THE RISKS ARE VERY REAL

In clinical trials, cerebral desaturation during cardiac surgery is associated with:

- Postoperative MOMM³
- Neurologic injury⁴,⁶,⁷
- Increased time on mechanical ventilation⁸
- Prolonged hospital stay³,⁴

Cerebral oximetry enables detection of desaturation, prompt intervention and improved patient outcomes.³*

* Interventions to return the patient’s rSO₂ to baseline using the INVOS™ system have been shown to improve outcomes after surgery
PUBLISHED CLINICAL EVIDENCE

Reduction in Major Organ Morbidity & Mortality (MOMM):³

- Death within 30 days
- Neurological injury including permanent stroke
- Need for ventilation (>48 hours)
- Renal failure requiring dialysis
- Re-operation for any reason
- Mediastinitis/deep sternal infection

KEY FINDINGS
Significant reduction in MOMM

No rSO₂  11%
INVOS™  3% System

INVOS™ System Comparative Effectiveness Analysis Results | February 2017
INVOSTM system use on cardiac surgery patients reduced permanent stroke, prolonged mechanical ventilation and length of hospital stay.\(^9\)

**KEY FINDINGS**

50% reduction in permanent stroke
- No rSO\(_2\) monitoring: 2%
- INVOS\(^\text{TM}\) system: <1%

Over 35% reduction in need for prolonged mechanical ventilation
- No rSO\(_2\): 10.6%
- INVOS\(^\text{TM}\) system: 6.8%
THE OPPORTUNITY

What is the INVOS™ system?

- Cerebral/somatic oxygenation monitor
- Using INVOS™ system monitoring may:
  - Expedite interventions\textsuperscript{10, 11}
  - Reduce postoperative complications\textsuperscript{3, 6, 9}
  - Reduce length of ICU and hospital stays\textsuperscript{3, 9}
  - Contribute to lower cost of care\textsuperscript{3, 9, 12}
  - Help improve outcomes following cardiac surgery\textsuperscript{3}
- Only technology specifically used in 600+ published, peer-reviewed articles\textsuperscript{13}

The top-ranked U.S. hospitals for cardiology and heart surgery, as identified by U.S. News & World Report,\textsuperscript{13} use INVOS™ technology

- 19 of the top 25 hospitals with adult cardiac programs
- 20 of the top 25 hospitals with pediatric programs
WHAT IF YOU COULD PREVENT COMMON, COSTLY AND DEBILITATING COMPLICATIONS IN YOUR CARDIAC OR?

**Our goal**
To prove the INVOS™ cerebral/somatic monitoring system has a definitive and measured association with **reduced complications, lowered costs and better outcomes in cardiac surgery**

**Did we succeed?**
Let’s review the results of our comparative effectiveness analysis of INVOS™ monitoring in cardiac surgeries
THE SOCIETY OF THORACIC SURGERY (STS)

- Non-profit organization founded in 1964 representing more than 7400 surgeons, researchers, and allied health professionals worldwide.
- Dedicated to ensuring the best possible outcomes for all surgical procedures involving the chest.
- Mission: to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.\(^\text{14}\)

STS Database

- Established in 1989 as a world registry for cardiac surgery. The purpose of this database was quality improvement and patient safety among cardiothoracic surgeons.
- Contains approximately 5.9 million surgical records and gathers information from 90% of facilities that perform cardiac surgery in the US.\(^\text{15}\)

STS Risk Calculator

- Users can calculate a patient’s risk of mortality and other morbidities, such as long length of stay and renal failure based on the patient’s risk factors.\(^\text{16}\)
COMPARATIVE EFFECTIVENESS
NEW FINANCIAL EVIDENCE

Collected 10,778 cases as submitted to and approved by STS:

- Across seven cardiac centers
- Spanning 5 years
- Data ratio:
  - 49% with the INVOS™ system
  - 51% without the INVOS™ system

![Bar chart showing procedure types with and without INVOS™](chart.png)
SURGICAL COMPLICATIONS
NOT EASILY PREDICTABLE

In analyzing STS data from 10,778 cases, the favorable association the INVOS™ monitoring system had on the incidence of complications was greater than expected. Non-users had more cases with renal failure than expected. Non-users had more cases with stroke than expected. Non-users had more cases of prolonged ventilation than expected. Users had fewer cases of renal failure. Users had fewer cases of stroke. Users had the expected number of cases of prolonged ventilation.
OUTCOME IMPROVEMENT AND COST AVOIDANCE
RENAL FAILURE

<table>
<thead>
<tr>
<th>OCCURRENCE</th>
<th>INVOS™ System</th>
<th>Non-INVOS™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Cases = 320</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected</td>
<td>232</td>
<td>211</td>
</tr>
<tr>
<td>Observed</td>
<td>106</td>
<td>214</td>
</tr>
<tr>
<td>Avoided Complication</td>
<td>(126)</td>
<td>+3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COST OF COMPLICATION</th>
<th>INVOS™ System</th>
<th>Non-INVOS™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Direct Cost/Case</td>
<td>$32,508</td>
<td>$41,879</td>
</tr>
<tr>
<td>Avoided/Incremental Cost</td>
<td>($4,096,008)</td>
<td>+$125,637</td>
</tr>
<tr>
<td>Total Cost Benefit</td>
<td>$4,221,645</td>
<td></td>
</tr>
</tbody>
</table>

Cost Impact of Renal Failure

- Median Cost/Renal Failure Case
- Total (Avoided)/Incurred Cost

Total Number of Cases = 320
Expected 232, Observed 106
Avoided Complication (126) +3

Total Cost Benefit $4,221,645
OUTCOME IMPROVEMENT AND COST AVOIDANCE
NEUROLOGICAL INJURY - STROKE

<table>
<thead>
<tr>
<th>OCCURRENCE</th>
<th>INVOS™ System</th>
<th>Non-INVOS™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occurrence of Complication (Total n=145)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected</td>
<td>71</td>
<td>71</td>
</tr>
<tr>
<td>Observed</td>
<td>53</td>
<td>92</td>
</tr>
<tr>
<td>Avoided Complications</td>
<td>(18)</td>
<td>+21</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COST OF COMPLICATION</th>
<th>INVOS™ System</th>
<th>Non-INVOS™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of Complication/Case</td>
<td>$33,360</td>
<td>$43,892</td>
</tr>
<tr>
<td>Avoided/Incremental Cost</td>
<td>($600,480)</td>
<td>+$921,732</td>
</tr>
<tr>
<td>Total Cost Benefit</td>
<td></td>
<td>$1,522,212</td>
</tr>
</tbody>
</table>

1. Data source: INVOS Comparative Effectiveness Analysis, September 2015
OUTCOME IMPROVEMENT AND COST AVOIDANCE
PROLONGED MECHANICAL VENTILATION (MV)\textsuperscript{17}

<table>
<thead>
<tr>
<th>OCCURRENCE</th>
<th>INVOS™ System</th>
<th>Non-INVOS™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Cases = 1,249</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected</td>
<td>614</td>
<td>594</td>
</tr>
<tr>
<td>Observed</td>
<td>616</td>
<td>633</td>
</tr>
<tr>
<td>Avoided Complications</td>
<td>+2</td>
<td>+39</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>COST OF COMPLICATION</th>
<th>INVOS™ System</th>
<th>Non-INVOS™ System</th>
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</thead>
<tbody>
<tr>
<td>Cost of Complication/Case</td>
<td>$51,215</td>
<td>$56,227</td>
</tr>
<tr>
<td>Incremental Cost</td>
<td>+$102,430</td>
<td>+$2,192,853</td>
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<tr>
<td>Total Cost Benefit</td>
<td></td>
<td>$2,090,423</td>
</tr>
</tbody>
</table>

Cost Impact of Prolonged MV

1. Data source: INVOS Comparative Effectiveness Analysis, September 2015
### OUTCOME IMPROVEMENT AND COST AVOIDANCE

#### 30-DAY READMISSION RATES

<table>
<thead>
<tr>
<th>OCCURRENCE</th>
<th>USER</th>
<th>NON-USER</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%) of cases readmitted within 30 days</td>
<td>302 (5.2%)</td>
<td>536 (9.7%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Cost Associated with 30-Day Readmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>User</td>
<td></td>
</tr>
<tr>
<td>Non-user</td>
<td></td>
</tr>
</tbody>
</table>
### OUTCOME IMPROVEMENT AND COST AVOIDANCE

**MORTALITY**

<table>
<thead>
<tr>
<th>OCCURRENCE</th>
<th>USER</th>
<th>NON-USER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observed Rate</td>
<td>158 (3.0%)</td>
<td>209 (3.8%)</td>
</tr>
</tbody>
</table>

![Image of surgical setting with monitoring equipment]

**Observed Mortality**

![Bar chart showing observed mortality rates for user and non-user groups]

INVOSTM System Comparative Effectiveness Analysis Results | February 2016
THE HOSPITAL’S BOTTOM LINE
OBSERVED IMPACT ON CONTRIBUTION MARGIN

Per 1,000 patients

$185,000 INVOS™ system spend

($1,459,362) Stroke, Renal Failure, Prolonged Vent Cost Avoidance

789% Hospital ROI
THE OPPORTUNITY
CASE VARIABILITY AND IMPACT ON PROFIT

CV Surgery Program Profitability

INVOS™ system users demonstrated a strong association with surgical complication reduction and contribution margin improvements.¹⁷

INVOS™ system user
Non-user
## SUMMARY OF REDUCTION IN COMPLICATIONS AND COST AVOIDANCE

### INVOSTM System Comparative Effectiveness Analysis Results | February 2017

<table>
<thead>
<tr>
<th></th>
<th>INVOS™ System Observed-Expected</th>
<th>Non-INVOSTM System Observed-Expected</th>
<th>Avoided Complications with INVOS™ System Use on All Patients</th>
<th>Cost Avoidance</th>
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</thead>
<tbody>
<tr>
<td><strong>Number of Patients</strong></td>
<td>5,271</td>
<td>5,506</td>
<td></td>
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</tr>
<tr>
<td><strong>Renal Failure</strong></td>
<td>-126</td>
<td>3</td>
<td>129</td>
<td>$4,221,645</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>-18</td>
<td>21</td>
<td>39</td>
<td>$1,522,212</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prolonged Mech Vent</strong></td>
<td>2</td>
<td>39</td>
<td>37</td>
<td>$2,090,423</td>
</tr>
<tr>
<td></td>
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<tr>
<td><strong>Totals</strong></td>
<td></td>
<td></td>
<td>205</td>
<td>$7,834,280</td>
</tr>
</tbody>
</table>
QUESTIONS?
REFERENCES


REFERENCES


17. Medtronic Internal Sales FY15; INVOS Comparative Effectiveness Analysis, September 2015.

18. PotentiaMED Proprietary Database.