TherOx® SuperSaturated Oxygen (SSO₂) Therapy

The Next Frontier in STEMI Care

Photo credit: MHH/Karin Kaiser
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.¹²

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 Reduction¹² 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. SSO₂ Therapy has been shown in preclinical studies to reduce endothelial swelling and restore microvascular flow, leading to reductions in infarct size.

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 STEMI

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\textsuperscript{6,7,†}

**Leiden Study**  
\[ n=42 \]  
\[ 18.0\% \]  
\[ \text{PCI} \]  
\[ \text{PCI + SSO}_2 \]  

**IC-HOT**  
\[ n=79 \]  
\[ -11.0\% \]  
\[ -8.10\% \]  
\[ \text{PCI} \]  
\[ \text{PCI + SSO}_2 \]  

\[ p<0.01 \]  

**Improvement from Baseline**  
(post-PCI, pre-discharge)  

Significant and consistent reductions in LV volume observed at 30 days\textsuperscript{†}

Low Rate of Death and Heart Failure at One Year  
Treatment with SSO\textsubscript{2} was associated with a lower one-year rate of all-cause death or new-onset heart failure (HF) hospitalization (0.0\% vs. 12.3\%, \( p = .001 \)).\textsuperscript{8}

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In a single-center subset analysis from AMIHOT I (\( n=50 \)), 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,\textsuperscript{6} suggesting SSO\textsubscript{2} Therapy benefit beyond infarct size reduction.

\( \dagger \) These statements are not reflected in the indications for use with SSO\textsubscript{2} Therapy and are observations from studies conducted prior to FDA approval.
Restore Microvascular Flow. Reperfuse Ischemic Myocardium. Reduce Infarct Size. ⁴‡

90% 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

¹ As demonstrated in preclinical studies
Capillary constriction continues post-PCI

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

Highly concentrated \( \text{O}_2 \) diffuses into endothelial and myocardial tissue

SSO\(_2\) Therapy delivers high levels of dissolved oxygen (\( \text{pO}_2 = 760-1000 \) 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 ($SSO_2$) Therapy
Closed-Loop System

SIMPLE SETUP AND USE

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

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

3. 5F catheter delivers super-oxygenated blood into the left main ostium via femoral or radial access.

Learn more at info.zoll.com/TherOx

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ZOLL MEDICAL CORPORATION
269 Mill Road | Chelmsford, MA 01824 | 978-421-9655 | 800-804-4356 | zoll.com

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.

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