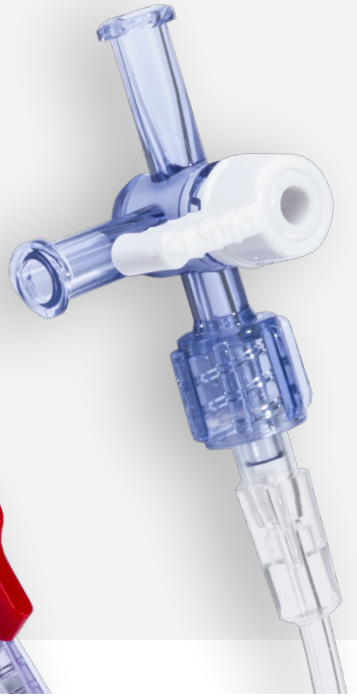
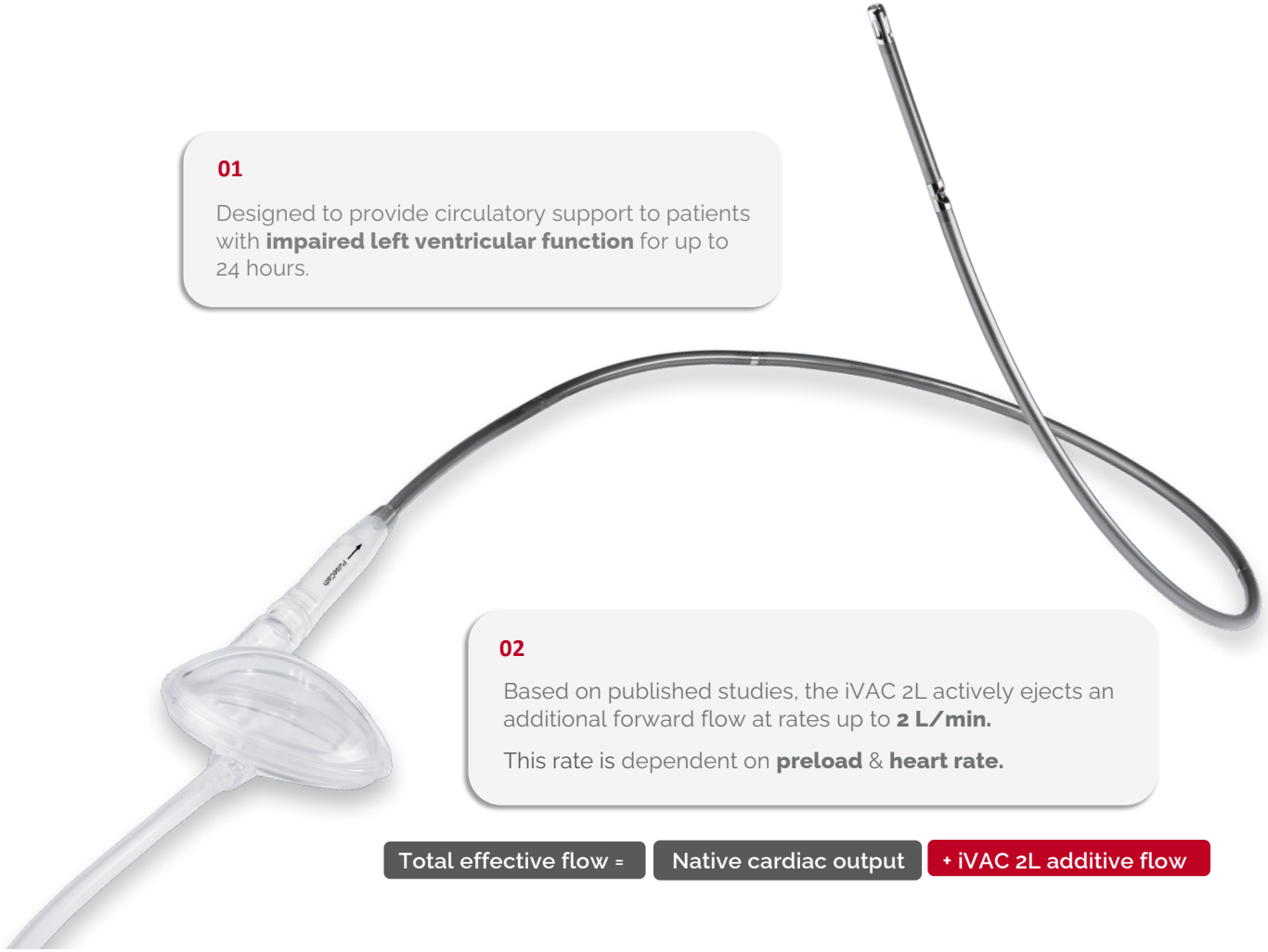
PulseCath

Engineering the Pulse of Life



Device Description



01

Designed to provide circulatory support to patients with **impaired left ventricular function** for up to 24 hours.

02

Based on published studies, the iVAC 2L actively ejects an additional forward flow at rates up to **2 L/min.**

This rate is dependent on **preload** & **heart rate.**

Total effective flow = | Native cardiac output | + iVAC 2L additive flow

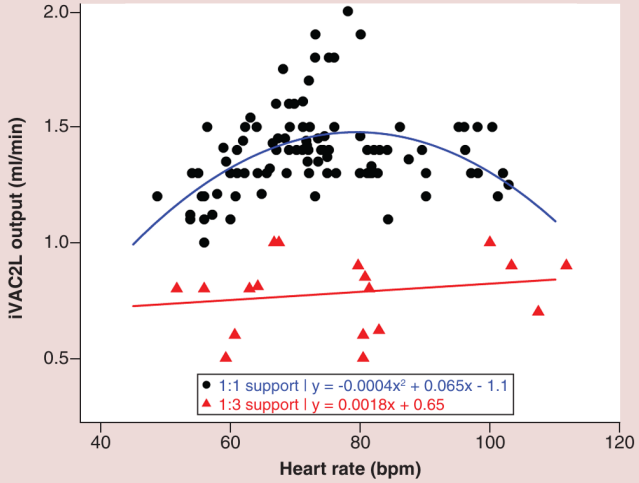


Figure 1: Scatterplot showing the relation between device output and heart rate 1:1 assist ratio (black circles).

Highest output is obtained between 70 and 90 bpm. Below 60 bpm, performance is limited by the lower-heart rate itself and above 90 bpm the shortened filling times become the major limiting factor. 1:3 support (red triangles) result in lower output that however remains consistent at higher heart rates.

Bastos, Marcelo B et al. "PulseCath iVAC2L: next-generation pulsatile mechanical circulatory support." Future cardiology vol. 16,2 (2020): 103-112.

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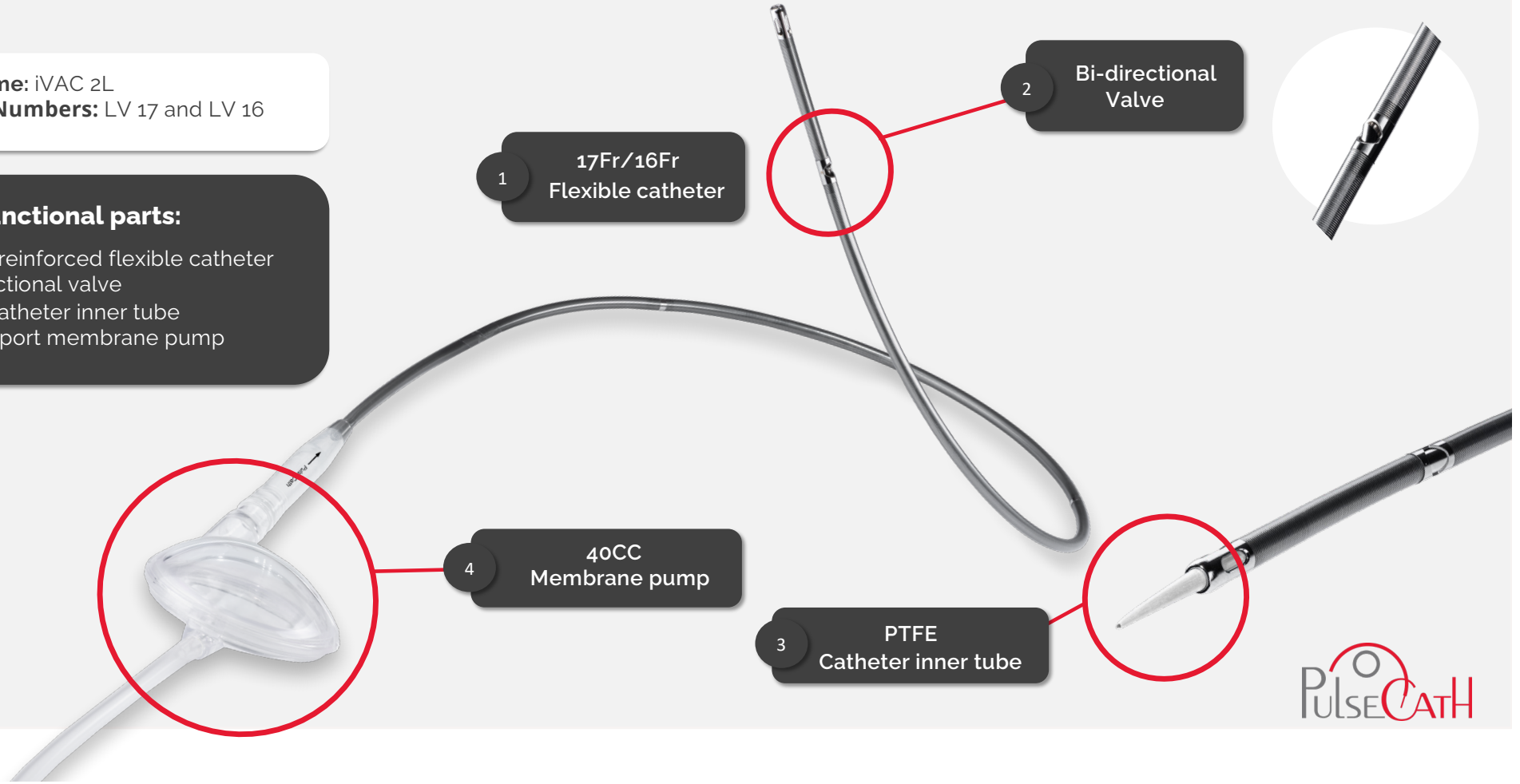
iVAC 2L Features

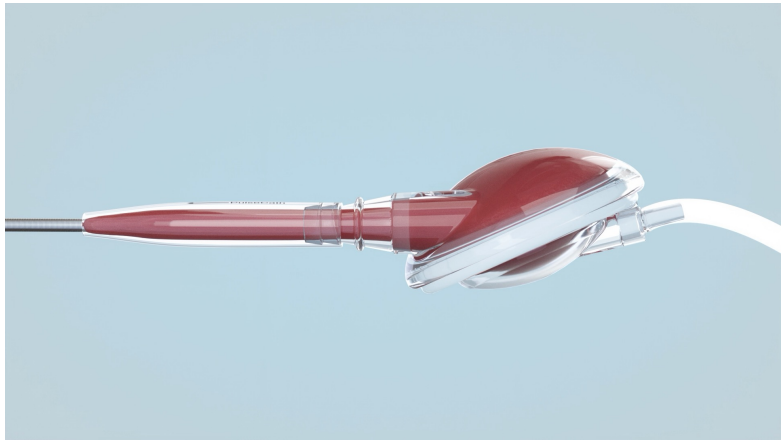
Product name: iVAC 2L
Catalogue Numbers: LV 17 and LV 16

iVAC 2L functional parts:

1. Nitinol reinforced flexible catheter
2. Bi-directional valve
3. PTFE catheter inner tube
4. Single-port membrane pump



How iVAC 2L works



01

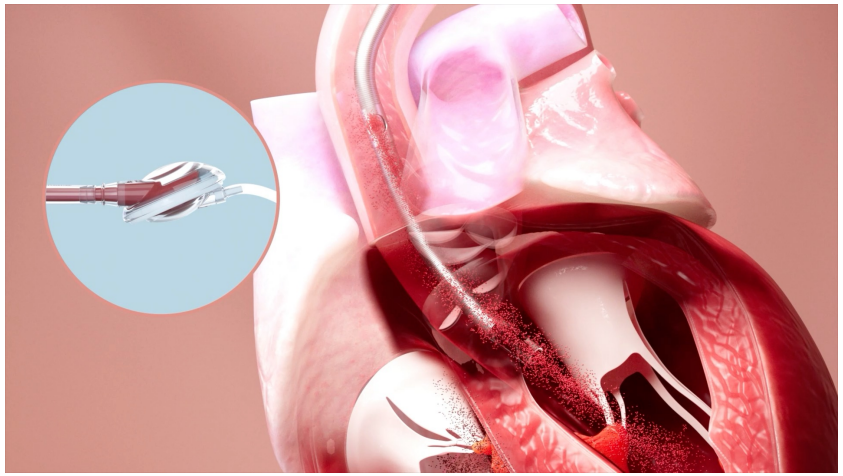
The iVAC 2L is driven by standard IABP console that is triggered by **ECG** or arterial **pressure waveform.**

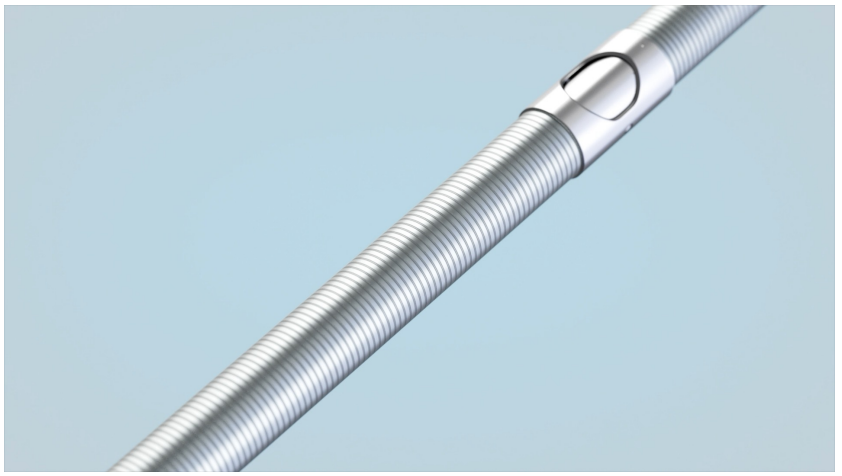
Internal mode can be used to maximize pump performance in cases of unregulated atrial fibrillation, severe bradycardia and tachycardia arrythmias. Optimal support is achieved in internal mode at 80 beats per minute.

02

The helium from IABP console is **“pushing and pulling”** the blood in the iVAC 2L membrane pump synchronized with systolic and diastolic phases of the myocardium.

How iVAC 2L works





03

At the **end of the systolic phase**, the helium **aspirates** the blood from the LV to the membrane pump.

04

During **diastole**, the helium pushes the blood in the membrane pump towards the bi-directional valve.

This blood is then **ejected** towards the coronary ostia forcing coaptation of the aortic leaflets.

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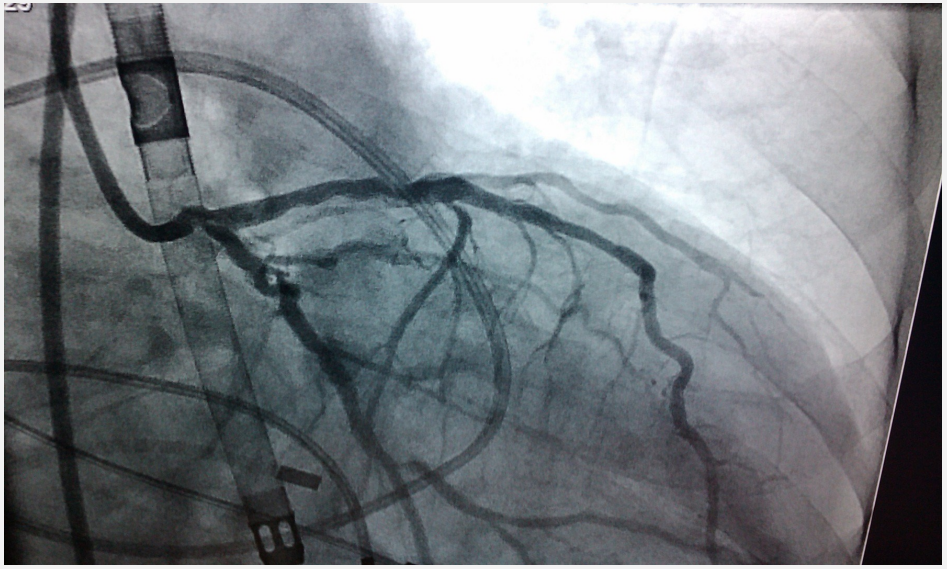
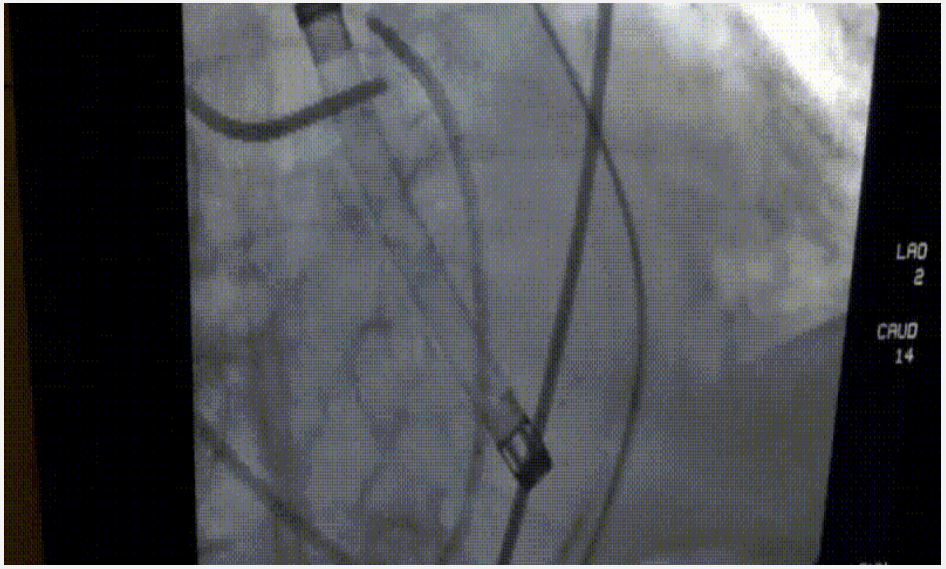
View on X-ray



iVAC 2L **in position** on X-ray



iVAC 2L **in action** as seen on Fluoroscopy

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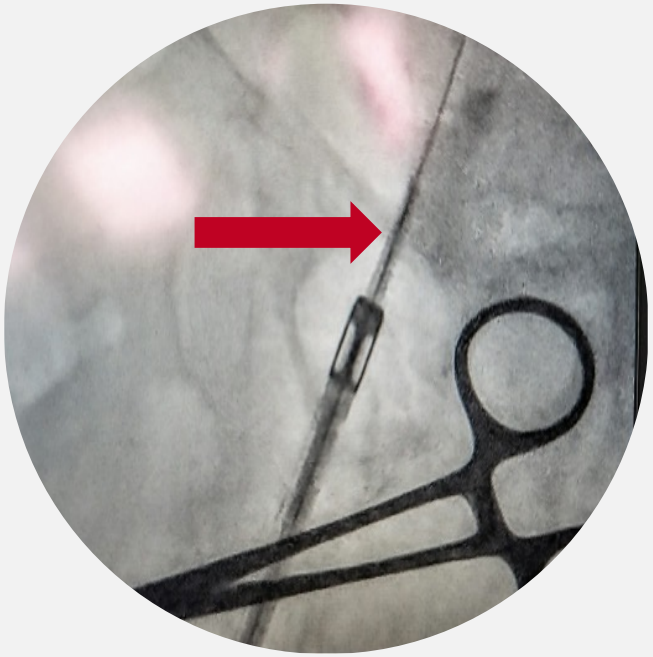
The iVAC 2L SLR

The iVAC 2L - Sheathless Ready

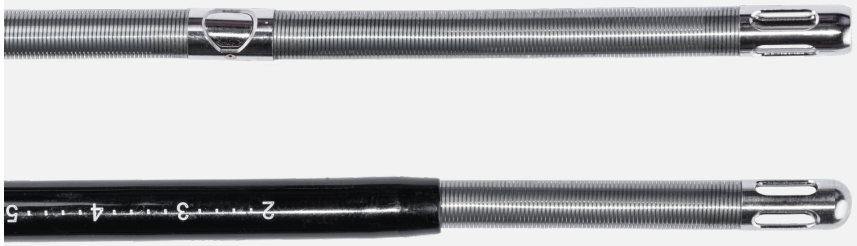
Wider proximal hole in the metal tip.

The PTFE inner tube is conical in shape, allowing it to **act as a dilator.**



This PTFE inner tube also contains **15% barium sulphate**, for X-ray detectability.

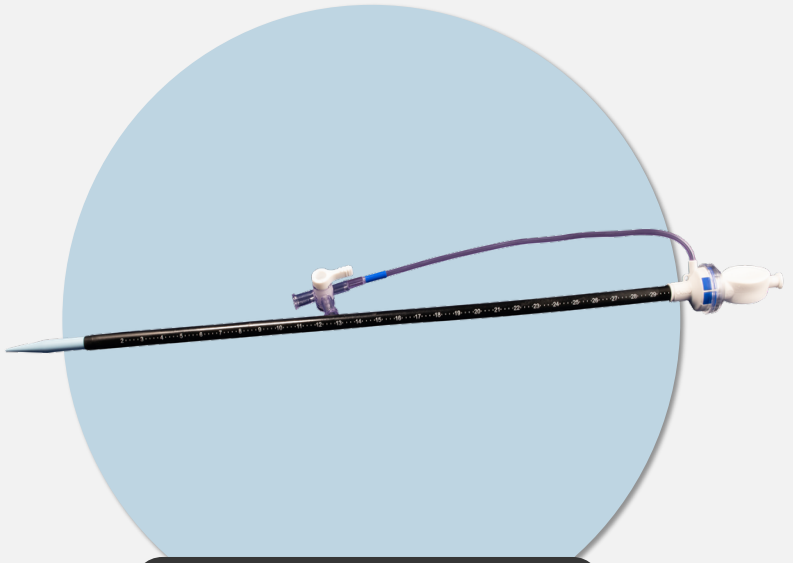
The iVAC 2L - Sheathless Ready



Without a sheath, the iVAC 2L SLR has:

4 Fr reduction in vascular access

Reduced outer diameter size to 5.7 mm



You have options!

The iVAC 2L can still be used with the **insertion sheath.**

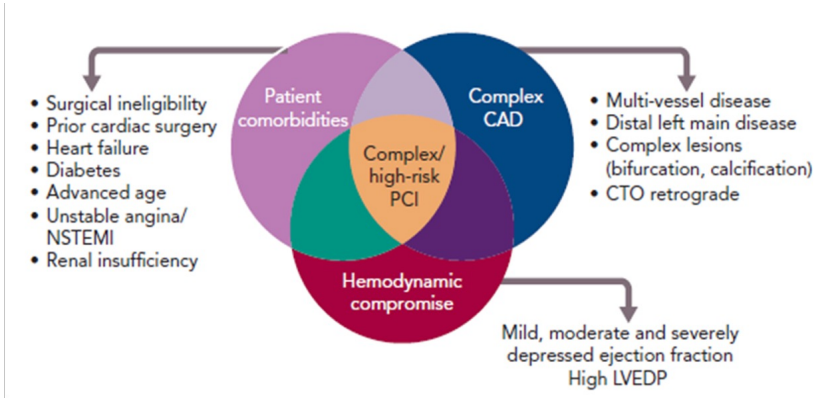
Indications & Contraindications

Indications

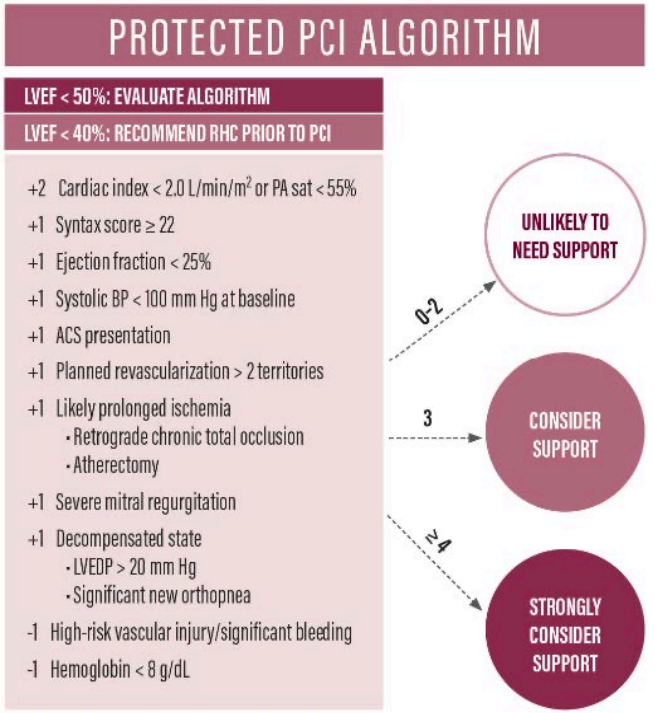
The iVAC 2L is intended for use in patients with **impaired left ventricular function** who require left ventricular mechanical circulatory support for up to 24 hours.

1 Elective or emergent high-risk PCIs for CAD

The risk of adverse events after PCI is multifactorial



Simonton C et al. The Role of Hemodynamic Support in High-risk Percutaneous Coronary Intervention. US Cardiology Review 2020;14:e13. https://doi.org/10.15420/usc.2020.18



Werner N, Burzotta F, Sinning JM. European best practice: a step forward to optimize Impellaprotected percutaneous coronary intervention to improve outcome after high-risk coronary interventions. Eur Heart J Suppl. 2022 Dec 8;24(Suppl J):J1-J3. doi: 10.1093/eurheartjsupp/suac065. PMID: 36518890; PMCID: PMC9730787.

Indications

The iVAC 2L is intended for use in patients with **impaired left ventricular function** who require left ventricular mechanical circulatory support for up to 24 hours.

1. Elective or emergent high-risk PCIs for CAD
2. Acute Myocardial Infarction (AMI)

Indications

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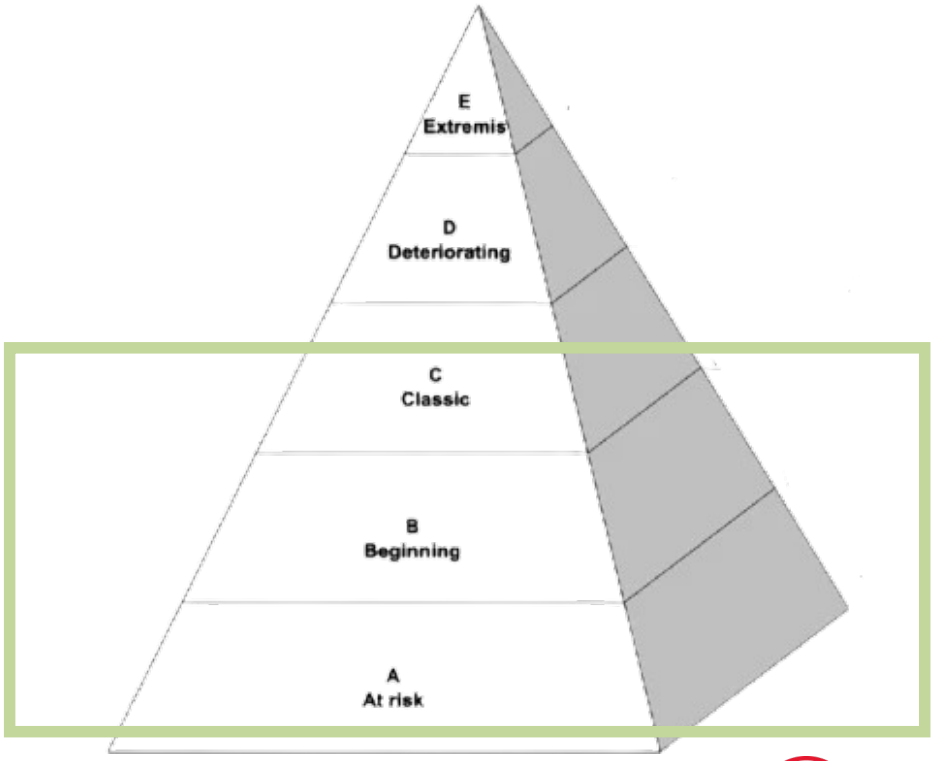
1. Elective or emergent high-risk PCIs for CAD
2. Acute Myocardial Infarction (AMI)
3. Cardiogenic shock (SCAI A-C)



SCAI
Society for Cardiovascular Angiography & Interventions

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The iVAC 2L is intended for use in patients with **impaired left ventricular function** who require left ventricular mechanical circulatory support for up to 24 hours.

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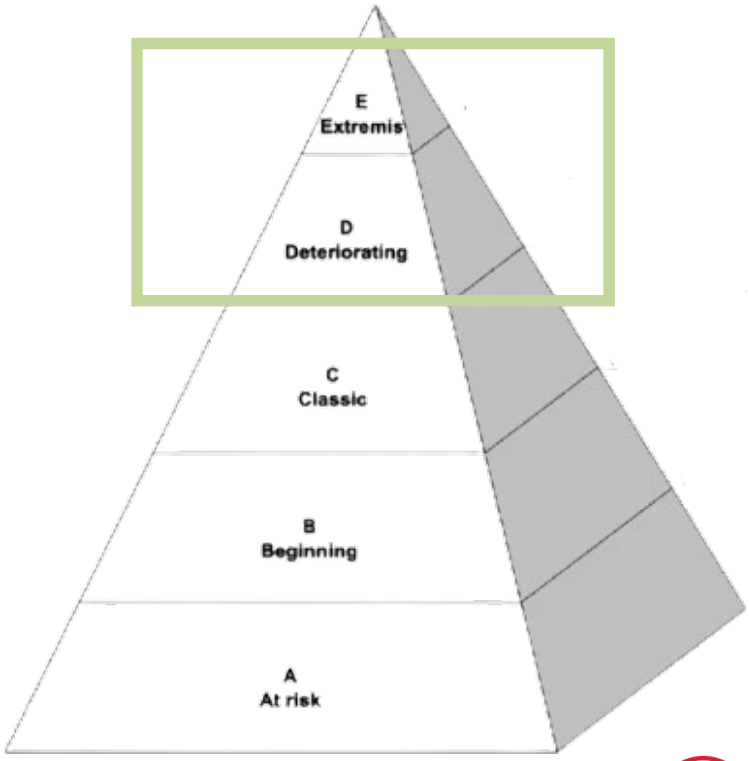
ECMO + iVAC 2L

For LV unloading in patients where IABP is not enough and ECMO is too severe



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frontiers in Cardiovascular Medicine

CASE REPORT
published: 25 September 2020
doi: 10.3389/fcvm.2020.563448

Case Report First-in-Man Method Description: Left Ventricular Unloading With iVAC2L During Veno-Arterial Extracorporeal Membrane Oxygenation: From Veno-Arterial Extracorporeal Membrane Oxygenation to ECMELLA to EC-iVAC®

OPEN ACCESS

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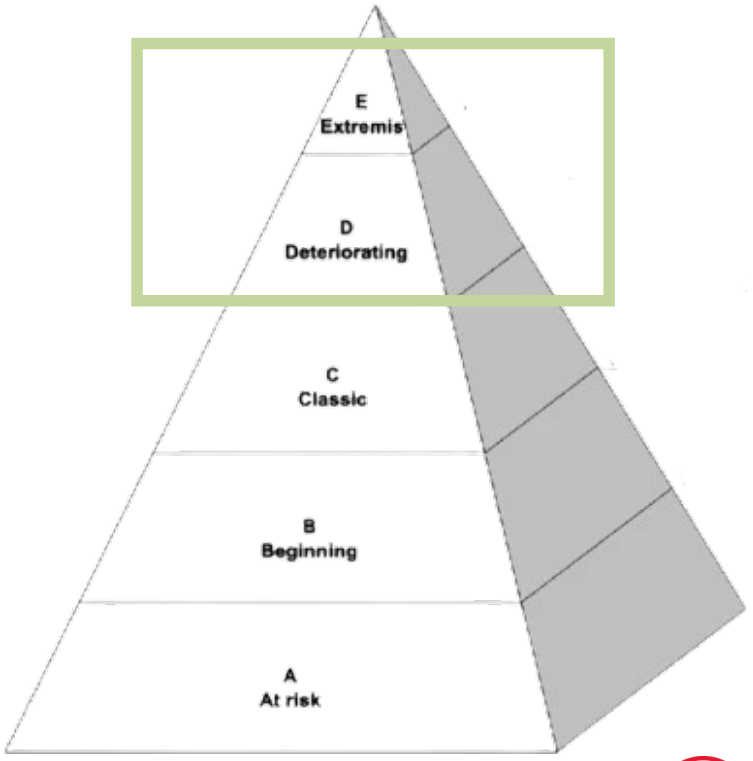
ECMO + iVAC 2L

For LV unloading in patients where IABP is not enough and ECMO is too severe



SCAI
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Indications

The iVAC 2L is intended for use in patients with **impaired left ventricular function** who require left ventricular mechanical circulatory support for up to 24 hours.

1. Elective or emergent high-risk PCIs for CAD
2. Acute Myocardial Infarction (AMI)
3. Cardiogenic shock (SCAI A-C)
4. High-risk ablation and mapping

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Contraindications

1. Aortic disease
2. Aortic valve disease
3. Aortic valve prosthesis
4. Aortic aneurysm
5. Femoral artery stenosis
6. Thrombus in LV
7. Ejection fraction lower than 10%
8. Right ventricular failure

Clinical Data

The PULSE Trial

- **Design:** prospective single-arm two center prospective cohort.
- **Study population:** patients undergoing HR-PCI with MCS.
- **Objective:** to understand the hemodynamic changes produced by iVAC 2L.
- **Primary endpoint:** reduction in pressure-volume area (PVA).
- **Secondary endpoints:** clinical endpoints at 30 days.

Clinical outcomes		
Outcomes	48 h	30 days
All-cause mortality	3.4 (1)	6.9 (2)
Stroke or TIA	6.9 (2)	10.3 (3)
MI	6.9 (2)	10.3 (3)
Repeat revascularization	0 (0)	0 (0)
Major bleeding	3.4 (1)	3.4 (1)
Major vascular complications	6.9 (2)	6.9 (2)
Acute renal dysfunction	6.9 (2)	6.9 (2)
Aortic regurgitation	0 (0)	0 (0)
Ventricular tachyarrhythmias	3.4 (1)	3.4 (1)
Need for CPR	3.4 (1)	3.4 (1)
Atrial fibrillation	17.2 (5)	17.2 (5)
Prolonged hypotension	3.4 (1)	N/A
Cardiogenic shock	3.4 (1)	N/A

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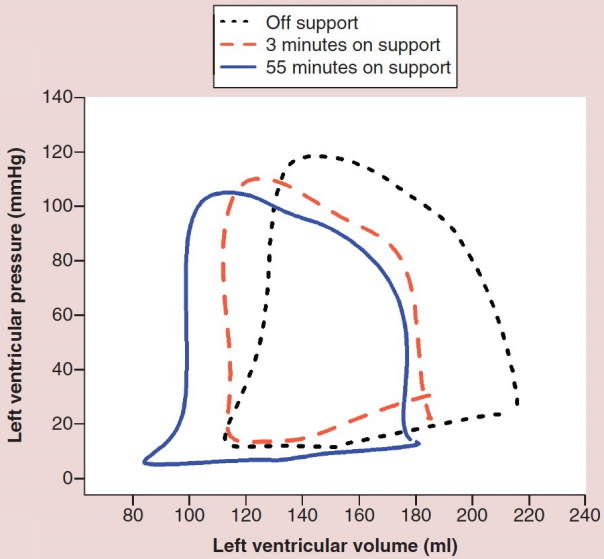


Figure 2: *Pressure–volume loops from a patient with ischemic cardiomyopathy and ejection fraction of 40%. Pressure–volume loops pre-support, immediately after activation and 55 min post-activation show progressive shifting of the PV loops to the left and downward, denoting left ventricle unloading.*

Conclusion

The efficacy of iVAC 2L is demonstrated by its capability to provide:

- Left ventricular unloading.
- 17% increase in the MAP and in the left ventricular afterload.
- 23% increase in the Cardiac Power Output.
- 7-8% reduction in myocardial oxygen consumption.
- 30-days mortality rates similar or better compared to other devices.
- Low rates of intraprocedural hemodynamical instability.
- Low rates of major bleeding if operated by qualified hands.

iVAC 2L Registry Data 2026 Vs. PROTECT III

496 Cases, 44 Countries, 198 Centers

Patients in the iVAC2L registry are more complex than Protect III registry

Currently, both registries have a similar age range. However, the iVAC2L Registry had more predictors of adverse events, such as:

Clinical and hemodynamic features:

- Older patients with higher prevalence of male gender; Median age was 71 (65 to 78) years
- Most cases (68%) had poor LV function (EF< 40%).
- More frequently showing previous history of revascularization, what suggests a more chronic disease profile;
- Relatively lower MAP at baseline.

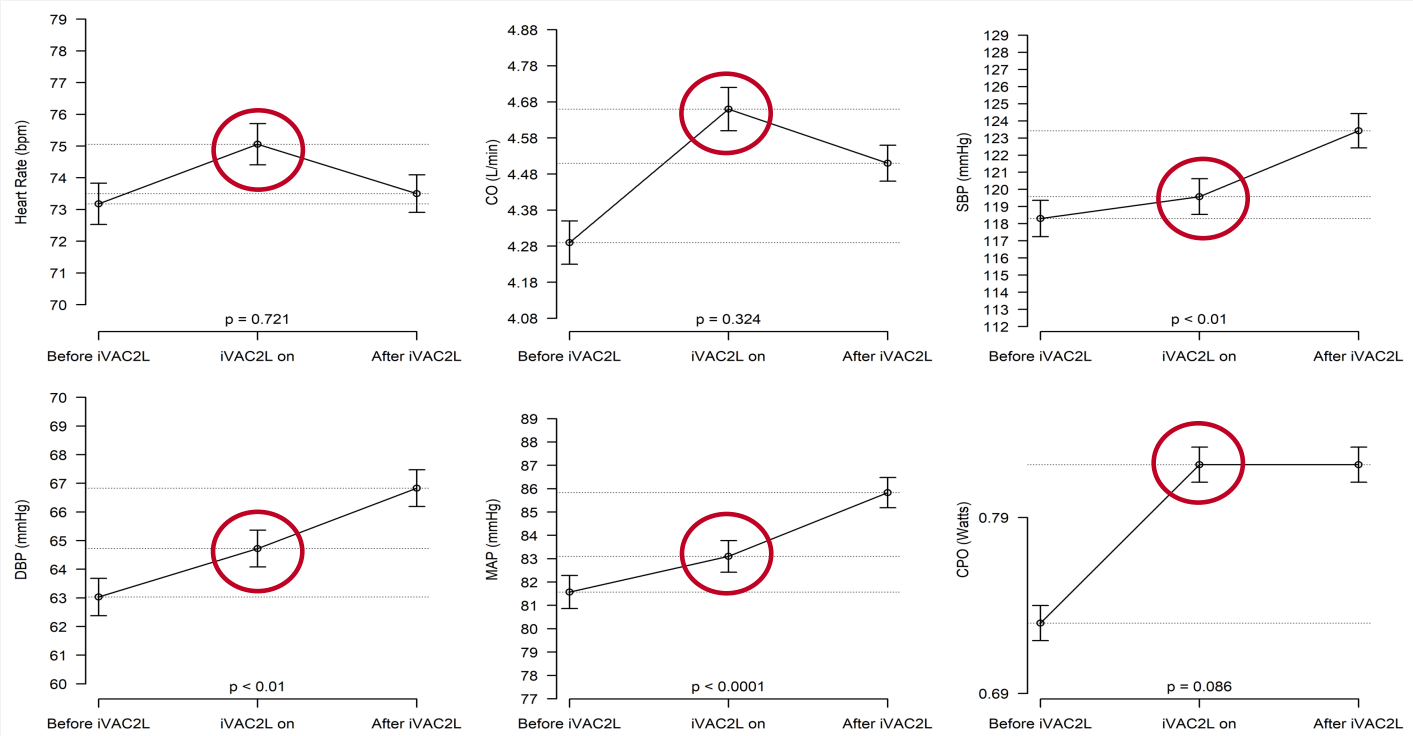
Anatomical features:

- Higher SYNTAX score, indicating that iVAC 2L patients had a more complex anatomy;
- Significant LM obstruction and three-vessel disease were present in 62% and 57%, respectively

The median support time of **70** (50 to 100) **minutes**, with an average flow of **1.5±0.2L/min.**

iVAC 2L Registry Data 2026

496 Cases, 44 Countries, 198 Centers



Note: Immediate hemodynamic improvement after starting iVAC 2L

Variation in hemodynamic variables **before** receiving iVAC 2L, **during** support with iVAC 2L and **after** support with iVAC 2L.
P-values derive from one-way ANOVA or Kruskal-Wallis test as appropriate.

iVAC 2L Registry Data 2026 Vs. PROTECT III

CLINICAL ENDPOINTS	iVAC 2L (IN-HOSPITAL)*	PROTECT III (IN-HOSPITAL)
Sample Size (n)	496	504
All-causes Mortality (%)	**1.2**	**4.4**
CVE (%)	1.73	0.6
AMI (%)	0.87	0.8
Repeat Revascularization (%)	0	0
Major Vascular Complications (%)	1.6	1.0
Major Bleeding (%)	**0.6**	**1.8**
Acute Kidney Injury (%)	**0.8**	**5.4**
CPR (%)	2.6	1.6
Aortic Insufficiency (%)	0.5	---
Angiographic Failure (%)	0.4	---
Severe Hypotension during support	5.9	2.2

* Due to operational limitations, in-hospital data is predominantly intraprocedural.
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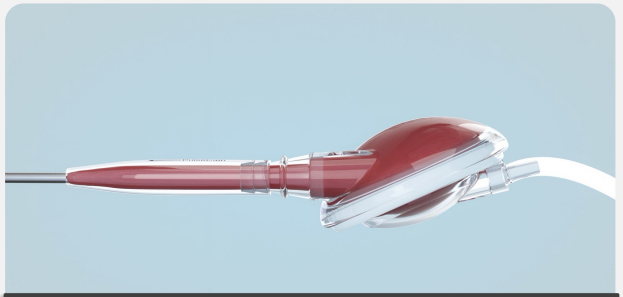
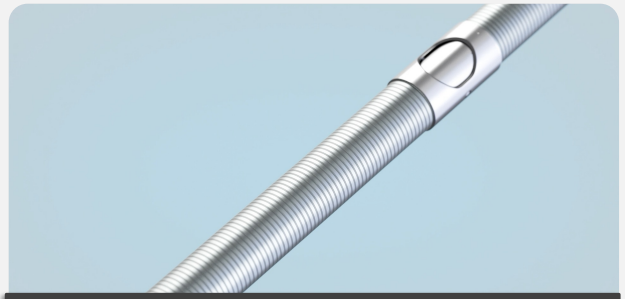
Product Benefits

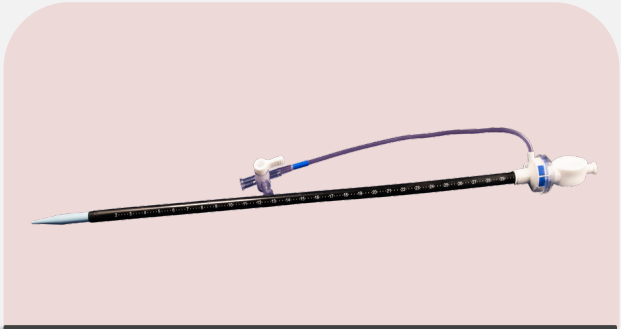
Product Benefits



Natural pulsatile support



No rotor involved



Optional sheathless approach

Designed for clinical & economic value

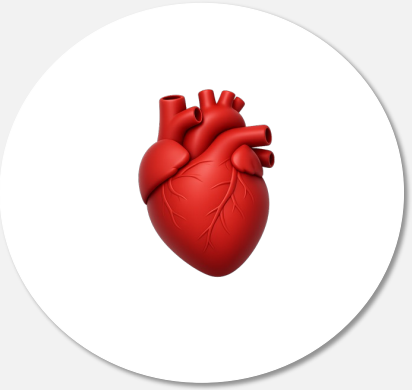
Pulsatile Flow Benefits

Decreased Afterload

Reduces resistance against which the heart pumps, lowering cardiac workload

Increased Coronary Perfusion

Enhances blood flow to heart muscle during diastole for optimal oxygenation



Physiological Synchronization

Aligns with natural cardiac cycle for improved hemodynamic efficiency

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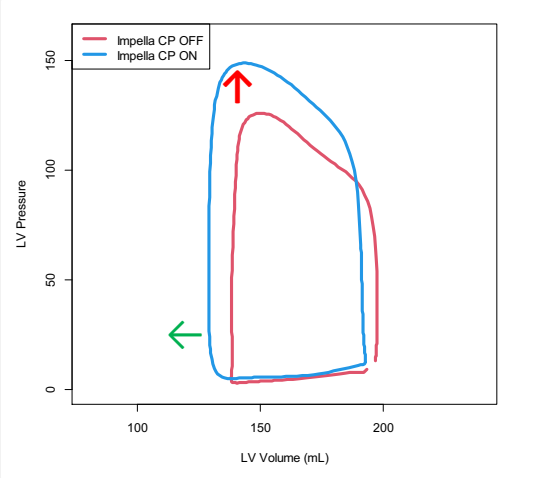
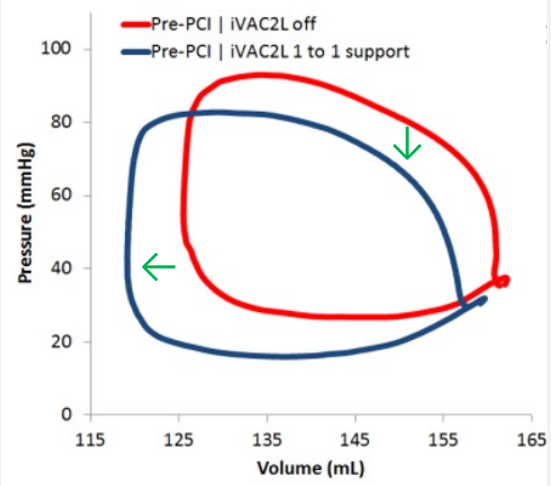
Continuous Vs. Pulsatile

Impella CP



Pump → aorta pressure ↑ → afterload ↑ → workload ↑

PulseCath iVAC 2L



Pump → aorta pressure ↕ → afterload ↓ → workload ↓

Clinical Benefits

Natural Pulsatile Support
Maintain motility of the aorta and improves end-organ perfusion.

LV Unloading
Reduces ventricular pressure and decreases wall stress.

Afterload Reduction
Lowers aortic resistance and facilitates forward flow.

Lowers Myocardial Workload
Reduced oxygen demand and improved cardiac efficiency.

Clinically Insignificant Hemolysis
iVAC 2L uses pneumatic flow to drive blood resulting in haemolysis <10mg/Dl compared to axial devises with haemolysis of 50-100mg/DL.

Improved Circulation
Improved cardiac output and lower acute kidney injury.

Hemodynamic Stability
Maintains Hemodynamic stability by increasing MAP (<50%), CO (<25%), CPO (<30%) & increased EF up to 50%.

PulseCath

Thank you

PulseCath