

# SORT OUT X

Comparison of combo Dual Therapy Sirolimus-eluting stent (DTS) to ultrathin strut Orsiro™ Biodegradable Polymer Sirolimus-eluting stent (BP-SES) in an all-comers population

## Conclusions

- Combo failed to show non-inferiority to Orsiro™ with respect to Target Lesion Failure (TLF) at 12 months (6.3 % vs. 3.7 %,  $p=0.00086$ ).
- Target Lesion Revascularization (TLR) rate for Combo was significantly higher compared to Orsiro™ (3.4 % vs. 1.5 %,  $p=0.0012$ ).
- Rates of Target Vessel Revascularization (TVR) and patient related endpoints were significantly higher in the Combo arm.

### Study design

Large scale, all-comers, multicentre, single-blind, two-arm, 1:1 randomized, non-inferiority trial comparing Combo to Orsiro™ stent in patients undergoing PCI.

### Endpoints

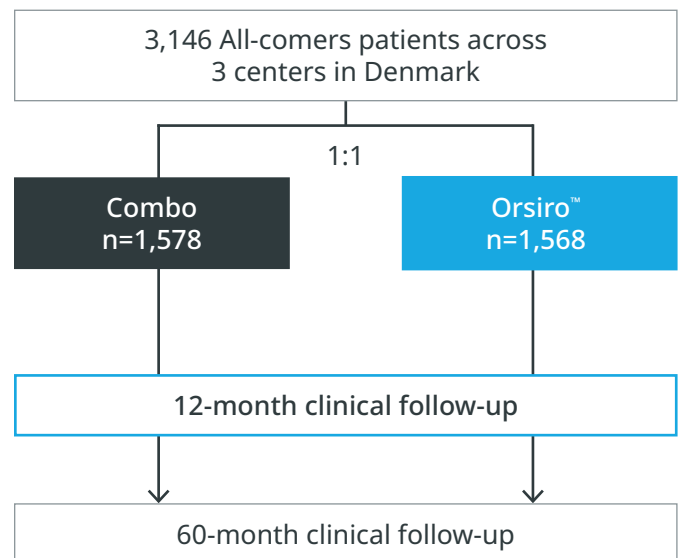
#### Primary endpoint

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

- Cardiac Death
- Target vessel Myocardial Infarction (TV-MI)
- Target Lesion Revascularization (TLR)

#### Secondary endpoints

- Individual components of the primary endpoint
- All-cause death
- Target Vessel Revascularization (TVR)
- Stent Thrombosis (ST)  
(all, definite, definite/probable, probable, possible ST)
- Patient related endpoint  
(death, MI or any revascularization)



### Patient characteristics<sup>1</sup>

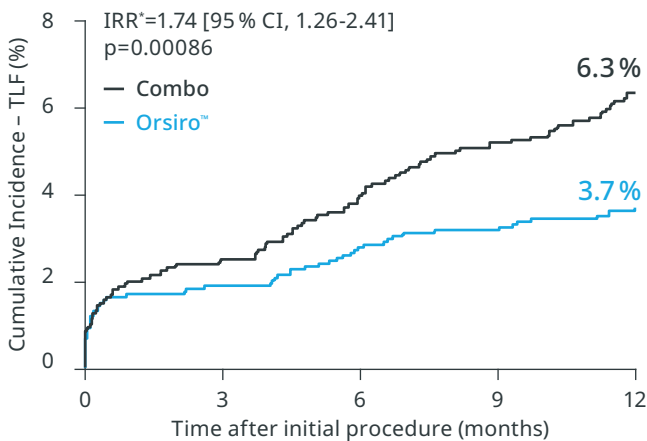
	COMBO N=1,578	ORSIRO™ N=1,568
Age (years)*	67.1±10.7	66.7±10.9
Male	76.9%	77.0%
Smoker	29.1%	30.5%
Diabetes mellitus	17.7%	17.3%
Hypertension	53.7%	56.6%
Hypercholesterolemia	50.3%	50.7%
Previous MI	15.4%	14.5%
Previous PCI	18.9%	19.7%
Previous CABG	7.1%	5.8%
<b>Clinical indication</b>		
STEMI	24.7%	22.6%
NSTEMI or Unstable Angina	29.6%	31.8%
Stable Angina	41.3%	41.7%

\*Data shown as mean±SD

### Lesion and Procedural characteristics<sup>1</sup>

	COMBO N=2,008	ORSIRO™ N=1,982
Number of target lesions/patient		
1	74.3%	74.9%
2	20.3%	19.9%
3	4.4%	3.6%
Lesion Type		
B2	21.5%	20.3%
C	41.1%	39.5%
Bifurcation lesions		
Chronic Total Occlusion	4.4%	5.2%
Lesion Length (mm)*	22.8±15.6	22.8±15.8
Reference vessel diameter (mm)*	3.4±0.6	3.4±0.6
Number of stents/patient*	1.7±1.0	1.7±1.1
Total stent length (mm)*	28.1±18.0	28.3±18.2

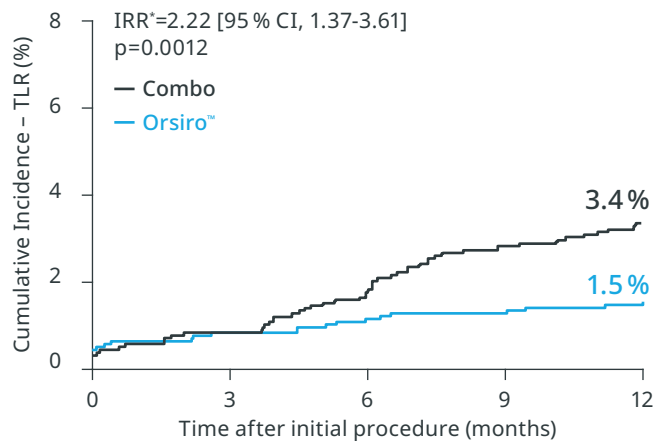
### TLF at 12 months<sup>1</sup>



\*Incidence rate ratios

Combo is inferior to Orsiro™ with respect to TLF at 12 months

### TLR at 12 months<sup>1</sup>



Significantly lower TLR rate for Orsiro™ compared to Combo

## Selected secondary endpoints at 12 months<sup>1</sup>

	COMBO N=1,578	ORSIRO™ N=1,568	P-VALUE
Cardiac Death	1.6%	1.5%	0.7800
TV-MI	2.7%	1.8%	0.1000
TLR	3.4%	1.5%	0.0012
TVR	5.1%	2.8%	0.0013
Definite ST	0.5%	0.4%	0.6000
Definite/probable ST	0.6%	0.4%	0.4700
Patient related endpoint	14.9%	11.9%	0.0150

## Subgroup analysis – TLF at 12 months<sup>1</sup>

		COMBO	ORSIRO™	RATE RATIO (95% BCI <sup>**</sup> )	FAVORS COMBO	FAVORS ORSIRO™	P FOR INTERACTION
ACS	no	43 (6.0%)	23 (3.2%)	1.88 (1.13–3.14)			0.690
	yes	57 (6.7%)	35 (4.1%)	1.65 (1.08–2.52)			
Diabetes mellitus	no	74 (5.7%)	45 (3.5%)	1.67 (1.15–2.42)			0.650
	yes	26 (9.3%)	13 (4.8%)	1.99 (1.02–3.90)			
Lesion Type C	no	48 (6.7%)	37 (5.3%)	1.29 (0.83–1.98)			0.044
	yes	52 (6.0%)	21 (2.4%)	2.54 (1.52–4.22)			
MVD	no	75 (5.9%)	45 (3.5%)	1.69 (1.17–2.45)			0.780
	yes	25 (8.2%)	13 (4.5%)	1.90 (0.96–3.77)			
STEMI	no	82 (6.9%)	48 (4.0%)	1.77 (1.24–2.54)			0.880
	yes	18 (4.6%)	10 (2.8%)	1.66 (0.76–3.62)			

.5                      1                      2                      4

**Principal investigator:** Lars Jakobsen, Aarhus University Hospital Skejby, Denmark

**Reference:**

<sup>1</sup> Jakobsen L et al. Randomized clinical comparison of the dual therapy CD34 antibody-covered sirolimus-eluting combo stent with the sirolimus-eluting orsiro stent in patients treated with percutaneous coronary intervention. The SORT OUT X trial. *Circulation* (2021).

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

Teleflex, the Teleflex logo, Orsiro, and Orsiro Mission are trademarks or registered trademarks of Teleflex Incorporated or its affiliates, in the U.S. and/or other countries. All other names are the trademarks or registered trademarks of their respective owners. Information in this material is not a substitute for the product Instructions for Use. Not all products may be available in all countries. Please contact your local representative.

Revised: 10/2025.

© 2025 Teleflex Incorporated. All rights reserved.

**Distributed by:**

**Teleflex Headquarters International, Ireland** · Teleflex Medical Europe Ltd. · IDA Business & Technology Park  
Dublin Road · Athlone · Co Westmeath · Tel. +353 (0)9 06 46 08 00 · Fax +353 (0)14 37 07 73 · orders.intl@teleflex.com  
**United Kingdom** Tel. +44 (0)14 94 53 27 61 · info.uk@teleflex.com  
**South Africa** Tel. +27 (0)11 807 4887 · assist.africa@teleflex.com

teleflex.com

**Teleflex™**  
Empowering the future of healthcare