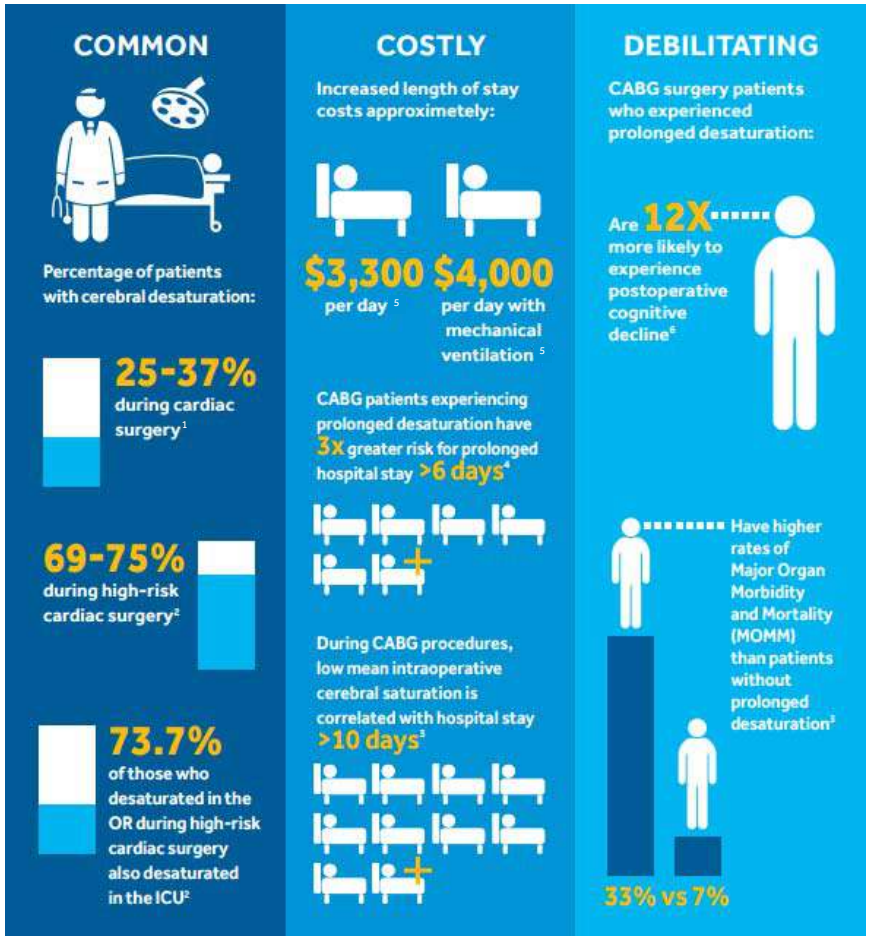
IMPACT OF CEREBRAL OXIMETRY MONITORING:

MITIGATING SURGICAL COMPLICATIONS IN THE CARDIAC OPERATING ROOM

Medtronic
Further, Together

SURGICAL COMPLICATIONS
COMMON, COSTLY & DEBILITATING



THE RISKS ARE VERY REAL

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

- Postoperative MOMM[3]
- Neurologic injury[4,6,7]
- Increased time on mechanical ventilation[8]
- Prolonged hospital stay[3,4]

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

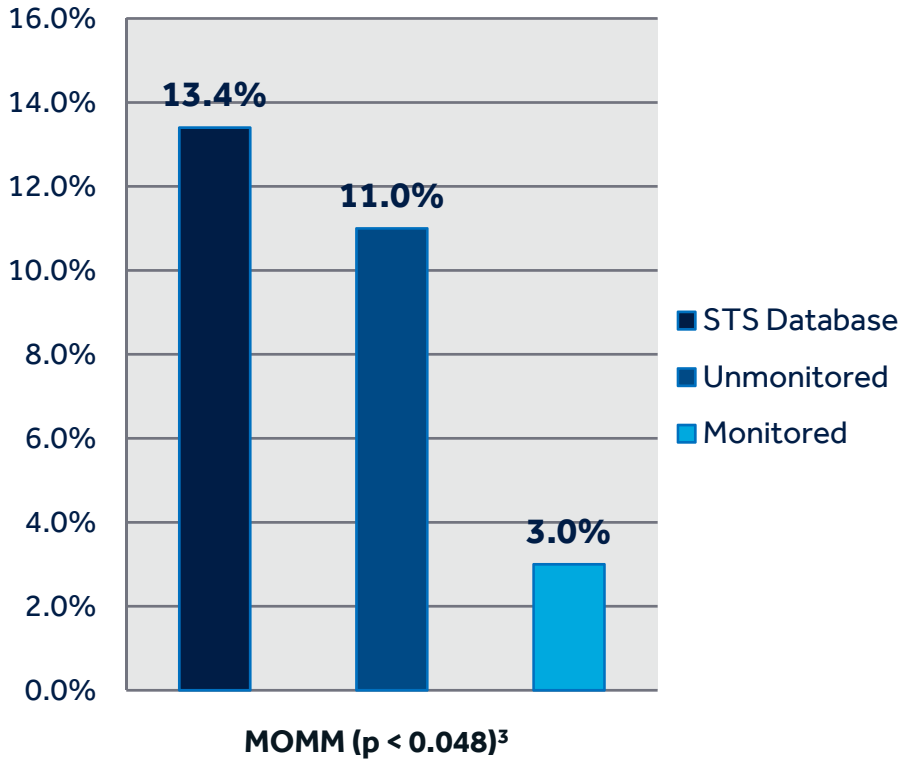
* Interventions to return the patient's rSO_2 to baseline using the INVOS™ system have been shown to improve outcomes after surgery

Medtronic

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

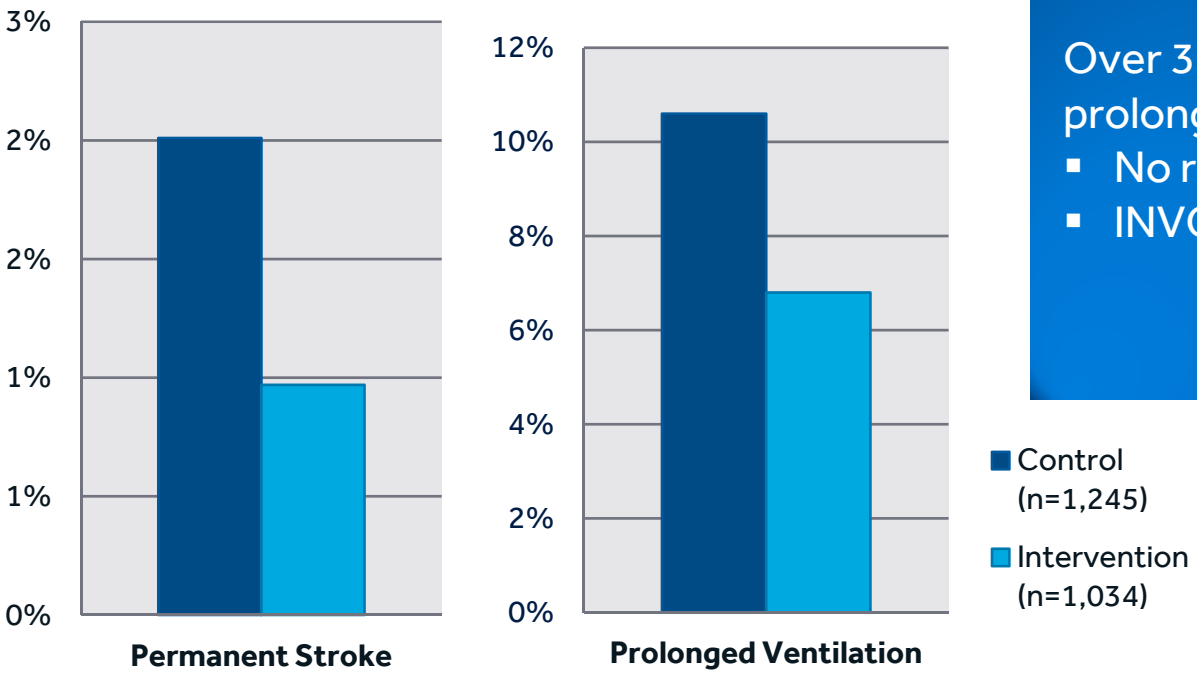
No rSO_2 11%

INVOS™ System 3%

Medtronic

PUBLISHED CLINICAL EVIDENCE

INVOS™ 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™ system <1%

Over 35% reduction in need for prolonged mechanical ventilation

- No rSO_2 - 10.6%
- INVOS™ system- 6.8%

Medtronic

THE OPPORTUNITY

What is the INVOS™ system?

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

The top-ranked U.S. hospitals for cardiology and heart surgery, as identified by U.S. News & World Report,[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

Medtronic
Further, Together

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.[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.[15]

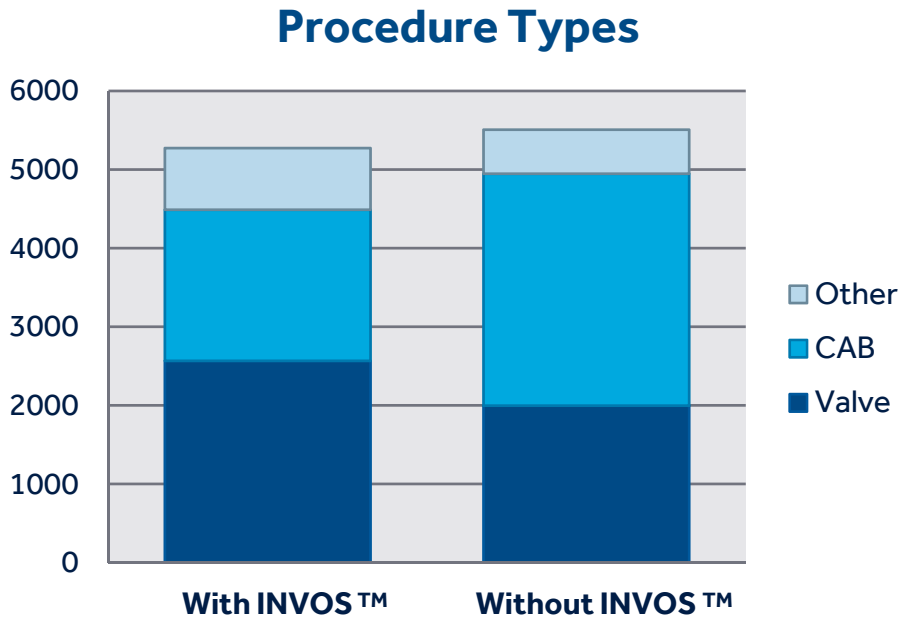
STS Risk Calculator

- 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.[16]

COMPARATIVE EFFECTIVENESS
NEW FINANCIAL EVIDENCE[17]

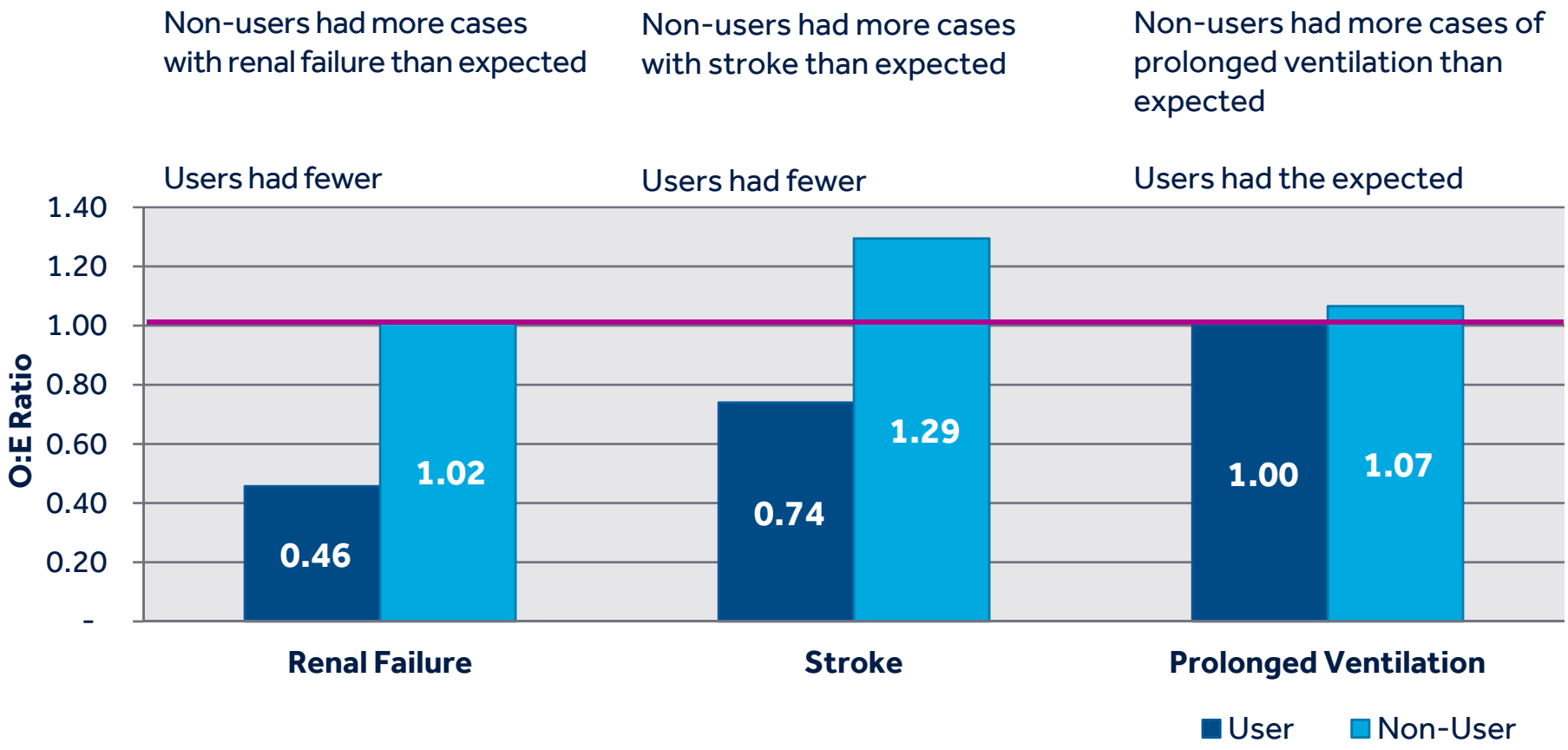
Collected 10,778 cases as submitted to and approved by STS:

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



SURGICAL COMPLICATIONS
NOT EASILY PREDICTABLE

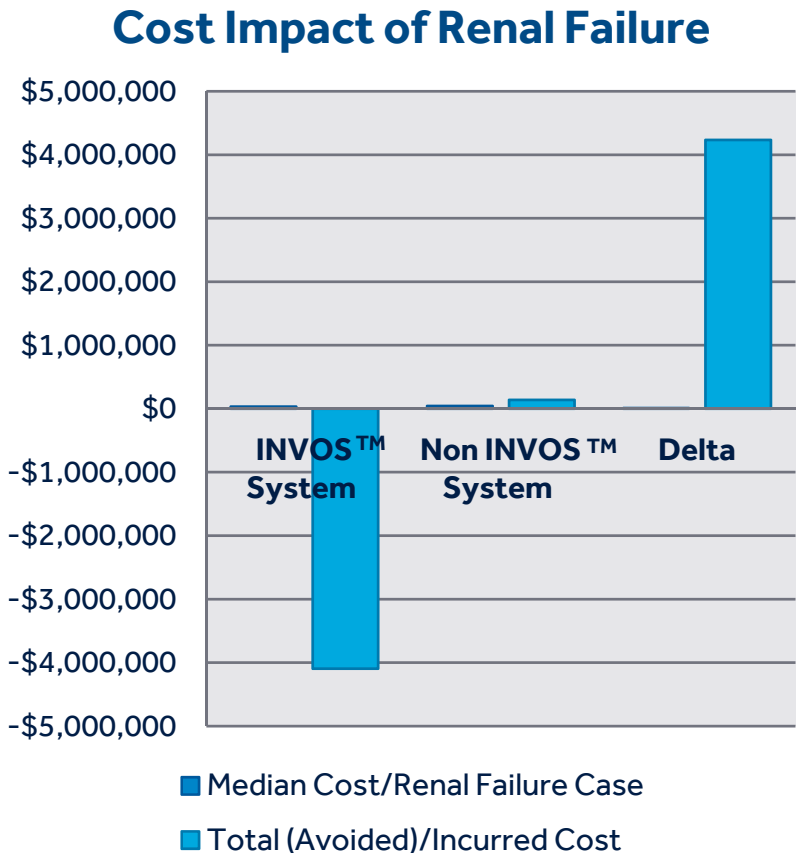
In analyzing STS data from 10,778 cases, the favorable association the INVOS™ monitoring system had on the incidence of complications was greater than expected[17]



OUTCOME IMPROVEMENT AND COST AVOIDANCE
RENAL FAILURE[17]

OCCURRENCE	INVOS ™ System	Non-INVOS™ System
Total Number of Cases = 320		
Expected	232	211
Observed	106	214
Avoided Complication	**(126)**	**+3**

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



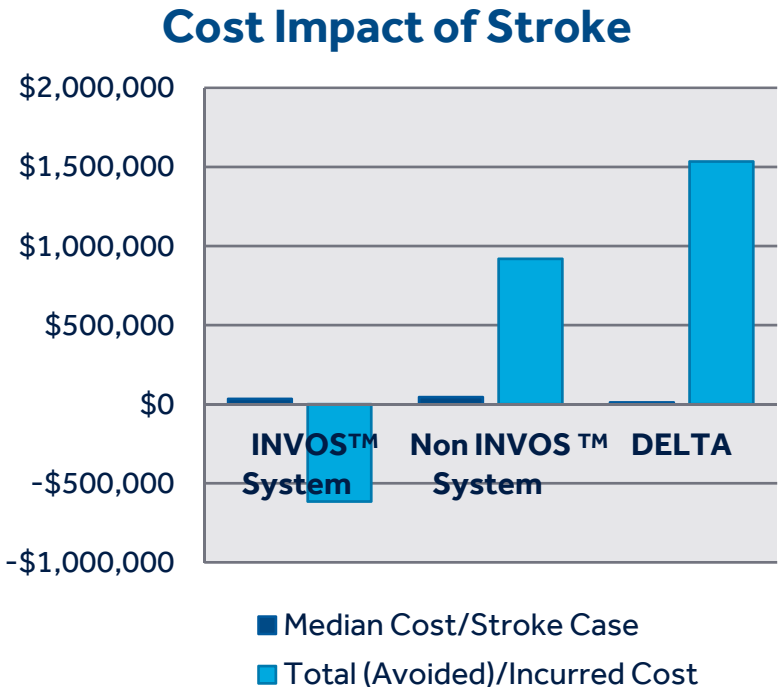
Medtronic

OUTCOME IMPROVEMENT AND COST AVOIDANCE

NEUROLOGICAL INJURY - STROKE[17]

OCCURRENCE	INVOS ™ System	Non-INVOS™ System
Occurrence of Complication (Total n=145)		
Expected	71	71
Observed	53	92
Avoided Complications	**(18)**	**+21**

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



1. Data source: INVOS Comparative Effectiveness Analysis, September 2015

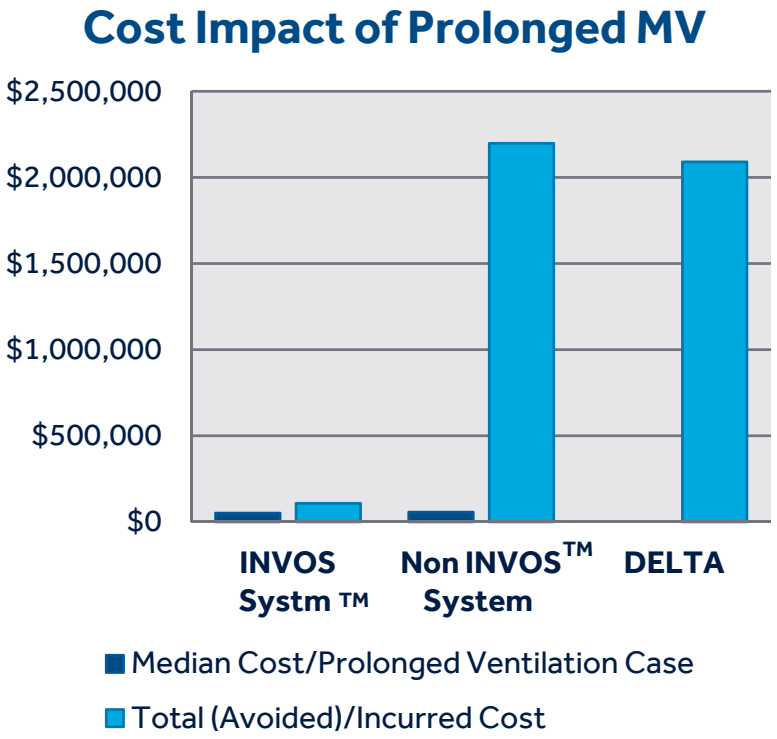
Medtronic

OUTCOME IMPROVEMENT AND COST AVOIDANCE

PROLONGED MECHANICAL VENTILATION (MV)[17]

OCCURRENCE	INVOS ™ System	Non-INVOS ™ System
Total Number of Cases = 1,249		
Expected	614	594
Observed	616	633
Avoided Complications	**+2**	**+39**

COST OF COMPLICATION	INVOS ™ System	Non-INVOS™ System
Cost of Complication/Case	$51,215	$56,227
Incremental Cost	+$102,430	+$2,192,853
Total Cost Benefit		$2,090,423



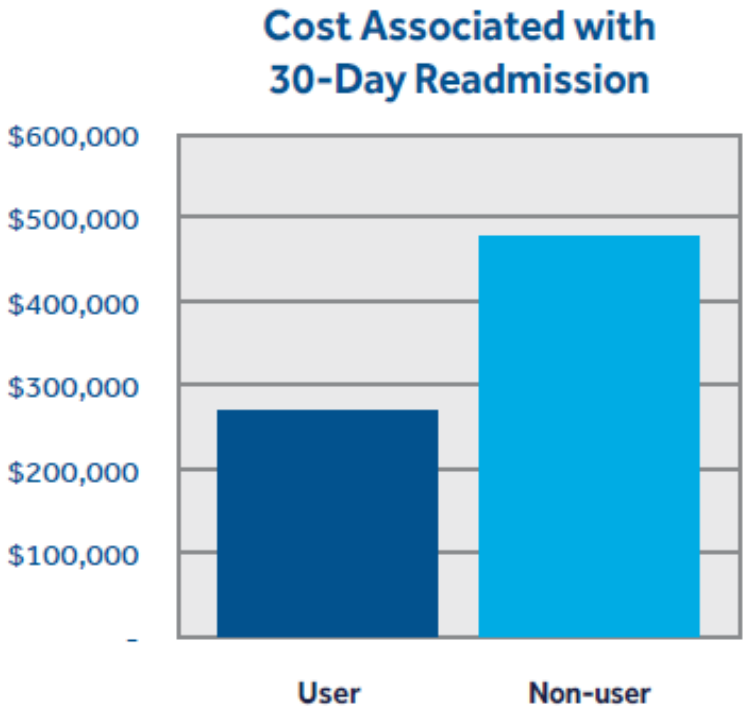
1. Data source: INVOS Comparative Effectiveness Analysis, September 2015

Medtronic

OUTCOME IMPROVEMENT AND COST AVOIDANCE

30-DAY READMISSION RATES[17]

OCCURRENCE	USER	NON-USER
N (%) of cases readmitted within 30 days	302 (5.2%)	536 (9.7%)

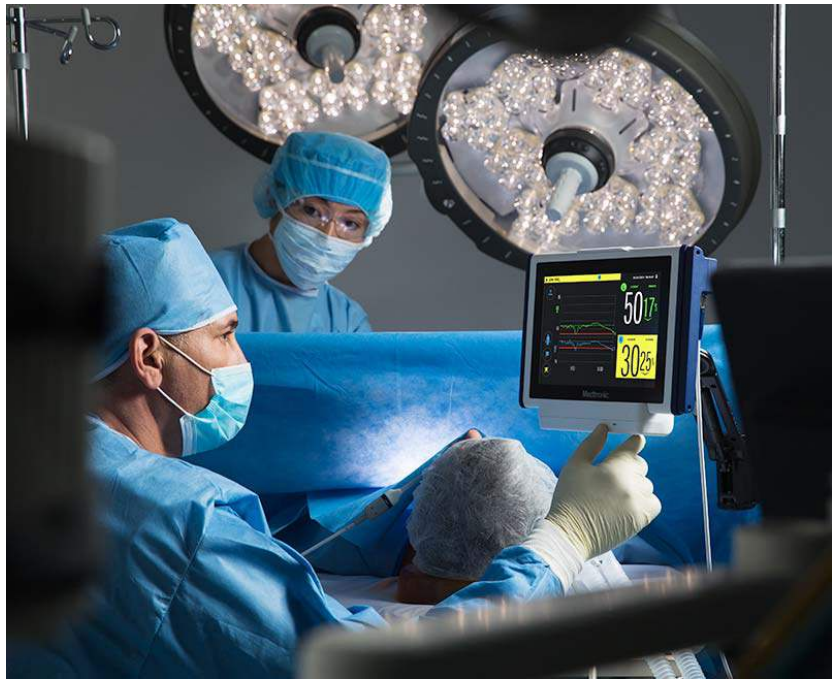


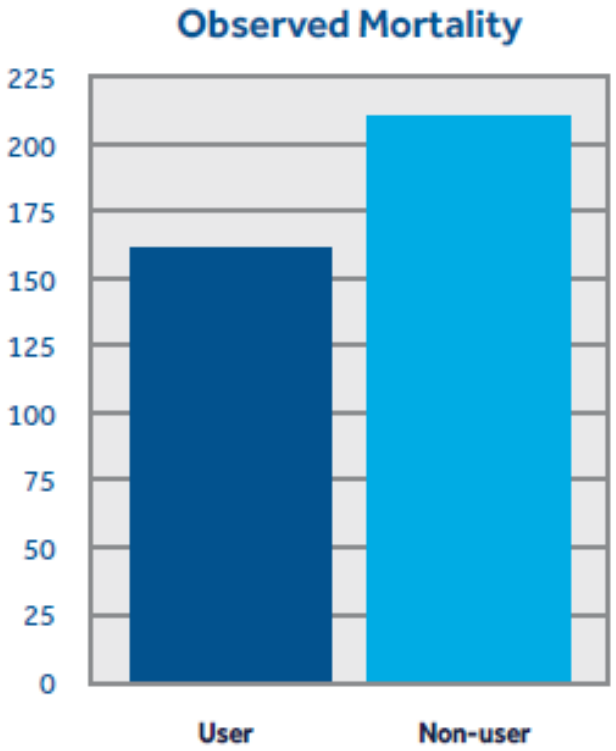
Medtronic

OUTCOME IMPROVEMENT AND COST AVOIDANCE

MORTALITY[17]

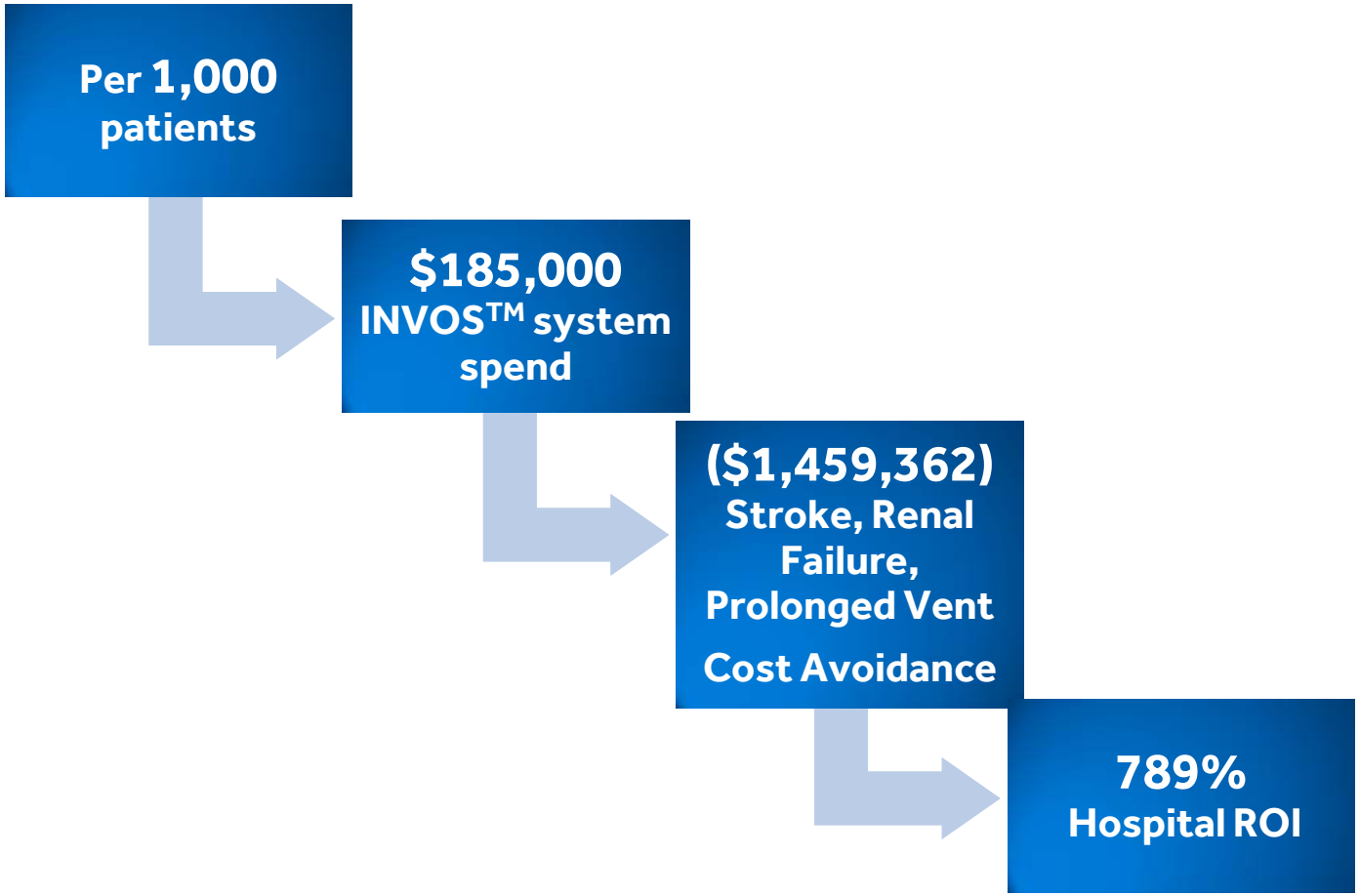
OCCURRENCE	USER	NON-USER
Observed Rate	158 (3.0%)	209 (3.8%)





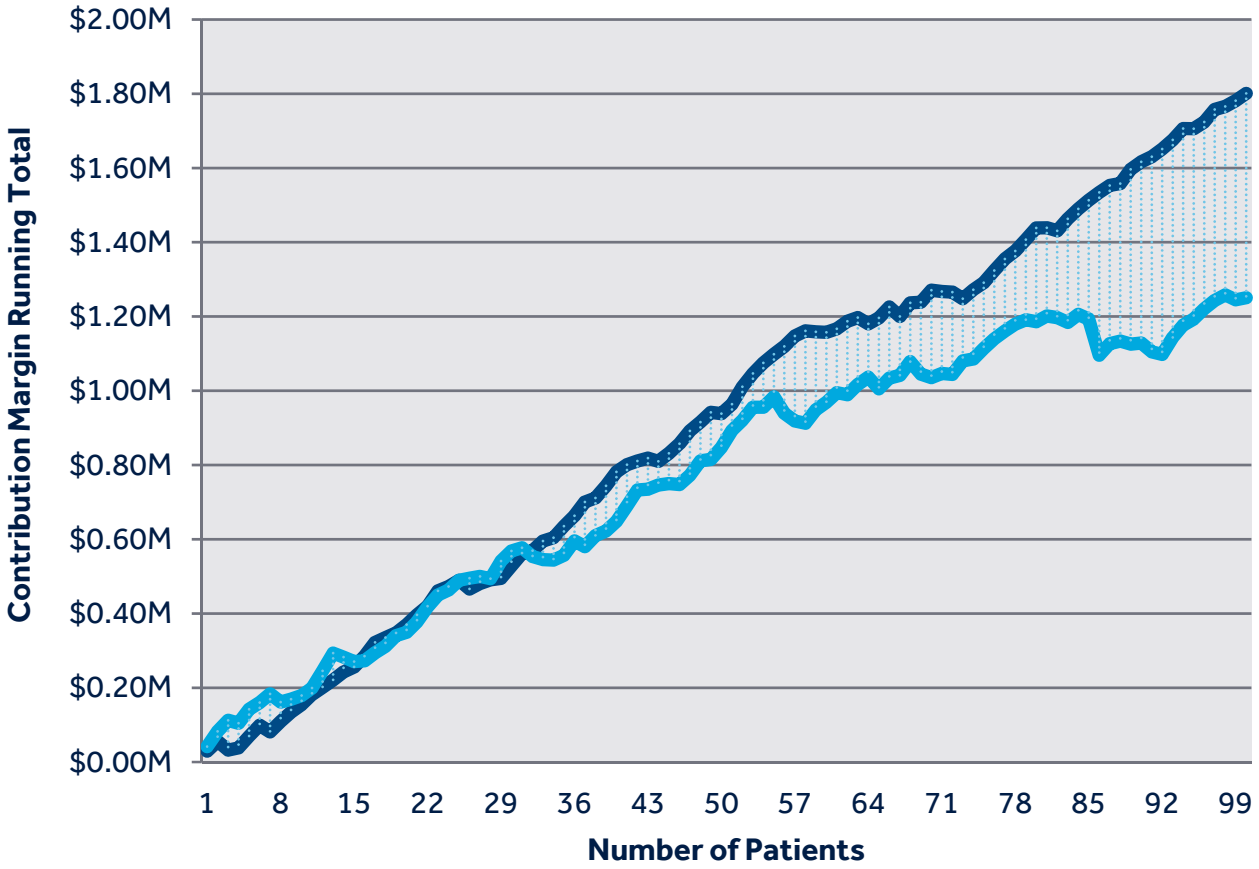
Medtronic

THE HOSPITAL'S BOTTOM LINE
OBSERVED IMPACT ON CONTRIBUTION MARGIN [17]



THE OPPORTUNITY
CASE VARIABILITY AND IMPACT ON PROFIT

CV Surgery Program Profitability[18]



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

INVOS™ system user
Non-user

Medtronic

SUMMARY OF REDUCTION IN COMPLICATIONS AND COST AVOIDANCE [17]

	INVOS™ System Observed-Expected	Non-INVOS™ System Observed-Expected	Avoided Complications with INVOS™ System Use on All Patients	Cost Avoidance
Number of Patients	5,271	5,506		
Renal Failure	-126	3	129	$4,221,645
Stroke	-18	21	39	$1,522,212
Prolonged Mech Vent	2	39	37	$2,090,423
Totals			*205*	*$7,834,280*

QUESTIONS?

Medtronic
Further, Together

REFERENCES

1. Schoen J, Husemann L, Tiemeyer C, et al. Cognitive function after sevoflurane vs propofol-based anaesthesia for on-pump cardiac surgery: a randomized controlled trial. *Br J Anaesth*. 2011;106 (6): 840-50.

2. Deschamps A, Lambert J, Couture P, et al. Reversal of decreases in cerebral saturation in high-risk cardiac surgery. *J Cardiothorac Vasc Anesth*. Available online 18 June 2013, ISSN 1053-0770.

3. Murkin JM, Adams SJ, Novick RJ, QuantzM, Bainbridge D, Iglesias I, Cleland A, Schaefer B, Irwin B, Fox S. Monitoring brain oxygen saturation during coronary bypass surgery: a randomized, prospective study. *Anesth Analg*. 2007;104(1):51–58.

4. Slater JP, Guarino T, Stack J, et al. Cerebral oxygen desaturation predicts cognitive decline and longer hospital stay after cardiac surgery. A*nn Thorac Surg*. 2009;87(1):36-44.

5. Dasta JF, McLaughlin TP, Mody SH, et al. Daily cost of an intensive care unit day: the contribution of mechanical ventilation. *Crit Care Med. 2005;33(6):1266-1271.*

6. Colak Z, Borojevic M, Bogovic A,et al. Influence of intraoperative cerebral oximetry monitoring on neurocognitive function after coronary artery bypass surgery: a randomized, prospective study. *Eur J Cardio Thorac Surg*. 2015;47(3):447-454. Epub 2014 May 7.

7. Yao FSF, Tseng CC, Ho CA, Levin SK, Illner P. Cerebral oxygen desaturation is associated with early postoperative neuropsychological dysfunction in patients undergoing cardiac surgery. *J Cardiothorac Vasc Anesth*. 2004;18:552-558.

8. Schön J, Serien V, Hanke T, et al. Cerebral oxygen saturation monitoring in on-pump cardiac surgery — a 1 year experience. *App Cardiopulm Pathophysiol*. 2009;13:243-52.

9. Goldman S, Sutter F, Ferdinand F, Trace C. Optimizing intraoperative cerebral oxygen delivery using noninvasive cerebral oximetry decreases the incidence of stroke for cardiac surgical patients. Heart Surg Forum. 2004;7(5):E376-381.

10. Prabhune A, Sehic A, Spence PA, Church T, Edmonds HL Jr. Cerebral oximetry provides early warning of oxygen delivery failure during cardiopulmonary bypass. *J Cardiothorac Vasc Anesth*. 2002; 16(2):204-6.

11. Moerman A, Vandenplas G, Bové T, Wouters PF, De Hert SG. Relation between mixed venous oxygen saturation and cerebral oxygen saturation measured by absolute and relative near-infrared spectroscopy during off-pump coronary artery bypass grafting. Br J Anaesth. 2013;110(2):258-265

REFERENCES

12. Goldman SM, Sutter FP, Wertan MC, Ferdinand FD, Trace CL, Samuels LE. Outcome improvement and cost reduction in an increasingly morbid cardiac surgery population. *Sem Cardiothorac Vasc Anesth*. 2006;10(2):171-175.

13. Medtronic data on file.

14. http://www.sts.org/about-sts

15. http://www.sts.org/sites/default/files/documents/pdf/pressreleases/STS%20Fact%20Sheet%202016%20November.pdf

16. http://www.sts.org/quality-research-patient-safety/quality/risk-calculator-and-models/risk-calculator

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

18. PotentiaMED Proprietary Database.