

Clinical Evidence

Strong, multi-centre clinical outcome data in both AV Access and Peripheral Bypass demonstrating consistent improvements over standard of care

Clinical Findings: Peripheral Vascular (PV) Access				
Investigator	Number Grafts	Year	Mean Follow-up	Primary Patency
Vermassen (Belgium)	39		12 months	86%
		Sept 2012	30 months	81%
		Nov 2013	5 years	62% (*)
Shaper (United Kingdom) ⁽¹⁾	68	Nov 2014	12 months	76%
Marusiak (Czech Republic)	75	March 2014	12 months	85%
Çetingök (Turkey)	73	Sept 2011	14 months	93%

Spiral Flow™ PV Graft Outcomes

- 5 year cumulative patency of 62% (*)
- **30% improvement in patency compared to standard ePTFE grafts at 12 months** ⁽¹⁾
- **reduced limb amputation rate to 2% vs. 10% for standard PV grafts** ⁽¹⁾

Clinical Findings: Arteriovenous (AV) Access in Haemodialysis					
Investigator	Number Grafts	Year	Mean Follow-up	Primary Patency	Secondary Patency
El Sayed (United States)	48	April 2015	14 months	72%	82%
	38	April 2014	12 months	81%	83%
	19	April 2013	6 months	90%	100%
Çetingök (Turkey)	16	April 2013	26 months	88%	100%
Hofmann (Austria) ⁽²⁾	16	April 2015	18 months	72%	85.5%
	16	April 2014	12 months	75%	88%
	15	Sept 2013	6 months	80%	80%
Inston (United Kingdom)	12	April 2013	6 months	75%	-

Spiral Flow™ AV Access Outcomes

- Standard ePTFE grafts have poor primary patency, <50% patent at 12 months.
- **35% improvement in patency compared to standard ePTFE at 18 months** ⁽²⁾