Advanta V12

Balloon expandable covered stent

Preparation Instructions

Step 1. Carefully remove the device from the sterile package and ensure the crimped stent or catheter shaft does not come in contact with any non-sterile surfaces or instruments.

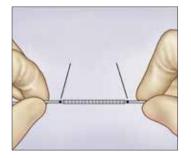


Step 6. Release the pressure to neutral by gently letting go of the syringe plunger (keeping syringe in an upright position) to allow contrast to fill the delivery catheter inflation lumen(s).

IMPORTANT: Do not apply positive pressure to the balloon as this can loosen the stent.



Step 2. Visually inspect the stent to ensure it is centered within the radiopaque markers which are viewable through the folded balloon.



Step 7. Repeat steps 5 and 6 at least 3 times until all of the air in the delivery system is expelled. Steps 5 & 6 remove the air from the inflation lumen(s) and balloon to allow diluted contrast media to fill the inflation lumen(s) in order to provide more uniform inflation of the balloon during stent deployment.

Step 3. Prefill a syringe with sterile saline.



Step 8. Prepare a 20cc inflation device equipped with a manometer by filling with 10cc of diluted contrast media for 5-10mm diameter balloons. Expel all of the air from the inflation device.

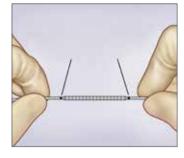
Step 9. Attach the pre-filled inflation device to the inflation lumen of the catheter hub (labeled I), ensuring no air bubbles remain at the catheter connection.



Step 4. Attach the prefilled syringe to the guidewire lumen port as shown (labeled W on the catheter hub) and flush the guidewire lumen until the fluid exits the guidewire exit at the distal tip of the device.



Step 10. After the inflation device is connected, confirm the covered stent is between the RO markers. This visual inspection step verifies all preparation steps did not create positive pressure (which could cause inadequate stent deployment) and the stent remains securely positioned within the RO markers prior to patient use.



Stent is centered between radiopaque markers

Step 5. Prepare a 20 cc syringe or balloon inflation device with saline or diluted contrast mixture and attach to the balloon inflation port (labeled I on the catheter hub). Hold the delivery system vertical with the distal tip pointing down. Draw back on the syringe applying negative pressure to the catheter and hold for 30 seconds with the syringe in the vertical position.



Advanta V12 5-10 mm



The V12 Covered Stent System is indicated for restoring and improving patency of iliac and renal arteries. Renal approval is for 5-7mmm sizes.

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