Bioadaptor vs Contemporary DES Long Term Clinical Studies

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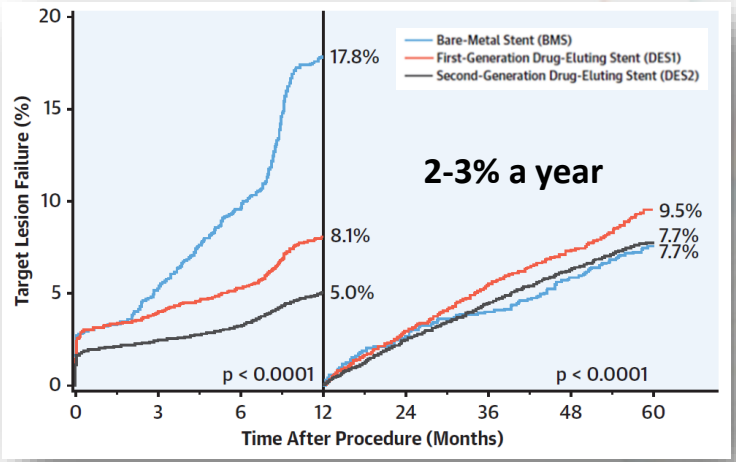
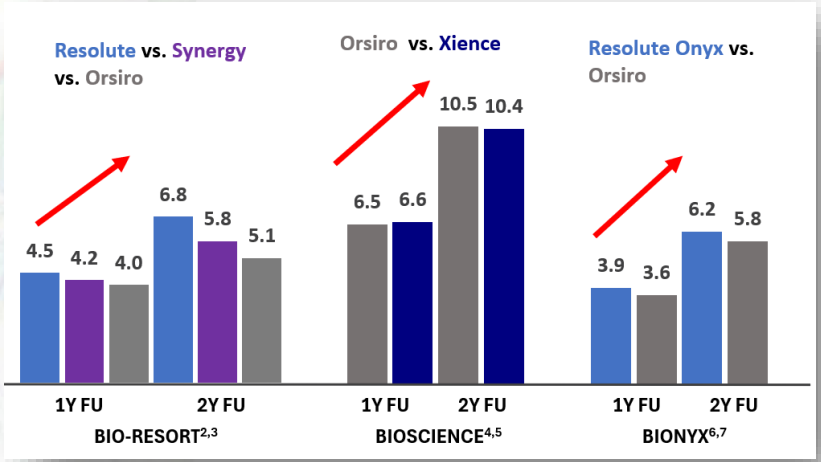
Stent Related Adverse Events Increase 2-3% Each Year After PCI

- Stent related adverse events continue to accrue after the first year at a non-plateauing rate of 2-3%[1]
- No device intervention to date has shown superiority vs. DES

Non-Plateauing Adverse Events Post 1-Year[1]

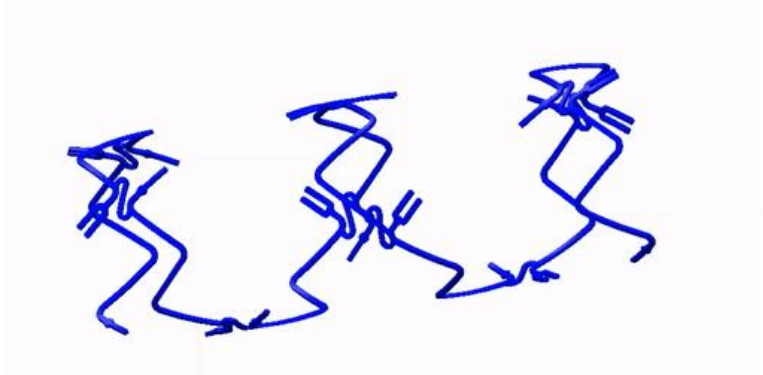


1 and 2-year TLF Rates With Contemporary DES[2-7]



1. Madhavan MV et al. *J Am Coll Cardiol* 2020;75:590-604
2. von Birgelen C et al The Lancet. 2016 Nov 26;388(10060):2607-17.
3. Buiten A et al JACC: Cardiovasc Interv., 2019. Vol. 12, No. 17.
4. Pilgrim T, et al. The Lancet. 2014 Dec 13;384(9960):2111-22.
5. Zbinden R et al. JAHA 2016 Mar 15;5(3):e003255.
6. von Birgelen C et al. The Lancet. 2018 Oct 6;392(10154):1235-45.
7. Ploumen EH et al. Circ J. 2021 Oct 25; 85(11):1983-1990

Bioadaptor is a novel coronary implant (DynamX®, Elixir Medical, California) designed to restore vessel function and address device related adverse events[1,2].

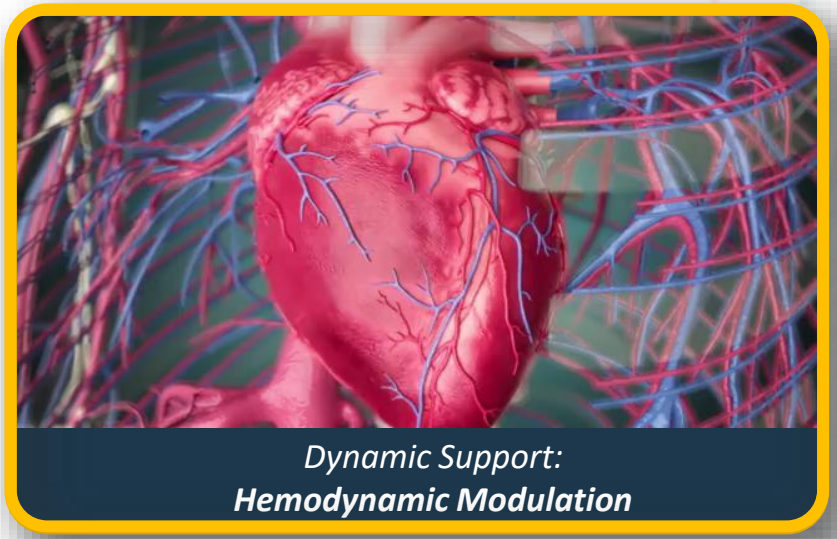


- *Three independent helical strands (CoCr 71µm) are temporary connected by bioresorbable polymer coating eluting antiproliferative agent*

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

Study Device: Bioadaptor Mechanism of Action

After 6 months, the three helical strands unlock, separate and provide dynamic support to the diseased vessel, enabling hemodynamic modulation and restoration of vessel function[1,2,3]



Bioadaptor demonstrated:

- 7-8% pulsatile lumen area changes (pulsatility)
- Restoration of device/RV compliance mismatch
- Adaptive device and vessel response (Glagov)
- Reduction in plaque progression

1. Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. The Lancet eClinicalMedicine. 2023;65:102304.
2. Verheye S et al. Twelve-month clinical and imaging outcomes of the uncaging coronary DynamX bioadaptor system, *EuroIntervention 2020*, *16*(12);E974
3. Kwak BR et al. Biomechanical factors in atherosclerosis: mechanisms and clinical implications. European heart journal. 2014 Nov 14;35(43):3013-20.

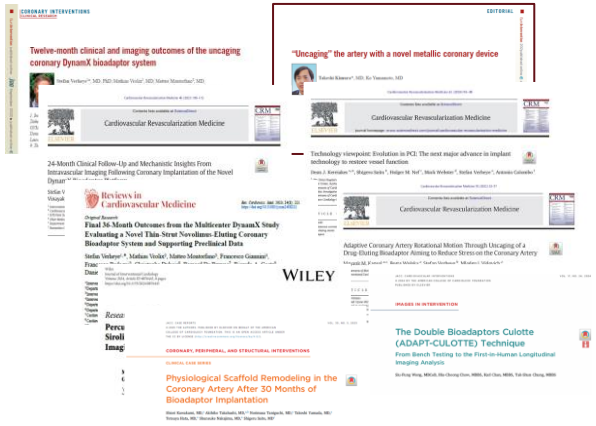
Bioadaptor Clinical Studies and Evidence Overview

Cohort Studies / Case Reports

Mechanistic and NZ Study (N=50; N=44): Intravascular imaging at 6-12 months; up to 3-year clinical follow-up

ADAPT-CULOTTE: Novel technique for treatment of bifurcations with bioadaptor; long term follow-up

30-Months Imaging Follow-up: Demonstrates long term adaptive remodeling in subjects from BIOADAPTOR-RCT



2 Large Randomized Clinical Trials

BIOADAPTOR-RCT (N=445)

- 1:1 compared to Resolute Onyx
- Non-inferiority
- **Powered intravascular imaging endpoints**
- 5-year clinical follow-up

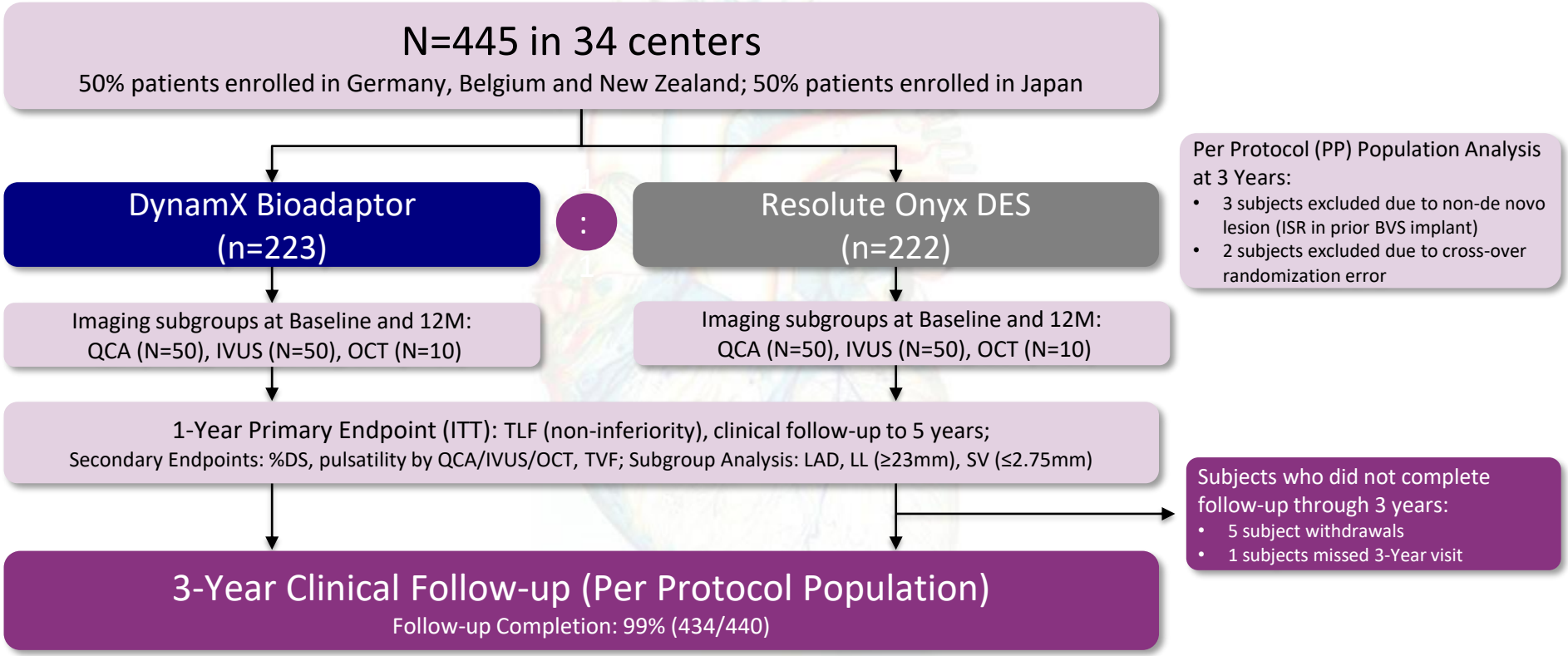
2Y FU: @2025 JACC Interv.

INFINITY-SWEDEHEART (N=2,400)

- 1:1 compared to Onyx DES
- Non-inferiority
- **Powered for Superiority**
- 5-year clinical follow-up

1Y FU: @2024 The Lancet

BIOADAPTOR RCT - Trial Design

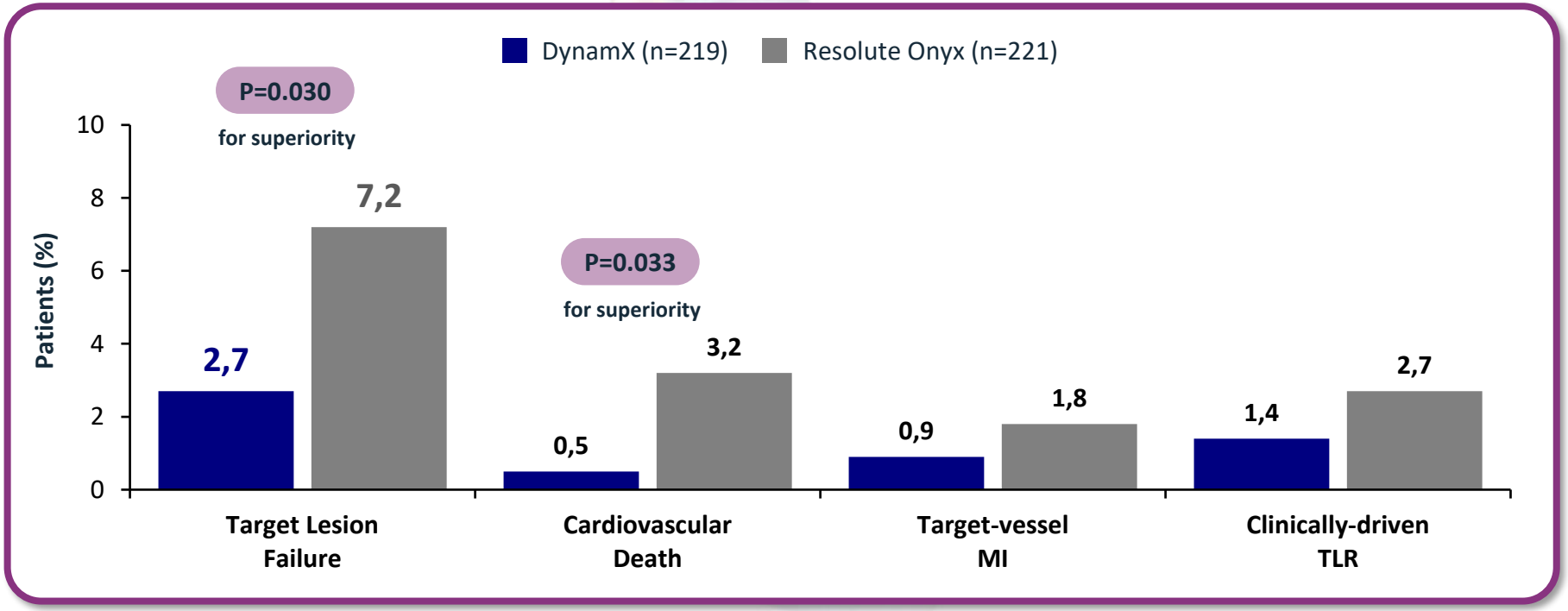


Patient Baseline Characteristics

Baseline Characteristics	DynamX (N=223)	**Resolute Onyx** (N=222)
Age, years	67.1 ± 10.3	66.2 ± 10.1
Female	49 (22.0%)	49 (22.1%)
Hypertension	**161 (73.2%)**	**156 (70.9%)**
Dyslipidemia	**178 (80.9%)**	**177 (80.5%)**
Diabetes Mellitus	59 (26.5%)	75 (33.8%)
Prior MI	42 (19.1%)	48 (21.8%)
Prior PCI/CABG	90 (40.9%)	84 (38.2%)
Stable Angina	144 (64.6%)	150 (67.6%)
ACS	79 (35.4%)	72 (32.4%)

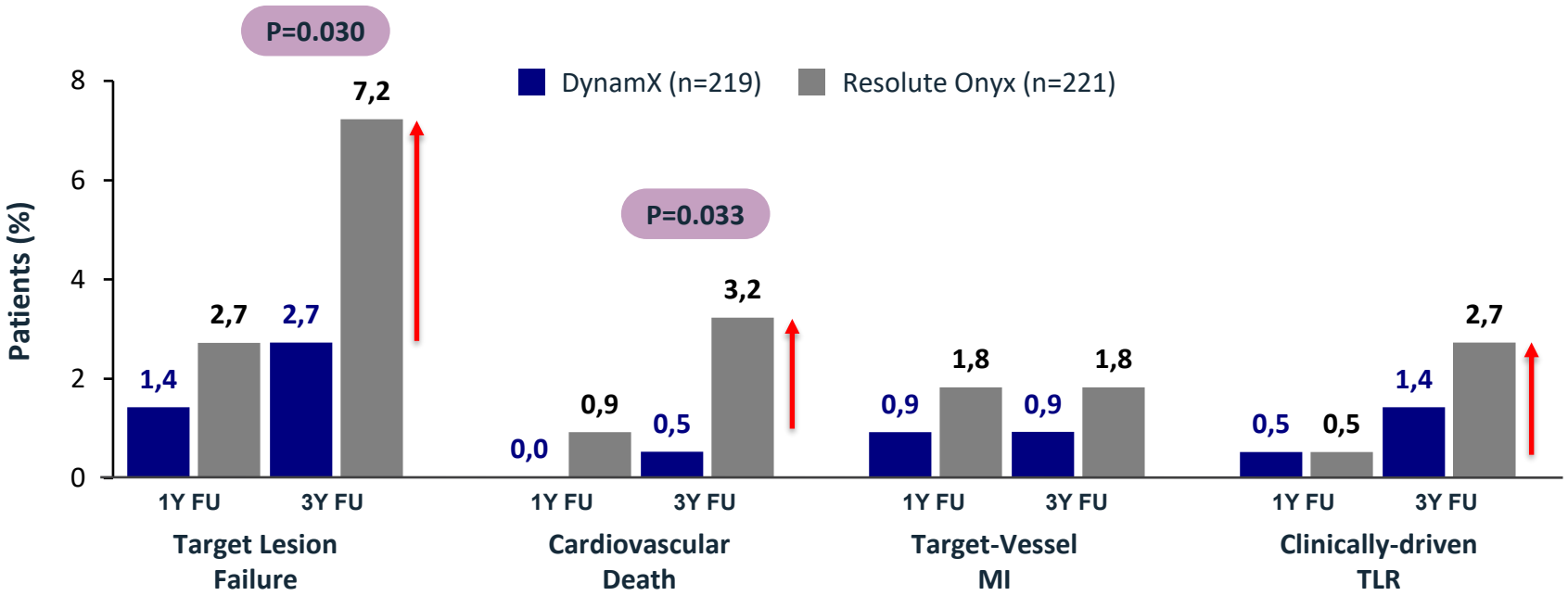
Anatomical Characteristics	DynamX (N=223)	**Resolute Onyx** (N=222)
Target lesion vessel		
LAD	**114 (50.4%)**	**104 (45.2%)**
LCX	35 (15.5%)	66 (28.7%)
RCA	77 (34.1%)	60 (26.1%)
Ostial lesion	**13 (5.8%)**	**8 (3.5%)**
Bifurcation lesion	**50 (22.1%)**	**55 (23.9%)**
Moderate/severe calcification	**43 (19.0%)**	**47 (20.4%)**
Moderate/severe tortuosity	**53 (23.5%)**	**46 (20.0%)**
ACC/AHA lesion B2/C	51 (22.6%)	49 (21.3%)
Target lesion length, mm	15.8 ± 6.0	16.2 ± 6.0

Significant Reduction in TLF with Bioadaptor at 3 Year Follow-up Compared to DES



*Chi-square test for p values. Per protocol analysis. Events adjudicated per the ARC-2 Criteria. Percentages indicate patients who had an event through the 1095±100 days follow up window.

Low TLF with Bioadaptor Sustained at 3Y Follow-up, while a Non-plateauing Increase in TLF, CVD and ID-TLR with DES



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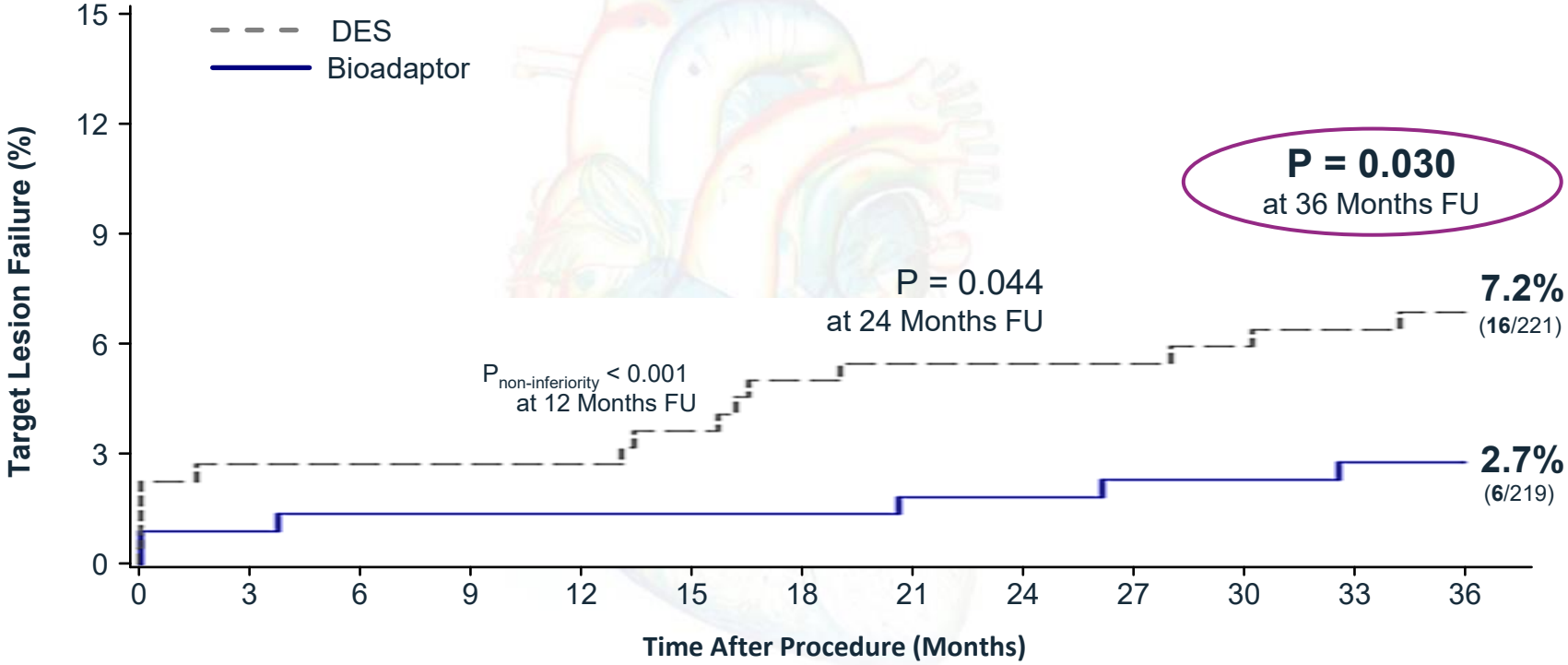
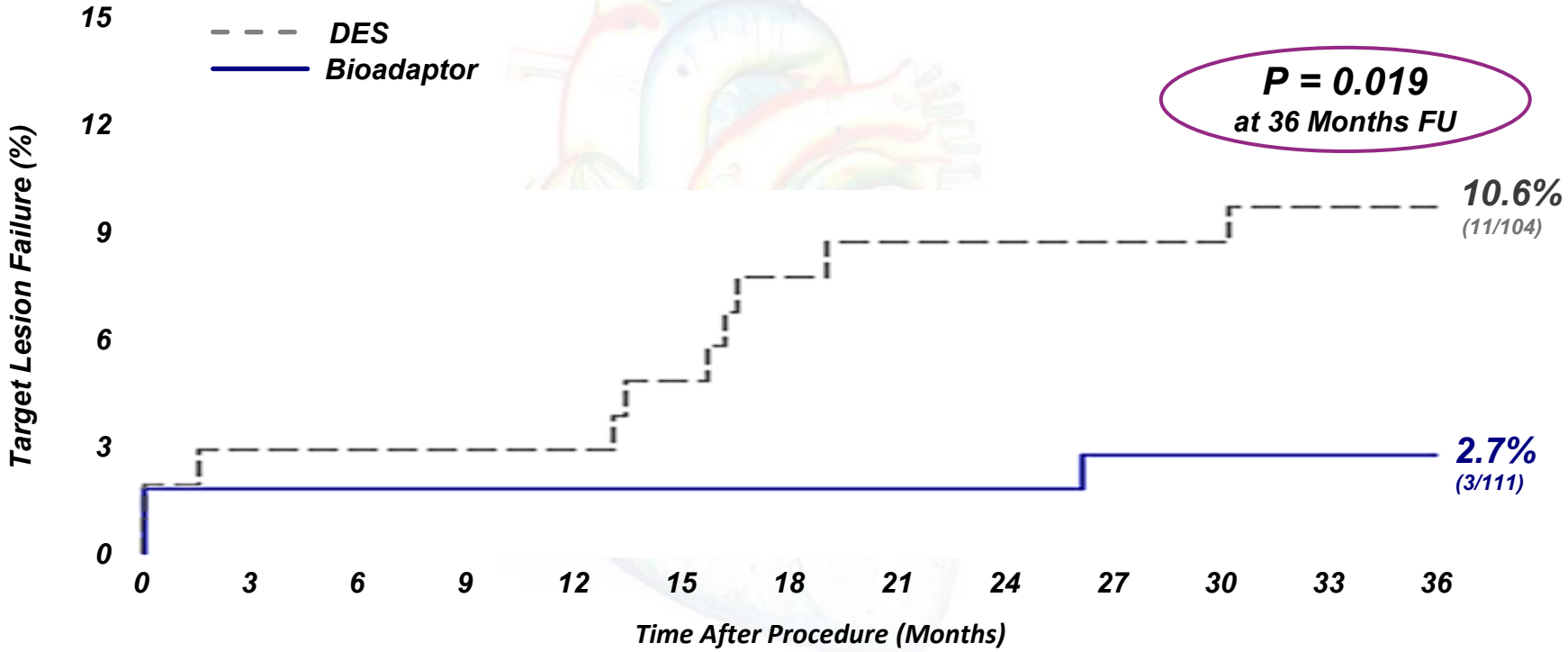
Sustained Treatment Benefit with Bioadaptor From 6 Months to 3 Years



Substantial Treatment Benefit Demonstrated in LAD Lesions at 3 Years



BIOADAPTOR RCT Conclusions

- Three-year clinical follow up results from the BIOADAPTOR-RCT shows:
  - **Sustained significantly lower TLF rates (2.7% versus 7.2%, p=0.030)** with bioadaptor compared to DES
  - **Significantly lower rate of Cardiac Death (0.5% versus 3.2%, p=0.033) compared to DES, and lower rate of clinically driven revascularizations**
  - **Substantial clinical benefit with bioadaptor in LAD lesions (TLF: 2.7% versus 10.6%, p=0.019),** consistent with bioadaptor mechanism of action of restoring vessel function
- Evidence from the BIOADAPTOR-RCT demonstrate **sustained significant reduction of device-related events with bioadaptor compared to DES**, confirming the durability of treatment benefit from 6 months and through long-term follow-up

INFINITY-SWEDEHEART RCT
Objectives and Powered Endpoints:

Objectives

- To evaluate the safety and efficacy of the bioadaptor implant compared to the DES in a large multi-center RCT
- To evaluate potential superior clinical benefit after 6 months on reducing event rates compared with a contemporary DES in a representative patient population, including:
    - High risk patients with Acute Coronary Syndrome (ACS) and complex lesion subsets

Powered Endpoints

Primary endpoint (non-inferiority):
Target lesions failure (TLF) at 1 year

Powered Secondary endpoints (superiority):
Landmark analysis of:

1. TLF from 6 months to End of Follow-up
2. TVF from 6 months to End of Follow-up
3. TLF in ACS from 6 months to End of Follow-up

Study Management and Site Enrollment

INFINITY-SWEDEHEART

UCR

- Study/Site Management, Data Mgmt., Statistics, CEC, DSMB

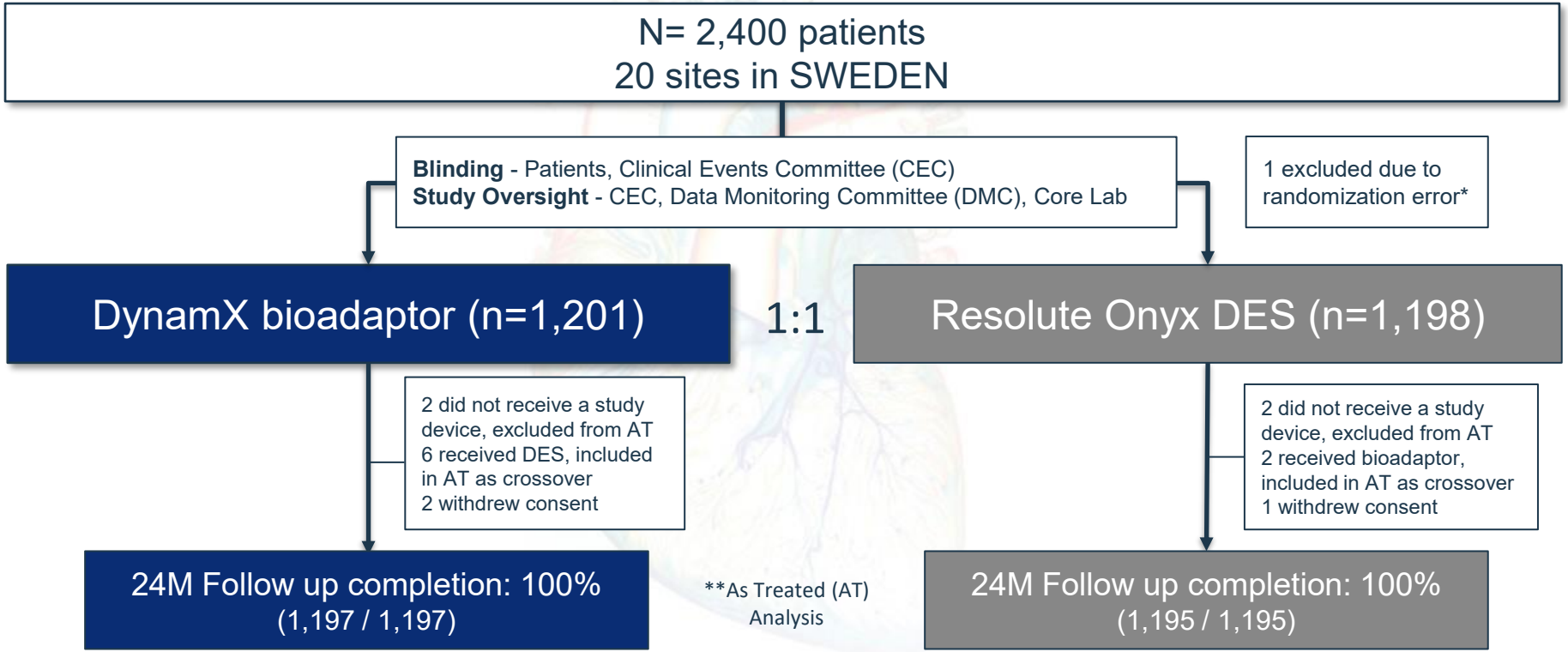
CERC European Cardiovascular Research Center

- Imaging Core Lab

PI	Hospital Name	# Enrolled
Jonas Andersson, MD, PhD	Umeå University Hospital	316
Stefan James, MD, PhD	Uppsala University Hospital	275
David Erlinge, MD, PhD	Skåne University Hospital, Lund	221
Ole Fröbert, MD, PhD	Örebro University Hospital	215
Mattias Törnerud, MD	Danderyd Hospital, Stockholm	198
Mehmet Hamid, MD	Mälarsjukhuset, Eskilstuna	170
Thomas Kellerth, MD	Central Hospital, Karlstad	146
Per Grimfjärd, MD, PhD	Västerås hospital,	133
Daniel Ohm, MD	Capio St Göran Hospital, Stockholm	107
Carl-David Dolata, MD	Helsingborg Hospital	84

PI	Hospital Name	# Enrolled
Sammy Zwackman, MD	Linköping University Hospital	81
Juliane Jurga, MD, PhD	Karolinska University Hospital, Huddinge	76
Martin Adielsson, MD	Halland Hospital, Halmstad	69
Patrik Alström, MD	Södersjukhuset, Stockholm	67
Elli Masoe, MD	Sundsvall Hospital	57
Juliane Jurga, MD, PhD	Karolinska University Hospital, Solna	49
Anders Ulvenstam, MD, PhD	Östersund Hospital	48
Jonas Millgård, MD, PhD	Sunderby Hospital, Luleå	43
Maria Tafesse, MD	Blekinge Hospital, Karlskrona	29
Mats Birgander, MD, PhD	Skåne University Hospital, Malmö	15

24-M Follow up completion: 100%



Patient Baseline Characteristics

INFINITY-SWEDEHEART

Baseline Characteristics	DynamX (N=1,201)	Onyx (N=1,198)
Age, years	68.2 ± 9.7	68.1 ± 9.6
Female	290 (24.1%)	285 (23.8%)
Hypertension	722 (60.5%)	710 (59.9%)
Hyperlipidemia	544 (45.6%)	492 (41.5%)
Diabetes Mellitus	231 (19.3%)	198 (16.6%)
Prior MI	**144 (12.1%)**	**141 (11.9%)**
Prior PCI	**176 (14.7%)**	**165 (13.9%)**
Prior CABG	**12 (1.0%)**	**8 (0.7%)**
Current Smoking	164 (14.2%)	187 (16.1%)

Clinical Presentation	DynamX (N=1,201)	Onyx (N=1,198)
Acute Coronary Syndrome (ACS)	**925 (77.0%)**	**913 (76.2%)**
STEMI	282 (23.5%)	317 (26.5%)
NSTEMI	458 (38.1%)	437 (36.5%)
Unstable Angina	185 (15.4%)	159 (13.3%)
Chronic Coronary Syndrome (CCS)	**276 (23.0%)**	**285 (23.8%)**

Baseline Lesion Characteristics

Baseline Characteristics	DynamX (N=1,201) (L=1,419)	Onyx (N=1,198) (L=1,431)
Target Lesion Location		
LAD	726 (51.2%)	728 (50.9%)
RCA	365 (25.7%)	384 (26.8%)
LCx	327 (23.0%)	318 (22.2%)
Lesion Classification		
A	160 (11.4%)	170 (11.9%)
B1	639 (45.4%)	666 (46.7%)
B2/C	609 (43.3%)	590 (41.4%)
Bifurcation	165 (11.8%)	161 (11.3%)
Calcified lesion*	239 (16.9%)	204 (14.3%)
Tortuous lesion*	109 (7.7%)	105 (7.3%)

Baseline Characteristics	DynamX (L=1,419)	Onyx (L=1,431)
Number of target lesions per subject, n (%)		
1	1009 (84.1%)	987 (82.6%)
≥2	191 (15.9%)	208 (17.4%)
RVD, mm	3.2 ± 0.5	3.2 ± 0.5
Lesion Length, mm	**24.4 ± 9.1**	**24.7 ± 9.4**
%DS, pre-procedure	**87.0 ± 12.1**	**87.3 ± 11.7**
%DS, post-procedure	**1.0 ± 5.4**	**0.6 ± 3.5**
Successful pre-dilation	1413 (99.7%)	1429 (99.9%)
Post-dilation	819 (58.5%)	754 (52.9%)

Target Lesion Failure at 12 Months

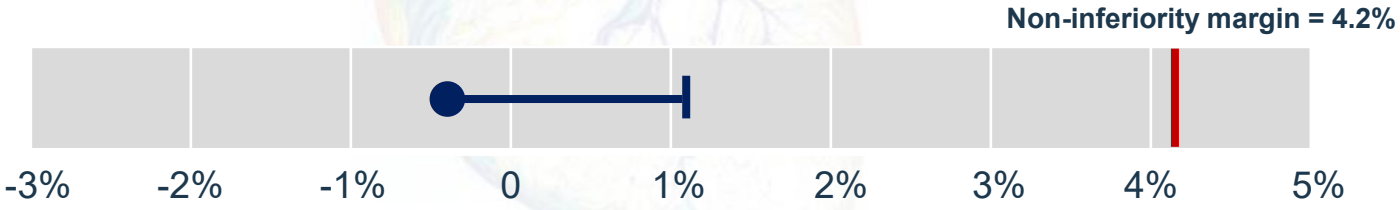
Primary Non-Inferiority Endpoint Met

DynamX
(N=1,189)
2.35%

p-value <0.0001

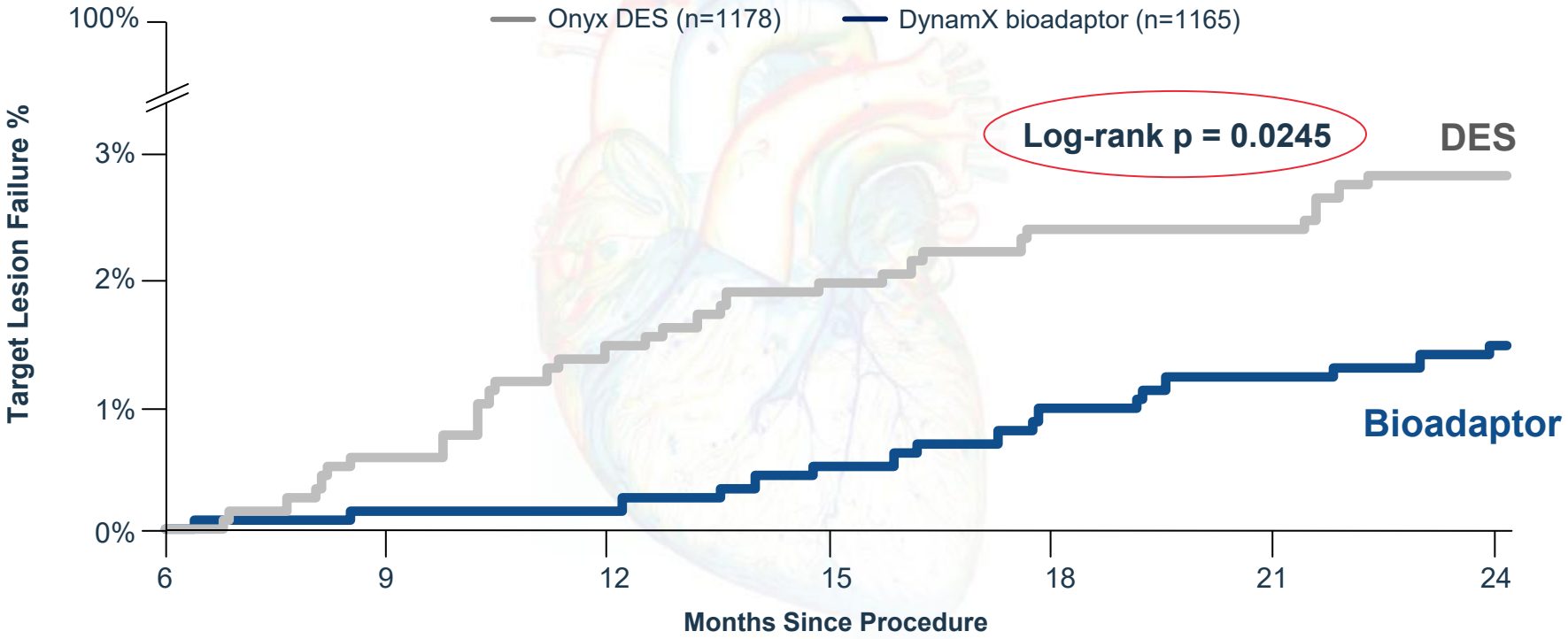
Difference: - 0.41%
[-1.94%, 1.11%]

Onyx DES
(N=1,192)
2.77%



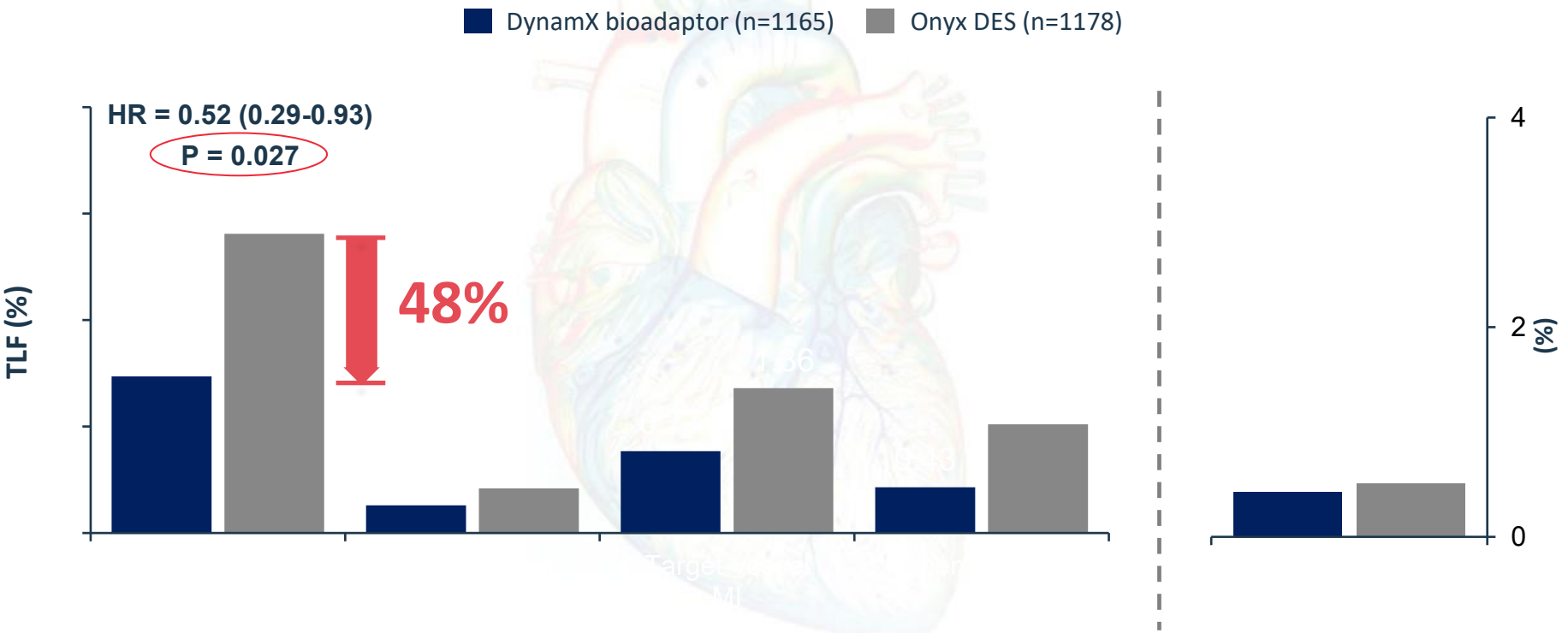
Powered Superiority Endpoint-1: TLF from 6M to 2 Years

Significant Reduction in TLF and Sustained Treatment Benefit After 6 Months



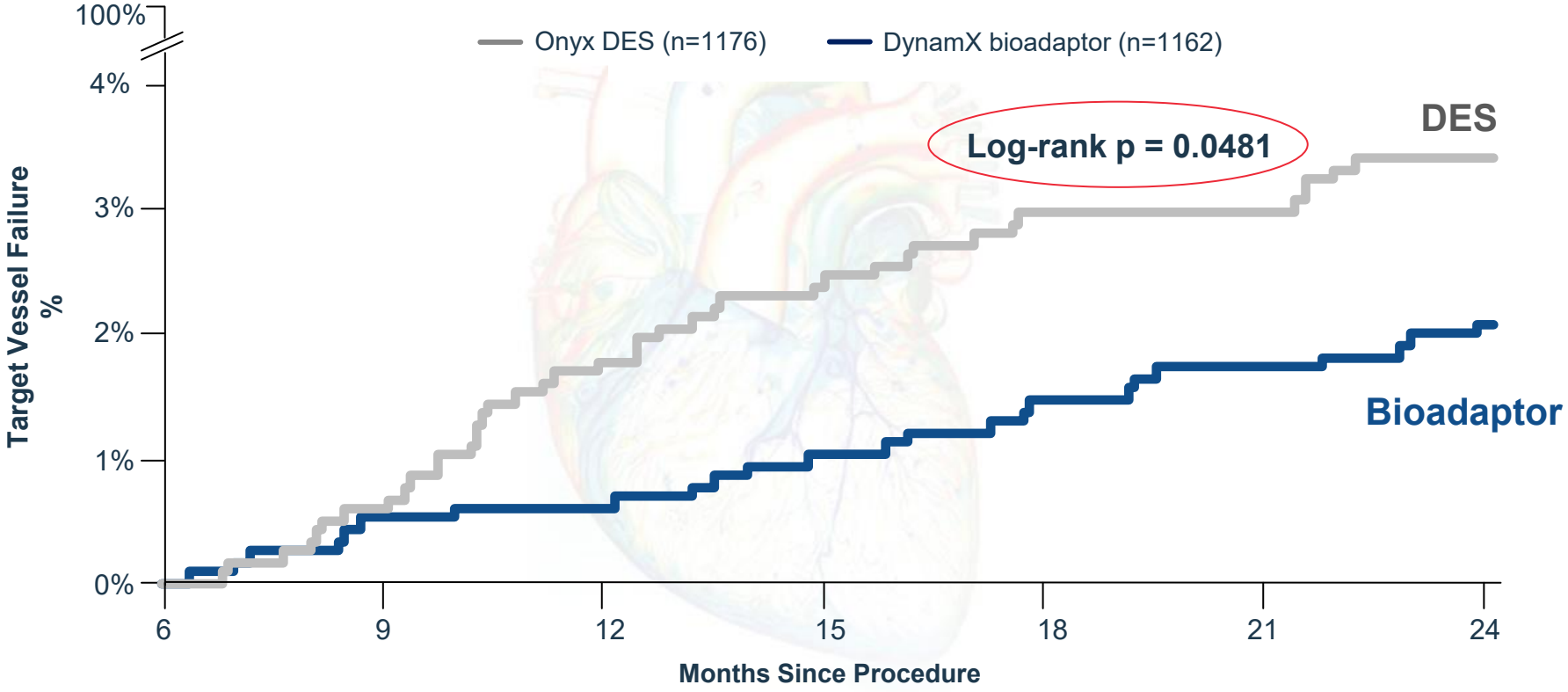
Hierarchical Components of TLF, and Stent Thrombosis

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



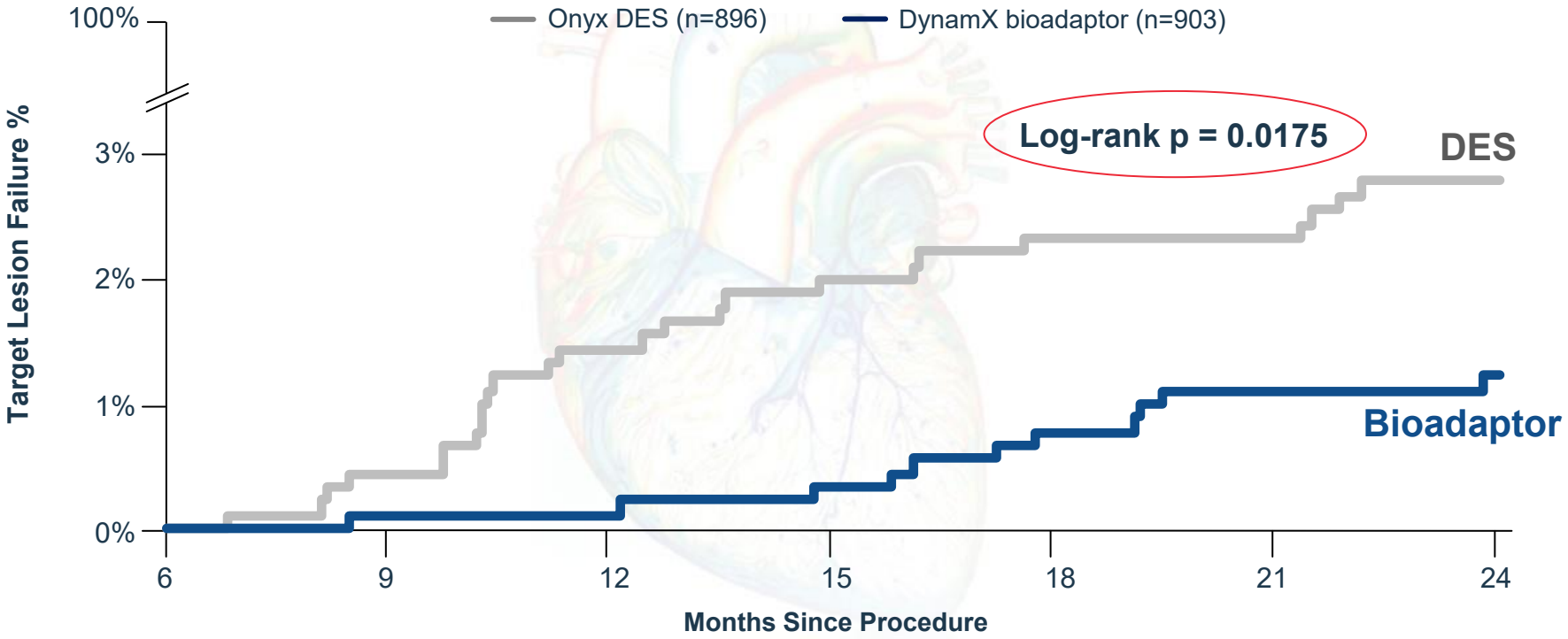
Powered Superiority Endpoint-2: TVF from 6M to 2 Years

Significant Reduction in TVF and Sustained Treatment Benefit After 6 Months



Powered Superiority Endpoint-3: TLF in ACS from 6M to 2 Years

Significant Reduction in TLF and Sustained Treatment Benefit After 6 Months



Conclusions

- The INFINITY-SWEDEHEART is a large-scale, multicenter RCT comparing bioadaptor implant versus DES in a representative, clinically complex ischemic patient population.
  - **48% reduction in TLF rate (HR: 0.52 [0.29-0.93], p=0.027) after 6 months through 2 years in favor of bioadaptor,** in prespecified powered landmark analysis.
  - **Significant reduction in TVF (p=0.0481) after 6 months through 2 years,** in prespecified powered landmark analysis.
  - **Substantial clinical benefit for the high-risk subgroup of patients with ACS (p=0.0175) after 6 months through 2 years**, in prespecified powered landmark analysis.
- Bioadaptor is the first technology to demonstrate through its novel mechanism of action a significant reduction in device-related events with sustained long-term clinical benefit, marking a major advancement in coronary interventions.