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**SuperSaturated Oxygen (SSO<sub>2</sub>) Therapy Fact Sheet  
New Heart Attack Treatment Saves Damaged Heart Muscle**

**An Unmet Need in Heart Attack Treatment**

- According to the American Heart Association, every year nearly 750,000 people in the U.S. have heart attacks, typically caused when the blood flow carrying oxygen to the heart is reduced or blocked.
- The standard of care in treating heart attacks is angioplasty and stenting (called percutaneous coronary intervention or PCI) to quickly restore blood flow and oxygen to the heart.
- It has been well established by the American College of Cardiology that speed to intervention is key. Without quick intervention, irreversible damage to the heart muscle (called an infarction) will occur.
- However, for many patients, PCI doesn't do enough to save the area of dead or damaged tissue (called infarct size) caused by the lack of oxygen, and this can lead to an increased risk of future complications such as heart failure and even death.<sup>1</sup>

**A Novel Treatment for Heart Attacks**

- SuperSaturated Oxygen (SSO<sub>2</sub>) Therapy delivers hyperbaric levels of oxygen directly to the oxygen deficient (ischemic) heart muscle immediately after the coronary artery has been opened by PCI.
- SSO<sub>2</sub> Therapy has been shown in multiple randomized prospective clinical trials to consistently and safely reduce infarct size and thereby improve outcomes in patients who suffer the most serious kind of heart attacks – left anterior descending ST-elevation myocardial infarction (LAD STEMI) also known as the widowmaker – treated within six hours of symptom onset.
- SSO<sub>2</sub> Therapy provides interventional cardiologists with the first and only FDA-approved treatment beyond PCI to save damaged heart muscle in heart attack patients.

**Clinical Study Results**

- The multiple clinical trials demonstrating SSO<sub>2</sub> Therapy's safety and efficacy include:
  - The pivotal AMIHOT II (Acute Myocardial Infarction With Hyperoxemic Therapy) trial demonstrated a relative median reduction of 26 percent in infarct size compared to PCI and stenting alone.<sup>2</sup> The trial enrolled 301 patients and met its pre-specified endpoints.
  - The IC-HOT (Evaluation of Intracoronary Hyperoxemic Oxygen Therapy) study confirmed the safety and effectiveness of SSO<sub>2</sub> Therapy in treatment of LAD STEMI patients who underwent successful PCI with stenting within six hours of experiencing symptoms. The study also showed left ventricular stability at 30 days with no deleterious enlargement.<sup>3</sup> The study enrolled 100 patients and met its pre-specified endpoint.

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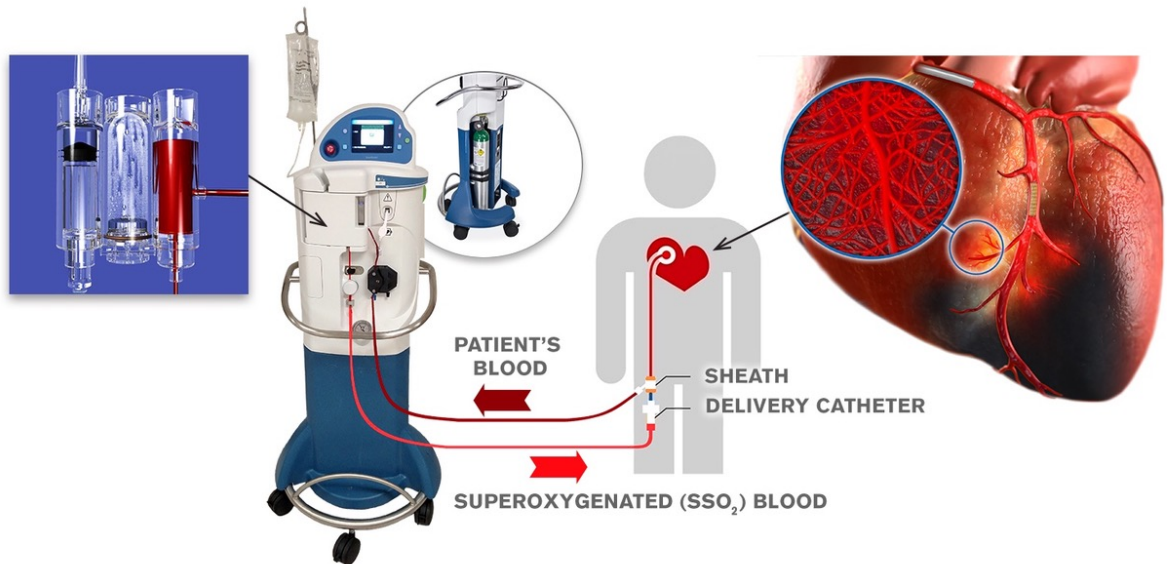
<sup>1</sup> Stone GW, Selker, HP, Thiele H, *et al.* Relationship between infarct size and outcomes following primary PCI. *JACC* 2016;67(14):1674-83

<sup>2</sup> 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 Intervent* 2009;2:366-75

<sup>3</sup> David SW, *et al.* Evaluation of intracoronary hyperoxemic oxygen therapy in acute anterior myocardial infarction: The IC-HOT study. *Catheter Cardiovasc Interv.* 2018;1-9.

## How SSO<sub>2</sub> Therapy Works

- SSO<sub>2</sub> Therapy is based on the known benefits of hyperbaric oxygen treatment in improving the body's ability to heal.
- SSO<sub>2</sub> Therapy, adjunctive to PCI, has been shown to save heart muscle by improving the microvascular flow<sup>4</sup>, reducing infarct size.
- SSO<sub>2</sub> Therapy delivers the patient's superoxygenated blood to the targeted ischemic area of the heart and restores normal oxygen levels to improve blood flow to surrounding tissue, decrease infarct size and save heart muscle.<sup>5,6</sup>
- SSO<sub>2</sub> Therapy is prepared by mixing highly oxygenated saline the with the patient's own blood, which is then delivered through a catheter directly to the targeted ischemic area of the heart within six hours of symptom onset.



- The therapy is administered by a special system, called the DownStream System, for 60 minutes, initiated in the cardiac catheterization lab immediately following successful PCI.
- SSO<sub>2</sub> Therapy is consistent with current guidelines for interventional cardiology procedures.

For more information, please visit [www.therox.com](http://www.therox.com).

The TherOx DownStream System is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO<sub>2</sub> 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.

Caution: Federal law restricts this device to sale by or on the order of a physician

<sup>4</sup> Bartorelli A, et al. Hyperoxemic Perfusion for Treatment of Reperfusion Microvascular Ischemia in Patients with Myocardial Infarction. *Am Jour of Cardio Drugs*. 2003. 3(4); 253-263.

<sup>5</sup> Spears JR, et al. Aqueous Oxygen Attenuation of Reperfusion Microvascular Ischemia in a Canine Model of Myocardial Infarction. *ASAIO Jour*. 2003 Nov-Dec;49(6):716-20.

<sup>6</sup> Bartorelli A, et al. Hyperoxemic Perfusion for Treatment of Reperfusion Microvascular Ischemia in Patients with Myocardial Infarction. *Am Jour of Cardio Drugs*. 2003. 3(4); 253-263.