

Epicardial Patency Is Not Enough

90%

of myocardial blood flow is supplied by the microvasculature.¹

Despite successful percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction (STEMI), microvascular perfusion is often suboptimal, resulting in large infarctions and higher rates of heart failure hospitalization and death at one year.²

Patient outcomes for anterior STEMI have been stagnant since the introduction of PCI, with a two-year mortality rate of approximately 15%.³ Additional treatment that goes beyond PCI is needed to improve STEMI care.



TherOx SSO₂ Therapy: Designed to Restore Microvascular Flow and Reduce Myocardial Damage⁴

- The first FDA-approved, catheter-based treatment delivering localized oxygen targeting regions of the left anterior descending (LAD) coronary artery and its microvasculature, immediately following PCI
- Compared to PCI alone, SSO₂ Therapy reduced median infarct size by 26% (relative) in patients with LAD STEMI.^{5,6}
- View the TherOx SSO₂ clinical compendium [here](#).

“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.”

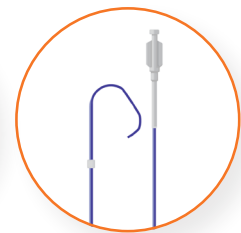
— Ramon Quesada, MD
Baptist Hospital of Miami, Fla.

26%
relative
infarct size
reduction

Simple Setup and Use

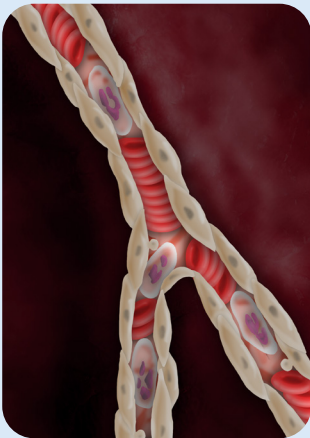
The TherOx SSO₂ closed-loop system includes three device components: console, cartridge, and SSO₂ catheter.

- < 5-minute device setup and 60-minute infusion via catheter to left main ostium post-PCI
- No impact on door-to-balloon time
- FDA-approved for use in LAD STEMI undergoing primary PCI within 6 hours of symptom onset

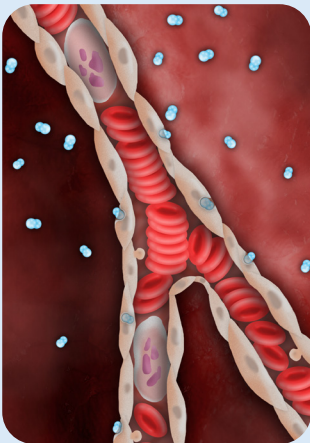


View the setup guide [here](#).

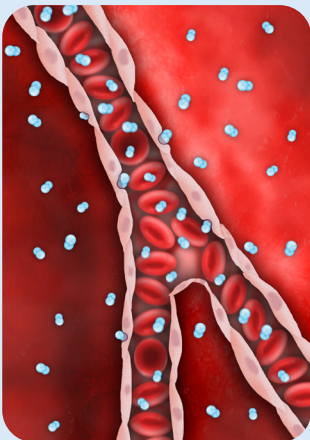
SSO₂ Therapy Mechanism of Action



Capillary constriction continues despite successful PCI.



Highly concentrated O₂ diffuses into endothelial and myocardial tissue.

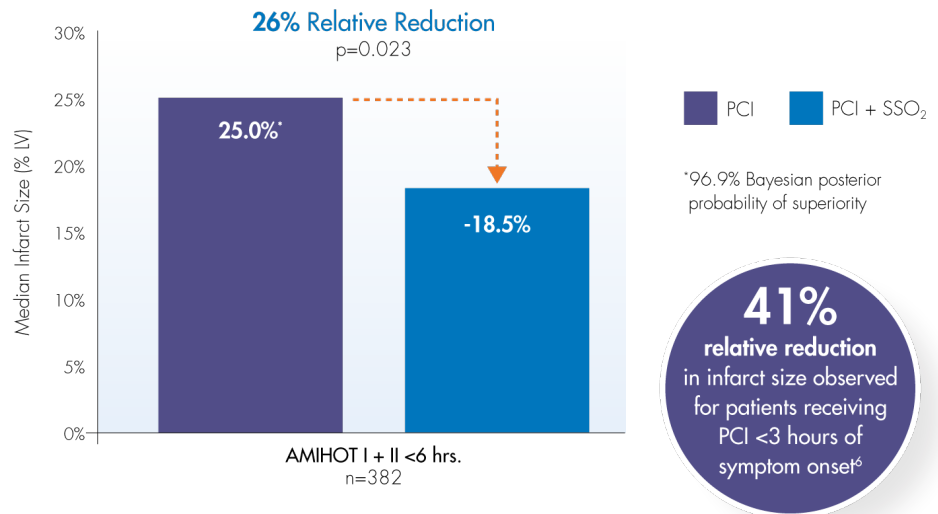


Microvascular flow is restored and ischemic myocardium reperused.⁴

[View the IFU here](#)

Advancing STEMI Care with TherOx SSO₂ Therapy

Clinically Significant Infarct Size Reduction with SSO₂ vs. Standard of Care⁵



ONE IN FIVE

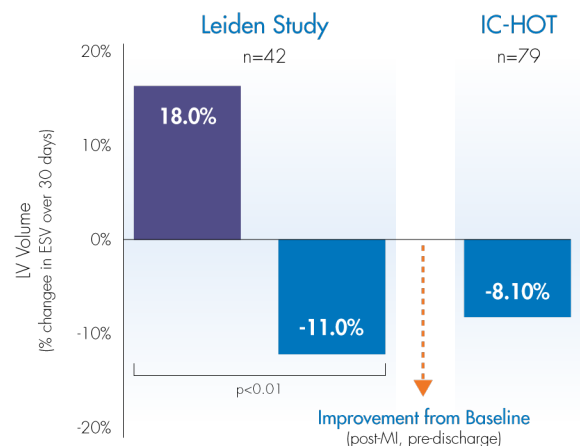
acute myocardial infarction (AMI) patients will develop heart failure within one year⁷ and of those, 50% will die within five years.⁸

Infarct Size Reduction Improves Clinical Outcomes

A large meta-analysis shows that a 26% relative reduction in infarct size is correlated with relative reductions in both death and heart failure hospitalization of approximately 25% at 1 year.⁹

Left Ventricular Recovery Post SSO₂ Treatment

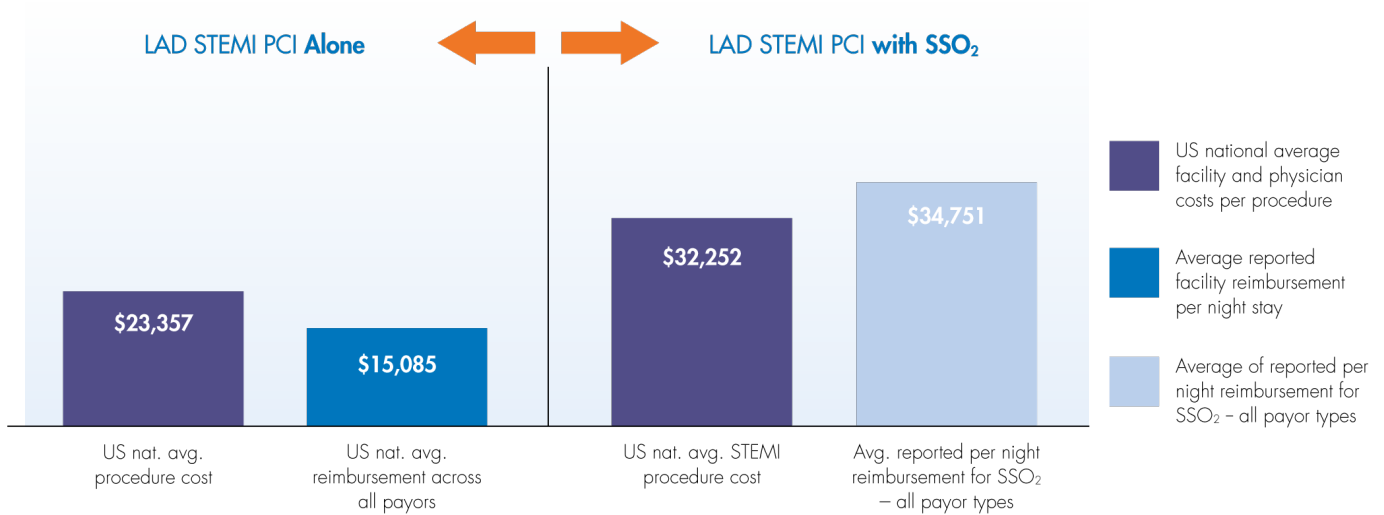
- LV enlargement is associated with a risk of progressive heart failure.¹⁰
- Significant and consistent reductions in LV volume were observed at 30 days.¹¹



Health Economics

US Average Costs and Reported Facility Reimbursements for LAD STEMI PCI Procedures, with and without SSO₂

On average, US facilities report losses on LAD STEMI PCI procedures.¹² However, early adopting facilities of SSO₂ Therapy report claim payment¹³ above national average procedure costs.



Notes: LAD STEMI-PCI alone assumes procedures without MCC/CC. LAD STEMI-PCI with SSO₂ reimbursement costs reported are inclusive of MCC/CC and no MCC/CC. Procedure Costs based on ICD-10: I21.01, I21.02 and I21.09. Reimbursement claim payments for PCI with SSO₂ as reported by existing TherOx customers. PCI with SSO₂ procedure costs includes SSO₂ plus an estimate of \$1,900 for incremental lab and physician time, added supplies, and amortized capital, maintenance, and service costs.

Average Cost Avoidance for Every Patient Who Doesn't Develop Progressive Heart Failure

Heart failure after myocardial infarction hospitalization is diagnosed in approximately 13% of patients at 30 days and 20 to 30% at one year after discharge for MI.⁷

	Per Patient Cost
Average US total cost for heart failure hospital admission ¹³	\$11,742
Average ongoing costs over two years in high-risk patients experiencing three heart failure events ¹⁵	\$108,319
Avg. Cost Avoidance per Heart Failure Patient	\$120,061

\$11,742
Avg US cost for heart failure admission¹³



For more information on SSO₂ reimbursement, contact SSO2reimbursement@zoll.com



TherOx SSO₂ Therapy The Next Frontier in STEMI Care

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

—Richard Schatz, MD



¹ Trifunovic, et al. *J Hypertens Res.* 2019;5(1):8–20.

² de Waha S, et al. *Euro Heart J.* 2017;38:3502–10.

³ Martin, et al. Analysis of 2005-2008, 2016-2019 Q2 Medicare inpatient claims data. Presented at HFSA; 2021; Denver, Colorado.

⁴ Kloner RA, et al. *J Am Coll Cardiol Basic Trans Science.* 2021;6:12:1021–1033.

⁵ Stone GW, et al. *Circ Cardiovasc Interv.* 2;366–375. Sep 2009.

⁶ Subset data of Stone GW, et al. *Circ Cardiovasc Interv.* 2009 Sep;2:366–375. Data on file at TherOx, Inc. and CRF.

⁷ Jenca D, et al. *ESC Heart Failure.* 2021;8:222–237.

⁸ Taylor C J, et al. *BMJ.* 2019; 364:1223.

⁹ Stone GW, et al. *J Am Coll Cardiol.* 2016;67(14):1674–83.

¹⁰ Pazos-Lopez P, et al. *Vasc Health Risk Manag.* 2011;7:237–254.

¹¹ Warda HM, et al. *Am J Cardiol.* 2005;96(1):22–24.

¹² Based on US national averages of CMS 2019 claim data from Definitive Healthcare.

¹³ Data on file collected from SSO₂ users.

¹⁴ Kim L, et al. *J Am Heart Assoc.* 2018;7:18:e009863.

¹⁵ Urbich M, et al. *Pharmacoeconomics.* 2020;38:1219–1236.

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.

ZOLL MEDICAL CORPORATION

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