

TherOx |

SSO₂ Therapy Patient Considerations

Indications for Use

The TherOx® System is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO₂) 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.

Patient Selection Criteria

- Patient must be ≥ 18 years and < 80 years of age.
- Less than 6 hours from symptom onset to successful reperfusion by means of PCI with stenting of left anterior descending coronary artery ST-elevation AMI.
- Successful revascularization by means of PCI with stenting as documented by < 50% diameter residual stenosis and TIMI flow grade II or III in the target vessel.
- Systemic arterial pO₂ greater than or equal to 10.7 kPa or 80 mmHg with supplemental oxygen.

Contraindications

- Ipsilateral insertion of a second sheath in a single femoral artery for SuperSaturated Oxygen Therapy is strictly contraindicated.
- Presence of an intra-aortic balloon pump.
- Proximal coronary stenosis that restricts flow with the SSO₂ Catheter in place.
- Presence of a post-intervention non-stented coronary dissection or perforation.
- Cardiac valvular stenosis or insufficiency, pericardial disease or non-ischemic cardiomyopathy.
- Pregnant or nursing women.
- Cardiogenic shock.
- Patients contraindicated for anticoagulation therapy.

- Subjects with ventricular pseudoaneurysm, VSD, or severe mitral valve regurgitation (with or without papillary muscle rupture).
- Hemoglobin < 10 g/dL.
- Gastrointestinal or genitourinary bleeding within the last two months, or any major surgery (including CABG) within the previous six weeks.

Patient-Related Warnings

- SuperSaturated Oxygen Therapy must be performed in the cardiac catheterization laboratory (cath lab). The patient must not be moved while the catheter is in place.
- Under no circumstances should the extracorporeal circuit be disconnected and restarted outside the cath lab.
- Do not use any type of catheter for SSO₂ Therapy other than the SSO₂ Catheter.
- The DownStream System may not be operated concomitantly with magnetic resonance imaging.
- Use aseptic technique throughout procedure.
- Use only 0.9% Normal saline (Isotonic solution).
- Do not exceed the SSO₂ Therapy duration of 60 minutes.
- Provide adequate anticoagulation prior to and during therapy per clinical practice standards. (Refer to anticoagulation section for details).



Anticoagulation Protocol

Bivalirudin is recommended for SSO₂ Therapy, but patient anticoagulation must consist of one of the following regimens:

- Bivalirudin and cangrelor, with provisional (bail-out) use of GP IIb/IIIa inhibitors allowed
- Bivalirudin, with provisional (bail-out) use of GP IIb/IIIa inhibitors allowed
- Heparin and cangrelor, with provisional (bail-out) use of GP IIb/IIIa inhibitors allowed
- Heparin and routine use of GP IIb/IIIa inhibitors

Procedural anticoagulation must consist of either bivalirudin with or without the addition of cangrelor (in which case GP IIb/IIIa inhibition is not recommended unless required for refractory procedural thrombotic complications) or heparin with either cangrelor or with routine use of a GP IIb/IIIa inhibitor. If a GP IIb/IIIa inhibitor is used, it should be continued during the SSO₂ infusion and for a total of at least 12 hours post procedure, as per standard of care. Intravenous cangrelor may also be used according to label per physician discretion, administered as a bolus plus infusion, with the infusion continued for 2-4 hours post-PCI.

If unfractionated heparin is selected, local dosing regimens may be used, although it is recommended that an initial bolus of 60 IU/kg is administered, followed by titration to the ACT of 200-250 seconds in patients receiving a GP IIb/IIIa inhibitor.

If bivalirudin is selected as the procedural anticoagulant, it should be administered as a bolus of 0.75 mg/kg IV prior to PCI, followed by an infusion of 1.75 mg/kg/h initiated as soon as possible. Intravenous cangrelor may also be used according to label per physician discretion, administered as a bolus plus infusion, with the infusion continued for 2-4 hours post-PCI.

Please refer to the Instructions for Use package insert for detailed instructions and a complete list of all contraindications, warnings, and precautions.

**For additional support, please contact our Technical Support Line:
1-800-699-4361. For Live Case Support, Press 1.**

Caution: Federal (USA) Law restricts this device to the sale by or on the order of a physician.

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