CONVERSION FROM RESTING HEART SYSTEM TO A CLOSED-BAG SYSTEM

MiECT Meeting

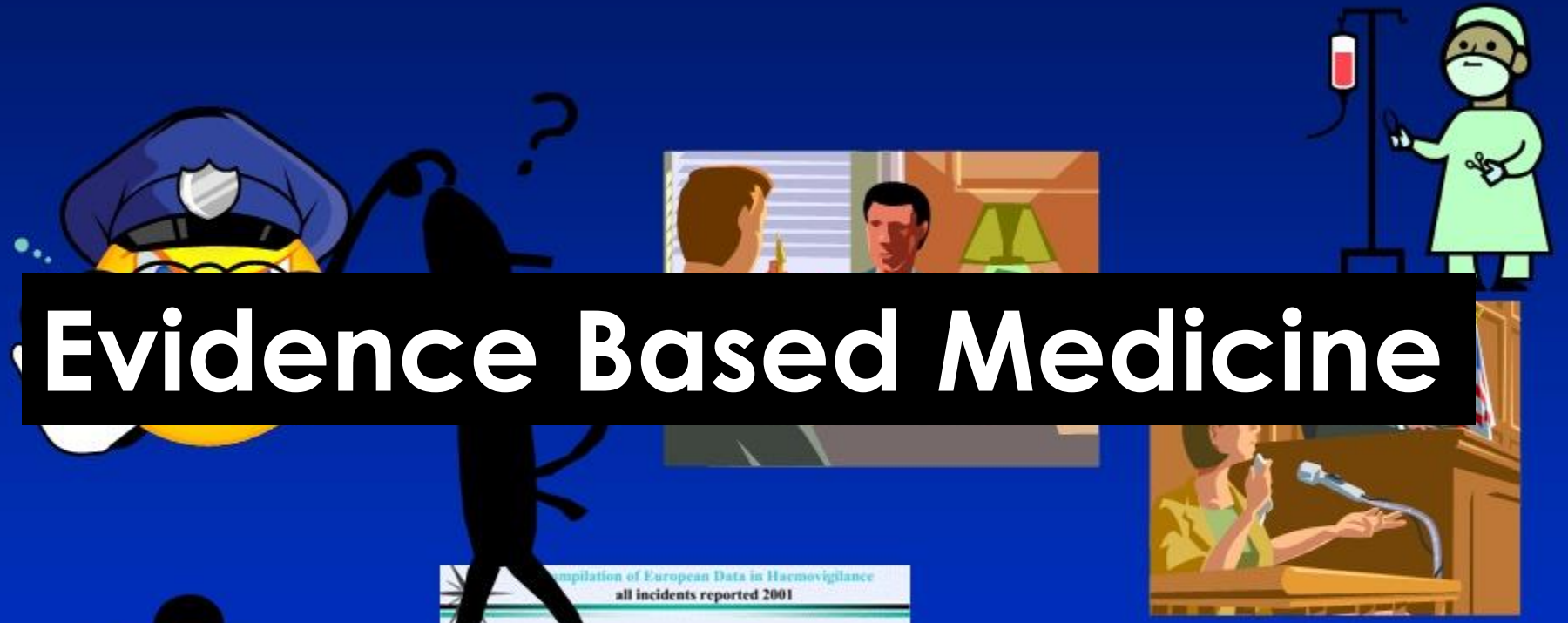
June 9th, 2016

James Ferguson MPS, CCP, CPBMT, MT(ASCP)

THE **"IDEAL"** CIRCUIT

- No hemodilution
- Completely endothelialized tubing
- Totally closed circuit
- No activation of the complement/Cytokine system
- Platelets/RBC's maintain integrity
- Excellent gas exchange and CO_2 removal
- Prevent Neurocognitive deficits
- No adverse sequelae – **SAFE**

How to Improve Practice?



Evidence Based Medicine

Look for EVIDENCE

STS GUIDELINES FOR MIECC'S

- **STS Guidelines 2007** – MiECC's were a Class IIb which indicates Benefit ≥ Risk: additional studies with broad objects needed; additional registry data would be helpful and IT IS NOT UNREASONBALBE to perform procedure/administer treatment.

- **STS Guidelines 2011 Update** – Now MiECC's are **Class I (A)** which indicates recommendation that procedure or treatment is useful/effective, sufficient evidence form multiple randomized trials or meta-analyses.

SPECIAL REPORT: STS WORKFORCE ON EVIDENCE BASED SURGERY

2011 Update to The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clinical Practice Guidelines*

The Society of Thoracic Surgeons Blood Conservation Guideline Task Force:
Victor A. Ferraris, MD, PhD (Chair), Jeremiah R. Brown, PhD, George J. Despotis, MD, John W. Hammon, MD, T. Brett Reece, MD, Silva P. Saha, MD, MBA, Howard K. Song, MD, PhD, and Ellen R. Clough, PhD

The Society of Cardiovascular Anesthesiologists Special Task Force on Blood Transfusion:
Linda J. Shore-Lesserson, MD, Lawrence T. Goodnough, MD, C. David Mazer, MD, Aryeh Shander, MD, Mark Stafford-Smith, MD, and Jonathan Waters, MD

The International Consortium for Evidence Based Perfusion:
Robert A. Baker, PhD, Dip Perf, CCP (Aus), Timothy A. Dickinson, MS, Daniel J. FitzGerald, CCP, LP, Donald S. Likosky, PhD, and Kenneth G. Shann, CCP

Ann Thorac Surg 2011;91:944–82

STANDARDS AND GUIDELINES

SPECIAL REPORT: STS WORKFORCE ON EVIDENCE BASED SURGERY

2011 Update to The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clin

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The International Consortium for Evidence
Robert A. Baker, PhD, Dip Perf, CCP (Aus),
Daniel J. FitzGerald, CCP, LP, Donald S. Li

Division of Cardiovascular and Thoracic Surgery, University of
Anesthesiology, University of Pittsburgh Medical Center, Pittsb
Care Medicine, Englewood Hospital and Medical Center, Englew
Stanford University School of Medicine, Stanford, California (LI
Montefiore Medical Center, Bronx, New York (IJS-L, KGS), Dep
University School of Medicine, St. Louis, Missouri (QD), Dartm
Cardiology, Dartmouth Medical School, Lebanon, New Hampshi
Medicine, Winston-Salem, North Carolina (WH), Department o
Ontario (CDM), Cardiac Surgical Research Group, Flinders Med
Medicine, Community and Family Medicine, and the Dartmouth
School, Hanover, New Hampshire (DSL), SpecialtyCare, Nashvi
Women's Hospital, Harvard University, Boston, Massachusetts (
University Medical Center, Portland, Oregon (HKS), Departmen
Center, Aurora, Colorado (TBR), Department of Anesthesiology,
The Society of Thoracic Surgeons, Chicago, Illinois (ERC)

SPECIAL REPORT

Background. Practice guidelines reflect published liter
ature. Because of the ever changing literature base, it
necessary to update and revise guideline recommend
tions from time to time. The Society of Thoracic Surgeon
recommends review and possible update of previous
published guidelines at least every three years. Th
summary is an update of the blood conservation guid
line published in 2007.

*The International Consortium for Evidence Based Perfusion formal
endorses these guidelines.

The Society of Thoracic Surgeons Clinical Practice Guidelines are i
tended to assist physicians and other health care providers in clini
decision-making by describing a range of generally acceptable a
proaches for the diagnosis, management, or prevention of specific di
eases or conditions. These guidelines should not be considered inclusive
all proper methods of care or exclusive of other methods of care reasonab
directed at obtaining the same results. Moreover, these guidelines a
subject to change over time, without notice. The ultimate judgment regar
ing the care of a particular patient must be made by the physician in light
the individual circumstances presented by the patient.

For the full text of this and other STS Practice Guidelines, visit http
www.sts.org/resource-publications at the official STS Web site (www.sts.org

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JECT. 2013;45:156–166
The Journal of ExtraCorporeal Technology

Report from AmSECT's International Consortium for Evidence-Based Perfusion: American Society of ExtraCorporeal Technology Standards and Guidelines for Perfusion Practice: 2013

Robert A. Baker, PhD, Dip Perf, CCP (Aus);* Shahna L. Bronson, CCP;†
Timothy A. Dickinson, MS;‡ David C. Fitzgerald, CCP;§ Donald S. Likosky, PhD;‖
Nicholas B. Mellas, CCP;¶ Kenneth G. Shann, CPP** on behalf of the International Consortium for Evidence-Based Perfusion for the American Society of ExtraCorporeal Technology

*Cardiac Surgery Research and Perfusion, Flinders Medical Centre and Flinders University, Adelaide, South Australia; †Mayo Clinic, Rochester, Minnesota; ‡SpecialtyCare, Inc., Nashville, Tennessee; §INOVA Fairfax Hospital, Falls Church, Virginia; the ‖Section of Health Services Research and Quality, Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; ¶Cardiovascular Perfusion, Montefiore–The University Hospital, Albert Einstein College of Medicine, Bronx, New York; and **Perfusion Services, Massachusetts General Hospital, Boston, Massachusetts

Abstract: One of the roles of a professional society is to develop standards and guidelines of practice as an instrument to guide safe and effective patient care. The American Society of Extracorporeal Technology (AmSECT) first published its Essentials for Perfusion Practice, Clinical Function: Conduct of Extracorporeal Circulation in 1993. The International Consortium for Evidence-Based Perfusion (ICEBP), a committee within AmSECT, was tasked with updating this document in 2010. The aim of this report is to describe the method of development and content of AmSECT's new professional standards and guidelines. The ICEBP committee independently evaluated and provided input regarding the current "Essentials and Guidelines." Structural changes were made to the entire document, and a draft document was developed, presented, and circulated to the AmSECT Board of Directors and broader membership for comment. Informed by these reviews, a revised document was then presented to the Society for a membership vote. The final document consists of 15 areas of practice covered by 50 Standards and 38 Guidelines (see Appendix 1) with the first standard focusing on the development of institutional protocols to support their implementation and use. A majority of the membership voted to accept the document (81.2% of the voting membership accepting, 18.8% rejecting). After an audit of the balloting process by AmSECT's Ethics Committee, the results were reported to the membership and the document was officially adopted on July 24, 2013. The Standards and Guidelines will serve as a useful guide for cardiac surgical teams that wish to develop institution-specific standards and guidelines to improve the reliability, safety, and effectiveness of adult cardiopulmonary bypass. The ICEBP recognizes that the development of a Standards and Guidelines statement alone will not change care. Safe, reliable, and effective care will be best served through the development and implementation of institutional protocols based on these standards. AmSECT's Standards and Guidelines for Perfusion Practice reflect the changing landscape of our profession as we work toward a safer and optimal provision of cardiopulmonary bypass for all our patients as well as a work environment that is supportive of delivering this care. **Keywords:** standards, guidelines, cardiopulmonary bypass, perfusion, cardiac surgery. *JECT. 2013;45:156–166*

INTRODUCTION/PREAMBLE

The American Society of ExtraCorporeal Technology's (AmSECT) mission is to "foster improved patient care and safety by providing for the continuing education and professional needs of the extracorporeal circulation technology community." In keeping with this mission, AmSECT, through its Perfusion Quality Committee, developed a draft standard for perfusion entitled the "Essentials for Perfusion Practice, Clinical Function: Conduct of Extracorporeal Circulation," which was initially endorsed by the membership in 1993 (1), and reviewed and revised on a number of occasions thereafter (2–4). In 2011 the AmSECT Board of Directors (BOD) asked the International Consortium for Evidence-Based Perfusion (ICEBP) subcommittee to review and update the Essentials and Guidelines (Figure 1).

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The senior author has stated that the authors have reported no material, financial, or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

CLINICAL STRATEGIES FOR AVOIDING AND CONTROLLING HEMORRHAGE AND ANEMIA WITHOUT BLOOD TRANSFUSION IN SURGICAL PATIENTS*

GENERAL NONBLOOD MANAGEMENT PRINCIPLES

1. Formulate a detailed and individualized clinical management plan to minimize blood loss and treat anemia. Comprehensive prospective planning should make optimal use of a combination of modalities to
5. Maintain surveillance for blood loss or physiological deterioration. Early recognition and involvement of appropriate senior staff and prompt action to prevent/control abnormal bleeding are essential. The threshold for intervention should be lower than for patients who will accept allogeneic blood transfusion.
6. Prompt action to secure hemostasis in the actively bleeding patient who refuses blood transfusion is lifesaving. Use diagnostic tests that will provide rapid results, minimize delays, and thus reduce blood loss. In general, avoid a "watch and wait" approach to the bleeding patient.
7. Exercising clinical judgment, be prepared to modify routine practice when conditions change.
8. Consult promptly with senior specialists with experience in managing patients without allogeneic transfusion at an early stage if complications arise.
9. Transfer a stabilized patient, if necessary, to a major center before the patient's condition deteriorates.

L THERAPEUTIC PRINCIPLES

4. Restrict diagnostic phlebotomy. Perform essential tests only and use less blood for analysis.
5. Combine surgical and anesthetic blood conservation techniques: meticulous surgical hemostasis and minimization of blood loss, and rigorous intraoperative blood management using appropriate autologous blood procurement strategies.
6. Optimize oxygen delivery and consider measures to minimize oxygen consumption.
7. In trauma or postoperative patients with active bleeding, perform immediate concomitant investigation and diagnosis and early intervention aimed at rapidly controlling hemorrhage. Consider moderate fluid underresuscitation in the presence of uncontrolled hemorrhage.

ANNING

a. Prescription and nonprescription drugs containing ASA or NSAIDs[8,9]
c. Dietary or herbal supplements that may affect coagulation[10-14]
6. Physical exam (e.g., hepatomegaly, splenomegaly, petechiae, purpura, ecchymoses, hemarthrosis, evidence of collagen-vascular defects, telangiectases, evidence of other disease associated with hemostatic dysfunction)

B. Selective Laboratory Assessment

1. Diagnosis of anemia[15-17]
a. Complete blood count (CBC)
b. Serum ferritin
c. Serum vitamin B_{12}[18]
d. Serum folate
e. Peripheral blood smear examination
2. Judicious additional tests (if indicated by medical history, abnormal clinical data, current medications, and degree of hemostatic challenge)[19]
a. Coagulation tests
(1) PT, PTT, template bleeding time
(2) Platelet function, adhesion, aggregation tests
(3) Fibrinogen concentration

convenient reference to assist in the development of management plans for avoiding
s, physicians should use sound clinical judgment, consult with senior specialist physicians,
d on the basis of the available resources. While the opinions contained in this table have
tific knowledge, they are subject to change.

ital Information Services for Jehovah's Witnesses 8/01

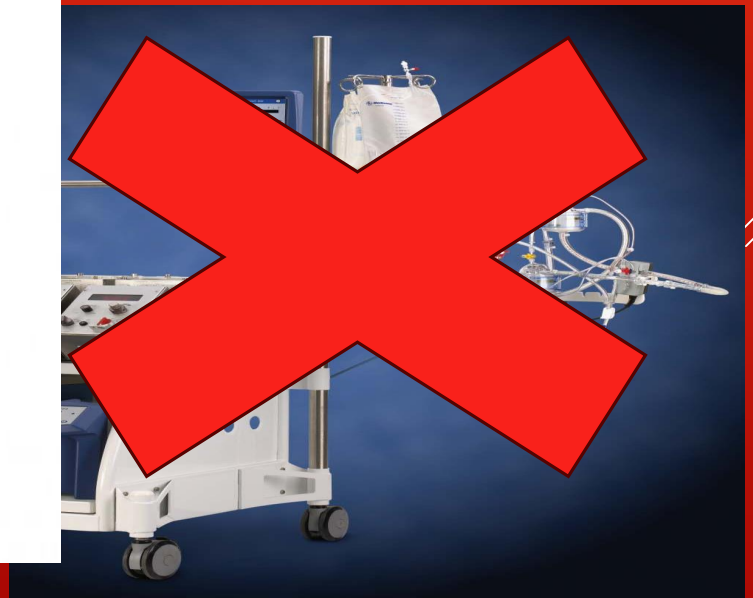
Maquet MECC System

Terumo RocSafe system

MIECC'S ON THE MARKET

Sorin Synergy Syster

Medtronic Resting Heart System



NUMBER OF MIECC USERS

- Europe – **20% - 25%** **(Does vary between countries)**
- US - **<2%**
- There are people using smaller conventional circuits but not many reservoir less systems

RESTING HEART CIRCUIT
UTILIZING THE FIRST GENERATION CART

OUR CURRENT PRACTICE AND OUR CONVERSION TO MINI-CIRCUITS

- We were looking to decrease our blood utilization
- Decreased our conventional circuit tubing lengths
- Always “RAP” the conventional circuit (Arterial and Venous)
- Use Coated Circuits
- Never use the pump sucker (Only use a Cell Saver)

WHY DID WE CHOOSE RESTING HEART?

A. Decreased prime volume -

1. **Prior Practice:** 1600 mL with a rap of 500 mL total of **1100 mL** of crystalloid prime
2. **Resting Heart:** 1100 mL with a rap of 800 mL total of **300 mL** of crystalloid prime

B. Open versus Closed Circuit-

1. **Prior Practice:** Open reservoir
2. **Resting Heart:** Closed reservoir

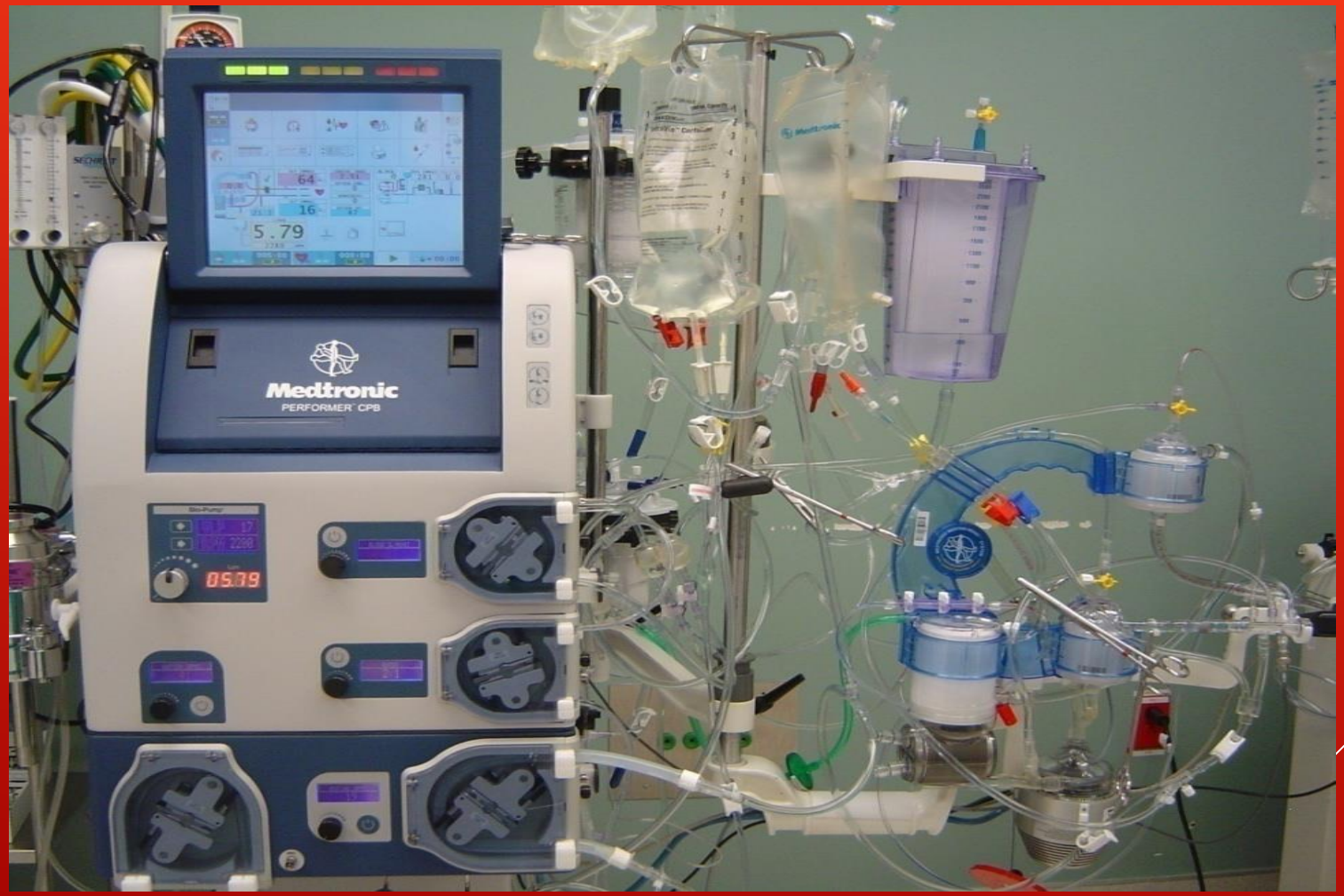
C. Pumps -

1. **Prior Practice:** Roller Pumps
2. **Resting Heart:** Centrifugal pump

D. Coated Circuits -

1. **Prior Practice:** Trillium coated (Currently in use)
2. **Resting Heart:** Carmeda coated Tip to Tip (Including the cannulae)

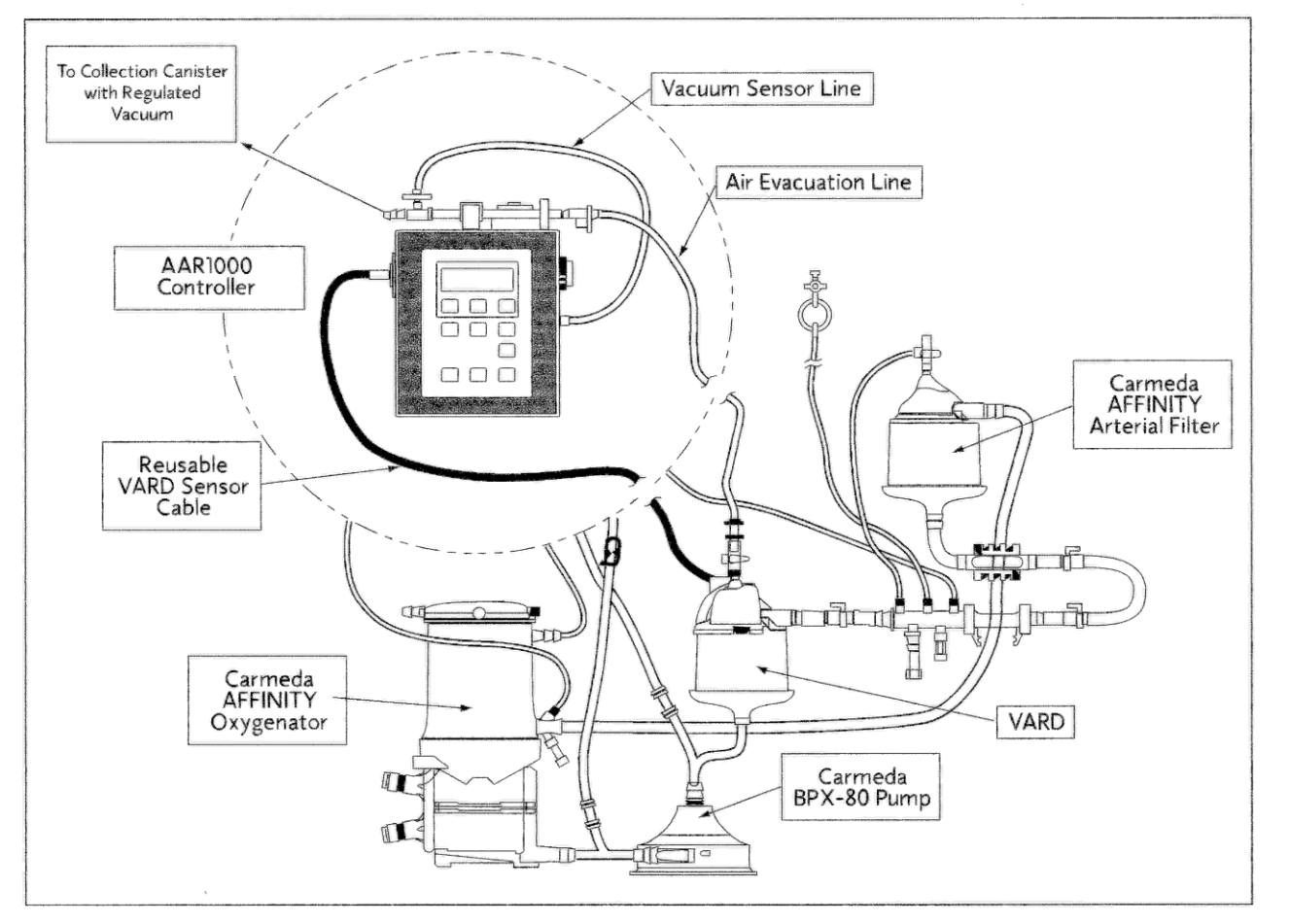
RESTING HEART WITH THE PERFORMER



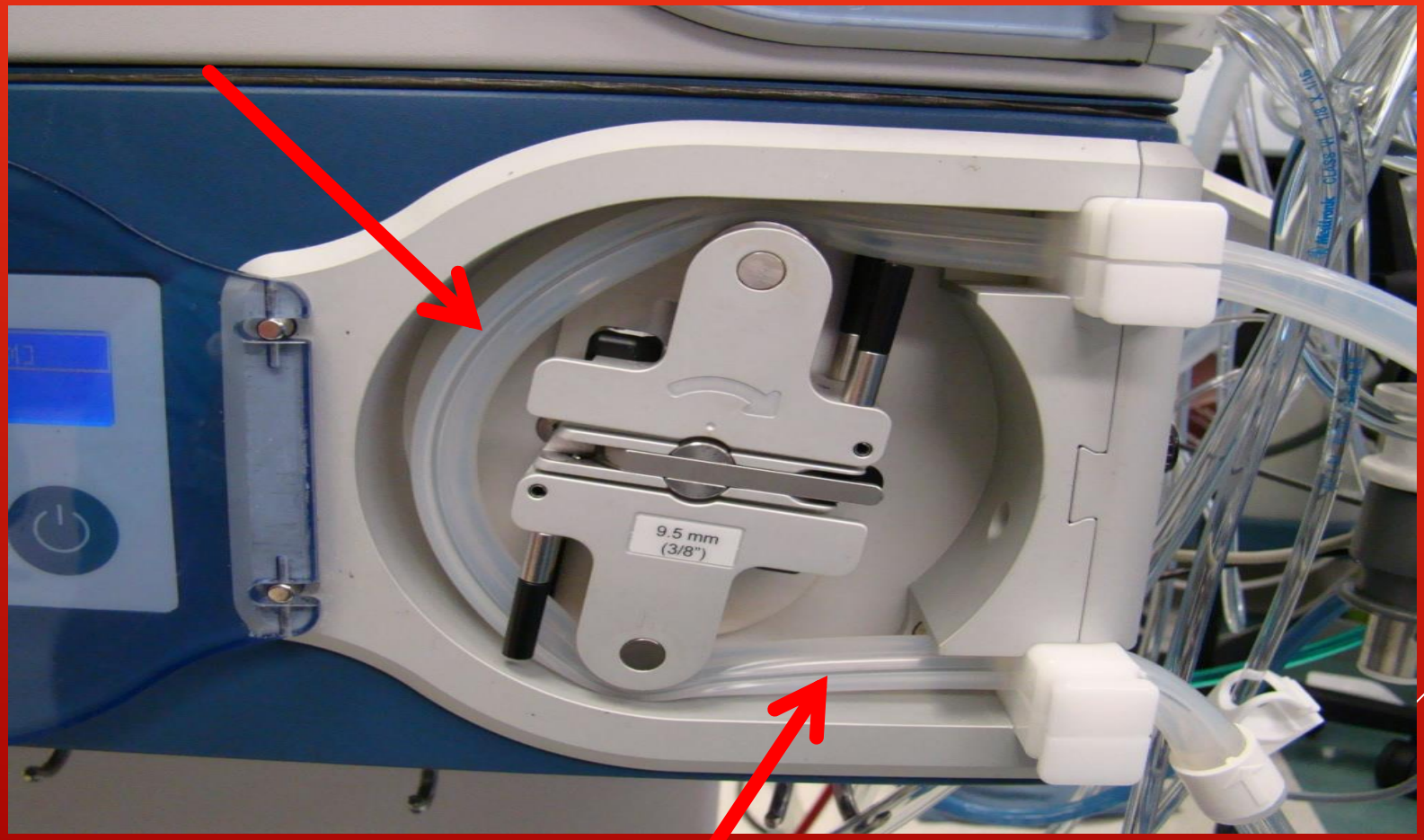
RESTING HEART COMPARED TO THE CONVENTIONAL CIRCUIT

- **The Resting Heart Circuit Utilizes:**
  - Lower Priming Volume (mini-circuit, MECC)
  - Closed System (Reduced air-blood interface)
  - Gentler on the Blood Elements (Centrifugal Pump)
  - Carmeda coated tip to tip Circuit (Decreased deleterious effects of SIRS, SIRAB)
  - Kinetic assisted Venous Drainage (KVAD)– (Smaller venous cannulae)
  - Utilizes the "Venous Air Removal Device "(VARD)

RESTING HEART CIRCUIT DESIGN



THE “GENTLE VENT”

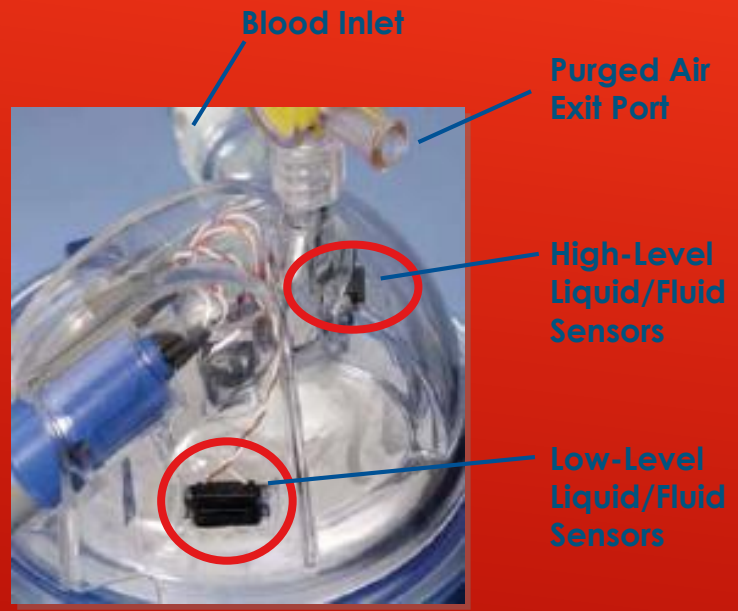


A KEY COMPONENT OF THE RESTING HEART SYSTEM IS THE "VARD"

AFFINITY® VARD

- **Product Features**
  - Low Prime = 212ml
  - 38-micron Screen
  - Flow Range = 1.0 to 6.0 L/min
  - Coated with Carmeda® BioActive Surface

- **Advanced Technology**
  - Ultrasonic sensors detect air at the inlet of the system as well as the fluid level in the AFFINITY® VARD
  - Chamber and port at the top of the device designed to automatically detect, collect and remove coalesced air



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Indicated for use in an extracorporeal circulation circuit during cardiopulmonary bypass procedures requiring a blood flow rate of 1-6 L/min and lasting up to 6 hours.

Detection and Elimination of Microemboli Related to Cardiopulmonary Bypass

Robert C. Groom, MS, CCP; Reed D. Quinn, MD; Paul Lennon, MD; Desmond J. Donegan, MD; John H. Braxton, MBA, MD; Robert S. Kramer, MD; Paul W. Weldner, MD; Louis Russo, MD; Seth D. Blank, MD; Angus A. Christie, MD; Andreas H. Taenzer, MD; Richard J. Forest, CCP; Cantwell Clark, MS, MD; Janine Welch, MS, CCP; Cathy S. Ross, MS;

Conclusions- Changes in CPB techniques and circuit components, including filter size and type of pump, resulted in a reduction rate of 75% of cerebral microemboli (Circ Cardiovasc Qual Outcomes. 2009;2:191-198.)

across phases, (Phase I, 702; Phase II, 572; Phase III, 596; Phase IV, 85; F [3,157]=13.1, $P<0.001$). Significant changes also occurred in median microemboli detected in the brain across phases, (Phase I, 604; Phase II, 429; Phase III, 407; Phase IV, 138; F [3,153]=14.4, $P<0.001$). Changes in the cardiopulmonary bypass circuit were associated with an 87.9% (702 versus 85) reduction in median microemboli in the outflow of the CPB circuit ($P<0.001$), and a 77.2% (604 versus 146) reduction in microemboli in the brain ($P<0.001$).

Conclusions—Changes in CPB techniques and circuit components, including filter size and type of pump, resulted in a reduction in more than 75% of cerebral microemboli. (***Circ Cardiovasc Qual Outcomes*. 2009;2:191-198.**)

Key Words: surgery ■ cardiopulmonary bypass ■ cerebrovascular circulation ■ embolism ■ coronary disease

MICROEMBOLI FROM CARDIOPULMONARY BYPASS ARE ASSOCIATED WITH A SERUM MARKER FOR BRAIN INJURY

GROOM ET AL.

- **Design:** 71 Patients undergoing isolated cardiopulmonary bypass were consented
- Blood flow and velocity were monitored with Doppler ultrasound on the inflow and outflow of the CPB circuit on each case
- Serum levels of S100β utilizing two immunoassays at baseline and 48 hours after surgery were measured
- **Results:** Microemboli leaving the circuit were recorded **in 67 patients**. Most patients had elevated serum levels of S100β
- **Conclusion: They identified an association between a biomarker of brain injury (S100β) and microemboli in the CPB circuit. Once again they suggest that reductions in neurological injury may result through redesign of the CPB circuit to prevent microemboli leaving the circuit**

JECT.2010;42:40-44

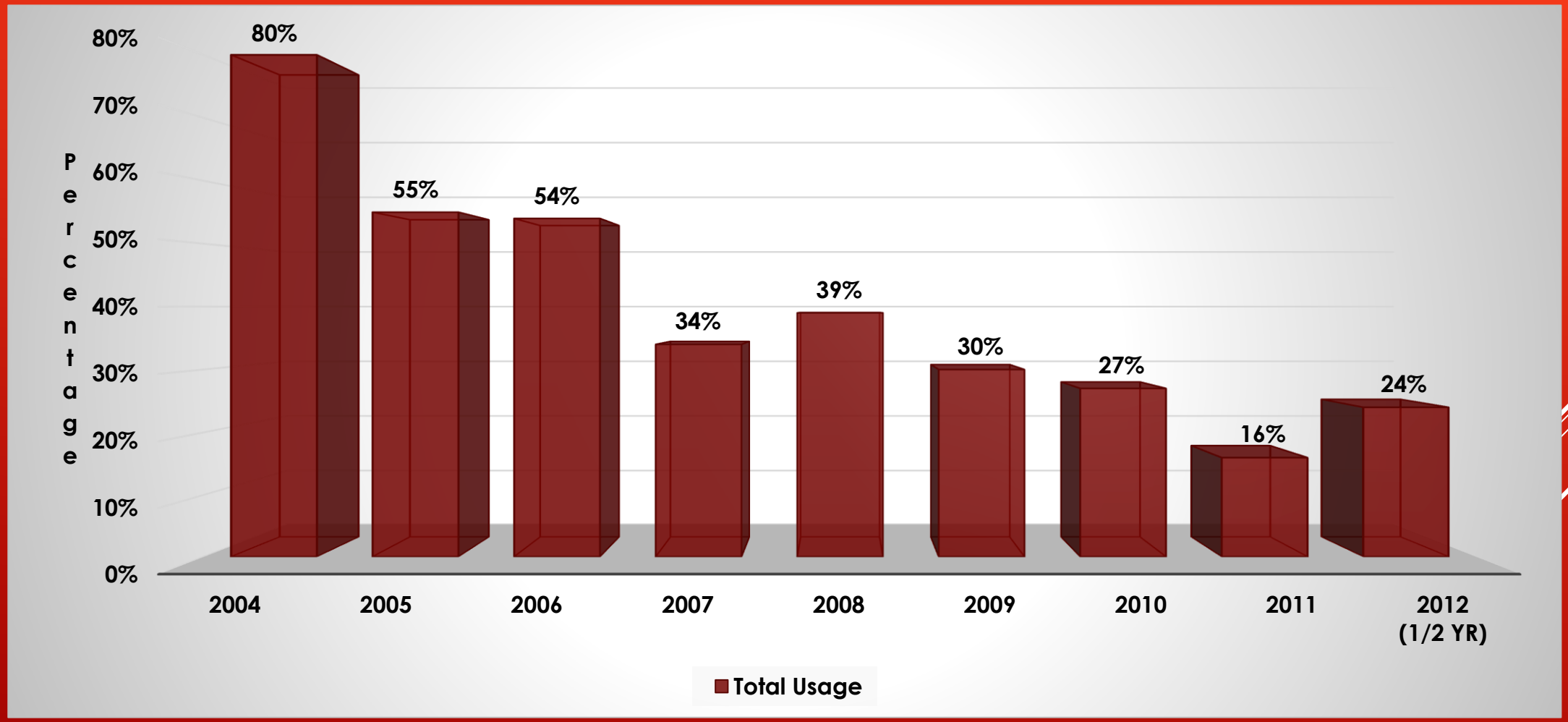
EVIDENCE

Review
Use of minimal extracorporeal circulation improves outcome after heart surgery; a systematic review and meta-analysis of randomized controlled trials
Kyriakos Anastasiadis

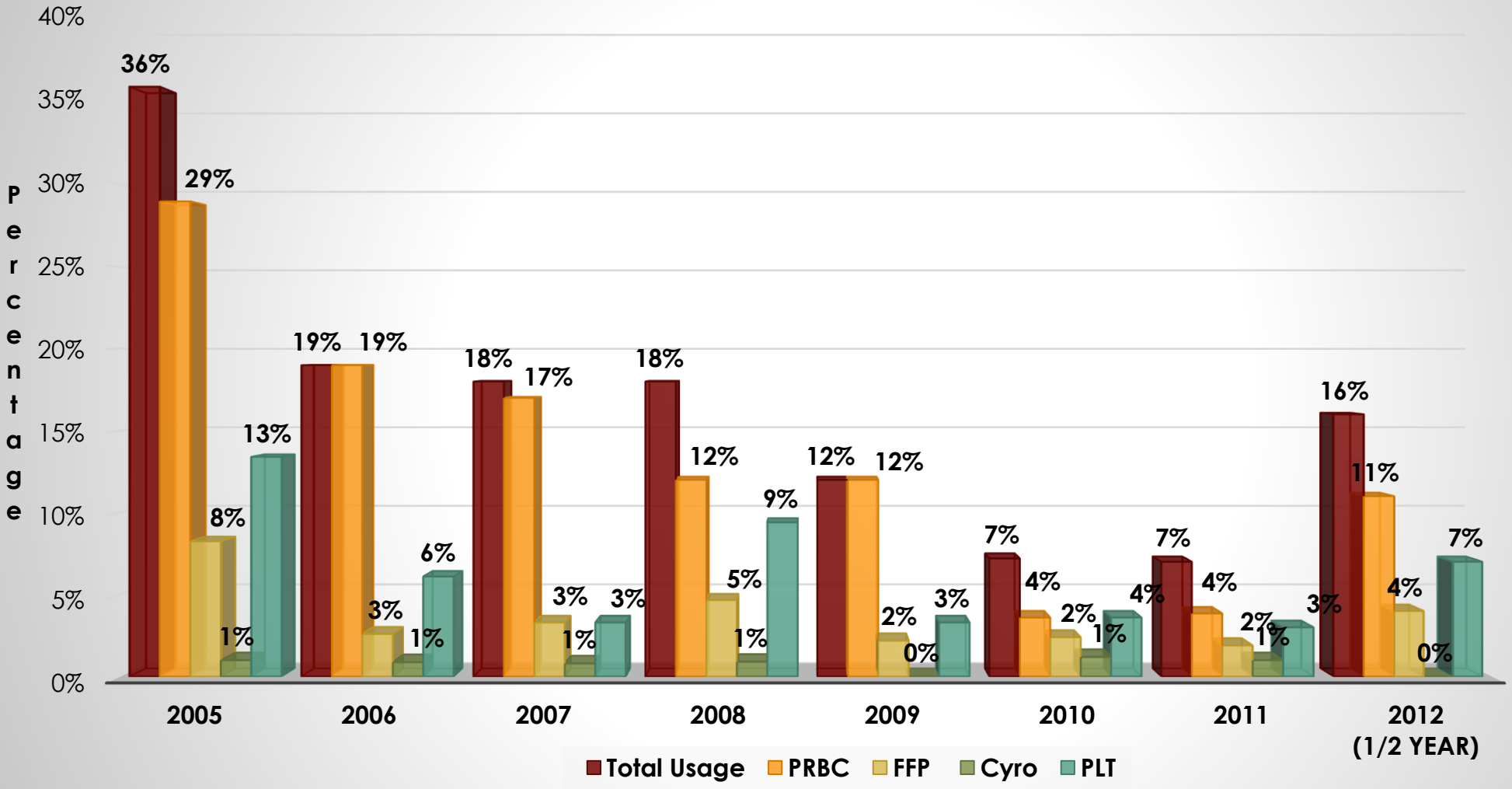
Even though there is **limited penetration** of MECC systems in the contemporary clinical practice, the present meta-analysis **advocates expansion** of MECC use in heart surgery based on significant **clinical and physiologic advantages.**

A LOOK AT THE DATA UTILIZING RESTING HEART

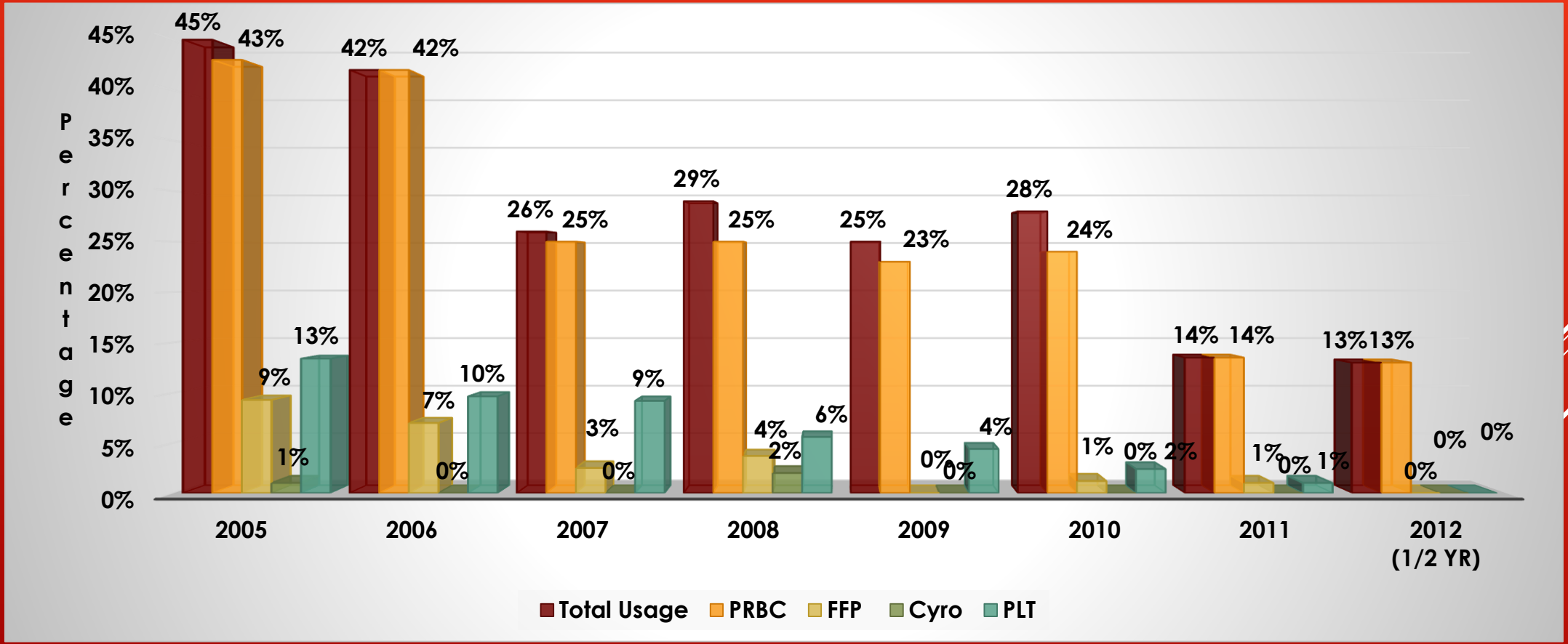
RESTING HEART SYSTEM RESULTS… ENTIRE HOSPITAL STAY AT BBHH..



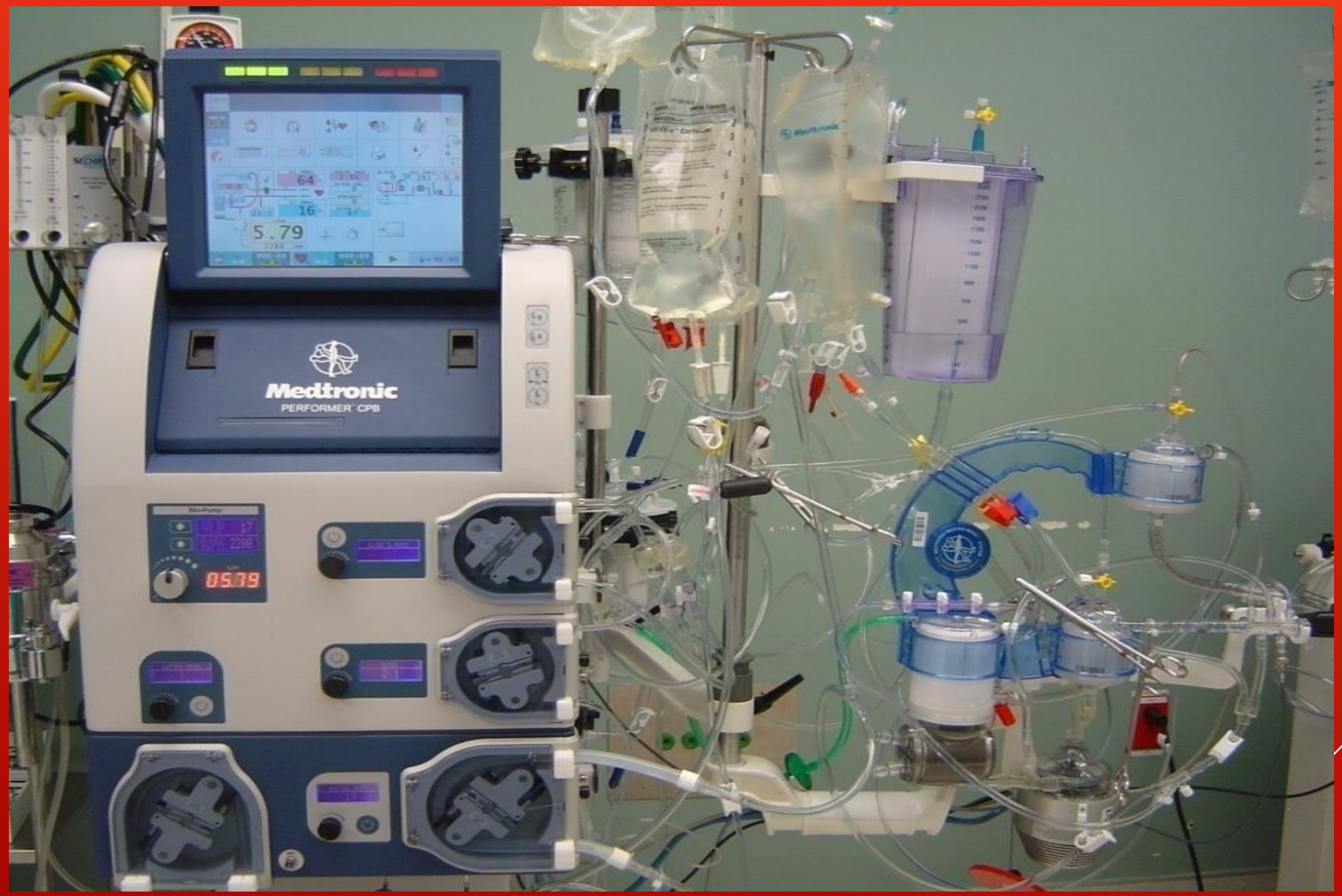
RESTING HEART SYSTEM RESULTS… INTRAOPERATIVELY AT BBHH..



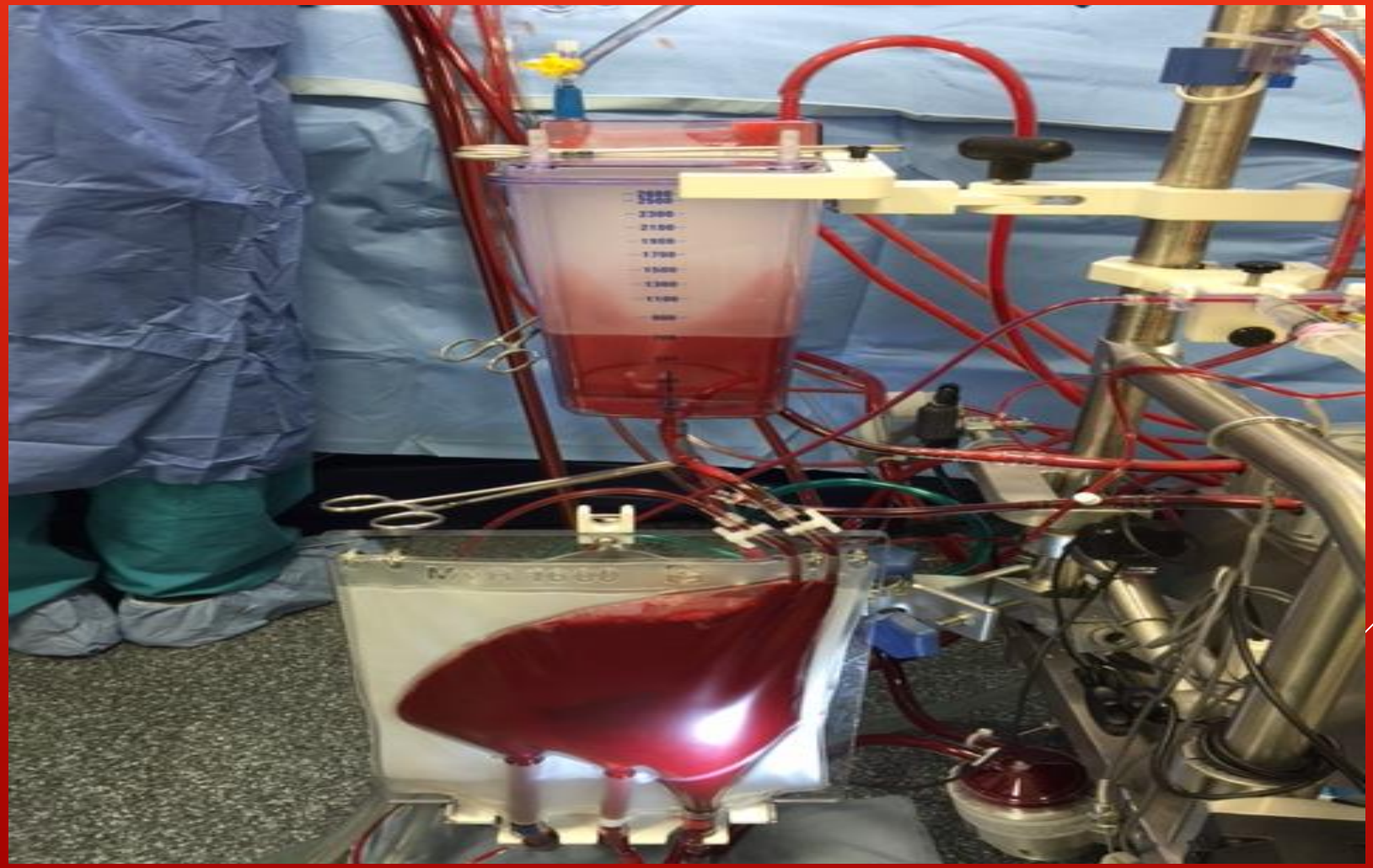
RESTING HEART SYSTEM RESULTS… POSTOPERATIVELY AT BBHH..



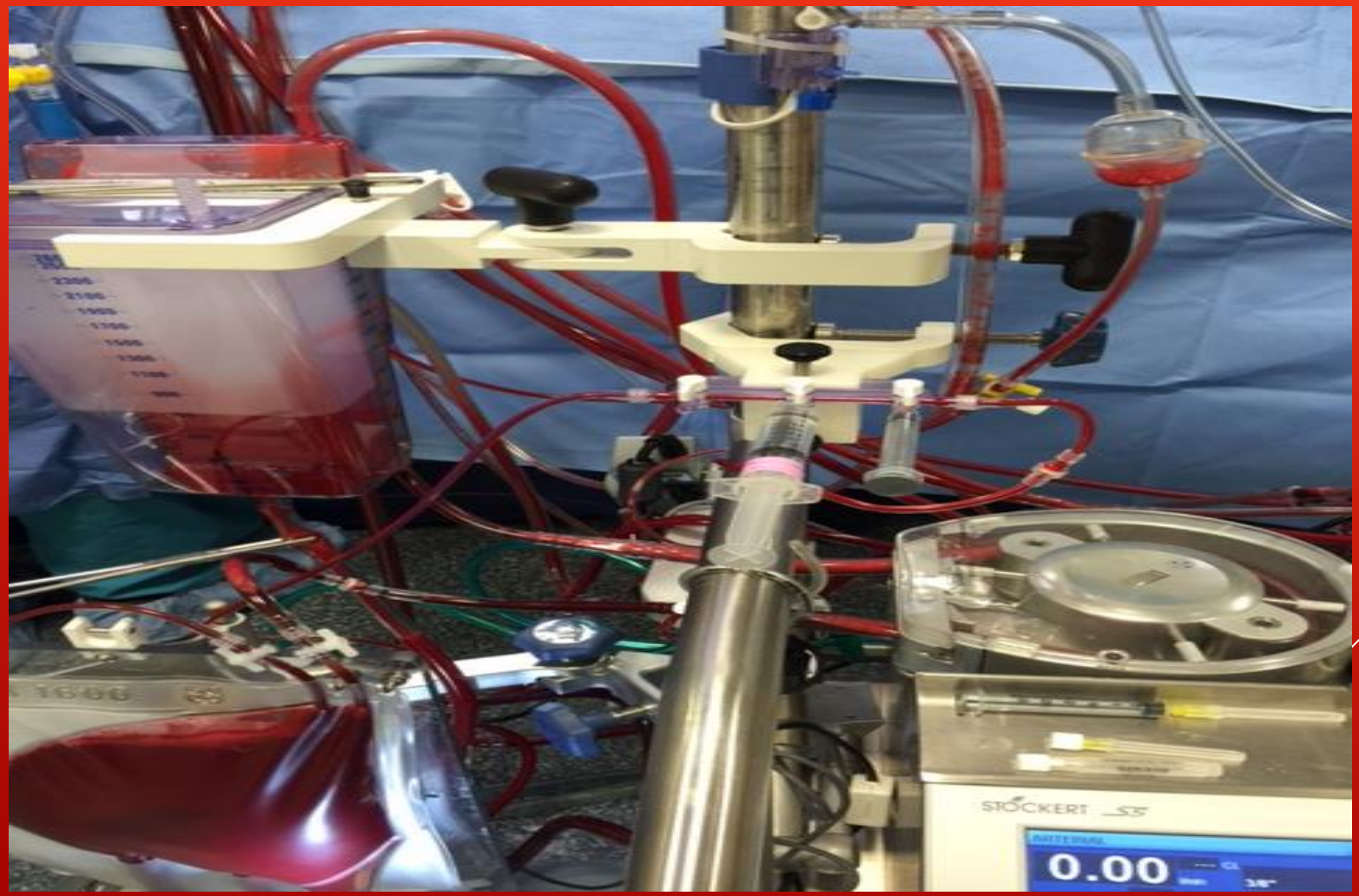
INITIAL SYSTEM:
RESTING HEART WITH THE PERFORMER



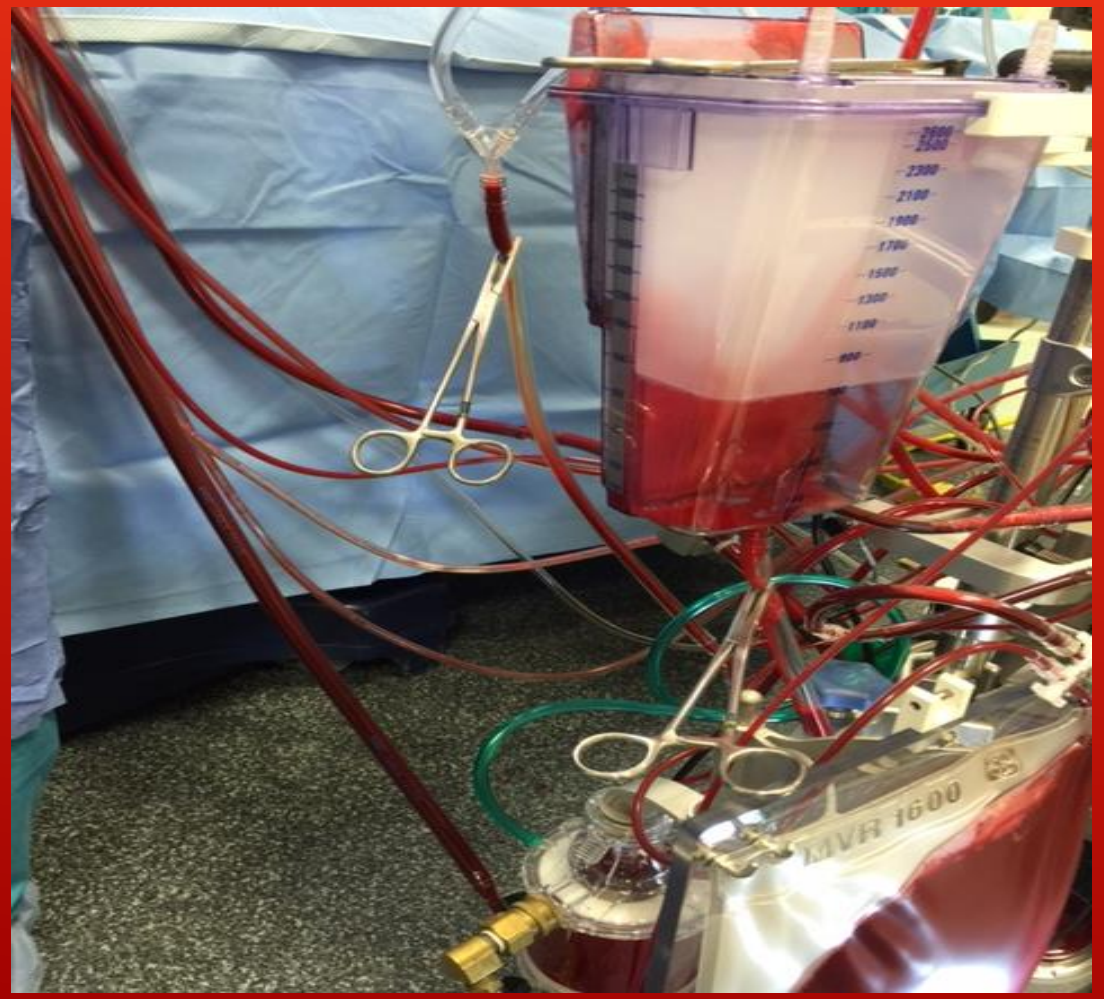
CLOSED CIRCUIT WITH A BAG

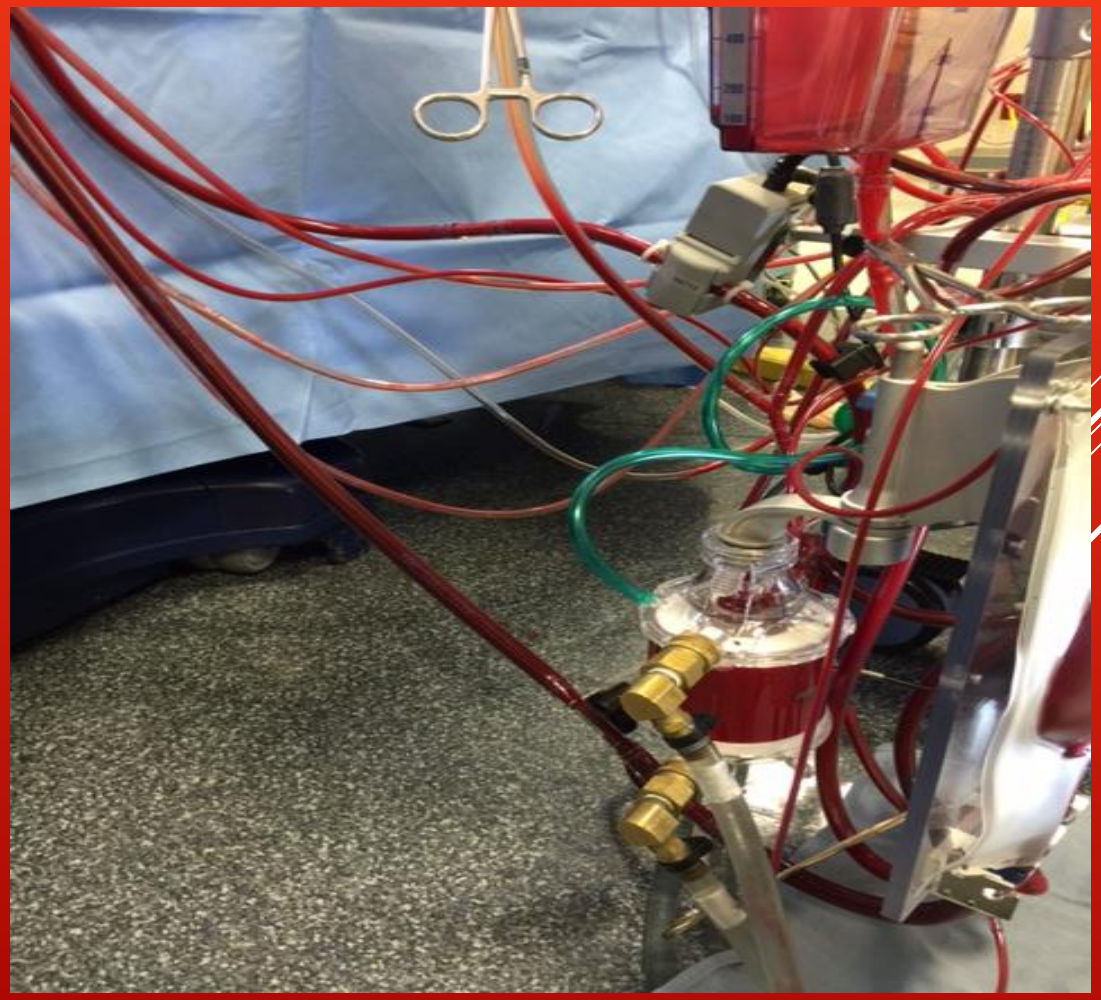


CLOSED CIRCUIT WITH A BAG



CLOSED CIRCUIT WITH A BAG





PATIENT DEMOGRAPHICS (TABLE1)

	Pre-Change Surgeon 1[a]	Post-Change, All	Post-Change, Surgeon 1	P, by Post-Change Surgeon[b]
N of cases	244	98	63	
Mean (Median, range)				
Age	71 (73,42-93)	72 (72,22-89)	72 (72,22-89)	0.574
Pre-operative Hb	14.0 (14,9-19)	13.4 (14,7-18)	13.7 (14,8-18)	0.016
Percentages				
Female	31.6%	25.5%	23.8%	0.604
Diabetes	29.5%	31.6%	30.2%	0.674
Hypertension	75.0%	79.6%	79.4%	0.940
CHF	22.1%	19.4%	17.5%	0.517
CAD	73.0%	82.7%	82.5%	0.968
PVD	6.6%	12.2%	11.1%	0.646
Acute renal failure	18.1%	30.6%	28.6%	0.556
Hyperlipidemia	62.3%	62.2%	63.5%	0.733
Alcohol abuse	5.3%	5.1%	6.3%	0.452
CKD	10.2%	17.3%	17.5%	0.968
Planned admission	71.5%	40.8%	50.8%	0.007
Previous surgery[c]	7.8%	8.2%	7.9%	0.912
Pre-admit anticoagulant[d]	2.5%	4.1%	0.0%	0.006
Hb <9 g/dL preoperative	0.0%	3.1%	3.2%	0.930
Hb <12 g/dL preoperative	9.4%	18.4%	9.5%	0.002

HOSPITAL STAY CHARACTERISTICS (TABLE 2)

	Pre-Change Surgeon 1[a]	Post-Change, All	Post-Change, Surgeon 1	P, by Post-Change Surgeon[b]
N of cases	244	98	63	
Mean (Median, range)				
Hb immediate post-op	11.1 (11,5-15)	10.7 (11,6-15)	10.9 (11,6-15)	0.102
Hb at discharge	10.7 (11,7-16)	10.5 (11,7-14)	10.7 (11,7-14)	0.112
Hb all post-op days[c]	10.6 (11,7-16)	10.2 (11,7-14)	10.4 (11,7-14)	0.068
Units transfused[d]	0.06 (0,0-6)	0.09 (0,0-4)	0.02 (0,0-1)	0.026
ICU LOS	2.9 (2,1-20)	3.4 (2,1-24)	2.7 (2,1-11)	0.009
Total LOS	7.4 (7,4-24)	7.6 (6,3-25)	7.0 (6,3-19)	0.045
Treatments (%)				
Units transfused (any)	3.9%	6.1%	1.6%	0.012
Expired	0.8%	1.0%	1.6%	0.454

OUR EXPERIENCE

- Same utilization between the 2 systems for blood product utilization (Packed Cells, FFP, Cry, and Platelets)
- Same Chest tube drainage between the 2 systems
- Slightly lower length of stay with the new circuit
- Same ventilator times between the 2 systems
- Still an overall lower cost to the hospital – even though pack price is a little higher than a CECC

RESTING HEART SYSTEM CLINICAL OBSERVATIONS

- Anecdotal morbidity observations:
  - Higher operative and post-operative Hct's
  - Noticeable reduction in blood product usage
  - Dryer patients with less operative weight gain
  - Improved neurocognative outcome
  - Reduced renal insufficiency

CONCLUSION

- Surgeon and Anesthesiologist affected very little
- Similar to our initial Perfusion training
- No Learning Curve for the Perfusionist unlike the Resting Heart system
- Takes 1 cases to feel comfortable
- Results are outstanding and equal to the Resting Heart system from a blood conservation standpoint
- Similar results between the 2 systems