

TherOx[®] SuperSaturated Oxygen (SSO₂) Therapy

ZOLL[®]



The Next Frontier
in STEMI Care

Photo credit: MHH/Karin Kaiser



Dissolved O₂ in the
microvasculature

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 high levels of dissolved oxygen (pO₂ = 760-1000 mmHg) to the heart, without impacting door-to-balloon time.

26%

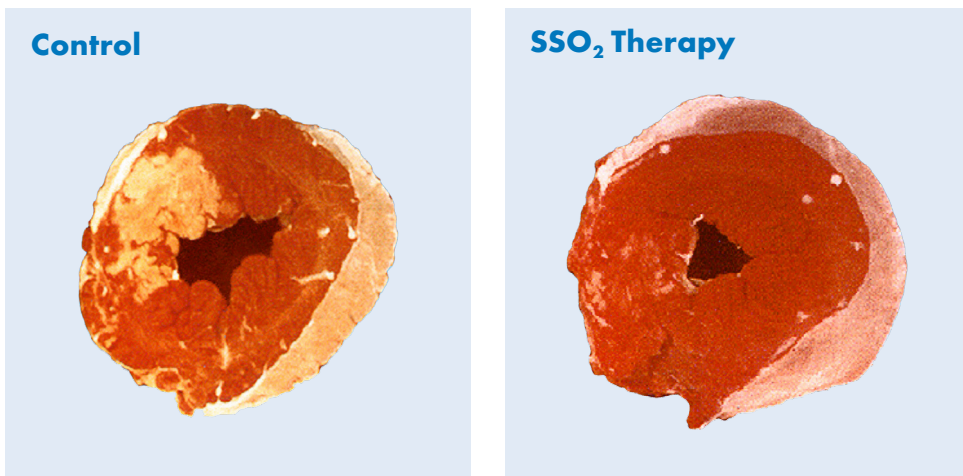
**Infarct Size
Reduction^{1,2}**

compared to PCI alone

Is Epicardial Patency Enough?

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

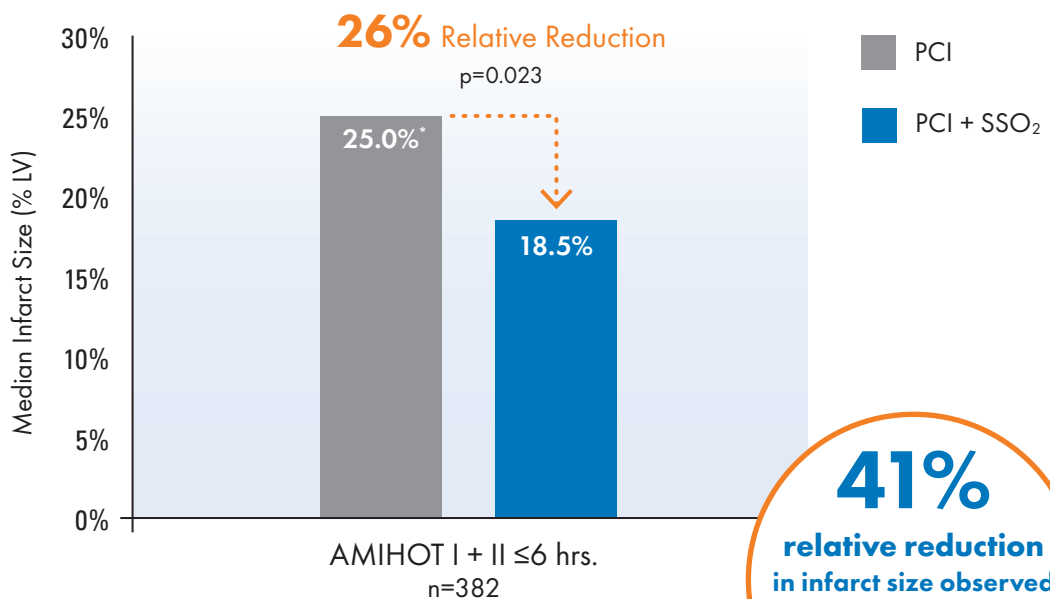
“

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, Fla.

Clinical Benefit

Clinically Significant Infarct Size Reduction Demonstrated in LAD STEMI¹



Successfully achieved effectiveness endpoint of infarct size reduction with posterior probability of superiority = 96.9%

41%
relative reduction
in infarct size observed
in patients receiving
PCI ≤ 3 hr from
symptom onset*

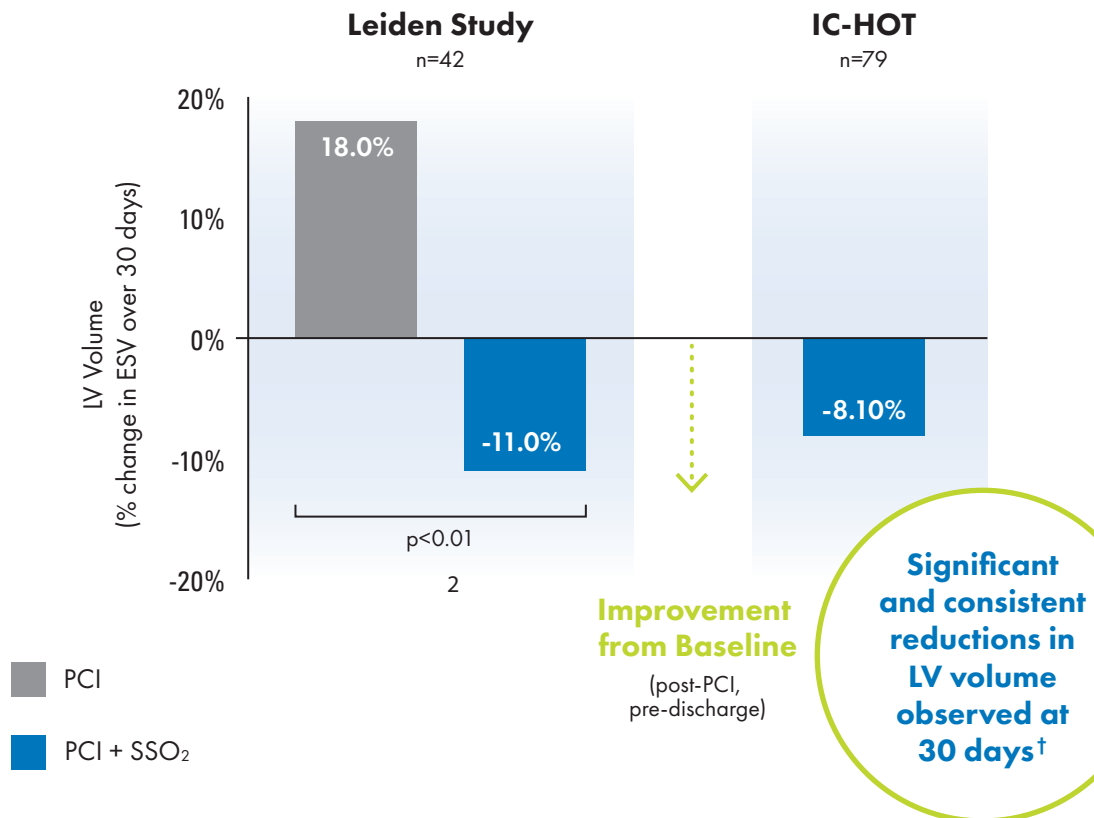
A 26% relative reduction in infarct size has been correlated with a **relative reduction in mortality and heart failure hospitalization of approximately 25% at one year.**⁵

* 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^{6,7†}



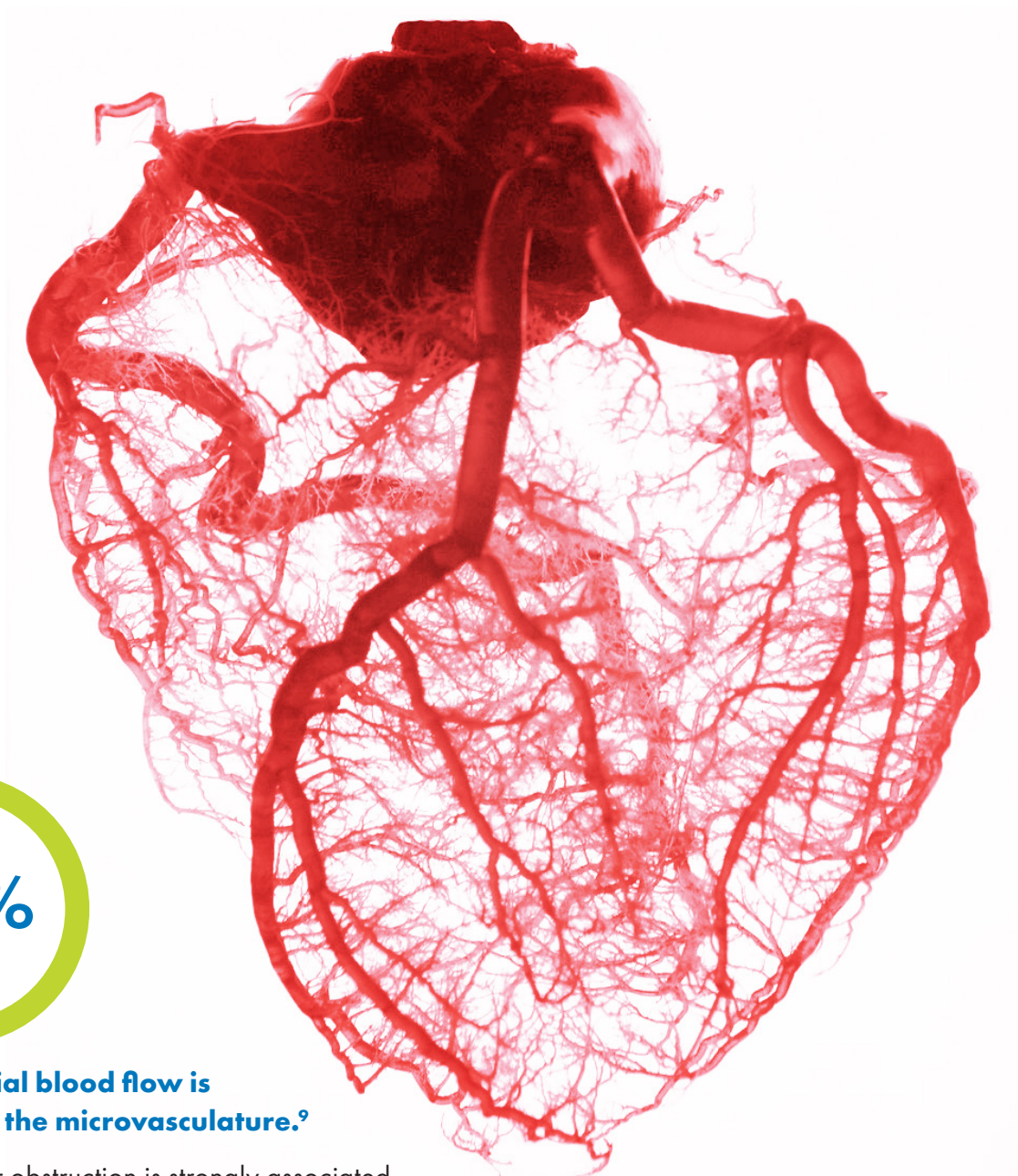
Low Rate of Death and Heart Failure at One Year

Treatment with SSO₂ was associated with a lower one-year rate of all-cause death or new-onset heart failure (HF) hospitalization (0.0% vs. 12.3%, $p = .001$).⁸

In a single-center subset analysis from AMIHOT I (n=50),⁵ 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 findings,⁶ 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†}

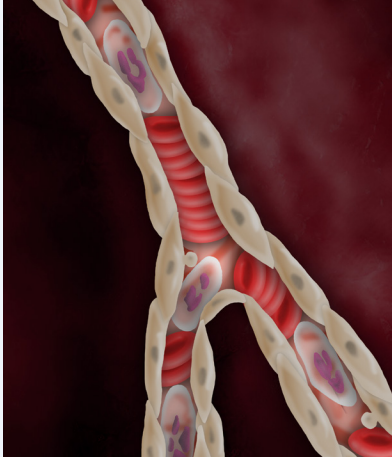


**of myocardial blood flow is
supplied by the microvasculature.⁹**

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

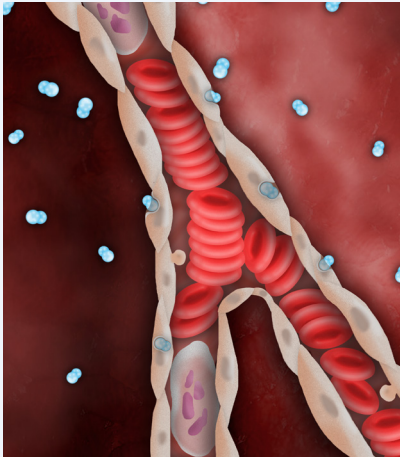
[†] As demonstrated in preclinical studies

SSO₂ Mechanism of Action



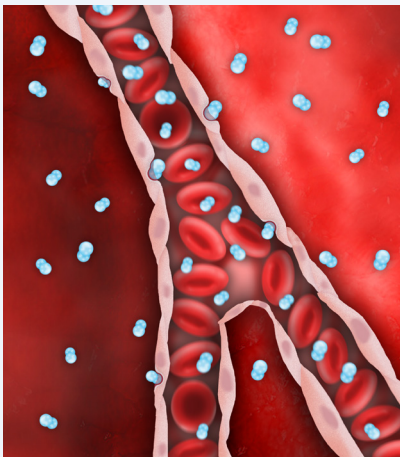
Capillary constriction continues post-PCI

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 high levels of dissolved oxygen ($pO_2 = 760-1000$ mmHg) via the plasma, even before flow is restored downstream.



Microvascular flow is restored and ischemic myocardium reperfused

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

TherOx SuperSaturated Oxygen (SSO₂) Therapy Closed-Loop System

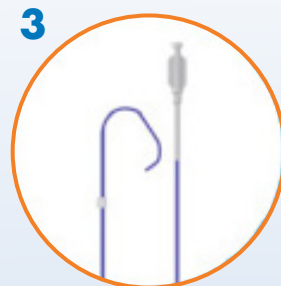
SIMPLE SETUP AND USE



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



Disposable cartridge
mixes patient's arterial
blood with highly
oxygenated infusate.



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

Learn more at info.zoll.com/TherOx

¹ Stone GW, et al. *Circ Cardiovasc Interv.* 2009;3:66–375. 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 Kloner RA, et al. *J Am Coll Cardiol Basic Trans Science.* 2021;6:12:1021–1033.

⁵ Stone GW, et al. *J Am Coll Cardiol.* 2016;67(14):1674–83.

⁶ Warda HM, et al. *Am J Cardiol.* 2005;96:1:22–24.

⁷ David SW, et al. *Catheter Cardiovasc Interv.* 2018;1–9.

⁸ Chen S, et al. *Catheter Cardiovasc Interv.* 2021;97:1120–1126.

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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