Evidence-Based Assessment of a Closed Blood Sampling System

Contents

Reflects an evidence-based assessment of the value of the VAMP system in context of:

Meeting the challenges of the new healthcare landscape

In a changing healthcare landscape, hospitals need to achieve new quality standards for patient care while balancing an increasing cost burden. Evidence-based decision-making, and measures such as value-based purchasing (VBP), have become essential in hospital healthcare reform, allowing for increased positive outcomes with the provision of cost-effective care.

Blood sampling is a routine and vital procedure conducted frequently in the hospital setting; however, it can be associated with a large amount of blood loss[1-7], unnecessary blood waste[3, 6, 8-12], and risk of contamination[13-16]. This can have important clinical consequences such as anemia[5, 17-22], transfusions[19, 23, 24], and infections which can result in poor patient outcomes[1, 22, 25], as well as increased hospital costs[26, 27].

The VAMP (Venous Arterial blood Management Protection) system is an evidence-based solution that combines the safety and simplicity of needleless blood sampling with a unique reservoir designed to conserve blood by allowing the clinician to re-infuse excess blood not needed for the sample. Several clinical studies have demonstrated improved patient outcomes with the VAMP system compared with conventional sampling methods[28-31]. In addition, economic analyses predict cost avoidance with the VAMP system such that acquisition cost can be completely offset[28,29, 30]. The VAMP system is thus aligned with health reform measures and can help hospitals optimize patient care and cost efficiencies.

Edwards

Blood Sampling Burden

Blood sampling is a common hospital procedure that results in notable blood loss, particularly in critically ill patients.

Blood Discarding: For the purpose of clearing catheter lines, a portion of blood is typically discarded as waste during blood sampling

- Blood samples may be drawn from 5 to 24 times a day in the intensive care unit (ICU)[1, 2] with daily blood draw volume between 26 to 478 mL depending on comorbidity.[2-7]
- Patients with catheters are subject to more blood sampling and blood loss vs. patients without catheters.[33]
- Discarding of blood is frequently conducted with traditional blood sampling[8, 9] and can substantially contribute to blood loss:
  - A European study found that 88% of ICU patients had blood discarded.[8]
  - The amount of blood discarded with each blood draw often varies from 2 to 10 mL.[3, 10-12]
  - This discarded blood can account for 24% to 30% of total daily blood loss in critically ill patients.[6]

Blood loss due to sampling with discarding can lead to a decline in hemoglobin (Hb), which can contribute to anemia.

Discarding blood after blood sampling is a predictor of Hb decline and anemia.[21,22]

- Blood sampling is highly associated with decreases in Hb *(Table 1)* and hematocrit and can contribute to anemia.[17]
- Several studies cite anemia as a result of blood loss from blood sampling with the risk of moderate to severe anemia increasing by 18% for every 50 mL of blood drawn.[5, 17-20]
- Anemia is associated with substantial burden and increased risk of organ injury and mortality.[1, 2, 34, 35]

TABLE 1: Volume of Blood Draw and Predicted Drops in Hb

Volume of Blood Draw	Expected Change in Hb (g/L); 95% CI
10 mL	0.7 (0.5 to 0.9)
50 mL	3.5 (2.4 to 4.6)
100 mL	8.0 (4.8 to 10.2)
200 mL	14.0 (9.6 to 18.4)

Improving Patient Outcomes

Closed blood sampling systems allow for blood re-infusion, providing an important alternative to conventional sampling methods.

FIGURE 1: VAMP Adult System

- Closed blood sampling systems, used with catheters, have reservoirs that hold blood and flush solution to allow sample collection without dilution and blood re-infusion rather than discard.[15]
- The VAMP system is a needleless device designed to reduce infection risk and promote blood conservation while providing consistent sampling for safety and reliability with unique features:

VAMP Reservoir: Allows clinicians to re-infuse "clearing volume" blood

Blunt Cannula: Used to draw samples from VAMP system, no needle required

Z-site sample port: Reduces residual blood build-up, allowing for *undiluted samples*

Blood loss and Hb level decline are reduced with the VAMP closed blood sampling system vs. conventional sampling.

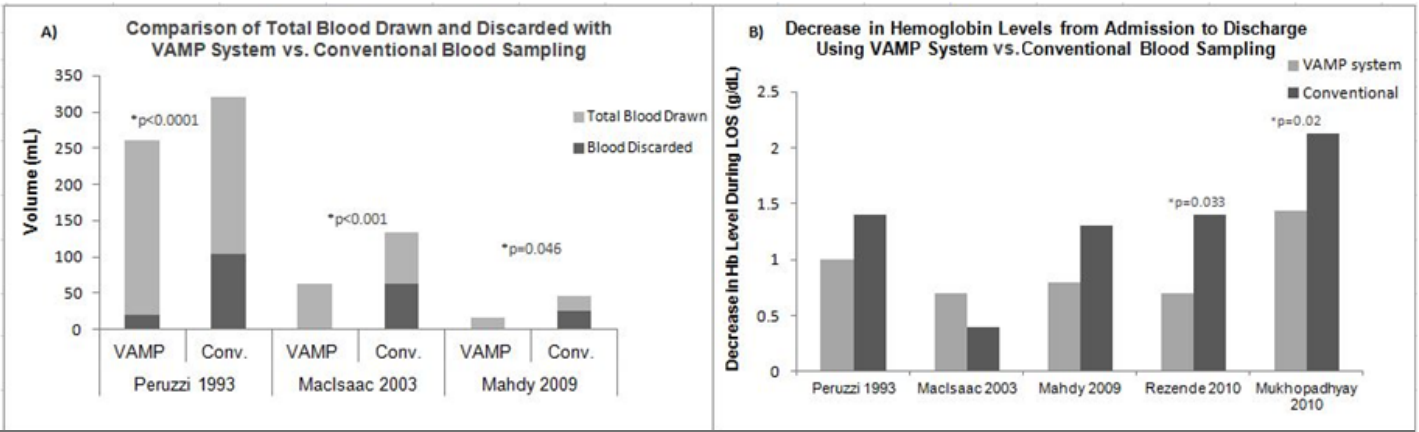


FIGURE 2: Comparison of VAMP system vs. conventional blood sampling for **A)** Blood drawn and discarded and **B)** Decrease in Hb levels from admission to discharge [21,28,36] [21,28,29,31,36]

Improving Patient Outcomes

The VAMP system has demonstrated reduced transfusion needs vs. conventional sampling. A lower transfusion risk may lead to less transfusion complications.

Use of the VAMP system significantly reduces transfusion risk compared to conventional blood sampling method. [28,31]

- Several studies demonstrate that greater blood loss from sampling is associated with higher transfusion risk in ICU patients.[19, 23, 24]
- A meta-analysis[32] of randomized controlled trials (RCTs) shows a significant reduction in transfusion risk with the VAMP system vs. conventional methods [28-30] (*Figure 3*).

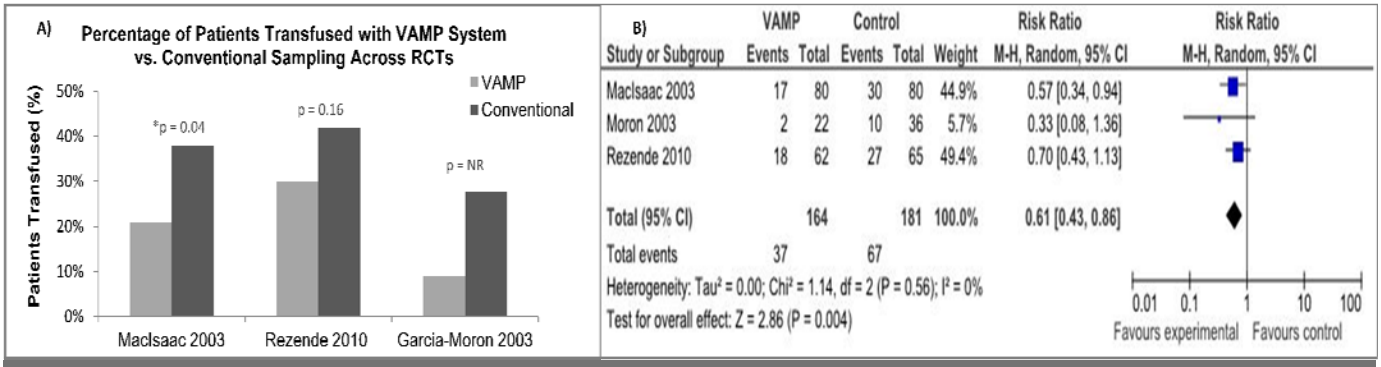


FIGURE 3: **A)** RCTs comparing transfusion risk between VAMP system and conventional blood sampling methods; **B)** Meta-analysis of the three RCTs showing significant reduction in risk of transfusion with VAMP system vs. conventional sampling (p=0.004). [28-30] **Caveat**: Meta-analysis results for transfusion risk should be interpreted in context of institution-specific patient populations and transfusion protocols.

Blood transfusions are associated with various types of complications and increased mortality risk. [1]

Blood transfusions are linked to many adverse outcomes:

- Transfusions may cause: hepatitis, infections, sepsis, transfusion-related acute lung injury, and many more complications.[1]
- In a U.S. study, the risk of infection increased by 29% per unit of red blood cell (RBC) transfusion.[37]
- Critically ill patients in the ICU are likely to be more at risk of the immunosuppressive and microcirculatory complications of blood transfusions than the general population.[22]
- The U.S. CRIT study found 44% of patients in ICU received one or more RBC units with 4% being associated with a transfusion-related complication.[25] The study also reported a mortality ratio of 1.65 (95%CI: 1.35 to 2.03) with RBC transfusions.[25]

Reducing Hospital Costs

The VAMP closed blood sampling system may lead to hospital-related cost avoidance compared with conventional sampling in hospitals.

The VAMP system may help avoid hospital costs by reducing transfusion incidence with one transfusion averted in every 6 to 8 patients that use the VAMP system. [28, 29, 30]

- Avoiding blood transfusions is associated with high cost-savings for hospitals given that transfusions are one of the largest cost centers in every hospital.[26, 27]
- The incremental cost of the VAMP system (Edwards, 2013) is only a fraction of the direct cost of a RBC transfusion which varies up to $210 (US) [32, 38, 39] and €439 (EU) per RBC unit.[40]

A U.S. economic analysis, informed by clinical studies, shows that the VAMP system is associated with cost-savings for hospitals[32]:

- For a hospital with 500 ICU patients annually, the VAMP system was associated with a cost avoidance of $29,270 per year (*Figure 4A*).[32]
- Results were robust to changes in assumptions as the VAMP system showed cost avoidance in many scenarios (*Figure 4B*).[32]

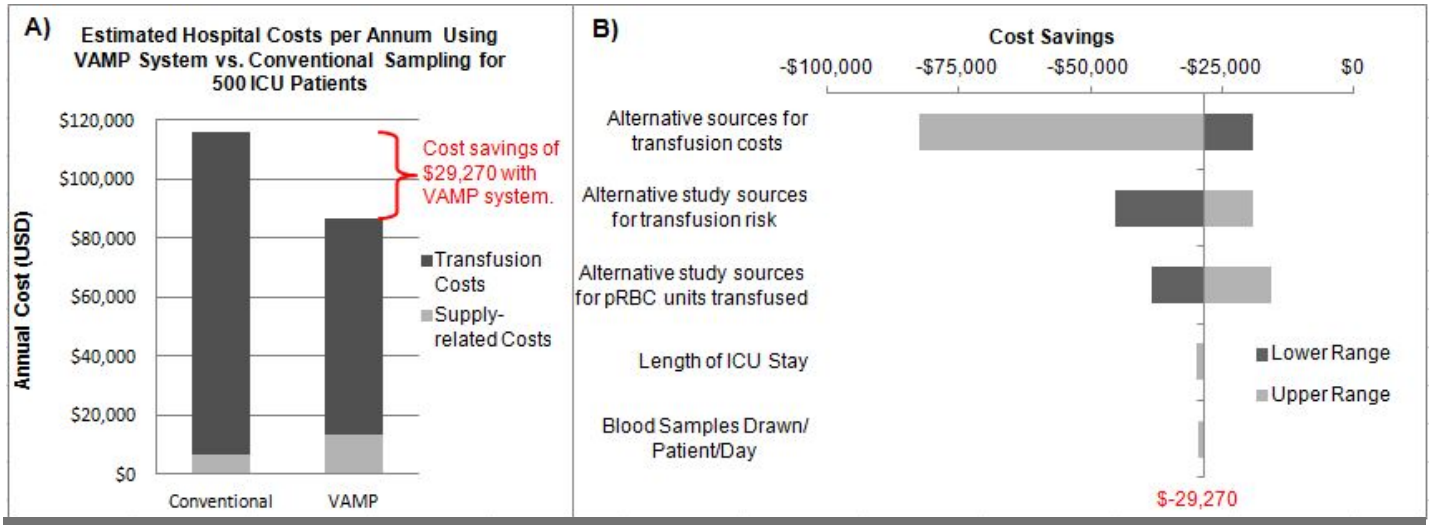


FIGURE 4: A) Comparison of annual transfusion and supply-related costs between VAMP system and conventional sampling.[32] **B)** Tornado diagram of sensitivity analysis results for VAMP system vs. conventional blood sampling methods. [32]

Reducing Hospital Infection

The risk of contamination is reduced with the VAMP closed blood sampling system versus conventional methods, thereby potentially leading to fewer hospital-acquired infections and associated costs.

Annually, 50,000 U.S. patients have a catheter-related bloodstream infection (CRBSI) with an average per case cost of $4,888 USD.[46,47]

There is a high contamination risk of the equipment used in conventional blood sampling with catheters:

- Stopcocks used as blood sampling ports can easily become contaminated with bacteria.[13, 14]
- Intra-operative 3-way stopcock contamination has been found to range between 3.2 to 61%.[14, 41-44]
- Transmission of bacteria, including vancomycin-resistant enterococci (VRE), to intravenous stopcock sets occurred in 32% of cases (95%CI: 20.6% to 44.9%) during the practice of general anaesthetists.[45]

Contamination risk can be reduced with closed versus open blood sampling methods by eliminating access through open blood sampling ports and the need for stopcocks.[16, 48]

Contamination rates have been found to be significantly lower with the VAMP system compared to conventional blood sampling.[16]

- An RCT shows the VAMP system is associated with significantly less contamination vs. conventional sampling (*Figure 5*).

A lower contamination risk, with the VAMP system vs. conventional sampling, may present potential for reduction in catheter-related bloodstream infection (CRBSI).

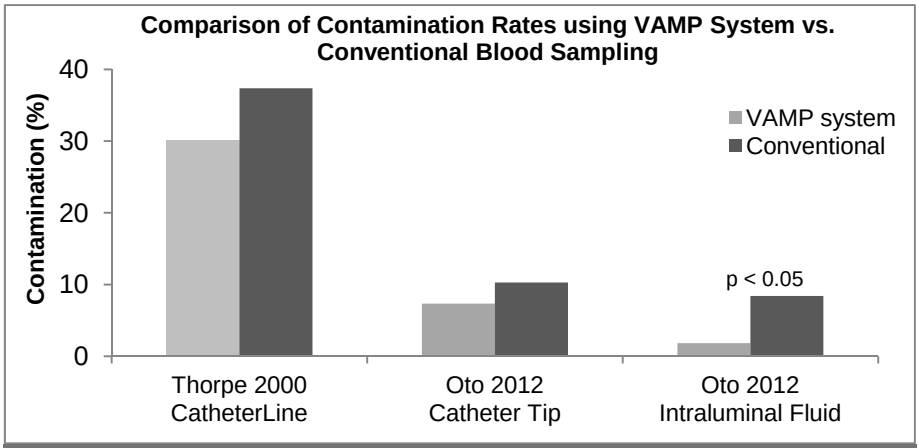


FIGURE 5: Study results comparing contamination rates using the VAMP system versus conventional blood sampling methods [15,16]

Improving Guideline Compliance

The VAMP closed blood sampling system may facilitate standardization to best practices for blood conservation.

TABLE 2: Several organizations recommend strategies to avoid blood waste through blood sampling devices

Blood Sampling Guidelines	
Agency for Healthcare Research & Quality, 2009 [49]	• Use of blood conservation devices for reinfusion of waste blood with sampling is associated with reduction in phlebotomy volume
British Committee for Standards in Haematology, 2013 [50]	• Blood conservation sampling devices should be considered to reduce phlebotomy-related blood loss
US Society for the Advancement of Blood Management (Clinical Standards), 2013 [51]	• Reducing or eliminating blood discard should be done and reinfusion of discard should be performed when practical

The VAMP system is needleless, thereby avoiding needle sticks in healthcare workers.

According to the CDC, 385,000 sharp-related injuries occur annually in the US while 1 million needle stick injuries are estimated annually in the EU. [58-60]

There is a high burden associated with needle stick injury:

- In the USA, hospital fines associated with needle stick injuries reported to range from $7,000 to $70,000 for failure to comply to the Needlestick Safety and Prevention Act.[52]
- Needle sticks have been blamed for causing 40% of hepatitis B infections, 40% of hepatitis C infections, and 2.5% of HIV infections among healthcare workers.[53]
- Clinical practice guidelines promote the use of needleless medical devices and systems to minimize risk of needle stick injury.[54-56]
- An estimated 83% of needle stick injuries could be avoided with the use of needle devices with safety features or by using needleless systems.[57]
- The blunt cannula attached to the VAMP system sampling syringe prevents the chance for needle injury when drawing blood (i.e. no needle). This is in contrast to some blood sampling methods where transferring of blood to a vial through a needle is required.

Aligning with Healthcare Reform Measures

The VAMP system demonstrates improved outcomes aligned with achieving U.S. healthcare reform objectives and hospital quality performance measures.

Hospitals require evidence-based decision-making to ensure better, affordable, cost-effective care to optimize population health.[61-65]

Changing Healthcare Landscape

Primary Objectives of the Triple Aim in Patient Protection and Affordable Care Act [61,62]

1) Improve quality of patient care

2) Improve population health

3) Affordable care

Hospital Goals with Healthcare Reform [63]

- Improve quality of care and patient satisfaction
- Improve patient outcomes
- Increase total performance score (TPS)
- Reduce hospital-acquired conditions (e.g., infection)
- Decrease episode of care costs

Several healthcare reform measures are applicable to hospital setting, such as [64,65]

- *Value Based Purchasing (VBP):* Encourages quality of care in hospitals; measured by TPS
- *Bundled Payments:* Payment for episode of care rather than fee for service (FFS)

Impact on Hospitals

With healthcare reform, hospitals will face financial accountability [63]

- Earn dollars or lose dollars based on quality improvements vs. benchmarks
- Restrictions in reimbursement related to hospital-acquired conditions

The VAMP System as an Evidence-Based Hospital Product

Hospital product adoption goals

Hospitals should choose products that are evidence-based and cost-effective to help support the changing healthcare landscape and achieve better and affordable care

The VAMP system is an evidence-based solution aligned with needs of new hospital landscape

- Improves patient outcomes (e.g., fewer blood transfusions)[28,31,32]
- Reduces contamination and potential for infections[15,16]
- Predicted cost avoidance due to less transfusions[28, 29, 30]
- Proven through numerous randomized studies (*Table 3*)

Evidence-Based Solution

The VAMP system is the only blood sampling system with published data proven to significantly reduce transfusion needs and contamination rates compared to conventional sampling. [16,22,28,31]

TABLE 3: Published Studies of Closed Blood Sampling Systems in Critical Care

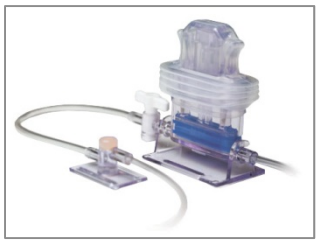
Study	Study Design	Comparators	Sample Size	Main Outcomes
Silver 1993 [66]	RCT (USA)	SafeDraw Conventional	31	Blood discarded over 7 day study period
Silver 1993 [67]	RCT (USA)	SafeDraw Conventional	20	Partial thromboplastin time
Peruzzi 1993 [21]	RCT (USA)	VAMP Conventional	100	Blood loss, hemoglobin concentrations, and blood transfusions
Peruzzi 1996 [48]	RCT (USA)	VAMP SafeDraw	40	Microbial contamination and infection
Woda 1999 [68]	RCT (USA)	SafeSet Conventional	99	Damping coefficient and resonant frequencies, discard volume, and blood sample size
Thorpe 2000 [15]	RCT (UK)	VAMP Conventional	100	Blood transfusions, hemoglobin levels, and microbial contamination
Morón 2003 [30]	RCT (Spain)	VAMP Conventional	58	Transfusion risk and hemoglobin concentrations
MacIsaac 2003 [28]	RCT (Australia)	VAMP Conventional	160	Hemoglobin concentration, blood loss, and transfusion risk
Mahdy 2009 [36]	RCT (UK)	VAMP Conventional	39	Diagnostic blood loss and hemoglobin concentration
Rezende 2010 [29]	RCT (Brazil)	VAMP Conventional	127	Blood loss, hemoglobin concentration, and transfusions
Mukhopadhyay 2010 [31]	Before-After (Singapore)	VAMP Conventional	250	Transfusion requirements, hemoglobin concentration, and blood loss
Oto 2012 [16]	RCT (Japan)	VAMP Conventional	216	Microbial contamination and infection

The VAMP system has been evaluated in numerous clinical studies across the world (*Table 3*).

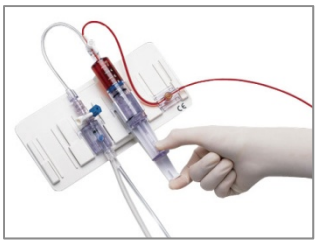
The Edwards Lifesciences Advantage

Partnering with Edwards for your blood management and hemodynamic monitoring needs provides important advantages to your hospital setting.

Edwards offers a comprehensive product range for closed blood sampling across patient populations:



VAMP Adult System



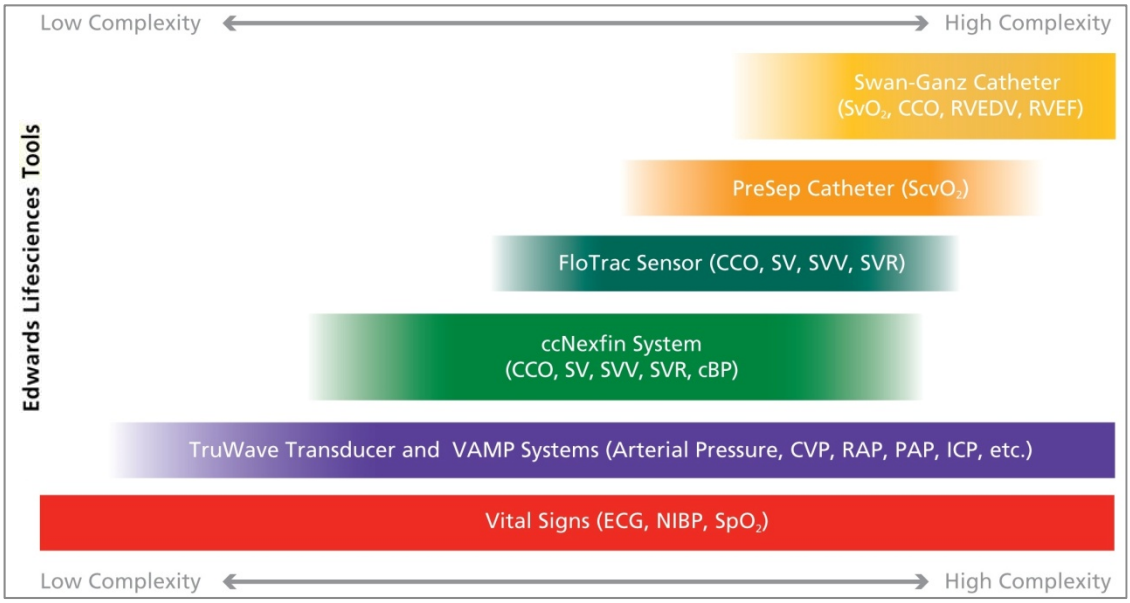
VAMP Plus System

VAMP Jr. System

For over 40 years, Edwards has partnered with clinicians to develop products and systems that advance the treatment of the acutely ill

Edwards is committed to hemodynamic excellence in caring for the acutely ill:

- The Edwards portfolio consists of hemodynamic management solutions for monitoring patients of varying clinical complexity. Each employs advanced technologies to provide optimum insight and maximum clinical efficiency.
- Several products are compatible and may smoothly integrate with the VAMP system, (e.g. TruWave disposable pressure transducer with various types of multi-channel pressure cables enabling connection to wide variety of bedside monitors).



Edwards is focused on helping clinicians enhance knowledge and standardize practice to improve the quality and efficiency of care. Edwards is dedicated to providing:

- Evidence-based programs such as Sepsis Management and Enhanced Surgical Recovery Programs that facilitate implementation and compliance of protocolized care in the OR and ICU
- Expansive educational tools, resources and clinical support

Edwards is committed to providing your institution, clinicians and staff with the highest levels of customer service and support, including:

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