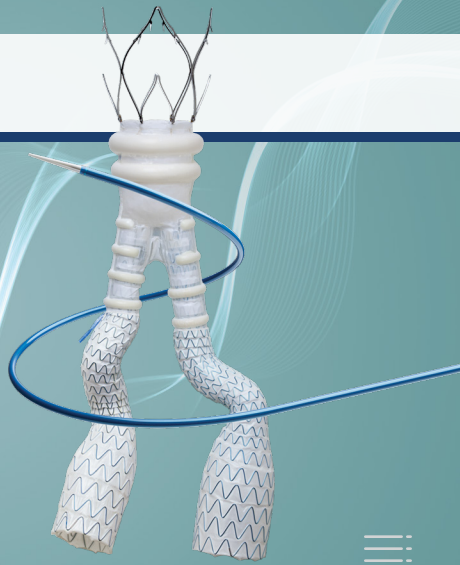
Endologix

Quick Reference Guide



Alto®

Abdominal Stent Graft System

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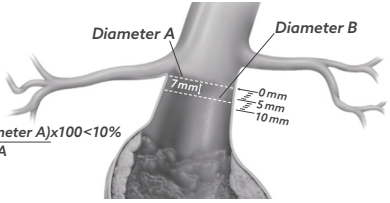
Indications for Use

The ALTO® Abdominal Stent Graft System is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device, which includes:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories,
- A proximal aortic landing zone for the sealing ring 7 mm below the inferior renal artery, (**Figures A and B**).



$$\text{Conicity} = \frac{(\text{Diameter B} - \text{Diameter A}) \times 100}{\text{Diameter A}} < 10\%$$

Figure A: *Proximal Landing Zone and Conicity*

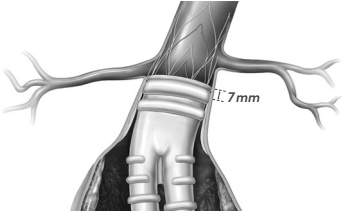


Figure B: *Proximal Landing Zone*

Indications for Use

- An aortic sealing zone comprised of healthy aorta defined as:
  - Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7 mm below the inferior renal artery (**Figure C**),
  - Lack of significant calcification at the level of 7 mm below the inferior renal artery,
  - Conicity < 10% as measured from the inferior renal artery to the aorta 7 mm below the inferior renal artery (**Figure A**),
  - An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
  - An aortic angle of ≤ 60 degrees (**Figure D**).
- A distal iliac landing zone:
  - With a length of at least 10 mm, and
  - With an inner wall diameter of no less than 8 mm and no greater than 25 mm.

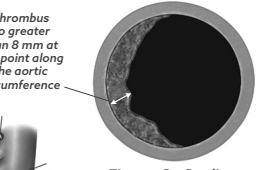


Figure C: *Sealing Zone Thrombus*

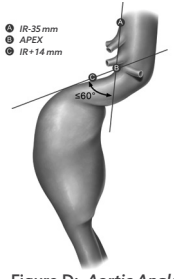
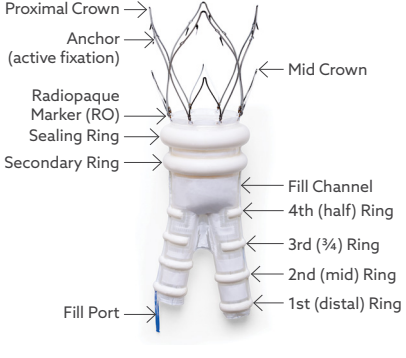


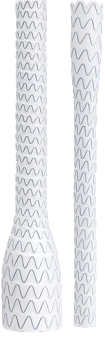
Figure D: *Aortic Angle*

ALTO® System Components

ALTO® Aortic Body



Ovation iX™ Iliac Limbs



Ovation iX™ Iliac Extension

Autoinjector 2

CustomSeal™ Polymer Fill Kit

ALTO® Procedure: Materials Required

Endologix Products

- ☐ ALTO Abdominal Stent Graft Aortic Body preloaded in delivery system—TV-ABXX80-N
- ☐ Ovation iX Iliac Limbs preloaded in delivery systems—TV-IL14XXX0-J (2) size one for each: ipsi and contralateral limbs (may require additional limbs if extending to external iliac or if long distance from IR to the internal iliac)
- ☐ Ovation iX Iliac Extension—TV-EXXXXX45-J (as required)
- ☐ CustomSeal Polymer Fill Kit (14-minute cure time)—TV-CS14-G
- ☐ Autoinjector 2—TV-AI01-N
- ☐ Endovascular Snare (have available)
- ☐ 0.035" compatible (260 cm) Guidewire

Equipment

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

Sheaths

- ☐ < 35 cm introducer sheath (choose appropriate size for specific delivery system)
- ☐ 6-8 F sheath for ipsilateral and contralateral percutaneous access
- ☐ 14 F-16 F sheath for a 12 F-15 F OD contralateral (depending on limb diameter) (optional)
- ☐ 16 F sheath for a 15 F OD ipsilateral device (optional)

ALTO® Procedure: Materials Required

Additional Wires:

- ☐ 0.035" Guidewires (2) 180 or 260 cm lengths* (e.g. Lunderquist, Meier, Amplatz SS, Glidewire, Bentson)
- ☐ 0.014" or 0.018", 300 cm Non-hydrophillic, snare compatible guidewires (e.g., Abbott Miracle Bros, Nitrex, SV5-Cordis, Treasure 12-Asahi Intecc)

Angiographic Catheters:

- ☐ 0.035" compatible radiopaque tip 5 F angiographic Pigtail catheter of adequate length**
- ☐ Exchange catheters and shaped catheters for contra gate cannulation (e.g. Berenstein, Kumpe, Head-hunter, C2, Multi-purpose, JR4, Vanschie5, etc.)

Balloons:

- ☐ 12x4 non-compliant balloons (for leg/limb overlap)
- ☐ Compliant Aortic balloon (e.g. Q50X, Coda, Reliant, etc.)
- ☐ PTA balloons

Other

- ☐ Destino Catheter
- ☐ Micro puncture
- ☐ 30 cc syringe for integrated balloon inflation
- ☐ Contrast
- ☐ Heparinized saline and flushing syringes
- ☐ Time-keeping device
- ☐ Palmaz P4010 balloon expandable stent with appropriately sized balloon
- ☐ 14 F 45 cm Cook sheath for Palmaz (Cook Medical Inc. G28438)
- ☐ Embolization devices (coils)
  If Percutaneous:
  - ☐ Pre-Close devices (Abbott Vascular Inc. Perclose Proglide closure device—4 minimum)

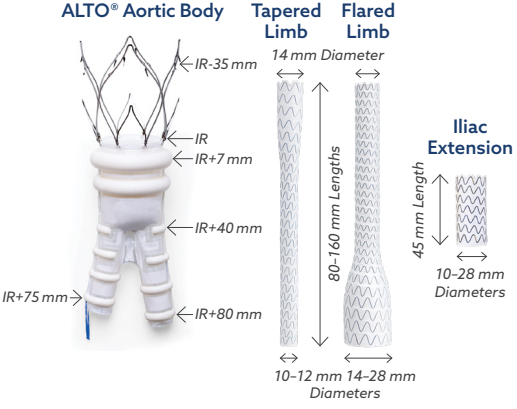
*180 cm guidewire for standard sheath/260 cm for integrated ALTO sheath
**Suggest using a 100 cm long pigtail when using the ALTO system

Pre-Case Sizing

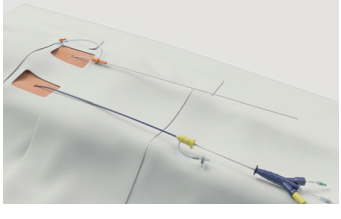
- Select sizes appropriate to the patient's anatomy.
- Confirm that devices on hand match pre-case planned implant sizes.

Aortic ID			Iliac Limb / Extension	
Stent Graft Diameter (mm)	Aortic ID* (mm)	Maximum Aortic Vessel Diameter at Anchors (mm) 35 mm above the lowest renal	Labeled Diameter (mm)	Native Iliac Vessel ID Range (mm)
20	16-17	≤ 24	10	8-9
23	18-20	≤ 26	12	10-11
26	21-23	≤ 29	14	12-13
29	24-26	≤ 32	16	14-15
34	27-30	≤ 35	18	16-17
			22	18-20
			28	21-25

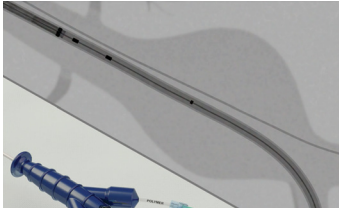
*At the intended proximal sealing ring location.



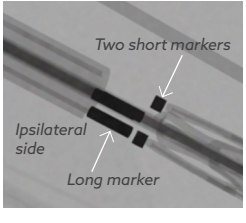
System Set-Up



- Orient the graft outside the patient in the planned orientation.

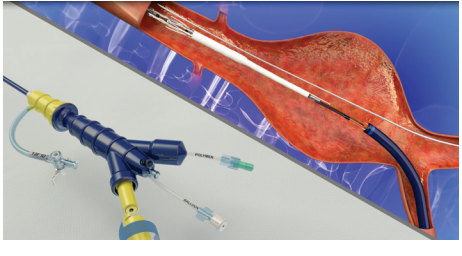


- Using fluoroscopic guidance, advance the delivery system until the radiopaque markers are about 1 cm proximal to the intended landing site.



- Orient the aortic body by rotating the entire delivery system as a unit to align the delivery system markers with the long marker so the ipsi-lateral (or nested knobs) are in desired orientation.

Main Body Deployment



Mid Crown Deployment

- To uncover the graft, stabilize the handle and retract the delivery system outer sheath until the sheath retraction knob meets the handle.
- Verify that aortic body radiopaque markers are approximately 1 cm proximal to the intended landing site.
- Stabilize the delivery system and deploy first segment of proximal stent (mid crown): rotate first deployment knob ¼ turn counterclockwise and then steadily pull knob and attached wire from handle.

Main Body Deployment

Aortic Body Stent Graft Diameter (mm)	Recommended Integrated Balloon Inflation Volume (mL)
20	5
23	
26	
29	10
34	

Integrated Balloon

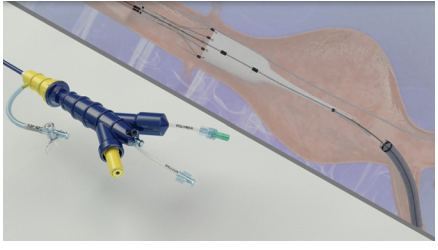
- Remove white cap from balloon injection port on handle.
- Inflate balloon with standard 4:1 saline and contrast mixture. Adhere to recommended inflation volumes (see table).
- Completely deflate the integrated balloon by pulling vacuum on the inflation syringe.

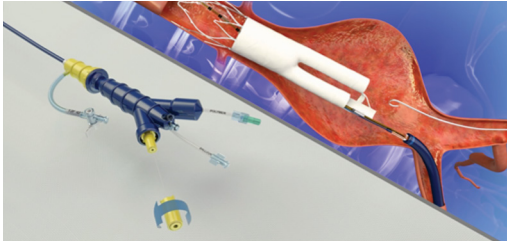
Warnings

- Maximum contrast concentration of integrated balloon solution is 4:1 saline and contrast mixture.
- Never use air or any gaseous medium to inflate the integrated balloon.
- Hand injections using a syringe are recommended for integrated balloon. Do not use a pressure inflation device for integrated balloon inflation.
- Don't inflate integrated balloon beyond recommended inflation volume. Rupture of balloon may occur. Over-inflation may result in damage to vessel wall and/or vessel rupture, or damage to the stent graft.
- Fully deflate integrated balloon and verify it is under syringe vacuum force prior to positioning of catheter.

Main Body Deployment

Proximal Crown Deployment



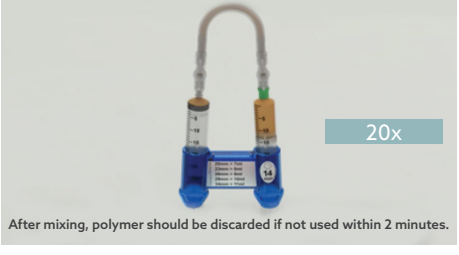


- Correct for parallax and repeat angiogram (if adjustments are made).
- Position bottom of RO markers at floor of inferior renal ostium.

- Stabilize the delivery catheter while retracting the angiographic catheter away from proximal stent.
- Deploy proximal crown. Stabilize the delivery system. Rotate second deployment knob ¼ turn counterclockwise, then pull knob and attached wire from handle.

Polymer Sealing

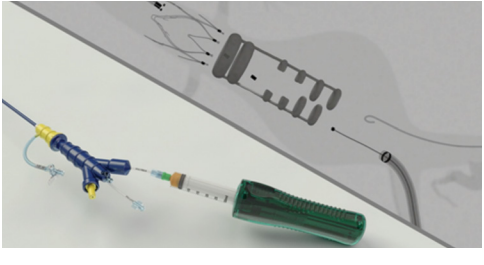
Polymer Fill



After mixing, polymer should be discarded if not used within 2 minutes.

- Open the fill polymer kit stopcocks and mix the polymer using a minimum of twenty full syringe strokes.
  - Note, confirm each syringe has bottomed out prior to beginning the 20 full uninterrupted strokes.
- Start a timer for 14 minutes when mixing is complete.
- Transfer contents to syringe with green band, then expel to the minimum fill syringe volume appropriate to the aortic body size. Close stopcocks. Remove green tear tab and disconnect fill syringe.

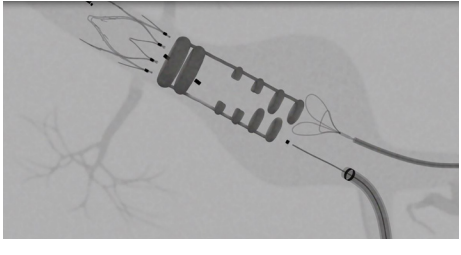
Polymer Sealing



- Remove green fill cap from the polymer injection port on the catheter handle and attach fill syringe.
- Push Autoinjector 2 over the syringe plunger and lock into place by rotating 90 degrees, until you hear an audible click. Fill polymer will begin filling aortic body in ~1 minute.
- Retract aortic body guidewire tip to radiopaque marker distal to aortic body. Under fluoroscopy, intermittently observe filling of graft with radiopaque fill polymer.

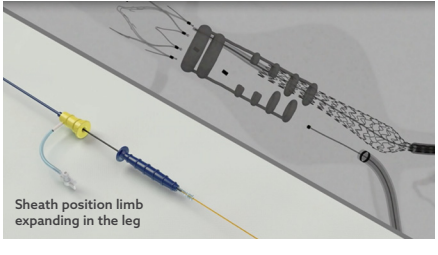
NOTE: Alert anesthesia that polymer fill will begin.

Contralateral Limb Deployment



- Cannulate the contralateral gate with guidewire. The integrated crossover lumen may be used to facilitate the process using a maximum 0.018″ guidewire through the crossover lumen port on the handle.
- Advance wire until the wire exits the crossover lumen at the second ring of the contralateral leg.
- Snare the guidewire and externalize on the contralateral side.
  - Insert a 5 F sheath over the contralateral crossover guidewire. Insert a buddy guidewire into the aortic body leg and advance proximally.
  - Retract wire within crossover lumen through the ipsilateral side and remove sheath on the contralateral side.

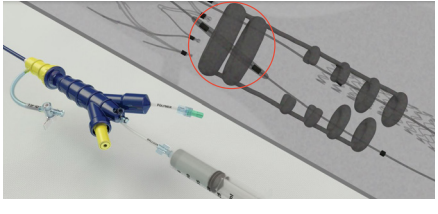
Contralateral Limb Deployment



Sheath position limb expanding in the leg

- Advance marker catheter over the wire to measure required length for the contralateral limb.
- Remove marker catheter and advance limb delivery system over guidewire and into the aortic body leg.
- Position iliac limb radiopaque markers (RO) between the third and fourth half ring of the aortic body leg to ensure appropriate overlap.
- Retract sheath to deploy iliac limb while maintaining catheter handle position.
- Maintain position of sheath and retract catheter handle to position nosecone in end of delivery system outer sheath.
- If maintaining the sheath, reposition sheath tip to desired location and continue to retract the blue handle until entire inner catheter is removed.
  - Alternatively, remove entire delivery system from vasculature and replace with access sheath of choice.

Ballooning to Improve Proximal Seal



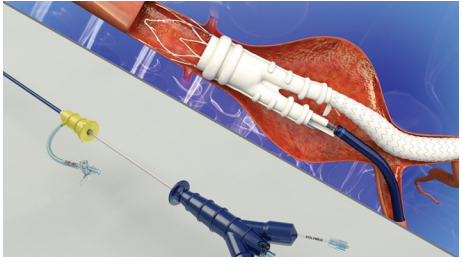
Aortic Body Stent Graft Diameter (mm)	Recommended Integrated Balloon Inflation Volume (mL)	Maximum Integrated Balloon Inflation Volume (mL)
20	5	7
23		8
26		12
29	10	15
34		19

Balloon Proximal Seal

- Verify 14-minute polymer cure time has elapsed.
- Remove the green autoinjector from fill syringe.
- Readvance aortic body guidewire through aortic body delivery system.
- Using fluoroscopy, position balloon radiopaque markers proximal to the primary sealing ring and distal to secondary ring.
- Manually inflate balloon with 4:1 saline and contrast mixture to recommended volume (see table).
- Completely deflate balloon by pulling vacuum and confirm seal angiographically.

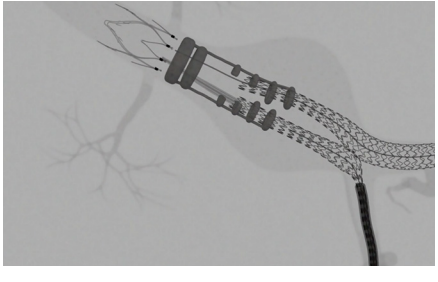
NOTE: In order to maximize polymer moldability, it may be necessary to balloon the proximal sealing ring prior to contralateral limb placement.

Aortic Body Delivery System Removal



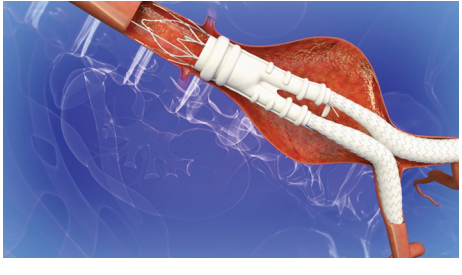
- Rotate the third deployment knob ¼ turn counter-clockwise and pull knob and wire from handle.
- Advance the delivery system sheath to the first ring of the aortic body. Stabilize the delivery system and retract inner catheter.
- When the nosecone is within the aortic body, stop retracting.
- Slightly retract the sheath 2-4 cm, then continue to retract the inner catheter handle to reseat the nosecone into the outer sheath.
- To use the integrated sheath, while maintaining guidewire position, move entire delivery system to desired position. Retract handle to remove the inner catheter from the outer sheath.
  - Alternatively, remove entire delivery system from vasculature.

Ipsilateral Limb Deployment



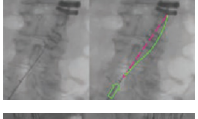
- Advance marker catheter over the wire to measure required length for the ipsilateral limb.
- Remove marker catheter and advance limb delivery system over guidewire and into the aortic body leg.
- Position iliac limb radiopaque markers (RO) between the third and fourth half ring of the aortic body leg to ensure appropriate overlap.
- Retract sheath to deploy iliac limb while maintaining catheter handle position.
- Maintain position of sheath and retract catheter handle to position nosecone in end of delivery system outer sheath.
- If maintaining the sheath, reposition sheath tip to desired location and continue to retract the blue handle until entire inner catheter is removed.
  - Alternatively, remove entire delivery system from vasculature and replace with access sheath of choice.

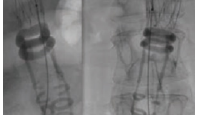
Confirm Aneurysm Exclusion and System Removal



- Advance angiographic catheter through the integrated sheath, through the aortic body and into the suprarenal space.
- Perform angiogram to confirm aneurysm exclusion and graft patency.
- If iliac extensions are required, proceed with deployment.
- Remove angiographic catheter.
- Remove delivery system sheath from the aortic guidewire.

Best Practices to Optimize Proximal Seal





Accuracy, Apposition, Seal, Balloon, Stent

1. Accuracy

a. Adjust C-Arm for parallax, magnify at renals, and ensure radiopaque markers are in a line.

b. Repeat angiogram if imaging orientation is changed in any way.

c. Position bottom of radiopaque markers at the floor of the renal ostium.

2. Apposition (prior to and during the polymer fill)

a. Retract angiographic catheter before deploying second yellow deployment knob for proximal crown deployment.

b. Retract aortic body guidewire until the stiff-to-floppy transition of the wire is in the ipsilateral leg of the aortic body.

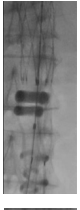
c. Ensure no tension on delivery system.

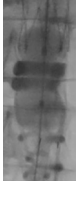
3. Confirm Seal

a. From 1 to 14 minutes post polymer mix, visually check that the edges of the sealing ring are flat vs rounded and are of uniform density (no apparent infolding).

b. Change orientation to see circular sealing ring.

Best Practices to Optimize Proximal Seal





4. Balloon

a. Integrated balloon can be used if the aortic body system is in place.

b. Non-compliant balloon use in the proximal sealing zone can only occur after AB delivery system has been removed.

c. If unable to achieve seal post balloon deployment, follow next steps.

5. Stent

a. Reinforce sealing ring with a balloon expandable stent (BES) if aneurysm is not excluded.

b. Align the proximal edge of the BES with proximal graft radiopaque markers. Ensure that stent and balloon are above the aortic body flow divider.

c. Consider coil embolization as secondary backup.

Balloon has greatest effect on molding customized seal immediately following 14 minutes post-polymer mix (with reduced efficiency after 25 minutes). By 30 minutes post-polymer fill the ability of the balloon to mold the seal is minimized. Prioritize this over limb deployment.

Procedural Considerations

Challenge	Solution
Aortic neck angulated anatomy	• Retract stiff guidewire so the stiff-to-floppy transition is in the ipsilateral leg of the aortic body after polymer has filled the graft. • Ensure delivery system does not place tension on aortic body. • Irregular sealing rings or straightened fill chambers are indicators of tension.

Challenge	Solution
Crossover lumen guidewire damaged during snaring	• Advance aortic body stiff guidewire, demate, confirm 14-minute polymer cure time has elapsed, and remove aortic body. The crossover lumen and damaged guidewire will come out with aortic body removal.

Procedural Considerations

Challenge	Solution
Limb is placed too high in aortic body	• >1 cm above 4th ring—place 2nd limb to match and use 12 mm non-compliant kissing balloon in proximal iliac limb. • 0-1 cm above 4th ring—use kissing balloons, if needed, to equalize flow lumen.

Challenge	Solution
Limb is placed too low in aortic body	• Between 2nd and 3rd ring—use 12 mm non-compliant kissing balloons at aortic body bifurcation to ensure good apposition and balanced lumens. • Below 2nd ring—place a 14 mm graft of appropriate length between 3rd and 4th ring. Use kissing balloon technique with 12 mm PTA balloons throughout aortic body leg and an overlap limb alignment.

Ballooning Considerations—Aortic Body

Timing (post polymer mix)	Type of Balloon
0 to 14 minutes	No ballooning allowed
≥14 minutes	Integrated balloon (or Compliant if integrated balloon has been removed or damaged)
>30 minutes	Ballooning much less effective

- Keep the lower margin of the balloon proximal to the AB bifurcation.
- Non-compliant balloons only used after AB delivery system has been removed.

ALTO® Aortic Body Graft Selection

Proximal Graft Nominal Size (mm)	Min–Max Vessel Diameter (mm)	Max Aortic Vessel Diameter at Anchors (mm)	Inner "Bore" Diameter (mm)	Labeled Length (mm)	ALTO Delivery Catheter ID/OD (F)
20	16–17	≤24	15	80	13/15
23	18–20	≤26	17		
26	21–23	≤29	20		
29	24–26	≤32	23		
34	27–30	≤35	26		

Note: Standard rounding rules apply to vessel diameter measurements. Indications are for proximal aortic neck inner wall diameter of no less than 16 mm and no greater than 30 mm.

Limb Graft Selection

Iliac Limb: Diameter Sizing

Distal Graft Nominal Size (mm)	Native Iliac Vessel ID Range (mm)	Min – Max Vessel Diameter (mm)	Ovation iX™ Delivery Catheter ID/OD (F)
10	8–9	8–9	10/12
12	10–11	10–11	
14	12–13	12–13	
16	14–15	14–15	11/13
18	16–17	16–17	
22	18–20	18–20	12/14
28[1]	21–25	21–25	13/15

Note: Standard rounding rules apply to vessel diameter measurements. Indications are for inner wall diameter of no less than 8 mm and no greater than 25 mm[2].

1. 28 mm limb diameter available with the Ovation iX™ Iliac Stent Graft.
2. Ovation iX™ Iliac Stent Graft allows treatment up to 25 mm iliac vessel.

Model Numbers

ALTO® Aortic Body

Catalog Number	Delivery System Inner Profile (F)	Delivery System Outer Profile (F)	Stent Graft Proximal Diameter (mm)	Stent Graft Length (mm)
TV-AB2080-N	13	15	20	80
TV-AB2380-N			23	
TV-AB2680-N			26	
TV-AB2980-N			29	
TV-AB3480-N			34	

Ovation iX™ Iliac Limb

Catalog Number	Delivery System Inner Profile (F)	Delivery System Outer Profile (F)	Stent Graft Proximal Diameter (mm)	Stent Graft Distal Diameter (mm)	Stent Graft Length (mm)	Stent Graft Length with Aortic Body (mm)
TV-IL141080-J	10	12	14	10	80	125
TV-IL1410100-J					100	145
TV-IL1410120-J					120	165
TV-IL1410140-J					140	185
TV-IL1410160-J					160	205

Model Numbers

Ovation iX™ Iliac Limb

Catalog Number	Delivery System Inner Profile (F)	Delivery System Outer Profile (F)	Stent Graft Proximal Diameter (mm)	Stent Graft Distal Diameter (mm)	Stent Graft Length (mm)	Stent Graft Length with Aortic Body (mm)
TV-IL141280-J	10	12	14	12	80	125
TV-IL1412100-J					100	145
TV-IL1412120-J					120	165
TV-IL1412140-J					140	185
TV-IL1412160-J					160	205
TV-IL141480-J	10	12	14	14	80	125
TV-IL1414100-J					100	145
TV-IL1414120-J					120	165
TV-IL1414140-J					140	185
TV-IL1414160-J					160	205
TV-IL141680-J	11	13	14	16	80	125
TV-IL1416100-J					100	145
TV-IL1416120-J					120	165
TV-IL1416140-J					140	185
TV-IL1416160-J					160	205

Model Numbers

Ovation iX™ Iliac Limb

Catalog Number	Delivery System Inner Profile (F)	Delivery System Outer Profile (F)	Stent Graft Proximal Diameter (mm)	Stent Graft Distal Diameter (mm)	Stent Graft Length (mm)	Stent Graft Length with Aortic Body (mm)
TV-IL141880-J	11	13	14	18	80	125
TV-IL1418100-J					100	145
TV-IL1418120-J					120	165
TV-IL1418140-J					140	185
TV-IL1418160-J					160	205
TV-IL142280-J	12	14	14	22	80	125
TV-IL1422100-J					100	145
TV-IL1422120-J					120	165
TV-IL1422140-J					140	185
TV-IL1422160-J					160	205
TV-IL142880-J	13	15	14	28	80	125
TV-IL1428100-J					100	145
TV-IL1428120-J					120	165
TV-IL1428140-J					140	185
TV-IL1428160-J					160	205

Model Numbers

Ovation iX™ Iliac Extension

Catalog Number	Delivery System Inner Profile (F)	Delivery System Outer Profile (F)	Stent Graft Proximal Diameter (mm)	Stent Graft Distal Diameter (mm)	Stent Graft Length (mm)
TV-EX101045-J	10	12	10	10	45
TV-EX121245-J	10		12	12	
TV-EX141445-J	10		14	14	
TV-EX161645-J	11	13	16	16	
TV-EX181845-J	11		18	18	
TV-EX222245-J	12	14	22	22	
TV-EX282845-J	13	15	28	28	

Autoinjector 2

Catalog Number
TV-AI01-N

CustomSeal™ Polymer Fill Kit

Catalog Number
TV-CS14-G

INDICATIONS FOR USE: The ALTO® Abdominal Stent Graft System is indicated for treatment of patients with infrarenal abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair with the device, which includes the following:

- Adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories,
- A proximal aortic landing zone for the sealing ring 7 mm below the inferior renal artery.
- An aortic sealing zone comprised of healthy aorta defined as:
  - Lack of significant thrombus > 8 mm in thickness; at any point along the aortic circumference at the level of 7 mm below the inferior renal artery,
  - Lack of significant calcification at the level of 7 mm below the inferior renal artery,
  - Conicity < 10% as measured from the inferior renal artery to the aorta 7 mm below the inferior renal artery,
  - An inner wall diameter of no less than 16 mm and no greater than 30 mm at 7 mm below the inferior renal artery, and
  - An aortic angle of ≤ 60 degrees
- A distal iliac landing zone:
  - With a length of at least 10 mm, and
  - With an inner wall diameter of no less than 8 mm and no greater than 25 mm.

CONTRAINDICATIONS: The system is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, contrast agents, fluorinated ethylene propylene [FEP], titanium, nickel, platinum, or iridium.

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

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

NOTE: Not all product components are available in every country. Please consult with your Endologix representative to confirm product availability.

Endologix