

# SOCRATES

## ShOrt neCk AAA RAndomized Trial - ESAR and FEVAR

SOCRATES is a randomized controlled trial designed to evaluate and compare **ESAR** (EndoSuture Aneurysm Repair) clinical outcomes to **FEVAR** (Fenestrated Endovascular Aneurysm Repair) clinical outcomes in the treatment of infrarenal AAA with short proximal neck lengths between 4mm and 15mm (core lab measured) and a minimum infrarenal sealing zone of 8mm

Prospective, multicenter, randomized (1:1), two arm, non-inferiority

The SOCRATES study will enroll approximately 200 subjects, equally randomized to ESAR and FEVAR, at up to 40 sites globally

Devices used: Endurant™ stent graft + Heli-FX™ EndoAnchor™ system (ESAR) versus Cook Z-Fenestrated™\*/ custom manufactured device or Terumo Fenestrated Anaconda™ (FEVAR)



### Primary endpoints

- **Effectiveness:** composite of technical success at index procedure, and freedom from type IA or type III endoleaks, freedom from aneurysm related mortality, freedom from secondary reinterventions through 12 months
- **Safety:** freedom from MAEs (all cause mortality (ACM), bowel ischemia, myocardial infarction (MI), respiratory failure, disabling stroke, access related complications, procedural blood loss >1000cc, permanent paraplegia or paraparesis, renal complications) through 30 days

**Follow-up:** 1M, 1YR, 2YR, and 3YR



# Medtronic

**Europe**  
Medtronic International Trading Sàrl.  
Route du Molliau 31  
Case postale  
CH-1131 Tolochenaz  
Tel: +41 (0)21 802 70 00  
Fax: +41 (0)21 802 79 00

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