



STENTYS

SIMPLE STENT SOLUTIONS

APPOSITION III STUDY

A Post- Market study to assess the Stentys self-exPanding
COronary Stent In AcuTe MyocardIal InfarctiON in real life

DEVICE

STENTYS™ CORONARY STENT SYSTEM

A self-expanding, nitinol stent on a rapid exchange (RX) delivery system (BMS and DES available).

STUDY DESIGN International, non- randomized, prospective, multi-center, clinical registry. Choice of BMS or DES at the discretion of the investigator.

OBJECTIVE This multicenter, prospective, observational registry will evaluate the long term safety and performance of the STENTYS™ coronary stent in routine clinical practice. Its objective is to measure the incidence of Major Adverse Cardiac Events (MACE) in STEMI patients.

SUBJECT POPULATION Subjects presenting with acute myocardial infarction (STEMI) with reference vessel diameter between 2.5 mm and 4.5 mm can be included in the registry. Approximately 500 subjects will be enrolled in up to 50 centres.

STUDY ENDPOINTS

Primary endpoints

Major Adverse Cardiac Events (MACE): defined as cardiac death, re-MI, emergent bypass surgery (CABG), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods at 12 months post-procedure.

Secondary endpoints

1. Major Adverse Cardiac Events (MACE): defined as cardiac death, re-MI, emergent bypass surgery (CABG), or clinically driven target lesion revascularization (TLR) by percutaneous or surgical methods at 30 days and 24 months post-procedure.
2. Target vessel failure (TVF), defined as cardiac death, target vessel myocardial infarction (MI) [Q or Non Q-Wave], or clinically driven target vessel revascularization (TVR) by percutaneous or surgical methods at 30 days and 12 and 24 months.
3. Success Rates:
 - a) **Device Success:** Attainment of <30% final residual stenosis of the segment of the culprit lesion covered by the STENTYS™ stent, by visual estimation.
 - b) **Procedure Success:** Device success and no peri-procedural complications.
 - c) **Clinical success:** Procedural success and no in-hospital MACE.
4. Reperfusion measured by:
 - a) **TIMI Flow:** Increase of TIMI flow with at least one grade at the end of the procedure.
 - b) **ST elevation resolution:** Reduction of ST segment elevation 90 to 120 min. post-procedure.
5. Incidence of stroke at 30 days, 12 and 24 months.
6. Stent thrombosis at 30 days, 12 and 24 months.
7. Abrupt closure of Side Branch >2.25 mm (TIMI<3).

STUDY DURATION 36 months (12 months enrollment and 24 months follow-up).

FOLLOW-UP All subjects will be contacted at 1, 12 and 24 months post procedure.

ENROLLMENT SIZE 500 patients.

INCLUSION CRITERIA

1. Patient presenting with acute myocardial infarction (STEMI) caused by a de novo stenotic lesion in a native coronary artery.
2. Reference vessel diameter ≥ 2.5 mm and ≤ 4.5 mm by visual estimate.
3. Subject understands the nature of the procedure and provides written informed consent for data collection purposes.
4. Subject is willing to comply with specified follow-up evaluation and can be contacted by telephone.

EXCLUSION CRITERIA

1. Unprotected left main coronary artery.
2. Cardiogenic shock.
3. Any vasculature lesions or characteristics preventing PTCA, introduction of the STENTYS™ delivery system or placement of the STENTYS™ Stent.
4. Allergies or contraindications to antiplatelet medication.
5. Known allergies to stent component (nitinol).
6. Female patient with child bearing potential not taking adequate contraceptives or currently breastfeeding.

STUDY SET-UP

CEC: A Clinical Event Committee (CEC) consisting of independent physicians will be installed for this study.

ETHICS COMMITTEE: Investigators must notify the appropriate Ethical Committee and, if necessary, obtain approval for this registry.

INFORMED CONSENT: Investigators must obtain a signed informed consent form from all patients.

MONITORING: An independent monitor will visit sites on a regular basis to ensure adherence to the protocol and to review source documents.

APPOSITION III STUDY CHART

Parameter	Baseline	Registry period					
		Procedure	Post procedure	Discharge	30 days Patient contact	12 months Patient contact	24 months Patient contact
Informed Consent	●						
Medical History	●						
CK-MB/Troponin	●		●				
ECG	●		● (1)				
Angiography	●	●					
Device Functionality		●					
Adverse Events		●	●	●	●	●	●
Medication	●	●	●	●	●	●	●

(1) Between 90-120 min post procedure

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