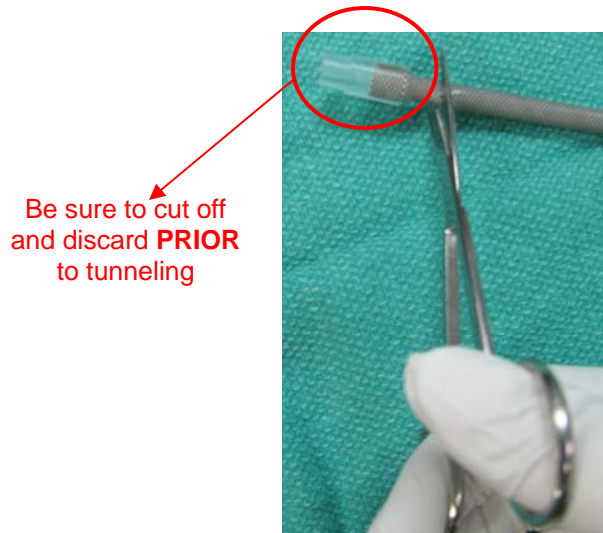


Connecting the HeRO Device During the Implant Procedure

The Instructions for Use document for the HeRO Device can be found in every packaged device component, or is available on the company website at www.heroaccess.com. These questions are frequently asked about device connection:

Question: What does it mean to cut the proximal end of the outflow component just distal to the silicone Luer?

Answer: **Before tunneling** the outflow component, **cut the outflow component** next to the silicone Luer end and discard the Luer end portion.



Question: What does it mean to straight cut the outflow component?

Answer: The end of the outflow component should be cut straight across, ensuring the cut is square to the outflow component and not angled.



Correct straight cut



Incorrect, angled cut

TECHNICAL BULLETIN





Connecting the HeRO Device During the Implant Procedure

Question: What does it mean to press fit the outflow component to the connector?

Answer: Press fitting the two components is done by grasping the outflow component approximately 2cm back from the cut edge and pushing so it slides easily over the first barb of the titanium connector. Continue to push the outflow component onto the connector until the cut edge is flush with the silicone sleeve hub past both barbs. Verify the graft component and outflow component are fully connected and that no portion of the titanium connector is exposed. After the connection is made, verify radiopaque tip placement in the mid to upper right atrium using fluoroscopy. Gently tuck the connected device into the connector site incision.

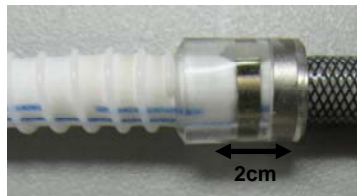
Correct technique is to hold the hub of the graft component and avoid pinching the graft beading during connection.



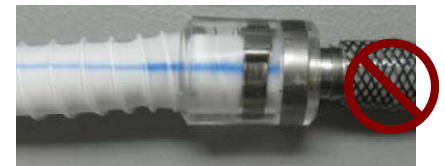
In this photo, the graft beading was gripped & crushed during connection. Blood flow inside this device may be disrupted.



Complete connection showing outflow component over both barbs and in contact with the silicone hub of the connector.



Incomplete connection showing outflow component away from the silicone hub of the connector & second barb.



Question: Should I test fit the connection to be sure the outflow component is cut to the correct length?

Answer: No. The HeRO Venous Outflow Component was designed to engage both barbs of the titanium connector tightly so that the pieces do not separate. If separation is necessary, a new straight cut should be made to the outflow component. The new cut should be near the connector, and special care should be taken when trimming and removing the excess outflow component piece from the connector. If damage occurs to the connector during separation, a new arterial graft component should be used. Use fluoroscopy to recheck distal tip placement after any adjustment is made.

Question: Is the beading on the graft component a surface to grip during device connection?

Answer: No. It is important during device connection to grasp the silicone sleeve of the graft component and avoid contact with the graft beading. Ensure the beading is not crushed or damaged. If damage to the graft beads is noted during implant, a new arterial graft component should be used. Damaged or crushed beading may lead to flow disruption with the device, and may contribute to early device occlusion and/or repeated occlusion.

For additional information, please refer to the HeRO Instructions for Use or contact Hemosphere Customer Service at 888.313.8233.