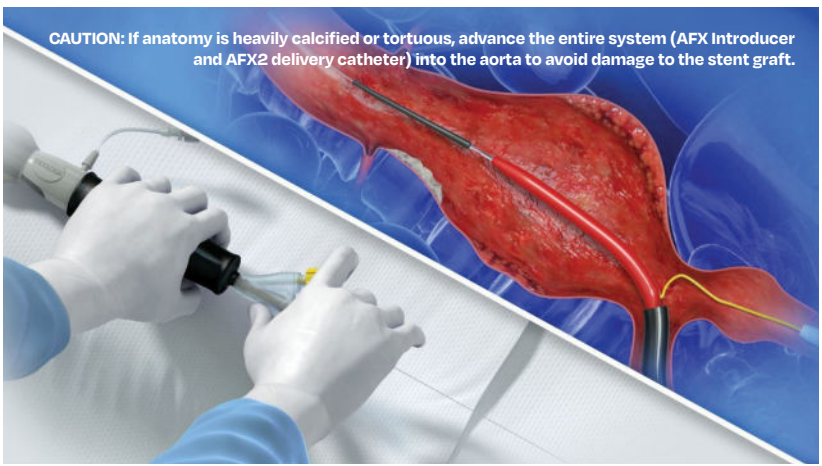
- While advancing the contralateral wire from the ipsilateral side, snare the floppy end of the wire at the aortic bifurcation.
- Withdraw the contralateral wire and snare out of the 7F contralateral sheath while simultaneously advancing the contralateral wire up the ipsilateral side.
- Advance the AFX2 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 full instructions: https://eifu.endologix.com/hcp/endologix/all

AFX2 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.

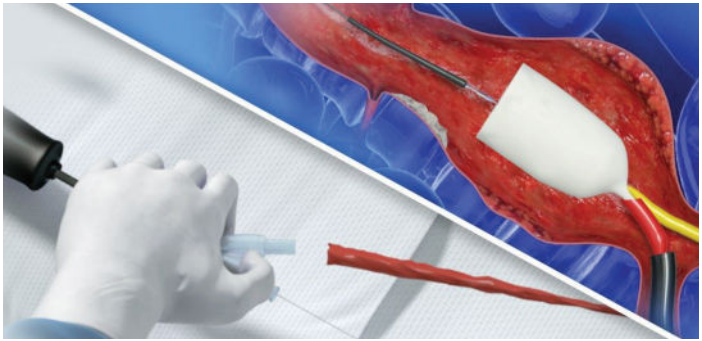
Best practices:

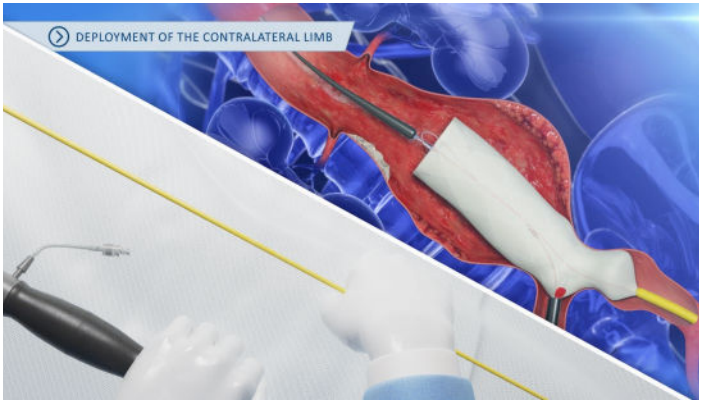
- Ensure delivery system remains parallel to direction of transfer.
- Use a dry sponge to enhance grip to aid in graft transfer.

4. Stent Graft Transfer

- Pin the AFX Introducer handle and advance the inner core.
- Correct for wire orientation by rotating the sheath and inner core together as a unit.
- Continue until the transfer stop is aligned with the device handle then remove the transfer stop.
- Advance the inner core 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.
- Once at the transfer stop pin the introducer sheath and inner core and twist to resolve wire orientation if misaligned.

AFX2 Bifurcated 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.

CAUTION: 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 Bifurcated Deployment

3. Contralateral Wire Release

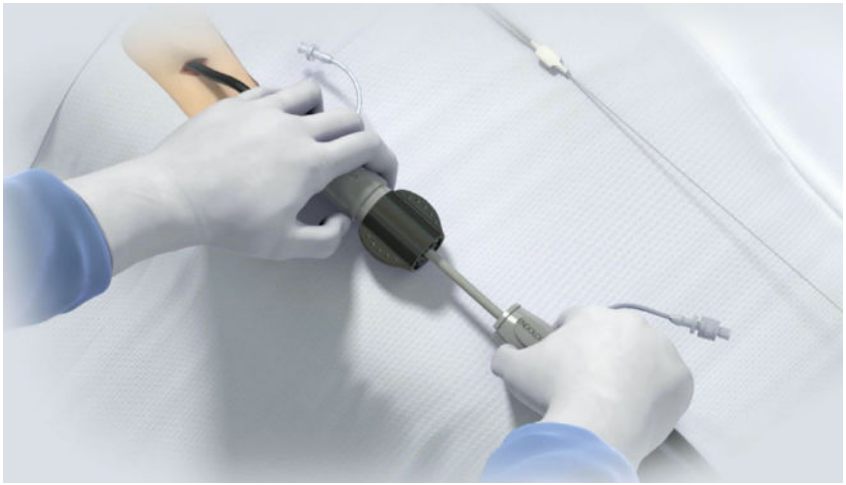
- Advance a pigtail catheter over the contralateral wire until the tip is in contact with the wire lock.
- Advance the pigtail and wire together until an arch is formed above the wire lock.
- Hold the pigtail catheter in place and pull on the contralateral wire to release it from the wire lock.

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 base of the nose cone is just above the aortic bifurcation, stabilize the inner core and retract the AFX Introducer sheath to deploy the ipsilateral limb inside the AFX Introducer sheath.

AFX2 System Removal

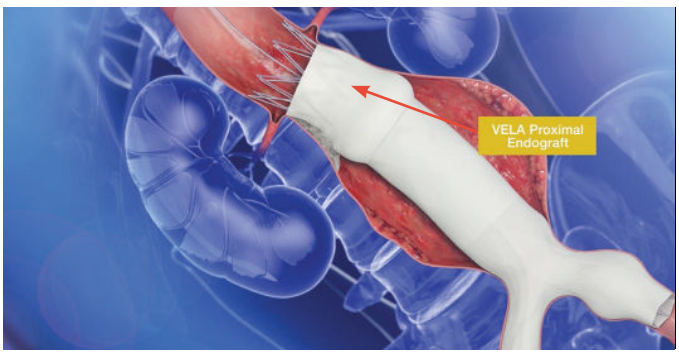


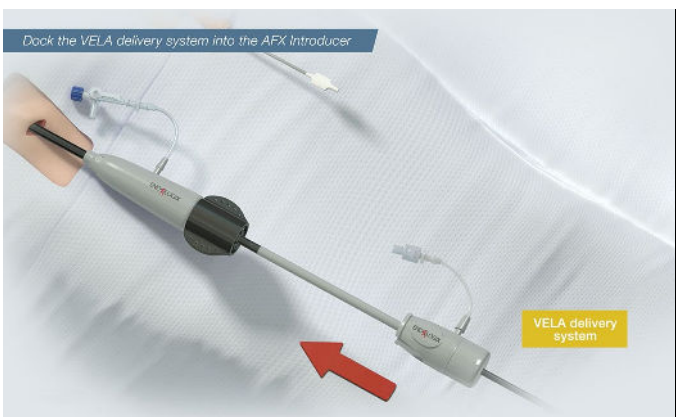
- Retract the inner core until it reaches a positive stop.
- Compress the docking tabs on the device handle to undock the AFX2 delivery system from the AFX Introducer.
- Remove the AFX2 delivery system from the aortic guidewire.

CAUTION: Fluoroscopic visualization during withdrawal of the AFX2 delivery catheter is necessary to ensure that it does not move the stent graft. Any resistance during withdrawal must be carefully monitored. 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.

System Removal

VELA Deployment





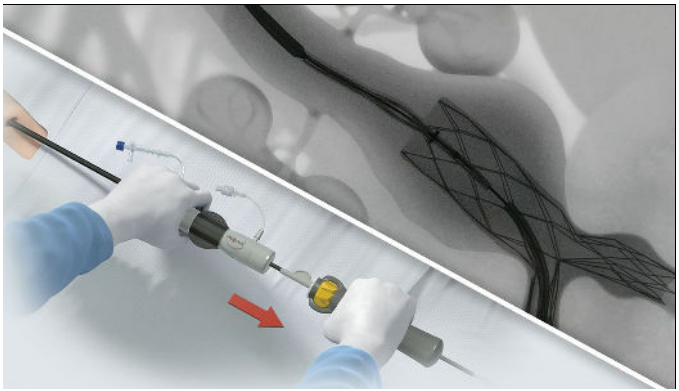
VELA Proximal Endograft Deployment

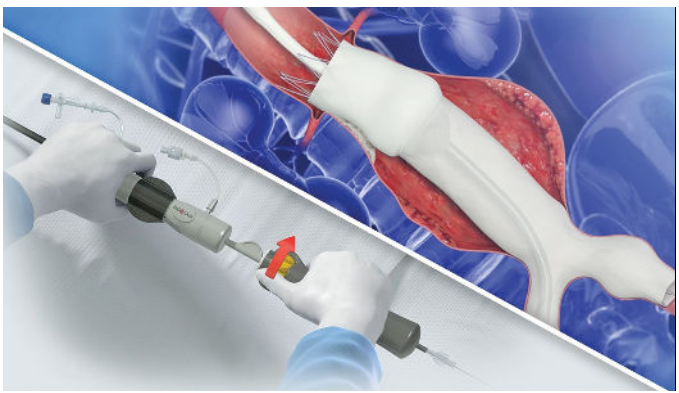
1. VELA Set-Up

- Under fluoro, re-insert 17fr sheath dialator.
- Advance 17fr sheath above the AFX2 main body to the area of the lowest renal ostium.
- Remove 17fr sheath dialator.
- Prep and advance the VELA delivery system over the guide wire and dock into the AFX Introducer sheath.
- Advance the VELA delivery system over the guide wire and dock into the AFX Introducer sheath.

Best practice: Orient the spine of the VELA proximal extension to the greater curve of the aortic neck.

VELA Deployment



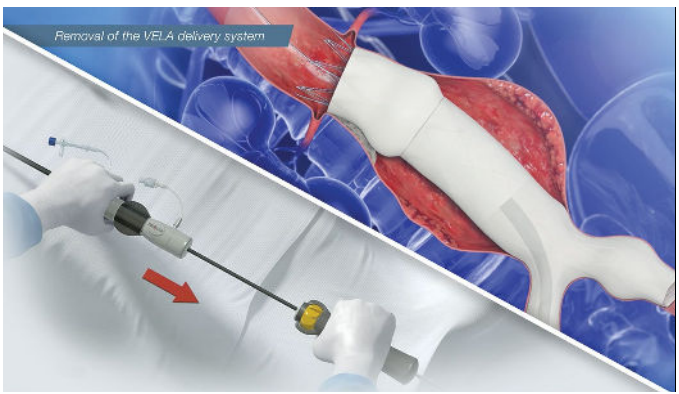


2. VELA Graft Deployment

- Adjust for expected parallax correction and perform angiogram to visualize target position.
- Move system to position the stent graft 1 to 2cm above the target position.
- Remove transfer stop and retract AFX Introducer sheath to back stop for partial graft deployment.
- Rotate the release knob until a tactile click is felt to deploy the proximal section of the graft.
- Utilize circumferential graft line to make c-arm angulation corrections and position graft as necessary. Repeat angiogram if c-arm adjustments were made.
- Remove back stop, pin VELA delivery system and retract AFX Introducer sheath to deploy distal stent segment.

VELA Deployment

VELA Deployment

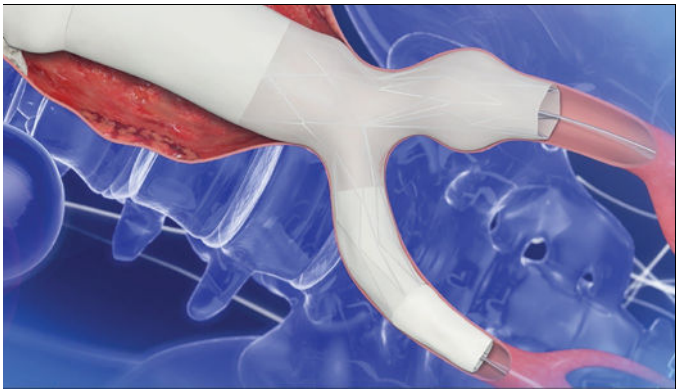


3. VELA Delivery System Removal

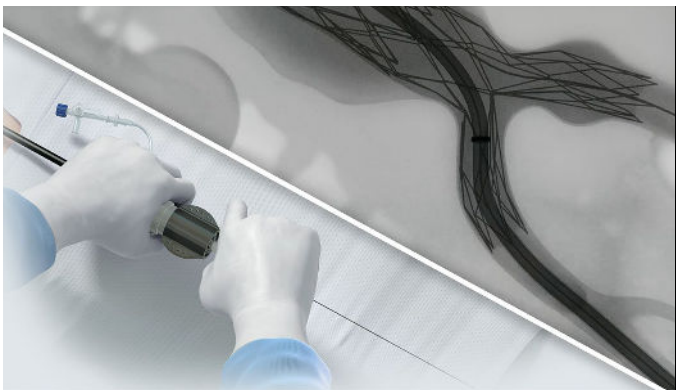
- Retract rear handle to remove the VELA delivery system into AFX Introducer.
- Compress docking tabs to undock the VELA delivery system and remove from guidewire.

CAUTION: If resistance is encountered when turning the knob to remove the release sleeve from the stent graft, stabilize the handle when rotating the knob to ensure the implanted endograft is not inadvertently moved.

Limb Extension Deployment



Limb Extension Deployment

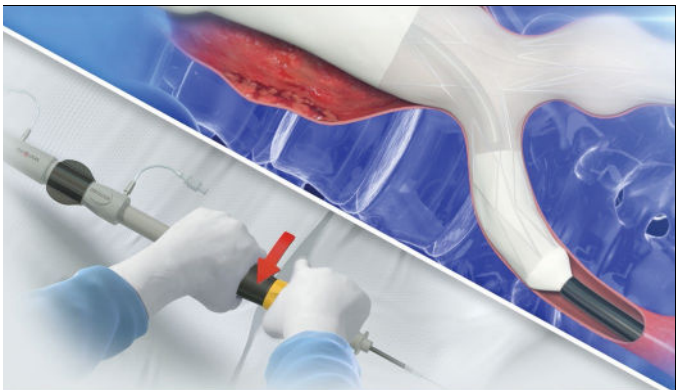


1. Limb Extension System Set-Up

- Insert lumen dilator into AFX Introducer sheath.
- Advance assembly until marker on AFX Introducer is in desired location, remove dilator.

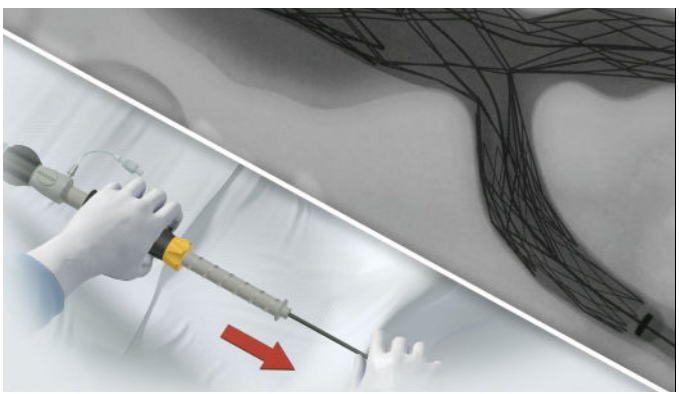
Limb Deployment

Limb Extension Deployment



2. Limb Extension Deployment

- Remove yellow safety clip and pin delivery system black handle.
- Rotate yellow dial counterclockwise to fully deploy limb extension.



3. Limb Extension Delivery System Removal

- Pin handle, press release button, rotate the inner core 90 degrees and slowly retract the inner core until a hard stop is felt.
- Release limb extension delivery system and remove from AFX Introducer sheath.*

* The iliac extension delivery system is a stand alone system and can be used without the introducer.

AFX2 System Graft Selection

STEP 1

Choose VELA 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

AFX2 System 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.

** Endologix products and associated components are not available in all countries or regions. Please consult with your Endologix representative for details regarding product availability.

AFX2 System Graft Selection

STEP 3

Select AFX2 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	60, 70, 80, 90	75, 95
28	25	60, 70, 80, 90, 100, 110, 120	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.

AFX2 System Graft Selection

STEP 4

Choose Limb 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

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AFX2 System Model Numbers

AFX2 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

* Not available outside of the US

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

AFX2 System 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

AFX2 System 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	20	25	-	C	/	55	S*	SA
I	20	25	-	C	/	65	S*	SA

* Stepped

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CONTRAINDICATIONS: The Endologix® AFX®2 Endovascular AAA System is contraindicated for use in patients 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. Rx only.

NOTE: Endologix products and associated components are not available in all countries or regions. Please consult with your Endologix representative for details regarding product availability.

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

Endologix