2019 euroPCR

MeRes-1 Extend: Imaging and two-year clinical outcomes of thin strut sirolimus-eluting bioresorbable vascular scaffold in patients with coronary artery disease

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On Behalf of MeRes-1 Extend Investigators

Disclosure Statement of Financial Interest

I do have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation, they are:

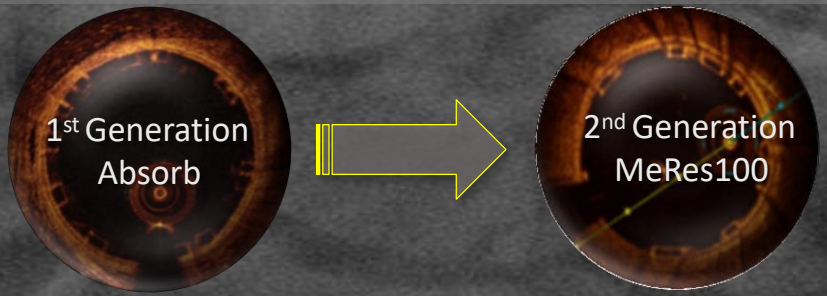
Affiliation/Financial Interest:	**Name of Organization:**
Scientific Advisor	Meril Life Sciences Pvt. Ltd.

BRS Under Siege – Due to Bulky 1st Gen BVS

- Large strut thickness
- Bulky, high profile device
- Compromised radiopacity
- Limited size matrix
- Storage conditions
- Shelf life constraints
- Increased dependence on imaging (IVUS/OCT)
- Overlapping not ideal
- Learning curve
- Poor clinical performance in small diameter vessels (Scaffold Thrombosis)

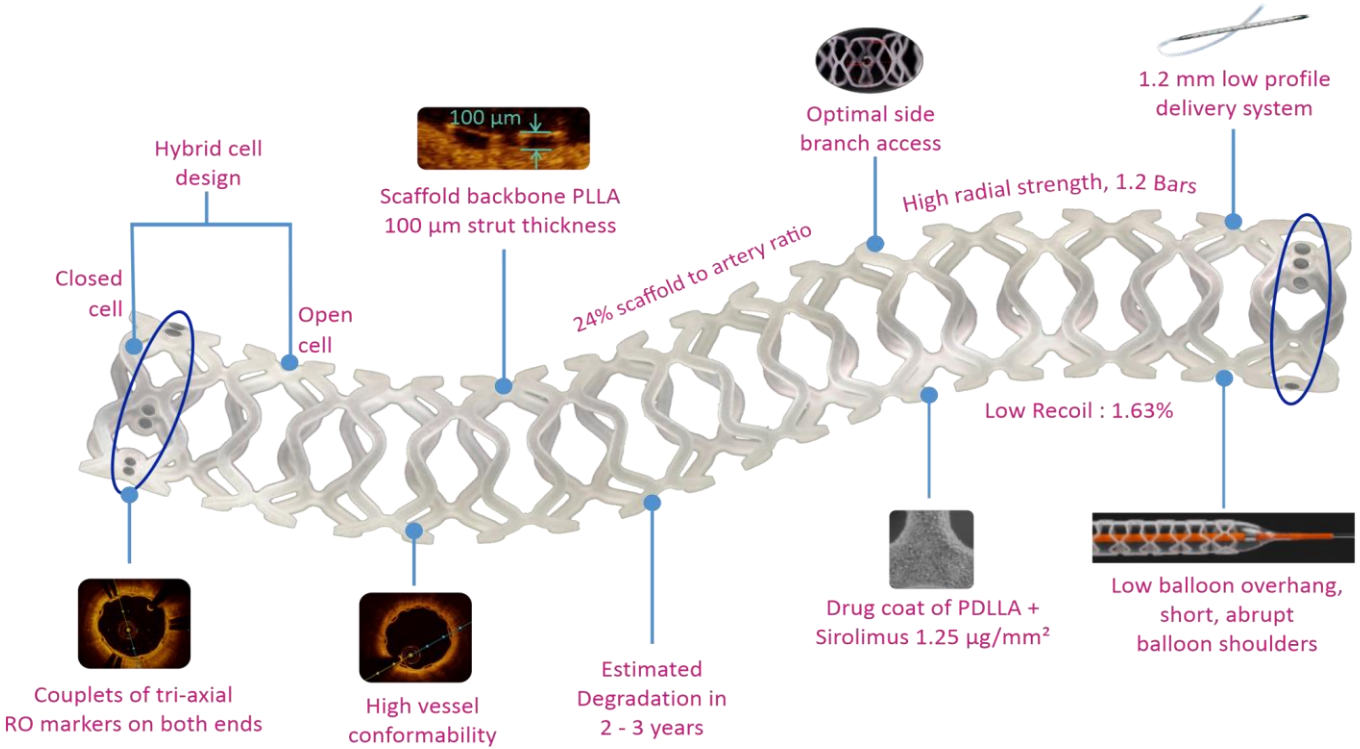
Drivers of BRS Adoption

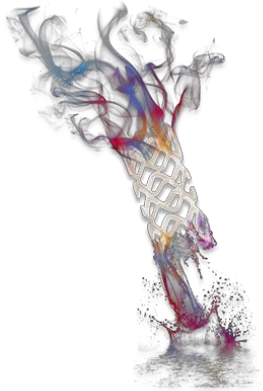
Acute Performance & Long Term Safety and Efficacy



- Reduced strut thickness, profile for deliverability
- Large size matrix to cover multitude of morphologies
- Ability to expand with resitance to fracture
- No increase in Tx duration or hardware consumed
- Regular Cath-lab storage conditions & long shelf life

MeRes100 (100µm BRS)
Sirolimus-Eluting Bioresorbable Vascular Scaffold





MeRes-1 Extend
Study Design

First-in-man safety and efficacy in patients with single, de-novo coronary lesion (in up to 2 vessels) treated by a single MeRes100 scaffold up to 24mm length

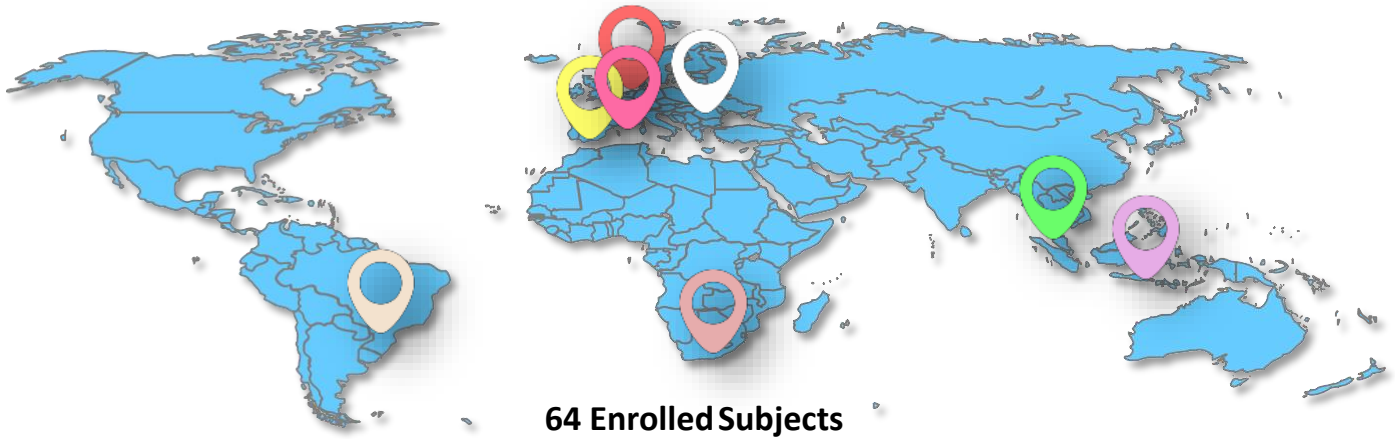
Clinical follow-up					
N = 64	**30-day**	**6-months**	**1-year***	**2-years**	**3-years**
*QCA, OCT follow-up					
Clinical follow-up	64	64	**64**	64	64
Angiographic follow-up	-	32	-	32	-
OCT follow-up	-	24	-	-	24

Diameters – 2.75, 3.00, 3.50 mm
Length – 19, 24 mm

PI – **Dr. Alexandre Abizaid, Dante Pazzanese, Sao Paulo**
Core Labs
Angiographic – Cardiovascular Research Center, Sao Paulo, Brazil
OCT – Cardialysis, Rotterdam, The Netherlands
Data Management
CRO – JSS, New Delhi, India

***1-year data presented during EuroPCR2018**

MeRes-1 Extend
Sites



64 Enrolled Subjects

Dr. Alexandre Abizaid, Sao Paulo	Dr. Sasko Kedev, Skopje
Dr. Robert-jan Van Geuns, Rotterdam	Dr. Rosli Mohd. Ali, Kuala Lampur
Dr. Bernard Chevalier, Paris	Dr. Teguh Santoso, Jakarta
Dr. Angel Cequier, Barcelona	Dr. Farrel Hellig, Johannesburg

MeRes-1 Extend
Key Eligibility Criteria

Key Inclusion Criteria

- Age >18 years
- Maximum 2 lesions in native coronary arteries (1 lesion/vessel)
- Reference vessel diameter 2.75-3.50mm
- Lesion length ≤ 20 mm
- Stenosis ≥ 50% & < 100%. TIMI ≥ 1
- Type A/B1 lesions

Key Exclusion Criteria

- Acute MI <7 days of Tx
- History of PCI or CABG
- LVEF ≤ 30%
- Ostial lesion (within 3mm)
- Lesion location in left main
- Lesion within 2mm of origin of LAD, LCX
- Moderate to severe calcification, aneurysm
- Bifurcation, Side branch >2mm in diameter
- Extreme tortuosity, angulation ≥ 90°
- Creatinine ≥ 1.3 mg/dL

Major Clinical Endpoints

- **Safety**
  - Primary Endpoint:
    - MACE at 6-month (Cardiac death, MI, ID-TLR)
  - Secondary Endpoints:
    - Device & procedure success
    - Scaffold thrombosis (ARC defined)

- **Efficacy**
  - QCA: Late lumen loss (in-scaffold/in-segment)
  - OCT: Minimum lumen area (flow area), NIH area

Baseline Characteristics in the ITT Population

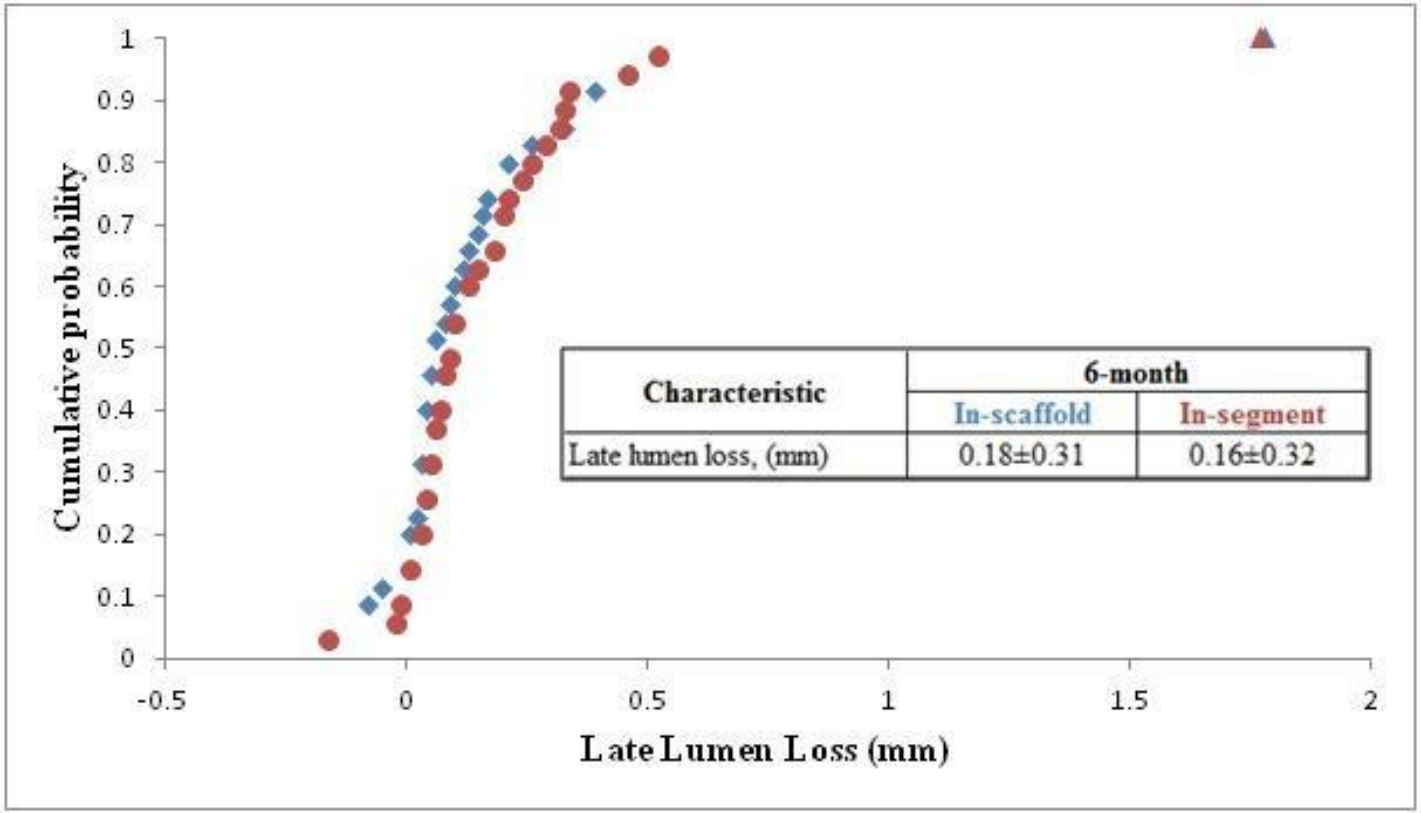
Variables	n = 64 Patients
Age (years), mean ± SD	58.30±9.02
Male, n (%)	44 (68.8)
Current smokers, n (%)	23 (35.94)
Diabetes mellitus, n (%)	17 (26.56)
Dyslipidemia, n (%)	31 (48.44)
Hypertension, n (%)	49 (76.56)
Previous myocardial Infarction, n (%)	18 (28.13)
Clinical presentation, n (%)	
Stable angina	44 (68.75)
Unstable angina	6 (9.38)
Silent ischemia	14 (21.88)
LVEF (%)	59.61±8.75

Cumulative MACE till 24-month Follow-up

Events, n (%)	1-month N=62*	6-month N=62	12-month N=62	24-month N=62
MACE	**0 (0.0%)**	**1 (1.61%)**	**1 (1.61%)**	**1 (1.61%)**
Cardiac death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Myocardial infarction	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ID-TLR	0 (0.0%)	1 (1.61%)	1 (1.61%)	1 (1.61%)
Scaffold thrombosis	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**
Non-cardiac death	0 (0%)	0 (0%)	0 (0%)	0 (0%)

***Data presentation is for PTE population**

Cumulative Frequency Distribution Curve for In-scaffold Late Lumen Loss



Characteristic	6-month	
	In-scaffold	In-segment
Late lumen loss, (mm)	0.18±0.31	0.16±0.32

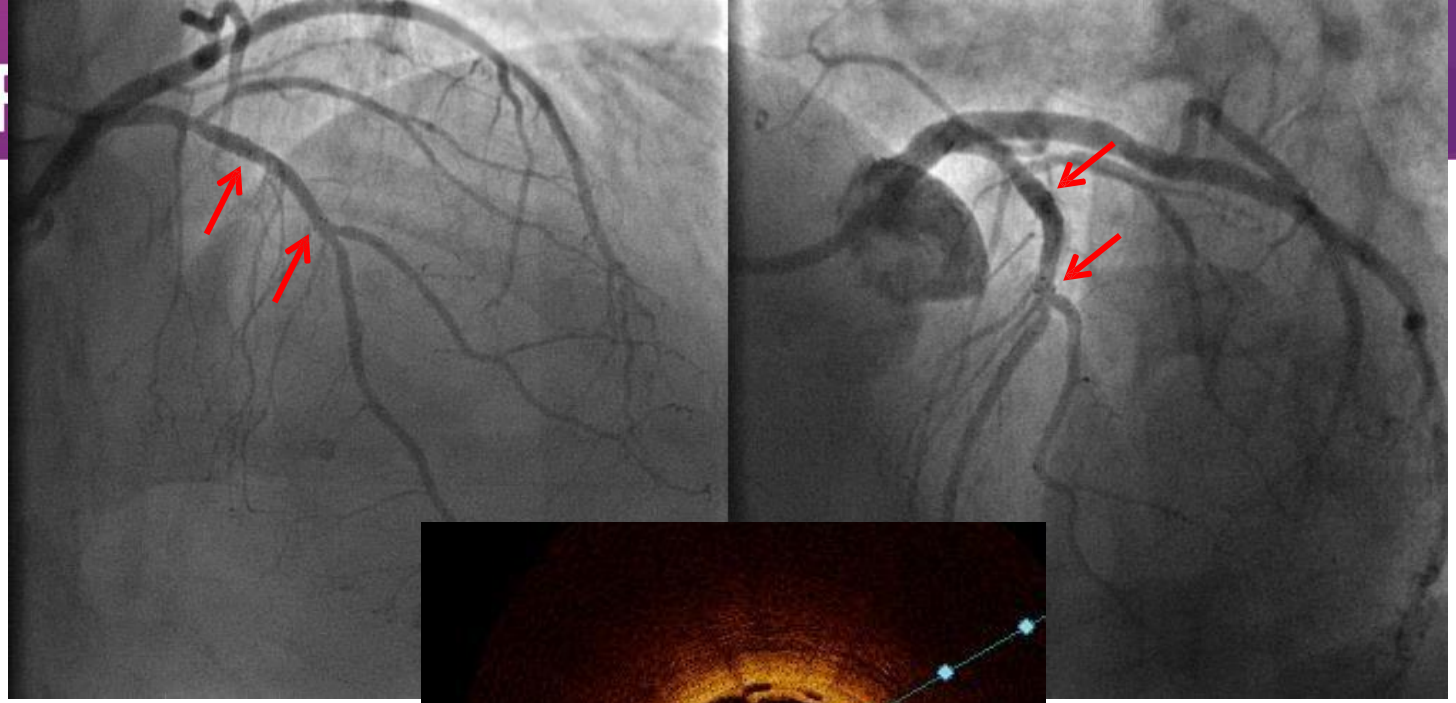
Angio QCA – CRC, Sao Paulo, Brazil

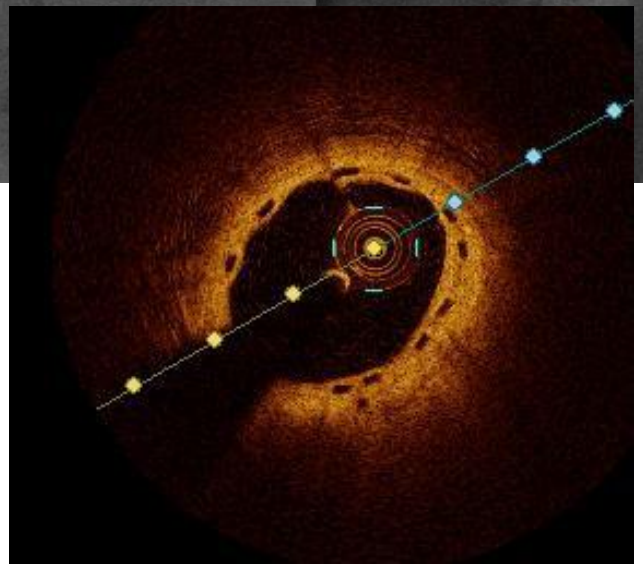
Paired OCT Analysis (n=21 patients)

Characteristic	Post-procedure	6-month[#]
Mean flow area, (mm^2)	6.7±1.7	6.0±1.8
Minimum lumen area, (mm^2)	5.5±1.4	4.2±1.2
Mean scaffold area, (mm^2)	7.4±1.7	7.6±1.8
Minimum scaffold area, (mm^2)	6.1±1.5	5.9±1.4
Mean neointimal hyperplasia area, (mm^2)	-	1.5±0.5
Covered struts, (%)	-	**97.9±3.7**

[#]6-month Clinical, Angiographic and OCT follow-up data was presented during TCT 2017

OCT– Cardialysis BV, Rotterdam, The Netherlands





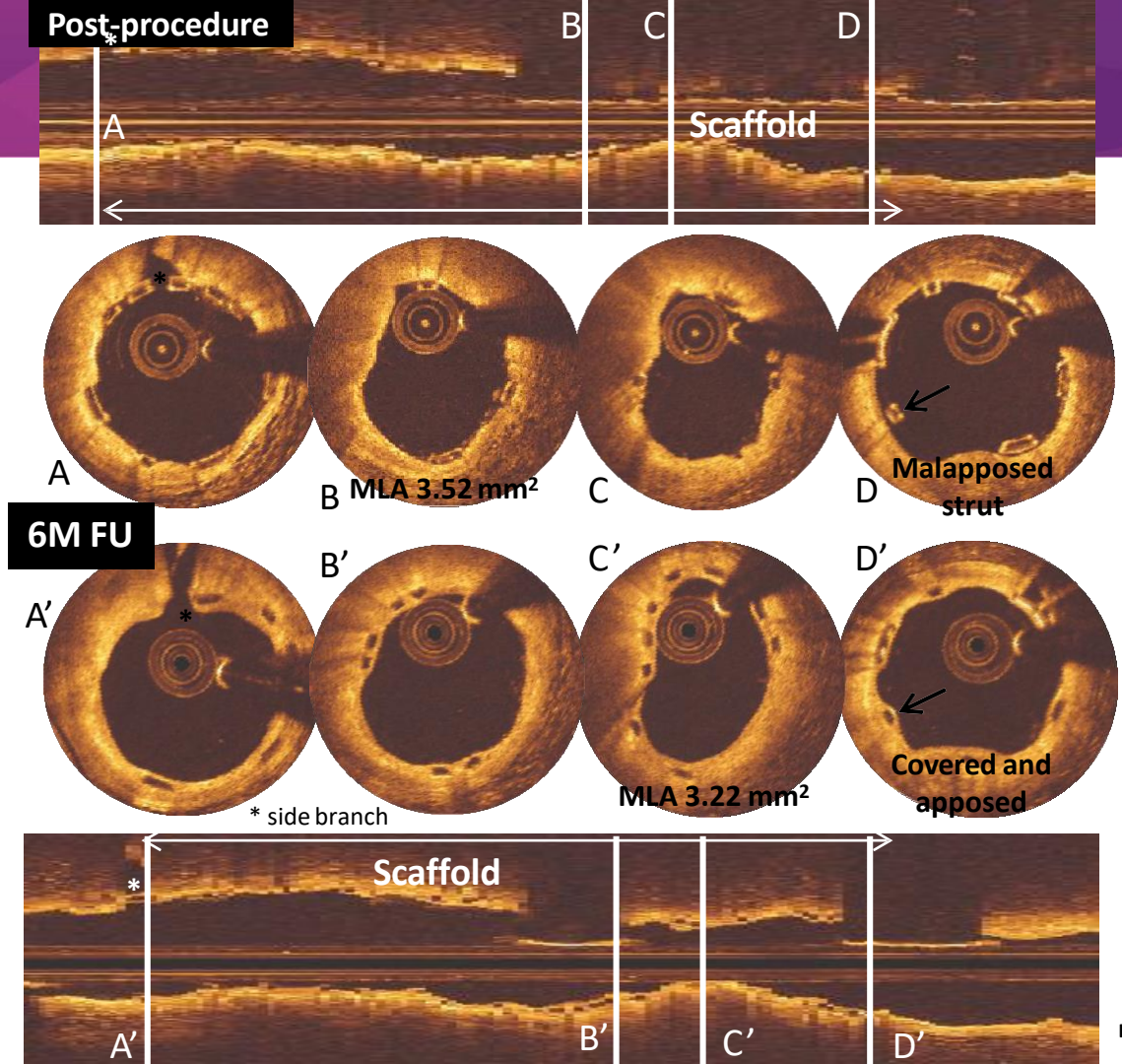
...Angio+OCT
Follow-up
At 6 months

Data on File

Case #2

MeRes100 + OCT
Follow-up at
6 months

	Post-PCI	6-Month
Mean LA (mm²)	4.56	4.28
Minimum LA (mm²)	3.52	3.22
Mean SA (abluminal) (mm²)	4.80	5.20
Minimum SA (abluminal) (mm²)	3.92	4.43
Neointimal area (abluminal) (mm²)	-	0.73



Data on File

Conclusions

- MeRes-1 trial, the 1st human evaluation of novel 2nd generation MeRes100 BRS with 100µm struts has demonstrated high acute success as well as long term clinical success up to 2-year follow-up with very low MACE 1.87% (2, ID-TLR) and Zero Scaffold Thrombosis (ST). 3-year follow-up will be presented today.
- MeRes-1 Extend trial has **2-year follow-up with very low MACE 1.61%** (1, ID-TLR) and **Zero Scaffold Thrombosis (ST**).
- Serial QCA analysis demonstrated relatively **low late lumen loss (0.18±0.31 mm)** at 6-month, suggesting high efficacy on inhibiting NIH at late follow-up
- OCT subset analyses demonstrated sustained mean flow area and virtually **complete strut coverage (97.9±3.7)** at 6-month follow-up.
- Cases presented provide positive evidence that Not all BRS technologies are made same and we should look forward to lower strut thickness BRS technologies as future of PCI.

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Thank You