

# CRUSH PAD: Real-world Outcomes Following Use of Shockwave Intravascular Lithotripsy (IVL) Technology in Calcified Common Femoral Lesions

NCT05145478

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Status	RECRUITING
Sponsor	Yale University
Enrollment	50 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Subjects presenting with claudication or CLI by Rutherford Clinical Category 2, 3, 4, 5, or 6 of the target limbs
  - Subject is a suitable candidate for angiography and endovascular intervention per the latest clinical guidelines
  - Patient is scheduled to undergo treatment with Shockwave Intravascular Lithotripsy (IVL) technology followed by standard of care treatment with DCB, BMS, DES at the physician's discretion.
  - Target lesion that is located in a native, de novo common femoral artery
  - Target lesion reference vessel diameter is between 4.0mm and 7.0mm by visual estimate.
- ... and 4 more (see full listing online)

### Exclusion (8)

- Subjects with any medical condition that would make him/her an inappropriate candidate for treatment with Shockwave Medical Peripheral Lithoplasty® System as per Instructions for Use (IFU) or investigator's opinion.
  - Subject is already enrolled in other investigational (interventional) studies that would interfere with study endpoints.
  - Cognitive impairment as documented in medical records
  - Not speaking English or Spanish
  - Currently a prisoner
- ... and 3 more (see full listing online)

## Locations (2 total)

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Yale New Haven Health, New Haven, Connecticut, United States  
The Miriam Hospital, Providence, Rhode Island, United States

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<https://clinicaltrials.gov/study/NCT05145478>

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