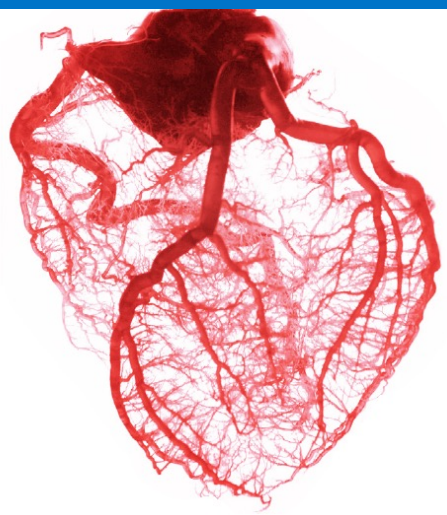
TherOx® SSO_2 Therapy
Clinical and Economic Summary

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 1 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 SSO_2 Therapy: Designed to Restore Microvascular Flow and Reduce Myocardial Damage[4]

- 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, SSO_2 Therapy reduced median infarct size by 26% (relative) in patients with LAD STEMI.[5,6]

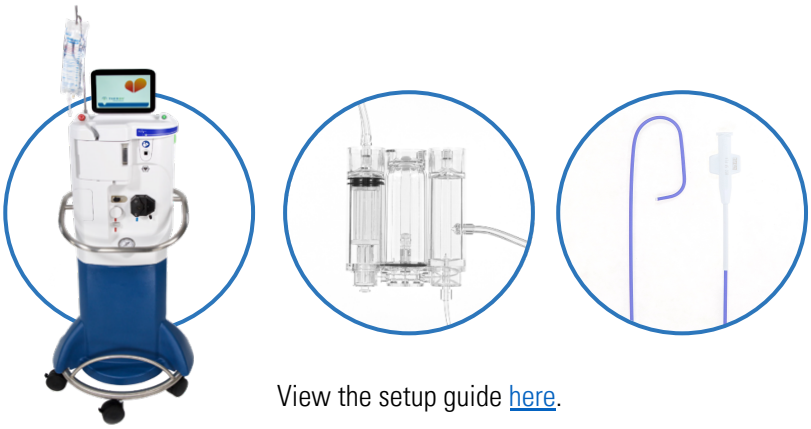
  View the TherOx SSO_2 clinical compendium here.

26% Infarct Size Reduction

> "Even with successful PCI, we still see patients go on to develop heart failure, which significantly impacts quality of life. SSO_2 allows us to do more to reduce infarct size and improve outcomes."
>
> — Ramon Quesada, MD
> Baptist Hospital of Miami, FL

Easy 3-in-1 Setup

The TherOx SSO_2 System includes three device components: console, cartridge, and SSO_2 catheter.



View the setup guide here.

- < 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

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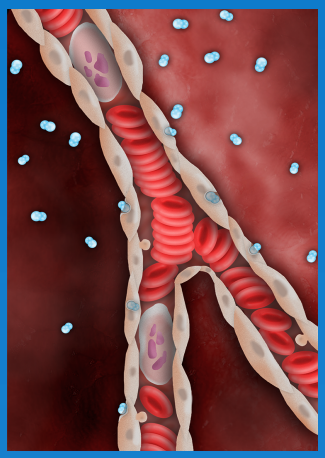
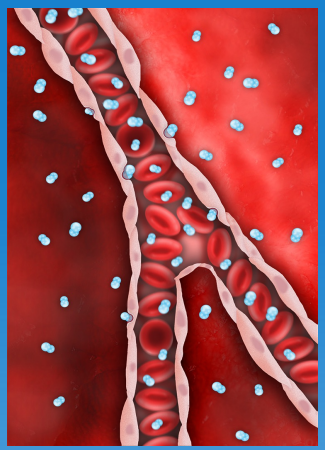
SSO_2 Therapy Mechanism of Action

Capillary constriction continues despite successful PCI



Highly concentrated O_2 diffuses into endothelial and myocardial tissue

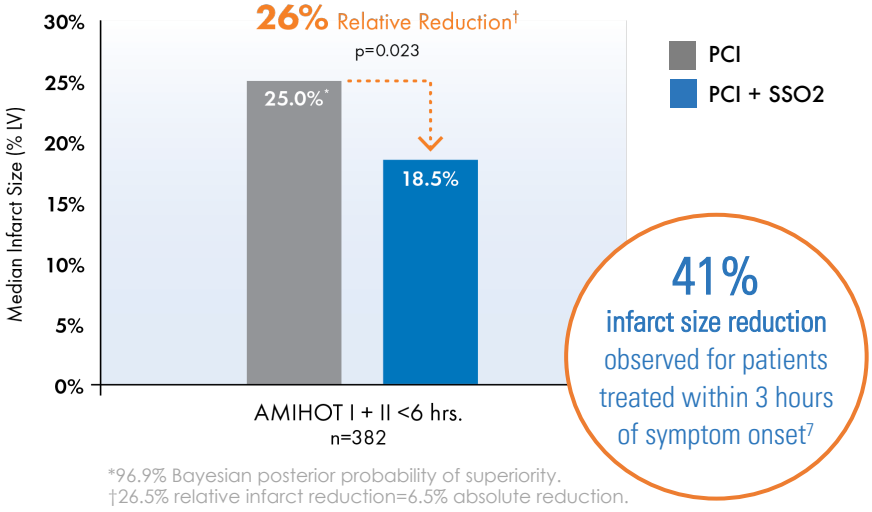


Microvascular flow is restored and ischemic myocardium reperfused[4]

View the IFU here

ADVANCING STEMI CARE WITH THEROX® SSO_2 THERAPY

Clinically Significant Infarct Size Reduction with SSO_2 vs. Standard of Care[5,6]



*96.9% Bayesian posterior probability of superiority.
†26.5% relative infarct reduction=6.5% absolute reduction.

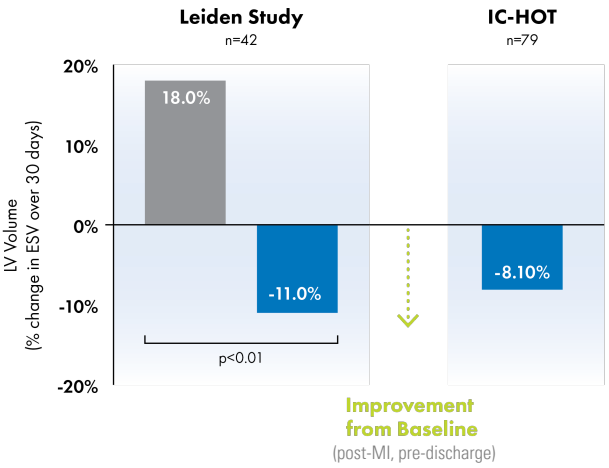
One in five acute myocardial infarction (AMI) patients will develop heart failure within one year[8] and of those, 50% will die within five years.[9]

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 approx. 25% at 1 year.[10]

Left Ventricular Recovery Post SSO_2 Treatment

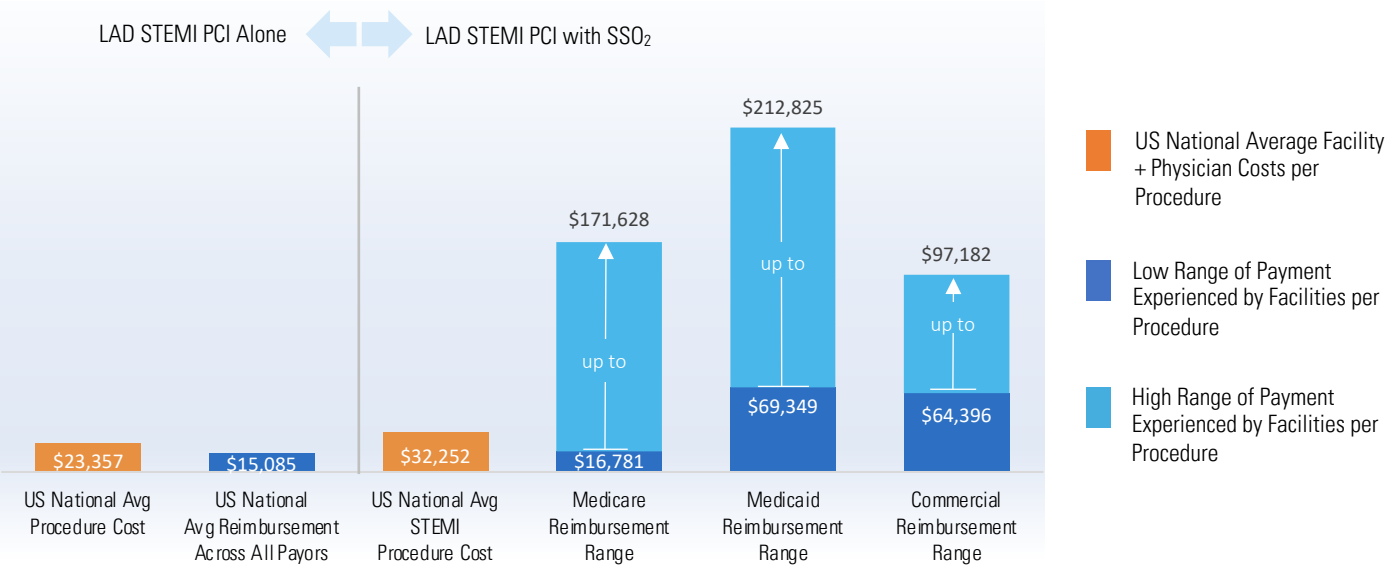
- LV enlargement is associated with a risk of progressive heart failure[11]
- Significant and consistent reductions in LV volume were observed at 30 days[12]



HEALTH ECONOMICS

US Average Costs and Reported Facility Reimbursements for LAD STEMI PCI Procedures, With and Without SSO_2

On average, US facilities report losses on LAD STEMI PCI procedures.[13] However, early-adopting facilities of SSO_2 Therapy report claim payment ranges[14] above national average procedure costs.



Notes: LAD STEMI-PCI alone assumes procedures without MCC/CC | LAD STEMI-PCI with SSO_2 reimbursement costs are reported reimbursements are inclusive of MCC/CC and no MCC/CC | Procedure Costs based on ICD-10: I21.01, I21.02 and I21.09 | Range of reimbursement claim payments for PCI with SSO_2 as reported by existing TherOx customers. Reimbursement ranges are determined by the variability of each patient's care and the length of stay. | PCI with SSO_2 procedure costs includes SSO_2 per procedure list price of $6,995 plus an estimate of $1,900 for incremental lab and physician time, added supplies, and amortized capital, maintenance, and service costs.

17.8% of STEMI patients readmitted are readmitted more than once; 11.3% of those readmissions are attributable to recurrent myocardial infarction, while 13.9% and 4.2% are attributable to heart failure and arrhythmic causes.[15]

$37,524
The average total cost of a PCI readmission.[16]

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 20–30% at 1 year after discharge for MI.[8]

	Per Patient Cost
Avg. US total cost for heart failure hospital admission[17]	$11,742
Avg. ongoing costs over 2 years in high-risk patients experiencing three heart failure events[18]	$108,319
Avg. Cost Avoidance per Heart Failure Patient	$120,061

For more information on SSO_2 reimbursement, contact SSO2reimbursement@zoll.com

TherOx® SSO_2 Therapy

The Next Frontier in STEMI Care

> "With SSO_2 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

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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 (SSO_2 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.

For subsidiary addresses and fax numbers, as well as other global locations, please go to zoll.com/contacts.

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