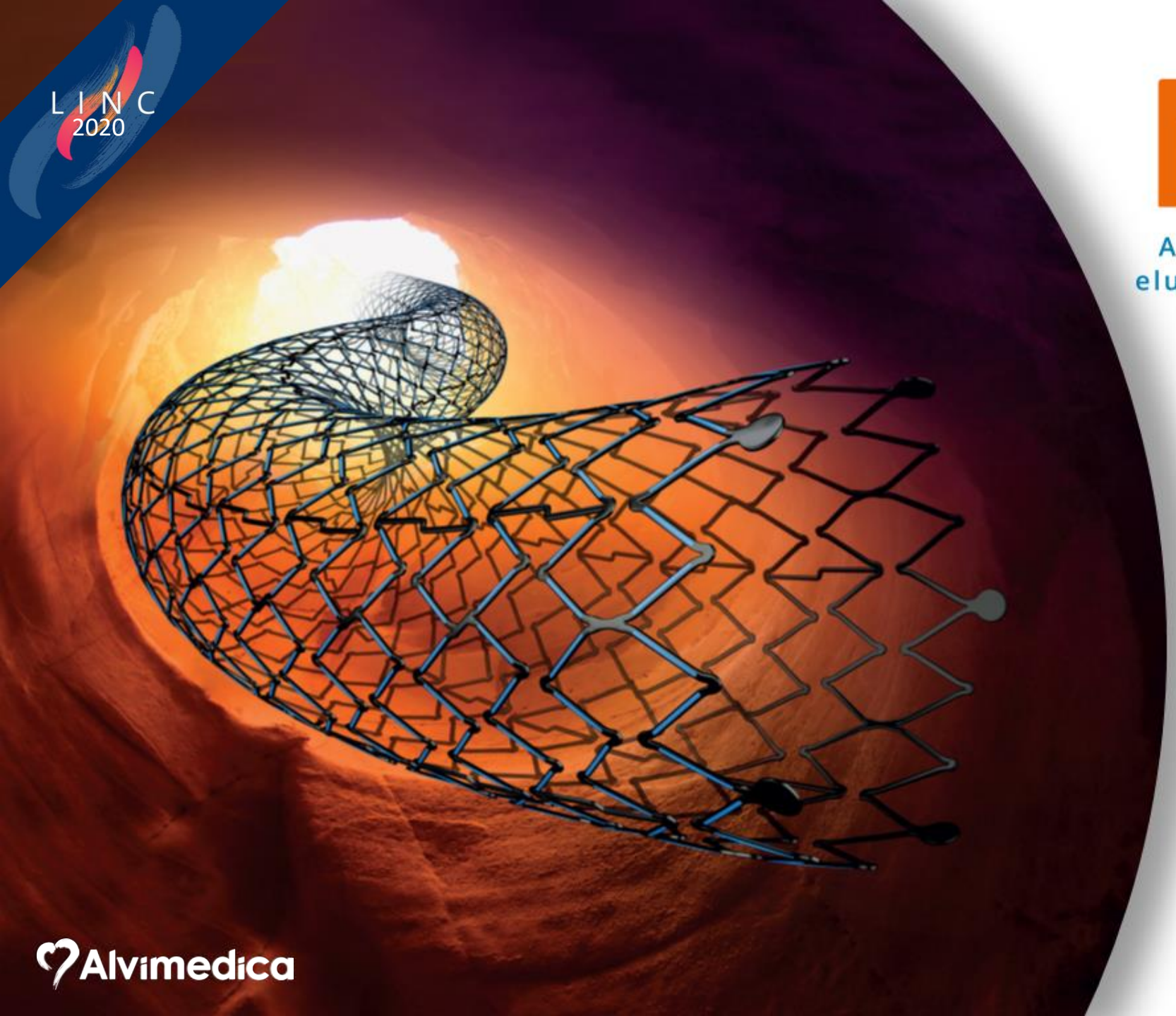
LINC 2020



NiTiDES

Amphilimus™(Sirolimus + Fatty Acid) eluting Peripheral Self-Expanding stent

The ILLUMINA study: 2 years results

Pr. D. Scheinert

Alvimedica

Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

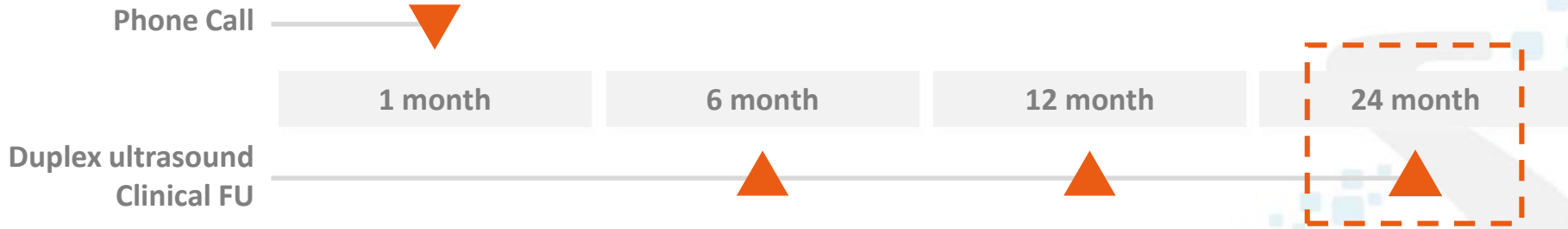
☐ I do not have any potential conflict of interest

ILLUMINA study design

Innovative siroLimus seLf expanding drUg-eluting stent for the treatMent of perIpheral disease: evaluation of safety aNd efficAcy

Patients over 18 years with ischemic obstruction of superficial femoral arteries and proximal popliteal arteries due to de novo or restenotic lesion(s) and no prior stent in the target lesion

Prospective, Single arm
10 centers in Europe (n= 100 pts)
Prof. Dierk Scheinert (Coordinating Clinical Investigator, Leipzig-Germany)
eCRFs; Core Lab; CEC



ILLUMINA study design

Innovative siroLimus seLf expanding drUg-eluting stent for the treatMent of perIpheral disease: evaluation of safety aNd efficAcy

Primary Endpoint:

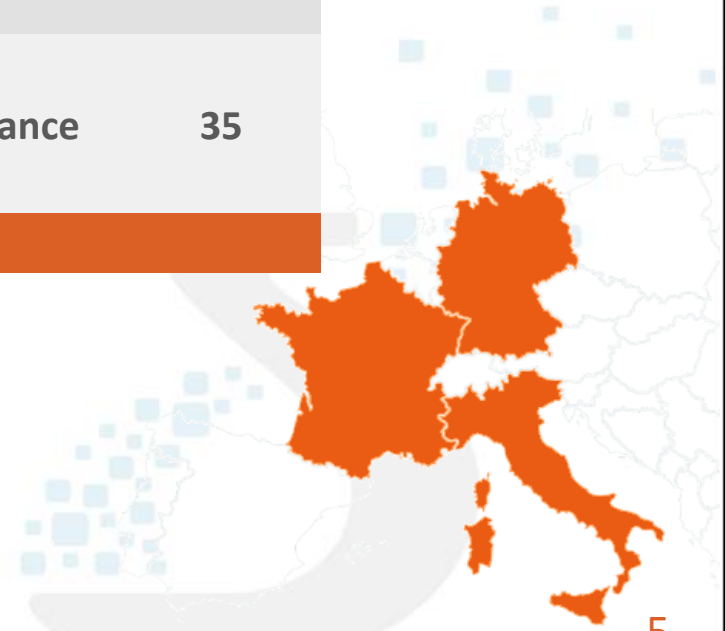
- **SAFETY: Composite event –free survival at 12 months:** Freedom from CEC adjudicated MAE (death, target limb amputation, target limb ischemia requiring surgical intervention or surgical repair of target vessel or clinically-driven target lesion revascularization) and freedom from worsening of the Rutherford score by 2 classes, or to class 5 or 6
- **EFFICACY: Primary patency at 12 months.** Primary patency is defined as absence of clinically-driven target lesion revascularization or binary restenosis. Binary restenosis is defined as a peak systolic velocity ratio (PSVR) >2.4 (duplex evaluation)

Main Secondary Endpoints:

- Technical Success
- Composite event-free survival and primary patency rate at 6 and 24 months follow-up
- Clinically driven TLR at 6, 12 and 24 months

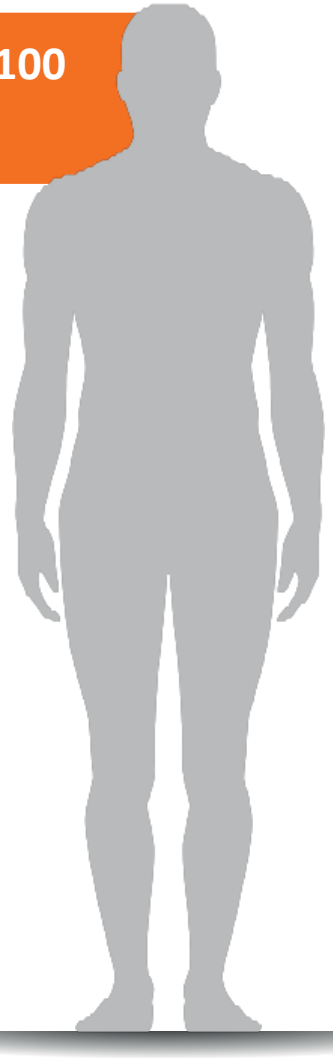
ILLUMINA study centers and enrolled pts.

Clinical Sites		Patients	Country	Pts per Country
Universitätsklinikum Leipzig	Scheinert	3	Germany	46
Universitäts-Herzzentrum Freiburg Bad Krozingen	Zeller	13		
Regiomed GefäBzentrum Sonneberg	Thieme	13		
St. Gertrauden Krankenhaus GmbH - Berlin	Langhoff	17		
San Raffaele Hospital - Milan	Chiesa/Kahlberg	15	Italy	19
Maria Cecilia Hospital - Cotignola	Cremonesi	2		
Fondazione IRCCS Policlinico San Matteo - Pavia	Marone	2		
Clinique Pasteur - Toulouse	Sauguet	24	France	35
Polyclinique Les Fleurs - Ollioules	Commeau	3		
Centre Prive Claude Galien - Quincy	Garot	8		
Total		100		



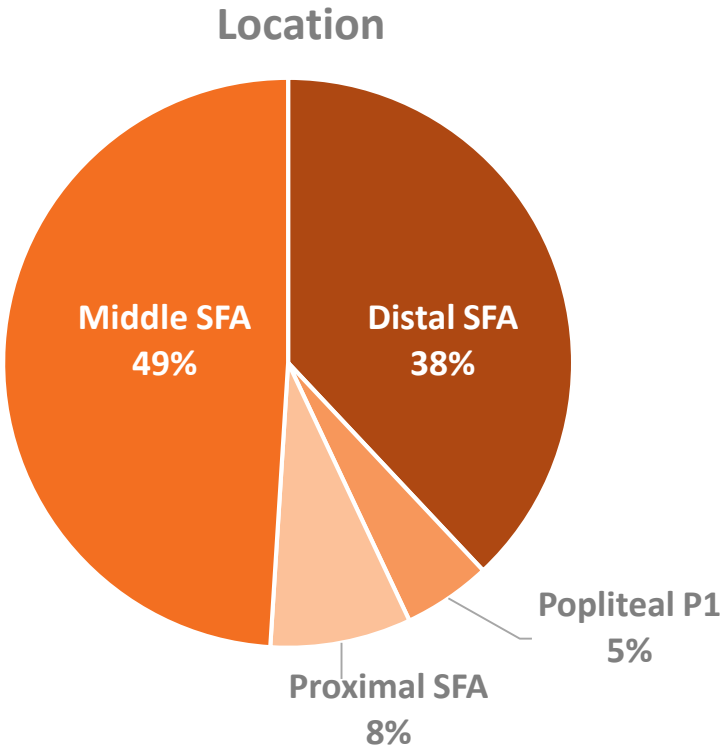
ILLUMINA study patients baselines

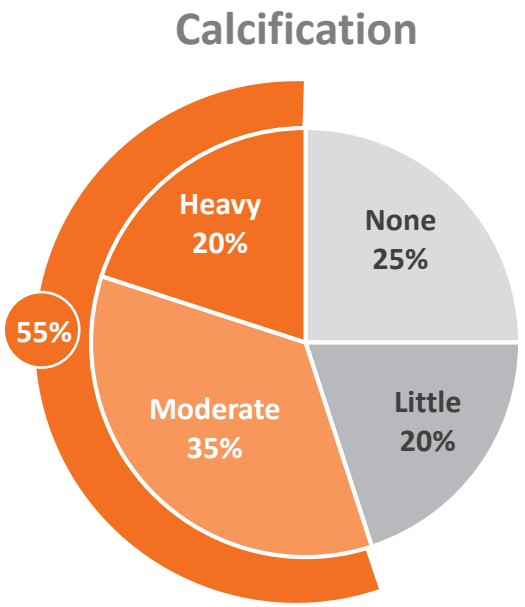
Enrolled Patients [n]: 100
Mean age [y]: 67



- Diabetic: 35%
- Male: 78%
- Hypertension: 69%
- Smoker: 39%
- Hypercholesterolemia: 54%

ILLUMINA study lesions characteristics





* In hospital assessment

ILLUMINA study procedural results

Procedural results

Stent deployment success: 100%

Procedural success: 100%

Stent per patient [n]: 1.09 ± 0.32

Total mean length of stent [mm]: 86.7 ± 40.8

ILLUMINA 24 months study results: Safety

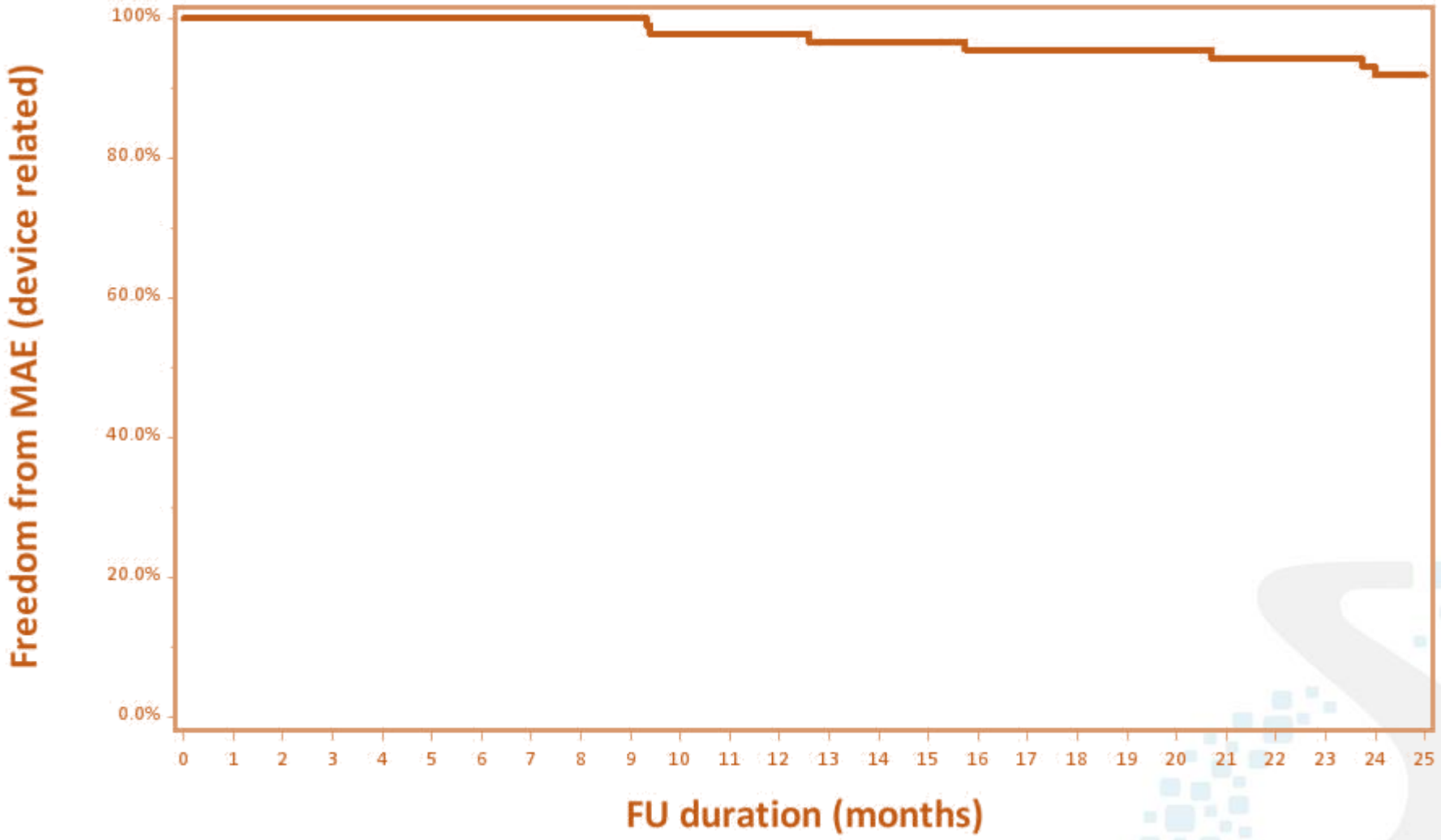
Major Adverse Event (MAE)		Device related
Clinically driven Target Lesion Revascularization (TLR)	6	6
Deaths throughout the entire study period*	3	0
Target limb amputation	0	0
Target limb ischemia requiring surgical intervention or surgical repair of the target vessel**	1	0
Worsening of the Rutherford score by two classes, or class 5 and 6***	1	1 (0)
MAE	**11**	**7 (6)**

*1 death due to Myocardial Infarction @ 5 months - non stent or procedural related (CEC adjudicated)
1 death due to severe septic shock @ 13 months - non stent or procedural related (CEC adjudicated)
1 death due to lung cancer @ 17 months - non stent or procedural related (CEC adjudicated)

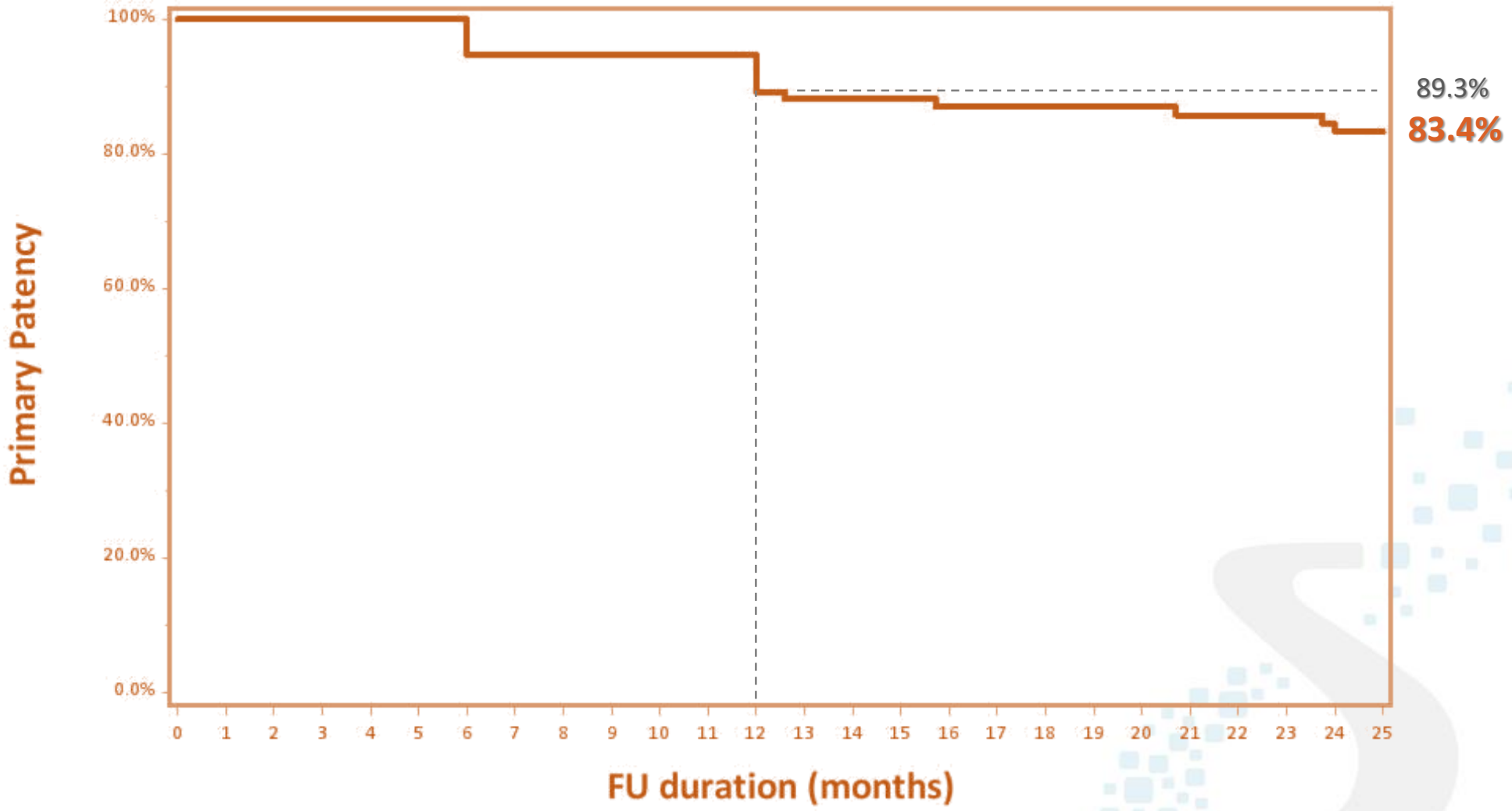
**1 thrombo-endo-arterectomy (far proximal to the lesion - CRFA) @ 18 months - non stent related (CEC adjudicated)

***Patient, asymptomatic at 1year, had femoral fracture 5months before 2years FU visit (Rutherford classes are not CEC adjudicated)

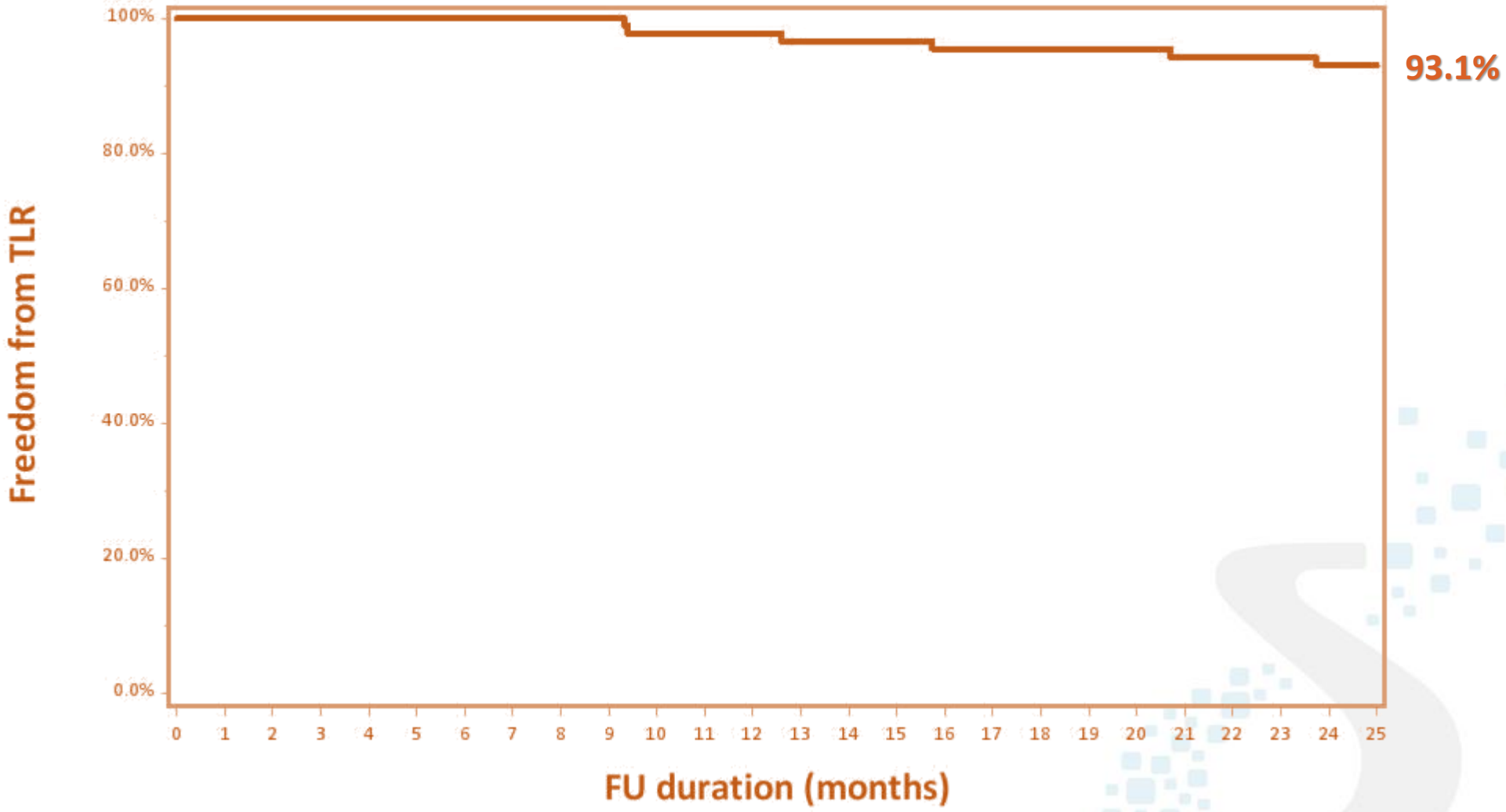
ILLUMINA 24 months study results: Safety



ILLUMINA 24 months study results: Efficacy

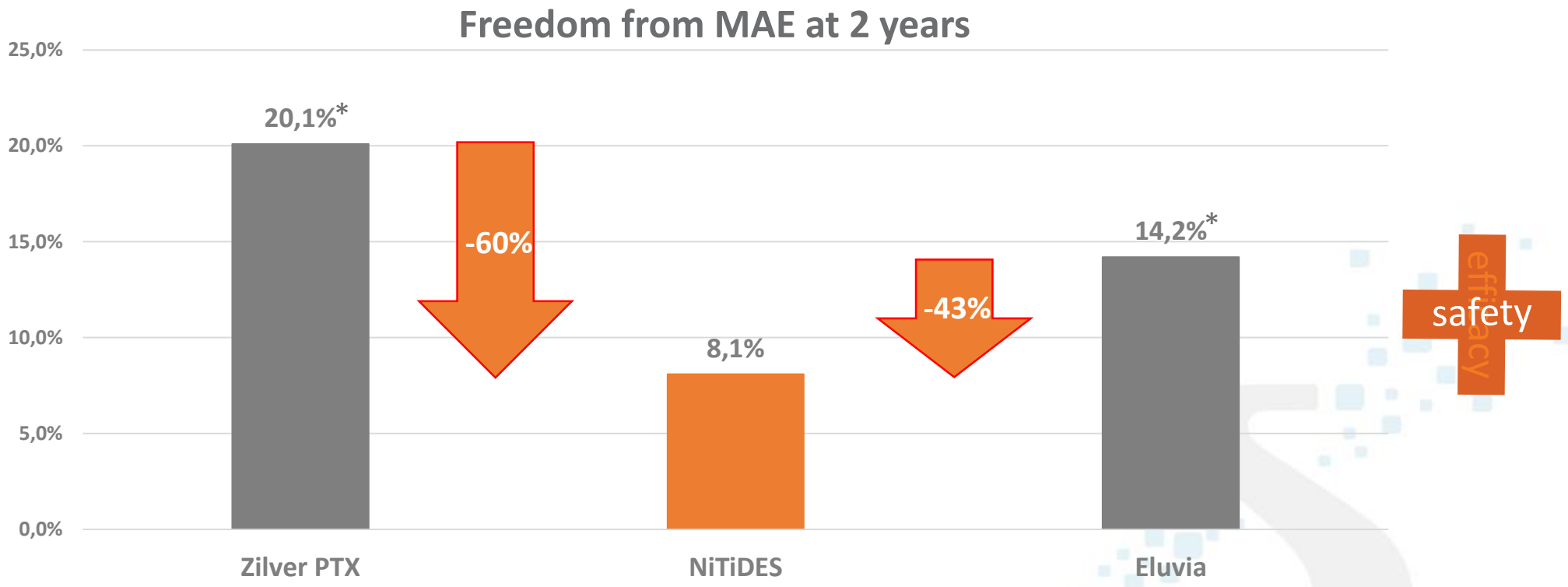


ILLUMINA 24 months study results: TLR



ILLUMINA study results in perspective:

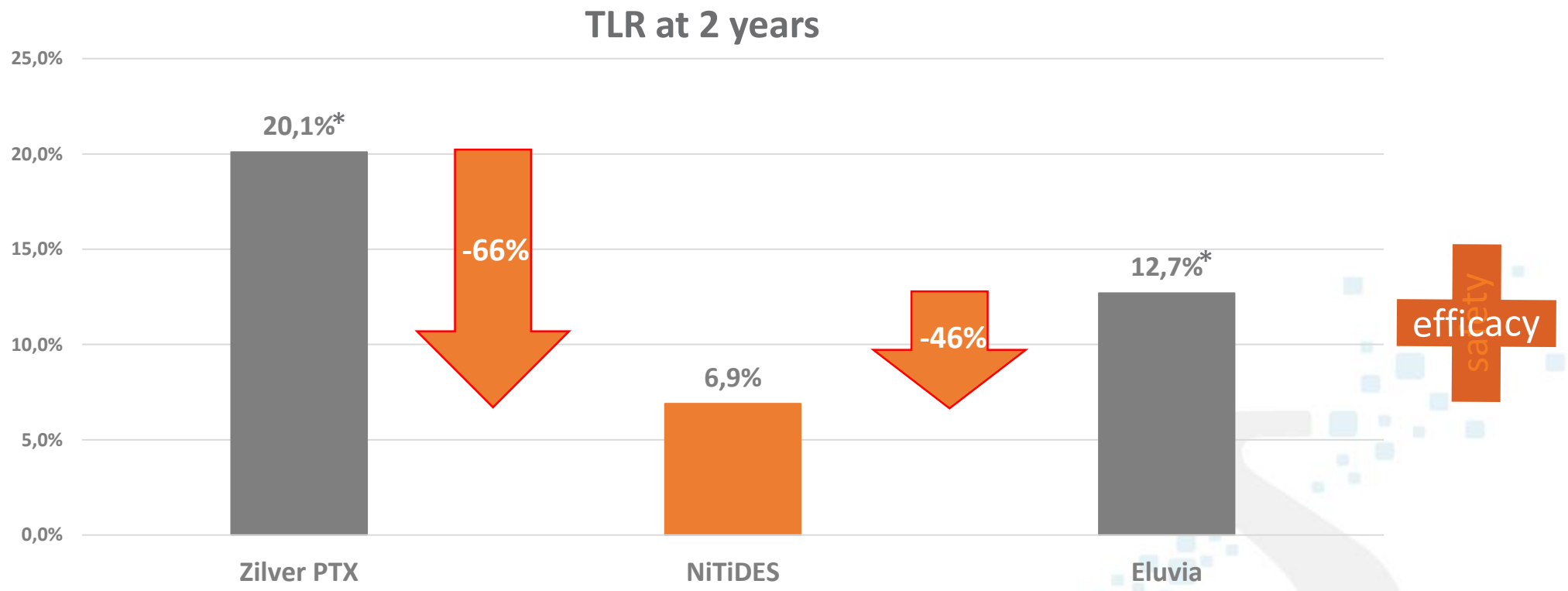
When referring to "**Freedom from Major Adverse Events (MAE)**", the ILLUMINA study results well compare to the outcomes of other DES studies recently released.



*US Boston Scientific website

ILLUMINA study results in perspective:

Similarly, referring to "**TLR**", the excellent NiTiDES efficacy challenges Eluvia's performance at 2years.



*US Boston Scientific website

ILLUMINA study conclusions

- NiTiDES represents the first and only Sirolimus eluting self-expanding peripheral stent today available.
- Although the ILLUMINA study included complex patients and complex lesions (2pts Rutherford 5, lesions up to 140mm and 55% of mod./ heavy calcifications), the study results at 24 months are remarkable:
  - SAFETY → 91.9% Freedom from device related MAE confirms the long term excellent performance of the NiTiDES device.
  - EFFICACY → 93.1% Freedom from TLR and 83.4% Primary Patency rate demonstrate that the high product efficacy is maintained over long time.
- The ILLUMINA study results stand NiTiDES at the top of excellence in today peripheral DES scenario.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