The ILLUMINA Study:

2-year results with a polymer free Sirolimus eluting DES in femoropopliteal arteries

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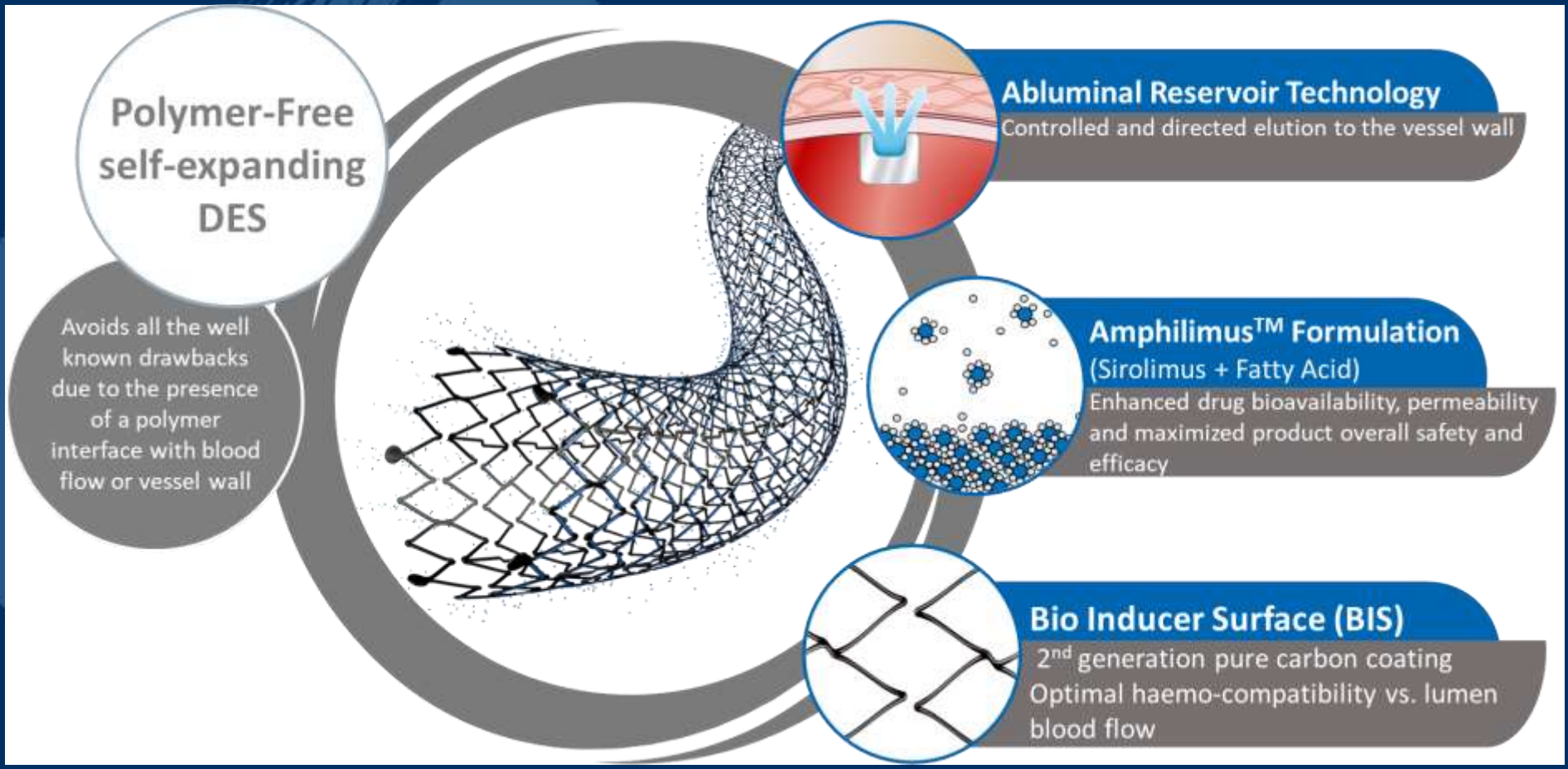
Disclosure

Advisory Board /Consultant:

Abbott, Alvimedica, Bayer, Boston Scientific, Cook Medical, Cardionovum, CR Bard, Gardia Medical/Allium, Medtronic, Philips, Upstream Peripheral Technologies

NiTiDES features description



ILLUMINA study design

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

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

Primary Endpoint:

- **SAFETY: Composite of Major Adverse Events – 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 (PSVR >2.4 - duplex evaluation)

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Centers and enrolled pts.

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**		

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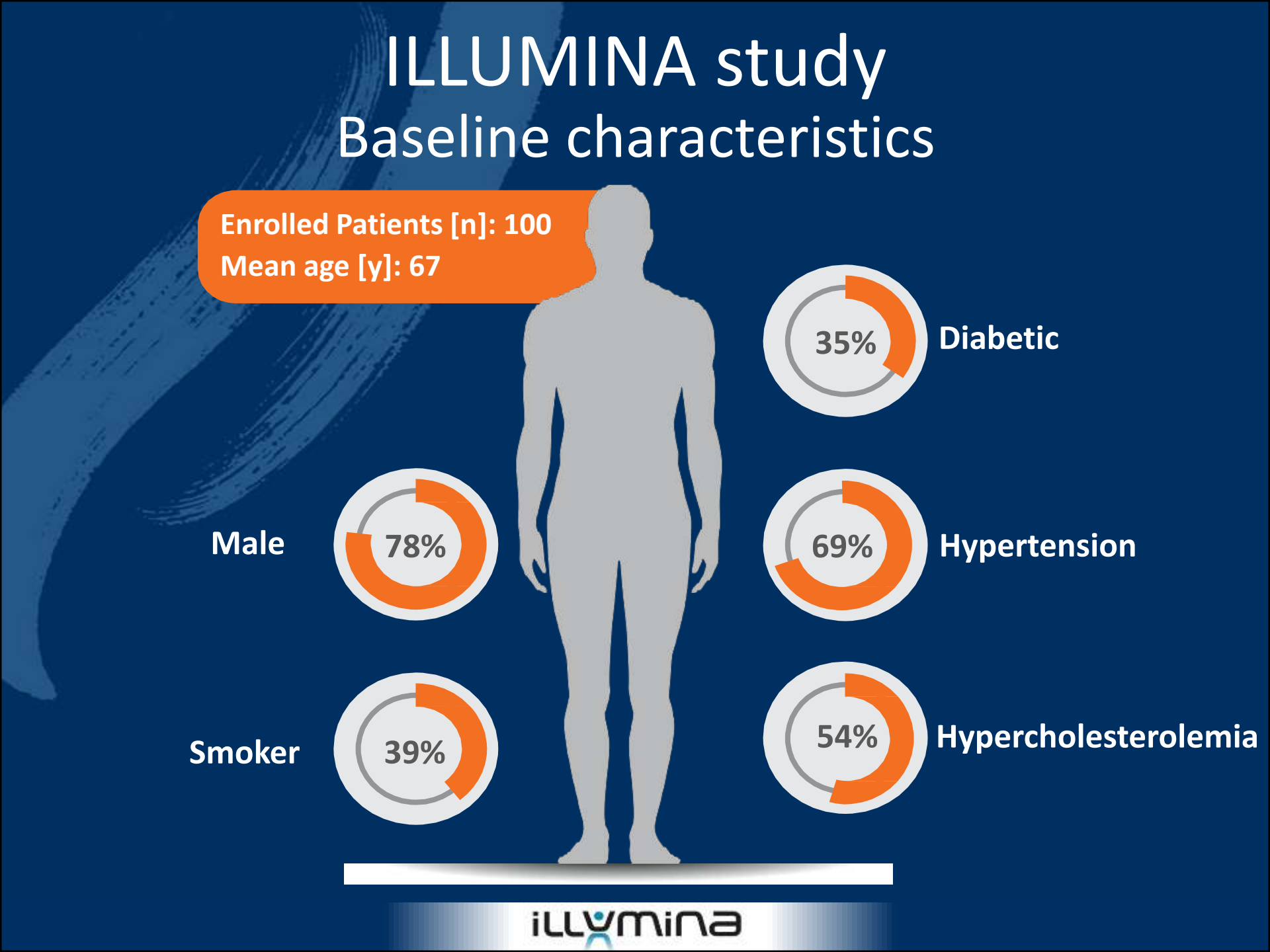
Baseline characteristics



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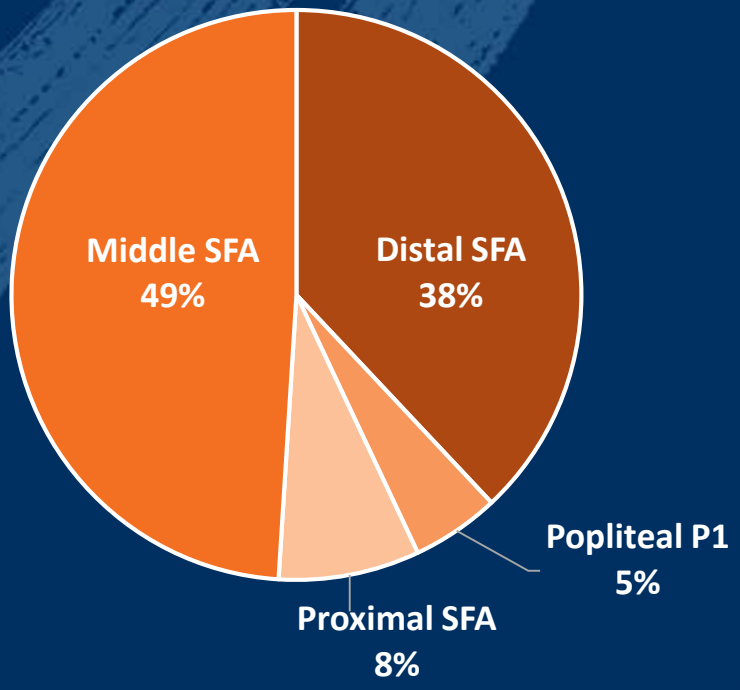
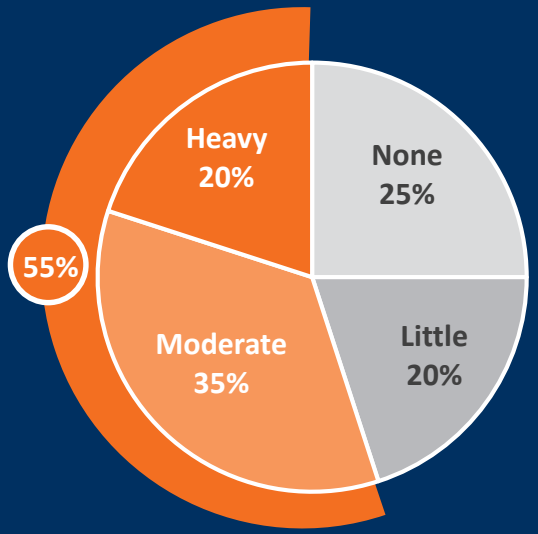
Pre-procedure information

Location



Calcification



* In hospital assessment

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Procedural results

Procedure 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

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24 months 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)

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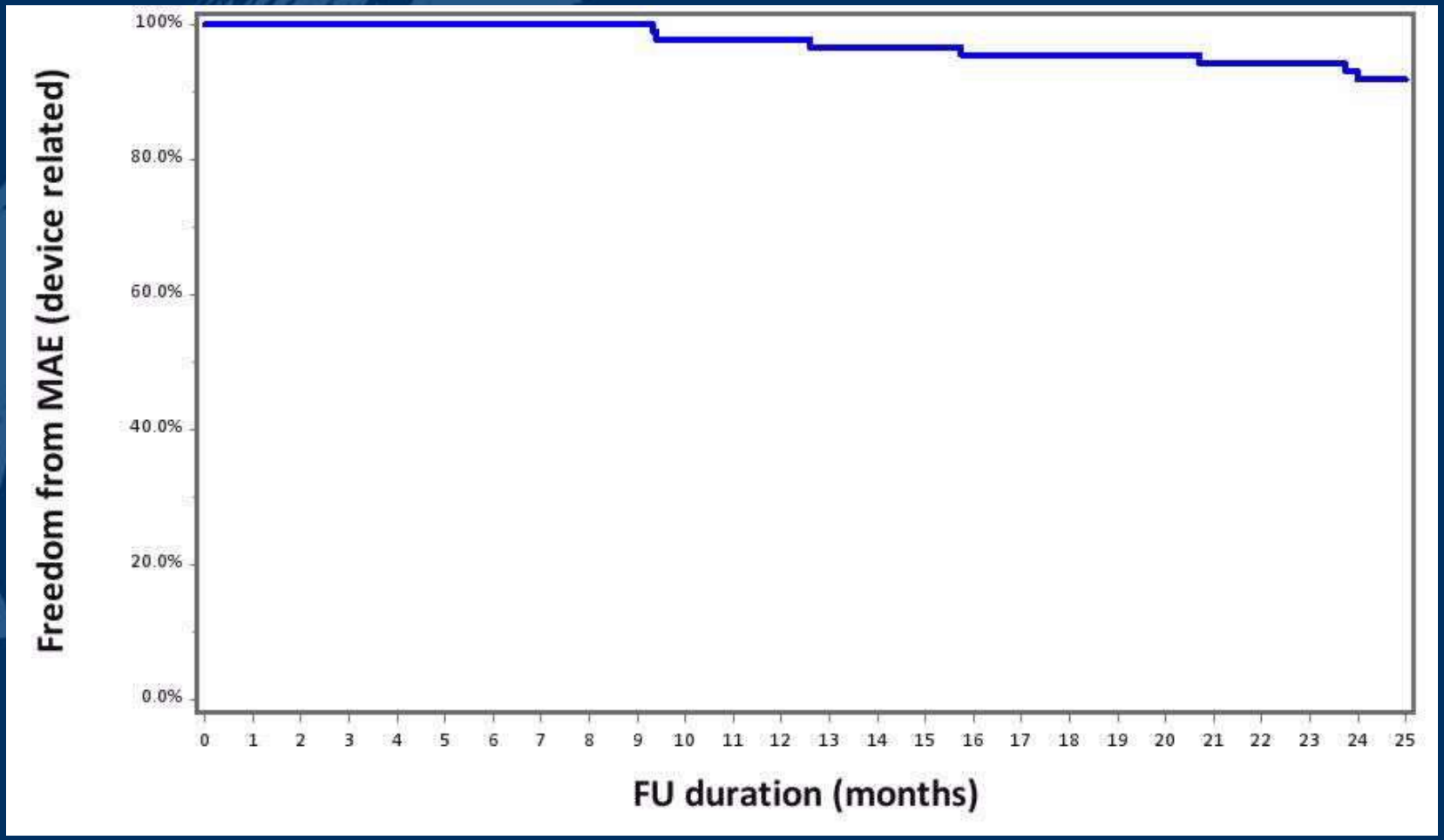
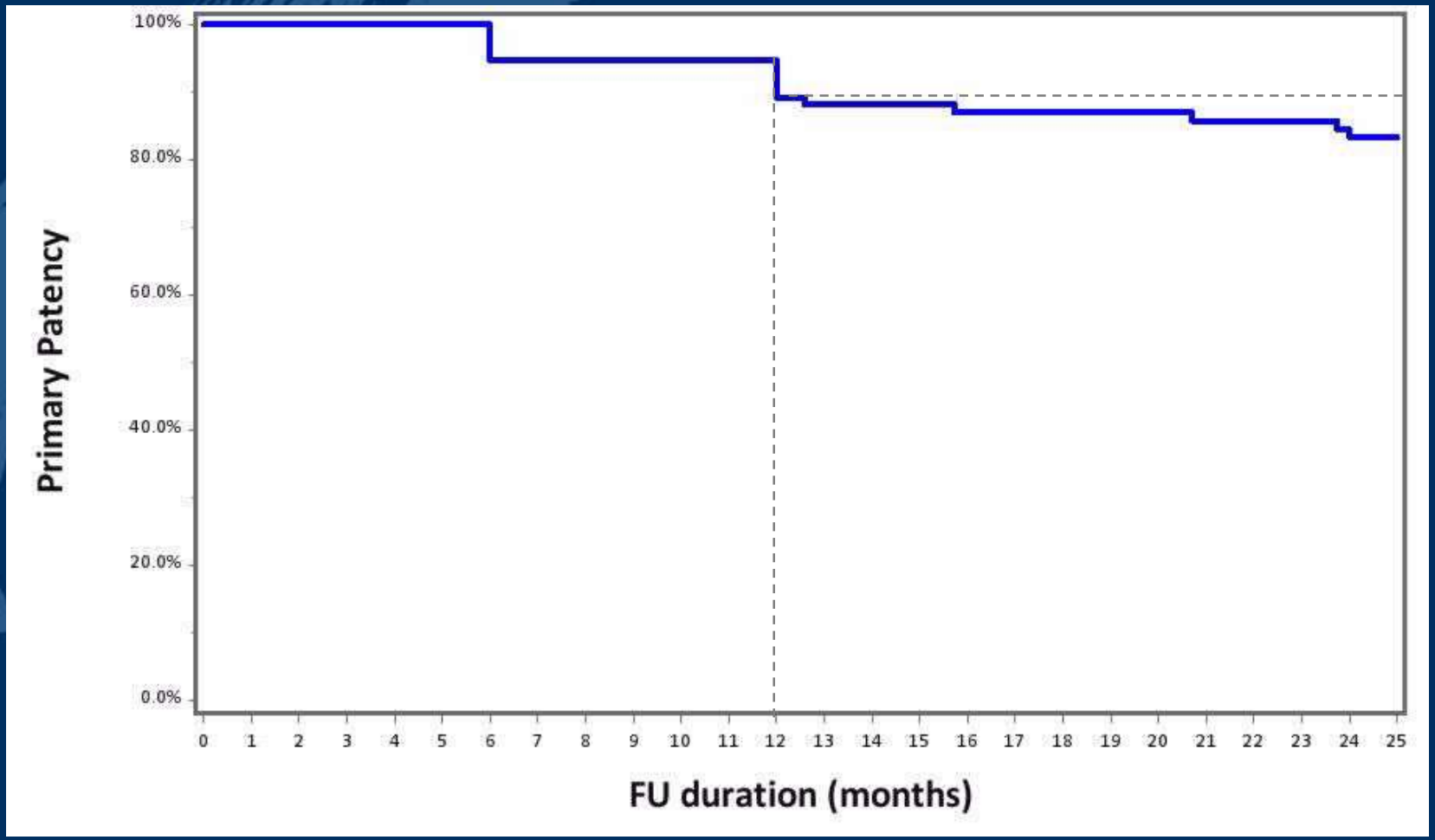
24 months results: SAFETY



91.9%

ILLUMINA study
24 months results: EFFICACY



89.3%

83.4%

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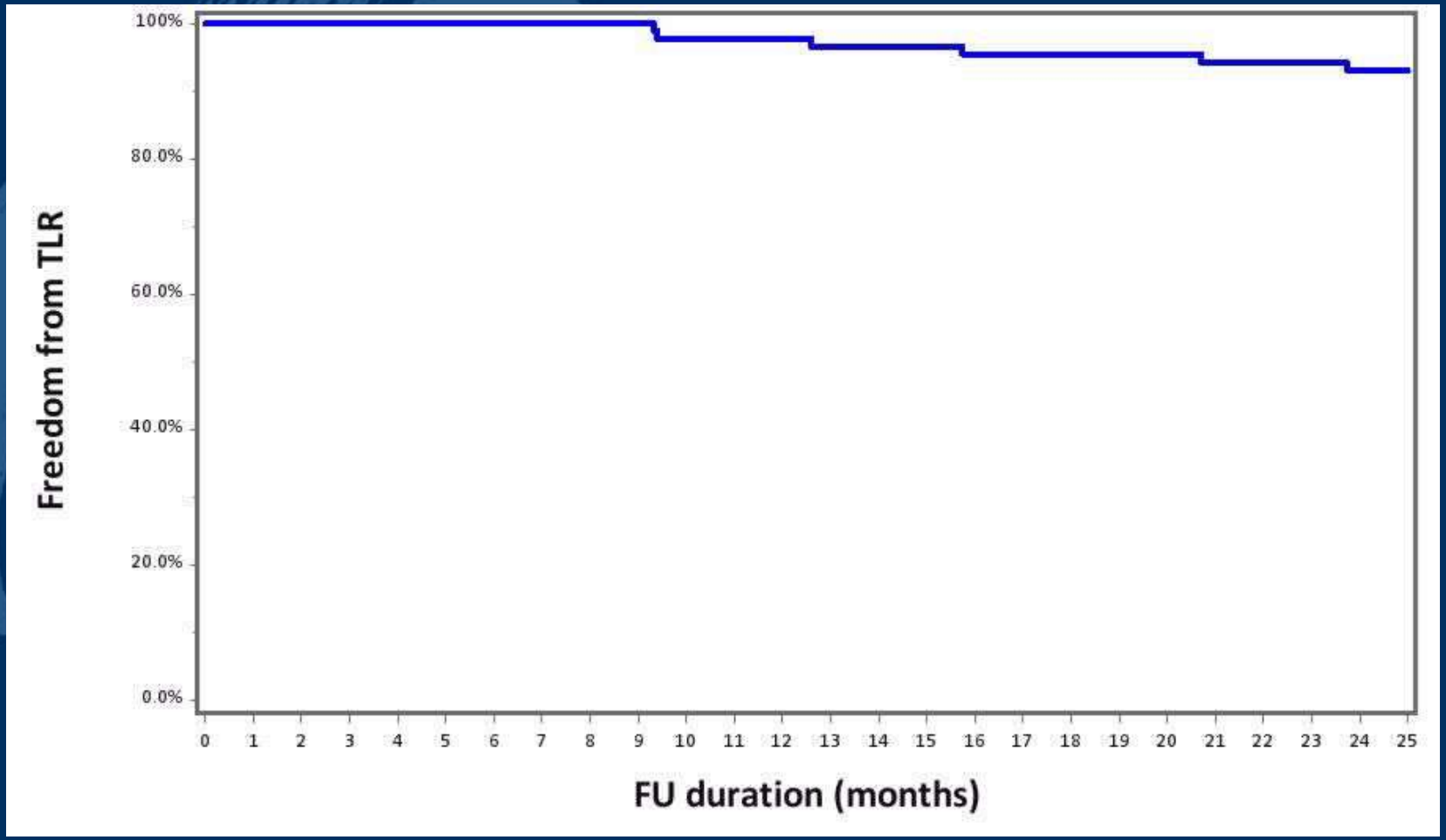
24 months results: TLR



93.1%

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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