



## TRANSFORMATION. UNLOCKED.

ElixirMedical.com

Elixir Medical Corporation 920 N McCarthy Blvd. Milpitas, CA 95035 www.elixirmedical.com

For OUS distribution only



PMN 1626 Rev D



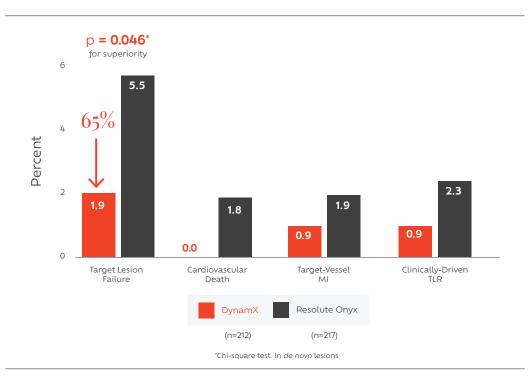
# EVOLVING PCI BY FOLLOWING NATURE'S BLUEPRINT

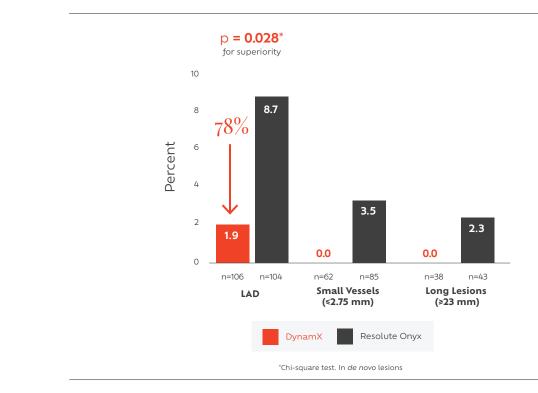
LETTING VESSELS FUNCTION AS INTENDED

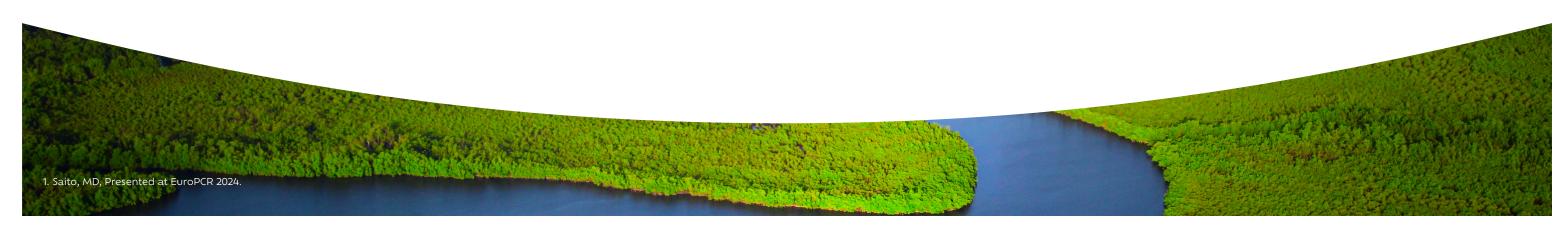
 $\mathcal{N}$ 

BREAKTHROUGH RESULTS IN CAD TREATMENT SUSTAINED CLINICAL BENEFIT POWERED BY THE NOVEL MECHANISM OF ACTION

### Significant TLF reduction at 2-years versus **Resolute Onyx DES'**







## SIGNIFICANCE WHERE IT MATTERS MOST **RESTORING VESSEL VIABILITY LEADS** TO OUTSTANDING CLINICAL BENEFITS

Significant TLF reduction at 2-years in LAD lesions versus Resolute Onyx DES<sup>1</sup>

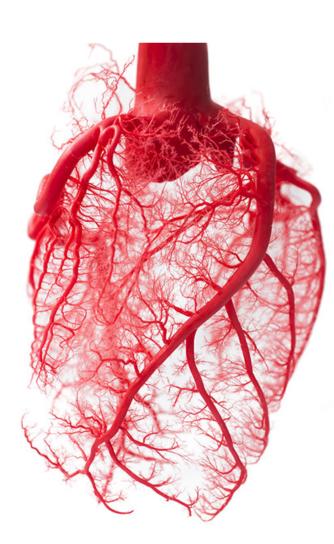
THE UNCOMFORTABLE TRUTH OF LIFE-LONG STENTING PERMANENT CAGING OF VESSELS LEAVES PATIENTS AT RISK OF LATE EVENTS<sup>1</sup>

Drug-eluting stents have shown

### lifetime risk of stent-related Major Adverse Cardiac Events<sup>1</sup>

Reinforced by findings showing ongoing risk of about 2% a year at least through 5-year follow-up with no sign of plateau, irrespective of stent type<sup>2</sup>

Caging natural vascular motion and physiology can contribute to stent fractures, restenosis, myocardial infarctions, and cardiac death<sup>3</sup>



The heart is a dynamic, pulsating, living organ, arteries are no different. They do what they need to adapt to the heart's changing demands and sustain life.

> Three-dimensional vasomotion To meet the demands of every heartbeat

**Pulsatility** To help maintain blood flow and pressure<sup>4</sup>

Positive adaptive remodeling To mitigate against disease progression<sup>5</sup>

1. Kufner S, Joner M, Thannheimer A, et al. Ten-Year Clinical Outcomes From a Trial of Three Limus-Eluting Stents With Different Polymer Coatings in Patients With Coronary Artery Disease - Results From the ISAR-TEST 4 Randomized Trial. Circulation. 2019;139:325-333 2. Madhavan MV, Kirtane AJ, Redfors B, et al. Stent-Related Adverse Events >1 Year After Percutaneous. Coronary Intervention. J Am Coll Cardiol 2020; 75:590–604. 3: Borovac JA, D'Amario D, Niccoli G. Neoatherosclerosis and Late Thrombosis After Percutaneous Coronal Translational Cardiology and Comparative Medicine from Bench to Bedside. Yale J Biol Med 2017;90:4





# THE ESSENTIALS OF TRIPLE STAGE THERAPY



First step in any intervention is restoring blood flow. And, with DynamX<sup>®</sup> you will establish maximum flow lumen and restore blood flow without compromising the ability for the vessel to naturally heal.1



After 6 months the magic happens. DynamX unlocks itself, releasing the vessel while maintaining the established lumen flow.1



Finally, the vessel returns back to its natural physiology, motion and function. The final phase provides continuing adaptive dynamic support to restore vessel hemodynamic modulation through restoration of pulsatility and adaptive blood flow volume and has shown evidence of plaque stabilization and regression in the lesion.<sup>1</sup>

Opening horizons in coronary interventions and early treatments for long-term outcomes. Welcome to the new natural state where technology works with the vessel, and not against it.

# <sup>1</sup>RESTORE FLOW

# <sup>3</sup>RETURN FUNCTION

## THE DYNAMX BIOADAPTOR: LEAVING THE RIGHT THING BEHIND

### 

Interlocked CoCr helical strands, fused by PLLA basecoat provide radial strength

Maximum flow lumen established and blood flow restored

### <sup>2</sup>UNLOCK AND SEPARATE

3-month resorption of polymer top coat and release of 'limus drug enables optimal healing and thin neointima formation

Controlled resorption of basecoat polymer over 6 months enables the helical strands to unlock and separate while maintaining the established blood flow lumen, and growth of smooth muscle cells around the struts

### <sup>3</sup>ADAPTIVE DYNAMIC SUPPORT

Separated helical strands provide continuing adaptive dynamic support to restore vessel hemodynamic modulation through restoration of pulsatility and adaptive blood flow volume

Thin struts and low metal volume make it possible for new smooth muscle cells to contract and achieve pulsatility and vasomotion



<sup>l</sup>OCKED

Three thin helical strands



Timed drug release and polymer resorption

**HEMODYNAMIC** MODULATION

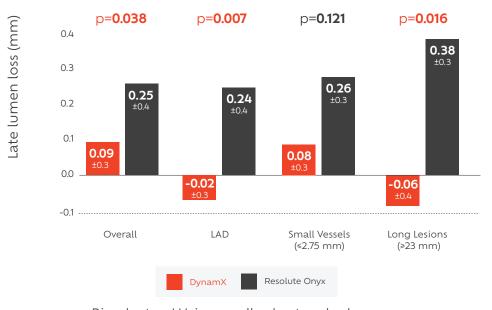
> Unique uncaging elements

NE



DYNAMX UNLOCKS TO RELEASE THE VESSEL *RESTORING POSITIVE ADAPTIVE REMODELING AND MAINTAINING ESTABLISHED LUMEN PATENCY* 

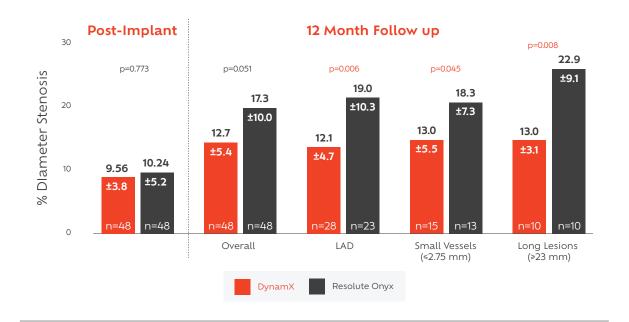
Significantly lower late lumen loss, especially in vessels and lesions at high risk of restenosis'

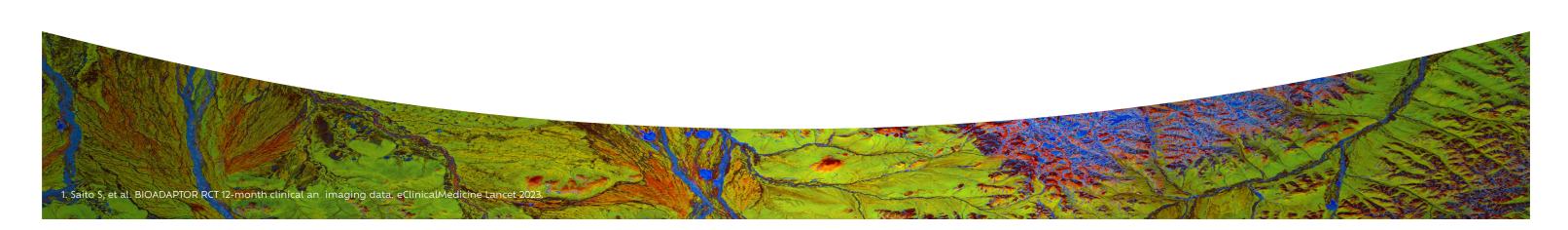


Bioadaptor: LLL in overall cohort and subgroups

# MAINTAINING *Flowlumen*

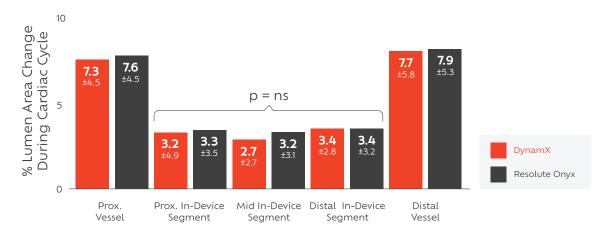
### Superior flow lumen maintained across vessel types<sup>1</sup>



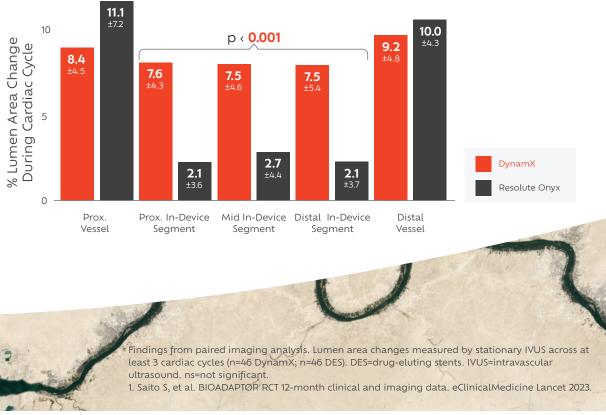


## Immediately post-procedure:

Pulsatility is constrained in both DynamX bioadaptor and DES (p=ns)<sup>1</sup>

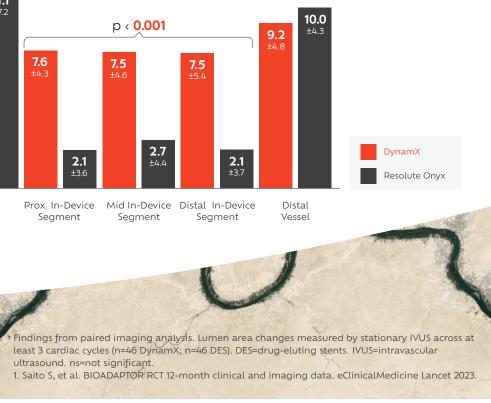


DynamX bioadaptor is unlocked to establish pulsatility and lumen area changes with every heartbeat vs DES<sup>1</sup>



# LIFE DOESN'T STAND STILL. AND NOR SHOULD VESSELS. **ONLY DYNAMX RESTORES** HEMODYNAMIC MODULATION AND PULSATILITY

J٢



### At 12-months:

THE DYNAMX FLOW EFFECT CHANGE IN BLOOD FLOW VOLUME WITH EVERY HEARTBEAT

Pulsatility

7.5%

increase in lumen area with every heartbeat

> In-device % increase in lumen area: 2.7% (±2.7) post-procedure and 7.5% (±4.6) at 12 months for DynamX<sup>1</sup>

Blood Flow

increase in blood flow volume with every heartbeat

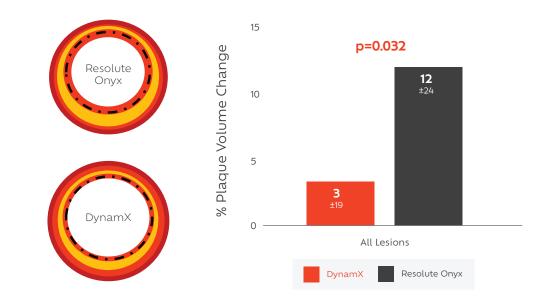
16.7%

Blood flow volume increase per heartbeat: 6.5% (±0.6) post-procedure and 16.7% (±1.3) at 12 months for DynamX<sup>1</sup>

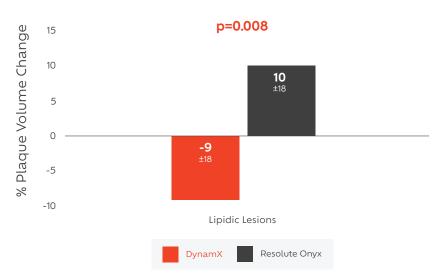


# WITH SUPPORT, THE VESSEL RETURNS TO ITS NATURAL STATE THEN SOMETHING EXTRAORDINARY HAPPENS

Plaque volume behind DynamX is stabilized, while increasing by 12% in the Resolute Onyx stent arm<sup>1</sup>



% plaque volume change at 12 months (IVUS)







## Plaque volume regression in lipid rich lesions with DynamX vs. an increase with DES<sup>1</sup>

An exploratory finding that points to a hypothesis of a synergistic effect between restoration of vessel motion and function and systemic use of lipid-lowering medications<sup>1</sup>