

# Efficacy and Safety of Sirolimus-Coated Spiral Balloon for Coronary Bifurcation Lesions

NCT06618248

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Dongguan TT Medical
Enrollment	280 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Patients aged between 18 and 85 years, regardless of gender.
- Patients must voluntarily participate in the study and sign an informed consent form.
- Patients must demonstrate sufficient adherence to the study protocol and agree to follow-up visits at 1 month ( $\pm 7$  days), 6 months ( $\pm 14$  days), 9 months ( $\pm 30$  days), 12 months ( $\pm 30$  days), and 24 months ( $\pm 30$  days) post-procedure, with angiography required at 9 months ( $\pm 30$  days).
- Patients must have evidence of myocardial ischemia.
- Angiographically confirmed primary coronary bifurcation lesions (Medina classification non-0, 0, 1) with branch stenosis  $\geq 70\%$  (estimated visually).

... and 3 more (see full listing online)

### Exclusion (16)

- Patients with bleeding disorders or active gastrointestinal ulcers, those who have had a stroke within the past 6 months, or those who are expected to be intolerant to dual antiplatelet therapy post-intervention.
- Patients with severe renal insufficiency (creatinine level  $> 3.0$  mg/dL or  $265.2$   $\mu\text{mol/L}$ ) and/or end-stage renal disease requiring dialysis.
- Patients in cardiogenic shock.
- Patients who have experienced a myocardial infarction within the week prior to enrollment.
- Patients with severe congestive heart failure or NYHA class IV severe heart failure.

... and 11 more (see full listing online)

## Locations (1 total)

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Peking University First Hospital, Beijing, Beijing Municipality, China