**InterGraft™ System for Minimally Invasive Sutureless Anastomosis**

John R Ross, MD

**Disclosure**

- National Principal investigator for clinical study of InterGraft™ System

*The InterGraft™ System is an Investigational Device. Limited by Federal (United States) law to investigational use.*

**Dialysis Access Institute Orangeburg, SC**

**Sutureless anastomoses to vein, artery and graft**

**Venous InterGraft**
- Use with 11F sheath, 0.018" guide wire
- Venous end flares to 10 mm
- Used in veins 4-7 mm diameter

**Arterial InterGraft**

**Venous InterGraft Connector**
- Use with 11F sheath, 0.018" guide wire
- Venous end flares to 10 mm
- Used in veins 4-7 mm diameter

[Diagram of Venous InterGraft Connector with anchoring barbs]
Deployment of Venous InterGraft Connector

- Use with 7F sheath, 0.014" guide wire
- Flange design for end-to-side anastomosis
- Used in arteries 3.5-6 mm in diameter

Deployment of Arterial InterGraft Connector

Visual exam of anastomoses prior to closing skin incisions

InterGraft First-in-Man Study
Adrian Ebner, MD and John Ross, MD
Italian Hospital, Asuncion, Paraguay

- InterGraft used to implant 6mm AVG (Flixene™, Atrium Medical Corp) in 9 patients
- 2 Groups:
  - Venous and Arterial InterGraft (5 patients)
  - Venous InterGraft and sutured arterial anastomosis (4 patients)

Procedure
1. Tunnel AV graft (standard 6 mm graft)
2. Access target vein and examine. Clamp tip marks site Venous InterGraft will exit vein when deployed.
3. Introduce Venous InterGraft over-the-wire, deploy.

4. Deployed Venous InterGraft Connector. Graft-end of Connector fitted into tunneled AVG and clamped.

5. Arterial InterGraft partially deployed. Connector Flange is deployed first (white arrow), then positioning balloon is inflated (black arrow).

6. Balloon and flange are retracted to arteriotomy site.

7. Extravascular segment of Arterial Connector is deployed (arrows).

8. Arterial Connector is fitted into tunneled AV graft.

2 weeks post-implant
InterGraft FIM Study: Angiogram at 5 months


Investigational Pivotal Study currently in progress:

Clinical Evaluation of a Vascular Anastomotic Connector System for Minimally Invasive Connection of an Arteriovenous Graft for Hemodialysis [InterGraft Study]

InterGraft Study

- Prospective, multicenter, non-randomized
- 104 subjects, up to 15 study sites
- Study Principal Investigator- John Ross, MD
- Sponsor- Phraxis, Inc., St. Paul, MN
- Primary endpoint- Patency at 6 months

Thank you!