

# BIOSOLVE-II

## 24-month results



### Conclusions

- Magmaris demonstrated a favorable safety and performance until 24-month follow-up
- The rate of definite/probable scaffold thrombosis remained at 0% at 24 months

### Study design

Prospective, multi-center, first-in-man trial to evaluate the safety and performance of Magmaris in 123 patients with a maximum of two de novo lesions in two separate coronary arteries

### Principal investigator

- Prof. Michael Haude, Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany

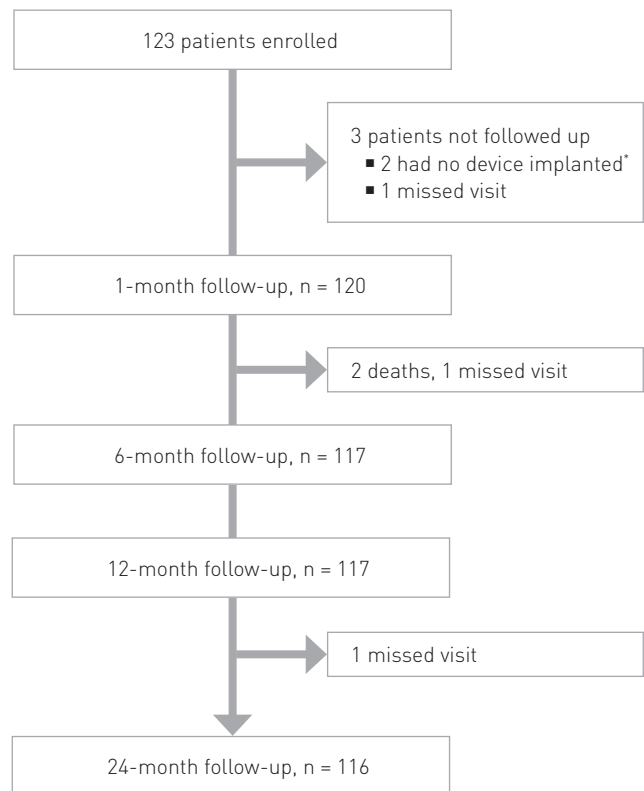
### Endpoints

#### Primary endpoint

- In-segment Late Lumen Loss (LLL) at 6-month follow-up

#### Secondary endpoints (selected)

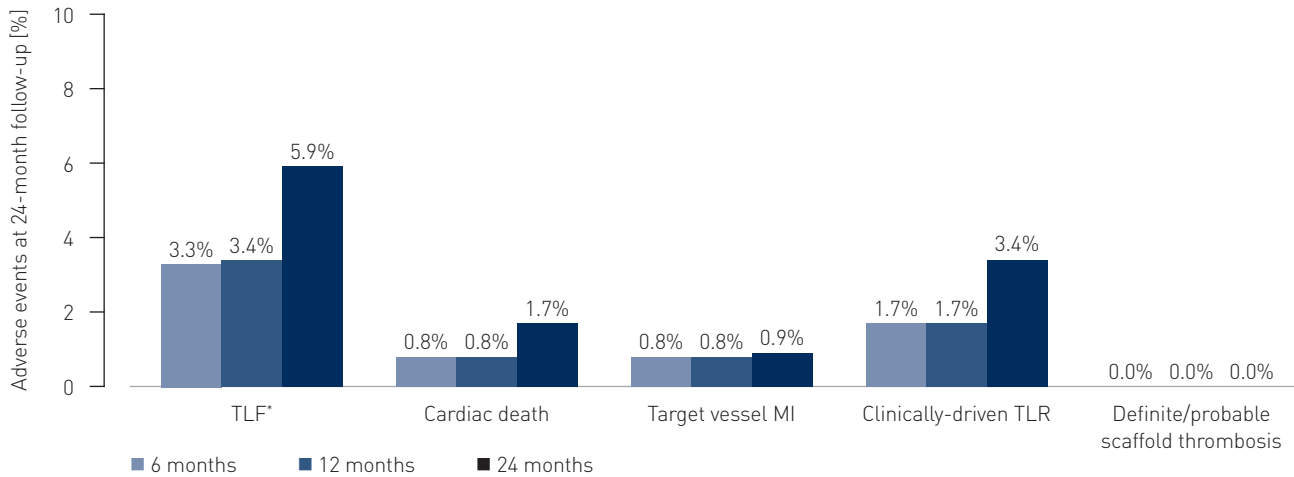
- Target Lesion Failure (TLF) defined as a composite of cardiac death, target vessel Myocardial Infarction (MI) and clinically-driven Target Lesion Revascularization (cd-TLR) at 24 months
- Definite/probable scaffold thrombosis at 24 months



\* Two patients who did not receive an implant were used for calculation of device and procedural success only.

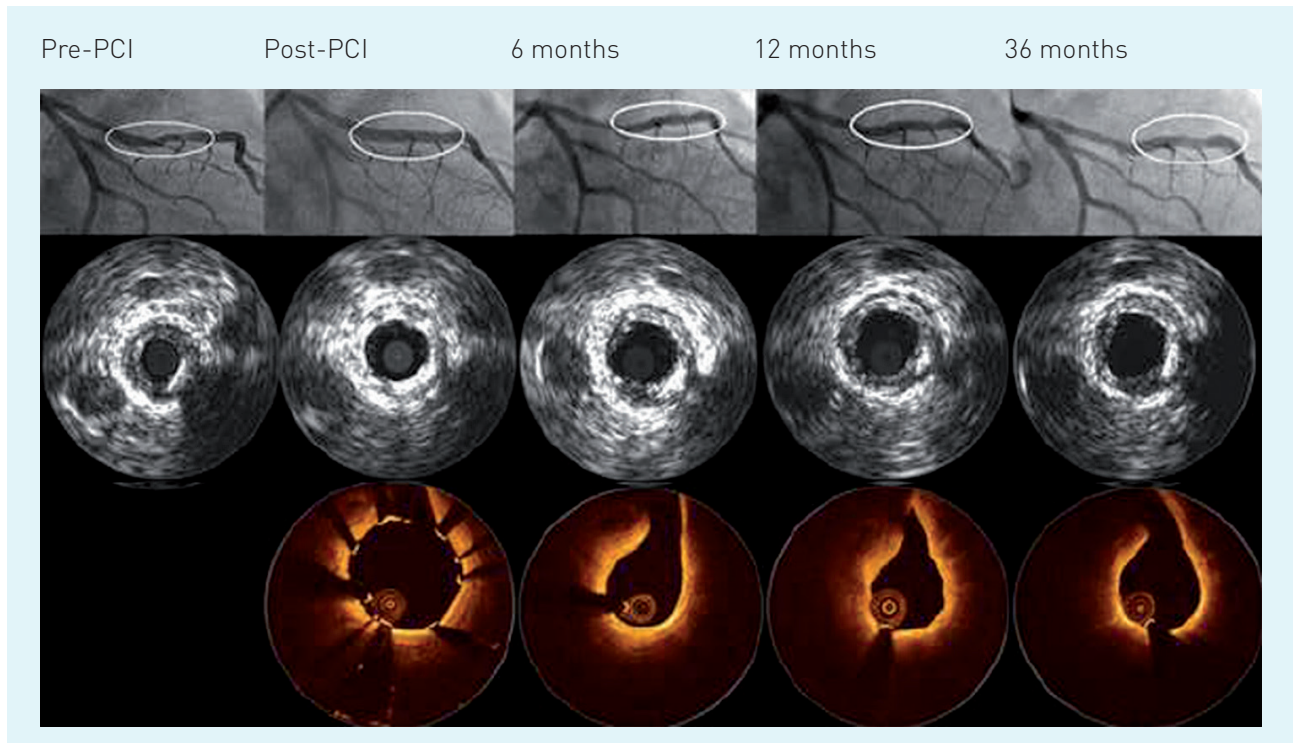
## Clinical results

Time of follow-up	6 months	12 months	24 months
TLF*	3.3%	3.4%	5.9%
Cardiac death	0.8%	0.8%	1.7%**
Target vessel MI	0.8%	0.8%	0.9%
Clinically-driven TLR	1.7%	1.7%	3.4%
Definite/probable scaffold thrombosis	0.0%	0.0%	0.0%



\* TLF defined as a composite of cardiac death, target-vessel MI and cd-TLR; \*\* 2 deaths of unknown cause were adjudicated as cardiac deaths

## Serial angiographic, IVUS and OCT of a patient implanted with Magmaris at 3-year follow-up



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