



*LivaNova Education Series:*

# Life Support Simplified

Intended for Investor Use Only - Not Intended for Use by Patients or HCPs



# Safe Harbor

Certain statements in this presentation, other than purely historical information, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements include, but are not limited to, LivaNova’s plans, objectives, strategies, financial performance and outlook, trends, the amount and timing of future cash distributions, prospects or future events and involve known and unknown risks that are difficult to predict. As a result, our actual financial results, performance, achievements or prospects may differ materially from those expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “seek,” “guidance,” “predict,” “potential,” “likely,” “believe,” “will,” “should,” “expect,” “anticipate,” “estimate,” “plan,” “intend,” “forecast,” “foresee” or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based on estimates and assumptions that, while considered reasonable by LivaNova and its management based on their knowledge and understanding of the business and industry, are inherently uncertain. These statements are not guarantees of future performance, and stockholders should not place undue reliance on forward-looking statements. There are a number of risks, uncertainties and other important factors, many of which are beyond our control, that could cause our actual results to differ materially from the forward-looking statements contained in this presentation, including the risks relating to the COVID-19 pandemic or settlement of litigation, as well as those described in the “Risk Factors” section of Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the United States Securities and Exchange Commission by LivaNova. All information in this presentation is as of the date of its release. The Company does not undertake or assume any obligation to update publicly any of the forward-looking statements in this presentation to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to place undue reliance on any forward-looking statements, which are made only as of the date of this presentation.

# Positioning LivaNova to Realize its Full Value

*Consistently deliver growth, pipeline and profitability*

## Core Growth

*Focus on portfolio optimization to support leadership positions in underserved markets*

- Expand the go-to market initiative for U.S. Epilepsy
- Forecast at least 30% ACS growth in 2020 and at least 20% in 2021

## Pipeline Execution

*Multiple existing and pipeline initiatives to accelerate growth*

- Achieve key study milestones in RECOVER and ANTHEM HFREF
- Continued progress on next generation Heart-Lung Machine

## Operational Excellence

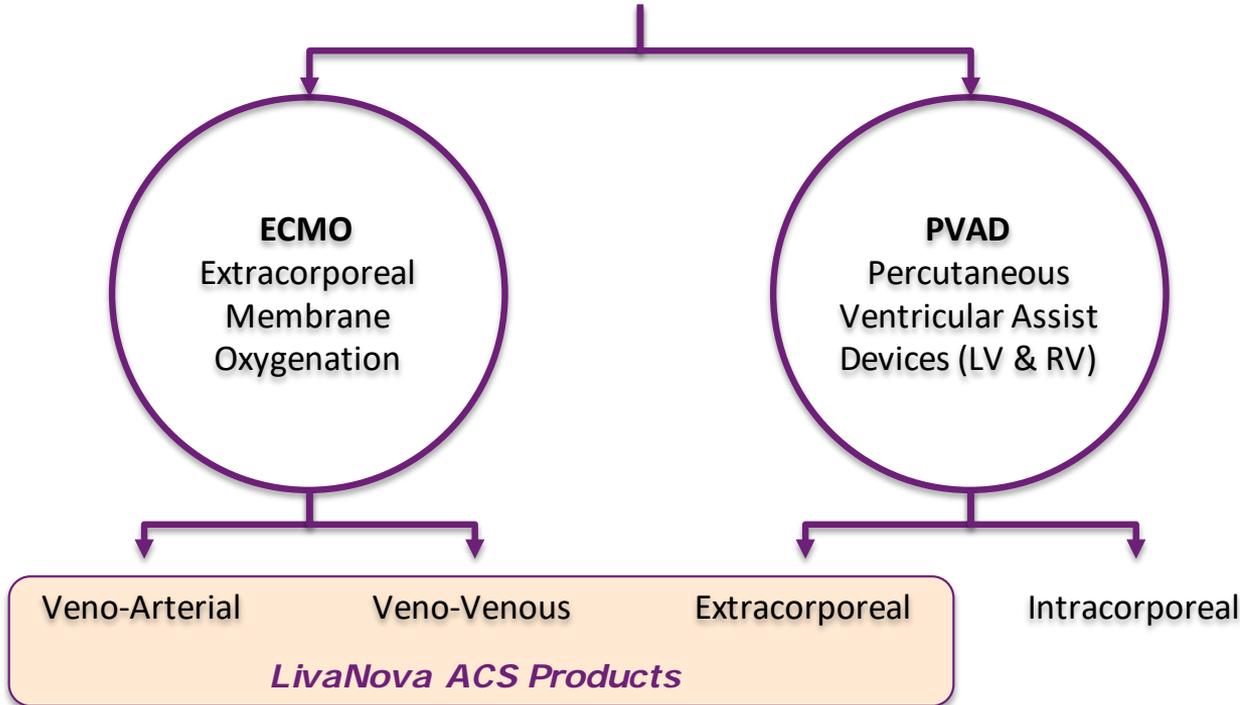
*Drive margin expansion*

- Expand Operating margin through cost discipline
- Drive improvement in free cash flow generation



# “Advanced Circulatory Support” Defined

## Advanced Circulatory Support (ACS)



### Does Not Include:

- Long-term MCS (LVAD devices)
- Cardiac support standard of care (intra-aortic balloon pump / IABP)
- Respiratory support standard of care (invasive mechanical ventilation / IMV)

# ACS candidate patients present to the hospital with multiple interrelated problems

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## CARDIAC: ELECTRICAL PROBLEM

- Unstable or lack of electrical impulse in the heart to trigger muscle firing
- **Therapies:** Pharmaceuticals, Percutaneous Coronary Intervention (PCI), Ablation (re-wiring the heart to fix signals), Pacemaker (long-term device)



## CARDIAC: PLUMBING PROBLEM (coronary or structural)

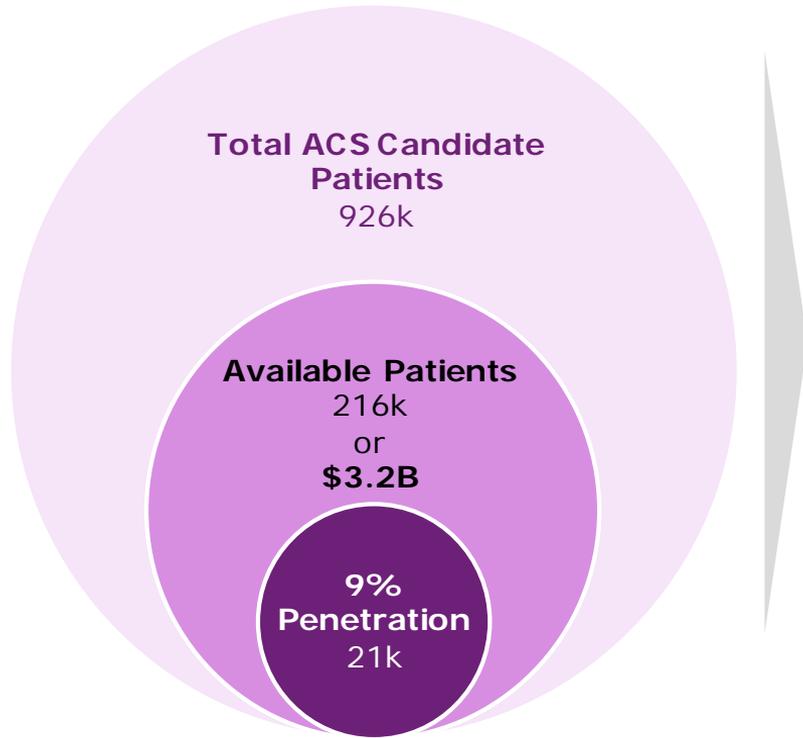
- Heart muscle has limited capacity to squeeze, create pressure in the circulatory system and move blood throughout the body
- **Therapies:** Pharmaceuticals, PCI (Angioplasty / Stent), Intra-aortic Balloon Pump (IABP), **Advanced Circulatory Support**, Implantable Ventricular Assist Device (long-term device), Heart Transplant



## RESPIRATORY PROBLEM

- Lung capacity to exchange oxygen & carbon dioxide into the bloodstream is reduced (COPD, long-term damage from smoking, H1N1, pneumonia, acute respiratory distress syndrome, COVID-19)
- **Therapies:** Pharmaceuticals, Non-Invasive Ventilation (NIV, mask/nasal oxygen), Invasive Mechanical Ventilation (IMV), **Advanced Circulatory Support**, **NO LONG-TERM RESPIRATORY DEVICES**, Lung Transplant

# Significant market opportunities in multiple underpenetrated patient populations



Patients	Total	Available	\$ TAM	Penetration
 <b>Cardiogenic Shock<sup>1</sup></b> <i>Available: Includes STEMI and without predominant RV infarction or mechanical complications</i>	49k	30k	<b>\$450M</b>	~50%
 <b>RV Failure<sup>2</sup></b> <i>Available: at hospitals with MCS capability</i>	36k	10k	<b>\$150M</b>	~20%
 <b>Respiratory Failure<sup>3</sup></b> <i>Available: severe ARDS or AE-COPD patients on invasive mechanical ventilation</i>	202k	98k	<b>\$1.5B</b>	~2%
 <b>Cardiac Arrest<sup>4</sup></b> <i>Available: IHCA at hospitals with eCPR capability</i>	639k	78k	<b>\$1.2B</b>	~1%
 <b>High Risk PCI</b>	121k	46k	<b>Not a primary focus of LivaNova</b>	

Source: 1. Thom et al. Heart disease and stroke statistics—2006 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2006; 113: e85–e151. Assumption: slight decline (0.5%) in annual patient population for cardiogenic shock. 2. Gerges 2014. "Right ventricle in acute and chronic pulmonary embolism (2013 Grover Conference series)". <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278597>. Peacock AJ, Murphy NF, McMurray JJV, et al. An epidemiological study of pulmonary arterial hypertension. *Eur Respir J* 2007;30: 104–9. 3. Lindenaun, P. Hospital patterns of Mechanical Ventilation for Patients with Exacerbations of COPD. *Ann Am Thorac Soc* Vol 12, No 3, pp 402-409, Mar 2015. The ARDS Definition Task Force, "Acute Respiratory Distress Syndrome, the Berlin Definition of ARDS" *JAMA* 2012;301(23):2526-25338. 4. US Average annual incidence in adults. AHA, *Circulation*, "Annual Incidence of Adult and Pediatric In-Hospital Cardiac Arrest in the US," July 2019.

Note: U.S. market only; data sources OUS limited but WW penetration also low  
\$TAM uses ASP of \$15-20K

LivaNova ACS products are not currently indicated for Cardiogenic Shock, RV Failure, or Cardiac Arrest. LivaNova ACS products are temporarily indicated for ECMO therapy greater than 6 hours. See Indications for Use for more information. LivaNova is currently pursuing PMA approval for a Right Ventricular Failure indication and 510(k) clearance for ECMO therapy greater than 6 hours.

# Highlights

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## Mission

- To save and improve the lives of critically-ill patients through the development and delivery of simple and effective life support solutions.

## Vision

- To become the extracorporeal membrane oxygenation (ECMO) **platform of choice** among U.S. hospital centers and establish a global footprint for the ACS portfolio.

## Positioning

- A simple and versatile ACS platform with differentiated cannulation enabling hospital centers to successfully deploy ACS to underserved patient populations.

## Markets

- Gain share in **Cardiogenic Shock** and **Right Ventricular Failure** in the short term while developing long term market opportunities in **Respiratory Failure** and **Cardiac Arrest**.

# Commercial success supported by multiple internal & external initiatives

<b>Commercial Execution</b>	Annual field sales expansion	Inside sales capability	Healthcare econ support
<b>Medical Education</b>	CME & hands-on product training	eLearning university	Partnership with KOLs & societies
<b>Regulatory Authorizations</b>	U.S. FDA label extensions	Full CE-mark (EU) approvals	Leverage INT channel
<b>Clinical Evidence</b>	Expand/publicize THEME registry	IIR case series & literature studies	Comparative clinical data
<b>Innovative Products</b>	Next generation oxygenation	Cannulae innovation	Remote monitor & sensors

## The need for LifeSPARC

- **Despite ACS growth, legacy technology has hindered success**
  - Less powerful than competing ECMO (lower flows or larger cannulae)
    - *LifeSPARC offers 40% more pumping power; on par with ECMO competition*
  - Legacy product priming process is unfamiliar and lengthy
    - *3-minute LifeSPARC setup process delivers "the perfect prime" every time*
  - Large, heavy controller inhibits patient mobility & ease of transport
    - *LifeSPARC 1/3 the size & weight with removable handheld controller*



Legacy "Escort"  
Platform



## LifeSPARC is a new circulatory support platform designed to simplify hospital programs



- LifeSPARC is a single operating system for simple but powerful circulatory support capabilities across departments / indications
  - **Streamlined** user interface minimizes the learning curve and ongoing training requirements for nursing staff and other patient caregivers
  - Small but powerful magnetically levitated pump enables **rapid** and **repeatable** deployment within the sterile field
  - **Lightweight** controller and docking station enables easy patient **mobility** and facilitates interdepartmental transport



## The LifeSPARC Platform: Designed to simplify life support from start to finish

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- No excess ports:
  - blood in/out + O<sub>2</sub> in/vent
- No heat exchanger
- No gas blender

## The LifeSPARC Platform: Designed to simplify life support from start to finish

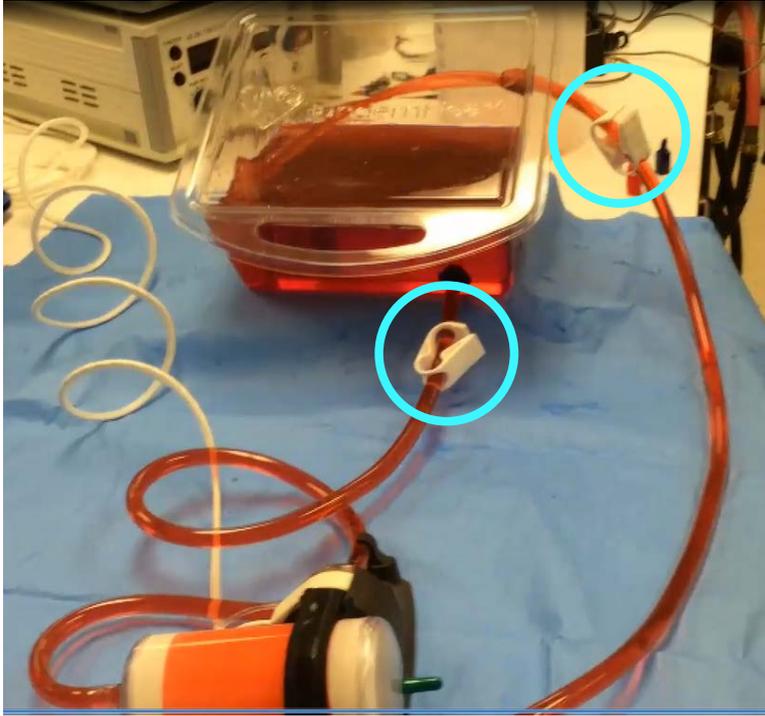
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- No excess ports:
  - blood in/out + O<sub>2</sub> in/vent
- No heat exchanger
- No gas blender
- Pre-connected pump & oxygenator

## The LifeSPARC Platform: Designed to simplify life support from start to finish

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- No excess ports:
  - blood in/out + O<sub>2</sub> in/vent
- No heat exchanger
- No gas blender
- Pre-connected pump & oxygenator
- Priming tray to prime circuit in 3 minutes or less
- Clamps built into the tubing

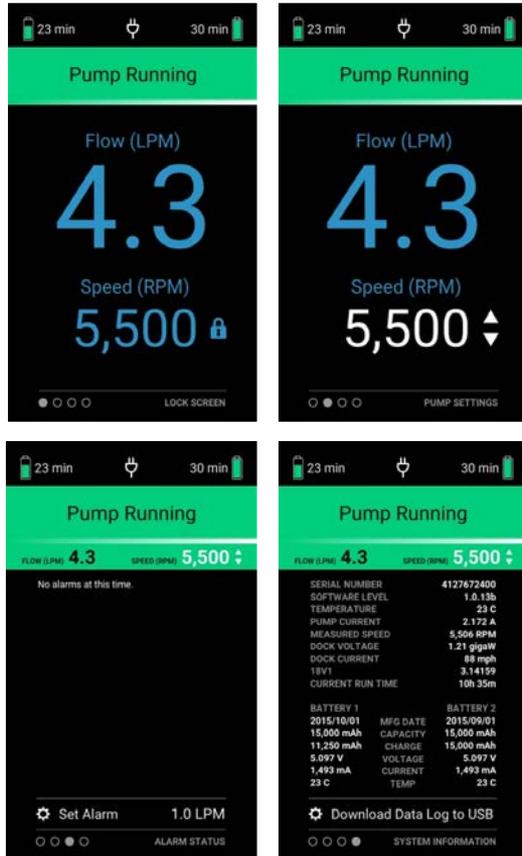
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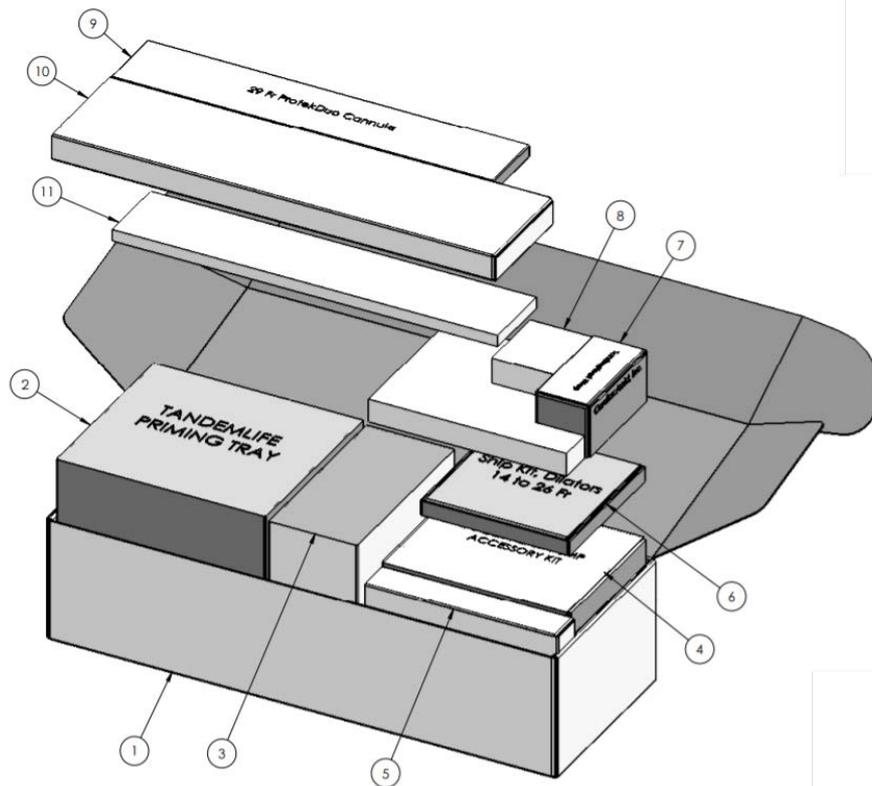
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- Clamps built into the tubing
- No infusion line

# The LifeSPARC Platform: Designed to simplify life support from start to finish



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- 4-screen GUI

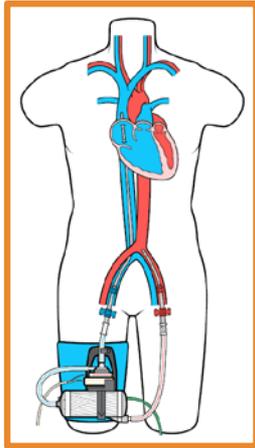
## The LifeSPARC Platform: Designed to simplify life support from start to finish



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- No heat exchanger
- No gas blender
- Pre-connected pump & oxygenator
- Priming tray to prime circuit in 3 minutes or less
- Clamps built into the tubing
- No infusion line
- 4-screen GUI
- Everything you need for the procedure in one Kit box

# LifeSPARC versatility offers all four primary modes of circulatory support in a single platform

## LifeSPARC

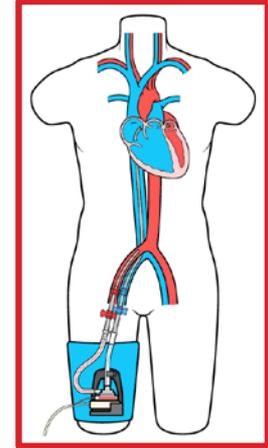


### TANDEMLIFE

#### Veno-Arterial (VA) ECMO

*Key Components:*

- Sterile, on-patient centrifugal pump
- Oxygenator (pre-connected)
- 24 Fr venous drainage cannula
- 15 or 17 Fr arterial cannula

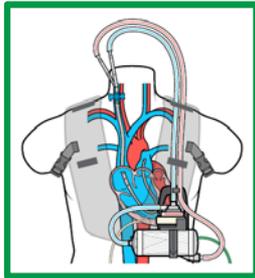


### TANDEMHEART

#### Percutaneous LA-FA Bypass

*Key Components:*

- Sterile, on-patient centrifugal pump
- 21 Fr transseptal cannula (62/72 cm)
- 15 or 17 Fr arterial cannula

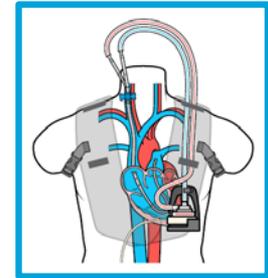


### TANDEMLUNG

#### Veno-Venous (VV) ECMO

*Key Components:*

- Sterile, on-patient centrifugal pump
- Oxygenator (pre-connected)
- 29 or 31 Fr dual-lumen cannula
- Venous dilator set



### PROTEKDUO

#### Percutaneous RA-PA Bypass

*Key Components:*

- Sterile, on-patient centrifugal pump
- 29 or 31 Fr dual-lumen cannula
- Venous dilator set



## Competing circulatory support platforms provide a limited subset of options

	VA-ECMO	VV-ECMO	PVAD (L)	PVAD (R)
LifeSPARC	✓	✓	✓	✓
Impella	✗	✗	✓	✓
CardioHelp	✓	✓	✗	✗
CentriMag*	✓	✓	✗	✗

\* CentriMag is a centrifugal pump only; additional technology (oxygenator and cannulae) are required to complete the circuit

LifeSPARC includes an integrated and sterilized extracorporeal pump motor for placement within the sterile field, designed to minimize hemodilution and reduced circuit volume.

LifeSPARC offers exclusive cannulation options in each support category:

- ProtekDuo Dual Lumen: Unique RA-to-PA cannulation via a single RIJ access point
- ProtekSolo Transseptal: Direct LV pre-load reduction via left atrial cannulation
- ProtekSolo Arterial: Advanced cannula securement features

Why **ECMO**? Because some patients need **MORE** circulatory support

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**The COVID-19 pandemic has revealed a lack of widespread extracorporeal circulatory support options across the U.S.**

Only ~ 4.9% of U.S. community hospitals currently offer advanced respiratory support capability.<sup>1</sup>

**LifeSPARC** enables mid-tier programs to emulate the most successful centers in the U.S.

# Why ECMO? Because some patients need **MORE** respiratory support.

JAMA | Original Investigation

## Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area

Safiya Richardson, MD, MPH; Jamie S. Hirsch, MD, MA, MSB; Mangala Narasimhan, DO; James M. Crawford, MD, PhD; Thomas McGinn, MD, MPH; Karina W. Davidson, PhD, MASc; and the Northwell COVID-19 Research Consortium

**Invasive Mechanical Ventilation (IMV) was utilized in 320 of 2,634 discharged COVID-19 patients across 12 New York area hospitals.**

	18-65y		>65y		TOTAL	
	#	%	#	%	#	%
<b>Discharged Alive</b>	33	23.6%	5	2.8%	38	11.9%
<b>Died</b>	107	76.4%	175	97.2%	282	88.1%
<b>TOTAL</b>	140		180		320	

*Excerpt from Table 5. Clinical Measures and Outcomes for Patients Discharged Alive, Dead, and In Hospital at Study End Point by Age*

Table 3. Hospital Characteristics and Admission Rates

Hospital <sup>a</sup>	No. (%)		
	Study admissions (N = 5700)	Acute beds (March occupancy), mean <sup>b</sup>	Annual emergency department visits (% admitted)
North Shore University Hospital	1073 (18.8)	637 (92)	51 000 (34)
Long Island Jewish Medical Center	1151 (20.2)	517 (91)	66 000 (28)
Staten Island University Hospital	674 (11.9)	466 (85)	93 000 (25)
Lenox Hill Hospital	558 (9.8)	324 (75)	40 000 (29)
Southside Hospital	445 (7.8)	270 (86)	59 000 (18)
Huntington Hospital	359 (6.3)	231 (81)	40 000 (22)
Long Island Jewish Forest Hills	608 (10.7)	187 (86)	42 000 (21)
Long Island Jewish Valley Stream	355 (6.2)	180 (75)	31 000 (23)
Plainview Hospital	231 (4.1)	156 (70)	24 000 (29)
Cohen Children's Medical Center	42 (0.7)	111 (78)	48 000 (14)
Glen Cove Hospital, nonteaching	117 (2.1)	66 (78)	15 000 (20)
Syosset Hospital	87 (1.5)	55 (70)	12 000 (21)

Why **ECMO**? Because some patients need **MORE** respiratory support.

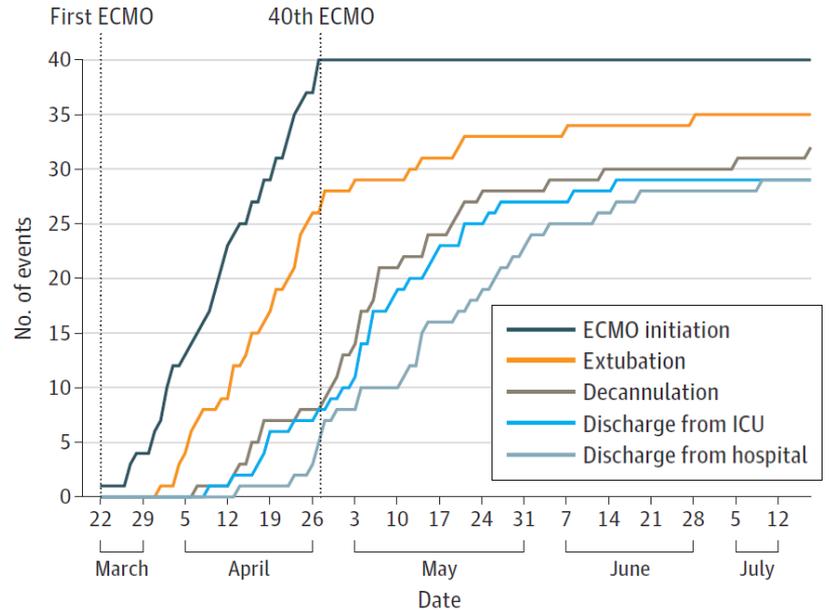
**RESEARCH LETTER**

**Extracorporeal Membrane Oxygenation for Patients With COVID-19 in Severe Respiratory Failure**

**88%**  
successful extubation

**73%**  
survival to discharge

**B** Cumulative No. of events





**We reduce complexity**  
so hospital caregivers can  
**focus on the patient**  
not the circuit.



# Indications for Use

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- COVID-19 UPDATES: The U.S. Food and Drug Administration (FDA) issued guidance on April 6, 2020 to temporarily expand the availability of devices used in extracorporeal membrane oxygenation (ECMO) therapy to address the novel coronavirus (COVID-19) public health emergency. While the FDA is permitting this temporary change to our indication for use, this change is not equivalent to an ECMO 510(k) clearance. As a result of the guidance, cardiopulmonary devices, including select devices from TandemLife | LivaNova, are now temporarily indicated for ECMO therapy greater than 6 hours. To read the full announcement, [click here](#).

# Indications for Use

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- **LifeSPARC System:** In the U.S., the LifeSPARC system is intended to pump blood through an extracorporeal circuit for periods lasting less than six hours for the purpose of providing either: (i) full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.
  - **Contraindications for Use:** The LifeSPARC System should not be used with extracorporeal circuits that create a pressure differential greater than 600 mmHg between the inflow and the outflow of the Pump. Because of the non-occlusive nature of the LifeSPARC Blood Pump, the Pump should not be used for cardiotomy suction.
  - **TandemHeart Controller:** The TandemHeart System is intended to pump the blood through an extracorporeal circuit for periods **lasting less than 6 hours** for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava
  - **TandemHeart Pump:** The TandemHeart pump is intended to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.
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# Indications for Use

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- **TandemLung Oxygenator:** The TandemLung Oxygenator (TLO) is intended to be used for adult patients for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.
  - **Contraindications for Use:** No contraindications are known provided the device is used within the Indications for Use and in accordance with the stated operating conditions.
  - **ProtexSolo 62 and 72 cm Transseptal Cannulae:** The Transseptal Cannula Set-EF is intended for transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (six hours or less) left ventricular bypass when connected to the TandemHeart extracorporeal blood pump, which returns blood to the patient via the femoral artery or other appropriate site.
  - **Contraindications for Use:** The Transseptal Cannula Set should not be used when any anatomical, medical, or physiological impairment may contraindicate the use of a femoral access procedure or transseptal access to the left atrium.
  - **ProtexSolo Venous Cannula:** The Venous Cannula is intended to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment. The introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal circulatory support. These devices are to be used by a trained physician only.
  - **Contraindications for Use:** Alone, the cannula and introducer are not medical treatment devices. There are no known contraindications for the use of the cannula, other than those generally contraindicated for cardiopulmonary bypass. The introducer is only to be used with the appropriately sized Venous Cannula. These devices are not intended for use except as indicated above.
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# Indications for Use

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- **ProtekSolo 15 and 17 Fr Arterial Cannulae:** These devices are to be used by a trained physician only. Cannulae are used to cannulate vessels, perfuse vessels or organs and/or connect with accessory extracorporeal circulatory support equipment for a duration of six hours or less. The Cannula Introducer is intended to facilitate proper insertion and placement of the Cannula within the vessel for extracorporeal circulatory support.
- **Contraindications for Use:** Alone, the cannula and introducer are not medical treatment devices. There are no known contraindications for the use of the cannula, other than those generally contraindicated for cardiopulmonary bypass. The cannula introducer is only to be used with the appropriately sized TandemHeart Cannula. These devices are not intended for use, except as indicated above.
- **ProtekDuo 29 and 31 Fr and ProtekDuo RD 31 Fr Veno-Venous Cannulae:** The ProtekDuo Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.
- **Contraindications for Use:** Alone, the cannula and introducer are not medical treatment devices. There are no known contraindications for the use of the cannula, other than those generally contraindicated for cardiopulmonary bypass. The cannula Introducer is only to be used with the appropriately sized ProtekDuo Veno-Venous Cannula. These devices are not intended for use except as indicated above.
- **VoyagerVest:** The Voyager Vest is intended to provide secure attachment of Extracorporeal Life Support (ECLS) components (pump, oxygenator, and tubing) to the patient during cardiopulmonary bypass.
- **Contraindications for Use:** The VoyagerVest kit is only intended for use with compatible products manufactured and tested by CardiacAssist, Inc. The VoyagerVest kit should not be used on patients with a known allergy to neoprene.

**LivaNova**

Health innovation that matters

**Q & A**

