

BIOFLOW-VIII

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

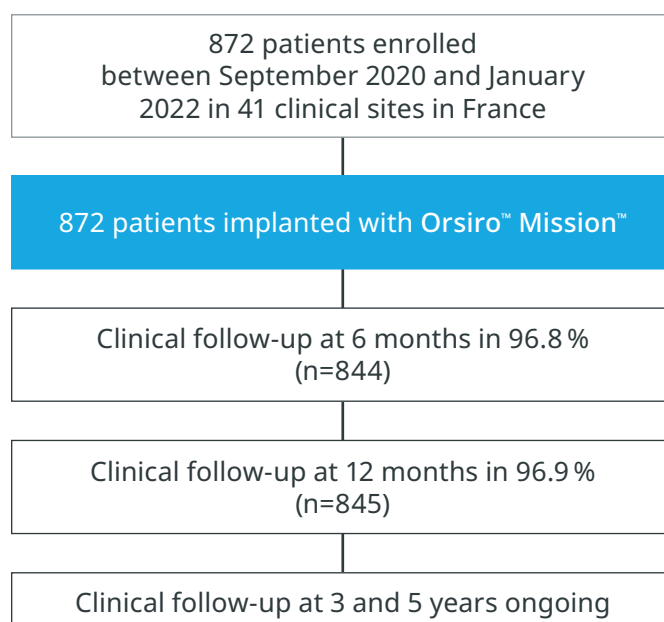
Target Lesion Failure (TLF) at 12 months, defined as the composite of:

- 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).

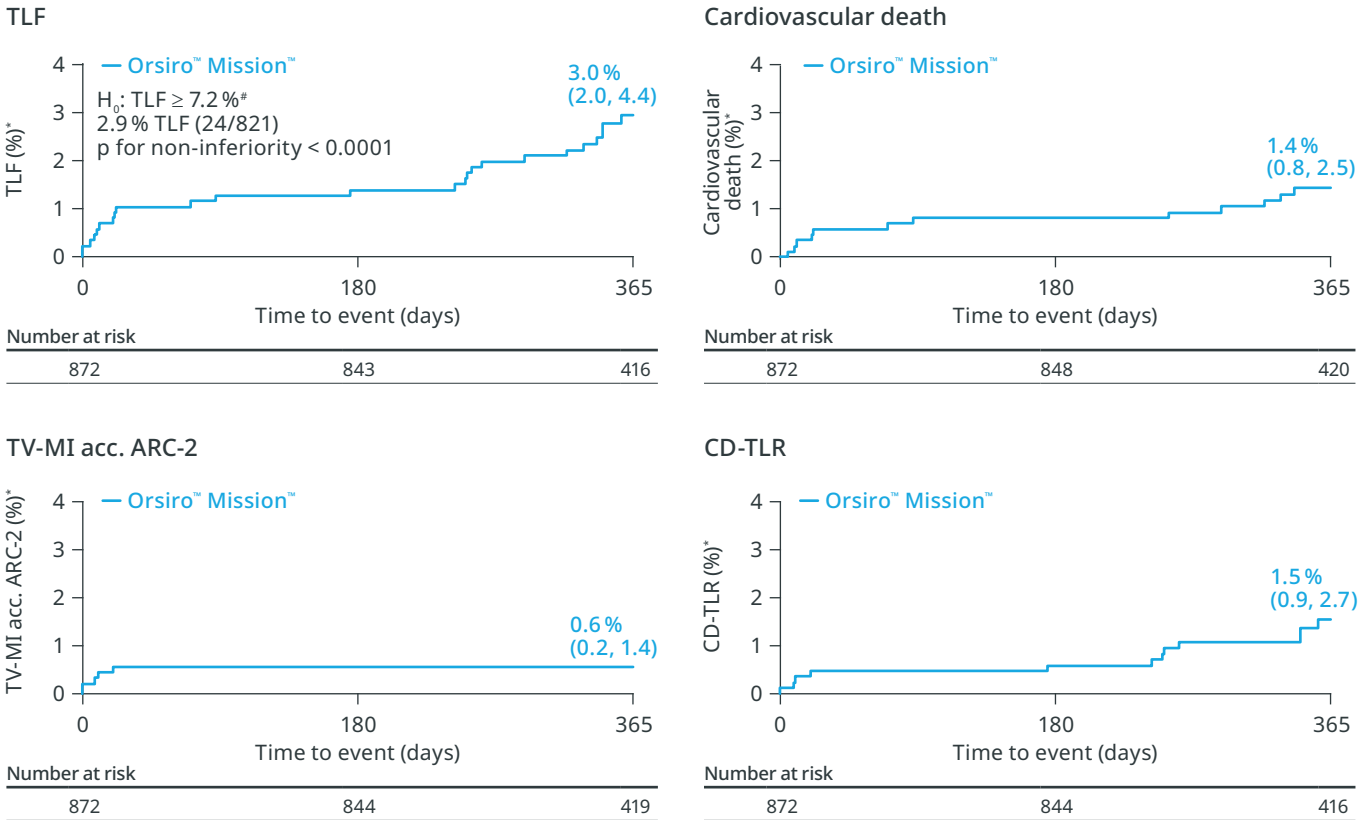
PATIENT CHARACTERISTICS ¹	N=872
Age (mean ±SD) (yrs)	67.3±10.5
Male gender	75.2 %
Hypertension	59.1 %
Hypercholesterolemia	54.5 %
Diabetes mellitus	27.5 %
History of smoking	51.9 %
History of MI	19.2 %
History of stroke or TIA	6.2 %
Previous PCI	35.4 %
Previous CABG	3.9 %
Clinical presentation	
Chronic 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 %

Primary Endpoint – TLF components* at 12 months¹

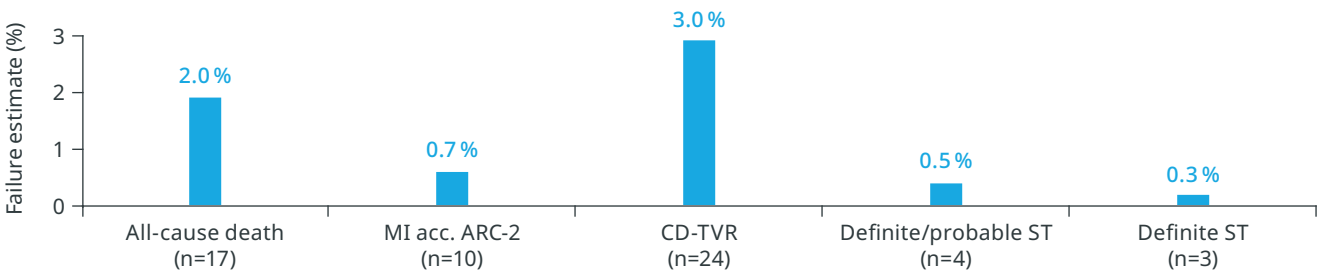
Orsiro™ Mission™ DES shows a very low TLF rate in an all-comers population.^{d,1}



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

Selected Secondary Endpoints at 12 months¹

Confirmed safety and efficacy of the Orsiro™ Mission™ DES in routine clinical practice.^{e,1}



Principal investigator: Paul Barragan, MD, Polyclinique Les Fleurs, Ollioules, France

Reference:

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.

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.

*At 1-Y FUP, compared to historical control from all-comer studies with the predecessor device Orsiro™ DES**^bAt 1-Y FUP, with a definite stent thrombosis rate of 0.3%*

*At 1-Y FUP, with a clinically-driven target lesion revascularization rate of 1.5%**^cAt 1-Y FUP, with a TLF rate of 2.9%**^dAt 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.

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