

MagicTouch™ Sirolimus-Coated Balloon for Treatment of Coronary Artery Lesions in Small Vessels

NCT06271590

Status	RECRUITING
Phase	Not Applicable
Sponsor	Concept Medical Inc.
Enrollment	1,605 participants

Key Eligibility Criteria

Inclusion (9)

- Adult patient with an indication for PCI due to stable angina, NSTEMI, post-infarction angina or silent ischemia (in absence of symptoms a visually estimated target lesion diameter stenosis of $\geq 70\%$, a positive non-invasive stress test, FFR ≤ 0.80 , or non-hyperemic pressure ratio [NHPR] ≤ 0.89 must be present)
- Subject is ≥ 18 and < 80 years old
- Subject is willing to comply with all protocol-required follow-up evaluations and provides written informed consent
- Target reference vessel diameter (visual estimation) ≥ 2.75 mm
- Successful lesion preparation (residual stenosis $< 30\%$), without flow-limiting complications (no or slow flow, dissection etc.)
- ... and 4 more (see full listing online)

Exclusion (28)

- Planned (staged) intervention in the target vessel
- ST-segment-elevation MI within 48 hours prior to index procedure
- Subjects with acute cardiac decompensation or cardiogenic shock
- Subject with a life expectancy of less than 24 months
- Impaired renal function (glomerular filtration rate [GFR] < 30 mL/min)
- ... and 23 more (see full listing online)

Locations (24 total)

Dignity Health - Mercy Gilbert Medical Center, Gilbert, Arizona, United States
Cedars-Sinai Medical Center, Los Angeles, California, United States
Clearwater Cardiovascular and Interventional Consultants, Clearwater, Florida, United States
... and 21 more locations