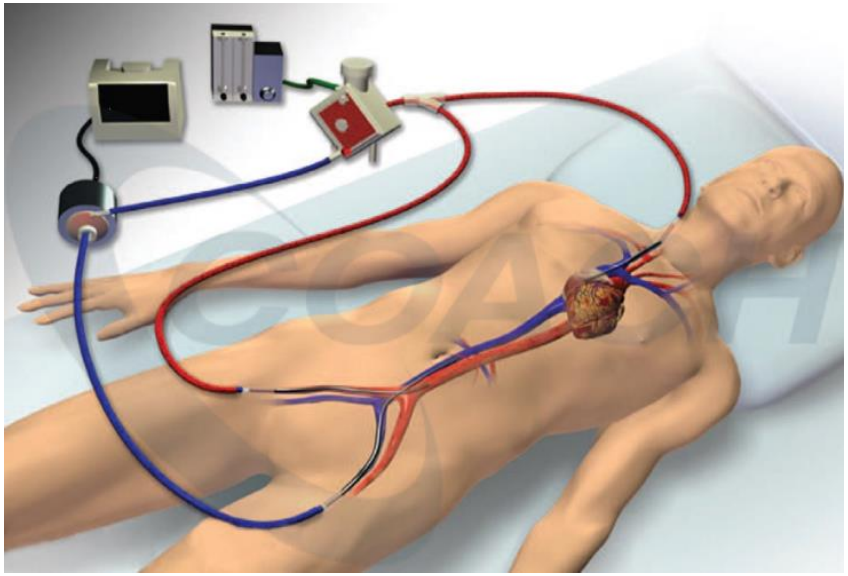
General Introduction of ECMO (1)



가천대 길병원 흉부외과

최 창 휴

대한흉부심장혈관학회 ECMO연구회

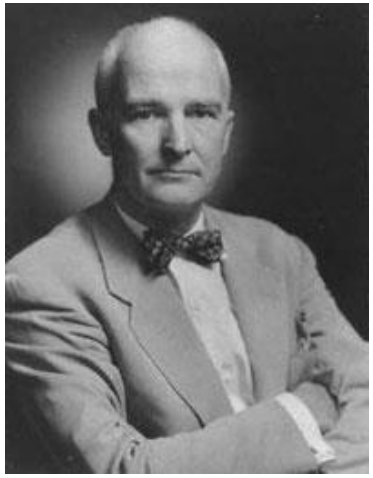
History

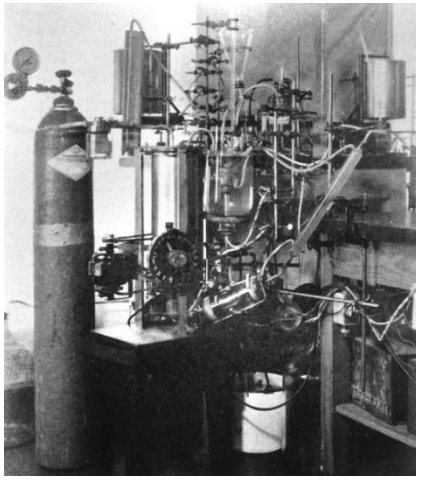
- 1953 Gibbon — Heart lung machine
- 1960s — Development of membrane oxygenators
- 1969 Dorson et al. — 1st neonate case
- 1971 Hill et al. — 1st successful adult case
- 1975 Bartlett et al. — 1st successful neonate case
- 1989 — ELSO was founded

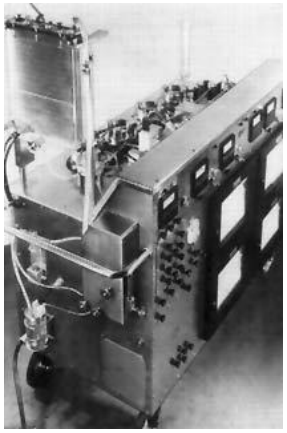
Heart Lung Machine

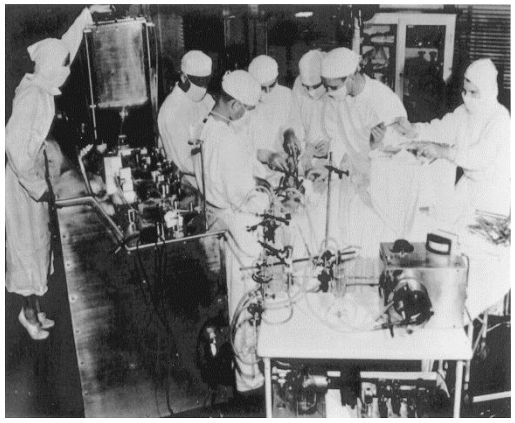
- The first heart – lung machine
  - John Gibbon (1937)
  - first successful heart operation (1953; Cecelia Bavolek)

- Limitation
  - minimize hemolysis, prevent air bubbles & infection
  - direct air– blood interface
  - duration of use limited to a few hours







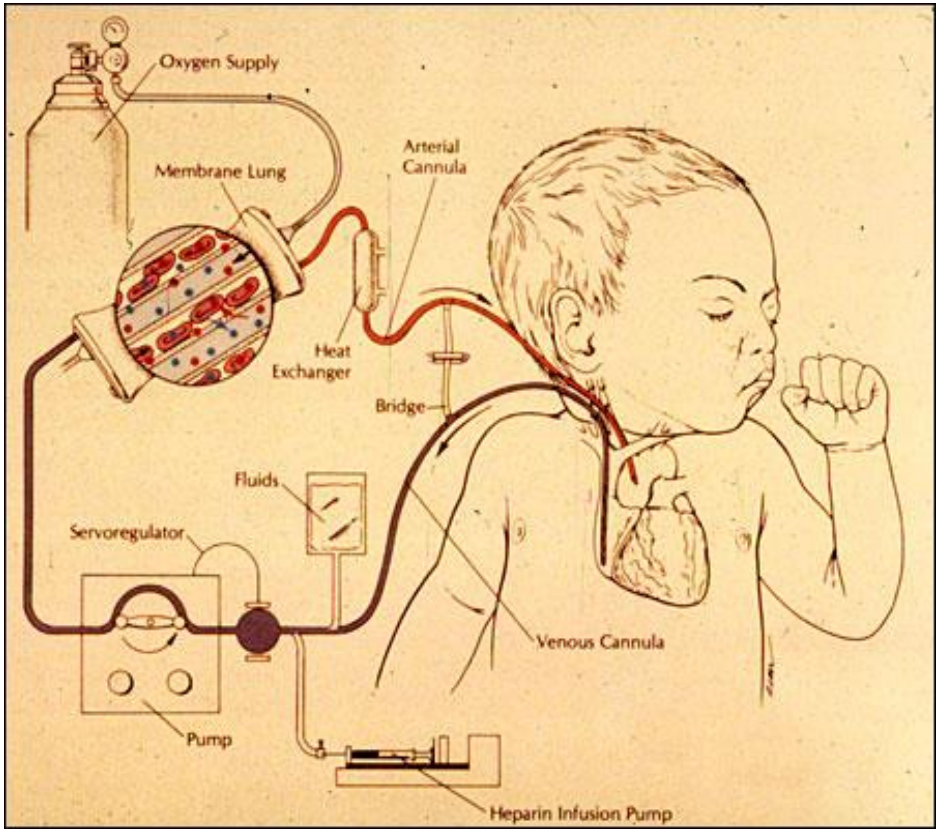


1st successful ECLS 1971

N Engl J Med 286:629-634,1972

J Donald Hill MD and Maury Bramson BME, Santa Barbara, Ca, 1971; Courtesy Dr. R. Bartlett

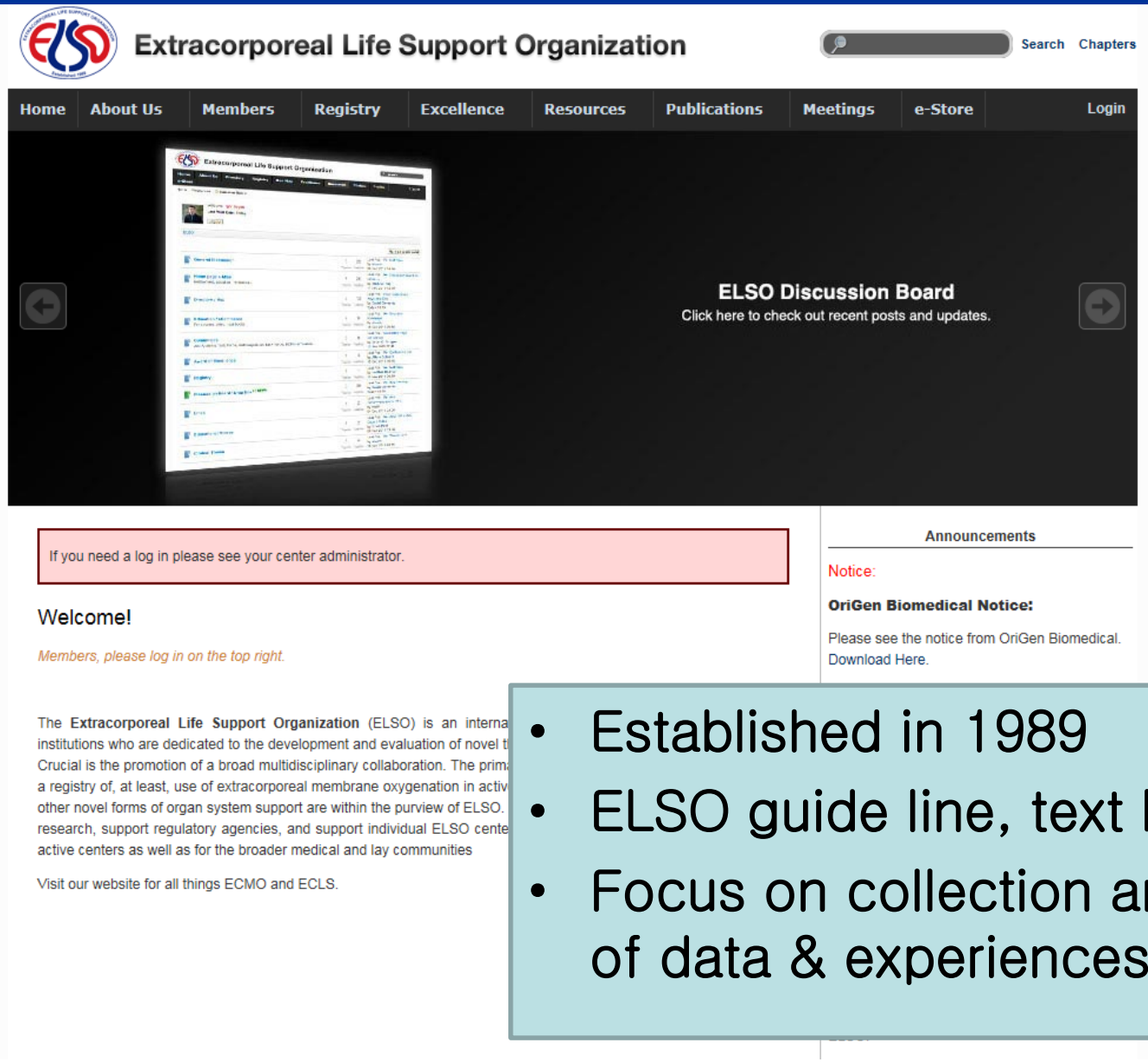
1st successful neonate case



1975, Dr. Robert Bartlett, the father of modern extracorporeal support

The 1st use of in a child (Esperanza), meconium aspiration

https://www.elso.org



- Established in 1989
- ELSO guide line, text book
- Focus on collection and sharing of data & experiences

ECLS Registry Report

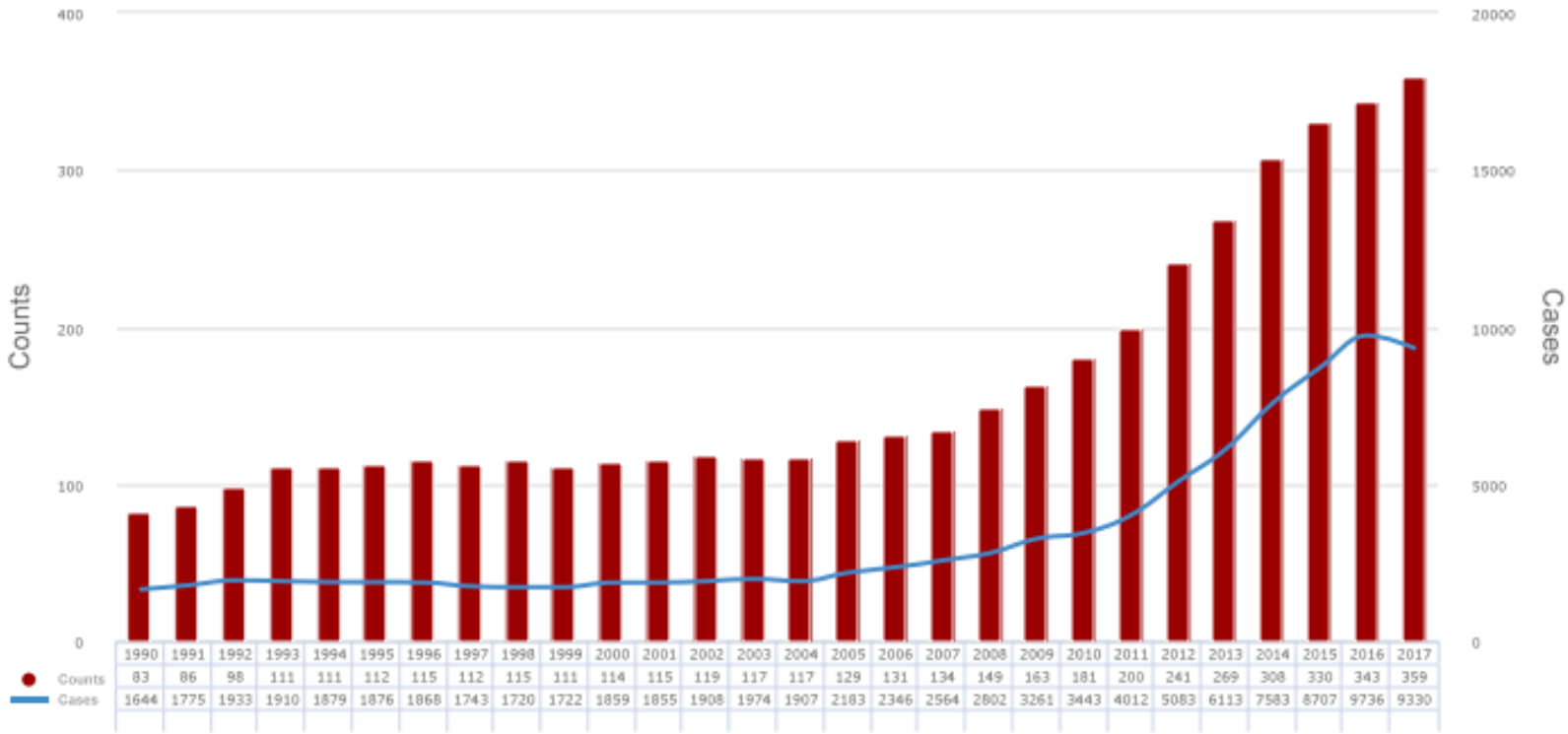
International Summary

January, 2018

Extracorporeal Life Support Organization
2800 Plymouth Road
Building 300, Room 303
Ann Arbor, MI 48109

Centers

Centers by year



	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Counts	83	86	98	111	111	112	115	112	115	111	114	115	119	117	117	129	131	134	149	163	181	200	241	269	308	330	343	359
Cases	1644	1775	1933	1910	1879	1876	1868	1743	1720	1722	1859	1855	1908	1974	1907	2183	2346	2564	2802	3261	3443	4012	5083	6113	7583	8707	9736	9330

ECLS Registry Report

International Summary

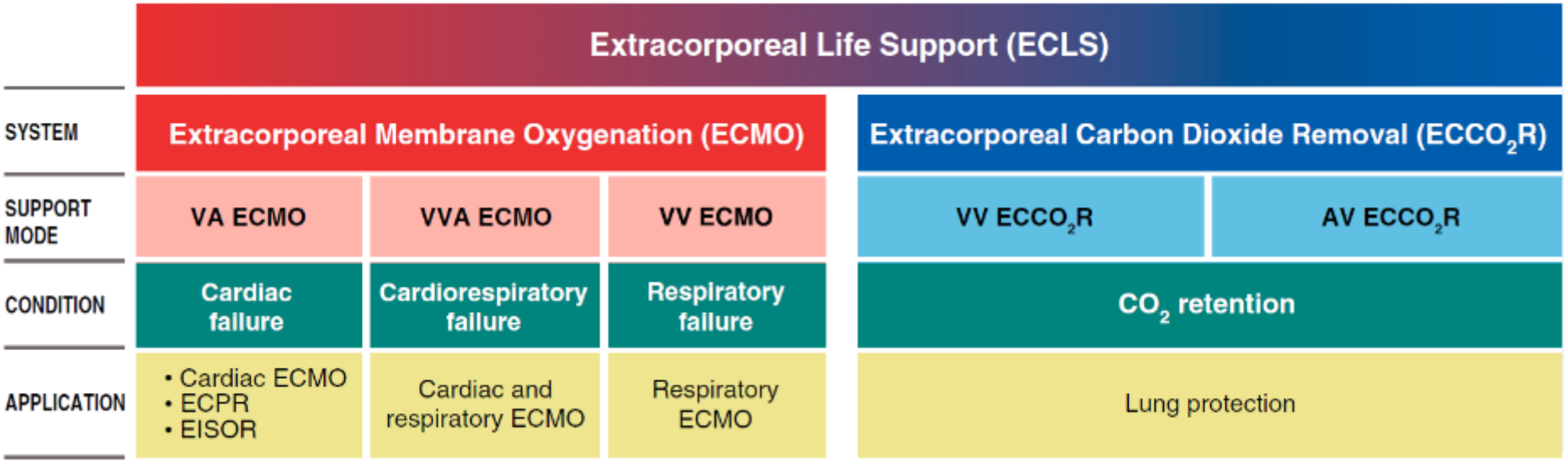
January, 2018

Extracorporeal Life Support Organization
2800 Plymouth Road
Building 300, Room 303
Ann Arbor, MI 48109

Overall Outcomes

	Total Runs	Survived ECLS		Survived to DC or Transfer	
Neonatal					
Pulmonary	30,844	25,922	84%	22,599	73%
Cardiac	7,718	5,011	64%	3,231	41%
ECPR	1,694	1,125	66%	694	40%
Pediatric					
Pulmonary	8,739	5,890	67%	5,079	58%
Cardiac	10,332	7,088	68%	5,375	52%
ECPR	3,881	2,223	57%	1,643	42%
Adult					
Pulmonary	15,686	10,463	66%	9,264	59%
Cardiac	15,201	8,489	55%	6,379	41%
ECPR	4,745	1,830	38%	1,381	29%
Total	98,840	68,041	68%	55,645	56%

Extracorporeal Life Support (ECLS) System



AV = arteriovenous; ECPR = extracorporeal cardiopulmonary resuscitation; EISOR = extracorporeal interval support for organ retrieval; VA = venoarterial; VV = venovenous; VVA = venovenoarterial

Am J Respir Crit Care Med 2018;198:447

Level 1: Cannula Hierarchy

- All cannulas contributing to the primary (major) draining and return circuit flow are written in upper case letters, such as "V-V"

- All cannulas with minor flow for secondary drainage are written in lower case letters after the major flow cannula to which side it belongs, such as "V-Aa"

- The use of a dual-lumen cannula for venovenous support would be indicated with a preceding "(dl)" abbreviation such as"(dl)V-V"

Level 2: Cannulation Site

- The next level of descriptors includes the vessel that is cannulated through the use of subscripted lowercase letters indexing the relevant drainage or return cannulation descriptor.

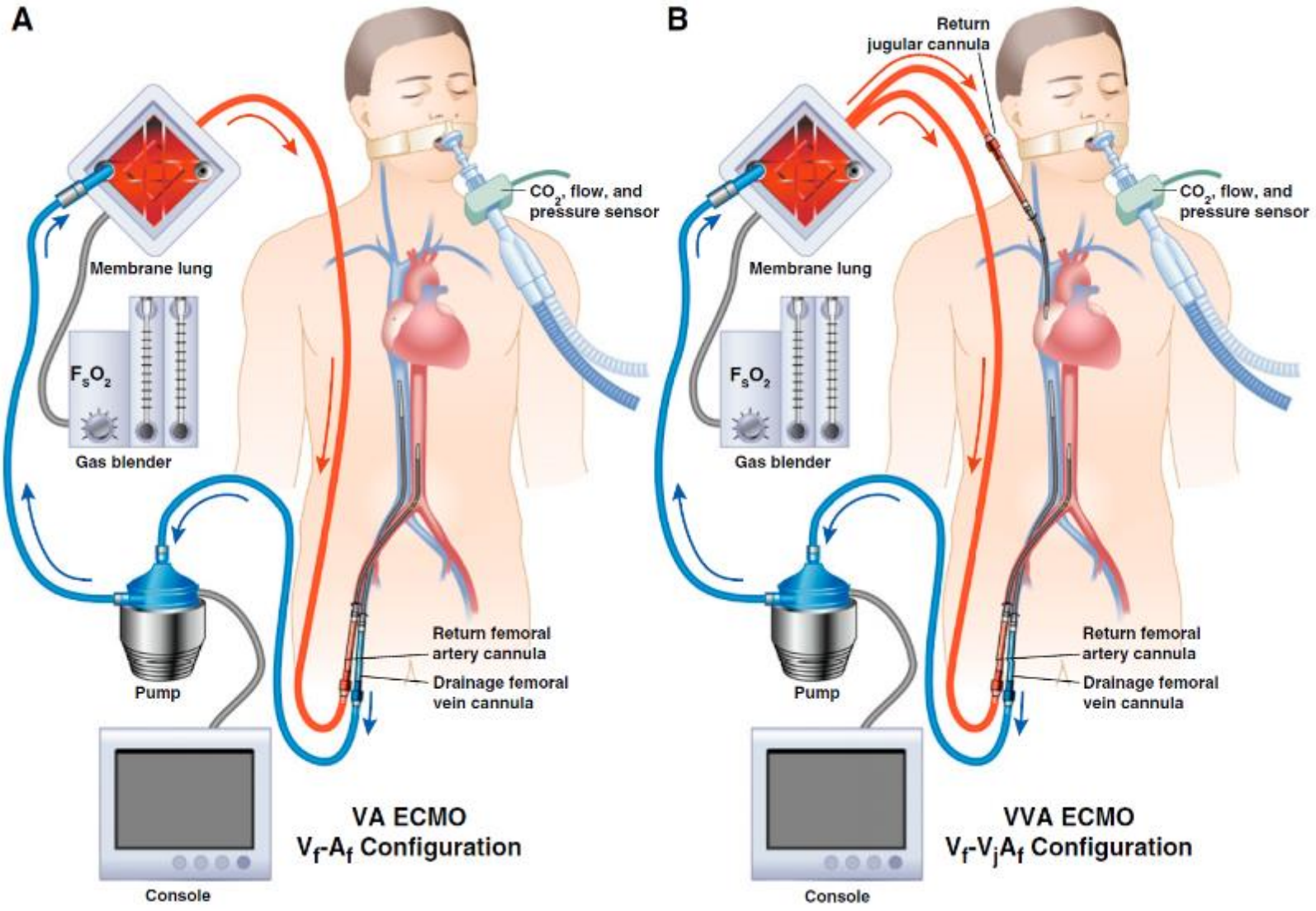
- Bifemoral cannulation for venoarterial support would be indicated as "V_f-A_f."

- The traditional two-cannula venovenous configuration with drainage from the femoral and return to the internal jugular would be indicated as "V_f-V_j."

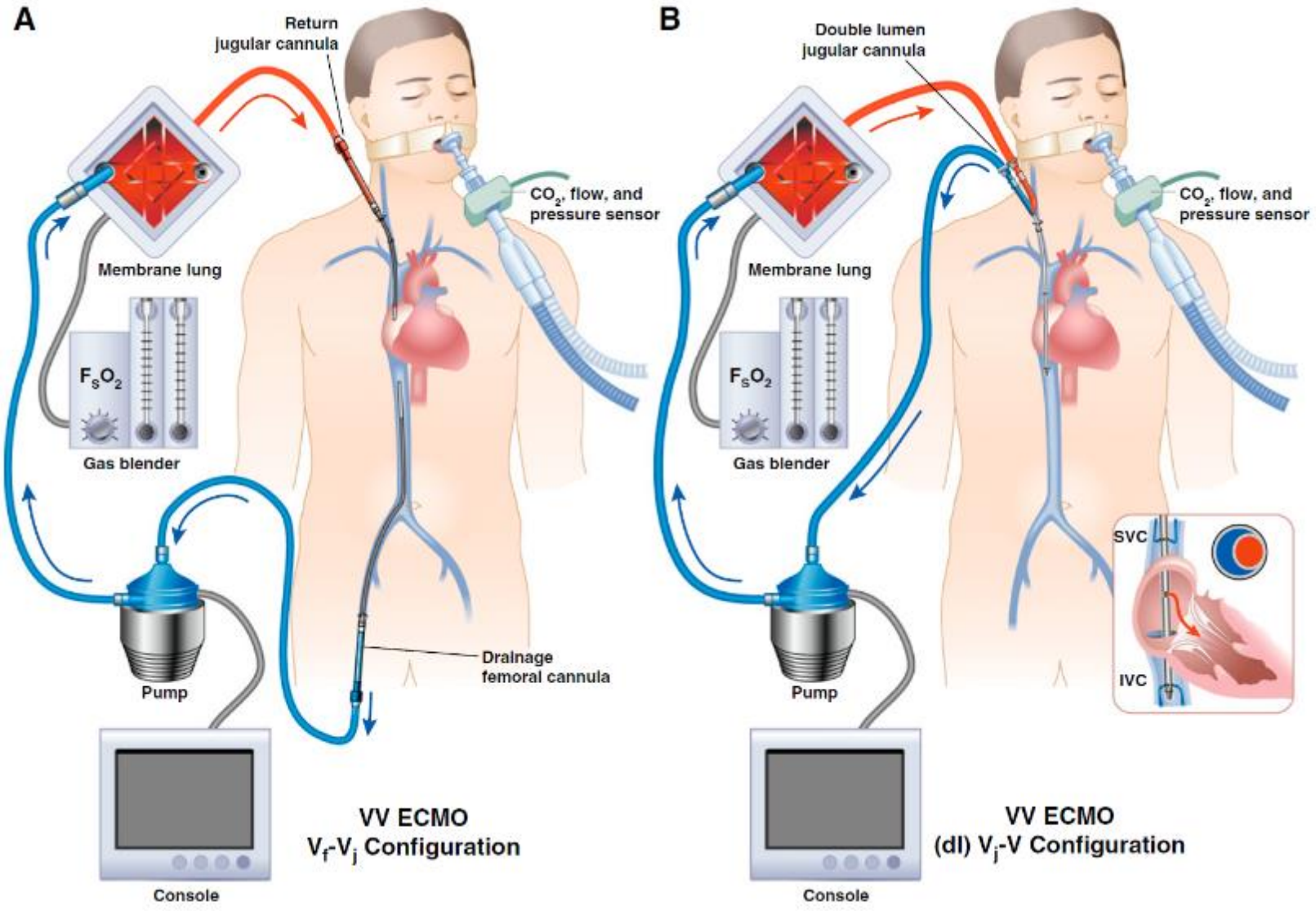
Abbreviations for Cannulation

Level	Abbreviation	Definition
Primary or secondary access	A or a	Systemic artery
	V	Systemic vein
	P	Pulmonary artery
Cannulation site	c	Carotid artery
	f	Femoral vessel
	j	Jugular vein
	s	Subclavian vessel
Central cannulation sites	RA	Right atrium
	LA	Left atrium
	LV	Left ventricle
	AO	Aorta
	PA	Pulmonary artery
	v_a	Left atrial vent

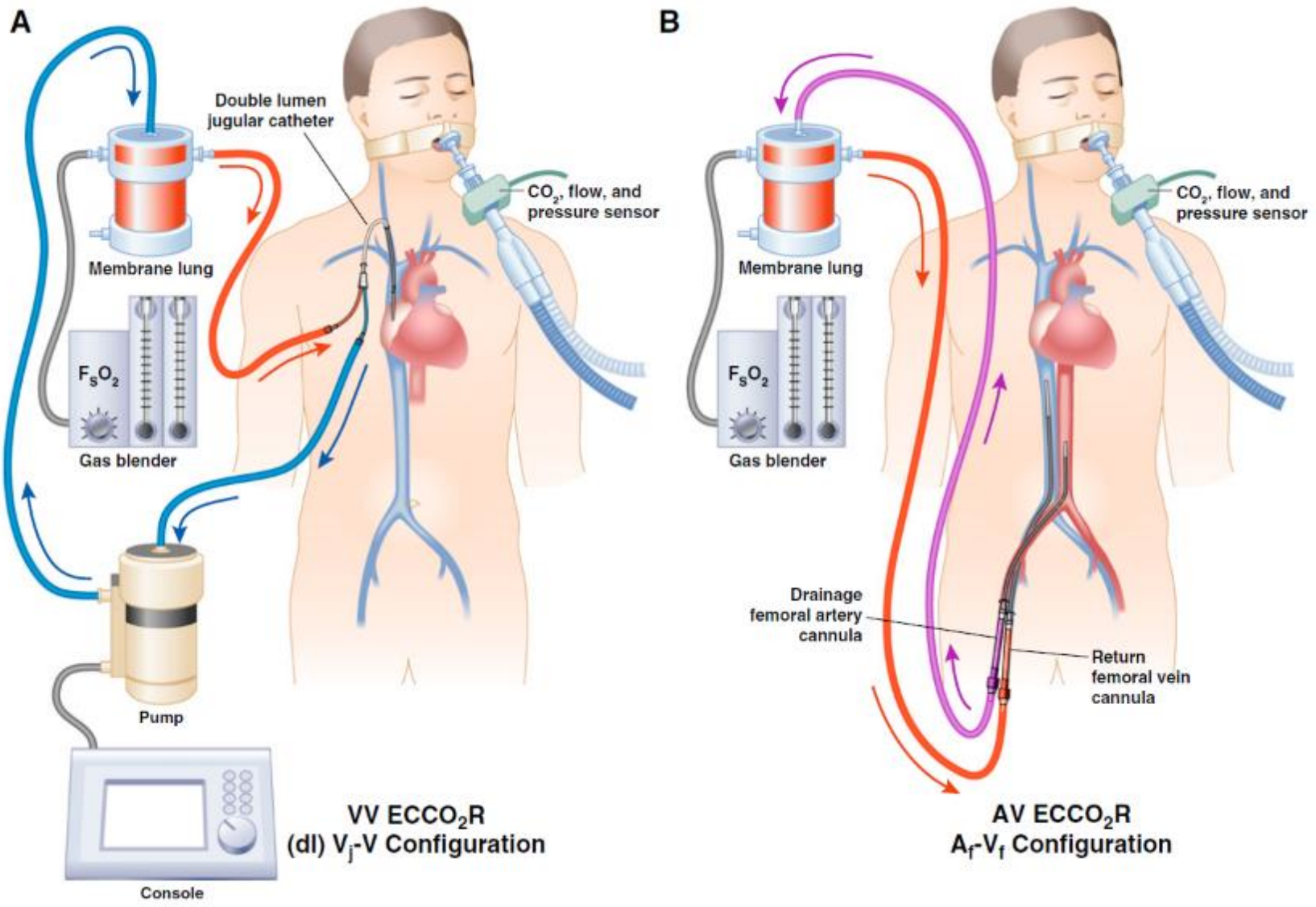
Schematic of VA & VVA ECMO



Schematic of VV ECMO

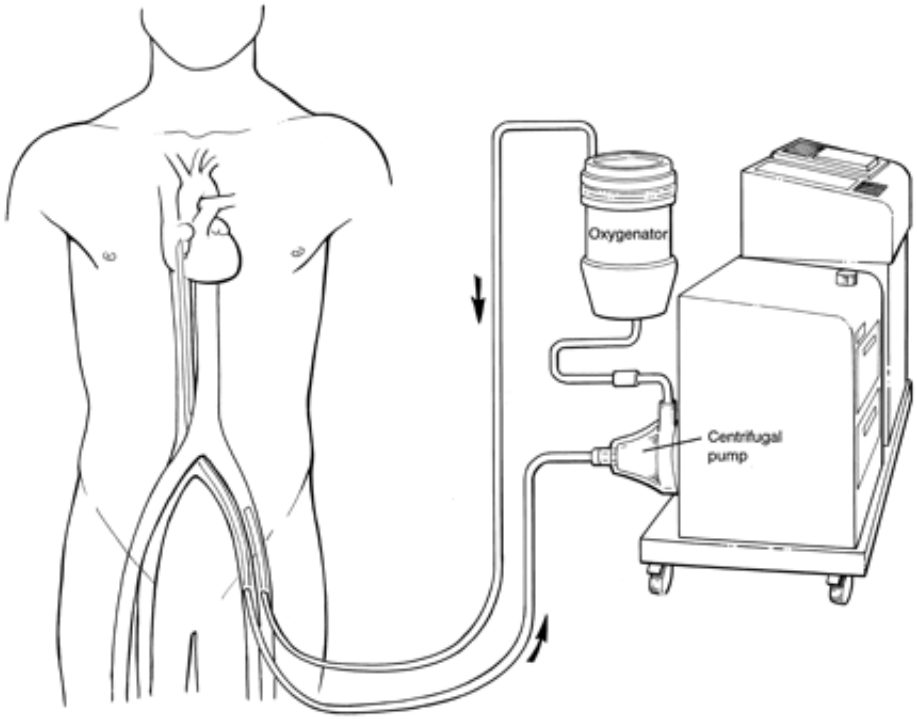


Schematic of $ECCO_2R$



Basic Physiology of ECMO

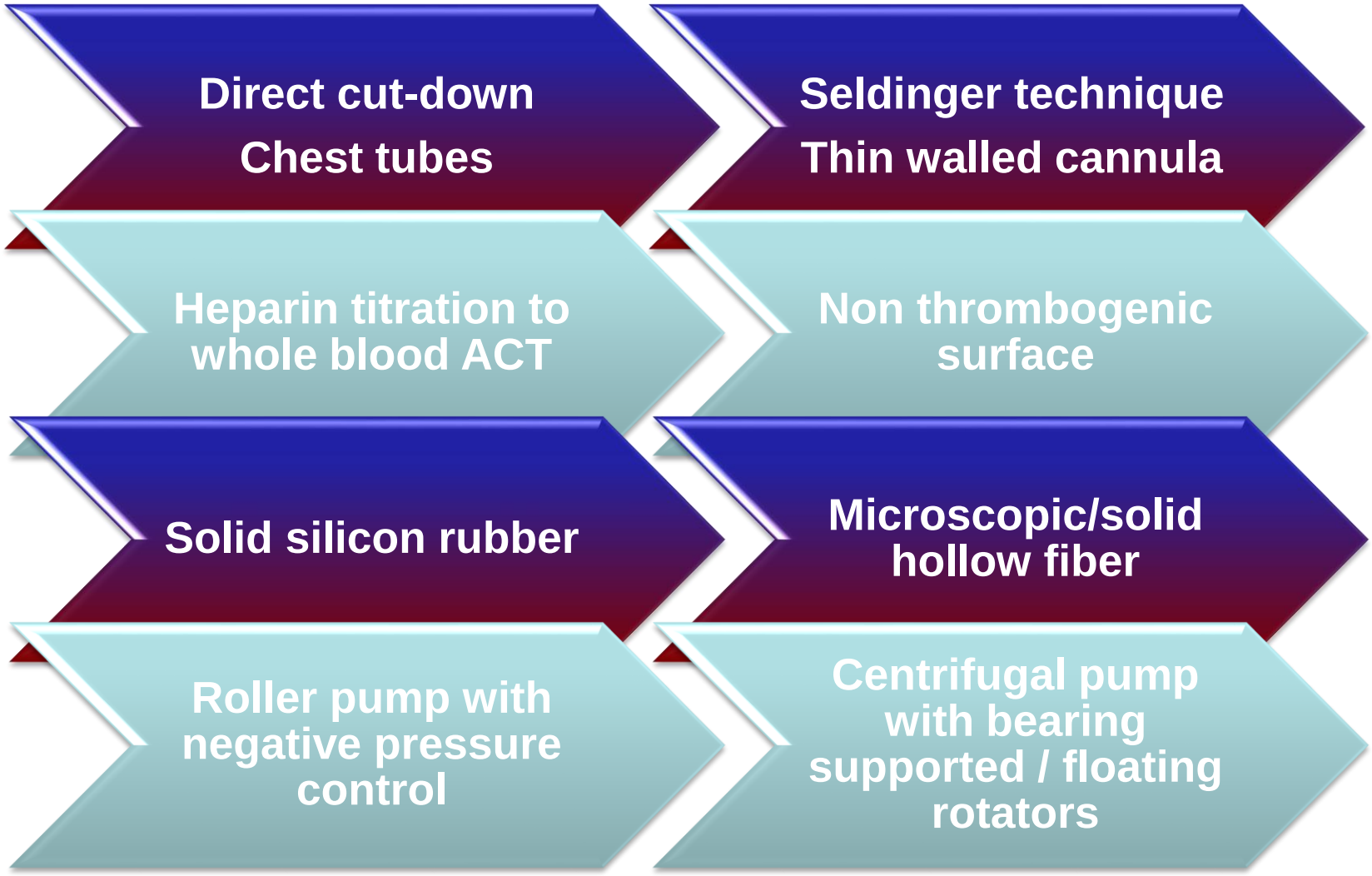
- Hollow-fiber membrane oxygenator
- Centrifugal pump: totally nonocclusive and afterload-dependent
- Circuitry interfaced between the patient and the system



Closed circuit → No Venous Reservoir

Drain amount = Reinfusion amount → Constant total volume

ECMO Equipment



EBS; 66.7%

Emergency Bypass?

PLS: 18.2%

Permanent life support ?

- Capiox EBS (Terumo com.)
- Quick, Compact and Simple (have the minimum number of necessary functions).

- Quadrox PLS® oxygenator
  - durability silicon membrane
  - approval for 14 days
  - Rota flow RF 32 pump
  - minimal priming volume
  - minimal hemolysis

Emergency Bypass System
(EBS®,Terumo, Japan)

- Quick / Compact / Simple / Safe

- 일본 1995년 개발
- 우리나라 2003년도 도입, 현재 국내 101대 사용

2010 : LX oxygenator

2015 : SP-200

専用カートでのシステム例

コントローラー

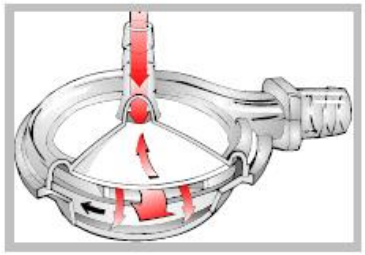
流量/気泡センサー
（チューブ取付け時）

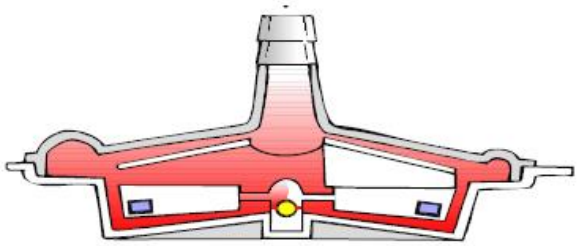
QUADROX PLS 2007

– Permanent Life Support –

MAQUET

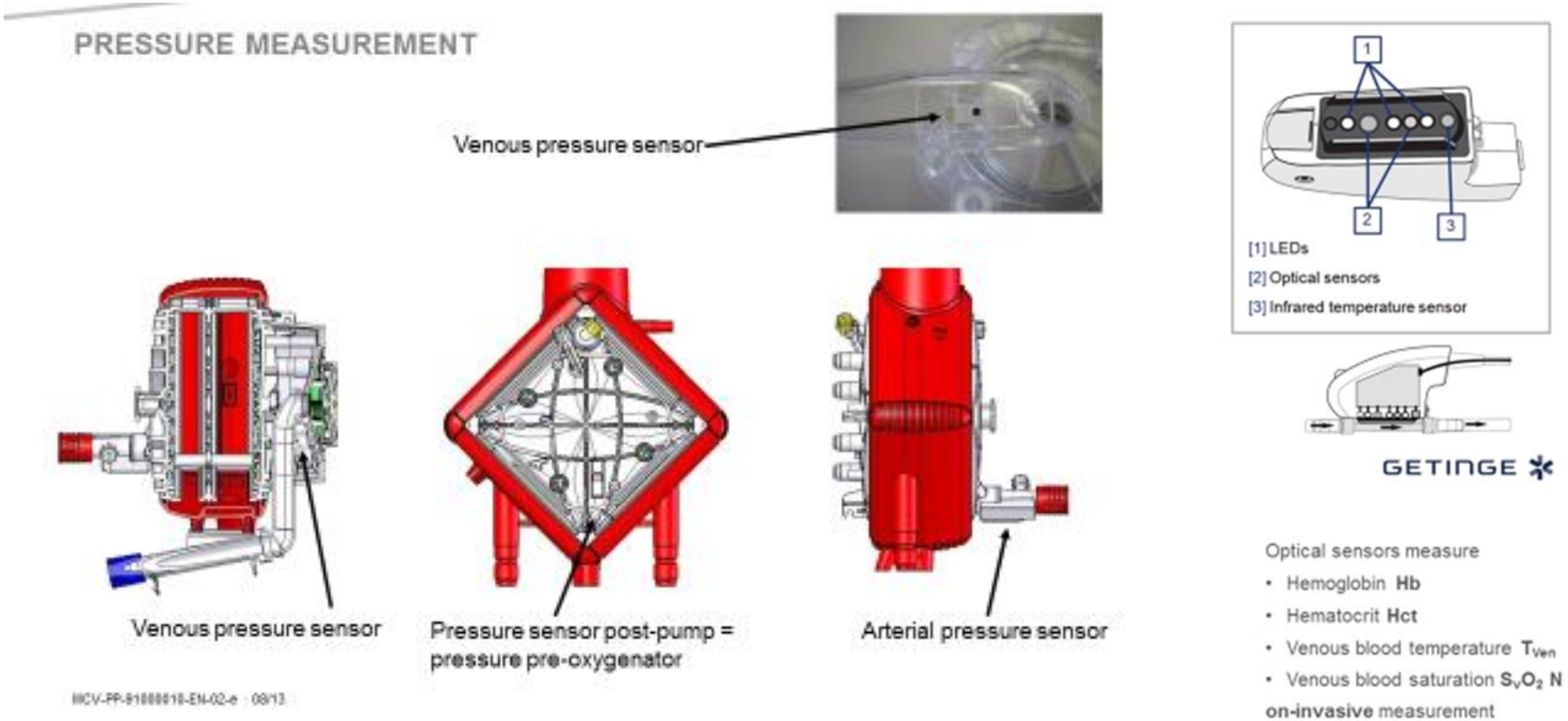
Centrifugal pumpe Rotaflow RF 32





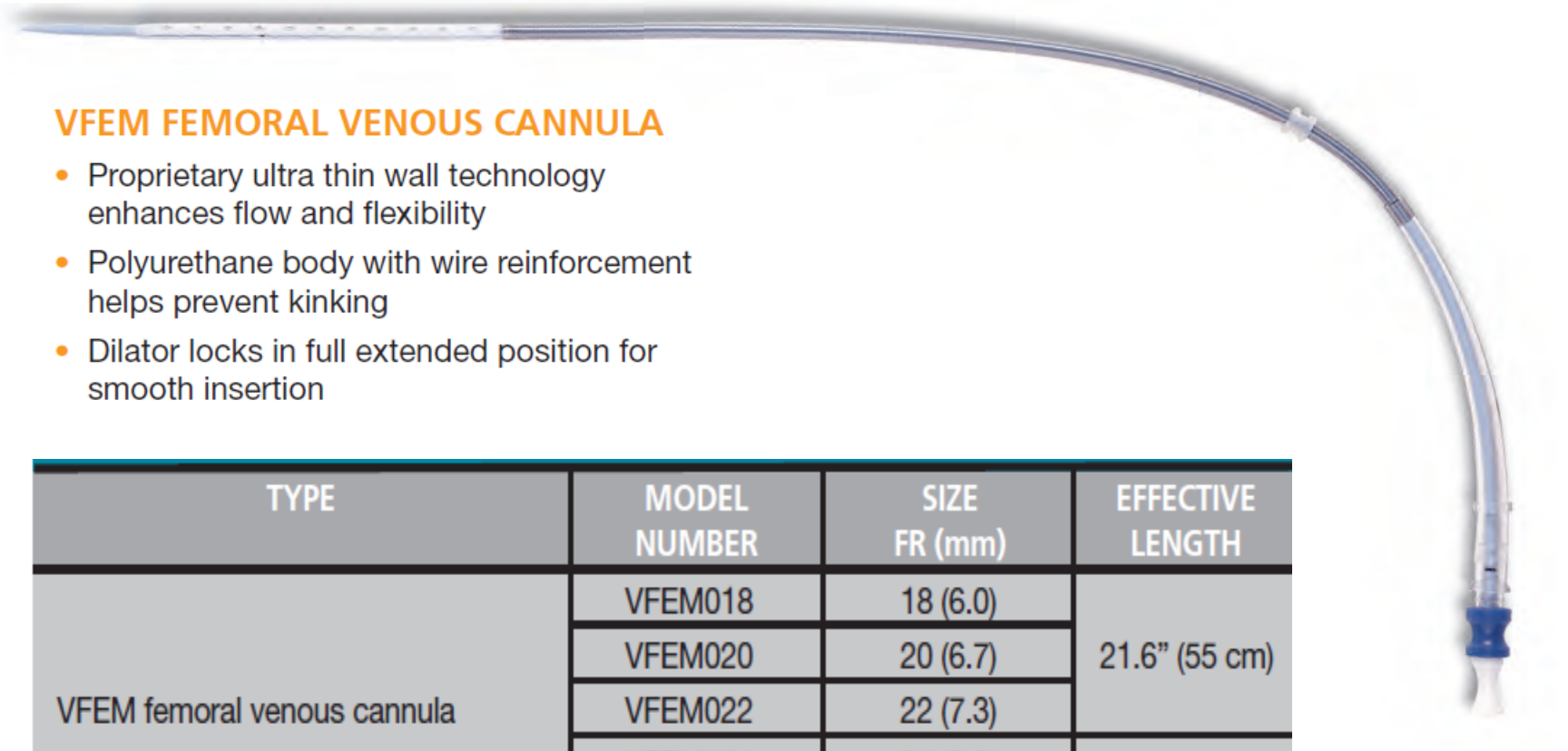
Cardiohelp (MAQUET)

HLS set advance(Cardiohelp-i)



12월중 치료재료 결정신청 접수예정, 6개월 심평원 검토기간 소요

VFEM®
Femoral Venous Cannula



VFEM FEMORAL VENOUS CANNULA

- Proprietary ultra thin wall technology enhances flow and flexibility
- Polyurethane body with wire reinforcement helps prevent kinking
- Dilator locks in full extended position for smooth insertion

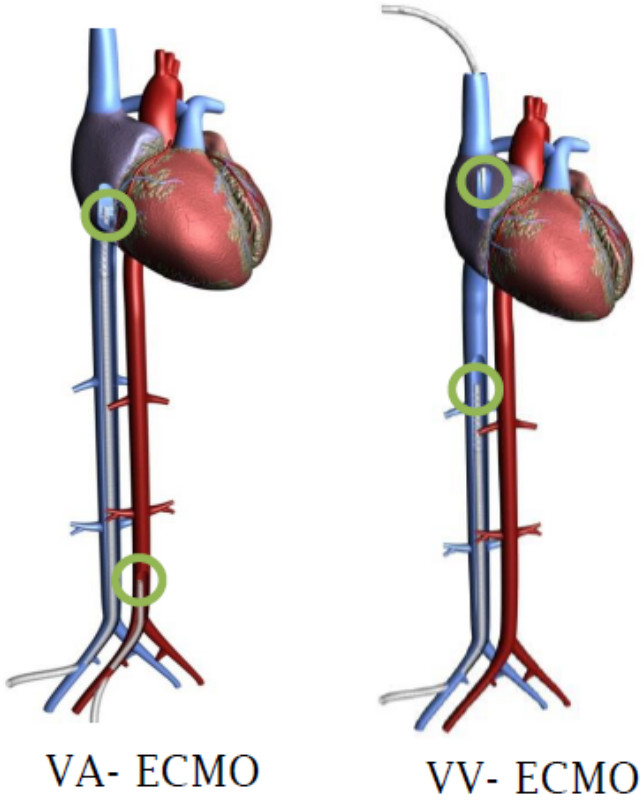
TYPE	MODEL NUMBER	SIZE FR (mm)	EFFECTIVE LENGTH
VFEM femoral venous cannula	VFEM018	18 (6.0)	21.6" (55 cm)
	VFEM020	20 (6.7)	
	VFEM022	22 (7.3)	
	VFEM024	24 (8.0)	26.8" (68 cm)
	VFEM028	28 (9.3)	

Bio-Medicus® Multi-Stage Femoral Venous Cannula

HLS CANNULAE

- Features & Benefits
- **Four different insertion lengths**
- Arterial short: 15 cm
- Arterial long: 23 cm
- Venous short: 38 cm
- Venous long: 55 cm

► **Covering of all applications (V-A / V-V)**



HLS cannula: 12월 1일 보험 고시, 선별급여 50%, 836,000원, 30 일 guarantee

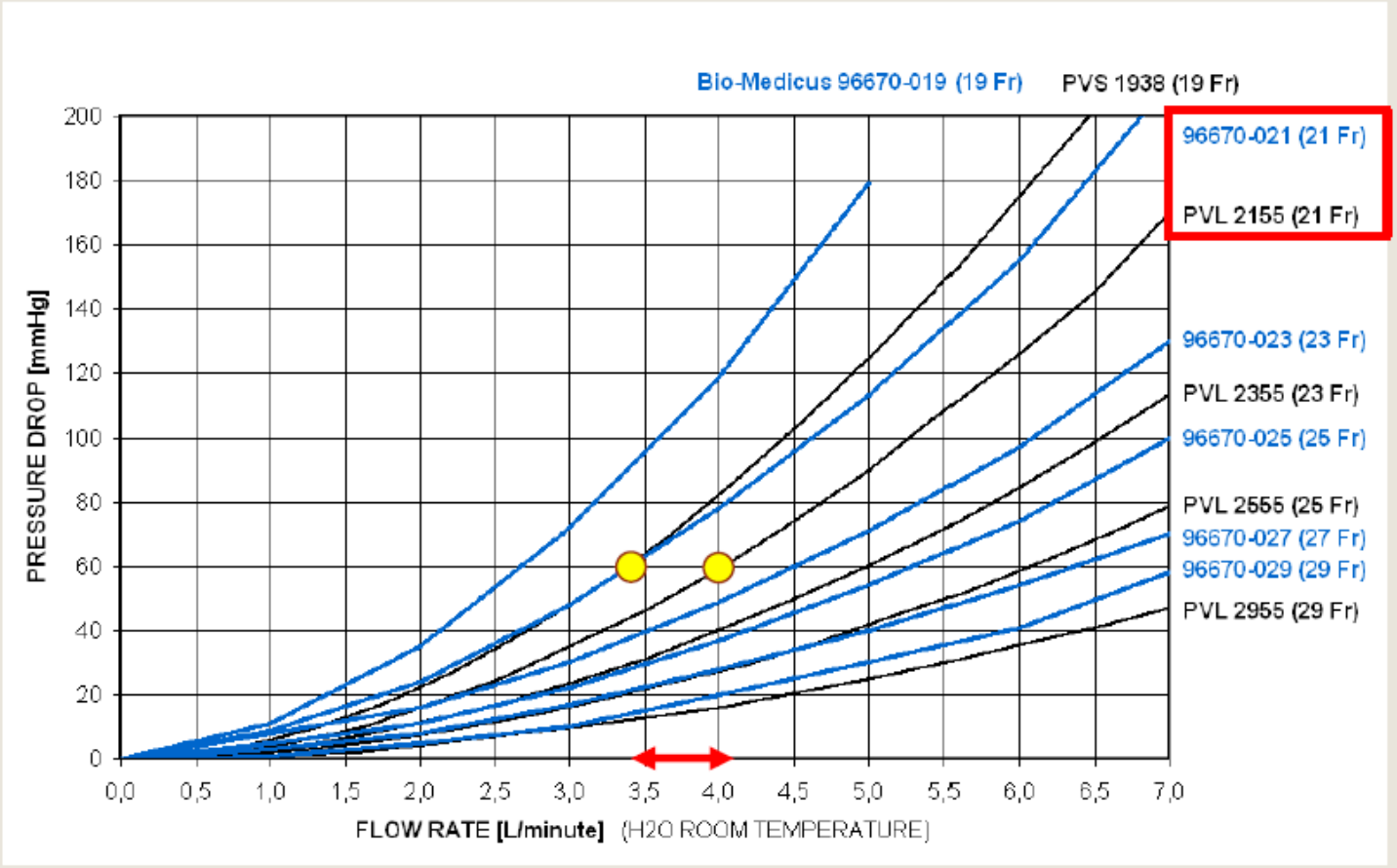
- Features & Benefits

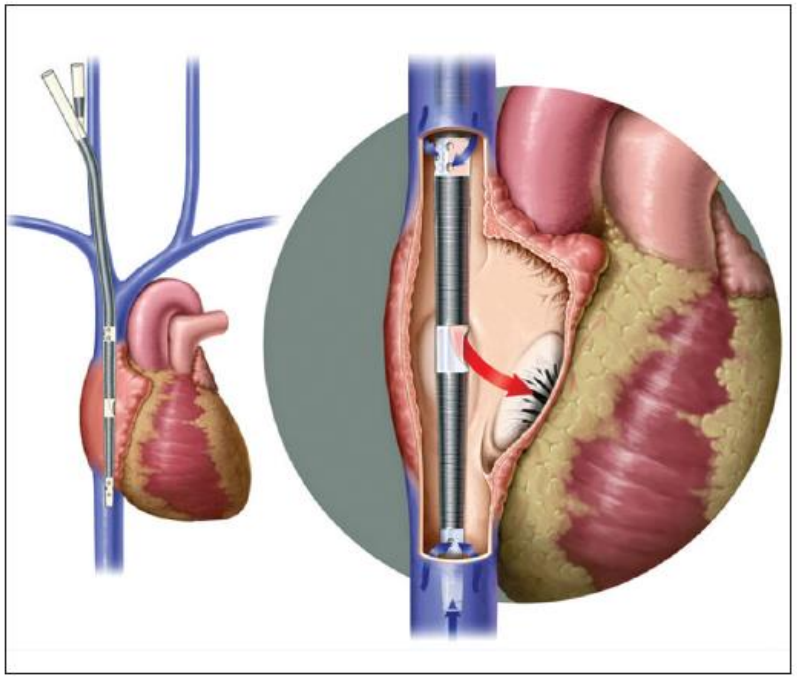
- **Side holes on arterial and venous**
- **cannulae tip**
  - Excellent flow/ drainage characteristics
  - Reduced risk of plaque embolism due to reduced infusion jet, efficient drainage characteri

- **One-piece design**
  - Reduced risk of hemolysis and thromboembolic events
  - Excellent flow/ drainage characteristics with minimized risk for flow turbulences

COMPETITOR COMPARISON - FLOWCHARTS

- Comparison: Venous HLS Cannula vs. Bio-Medicus/Medtronic

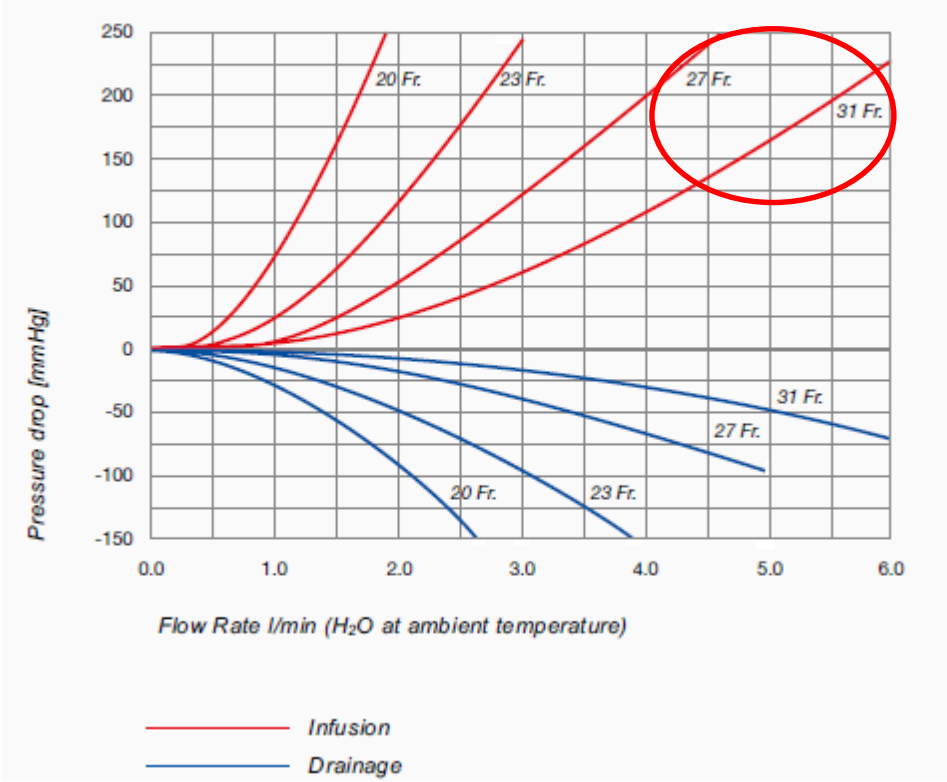




Avalon Elite Bi-Caval Dual Lumen Catheters

Article No.	Size
10013	13 Fr. (4.3 mm)
10016	16 Fr. (5.3 mm)
10019	19 Fr. (6.4 mm)
10020	20 Fr. (6.7 mm)
10023	23 Fr. (7.7 mm)
10027	27 Fr. (9.0 mm)
10031	31 Fr. (10.3 mm)

Pressure drop vs. flow 20, 23, 27, 31 Fr.



Avalone Elite DLC, 식약청 접수 6 개월, 심평원 검토 6 개월

1st ECMO Cases in Korea

- 1st case report (4cases 1990.7~1991.12)

Prolonged Extracorporeal Lung and Heart Assist
(Extracorporeal Membrane Oxygenation)
−4 cases report−

Hyun Choi, M.D., Wang Gyu Lee, M.D., Sang Min Lee, M.D.*, Hyun Soo Moon, M.D.*
Young Kyun Chung, M.D., Kook Hyun Lee, M.D.[1], Byung Moon Ham, M.D.[1] and Kwang Woo Kim, M.D.[1]**

Department of Anesthesiology, College of Medicine, Hallym University
**Department of Anesthesiology, Sejong General Hospital*
***Department of Anesthesiology, College of Medicine, Kyung Sang University*
[1]Department of Anesthesiology, College of Medicine, Seoul National University

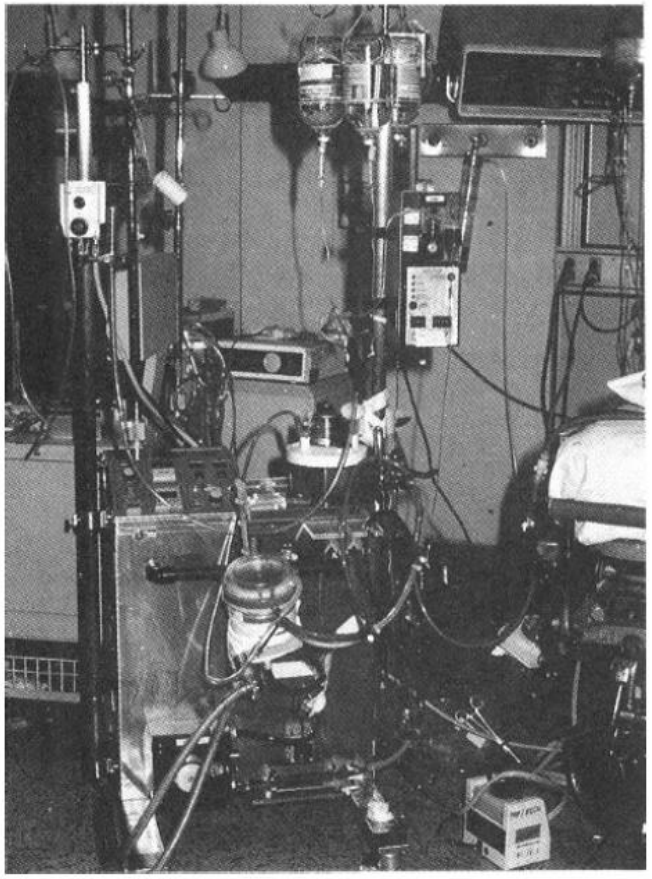
- korean J Anestheisol 1992;025(02):424-32

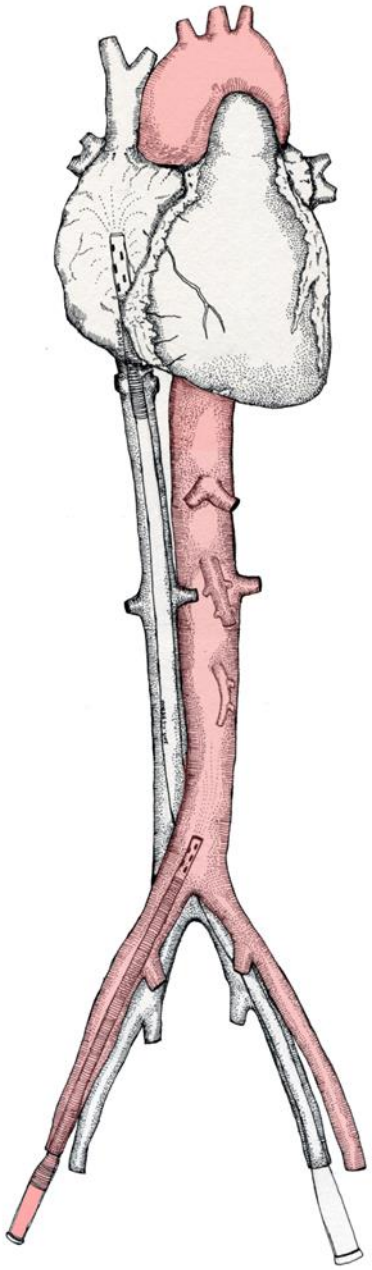
- 1st Respiratory support

- KP Hong KJTC Surg 1994;27:60-2

- 1st Extracorporeal Cardiopulmo Resuscitation (E-CPR)

- JH JUN KJTC Surg 1999;32:53-7





1st APESLO. in Beijing , 2013 Oct

Current ECMO in Korea from 15 Center Data

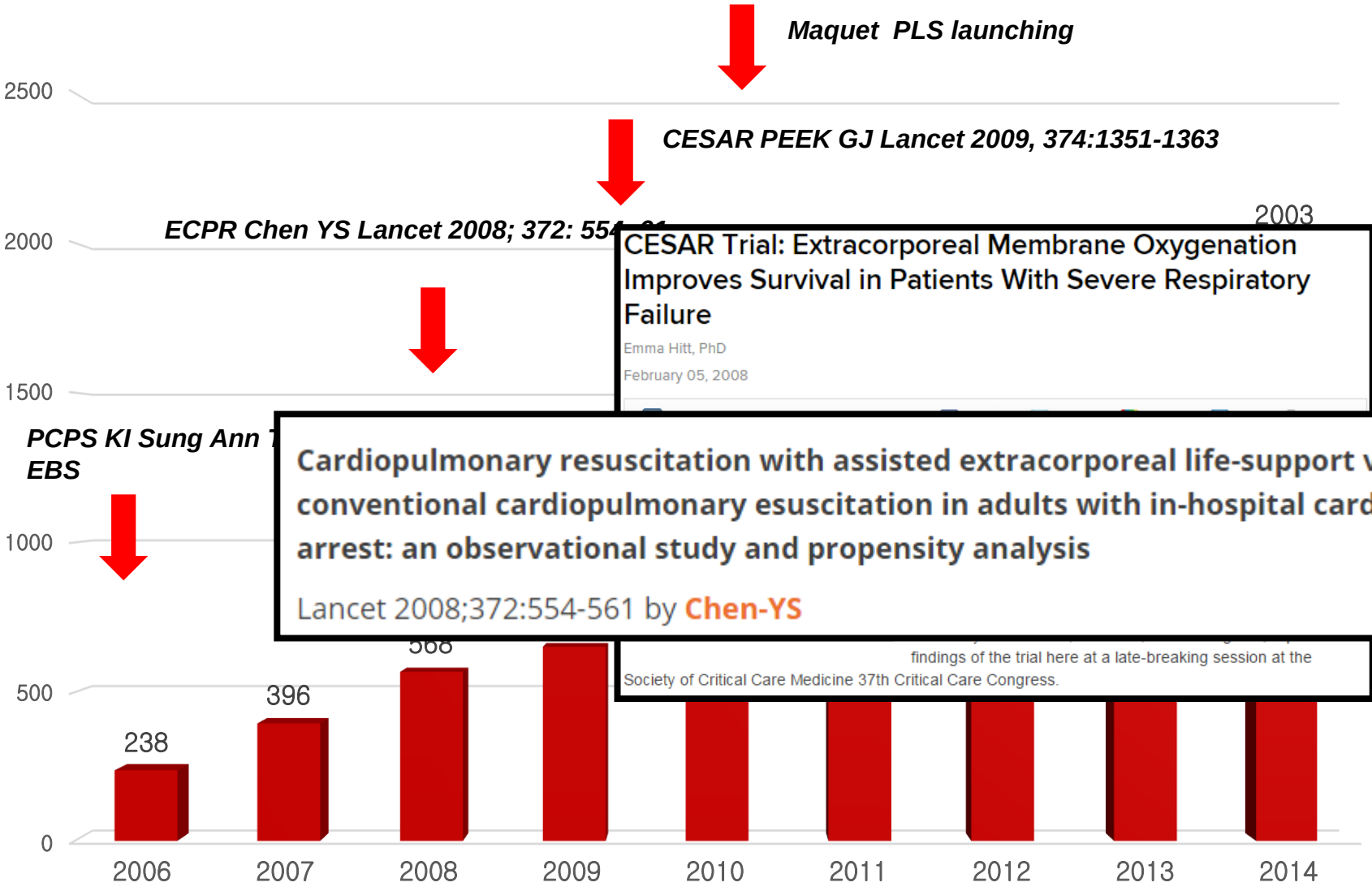
Total: 2668 (based on HIRA, 2011: 1174, 2012: 1494)

N=1087 (based on 15 Center data)

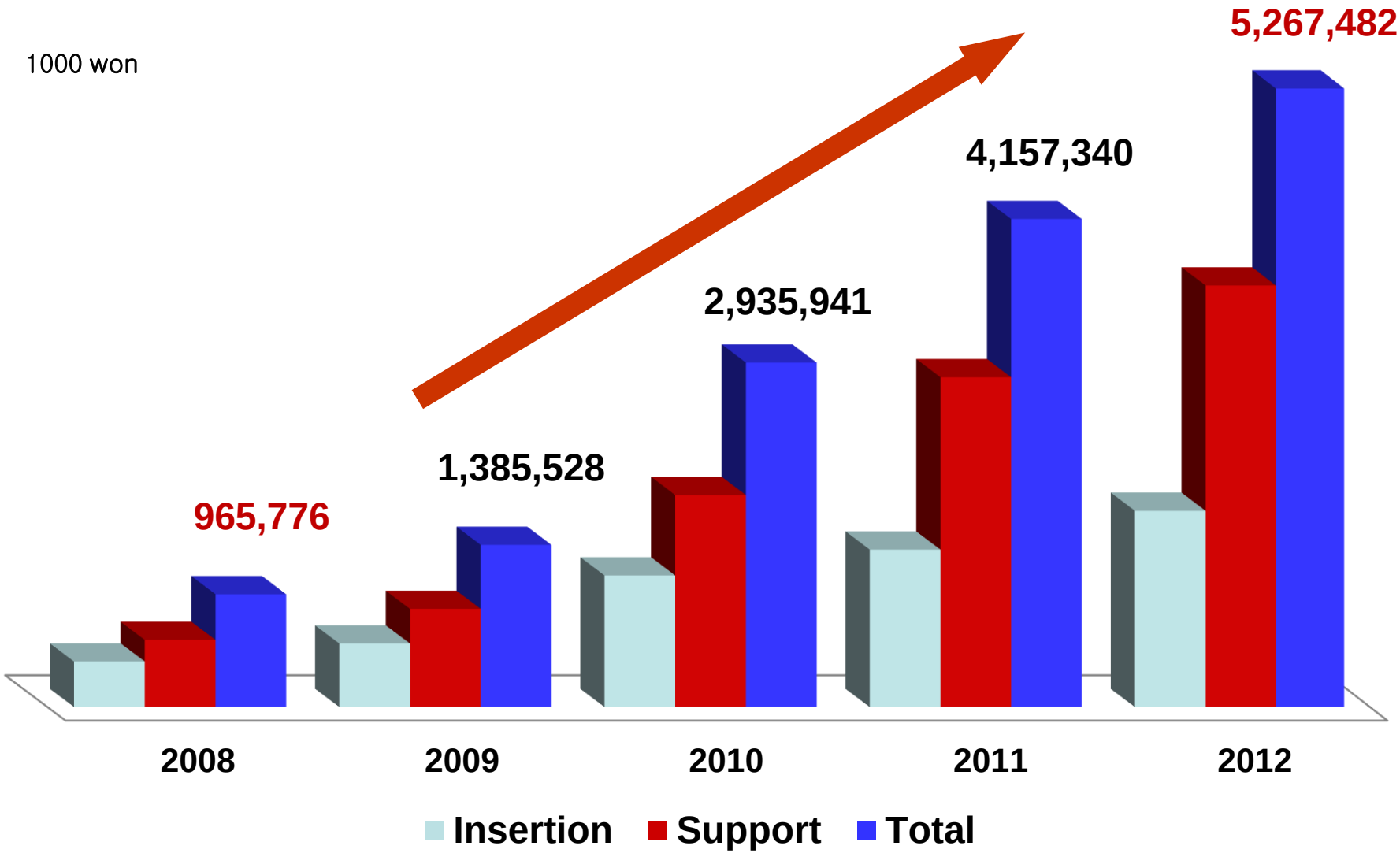
- M:F = 685:401
- mean age: 52.8±21.9yrs

● 국내 에크모 현황

(2006~2014 건강심사평가원 자료) http://www.hira.or.kr



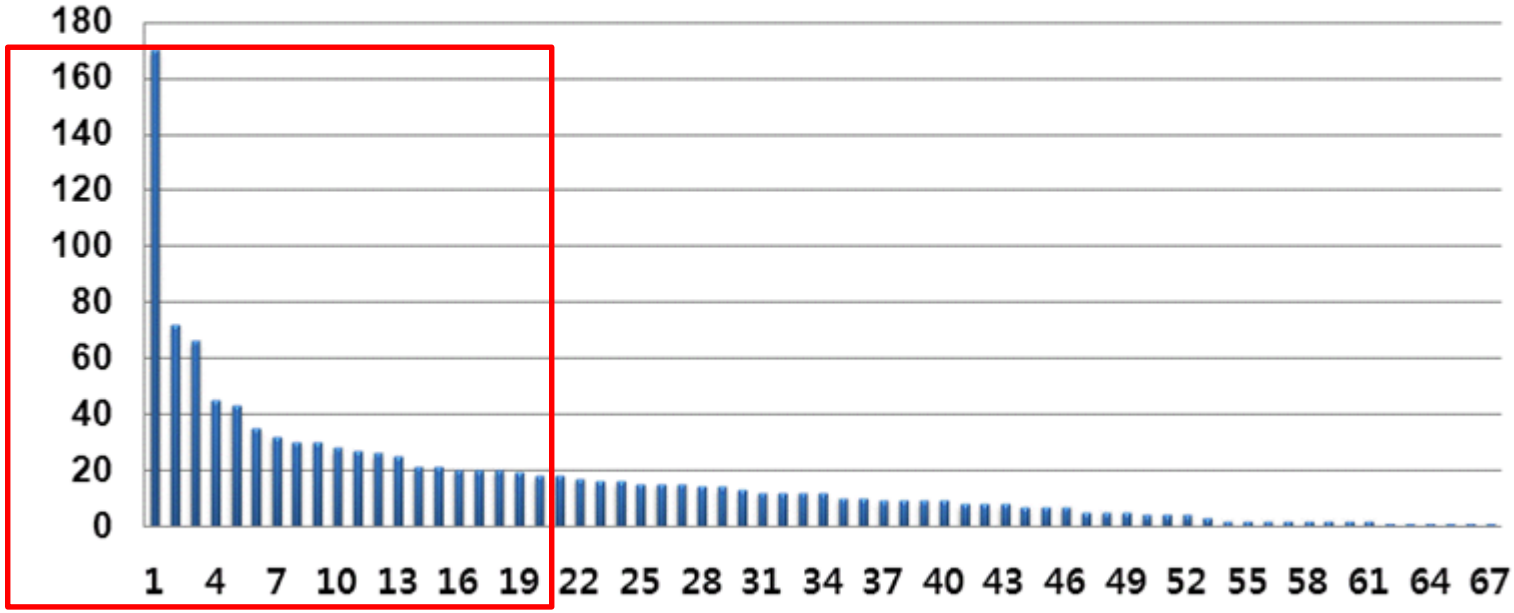
ECMO in KOREA



Korean Health Insurance Review, HIRA-NPS-2009-0051 & http://www.hira.or.kr

ECMO in KOREA

- ECMO center (2011) — 71(1122 cases)
- More than 20 cases — 19 center
- Planed to open — 15 hospital

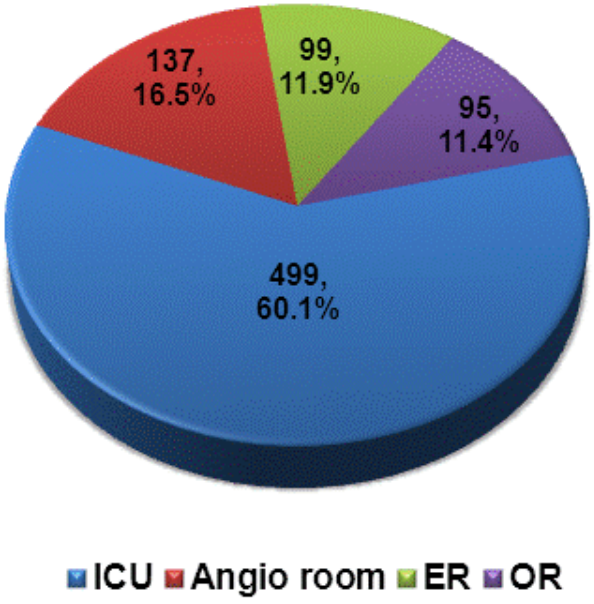


Telephone Survey(2011)

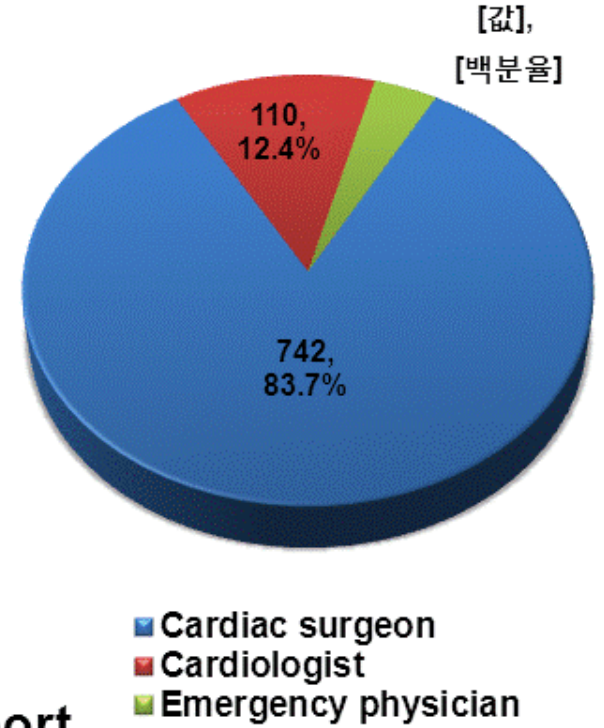
ECMO in KOREA

ECMO Insertion I

- **Where?**
  (RR 830/1087, 76.3%)



- **Who?**
  (RR 887/1087, 81.6%)

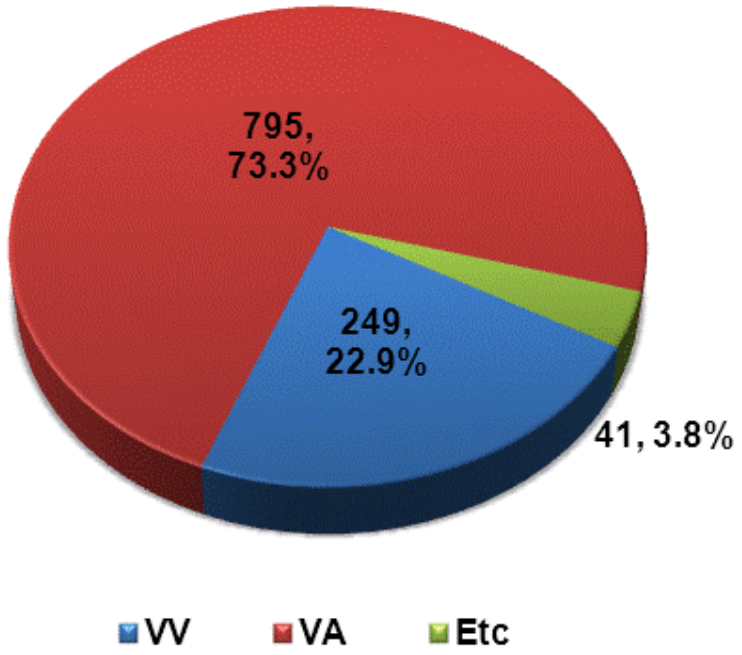


- **Patients status before ECMO support**
  - Arrest = 304/833(36.5%) (RR 833/108, 76.6%)

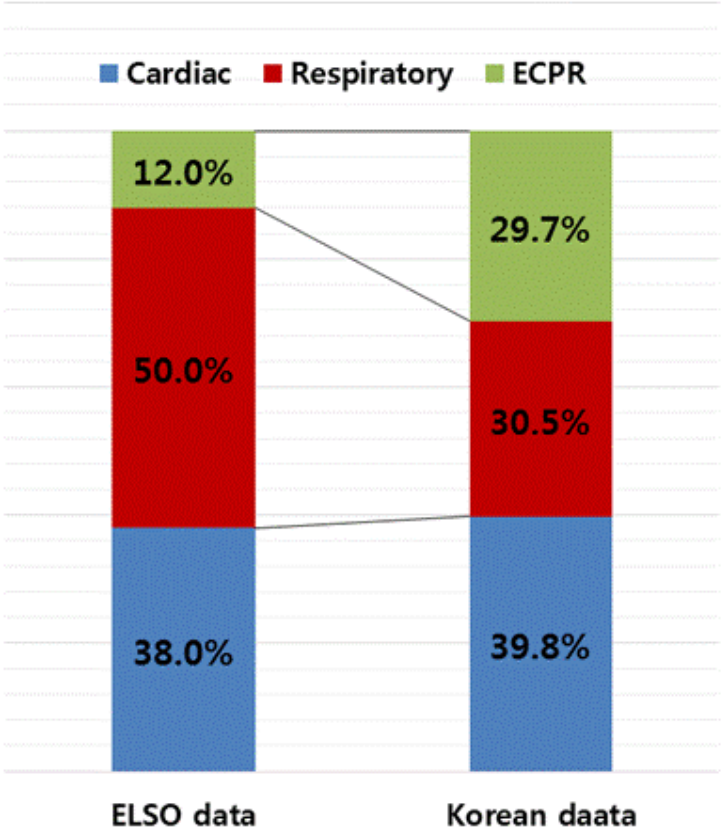
ECMO in KOREA

ECMO Management I

- **Support Type of ECMO (RR1087/1085,99.8%)**



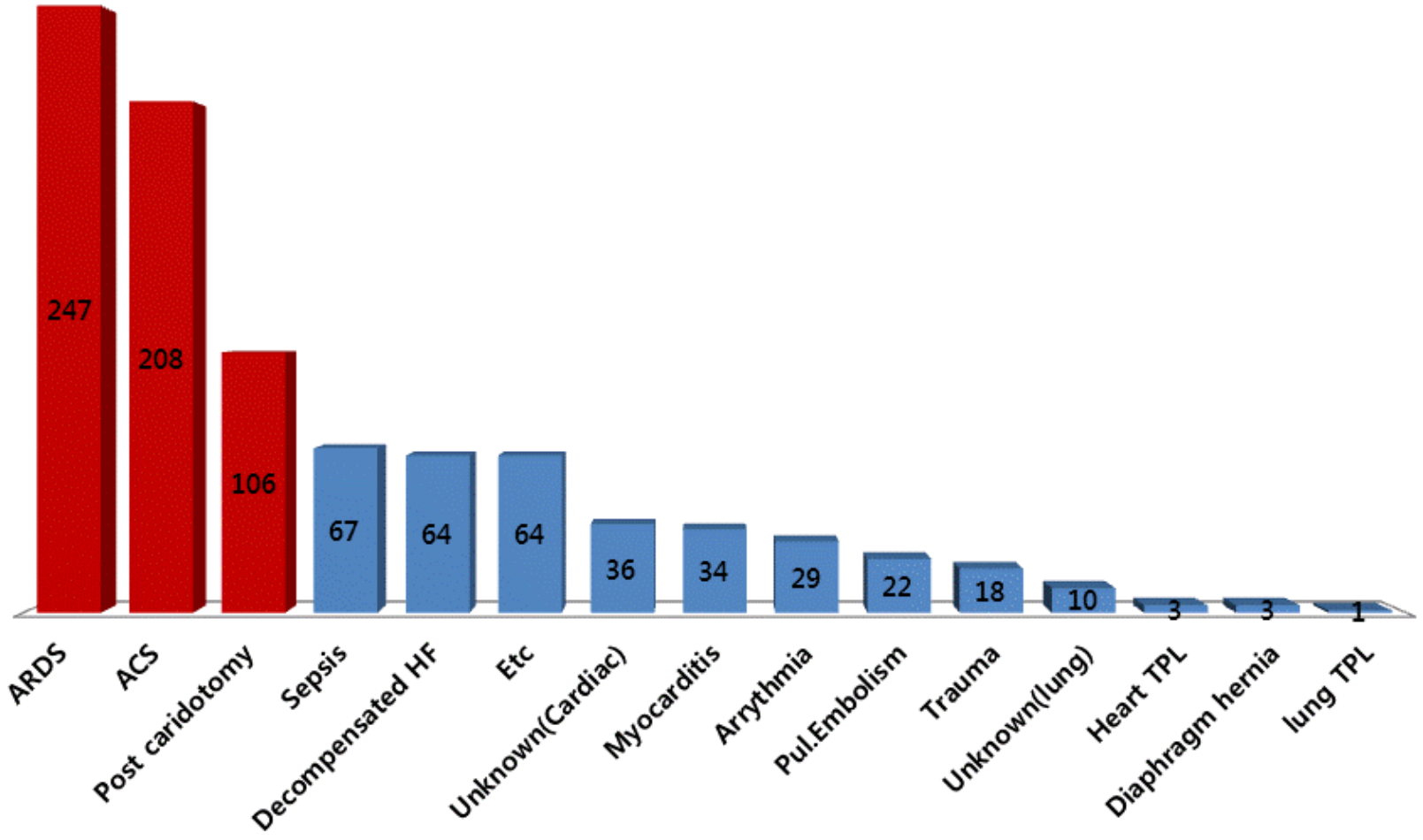
- **Target of ECMO (RR 1087/1087, 100.0%)**



ECMO in KOREA

ECMO Management II

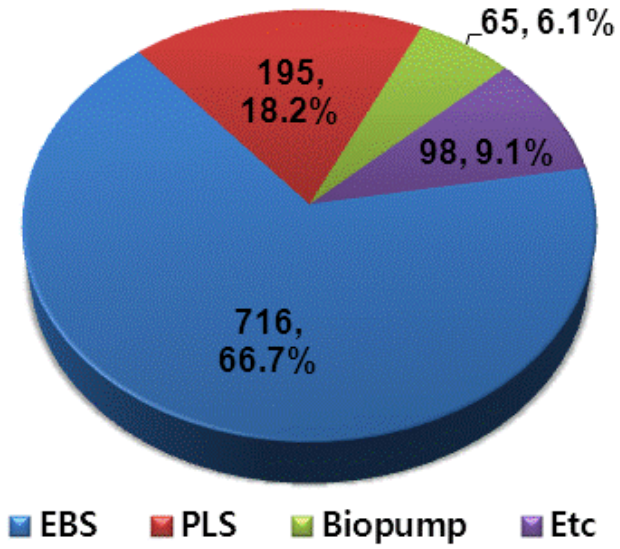
- Indication (Response Rate(RR), 912/1087, 84.2%)



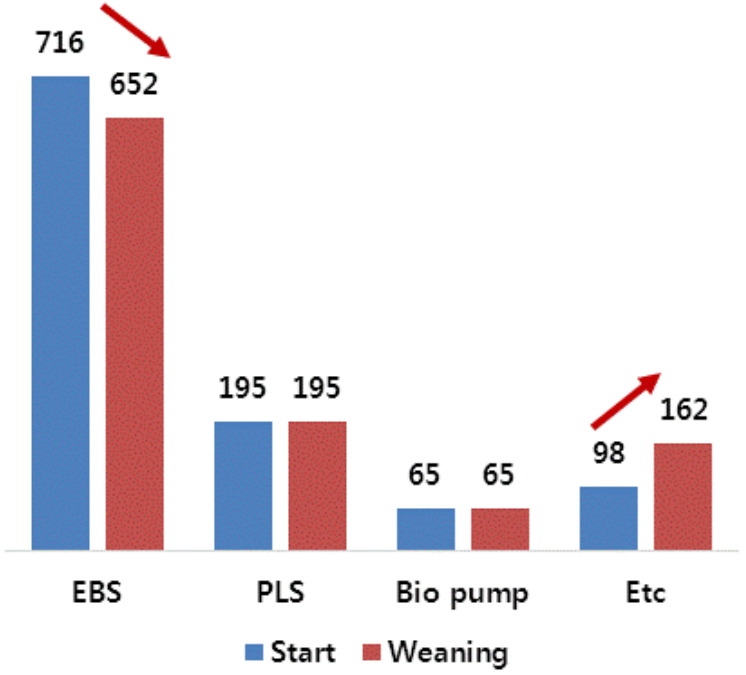
ECMO in KOREA

ECMO Management IV

- **ECMO Equipment (RR 1074/1087, 98.8%)**

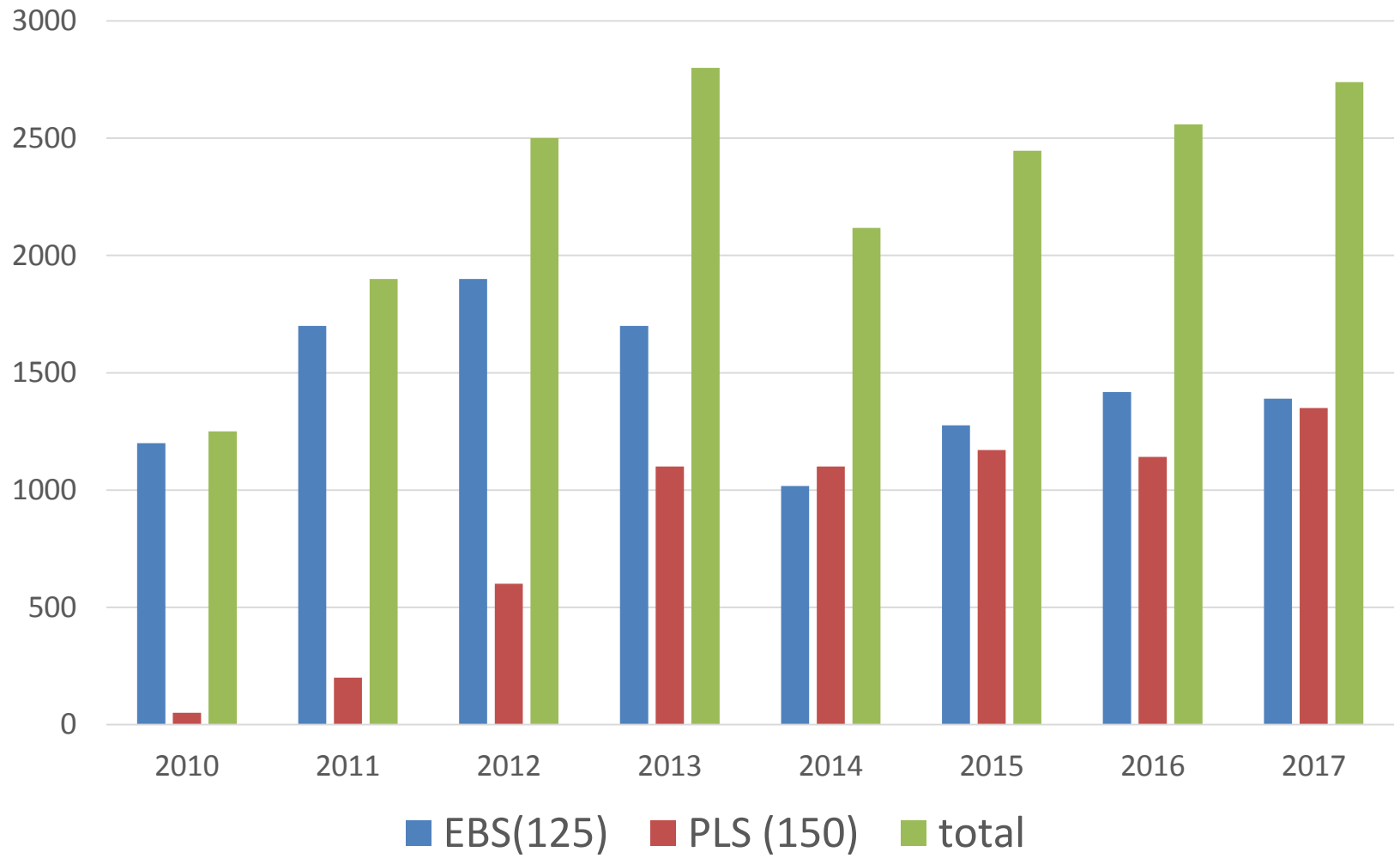


- **Equipment change 'from start to wean' (RR 1074/1087, 98.8%)**



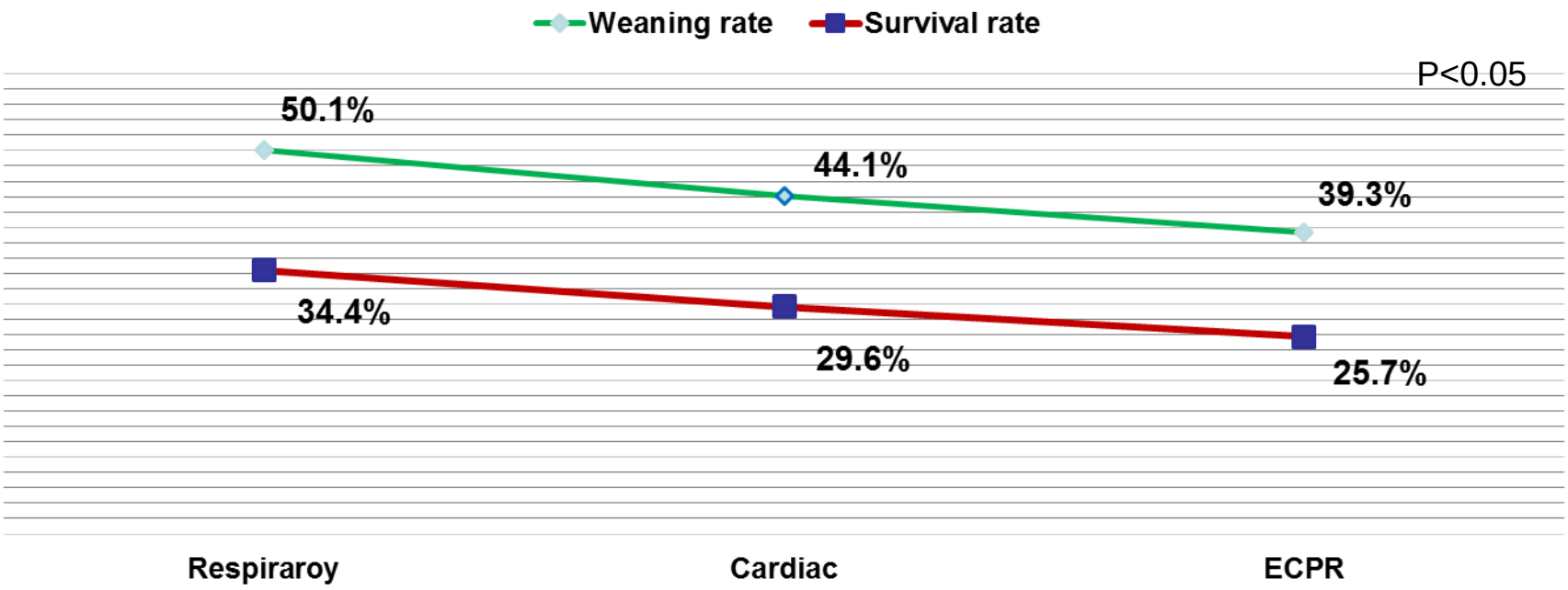
- **Anticoagulation(RR 427/1087, 38.8%)**
  - **Heparin 233/425(54.6%), Futhan102/422(23.9%), None 82/422(19.4%)**

ECMO in KOREA



ECMO in KOREA

Results of ECMO

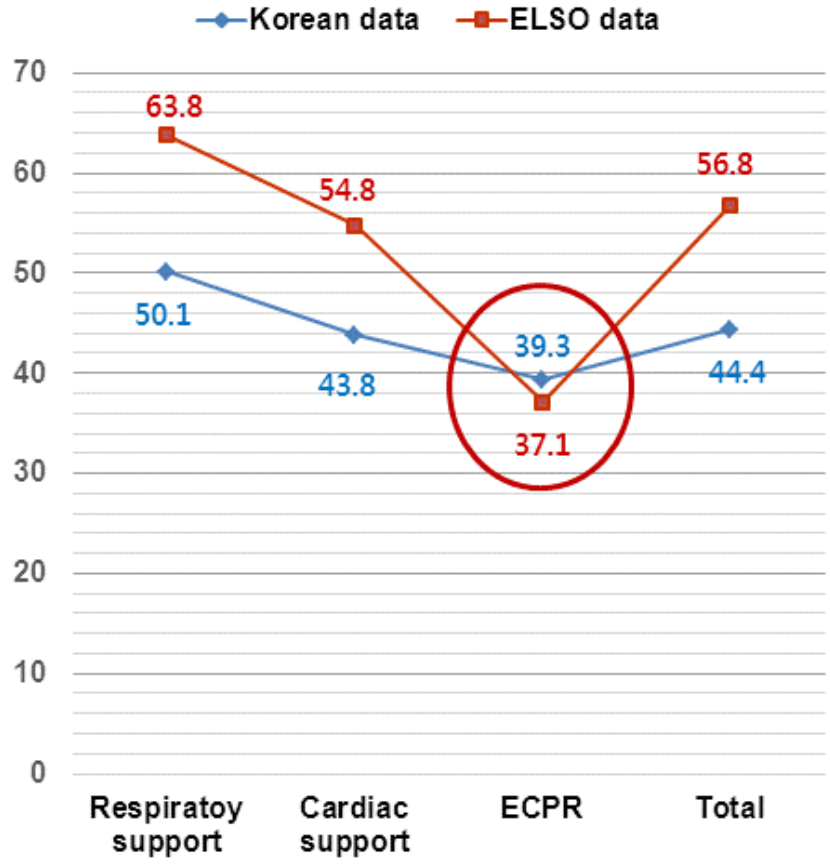


	Cases	Weaning	Survival discharge
Respiratory	331	166(50.1%)	114(34.4%)
Cardiac	433	191(44.1%)	128(29.6%)
ECPR	323	128(39.6%)	83 (25.7%)
Total	1087	483(44.4%)	325(29.9%)

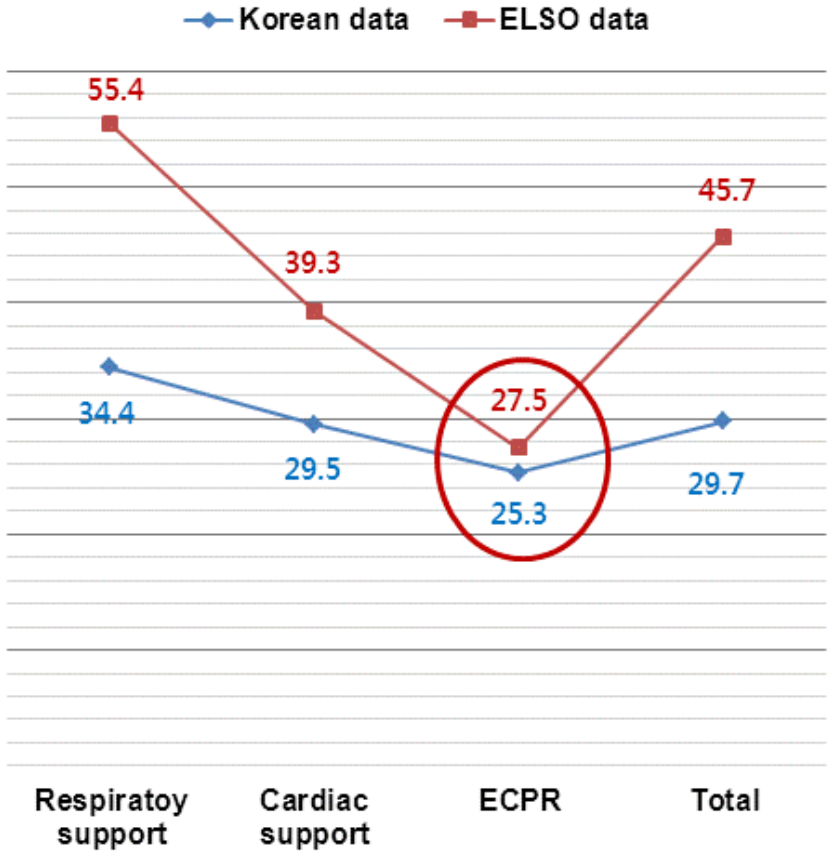
ECMO in KOREA

Summary of ECMO Results

ECMO Weaning Rate

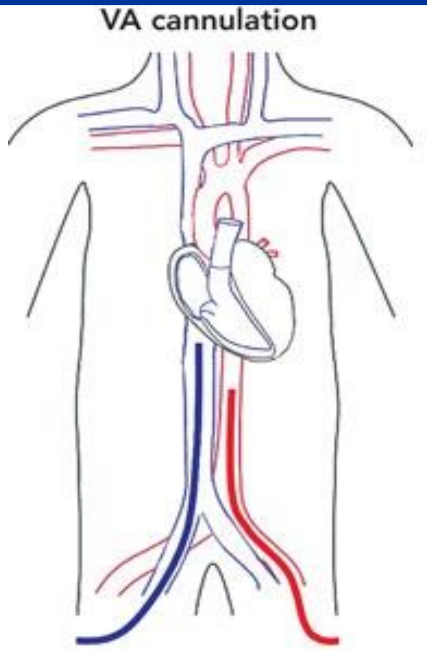


Survival Rate

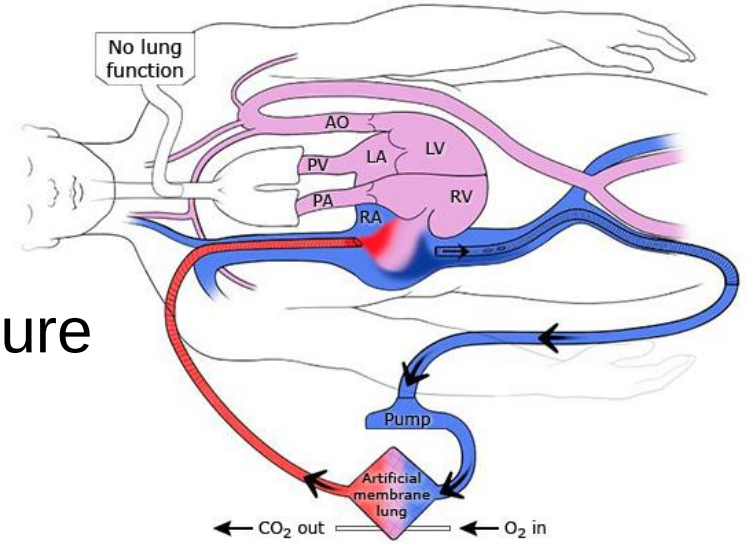


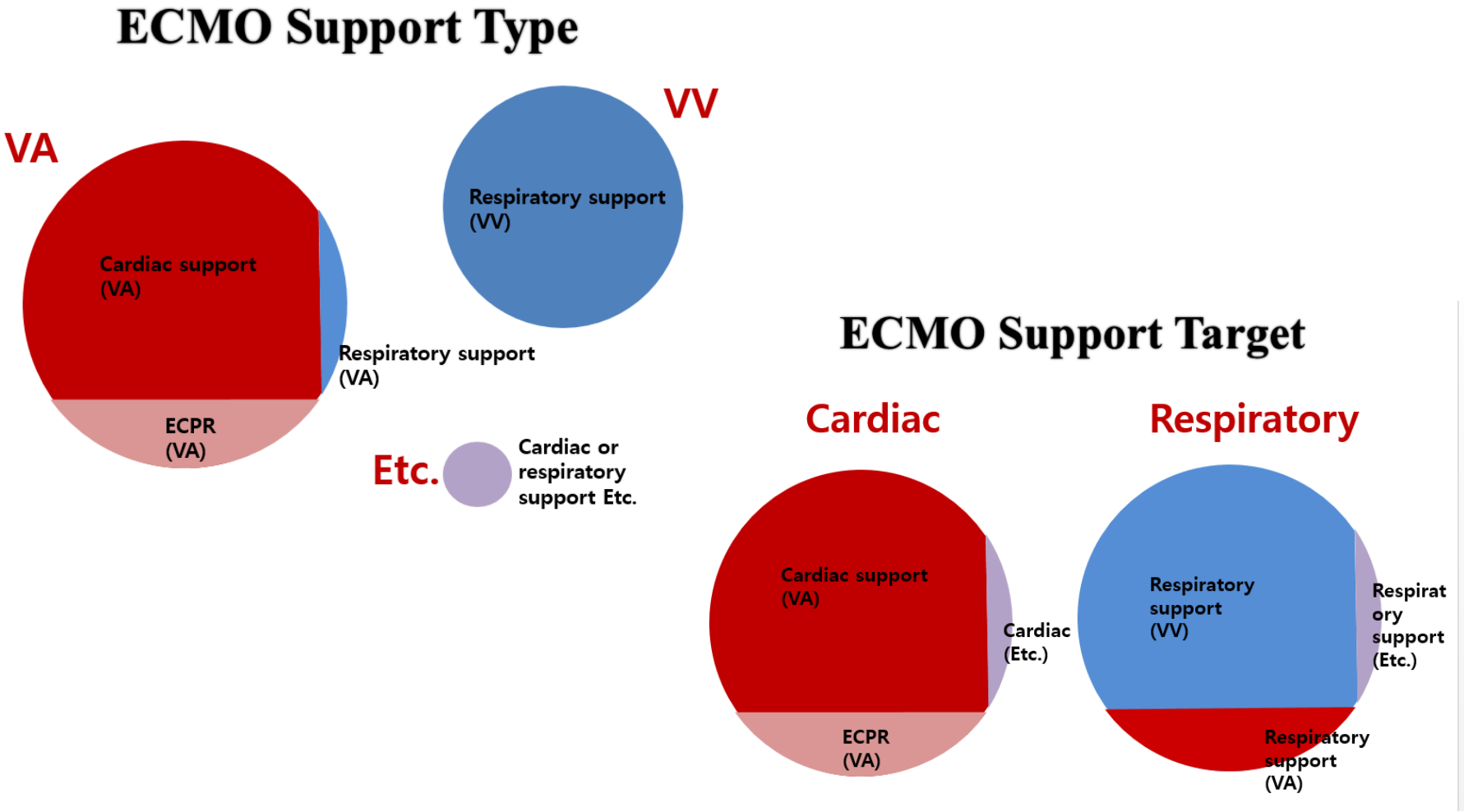
ECMO Type

- Cardiac ECMO (VA)
  - Support for both heart & lungs
  - Severe cardiopulmonary failure
  - As a bridge to heart transplantation



- Respiratory ECMO (VV)
  - Support for lungs only
  - Potentially reversible respiratory failure

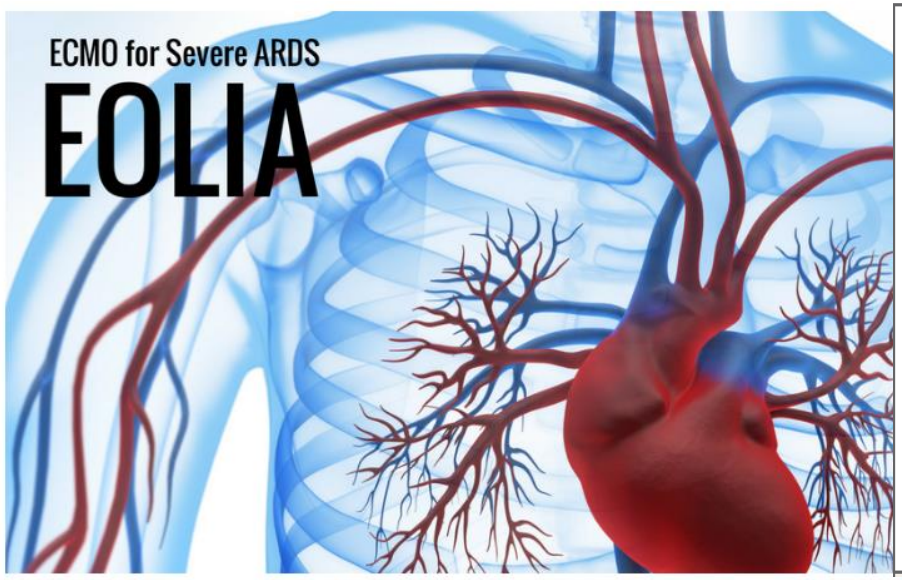


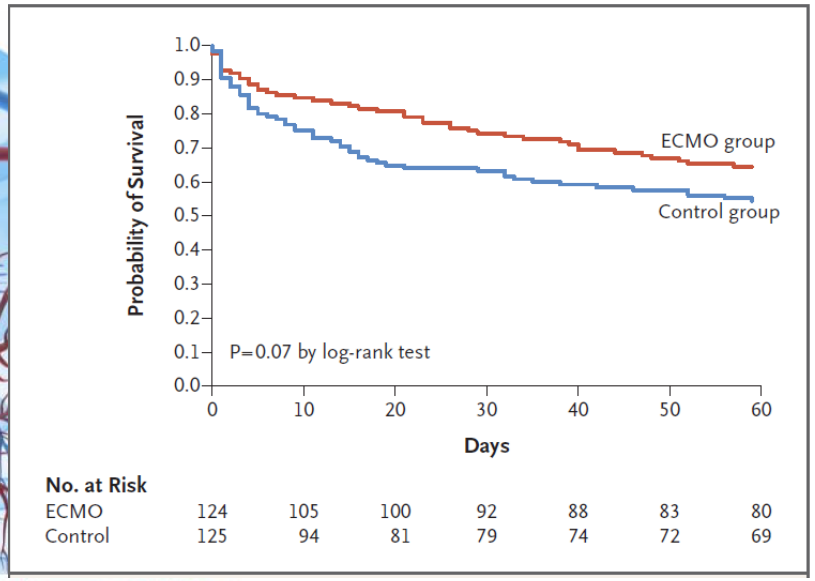


VA ≒ Cardiac support

VV ≒ Venous support

ECMO to Rescue Lung Injury in Severe ARDS (EOLIA) trial





Extracorporeal Membrane Oxygenation for Severe Acute Respiratory Distress Syndrome

Combes et al. N Engl J Med 2018; 378:1965-1975. DOI: 10.1056/NEJMoa1800385

△11% (p = 0.09)

After 6.5 ± 9.7 days, 35 (28%) patients in control arm crossover to ECMO

ECMO in ARDS

- 1950s Development of membrane oxygenator in lab
- 1972 First adult ECMO successful case
- 1975 First neonatal case
- 1979 Trial in ARDS, 10% survival **(1st RCT by Zapol)**
- 1986 48.8% survival rate by $ECCO_2R$ (Gattinoni et al)
- 1989 ELSO registry
- 1994 42% vs 33% survival rate **(2nd RCT by Morris)**
- 2009 **CESAR trial (3rd RCT by Peek)**
- 2009 ECMO during H1N1 influenza pandemic

Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial

Giles J Peek, Miranda Mugford, Ravindranath Tiruvoipati, Andrew Wilson, Elizabeth Allen, Mariamma M Thalanany, Clare L Hibbert, Ann Truesdale, Felicity Clemens, Nicola Cooper, Richard K Firmin, Diana Elbourne, for the CESAR trial collaboration

Summary

Background Severe acute respiratory failure in adults causes high mortality despite improvements in ventilation techniques and other treatments (eg, steroids, prone positioning, bronchoscopy, and inhaled nitric oxide). We aimed to delineate the safety, clinical efficacy, and cost-effectiveness of extracorporeal membrane oxygenation (ECMO) compared with conventional ventilation support.

Methods In this UK-based multicentre trial, we used an independent central randomisation service to randomly assign 180 adults in a 1:1 ratio to receive continued conventional management or referral to consideration for treatment by ECMO. Eligible patients were aged 18–65 years and had severe (Murray score >3·0 or pH <7·20) but potentially reversible respiratory failure. Exclusion criteria were: high pressure (>30 cm H_2O of peak inspiratory pressure) or high FiO_2 (>0·8) ventilation for more than 7 days; intracranial bleeding; any other contraindication to limited heparinisation; or any cont… …e was death or severe disability at 6 months afte… …s was by intention to treat. Only researchers wh… …. Data about resource use and economic outcon… …ost generating events were undertaken, and we… …odelled lifetime cost-utility. This study is regist…

ECMO vs Conventional
→ 63% vs 47% (p=.03)

Findings 766 patients were screened; 180 were enrolled and randomly allocated to consideration for treatment by ECMO (n=90 patients) or to receive conventional management (n=90). 68 (75%) patients actually received ECMO; 63% (57/90) of patients allocated to consideration for treatment by ECMO survived to 6 months without disability compared with 47% (41/87) of those allocated to conventional management (relative risk 0·69; 95% CI 0·05–0·97, p=0·03). Referral to consideration for treatment by ECMO treatment led to a gain of 0·03 quality-adjusted life-years (QALYs) at 6-month follow-up. A lifetime model predicted the cost per QALY of ECMO to be £19 252 (95% CI 7622–59 200) at a discount rate of 3·5%.

Lancet 2009; 374: 1351–63

Published Online September 16, 2009 DOI:10.1016/S0140-6736(09)61069-2

See Comment page 1307

See Department of Error page 1330

Department of Cardiothoracic Surgery (G J Peek MD, R K Firmin MBBS) and Department of Extracorporeal Membrane Oxygenation (G J Peek, R Tiruvoipati FRCSEd, R K Firmin), Glenfield Hospital, Leicester, UK; School of Medicine, Health Policy and Practice, University of East Anglia, Norwich, UK (Prof M Mugford DPhil, M M Thalanany MSc); Department of Health Sciences, University of Leicester, Leicester, UK (Prof A Wilson MD, N Cooper PhD); Medical Statistics Unit, London School of Hygiene and Tropical Medicine, London, UK (E Allen PhD, A Truesdale BSc,

체외순환막형산화요법(ECMO)의 인정기준 (~2017)

가. 적응증

(1) 기존의 치료법에 의해 교정되지 않는 **중증 심부전**

(2) 기존의 기계적 인공호흡기 치료로 생명유지가 불가능한

중증 급성 호흡부전

나. 금기증

(1) 이미 진행된 **다발성 장기부전**으로 **회복 가능성이 없는** 경우

(2) **불가역적 중추신경 장애**

(3) 지혈이 곤란한 출혈부위가 있어서

항응고요법의 절대적 금기증에 해당하는 경우

(4) **말기암환자** 등 동 시술이 의의가 없다고 판단되는 경우

가. 적응증

2018 현재

1) 기존의 치료법에 의해 교정되지 않으나 회복 가능성이 있는 중증 급성 심부전

가) 급성심근경색증, 급성심근염, 주산기심근증(Peripartum Cardiomyopathy), 대상부전의 만성 심부전(Decompensated chronic heart failure), 수술 후 심기능부전, 불응성 심실성 빈맥(Refractory ventricular tarchycardia) 등

나) 충전(volume replacement), 약물치료(drug intervention), 대동맥내풍선 등 기존의 심부전 치료에 반응하지 않는 급성 쇼크

2) 목격된 심정지(witnessed arrest)이거나 심정지 시점이 비교적 정확히 유추 가능한 경우로 심폐소생술이 시행되어 회생가능성이 있는 경우 또는 가역적 심정지(accidental hypothermia, drug intoxication)

3) 기존의 기계적 인공호흡기 치료로는 생명유지가 불가능하지만 ECMO 시술로 회복 가능성이 있는 중증 급성 호흡부전

가) 급성호흡곤란증후군, 중증폐렴, 폐이식 후 원발성 이식실패

나) 일시적인 air way유지를 위해 실시하는 경우(기도 이물질, 기도 시술(수술) 등)

다) 심한 폐공기누출증후군(Severe air leak syndromes)

라) 폐이식 전 기관내삽관이 필요한 급성호흡곤란증후군

마) 급박한 심장 또는 폐의 허탈(최선의 치료에 반응하지 않는 폐색전증, 기도폐쇄)

4) 심장 또는 폐 이식대상환자의 교량치료 (Bridge to transplantation)로써 이식등록과정이 사전.사후에 확인된 경우

나. 금기증

2018 현재

1) 회복이 불가능한 심장질환으로, 이식 또는 심실보조장치를 시행 할 수 없는 경우
2) 충분한 조직관류(adequate tissue perfusion)없이 60분을 초과하여 심폐소생술을 시행하는 경우
3) 심폐소생술을 거부한 경우
4) 의학적으로 심폐소생술이 필요한 심정지가 목격되지 아니하여, 심정지 시간과 심폐소생술이 적시에 시행되었음을 확인할 수 없는 경우
5) 호흡부전환자에서 FiO2>90% 이거나 Pplat>30cmH2O의 높은 설정의 인공호흡기를 7일 이상 유지하는 경우
6) 지혈이 불가능한 출혈부위가 있어서 항응고요법의 절대적 금기증에 해당하는 경우
7) 최근(recent) 뇌출혈이 있거나 출혈이 증가하는 경우
8) 이미 진행된 다발성장기부전 등으로 회복가능성이 없는 경우
9) 진행성 혈액암, 골수이식 실패, 무과립구증, 절대호중구수(ANC)<400/mm3 등 심한 면역기능저하상태인 경우
10) 회복 불가능한 뇌손상, 비가역적 중추신경계 장애가 있는 경우
11) 말기암, 회복가능성이 없는 폐, 간, 신장 등의 만성중증장기부전
12) 동 시술이 의의가 없는 고령 환자의 경우

사전・사후관리를 위한 요건

가. 시술 동의서 작성

시술 환자 또는 가족의 동의서를 작성 및 비치하여야 함

(시술의 성공가능성, 합병증, 예후 등에 대해 설명하고 소정 양식의 동의서를 작성・비치).

다만, 동의서 작성이 불가능한 경우에는 의사소견서(사유서) 등을 참조할 수 있음

나. 시술 후 정기적 재평가

동 시술 적용 중 정기적인 반응 평가를 통해 지속여부를 결정해야 하며, 진료기록부에 평가결과를 기재하여야 함

(반응평가: 심장・폐기능, 뇌손상 평가 등 **최소 3일** 마다 실시)

「건강보험 행위 급여・비급여 목록표 및 급여 상대가치점수」

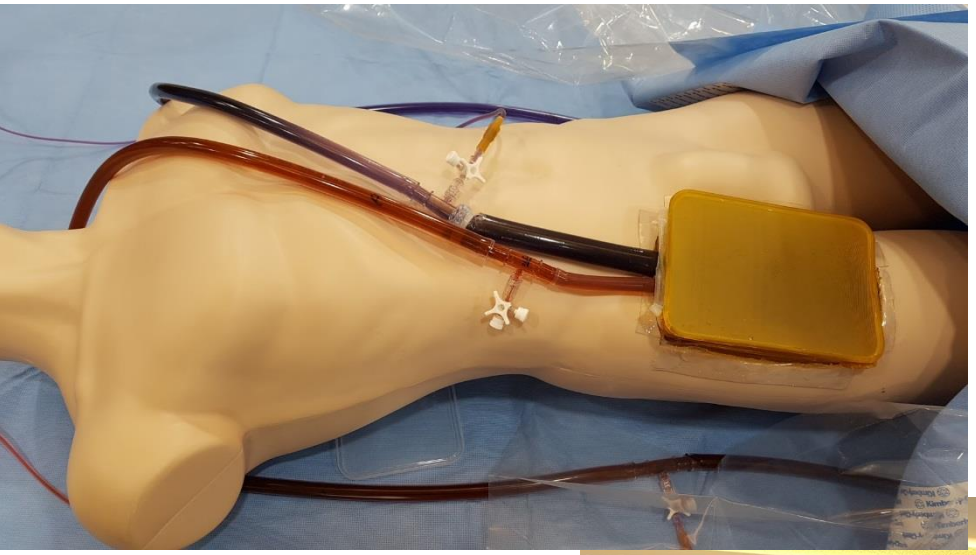
('18.1.1. 점수당 단가 병원 73.5원 기준)

분류번호	코 드	분 류	점 수	금액(원)
		제9장 처치 및 수술료 등		
		제1절 처치 및 수술료		
		[순환기]		
자-190	O1903	부분체외순환-ECMO 사용	9,079.03	667,310
		Partial Extracorporeal Circulation		
	O1904	부분체외순환10시간 초과 익일부터[1일당]	4,766.98	350,370
		-ECMO사용		

* 3차병원 가산(30%), 흉부외과 가산(100%)

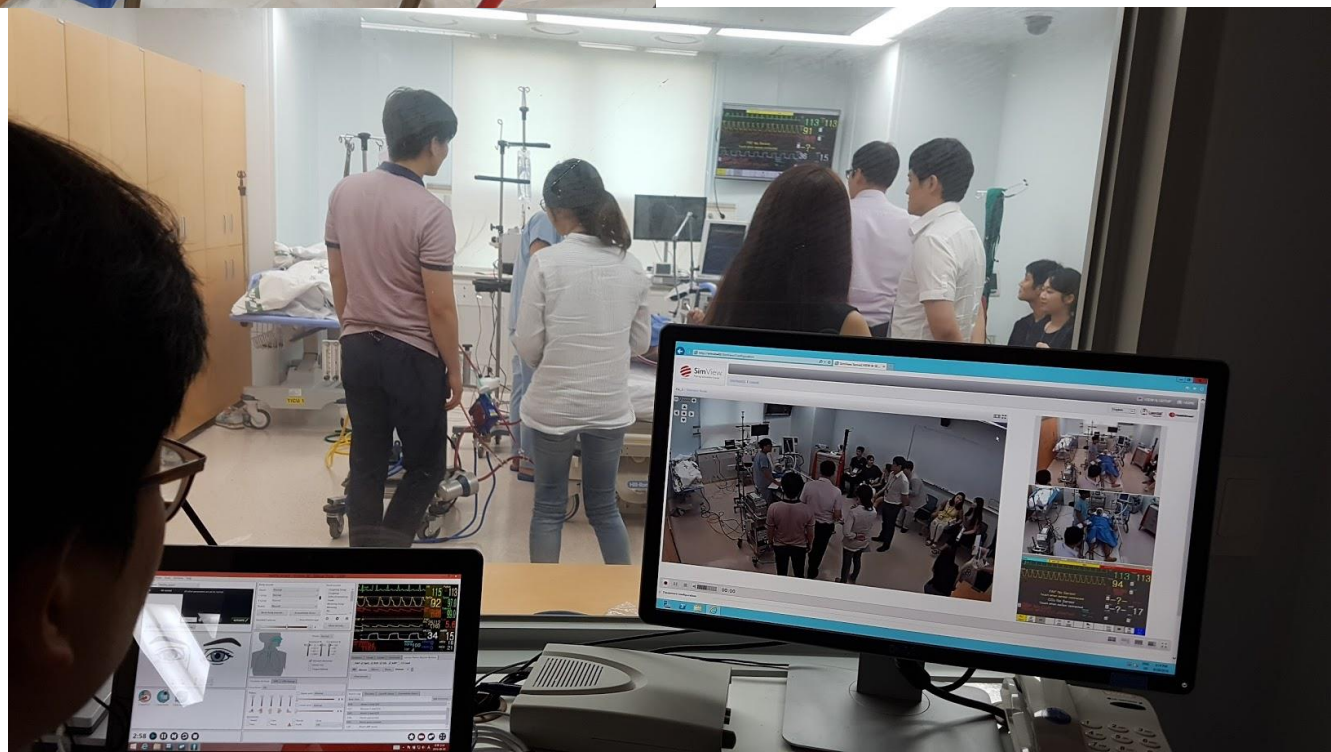
환자 부담	
HF, OHS = 5%	I1903 -> 1.735.620 x 0.05 = 86.750
	I1904 -> 910.962 x 0.05 = 45.548
그 외 (ARDS 포함) = 20%	I1903 -> 1.735.620 x 0.2 = 347.001
	I1904 -> 910.962 x 0.2 = 182.192

Traning & Simulation



2016 Basic course of ECMO
: Hand on simulation

부산대병원
외상 시뮬레이션센터


SimView

Take Home Massage

- 국내 에크모 현황은 심장보조, ECPR이 많은 특징을 가지고 있으나 최근 폐이식 수술의 증가와 더불어 폐 보조를 의한 에크모도 크게 증가하고 있다. 현재 에크모의 성적은 ELSO의 결과에 비교해 전체적으로 약간 낮은 수준을 보여주나,향후 적응증 조절 및 관리 기술의 등의 발달로 향상 될 것을 기대한다.

- 국내 에크모 건수는 빠르게 증가하여 연간 2000례를 넘고 있으며 심평원의 **적응증** 조절과 함께, 자체적인 **레지스트리** 구축이 필요할 것으로 여겨진다.

- 향후 에크모는 장비 발달, 시스템의 표준화 등으로 좀더 확대 될 것으로 보이며, **새로운 장비**들이 개발 되 현재의 한계 등을 극복하게 될 것으로 판단되므로 이에 대한 준비로 다양한 **연구와 교육**이 필요할 것으로 생각된다.