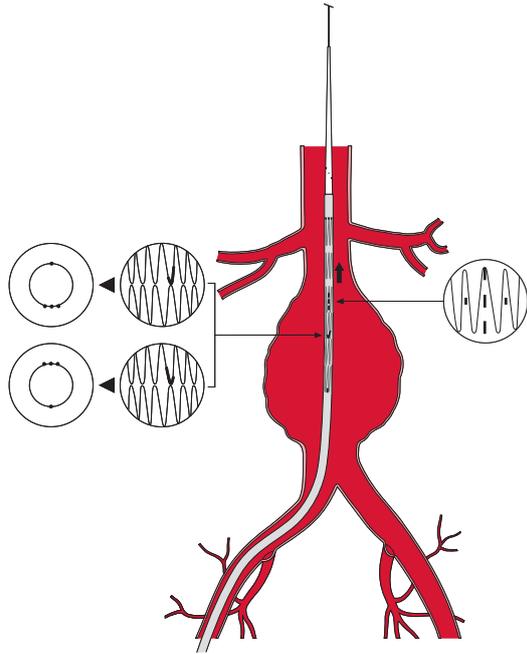


DEPLOYMENT OVERVIEW*

1

POSITION PROXIMAL BODY



Before insertion, position proximal body delivery system on patient's abdomen under fluoroscopy to assist with orientation and positioning. Rotate to a position where the anterior markers are situated in the most anterior (12:00 o'clock) position.

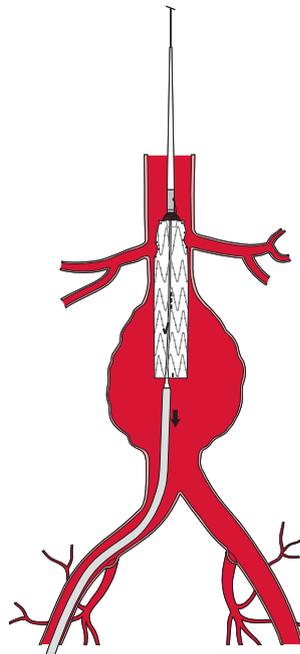
Advance the delivery system until the radiopaque markers indicating the fenestration(s) and/or scallop(s) are at the level of the appropriate arteries. Check that the distal end of the graft is in a satisfactory position above the aortic bifurcation and that the anterior and posterior markers indicate that the graft is in satisfactory orientation.

Verify position of the wire guide in the thoracic aorta. Ensure that fenestration(s) and/or scallop(s) are at the level of the appropriate arteries and the anterior markers are in the most anterior (12:00 o'clock) position.

NOTE: The vertical anterior markers and the horizontal posterior markers should form a cross on the fluoroscopic image when correctly oriented.

NOTE: The fenestration/scallop markers should be in close apposition to the appropriate side branch vessels.

1A



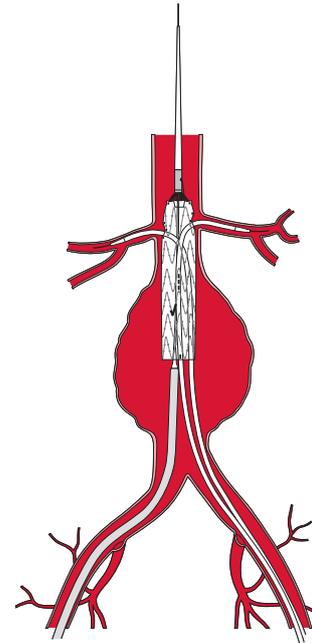
Stabilise the grey positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two (2) covered stents by withdrawing the sheath while monitoring device location.

Perform angiography, and adjust graft placement as necessary. Continue to withdraw the sheath making positional adjustments as necessary.

Proceed with deployment until the graft has been fully unsheathed.

2

CANNULATE FENESTRATIONS



When a satisfactory graft position has been achieved, withdraw the angiographic catheter and wire guide, then exchange to selective wire guide/selective catheter to below the level of the proximal body. Cannulate the partially deployed proximal main body.

NOTE: If a small fenestration is being utilised, care should be taken to properly align the fenestration with the respective vessel.

Utilising contralateral access sheath and wire guide, advance a guiding catheter into each small fenestration and its respective vessel.

3

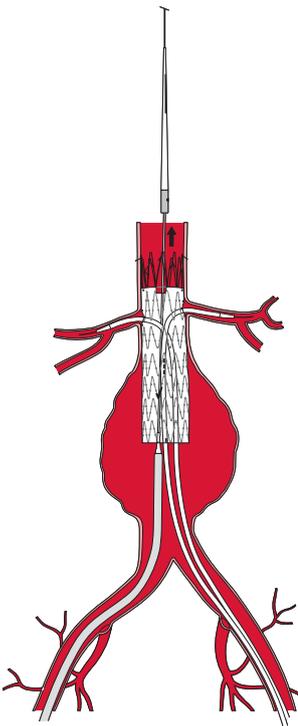
RELEASE DIAMETER REDUCING TIES AND UNLOCK TOP CAP

Verify proper position of proximal body. Remove the safety lock from the gold trigger-wire release mechanism. Withdraw and remove the trigger-wire by sliding the gold trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula.

Remove the safety lock from the black trigger-wire release mechanism. Withdraw and remove the trigger-wire to unlock the suprarenal stent from the top cap by sliding the black trigger-wire release mechanism off the handle and then remove via its slot over the inner cannula.

4

DEPLOY SUPRARENAL STENT



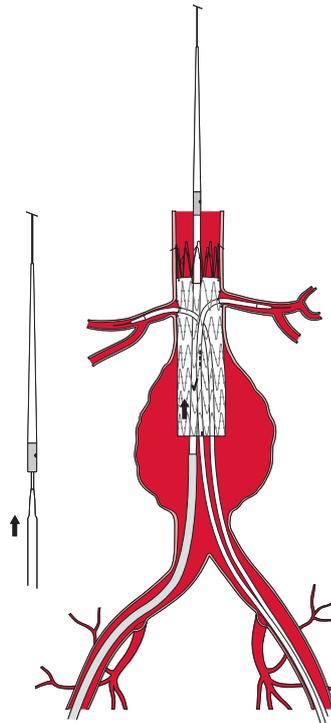
Loosen the pin vise. Control the position of the graft by stabilising the grey positioner of the introducer.

Deploy the suprarenal stent by advancing the top cap inner cannula 1 to 2 mm at a time while controlling the position of the proximal body until the top stent is fully deployed. Advance the top cap cannula an additional 1 to 2 cm and then re-tighten the pin vise to avoid contact with the deployed suprarenal stent.

Remove the safety lock from the white trigger-wire release mechanism. Withdraw and remove the trigger-wire to detach the distal end of the endovascular graft from the delivery system by sliding the white trigger-wire release mechanism off the handle and then remove via its slot over the device inner cannula.

5

DOCK TOP CAP



Loosen the pin vise.

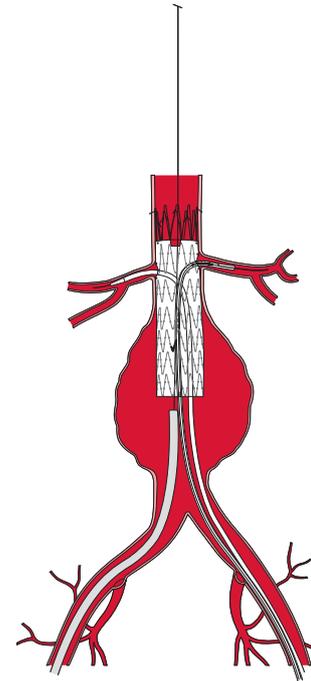
Secure sheath and inner cannula to avoid any movement of these components.

Advance the grey positioner over the inner cannula until it docks with the top cap.

Re-tighten the pin vise and withdraw the entire top cap and grey positioner through the graft and through the sheath by pulling on the inner cannula. Leave the sheath and wire guide in place.

6

PLACE FENESTRATION STENT

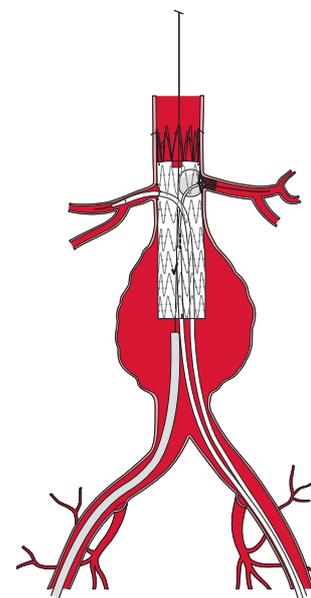


Return to the guide catheter and wire guide which cannulate the small fenestration and respective vessel.

Introduce appropriately sized balloon expandable stent and advance to the ostium of the fenestration/vessel. Advance into the vessel, leaving approximately 5 mm of stent in the aorta.

NOTE: Fluoroscopic views tangential to the fenestration will optimize visualization of the stent position relative to the stent graft.

6A



Expand stent.

Remove the balloon and replace with an oversized angioplasty balloon.

Advance the balloon until the proximal tip is positioned at the ostium.

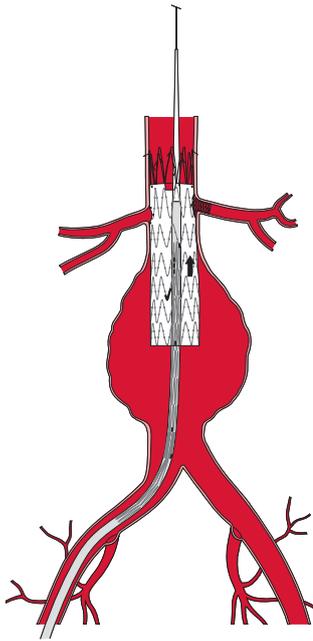
Inflate the balloon to flare the intra-aortic segment of the stent.

Remove the angioplasty balloon.

NOTE: Repeat the preceding steps for each additional small fenestration.

7

POSITION DISTAL BIFURCATED BODY



Before insertion, position distal bifurcated body delivery system on patient's abdomen under fluoroscopy to determine the orientation of the contralateral limb. Note position of sidearm of hemostatic valve.

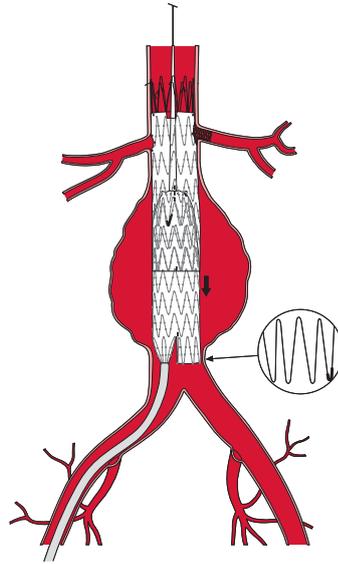
Insert distal bifurcated body delivery system over the wire, into the femoral artery with attention to sidearm reference.

Advance delivery system until the contralateral limb is positioned above and anterior to the origin of the contralateral iliac. If the contralateral limb radiopaque marker is not properly aligned, rotate the entire system until it is correctly positioned halfway between a lateral and an anterior position on the contralateral side.

Repeat angiogram and reposition distal bifurcated body as required.

8

DEPLOY DISTAL BIFURCATED BODY CONTRALATERAL LIMB



CAUTION: When introducing distal bifurcated body, observe proximal body closely to avoid any disruption to its position.

Stabilise the grey positioner (the shaft of the delivery system) while withdrawing the sheath. Deploy the first two (2) covered stents by withdrawing the sheath while monitoring device location. Proceed with deployment until contralateral limb is fully deployed.

9

POSITION CONTRALATERAL ILIAC WIRE GUIDE

Manipulate catheter and the wire guide into the contralateral limb and into the distal bifurcated body. AP and oblique fluoroscopic views can aid in verification of device cannulation.

Advance the angiographic catheter into the body of the graft. Perform angiography to confirm correct position inside the distal bifurcated body. Advance the catheter to where the proximal end of the distal bifurcated body is attached to the introducer.

10

DEPLOY DISTAL BIFURCATED BODY

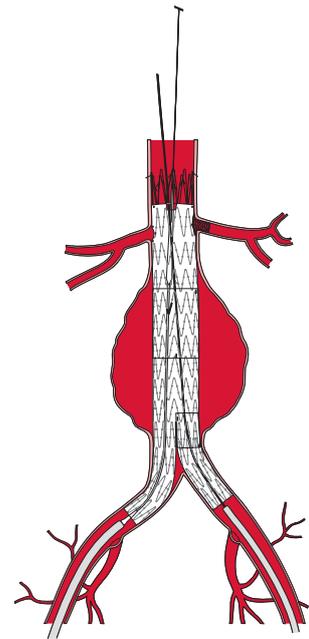
Perform angiography to confirm proper position of the iliac leg with respect to the internal iliac (hypogastric) artery.

Adjust position if necessary.

Withdraw sheath until the iliac leg is fully deployed. Remove the safety lock from the black trigger-wire release mechanism. Withdraw and remove the black trigger-wire release mechanism. Stop withdrawing sheath.

11

POSITION CONTRALATERAL ILIAC LEG



Introduce the contralateral iliac leg delivery system into the artery. Advance slowly until the iliac leg graft overlaps at least one full iliac leg stent (i.e., proximal stent of iliac leg graft) inside the contralateral limb of the main body.

Reposition the iliac leg graft if necessary to ensure both internal iliac patency and a minimum overlap of one full iliac leg stent (i.e., proximal stent of iliac leg graft, maximum overlap of 1.5 stents) within the main body endovascular graft.

To deploy, hold the iliac leg graft in position with the grey positioner while withdrawing the sheath. Stop withdrawing the sheath as soon as the distal end of the iliac leg graft is released.

Verify iliac leg graft position, loosen pin vise, retract inner cannula to dock tapered dilator to grey positioner. Tighten pin vise and withdraw grey positioner with secured inner cannula.

12

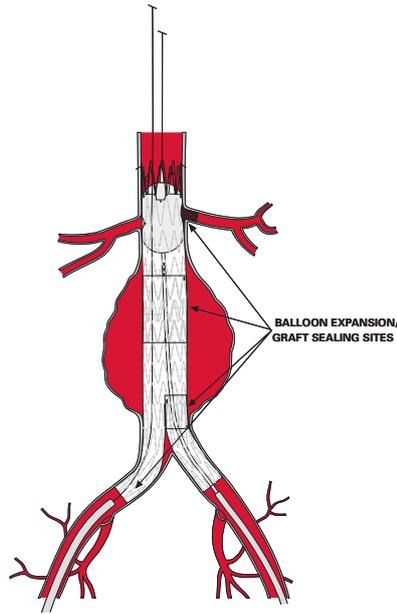
DEPLOY DISTAL BIFURCATED BODY

Remove the safety lock from the white trigger-wire release mechanism. Withdraw and remove the white trigger-wire release mechanism. Verify iliac leg graft position, loosen pin vise, retract inner cannula to dock tapered dilator to grey positioner. Tighten pin vise and withdraw grey positioner with secured inner cannula.

Leave sheath and wire guide in place. Close the Captor® Hemostatic Valve on the introducer sheath.

13

INSERT MOLDING BALLOON



Advance the molding balloon over the wire guide and through the Hemostatic Valve of the distal bifurcated body introduction system.

NOTE: Captor Hemostatic Valve should always be in the "open" position when repositioning molding balloon.

Expand the molding balloon with diluted contrast media, starting proximally and working in the distal direction.

CAUTION: Prior to molding in the vicinity of any fenestration stent(s), confirm that the aortic section of the stent has been flared.

Withdraw the molding balloon to the ipsilateral limb distal fixation site and expand.

CAUTION: Do not inflate balloon in iliac vessel outside of graft.

Deflate and remove molding balloon. Transfer the molding balloon onto the contralateral wire guide and into the contralateral iliac leg introduction system. Advance molding balloon to the contralateral limb overlap and expand.

CAUTION: Confirm complete deflation of balloon prior to repositioning.

Withdraw the molding balloon to the contralateral iliac leg/vessel distal fixation and expand.

Deflate and remove molding balloon and replace it with an angiographic catheter to perform completion angiograms.



www.cookmedical.com

COOK MEDICAL INCORPORATED

P.O. Box 4195, Bloomington, IN 47402-4195 U.S.A.
Phone: 812 339-2235, Toll Free: 800 457-4500, Toll Free Fax: 800 554-8335

COOK (CANADA) INC.

111 Sandiford Drive, Stouffville, Ontario, L4A 7X5 CANADA
Phone: 905 640-7110, Toll Free: 800 668-0300

WILLIAM A. COOK AUSTRALIA PTY. LTD.

Brisbane Technology Park, 12 Electronics Street, Eight Mile Plains
Brisbane, QLD 4113 AUSTRALIA, Phone: +61 7 38 41 11 88

WILLIAM COOK EUROPE ApS

Sandet 6, DK-4632, Bjaeverskov, DENMARK, Phone: +45 56 86 86 86

© WILLIAM COOK EUROPE 2007 OUS-FENDO-0706-437-01EN