

### 5-Year Outcomes Of The Cook PRESERVE II Study Of The Cook IBD (ZBIS): Why Is It Different From Other Iliac Branch Devices

W. Anthony Lee, MD, Vito Marrese, MD, Jason T. Lee, MD, Graham Long, MD, David Cable, MD, and Miriam Hu on behalf of the PRESERVE II Clinical Trial Investigators


### Disclosures

W. Anthony Lee is a consultant for Cook Medical and National Principal Investigator of PRESERVE II study

### Zenith® Iliac Branch

- Acute internal iliac artery (IIA) occlusion is associated with a risk of pelvic ischemic symptoms or complications.
- Surgical and off-label endovascular techniques to maintain IIA perfusion can lead to increased morbidity.
- The Zenith Iliac Branch Graft (IBD) is a branched endograft intended to maintain perfusion to the IIA in aortoiliac or iliac aneurysms during EVAR.

### Comparison of Iliac Branch Endografts



Description	Cook Iliac Branch	Gore IBE
Proximal IBD Graft Diameter	12 mm	23 mm
Common Iliac Segment Length	45 mm 61 mm	~55 mm
External Iliac Segment Length	41 mm 58 mm	~45 mm
External Iliac Segment Diameter	10 mm 12 mm	10 mm 12 mm 14.5 mm
IIA Side Branch Diameter x Length	8 x 14 mm	13 x 25 mm
Branch Stent	iCast (V12)	Internal iliac component
Sheath size (ID)	20 Fr	16 Fr

U.S. Caution: Investigational Device

### Study Design

- Prospective, multicenter, non-randomized study in 18 US sites (40 subjects)
- Objective:** evaluate safety and effectiveness of the Zenith IBD with iCAST branch stent in repair of aortoiliac or iliac aneurysms with an unsuitable distal sealing site for an iliac component proximal to the iliac bifurcation
- Endpoints:**
  - Primary: 6-month freedom from patency-related interventions
  - Secondary: 6-month branch vessel patency  
30-day freedom from morbidity
- Follow-up through 5 years (complete)

### Study Outcomes

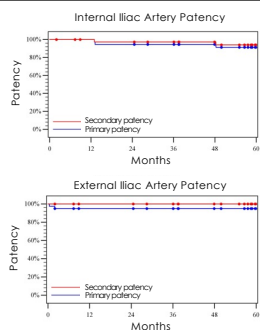
- Demographics**  
Mean age 67.8 years, male 95%, mean CIA aneurysm size 36mm
- Primary endpoint** (6-month freedom from patency-related secondary interventions) → 100%
- Secondary endpoints**
  - 30-day freedom from morbidity → 85%
  - 6-month branch vessel patency → 100%

## 5-Year Outcomes

### Freedom from:

- All-cause mortality: 89%
- Buttock claudication: 97%
- Lower extremity ischemia: 97%
- Impotence: 87%

No aneurysm-related mortality, ruptures, migrations, device integrity issues, or Type Ia, Ib, or Type III endoleaks (1-Type Ic endoleak)



## Secondary Interventions Through 5-Year Follow-Up

9 patients underwent 15 secondary interventions (6 ipsilateral to the IBD)

Location	Event	Type of intervention
Ipsilateral	External iliac artery occlusion (2)	Thrombolysis/stent placement
	External iliac artery stenosis	Balloon angioplasty and stent placement
	Stent thrombosis (ZBIS)	Stent placement
	Stent thrombosis (iCAST)	Thrombectomy/stent placement
	Type Ic endoleak	Stent placement

## Conclusion

The PRESERVE II study exceeded both its primary and secondary endpoints, achieving their predefined performance goals

5-year outcomes support the sustained safety and effectiveness of the Zenith IBD in with the iCAST branch stent for the treatment of aortoiliac aneurysms and preservation of IIA perfusion during EVAR