

## TherOx Super Saturated Oxygen (SSO<sub>2</sub>) System

### Overview

The TherOx SSO<sub>2</sub> System by Zoll Medical is a three-part system that delivers a hyperoxemic oxygen infusion to the coronary arteries in patients who have suffered a left anterior descending ST-elevated myocardial infarction (STEMI).<sup>1</sup> The infusion consists of a targeted 60-minute single transfer of super oxygenated blood carried via catheter to the patient’s left anterior descending (LAD) artery. The treatment is intended to be delivered after revascularization of the LAD via angioplasty and stenting in the cardiac catheterization laboratory.<sup>1</sup> The three components of the system include a console, cartridge, and SSO<sub>2</sub> catheter which work together to deliver the blood with a partial pressure of oxygen (pO<sub>2</sub>) content approximately 7-10 times higher than normal.

System Component	Description
TherOx Console	Reusable mobile hardware device that control operation of the cartridge and monitors the administration
TherOx Cartridge	Single-use disposable component, uses saline, oxygen, and autologous arterial blood to create super oxygenated blood
SSO <sub>2</sub> Catheter	5F over the wire catheter (100 cm in length, Judkins Left tip shape)

### Indications for Use

The TherOx DownStream System carries an FDA indication for use to prepare and deliver Super Saturated Oxygen Therapy (SSO<sub>2</sub>) following a percutaneous coronary intervention with stenting, completed within 6 hours of symptom onset of a heart attack due to a LAD lesion. Specific contraindications for the use of this therapy are listed in the Summary of Safety and Effectiveness Data sheet (FDA Database Listing: [PMA](#); PMA number P170027).

### Clinical Data

Clinical studies supporting the use of SSO<sub>2</sub> therapy are industry sponsored. Sample studies are described below:

- Chen et al. (2020) described the one-year outcomes of SSO<sub>2</sub> therapy for patients after percutaneous coronary intervention (PCI) of the LAD artery.<sup>2</sup> This prospective, single arm study was titled IC-HOT and included 100 patients receiving SSO<sub>2</sub> post-PCI after an anterior STEMI. The authors concluded that clinical outcomes (lower rate of death, new onset heart failure (HF) were lower at one year in the group receiving SSO<sub>2</sub>, when compared with a propensity-matched control group of patients receiving intracoronary medication and aspiration thrombectomy (INFUSE AMI trial).<sup>2</sup>
- Stone et al. (2009) described the results of a trial in which patients receiving PCI within 6 hours of symptom onset for an anterior STEMI were randomized to receive a 90-minute SSO<sub>2</sub> infusion to the LAD (treatment group, n = 222; control, n = 79). Clinical outcomes included infarct size and major adverse cardiovascular events at 30 days. The authors concluded that patients in the treatment group demonstrated a significant reduction in infarct size and demonstrated non-inferiority in cardiovascular events at 30 days.<sup>3</sup>

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### Physician Advisor Insight

A panel of interventional cardiologists within our HealthTrust Physician Advisor Network offered the following insight with regard to the TherOx SSO<sub>2</sub> System.<sup>4</sup>

- Potential benefits include improved microcirculation in the setting of acute infarct and potential reduction in cardiovascular events within the first year of therapy.
- Staff training on the device was noted to be minimal.
- Challenges were noted to include cost of the device, additional time in the catheterization lab, need for further medication and testing and problems related to labor shortages.
- Safety concerns related to prolonged catheter dwell time in the ostium of the left main for one full hour.
- Additional clinical data including large randomized controlled trials to provide evidence and safety data for the device are recommended.

### References

1. Zoll Medical Corporation. How SSO<sub>2</sub> Therapy Works. <https://www.zoll.com/products/supersaturated-oxygen-therapy/how-it-works>. Published 2022. Updated 2022. Accessed 7/21/2022.
2. Chen S, David SW, Khan ZA, et al. One-year outcomes of supersaturated oxygen therapy in acute anterior myocardial infarction: The IC-HOT study. *Catheterization and Cardiovascular Interventions*. 2021;97(6):1120-1126.
3. Stone GW, Martin JL, de Boer MJ, et al. Effect of supersaturated oxygen delivery on infarct size after percutaneous coronary intervention in acute myocardial infarction. *Circ Cardiovasc Interv*. 2009;2(5):366-375.
4. 2022 Physician Advisory Network: Interventional Cardiology. Survey. June 30th through July 14<sup>th</sup>, 2022.

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