An early warning indicator of tissue hypoxia.

Continuous \( \text{ScvO}_2 \) monitoring with the PreSep oximetry catheter
Are your vital signs telling you everything?

Valuable time may be lost before traditional vital signs or intermittent ScvO₂ samplings indicate tissue hypoxia – potentially delaying intervention and putting the patient at greater risk. Continuously monitoring central venous oxygen saturation (ScvO₂), through the PreSep oximetry catheter, enables the early detection and management of tissue hypoxia.¹ ⁵

**ScvO₂ = Early Warning and Prevention**

<table>
<thead>
<tr>
<th>Hemodynamic Trends</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
</tr>
<tr>
<td>100</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

**Guides therapy and enables early intervention**

- Continuous ScvO₂ is a more sensitive indicator of tissue perfusion compared to intermittent sampling and traditional vital signs alone.¹ ⁵
- Continuous ScvO₂ monitoring reveals the true adequacy of tissue oxygenation, enabling early detection and assessment of clinical response to intervention.¹ ²
- Continuous ScvO₂ highly correlates and trends with SvO₂¹ ² while providing the same utility in monitoring, which is essential in defining the adequacy of cardiac output.⁷

**Convenient, accurate and easy-to-use**

- The first proven triple lumen catheter with continuous ScvO₂ monitoring
- Accurate versus CO-oximeter⁶
- Simple to use – uses same insertion techniques as that of a central line
- Designed for use with Edwards oximetry monitors and optical cables

---

PreSep Oligon oximetry catheter with integrated antimicrobial protection†
ScvO\textsubscript{2} monitoring of at-risk patients.

The prognostic value of ScvO\textsubscript{2}\textsuperscript{2} has been demonstrated in post-op high-risk surgeries,\textsuperscript{9} trauma,\textsuperscript{4} sepsis,\textsuperscript{8,10} cardiac failure in CHF\textsuperscript{5,10} and recovery in cardiac arrest.\textsuperscript{11,12}

**High-risk surgery**

Reductions in ScvO\textsubscript{2} are common after major surgery and are independently associated with post-operative complications.\textsuperscript{9} ScvO\textsubscript{2} monitoring in high-risk surgery has multiple applications in the intra- and post-op stages, including:

- Risk for high blood loss, such as hepatic resections, trauma, vascular cases
- High fluid shifts in gastrointestinal cases
- Tolerance of single-lung ventilation in thoracic procedures

Early treatment directed to maintain extraction ratio at < 27% reduces organ failures and hospital stay of high-risk surgical patients.\textsuperscript{15}

**Intensive care**

An ScvO\textsubscript{2} reading of less than 60% on unplanned admission to the ICU was associated with high mortality rates.\textsuperscript{14} Types of ICU patients affected include those with:

- Heart failure
- Complex respiratory disease
- Coagulopathies
- Burns
- Trauma
- Sepsis

- Up to 50% of critically ill patients resuscitated from shock may have continued global tissue hypoxia despite the normalization of vital signs and CVP\textsuperscript{2}

- Up to 39% of trauma patients have tissue hypoxia (ScvO\textsubscript{2} < 65%) despite stable vital signs\textsuperscript{1}

---

PreSep oximetry catheter
Sepsis

Evidence-based protocols, such as Early Goal-Directed Therapy (EGDT), have been shown to be effective at improving patient costs and outcomes, including significant reductions in sepsis-related mortality. EGDT with the PreSep oximetry catheter has been shown to:

- Reduce in-hospital mortality by 34% in adult patients with severe sepsis and septic shock when used with Early Goal-Directed Therapy\(^7,8\)
- Reduce in-hospital length-of-stay by 3.8 days\(^7,8\)
- Reduce hospital charges by $12,000\(^8\)

Screen Early for At-Risk Patients

<table>
<thead>
<tr>
<th>2 Signs of the Systemic Inflammatory Response Syndrome (SIRS)(^4)</th>
<th>Sign of Global Tissue Hypoxia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp C(^\circ) &lt; 36(^\circ)C or &gt; 38(^\circ)C</td>
<td>Systolic BP ≤ 90 mm Hg</td>
</tr>
<tr>
<td>HR &gt; 90 beats/min</td>
<td>Or</td>
</tr>
<tr>
<td>Resp &gt; 20 breaths/min or PaCO(_2) &lt; 32 mm Hg</td>
<td>Lactate ≥ 4 mmol/L</td>
</tr>
<tr>
<td>WBC &gt; 12,000/mm(^3) or &lt; 4,000/mm(^3) or &gt;10% immature bands</td>
<td></td>
</tr>
</tbody>
</table>

Early Goal-Directed Therapy Treatment Protocol\(^7\)

- Supplemental oxygen ± endotracheal intubation and mechanical ventilation
- Central venous oximetry catheter and continuous arterial pressure monitoring
- Sedation, paralysis (if intubated), or both
  - CVP ≤ 8 mm Hg
  - 8-12 mm Hg
  - ≥ 12 mm Hg
- MAP
  - < 65 mm Hg
  - ≥ 65 mm Hg
- ScvO\(_2\)
  - < 70%
  - ≥ 70%
- Goals Achieved
  - Transfusion of red cells until hematocrit ≥ 30%
  - Inotrope Agents
    - Vasoactive Agents
    - Crystalloid
    - Colloid
  - No
  - Yes
  - Hospital Admission

Septic patients are still not being adequately resuscitated early enough in the course of illness… targeting this resuscitation to clearly defined and easily measurable end-points is the most appropriate course of action.\(^{16}\)
Balance of oxygen delivery and consumption for high-risk surgical, intensive care and sepsis patients.

In the critically ill, traditional vital signs may be late indicators of compromised or inadequate oxygen delivery to the tissues. Continuous ScvO\textsubscript{2} monitoring is key to assessing the adequacy of the balance of oxygen delivery and consumption. The goal of continuous ScvO\textsubscript{2} monitoring with the PreSep oximetry catheter is to bring into balance the relationship between oxygen consumption and oxygen delivery to improve the care of high-acuity patients.\textsuperscript{13}

For over 30 years, Edwards Lifesciences has been helping critical care clinicians worldwide. From developing the gold standard Swan-Ganz catheter, to offering the first continuous central venous oximetry catheter, Edwards continues its heritage as a global leader in hemodynamic monitoring and patient insight.

Visit www.Edwards.com/PreSep or call us at 800.424.3278 for more information.
Presep oximetry catheter specifications

<table>
<thead>
<tr>
<th>Model Description</th>
<th>Oligon Antimicrobial Material</th>
<th>Continuous SVC02</th>
<th>Lumens</th>
<th>Length cm</th>
<th>Size F (mm)</th>
<th>Lumen Size Gauge (mm)</th>
<th>Recommended Dilator F (mm)</th>
<th>Minimum Guidewire Size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PreSep oximetry catheter</td>
<td>Yes</td>
<td></td>
<td>3</td>
<td>16* 20</td>
<td>8.5 (2.83)</td>
<td>15 (1.77)</td>
<td>18 (1.33)</td>
<td>10.5 (3.5)</td>
</tr>
<tr>
<td>PreSep Oligon oximetry catheter</td>
<td>Yes</td>
<td></td>
<td>3</td>
<td>16* 20</td>
<td>8.5 (2.83)</td>
<td>15 (1.77)</td>
<td>18 (1.33)</td>
<td>10.5 (3.5)</td>
</tr>
</tbody>
</table>

*6cm length available in the U.S. only. **PreSep catheters are designed for use with Edwards Lifesciences oximetry monitors and OMO Optic Modules to continuously monitor ScvO2. PreSep catheters are available with AMC Thromboshield, an antibacterial heparin coating that decreases visible microbe count on the surface of product during handling and placement. PreSep Oligon oximetry catheters contain an integrated Oligon antimicrobial material. The activity of the antimicrobial material is localized at the catheter surfaces and is not intended for treatment of systemic infections. In vitro testing demonstrated that the Oligon material provided broad spectrum effectiveness (a 3 log reduction from initial concentration within 48 hours) against the organisms tested: Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Klebsiella pneumoniae, Acinetobacter baumannii, Stenotrophomonas maltophilia, Enterococcus faecalis, Enterococcus faecium, Pseudomonas aeruginosa, Staphylococcus epidermidis, Escherichia coli, Klebsiella pneumoniae, Acinetobacter baumannii, Stenotrophomonas maltophilia, Enterococcus faecalis, Enterococcus faecium.

Vigileo monitor product specifications

- Color Display: 5.2 in. (132.5 mm) x 3.9 in. (99.4 mm) TFT | 640 x 480 pixels
- Power/Electrical: AC Mains: 100-240 VAC, 50/60 Hz | 1A maximum consumption
- Trend Range: 0.1 – 72 hours
- Size: H: 7.3 in. (185.4 mm) | W: 10.7 in. (271.8 mm) | D: 8.4 in. (213.4 mm)
- Weight: 6 pounds (2.73 kg) | IV pole-mount capability
- Bi-directional Patient Monitor Communications: Analog input/output (selectable voltage) | Input: 0 to 1V, 0 to 5V, 0 to 10V | Output: 0 to 1V, 0 to 10V
- Digital input/output, serial communication interface (RS232)
- Maximum data rate — 57.6 kilobaud
- Printer Communications: USB Port: V1.1-compatible type A connector

References:
17. Adapted with permission from Rivers et al. Early Goal-Directed Therapy in the Treatment of Severe Sepsis and Septic Shock. New England Journal of Medicine 2001;345(18):1368-77, Figure 2.

Dr. Emanuel Rivers is a paid consultant of Edwards Lifesciences. Rx only. See instructions for use for full prescribing information.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 8 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards is a trademark of Edwards Lifesciences Corporation. Edwards Lifesciences, the stylized E logo, AMC Thromboshield, PreSep, Swan-Ganz and Vigileo are trademarks of Edwards Lifesciences Corporation and are registered in the United States Patent and Trademark Office. Oligon is a trademark of Implanted, Inc. Early Goal-Directed Therapy and EGDT are trademarks of Dr. Emanuel Rivers.

©2008 Edwards Lifesciences LLC. All rights reserved. AR03768

Visit www.Edwards.com/PreSep or call us at 800.424.3278 for more information.