

**TherOx® SuperSaturated
Oxygen (SSO₂) Therapy**

ZOLL®



**The Next Frontier
in STEMI Care**



Designed to restore microvascular flow and reduce myocardial damage.

TherOx® SuperSaturated Oxygen (SSO₂) Therapy

Introducing the first FDA-approved, catheter-based therapy to safely and effectively reduce infarct size in randomized controlled trials.^{1,2}

SSO₂ treats ischemic myocardium by delivering localized hyperoxemic ($pO_2 = 760\text{-}1000$ mmHg) levels of oxygen to the heart, without impacting door-to-balloon time.

26%

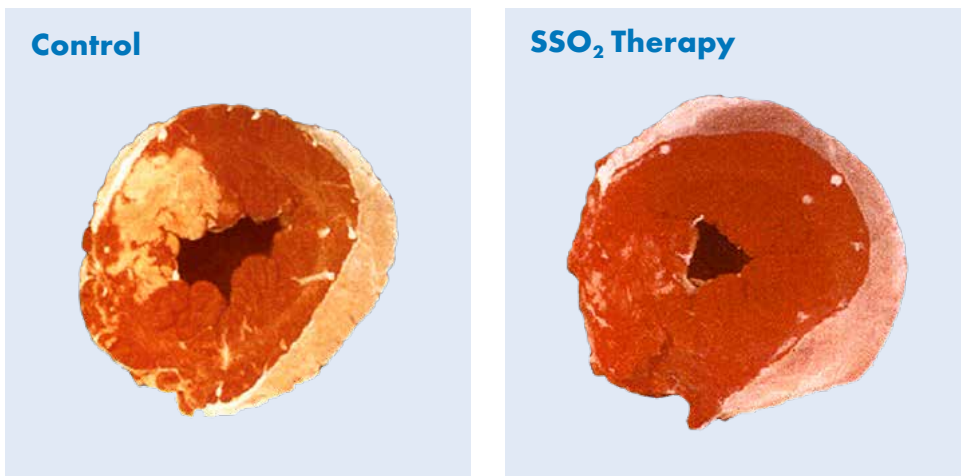
**Infarct Size
Reduction^{1,2}**

compared to PCI alone

Is Epicardial Patency Enough?

Despite successful primary PCI for STEMI, microvascular perfusion is often suboptimal, resulting in large infarctions and higher rates of heart failure hospitalization and death at 1 year.³

SSO₂ Therapy has been shown in preclinical studies to reduce endothelial swelling and restore microvascular flow, leading to reductions in infarct size.⁴



Swine AMI Model. LAD infarct created via balloon occlusion for 1 hour.

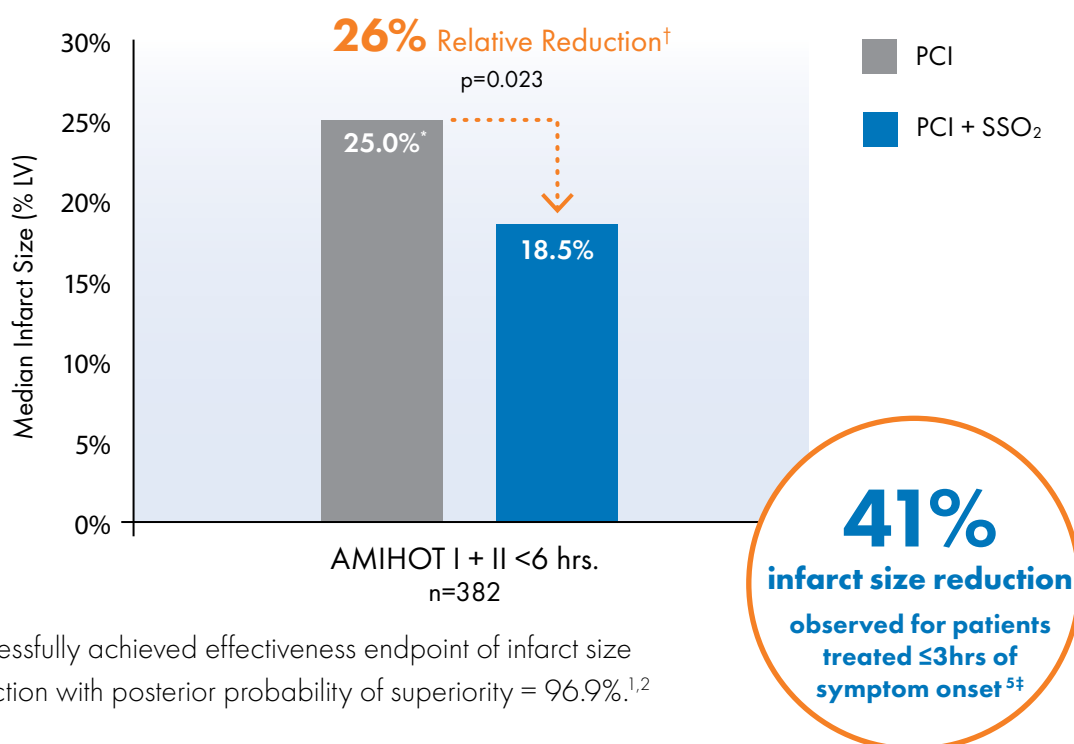
“

Even with successful PCI, we still see patients go on to develop heart failure, which significantly impacts quality of life. SSO₂ allows us to do more to reduce infarct size and improve outcomes.”

— **Ramon Quesada, MD** | Baptist Hospital of Miami, FL

Clinical Benefit

Clinically Significant Infarct Size Reduction Demonstrated in Anterior STEMI^{1,2}



Successfully achieved effectiveness endpoint of infarct size reduction with posterior probability of superiority = 96.9%.^{1,2}

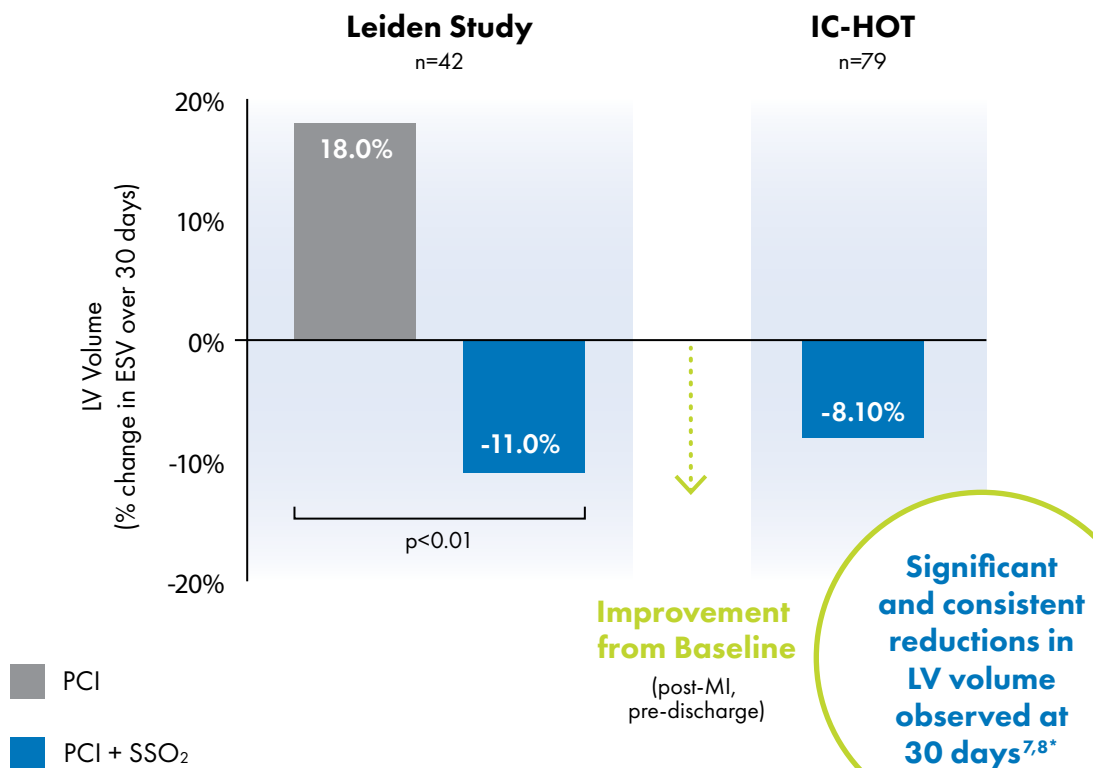
A 26% reduction in relative infarct size has been correlated with a **relative reduction in mortality and heart failure hospitalization of approximately 25% at 1 year.**⁶

[†] 26% relative infarct reduction=6.5% absolute reduction.

[‡] Data subsets from AMIHOT I and AMIHOT II trials. Symptom onset is defined as severe symptom onset, not waxing and waning symptoms.

For complete safety information visit https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170027B.pdf

Left Ventricular Recovery Demonstrated at 30 Days^{7,8*}



“

With SSO₂ we see bad ventricles in the 30% to 40% range recovering completely to an ejection fraction of 60% – and that is strikingly rare.”

— Richard Schatz, MD

In a single-center subset analysis from AMIHOT I (n=50)⁶, patients' cardiac MRI data was evaluated to determine end systolic volumes, which demonstrated an improvement in LV recovery. Additionally, IC-HOT study results demonstrating left ventricular stability over 30 days were consistent with these earlier findings⁷, suggesting SSO₂ Therapy benefit beyond infarct size reduction.[‡]

* These statements are not reflected in the indications for use with SSO₂ Therapy and are observations from studies conducted prior to FDA approval.

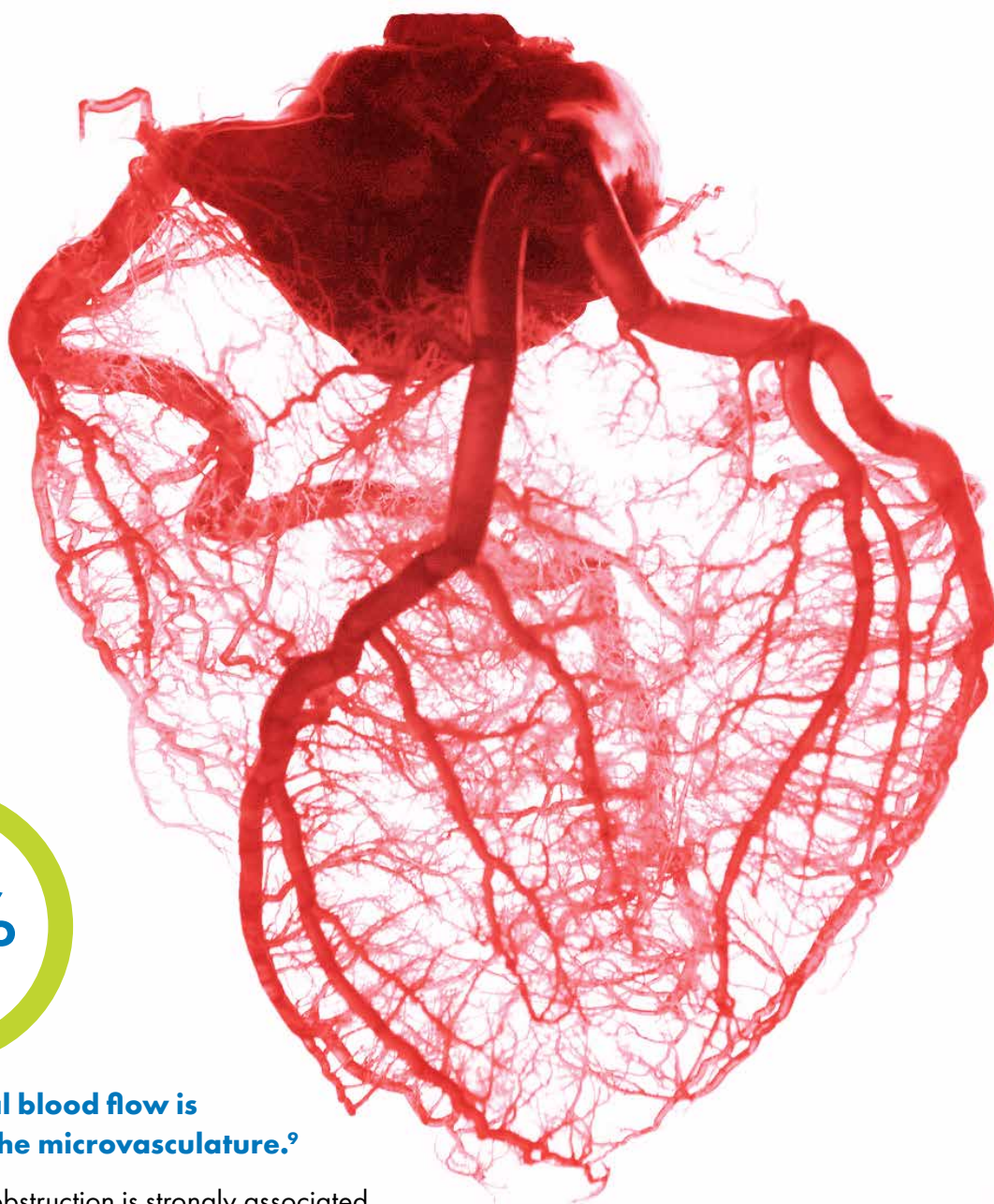
**Restore Microvascular Flow.
Reperfuse Ischemic Myocardium.
Reduce Infarct Size.^{4§}**



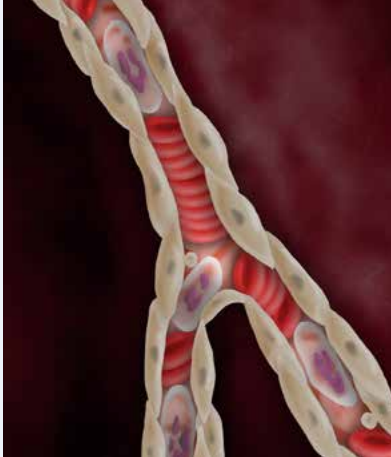
**of myocardial blood flow is
supplied by the microvasculature.⁹**

Microvascular obstruction is strongly associated
with mortality and heart failure hospitalization
within 1 year.³

§ As demonstrated in preclinical studies.



SSO₂ Mechanism of Action



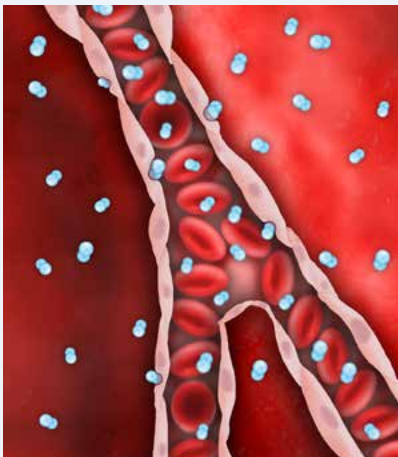
Capillary constriction continues post-PCI

Despite successful PCI, capillaries can remain obstructed by endothelial edema, neutrophils and other physiologic factors.



Highly concentrated O₂ diffuses into endothelial and myocardial tissue

SSO₂ Therapy delivers hyperoxemic levels of dissolved O₂ (pO₂ = 760-1000 mmHg), allowing for a high rate of diffusion to address microvascular obstruction.



Microvascular flow is restored and ischemic myocardium reperfused

Endothelial edema is resolved, restoring capillary flow and reperfusing ischemic myocardium.

TherOx SuperSaturated Oxygen (SSO₂) Therapy

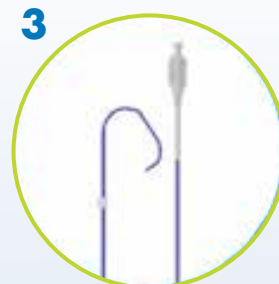
EASY, 3-IN-1 SETUP



Mobile console with easy < 5-minute post-PCI setup.



Disposable cartridge mixes patient's arterial blood with hyperoxemic infusate.



5F catheter delivers hyperoxemic blood into the left main ostium via femoral or radial access.

Learn more at zoll.com/TherOx

- 1 Stone GW, et al. *Circ Cardiovasc Interv*; 2; 366-375. Sep 2009. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170027B.pdf
- 2 O'Neill WW, et al. *J Am Coll Cardiol*. 2007;50; No.5. 397-405.
- 3 de Waha S et al. *Euro Heart J* 2017;38:3502-10.
- 4 Spears et al. *J Invasive Cardiol* 2002;14(4):160-6.

- 5 Subset data of Stone GW, et al. *Circ Cardiovasc Interv*; 2; 366-375. Sep 2009. Data on file at TherOx, Inc. and CRF.
- 6 Stone GW et al. *J Am Coll Cardiol*. 2016;67(14):1674-83.
- 7 Warda HM, et al. [2005]. *Am J Cardiol* 96(1): 22-24.
- 8 David SW, et al. *Catheter Cardiovasc Interv*. 2018;1-9.
- 9 Trifunovic, et al. *J Hypertens Res* 2019;5(1):8-20.

ZOLL MEDICAL CORPORATION

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Caution: Federal law restricts this device to sale by or on the order of a physician.

Indications For Use: The TherOx DownStream System is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO₂ Therapy) to targeted ischemic regions perfused by the patient's left anterior descending coronary artery immediately following revascularization by means of percutaneous coronary intervention (PCI) with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction (AMI) symptoms caused by a left anterior descending artery infarct lesion.

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