



## Randomized comparison of Ultrathin Strut Orsiro with Xience Prime. All-comers results out to 5 years

### Conclusions

- In this 2,119 patient, randomized, all-comers trial, Orsiro<sup>®</sup> demonstrated non-inferiority to Xience Prime\* for TLF at 12 months. At 5-years, TLF rates show no significant difference
- Landmark analysis provided an indication that Orsiro may reduce the rate of Stent Thrombosis (ST) after the first year of follow-up
- A meta-analysis including the BIOSCIENCE 5-year data shows lower rates of Myocardial Infarction (MI) for Orsiro versus Xience which could be attributed to Orsiro's ultrathin struts<sup>1</sup>

### Study design

Prospective, all-comers, multi-center, randomized, non-inferiority design

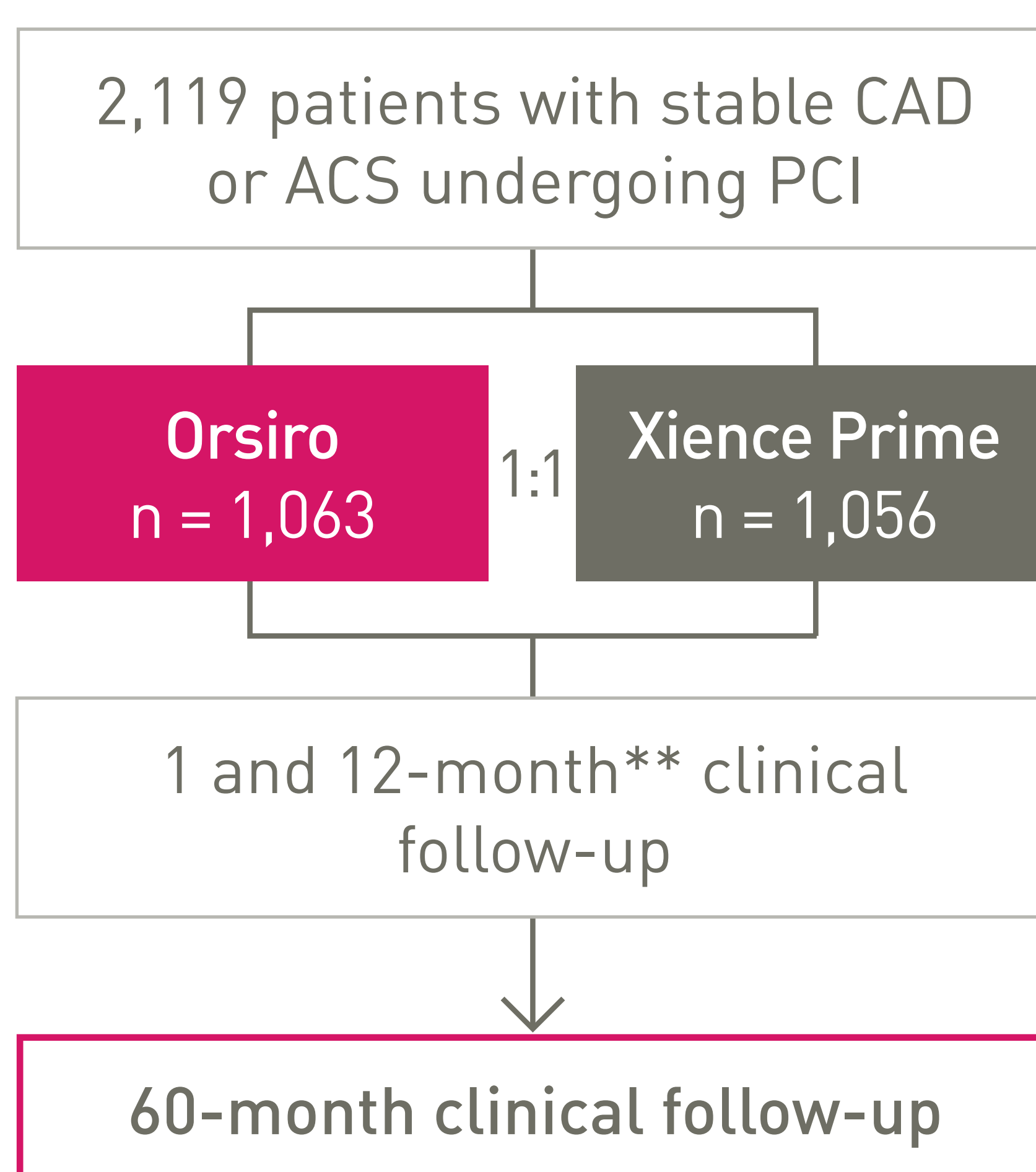
### Endpoints

#### Primary endpoint

- Target Lesion Failure (TLF)

#### Secondary endpoints

- Death
- Cardiac death
- Myocardial Infarction (MI)
- Target Lesion Revascularization (TLR)
- Target Vessel Revascularization (TVR)
- Definite ST<sup>§</sup>
- Definite or Probable ST
- Target Vessel Failure (TVF)



### Patient characteristics<sup>2</sup>

	Orsiro n = 1,063	Xience Prime n = 1,056
Diabetes	24%	22%
<b>Indication</b>		
Unstable angina	7%	7%
NSTEMI	27%	27%
STEMI	20%	19%
Stable angina	31%	31%
Silent ischemia	15%	16%

### Lesion characteristics<sup>2</sup>

	Orsiro n = 1,594 <sup>¶</sup>	Xience Prime n = 1,454 <sup>¶</sup>
Left main artery	2%	2%
Left anterior descending artery	41%	44%
Left circumflex artery	23%	22%
Right coronary artery	32%	29%
Coronary artery bypass graft	11%	9%
Long lesion (>20 mm)	54%	57%
Small vessel (<2.75 mm)	29%	32%

\* Xience and Xience Prime are registered trademarks of Abbott Cardiovascular Systems

\*\*Primary endpoint

§ ST as per ARC definition

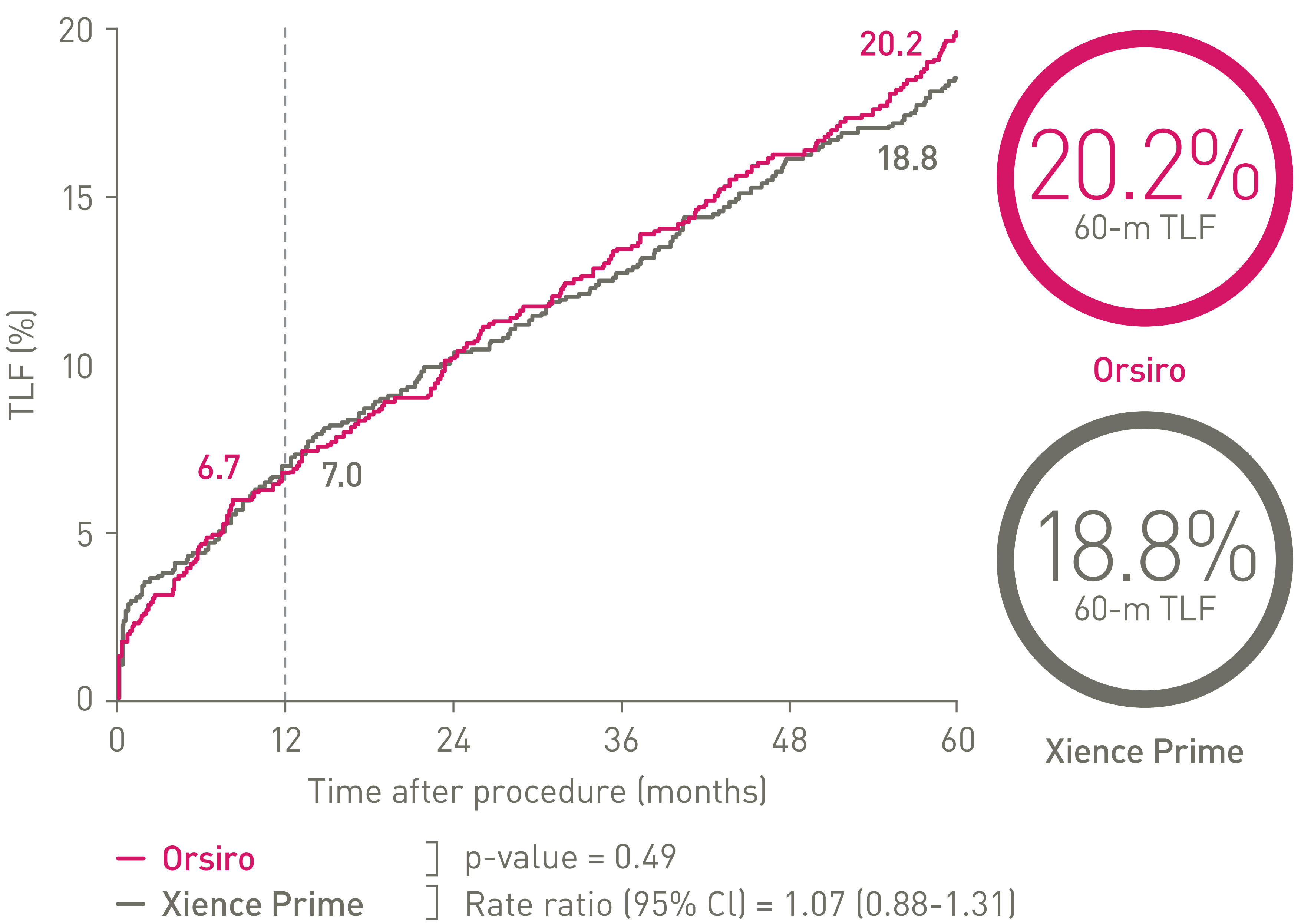
¶ Number of lesions

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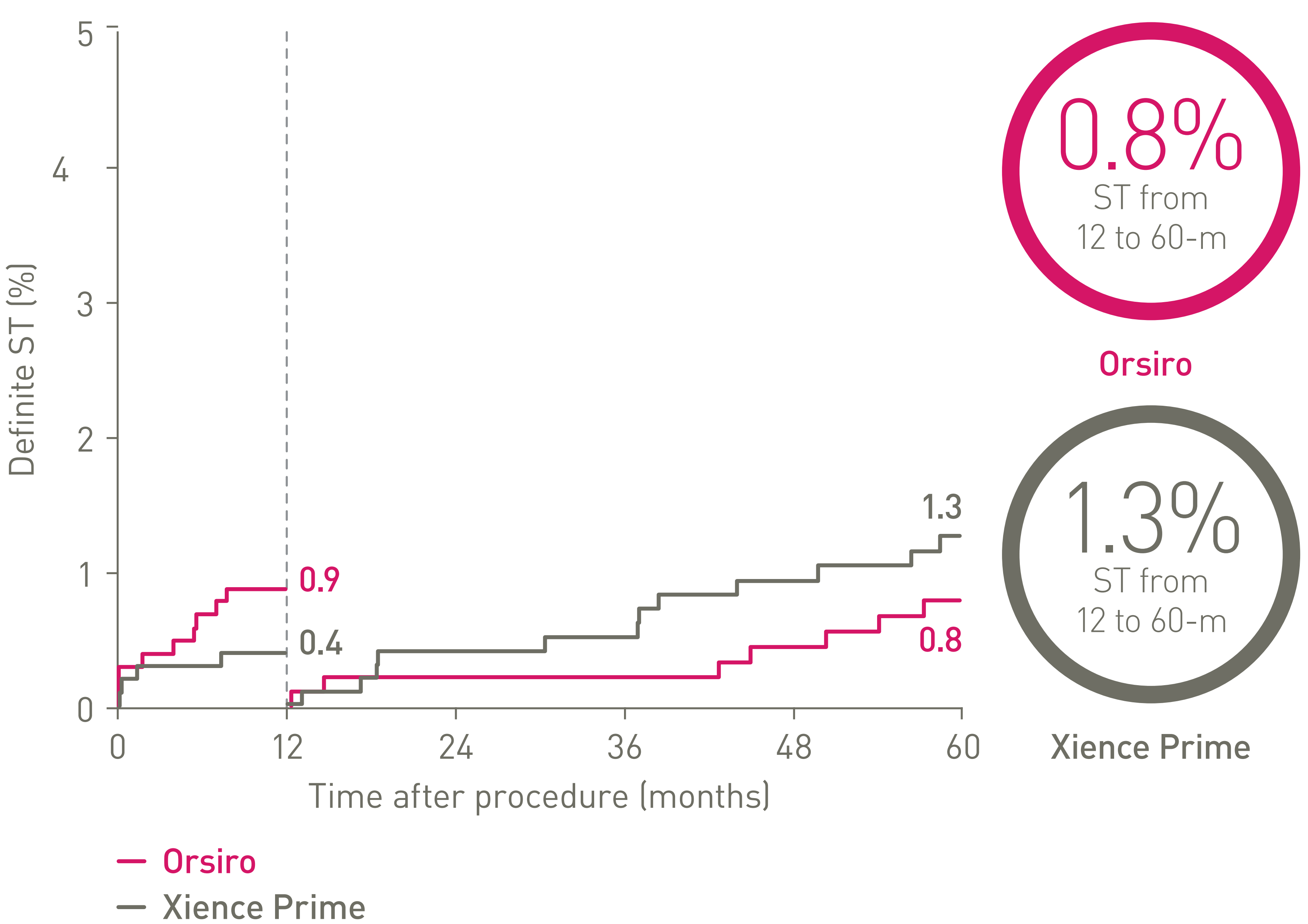
## TLF rates - all subjects out to 5 years<sup>3, 4</sup>



## Components of TLF<sup>4</sup>

	Orsiro n = 1,063	Xience Prime n = 1,056	p-value
<b>12 months</b>			
Cardiac death	1.9%	2.1%	0.7627
Target Vessel MI	2.9%	3.3%	0.6057
Clinically indicated TLR	3.5%	2.4%	0.1498
<b>60 months</b>			
Cardiac death	8.6%	7.5%	0.5686
Target Vessel MI	6.3%	7.1%	0.5950
Clinically indicated TLR	10.8%	10.0%	0.5036

## Landmark analysis for definite ST<sup>3</sup>



## ST at 1 year,<sup>\*\*</sup> between 1 year and 5 years, and at 5 years<sup>4</sup>

	Orsiro n = 1,063	Xience Prime n = 1,056	p-value
<b>Definite ST</b>			
At 1 year	0.9%	0.4%	0.1650
From 1 to 5 years	0.8%	1.3%	0.2861
At 5 years	1.6%	1.6%	0.9497
<b>Definite or Probable ST</b>			
At 1 year	2.8%	3.6%	0.2623
From 1 to 5 years	3.6%	4.3%	0.6389
At 5 years	6.3%	7.7%	0.2637

\*\*Includes additional ST events identified by sites after the 12-month follow-up. Therefore, this rate updates the original analysis reported in Pilgrim T et al. The Lancet 384.9960 (2014): 2111-2122.

## Principal investigator

Prof. Stephan Windecker, Bern, Switzerland

1. Pilgrim T. et al. Randomized comparison of a novel, ultrathin cobalt-chromium biodegradable polymer sirolimus-eluting stent with a thin strut durable polymer everolimus-eluting stent for percutaneous coronary revascularization – final 5 year outcomes; Presented at: ESC Congress; August 28, 2018; Munich, Germany; ClinicalTrials.gov: NCT01443104; 2. Pilgrim T. et al. BIOSCIENCE: a randomised, single-blind, noninferiority trial. The Lancet 384.9960 (2014): 2111-2122; 3. Pilgrim T, Piccolo R, Heg D, et al. Ultrathin-strut, biodegradable-polymer, sirolimus-eluting stents versus thin-strut, durable-polymer, everolimus-eluting stents for percutaneous coronary revascularisation: 5-year outcomes of the BIOSCIENCE trial. The Lancet. 2018 Sep 1;392(10149):737-46; 4. Pilgrim T. et al. 5-year outcomes of the BIOSCIENCE randomised trial. Supplementary appendix; Lancet 2018; published online Aug 28. [http://dx.doi.org/10.1016/S0140-6736\(18\)31715-X](http://dx.doi.org/10.1016/S0140-6736(18)31715-X).



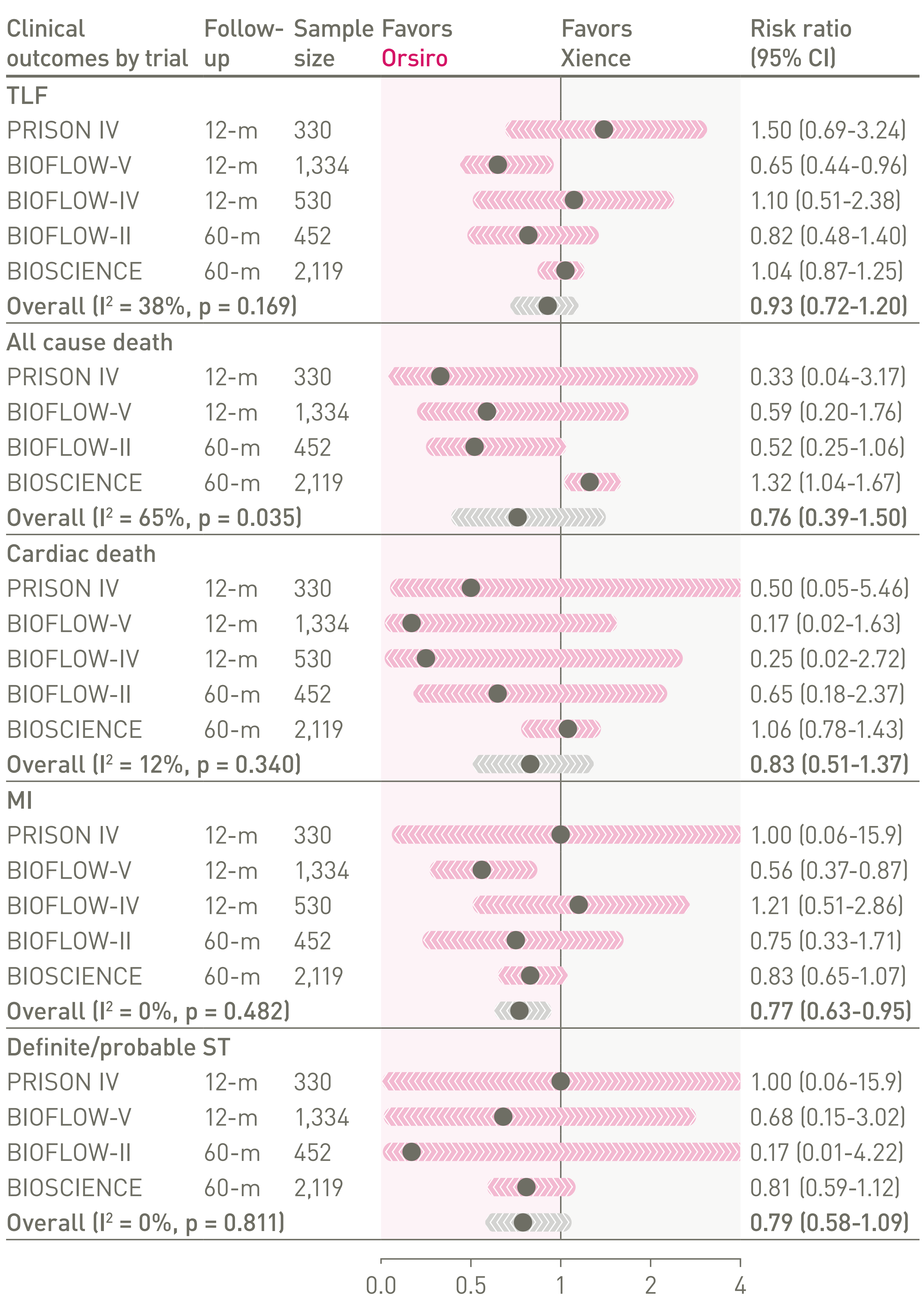
Vascular Intervention // Coronary // Orsiro

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### Meta-analysis of five RCTs comparing Orsiro vs. Xience<sup>1</sup>



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