

# Real-World Registry of the Rotarex(TM) Rotational Excisional Atherectomy System (XTRACT Registry)

NCT07016698

---

Status	RECRUITING
Phase	Not Applicable
Sponsor	C. R. Bard
Enrollment	600 participants

## Key Eligibility Criteria

---

### Inclusion (6)

- Subject or legally authorized representative provides written informed consent using an Informed Consent Form (ICF) that is reviewed and approved by the IRB for the site.
- Subject is e22 years old at the time of signing the informed consent.
- Subject must have a lesion(s) in their infra-inguinal peripheral arteries that can be treated with the Rotarex™ Rotational Excisional Atherectomy System according to Instructions For Use (IFU).
- Rutherford 2-5 for chronic limb ischemia and Rutherford I to IIb for acute limb ischemia.
- Target lesion can be crossed intra-luminally by guidewire.

... and 1 more (see full listing online)

### Exclusion (6)

- Subject is unable or unwilling to comply with follow-up procedures and visits.
- Subject has a target lesion in a vessel with less than 3 mm in diameter.
- Subject is participating in another device or drug clinical trial that interferes with this protocol and confounds results.
- Treatment plan includes use of a thrombectomy and/or atherectomy device other than Rotarex™ Rotational Excisional Atherectomy System.
- Life expectancy is below 1 year.

... and 1 more (see full listing online)

## Locations (2 total)

---

Radiology and Imaging Specialists, Lakeland, Florida, United States  
Vital Heart and Vein, Humble, Texas, United States