Safety and Performance Registry for an All-Comers Subject Population with the Limus Eluting Orsiro Mission Stent System Within Daily Clinical Practice: Twelve-Month Results of the BIOFLOW-VIII Registry

Conclusions

- Orsiro Mission DES proven non-inferiority for TLF in an all-comers population compared to its predecessor device.[a,1]
- Orsiro Mission DES shows a very low definite stent thrombosis rate[b,1] (0.3%) and a very low clinically-driven target lesion revascularization rate at 1 year in an all-comers population (1.5%).[c,1]

Study design

Prospective, national, multi-center, all-comers registry

Endpoints at 12-month follow-up

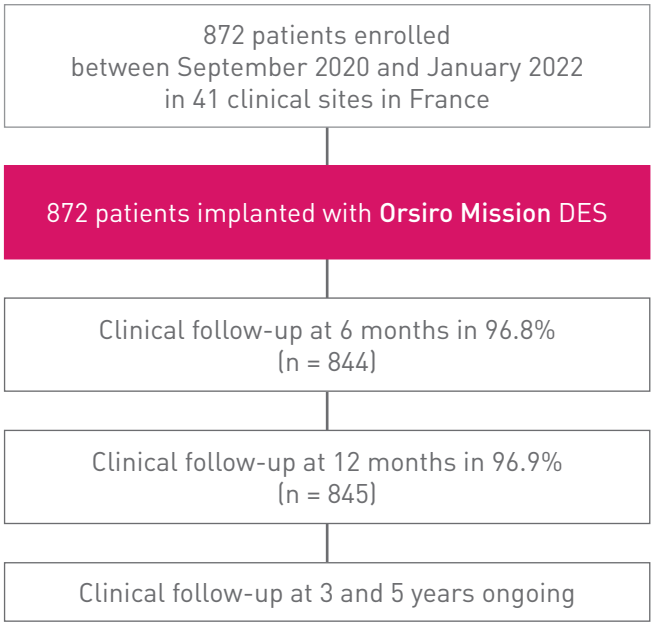
Primary endpoint

Target Lesion Failure (TLF) at 12 months, defined as the composite of:

- Cardiovascular Death
- Target Vessel-Myocardial Reinfarction (TV-MI) according to Academic Research Consortium-2 (ARC-2) definition
- Clinically Driven-Target Lesion Revascularization (CD-TLR)

Selected Secondary Endpoints

All cause death, Myocardial Infarction (MI) acc. ARC-2, Clinically Driven Target Vessel Revascularization (CD-TVR), Stent Thrombosis (Def/Prob ST), Definite Stent Thrombosis (ST).



Patient characteristics[1]	n = 872
Age (mean ± SD) (yrs)	67.3 ± 10.5
Male gender	75.2%
Hypertension	59.1%
Hypercholesterolemia	54.5%
Diabetes mellitus	27.5%
History of smoking	51.9%
History of MI	19.2%
History of stroke or TIA	6.2%
Previous PCI	35.4%
Previous CABG	3.9%
Clinical presentation	
Chronic Coronary Syndrome	67.6%
Stable angina	27.1%
Documented silent ischemia	40.5%
Acute Coronary Syndrome	**32.5%**
Unstable angina	8.4%
STEMI	10.2%
NSTEMI	13.9%

Lesion and Procedural characteristics[1]	n = 1,166 lesions
Lesion length (mean ± SD) (mm)	21.0 ± 10.7
RVD (mean ± SD) (mm)	3.0 ± 0.5
Target lesion per subject	1.3 ± 0.6
Lesion location	
Right coronary artery	32.2%
Left anterior descending artery	46.1%
Left circumflex artery	20.4%
Left Main coronary artery	1.2%
CABG	0.1%
ACC/AHA class B2/C	**40.7%**
Severe calcification	**6.6%**
ISR	3.0%
Chronic total occlusion	3.4%
Bifurcations	23.3%
Device success	98.7%
Procedural success	97.6%

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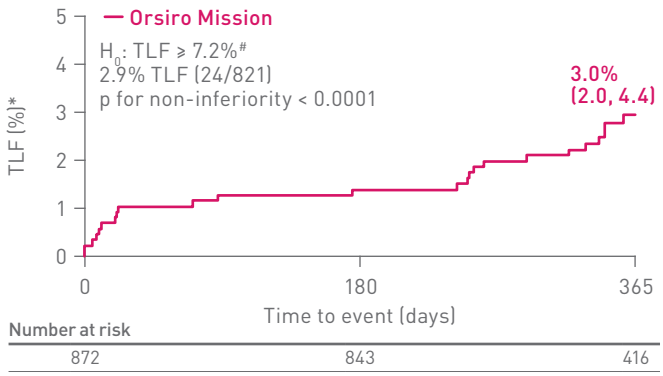
Primary Endpoint – TLF components* at 12 months[1]

Orsiro Mission DES shows a very low TLF rate in an all-comers population.[d,1]

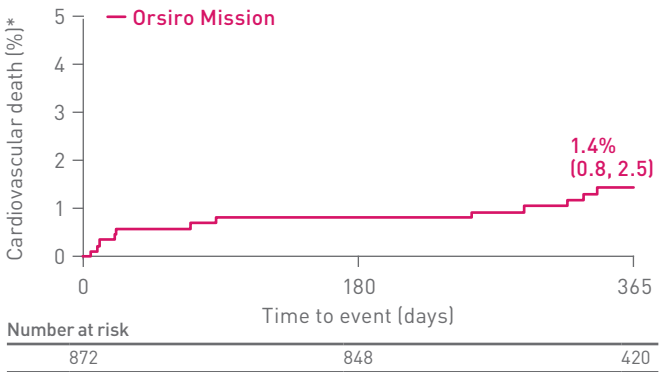
TLF



Number at risk

872	843	416

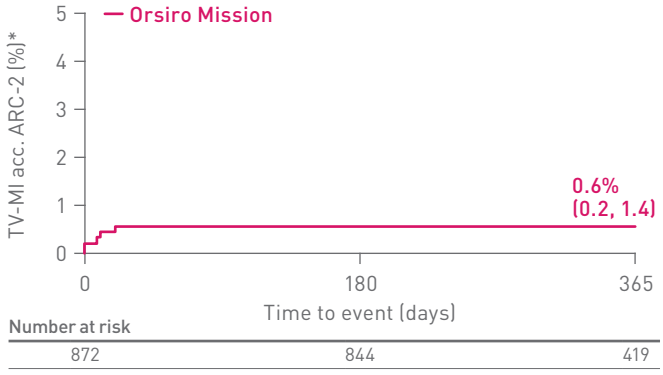
Cardiovascular death



Number at risk

872	848	420

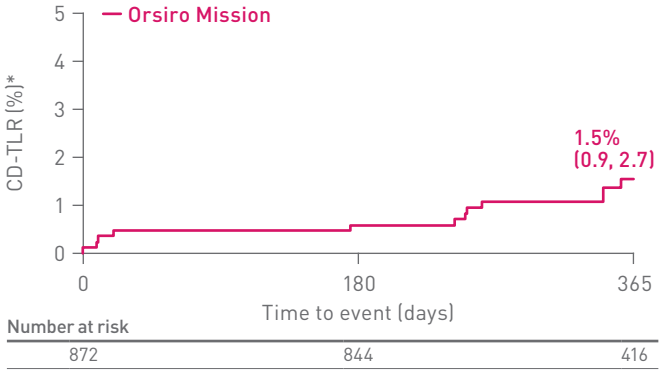
TV-MI acc. ARC-2



Number at risk

872	844	419

CD-TLR



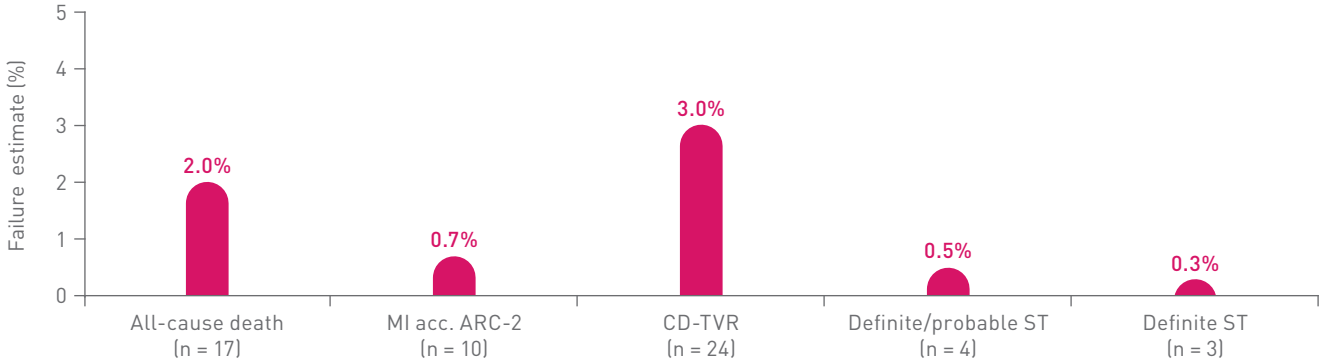
Number at risk

872	844	416

4.8% TLF from Orsiro DES all-comer studies +2.4% NIM; * Kaplan-Meier failure estimates (CI)

Selected Secondary Endpoints at 12 months[1]

Confirmed safety and efficacy of the **Orsiro Mission** DES in routine clinical practice.[e,1]



Principal investigator

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AHA / ACC: American Heart Association / American College of Cardiology, ARC-2: Academic Research Consortium. BCI: Bayesian Credible Interval, BPP: Bayesian Posterior Probability, CABG: Coronary Artery By-Pass Graft, CD: Clinically Driven, CD-TLR: Clinically Driven Target Lesion Revascularization, CD-TVR: Clinically Driven Target Vessel Revascularisation, NIM: Non Inferiority Margin, MI: Myocardial Infarction, PCI: Percutaneous Coronary Intervention, RVD: Reference Vessel Diameter, SD: Standard Deviation, ST: Stent Thrombosis, STEMI: ST Segment Elevation Myocardial Infarction, TIA: Transient Ischemic Attack, TLF: Target Lesion Failure, TLR: Target Lesion Revascularisation, TVF: Target Vessel Failure, TV-MI: Target Vessel-Myocardial Infarction.

a. At 1-Y FUP, compared to historical control from all-comer studies with the predecessor device Orsiro DES**; b. At 1-Y FUP, with a definite stent thrombosis rate of 0.3%**; c. At 1-Y FUP, with a clinically-driven target lesion revascularization rate of 1.5%**; d. At 1-Y FUP, with a TLF rate of 2.9%**; e. At 1-Y FUP, for TLF in an all-comers population, compared to historical control from all-comer studies with the predecessor device Orsiro DES**.

** Clinical data collected with the Orsiro Mission DES device within the Orsiro family clinical program.

1. Nollert G. et al., "Safety and Performance Registry for an All-Comers Subject Population with the Limus Eluting Orsiro Mission Stent System Within Daily Clinical Practice: Twelve-Month Results of the BIOFLOW-VIII Registry" TCT Presentation 2023.

Clinical data collected with the Orsiro DES device within the Orsiro family clinical program.

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