# Randomized Clinical Outcomes in Patients Treated with the Bioadaptor Compared with Contemporary Drug-Eluting Stents: Individual Patient Data Pooled Analysis of INFINITY-SWEDEHEART R-RCT and BIOADAPTOR RCT

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On behalf of SWEDEHEART R-RCT and BIOADAPTOR RCT Investigators

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# Disclosure of Relevant Financial Relationships

Within the prior 24 months, I, *David Erlinge,* have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

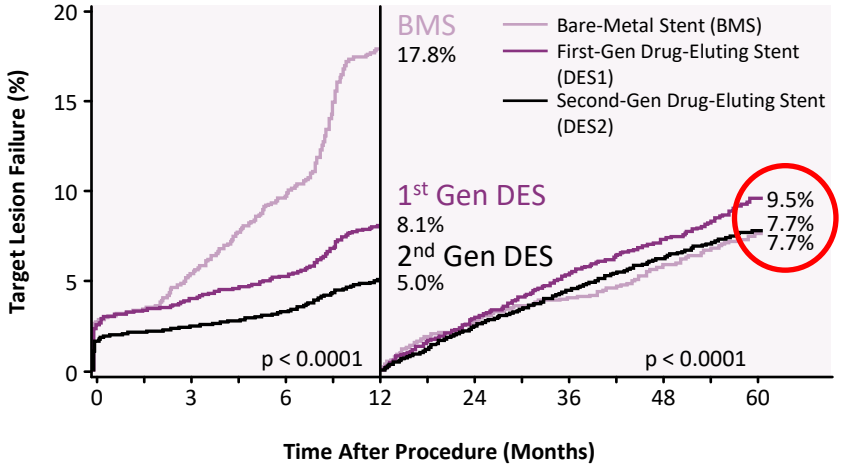
| Nature of Financial Relationship | Ineligible Company |
| --- | --- |
| Consultant Fees/Honoraria | Amgen, AstraZeneca, Chiesi, Sanofi, NovoNordisk, InfraredX/Nipro and Kaminari Medical |



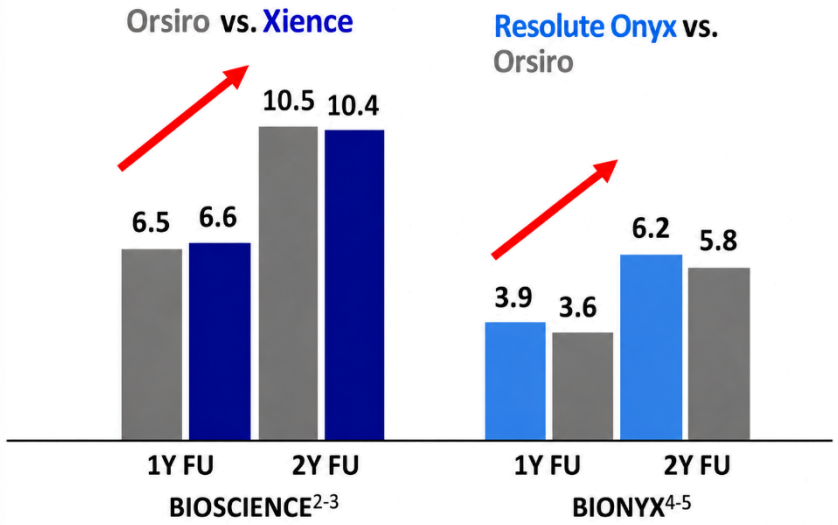
**All Relevant Financial Relationships have been mitigated.**
Faculty disclosure information can be found on the app.

# Long Term Durability of PCI Outcomes Remains A Challenge

**Stent Related Adverse Events Continue to Increase Post 1-Year[1]**




**1 and 2-year TLF Rates With Contemporary DES[2-5]**



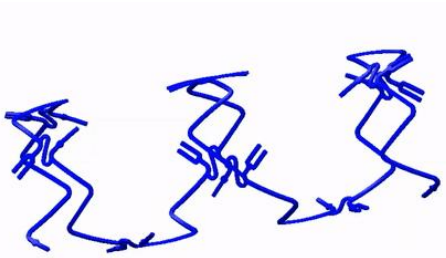

**No device intervention to date has shown superiority vs. DES**

**Increase in adverse events attributed to constraining the vessel and loss of vessel function[6]**


1. Madhavan MV et al., JACC 2020, Stent-related adverse events >1 year after PCI,
2. Pilgrim T, et al. The Lancet. 2014 Dec 13;384(9960):2111-22.
3. Zbinden R et al. JAHA 2016 Mar 15;5(3):e003255.
4. von Birgelen C et al. The Lancet. 2018 Oct 6;392(10154):1235-45.
5. Ploumen EH et al. Circ J. 2021 Oct 25; 85(11):1983-1990
6. Stone et al., JAMA Cardio. 2019, Time-varying outcomes with the absorb bioresorbable vascular scaffold

# Bioadaptor Implant and Mechanism of Action

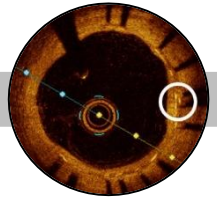
Bioadaptor coronary implant (DynamX® bioadaptor, Elixir Medical) is ***designed to adapt to vessel physiology to restore vessel function*** and address device related adverse events[1-3].



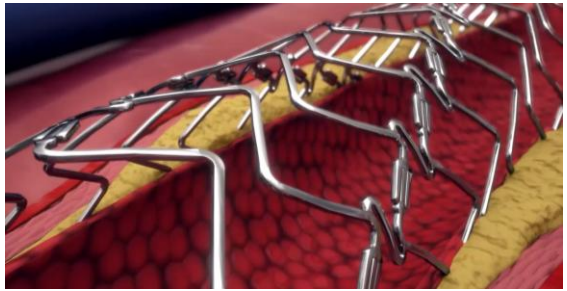
**Novel Implant Design**

***Three independent helical sinusoid strands*** *(CoCr 71µm)* ***are temporarily connected*** by bioresorbable polymer coating eluting antiproliferative agent

***6 months***



*Reendothelialization, neointima formation and polymer resorption*



**Dynamic Support After 6 Months:** Restore Hemodynamic Modulation

***After 6 months, helical strands unlock, separate and provide dynamic support to the diseased vessel enabling arterial pulsatility and compliance, adaptive remodeling (Glagov)***[1,2]


[1]Saito S, et al. The Lancet eClinicalMedicine 2023;65:102304
[2]Verheye S, et al. EuroIntervention 2020;16(12):e974
[3]Kwak BR, et al. Eur Heart J 2014;35(43):3013-3020



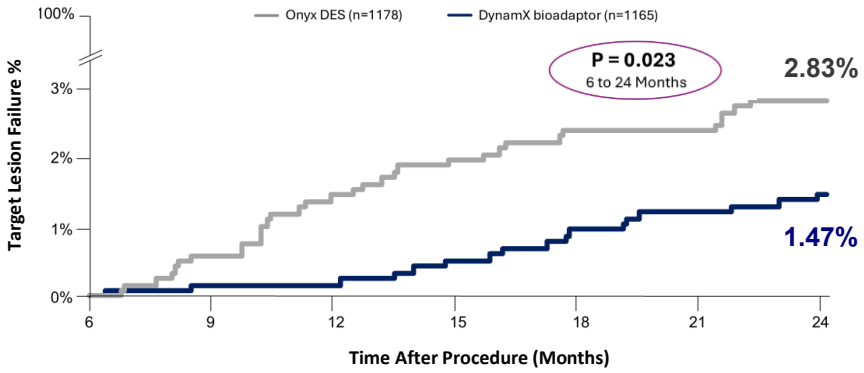
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*The DynamX Coronary Bioadaptor System is CE Mark approved.*
*The DynamX Sirolimus Eluting Coronary Bioadaptor System is an investigational device. Limited by Federal (or United States) law to investigational use.*

# BIOADAPTOR RCT and INFINITY R-RCT independently demonstrated sustained long-term clinical benefit with bioadaptor compared with DES

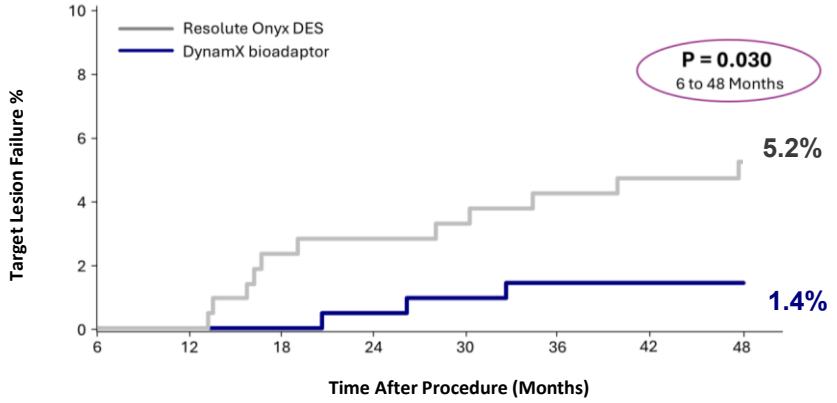
## INFINITY SWEDEHEART RCT[1,2]

### TLF from 6 M to 2 Year FU




## BIOADAPTOR RCT[3,4]

### TLF from 6 M to 4 Year FU





[1]Erlinge D. et al. 12-Month Outcomes INFINITY SWEDEHEART R-RCT, The Lancet. 2024 Nov 2;404(10464):1750-9

[2] Erlinge D. et al. 24-Month Outcomes INFINITY SWEDEHEART R-RCT, LBCT presentation, TCT 2025

[3]Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. The Lancet eClinicalMedicine. 2023;65:102304

[4]Yamanaka F. et al. 48-Month Clinical Outcomes, BIOADAPTOR-RCT, LBCT presentation, EuroPCR 2026

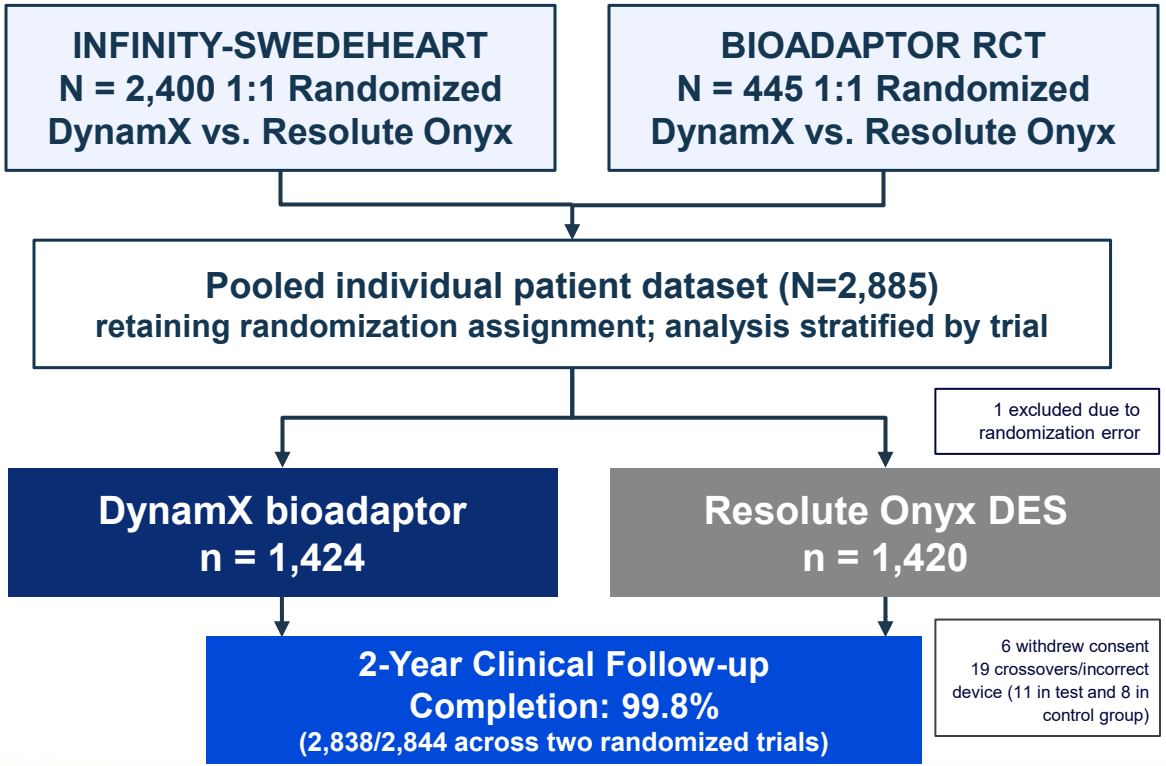
# Individual Patient Data Pooled Analysis

## Study Objective

*Evaluate the clinical performance of DynamX bioadaptor compared to Resolute Onyx DES, using individual patient data pooled from two large randomized trials, INFINITY SWEDEHEART R-RCT and BIOADAPTOR RCT in patients receiving treatment device in accordance with the device indication.*

# Individual Patient Data Pooled Analysis

## INFINITY-SWEDEHEART R-RCT and BIOADAPTOR RCT




### *Consistent Trial Designs*[1,2]

- Inclusion/exclusion criteria
- Endpoint definitions per ARC-2[3]
- Independent event adjudication
- Core lab data assessment
- Complete follow-up through 2 years

### *IPD Pooled Analysis*

- **Primary endpoint: Landmark analysis of target lesion failure from 6 months to 2 Years (superiority) in as treated (AT) population**
- Other endpoints: Outcomes in high-risk subgroups of ACS and LAD patients
- Cox regression stratified by study HRs with 95% confidence intervals


1. Erlinge D et al., Rationale and design of INFINITY-SWEDEHEART. American Heart Journal. 2024 Nov 1;277:1-0.
2. Saito S. et al., BIOADAPTOR-RCT 24-month Clinical Outcomes JACC, 2025 Apr 28;18(8):988-97.
3. Garcia-Garcia HM et al., ARC-2 Standardized end point definitions for coronary intervention trials:. Circulation. 2018 Jun 12;137(24):2635-50.

# Patient Baseline Characteristics

| Baseline Characteristics | DynamX (N=1,424) | Onyx (N=1,420) |
|---|---|---|
| Age, years | 68.0 ± 9.80 | 67.8 ± 9.70 |
| Female | 339 (23.8%) | 334 (23.5%) |
| Hypertension | 883 (62.4%) | 866 (61.6%) |
| Hyperlipidemia | 722 (51.1%) | 669 (47.6%) |
| Diabetes Mellitus | 290 (20.4%) | 273 (19.3%) |
| **Prior MI** | **186 (13.2%)** | **189 (13.4%)** |
| **Prior PCI/CABG** | **275 (19.4%)** | **252 (17.9%)** |
| Current Smoking | 216 (15.7%) | 235 (17.1%) |

| Clinical Presentation | DynamX (N=1,424) | Onyx (N=1,420) |
|---|---|---|
| **Acute Coronary Syndrome (ACS)** | **956 (67.1%)** | **932 (65.6%)** |
| STEMI | 282 (19.8%) | 317 (22.3%) |
| NSTEMI | 473 (33.2%) | 447 (31.5%) |
| Unstable Angina | 201 (14.1%) | 168 (11.8%) |
| **Chronic Coronary Syndrome (CCS)** | **468 (32.9%)** | **488 (34.4%)** |

# Baseline Lesion Characteristics

| Baseline Characteristics | DynamX (N=1,424) (L=1,647) | Onyx (N=1,420) (L=1,668) |
|---|---|---|
| **Target Lesion Location** | | |
| LAD | 841 (51.1%) | 835 (50.1%) |
| RCA | 442 (26.8%) | 445 (26.7%) |
| LCx | 363 (22.0%) | 387 (23.2%) |
| **Lesion Classification** | | |
| A | 241 (14.7%) | 250 (15.0%) |
| B1 | 734 (44.8%) | 768 (46.2%) |
| B2/C | 662 (40.4%) | 644 (38.7%) |
| Bifurcation | 216 (13.3%) | 219 (13.2%) |
| Calcified lesion* | 282 (17.1%) | 252 (15.1%) |
| Tortuous lesion* | 162 (9.8%) | 152 (9.1%) |

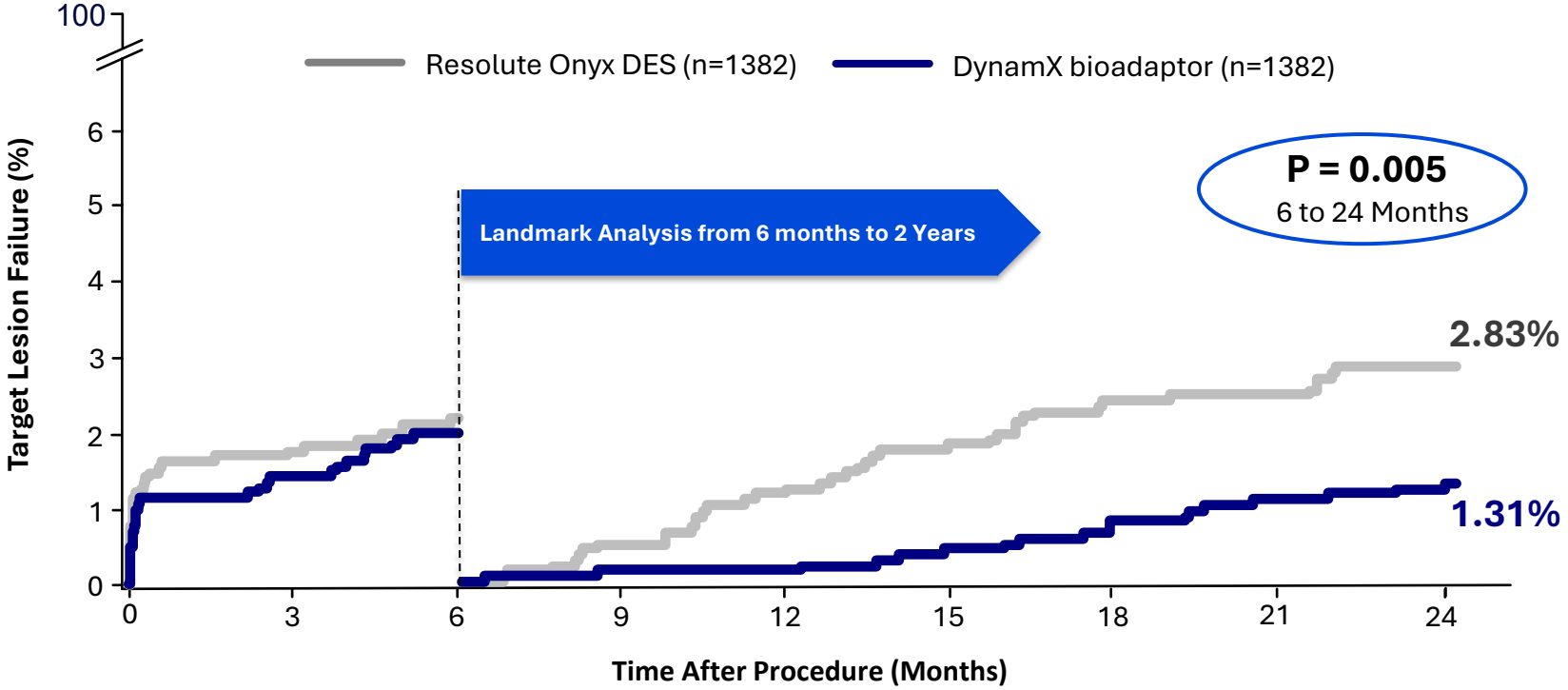
| Baseline Characteristics | DynamX (L=1,647) | Onyx (L=1,668) |
|---|---|---|
| **Number of target lesions per subject, n (%)** | | |
| 1 | 1229 (86.4%) | 1201 (84.8%) |
| ≥2 | 194 (13.6%) | 216 (15.2%) |
| RVD, mm | 3.2 ± 0.5 | 3.1 ± 0.5 |
| **Lesion Length, mm** | **23.3 ± 9.3** | **23.5 ± 9.5** |
| **%DS, pre-procedure** | **83.7 ± 14.7** | **83.8 ± 14.8** |
| **%DS, post-procedure** | **2.2 ± 6.0** | **1.8 ± 4.9** |
| Successful pre-dilation | 1642 (99.8%) | 1666 (99.9%) |
| Post-dilation | 1001 (63.2%) | 918 (57.8%) |

*moderate to severe

IPD Pooled Analysis of INFINITY SWEDEHEART AND BIOADAPTOR RCT Trials

# PRIMARY ENDPOINT: TLF from 6 months to 2 Years

## Sustained Reduction with Bioadaptor compared to DES




IPD: Individual patient data. Log-rank p of Kaplan Meier analysis. As treated population analysis.

# IPD Pooled Analysis of INFINITY SWEDEHEART AND BIOADAPTOR RCT Trials

**PRIMARY ENDPOINT:**
**TARGET LESION FAILURE FROM 6 TO 24 MONTHS**

# 54%

relative reduction in primary endpoint comparing bioadaptor to DES

**2,764**
patients randomized

**0.46**
hazard ratio (95% CI 0.26–0.80)

**p = 0.006**
for superiority

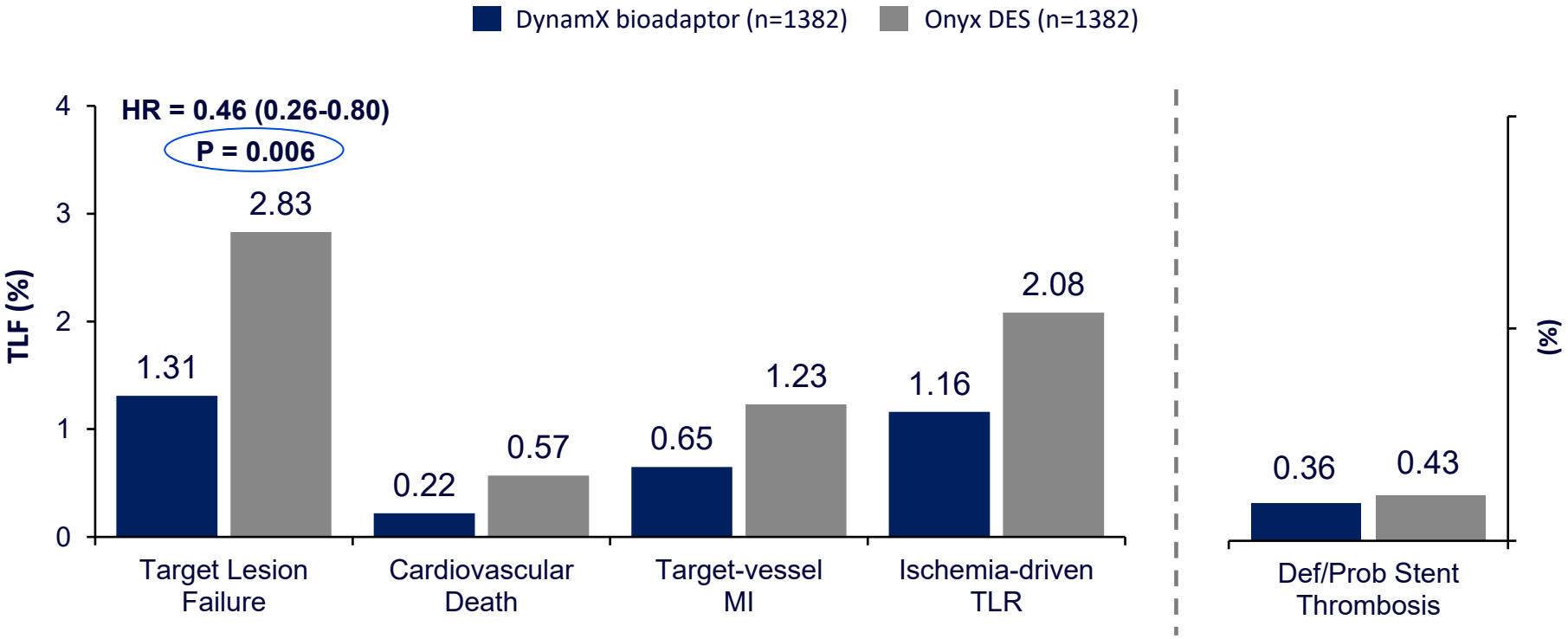
**STATISTICAL SIGNIFICANCE MET**



IPD: Individual patient data. CI: confidence interval; HR = hazard ratio; P value for Cox Proportional Hazard

# Hierarchical Components of TLF, and Stent Thrombosis

## Reduction in TLF driven by All Components from 6 months to 2 years



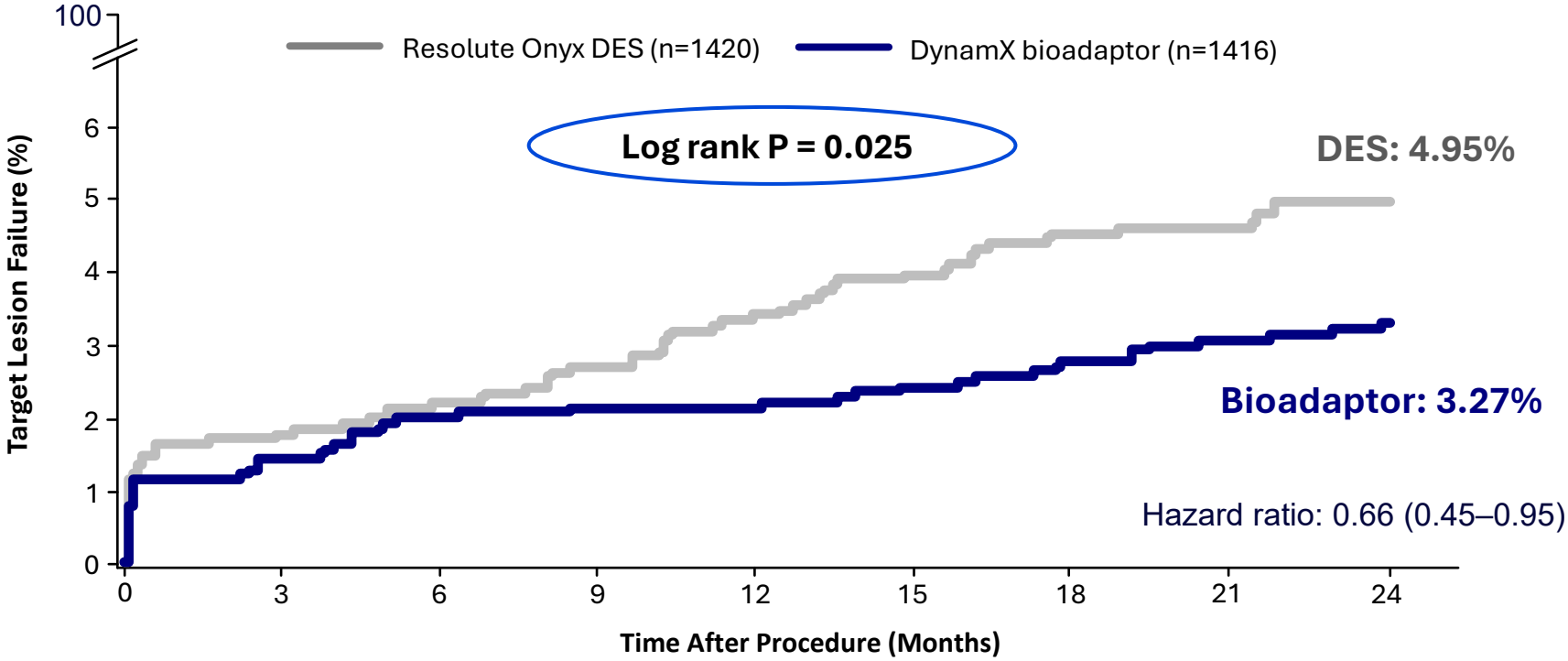



CI: confidence interval; HR: hazard ratio. As treated population analysis.

IPD Pooled Analysis of **INFINITY SWEDEHEART AND BIOADAPTOR RCT Trials**

# Target Lesion Failure Through 2 years:

## Significant Treatment Benefit with Bioadaptor compared to DES

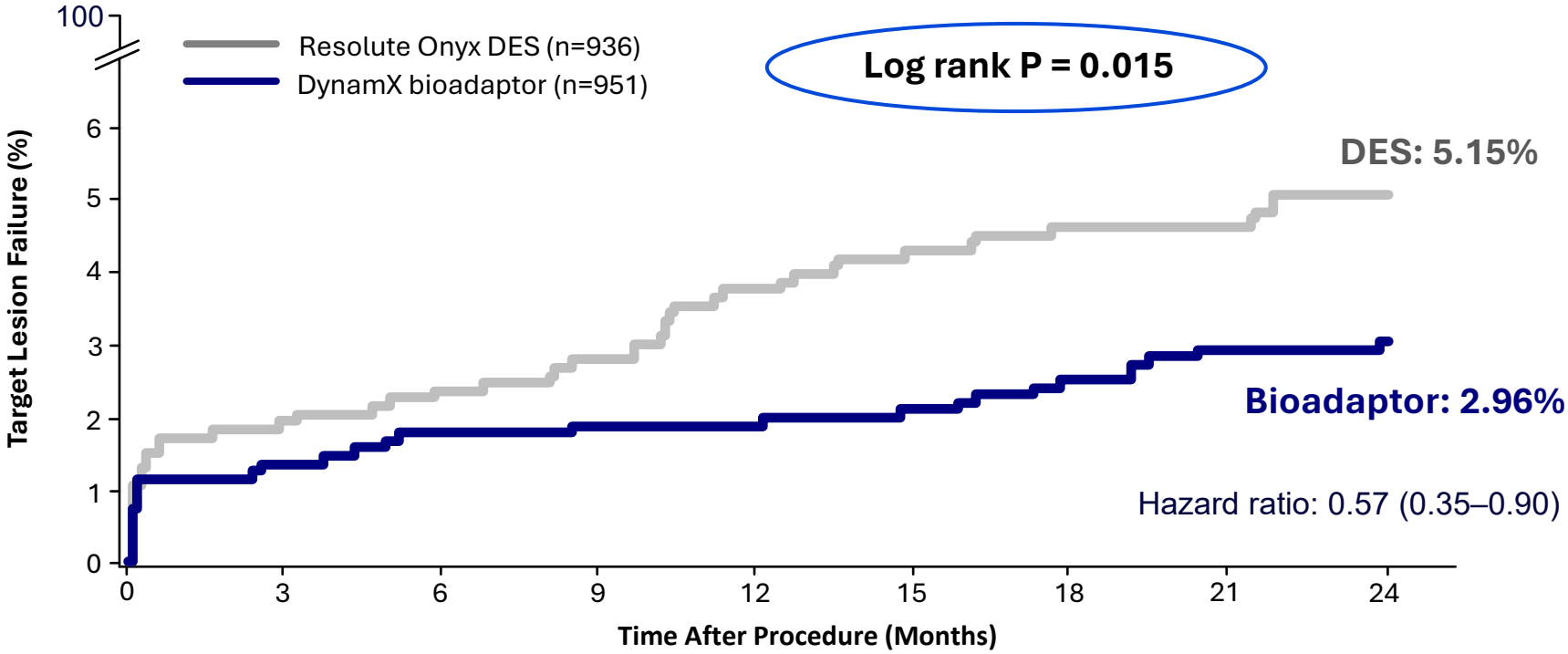



IPD: Individual patient data. Log-rank p of Kaplan Meier analysis.

IPD Pooled Analysis of **INFINITY SWEDEHEART AND BIOADAPTOR RCT Trials**

# Outcomes in ACS Patients:

## Substantial Benefit through 2 years with Bioadaptor compared to DES

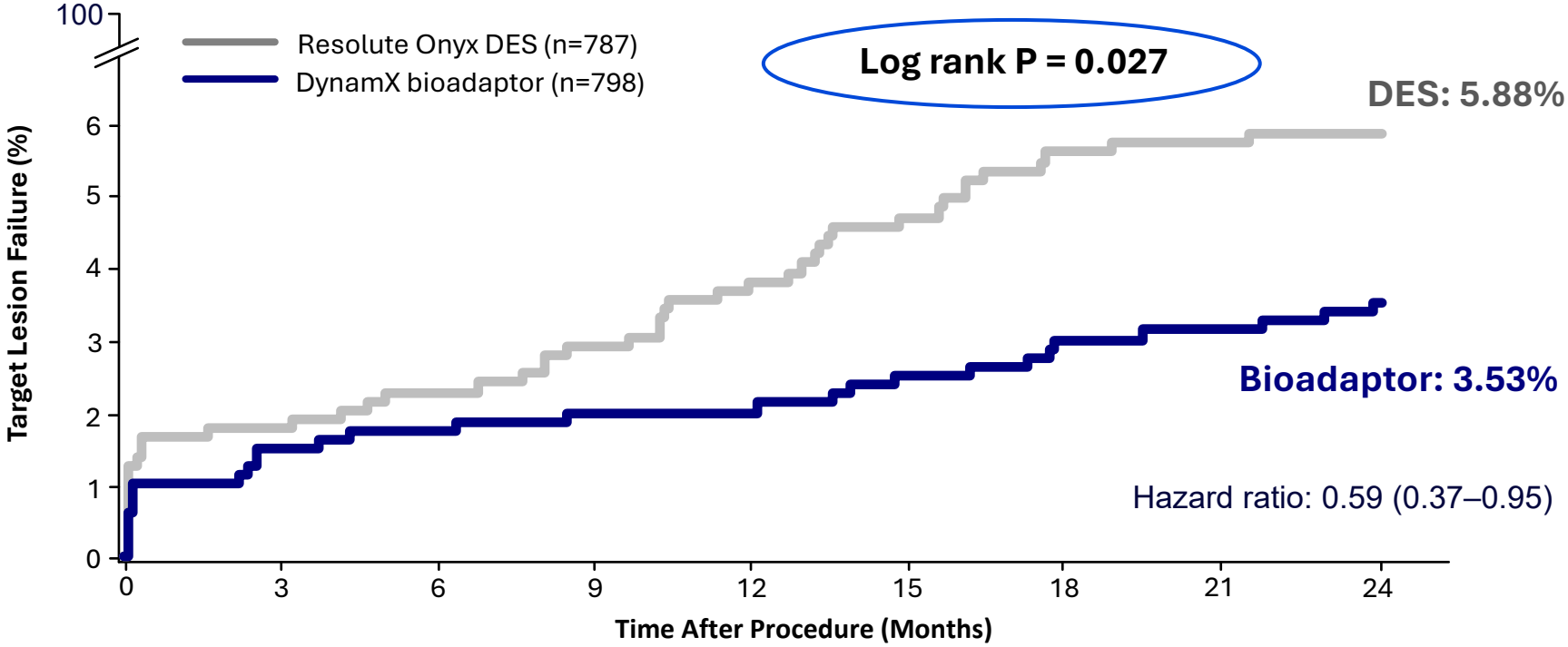



IPD: Individual patient data. Log-rank p of Kaplan Meier analysis.

IPD Pooled Analysis of **INFINITY SWEDEHEART AND BIOADAPTOR RCT Trials**

# Outcomes in LAD Lesions:

## Substantial Benefit through 2 years with Bioadaptor compared to DES



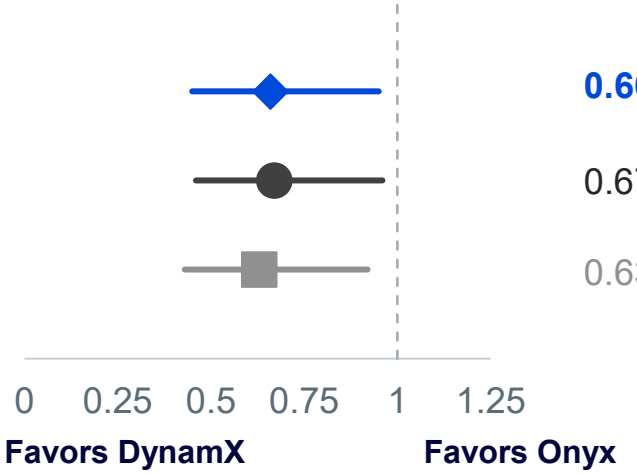

IPD: Individual patient data. Log-rank p of Kaplan Meier analysis.

IPD Pooled Analysis of INFINITY SWEDEHEART AND BIOADAPTOR RCT Trials

# Consistent Treatment Benefit with Bioadaptor Across Analysis Populations

## Target Lesion Failure through 2 years

| Population | DynamX | Onyx | HR (95% CI) | p-value |
|---|---|---|---|---|
| **AT** N = 1,416 / 1,420 | **3.27%** | **4.95%** | **0.66 (0.45–0.95)** | **0.026** |
| ITT N = 1,424 / 1,420 | 3.32% | 4.95% | 0.67 (0.46–0.96) | 0.031 |
| PP N = 1,373 / 1,390 | 3.15% | 4.98% | 0.63 (0.43–0.92) | 0.016 |




**33–37% lower TLF with bioadaptor compared to DES across analysis populations**

ITT, Intention to treat population: all randomized patients in the pooled trials included in the analysis
AT, As treated population: all randomized patients in the pooled trials included, analyzed based on the device treated
PP, per protocol population: patients with major protocol deviations including ISR, CTO, LM are excluded from the analysis per study protocol

# Conclusions

In the first individual patient data pooled analysis of INFINITY SWEDEHEART R-RCT AND BIOADAPTOR RCT randomized clinical trials,

- **From 6 to 24 months, DynamX bioadaptor demonstrated 54% reduction in target lesion failure over Resolute Onyx DES (HR 0.46, 95% CI 0.26–0.80; p=0.006)**, demonstrating sustained clinical advantage after the early healing period, consistent with the bioadaptor's mechanism of restoring vessel function.

- **Through two years, bioadaptor significantly reduced target lesion failure (3.27% vs. 4.95%, p=0.026), with greater treatment benefit observed in clinically important ACS and LAD populations** which are at elevated risk of recurrent ischemic events.

KEY TAKEAWAY

**Pooled analysis from bioadaptor trials provides the continued randomized evidence to date supporting restoration of vessel function as a novel therapeutic strategy for improving long-term outcomes after PCI.**