



Cardiac Perfusion with Intra-arterial Supersaturated Oxygen

Presentation to the
ICD-10-PCS Coordination and Maintenance Committee

Tuesday, March 8, 2022

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Presentation

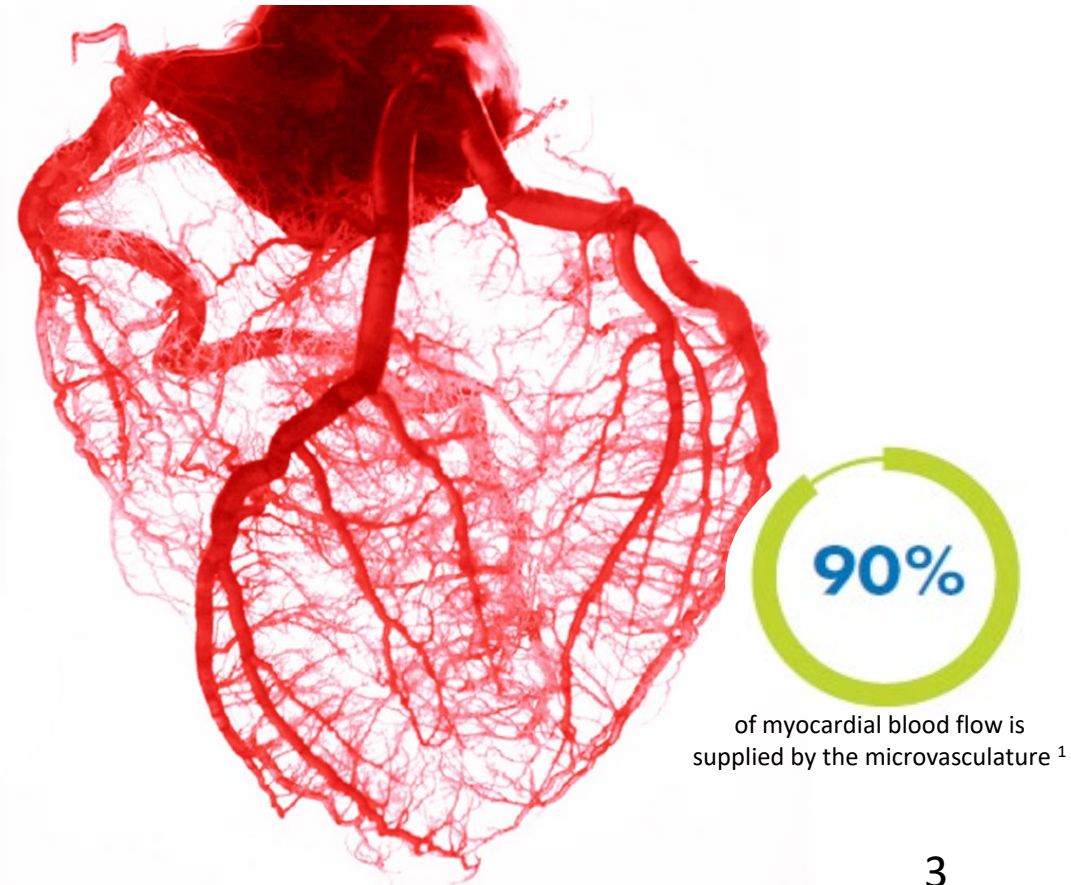
Objective and Outline

- Objective: To provide clinical background to help CMS consider updated coding terminology
- Outline
 - Describe the therapy background
 - Review the unique features of Intra-Arterial Perfusion of SuperSaturated Oxygen (SSO₂) Therapy with a Closed Loop Pump System
 - Identify key procedural components
 - Review code history

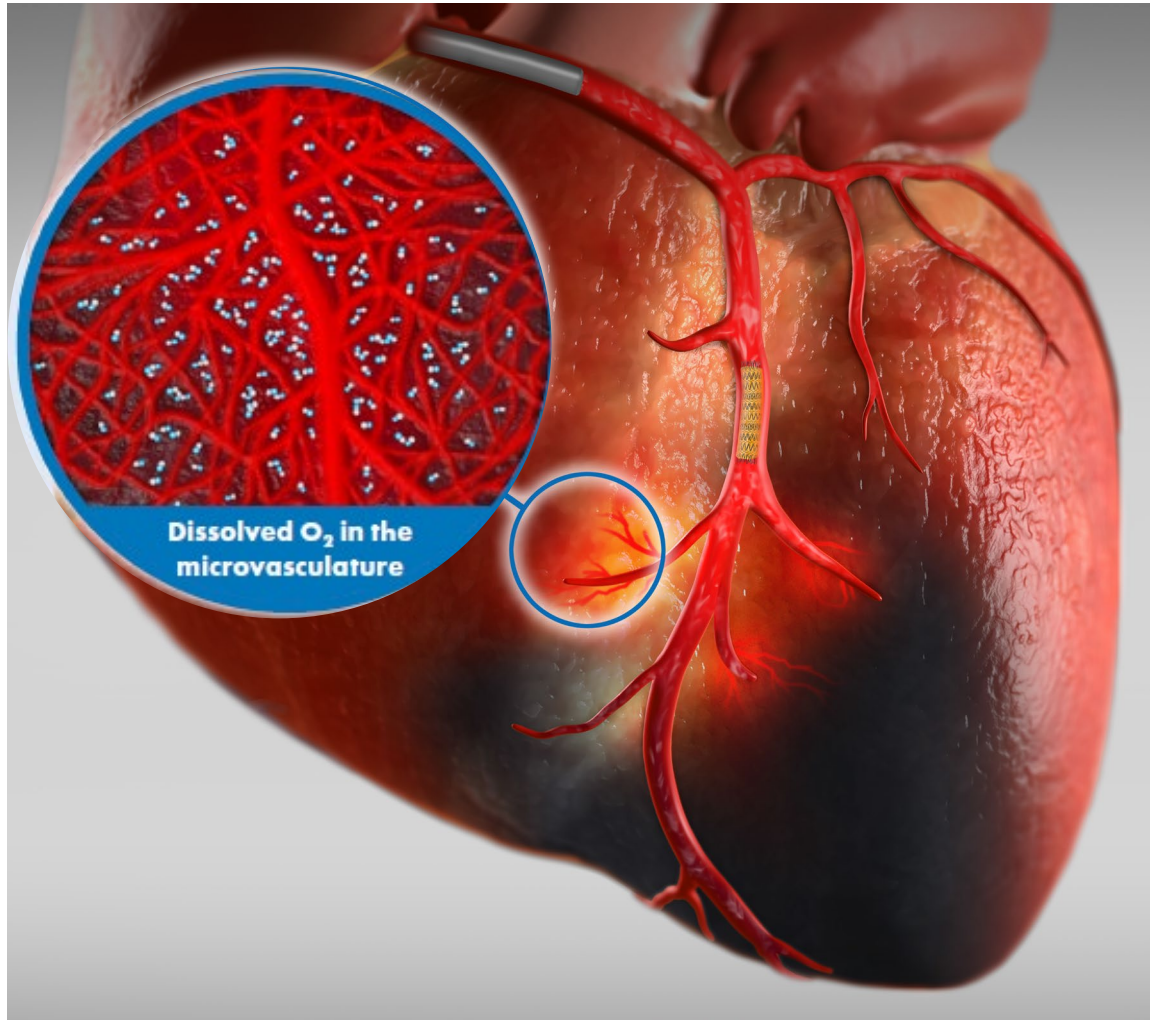
Therapy Summary

- SuperSaturated Oxygen Therapy (SSO₂) prepares and delivers SSO₂
 - Needed by patients with a left anterior descending artery infarct lesion
 - Following the percutaneous coronary intervention (PCI) completed within 6 hours after the onset of acute myocardial infarction symptoms
 - By infusing high potency oxygen that is mixed with the patient's drawn arterial blood
 - The only FDA approved therapy that reduces infarct size associated with reperfusion after successful PCI/stenting in ST Segment Elevated Myocardial Infarction (STEMI) patients.
- SSO₂ improves microcirculatory flow and tissue level perfusion in the capillary beds and at-risk myocardium, as the microvasculature supplies 90% of myocardial blood flow.¹
- Looking ahead, an FDA approved trial is investigating expanded use of SSO₂ in STEMI patients with cardiogenic shock and advanced mechanical circulatory support.

Microvascular obstruction is strongly associated with mortality and heart failure hospitalization within 1 year, independent of infarct size.²



SuperSaturated Oxygen (SSO₂) Therapy



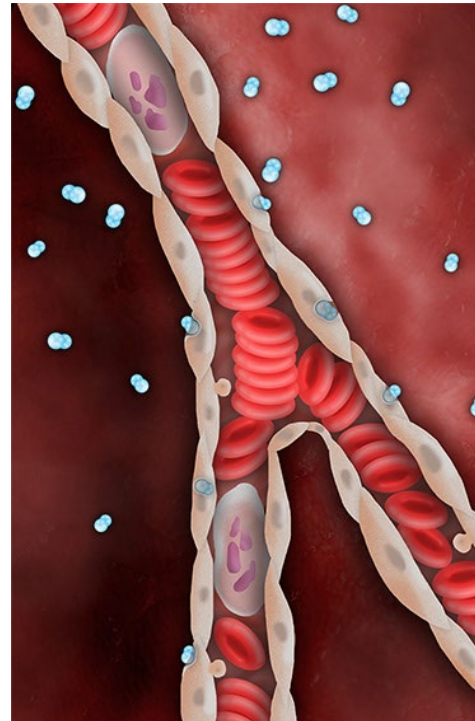
- SSO₂ treats ischemic myocardium by delivering localized hyperoxemic (pO₂ = 760-1000 mmHg) levels of O₂ to the heart post-PCI.
- No impact on door-to-balloon time
- 26% relative reduction in infarct size¹



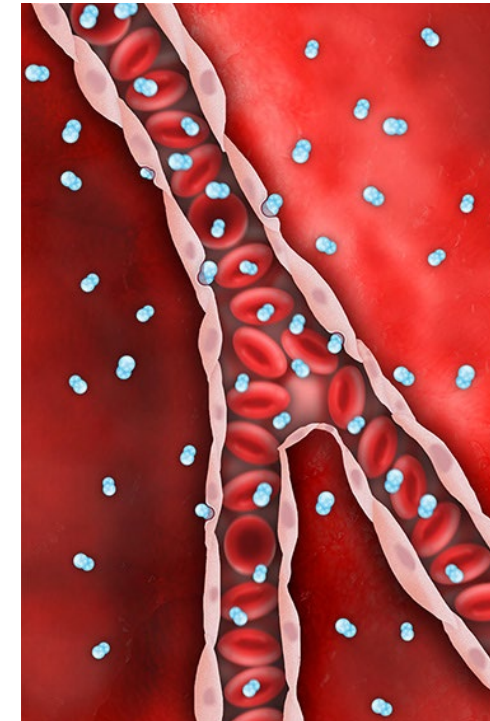
SSO₂ Mechanism of Action



Despite successful PCI, capillaries can remain obstructed by endothelial edema, neutrophils and other physiologic responses.¹



Highly concentrated O₂ diffuses into myocardial and endothelial tissue to relieve swelling.¹



Microvascular flow is restored and ischemic myocardium is reperfused.¹

Technology Set Up

1



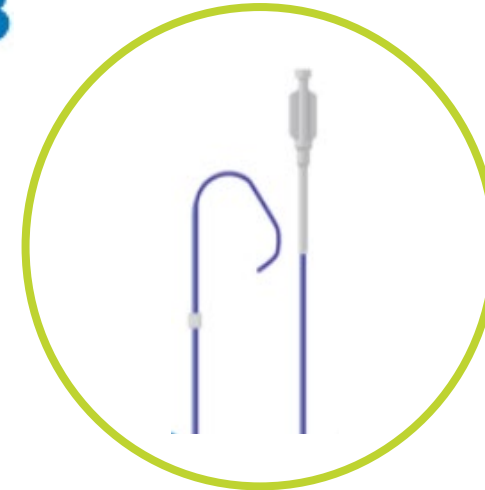
Mobile console
with post-PCI set
up.

2



Disposable
cartridge mixes
hospital-supplied
saline and O₂ with
arterial blood.

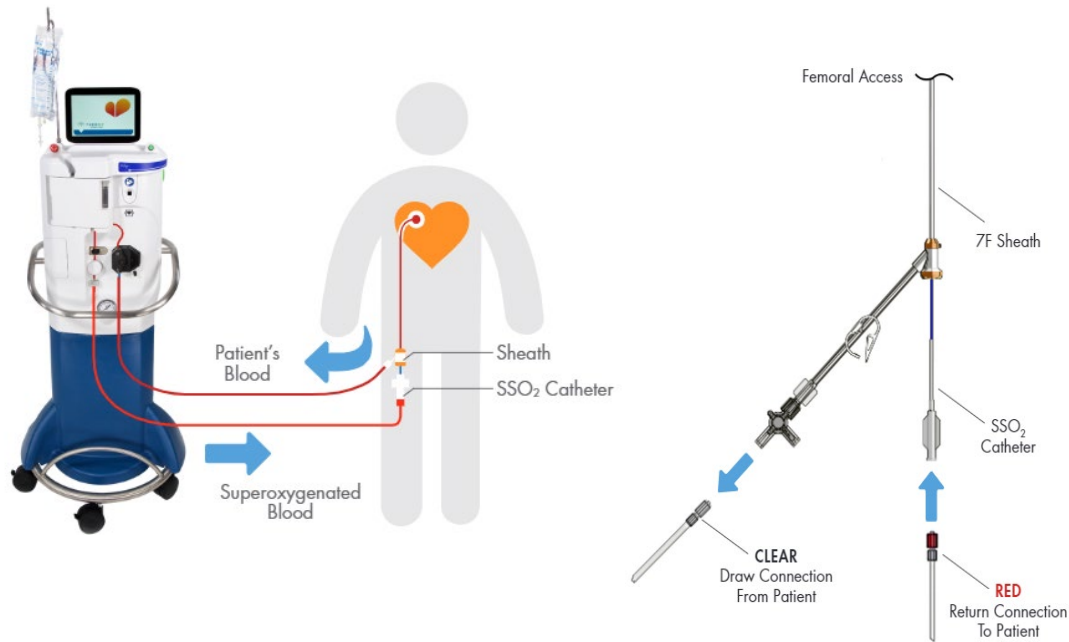
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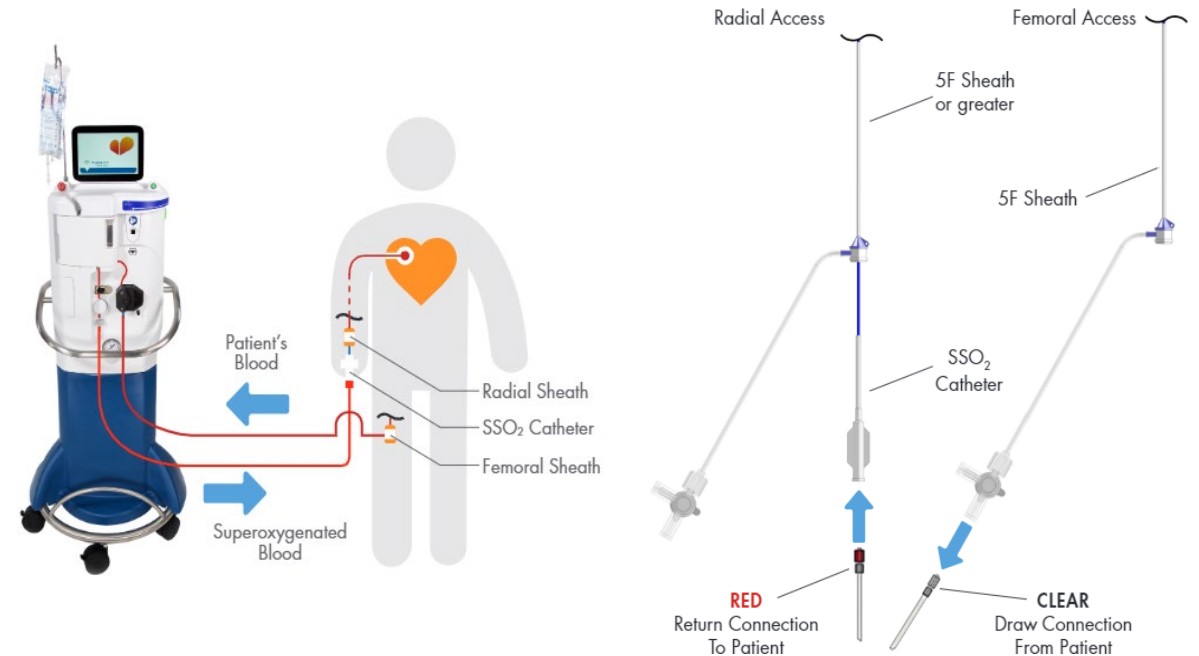
5F catheter delivers
hyperoxemic
supersaturated blood
into the left main
ostium via femoral or
radial access.

Surgical Approaches: Arterial to Arterial Blood Loop

Coaxial Femoral Access Approach



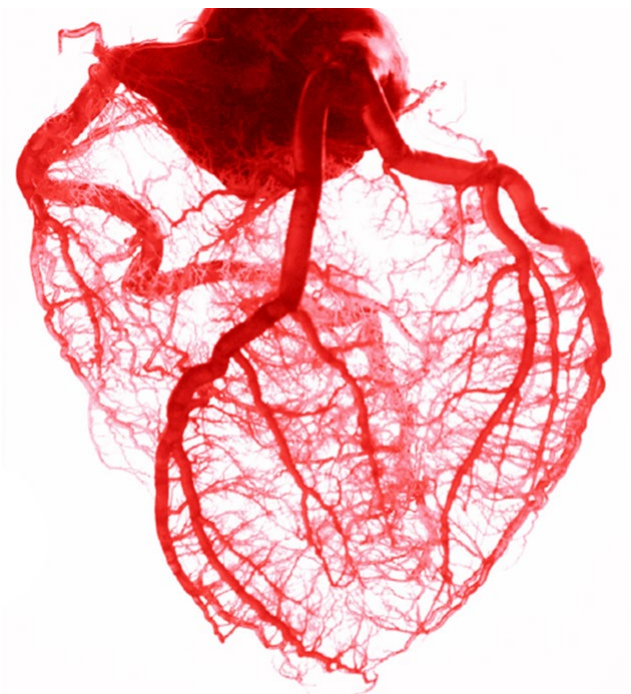
Coaxial Radial Access Site Delivery with Femoral Access Site Draw



The surgeon inserts catheters to acquire and deliver SSO₂ through autologous arterial blood line from the femoral artery, with the tip of the SSO₂ catheter located in the left main ostium. The unique SSO₂ chamber pump mixes the arterial blood and supersaturated oxygen. The procedure is performed in a closed loop, continuous (60 minute) intraoperative SSO₂ perfusion and returns superoxygenated infusate through the femoral or radial artery.

SSO₂ Has A Favorable Safety Profile¹

- Noninferior rates of major adverse clinical events at 30 days^{1, 2}
- No toxicity to the coronaries, myocardium or end organs³



Effect of Supersaturated Oxygen Delivery on Infarct Size After Percutaneous Coronary Intervention in Acute Myocardial Infarction

Gregg W. Stone, Jack L. Martin, Menko-Jan de Boer, Massimo Margheri, Ezio Bramucci, James C. Blankenship, D. Christopher Metzger, Raymond J. Gibbons, Barbara S. Lindsay, Bonnie H. Weiner, Alexandra J. Lansky, Mitchell W. Krucoff, Martin Fahy, W. John Boscadin and for the AMIHOT-II Trial Investigators
Circ Cardiovasc Interv 2009;2;366-375; originally published online Sep 15, 2009;
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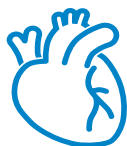
<http://circinterventions.ahajournals.org/cgi/content/full/2/5/366>

Data Supplement (unedited) at:

<http://circinterventions.ahajournals.org/cgi/content/full/CIRCINTERVENTIONS.108.840066/DC1>

SSO₂ Therapy May Reduce Death and Heart Failure at One Year¹⁻³

A 26% relative reduction in infarct size has been correlated with relative reductions in both death and heart failure hospitalization of ~25% at 1 year.^{2,3}



Event	IC-HOT (n=83)	INFUSE-AMI (n=83)	P-value
Death	0.0%	7.6%	0.012
Heart Failure (HF)	0.0%	7.4%	0.012
Death + HF	0.0%	12.3%	0.001

IC-HOT population compared to matched historical control group
Propensity score-matched comparison between IC-HOT and
INFUSE-AMI control group (no abciximab)

Repositioning and Rephrasing SSO₂ in ICD-10-PCS

- **Clinical data collection**: More precise ICD-10-PCS code will enable uniform hospital reporting and better collection of clinical data in current clinical practice and new clinical trials for cardiogenic shock and mechanical circulatory support.
- **Hospital perspectives**: SSO₂ has been mistaken by hospital coders as Extracorporeal Membrane Oxygenation (ECMO) and SSO₂ is not related to hyperbaric oxygenation (where it is currently tabled)
- **Reported**: as separate inpatient procedure in cath lab medical record (procedure report)
- **Commercial name**: TherOx Downstream System, Supersaturated Oxygen, Intra-Arterial Perfusion of SuperSaturated Oxygen

Background on Code Descriptor

- “SuperOxygenation Therapy” was presented at the ICD-9 Coordination and Maintenance Committee Meeting in September 2007.
 - The Committee approved: 00.49 Supersaturated Oxygen Therapy
- The ICD-10-PCS transitioned to
 - 5A0512C - Extracorporeal Supersaturated Oxygenation, Intermittent and
 - 5A0522C - Extracorporeal Supersaturated Oxygenation, Continuous
- Looking ahead, an FDA approved trial is investigating expanded use of SSO₂ in STEMI patients with cardiogenic shock and advanced mechanical circulatory support.

Thank You

Thank you for your consideration.

We welcome your questions and comments.

Appendix

Favorable Safety Profile¹

Following primary PCI in acute anterior STEMI, infusion of SSO2 via the LMCA was feasible and was associated with a favorable early safety profile.

TABLE 4 Adverse events occurring within 30 days

Eligible patients	N = 98
Net adverse clinical events	7 (7.1%)
Death	0 (0%)
Reinfarction	1 (1.0%)
TVMI	0 (0%)
Non-TVMI	1 (1.0%)
Q-wave	0 (0%)
Non-Q-wave	1 (1.0%)
Stent thrombosis, definite or probable	1 (1.0%)
Definite	1 (1.0%)
Probable	0 (0%)
Clinically driven TVR	1 (1.0%)
Clinically driven TLR	1 (1.0%)
PCI	1 (1.0%)
CABG	0 (0%)
TIMI major or minor bleed	4 (4.1%)
Major	0 (0%)
Minor	4 (4.1%)
Severe heart failure	1 (1.0%)
Readmission for heart failure	1 (1.0%)
Stroke or transient ischemic attack	0 (0%)
Myocardial rupture	0 (0%)
Target lesion failure	1 (1.0%)

ORIGINAL STUDIES

Evaluation of intracoronary hyperoxemic oxygen therapy in acute anterior myocardial infarction: The IC-HOT study

Shukri W. David MD¹ | Zubair A. Khan MD^{1,2} | Nainesh C. Patel MD³ |
D. Christopher Metzger MD⁴ | Frances O. Wood MD⁵ | Hal S. Wasserman MD⁶ |
Amir S. Lotfi MD⁷ | Ivan D. Hanson MD⁸ | Simon R. Dixon MBChB⁹ |
Thomas A. LaLonde MD⁹ | Philippe G  n  reux MD^{10,11,12} | Melek Ozgu Ozan MS¹² |
Akiko Maehara MD^{12,13} | Gregg W. Stone MD^{12,13}

Results 30 Days after Therapy

SSO2 delivery was successful in 98% of patients.

NACE (Net Adverse Clinical Events) at 30 days occurred in 7.1% of patients (meeting the primary safety endpoint of the study [less than 10.7%]);

- there were no deaths
- only one stent thrombosis and
- one case of severe heart failure.
- Most adverse events were minor bleeding.