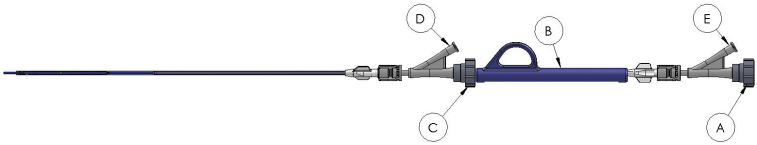
Required supplies for InterGraft procedures

1. Two micro puncture kits (needle, access wire, 4F sheath)
2. One 11F introducer sheath (maximum length 11 cm)
3. One 7F introducer sheath (maximum length 11 cm)
4. One 0.018” diameter soft tip guidewire (length 145 cm)
5. One 0.014” diameter soft tip guidewire (length 145-185 cm)
6. Three stopcocks
7. Graft tunneling set
8. Atraumatic vascular graft clamp
9. One each sterile 3 cc and 10 cc syringe
10. Sterile saline solution
11. Sterile 50:50 heparinized saline for flush
12. Contrast agent
13. 6 mm sterile straight graft (non-tapered), length appropriate for planned AV access

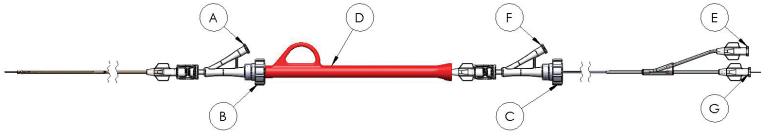
Caution: Investigational device. Limited by United States law to investigational use.


Phraxis



Venous InterGraft delivery system preparation

1. Using sterile technique, open VIG package and place InterGraft delivery system in sterile field. Remove the white graft grippers.
2. Attach a stopcock to each of the T-B ports **D,E**. Loosen the T-B valves **A**,**C**.
3. Using a 10 cc syringe, flush the delivery system with sterile saline solution. Close valve **A** and flush through port **E**. Close stopcock on port **E** and remove 10 cc syringe. Then close valve **C** and flush through port **D**. Close stopcock on port **D** and remove 10 cc syringe.
4. To load the 0.018” guide wire into the VIG delivery system, loosen both T-B valves **A**,**C**. Backload wire into delivery system and gently close T-B valve **C**.

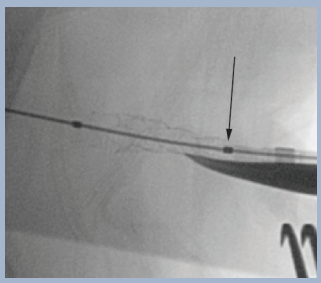


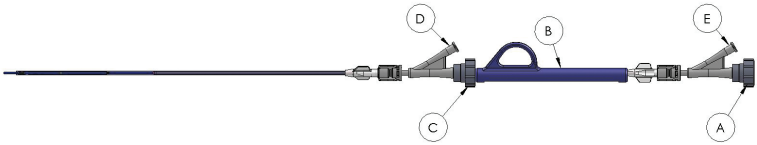
Arterial InterGraft delivery system preparation

1. Using sterile technique, open AIG package and place InterGraft delivery system in sterile field. Remove the white graft grippers.
2. Attach stopcocks to each of the two T-B ports **A**,**F** and open the valves **B**,**C**. Close valve **C** and flush sterile saline through port **F**. Close stopcock on port **F** and remove 10 cc syringe. Then close valve **B** and flush sterile saline through port **A**. Close stopcock on port **A** and remove 10 cc syringe. Flush guidewire lumen through port **G** using sterile saline. Gently tighten T-B valves **B**,**C**.
3. Attach stopcock to balloon luer **E**. Evacuate balloon using a 10 cc syringe, close stopcock and remove syringe. Draw up 50:50 contrast/saline solution in a 3 cc syringe, attach to stopcock, open stopcock and inject the solution. Visually confirm positioning balloon inflation. Withdraw contrast from balloon, close stopcock, and leave 3 cc syringe connected to luer.
4. Loosen T-B valves **B**,**C**, backload 0.014” wire into AIG delivery system and gently tighten T-B valve **B**.

Venous InterGraft implant procedure

1. Prep VIG delivery system according to VIG pre-implant preparation instructions.
2. Pre-tunnel graft with ends adjacent to target vein and artery anastomotic sites using specified tunneling procedure.
3. Identify target venotomy site and mark with surgical clamp.
4. Access the vein using micropuncture kit, insert wire, remove needle and insert 4F sheath.
5. Exchange 4F sheath for 11F sheath – replace micropuncture wire with 0.018” wire.
6. Load VIG delivery system over the wire.
7. Under fluoroscopic guidance, advance VIG over the wire and into vein, approximately 1 cm past venotomy.
8. Remove blue deployment lock labeled **B** (see illustration next page) and position VIG marker band (at arrow right) ~ 1cm peripheral to clamp tip that marks the venotomy site.





9. Loosen T-B valve **C** and under fluoroscopic guidance slowly advance the hypotube until it just engages the VIG (i.e., “closes the gap”).

10. Reconfirm marker band position and remove 11F sheath from vein.

11. Deploy VIG under fluoroscopy using standard “pin and pull” technique, ensuring the marker bands and venotomy clamp remain in position throughout deployment.

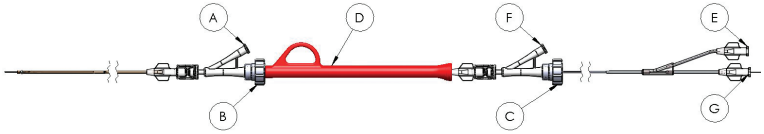
12. Remove VIG delivery system and wire, gently grasp and compress protruding end of VIG to control bleeding and insert VIG into pre-tunneled graft end.

13. Verify blood flow through graft, clamp graft to stop venous back-bleeding, prepare 10 cc syringe with heparinized flush, remove graft clamp and flush graft and reattach clamp.

Arterial InterGraft implant procedure

1. Prep AIG delivery system according to AIG pre-implant preparation instructions.
2. Identify arteriotomy site and mark with surgical clamp.
3. Attach vessel loops or vascular clamps for proximal and distal control of artery. Do not tighten at this stage.
4. Gain access to artery using a micropuncture kit, insert wire, remove needle and insert 4F sheath.
5. Exchange 4F sheath for 7F sheath – replace micropuncture wire with 0.014” wire.
6. Load AIG delivery system over the 0.014” wire.
7. Under fluoroscopic guidance advance AIG over the wire and into artery ~ 1 - 2 cm past arteriotomy (at arrow right).

8. Remove red deployment lock labeled **D** (see illustration next page) and position AIG marker band ~ 2 cm central to clamp tip that marks the arteriotomy site (at arrow above).



9. Loosen T-B valve labeled **B** in diagram.

10. Reconfirm marker band position, remove 7F sheath and deploy AIG under fluoroscopy using standard “pin and pull” technique until **only the tines** emerge from delivery sheath.

11. Inflate positioning balloon, pull inflated balloon back to engage tines, tighten T-B valve **B** and slowly pull entire AIG system up vertically from the artery until resistance is felt, indicating apposition of the tines at the artery wall.

12. Complete deployment of the AIG using “pin and pull” technique, deflate balloon and remove entire system and guidewire.

13. Grasp protruding end of AIG to control bleeding, stabilize base of AIG by grasping, and insert AIG into graft. Remove clamp and verify flow through circuit.

14. Release vessel loops or vascular clamps, close incisions.