Safety and Clinical Performance of the Freesolve Resorbable Magnesium Scaffold System in the Treatment of Subjects With Long de Novo Lesions

NCT07091682

Status	RECRUITING
Phase	Not Applicable
Sponsor	Biotronik AG
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (11)

- Subject is e 18 years and d 80 years of age
- Subject has provided written informed consent as approved by the Independent Ethical Committee (IEC) or Institutional Review Board (IRB) of the respective clinical site prior to the study related procedures
- Subject is eligible for PCI according to the applicable guidelines
- Subject is an acceptable candidate for coronary artery bypass surgery
- Subjects with stable or unstable angina pectoris, documented silent ischemia/abnormal physiologic testing or hemodynamically stable non-ST elevation myocardial infarction (NSTEMI) patients without angiographic evidence of thrombus at target lesion

... and 6 more (see full listing online)

Exclusion (30)

- Subject is hemodynamically stable with documented declining cardiac biomarkers;
- Target lesion(s) to be treated are not located in the culprit vessel(s) and are not culprit lesion(s)
- Subject is eligible for Dual Antiplatelet Therapy (DAPT) with aspirin plus either clopidogrel, prasugrel, ticagrelor, cangrelor or ticlopidine
- Documented left ventricular ejection fraction (LVEF) e 30% within 6 months prior to or during the procedure (prior to enrollment)
- Subject is willing and able to comply with protocol requirements, including completion of study visits for the duration of the study

... and 25 more (see full listing online)

Locations (8 total)

Katholisches Krankenhaus "St. Johann Nepomuk", Erfurt, Germany
Universitätsklinikum Halle (Saale), Halle, Germany
Klinikverbund Allgäu gGmbH, Immenstadt and Kempten, Germany
... and 5 more locations