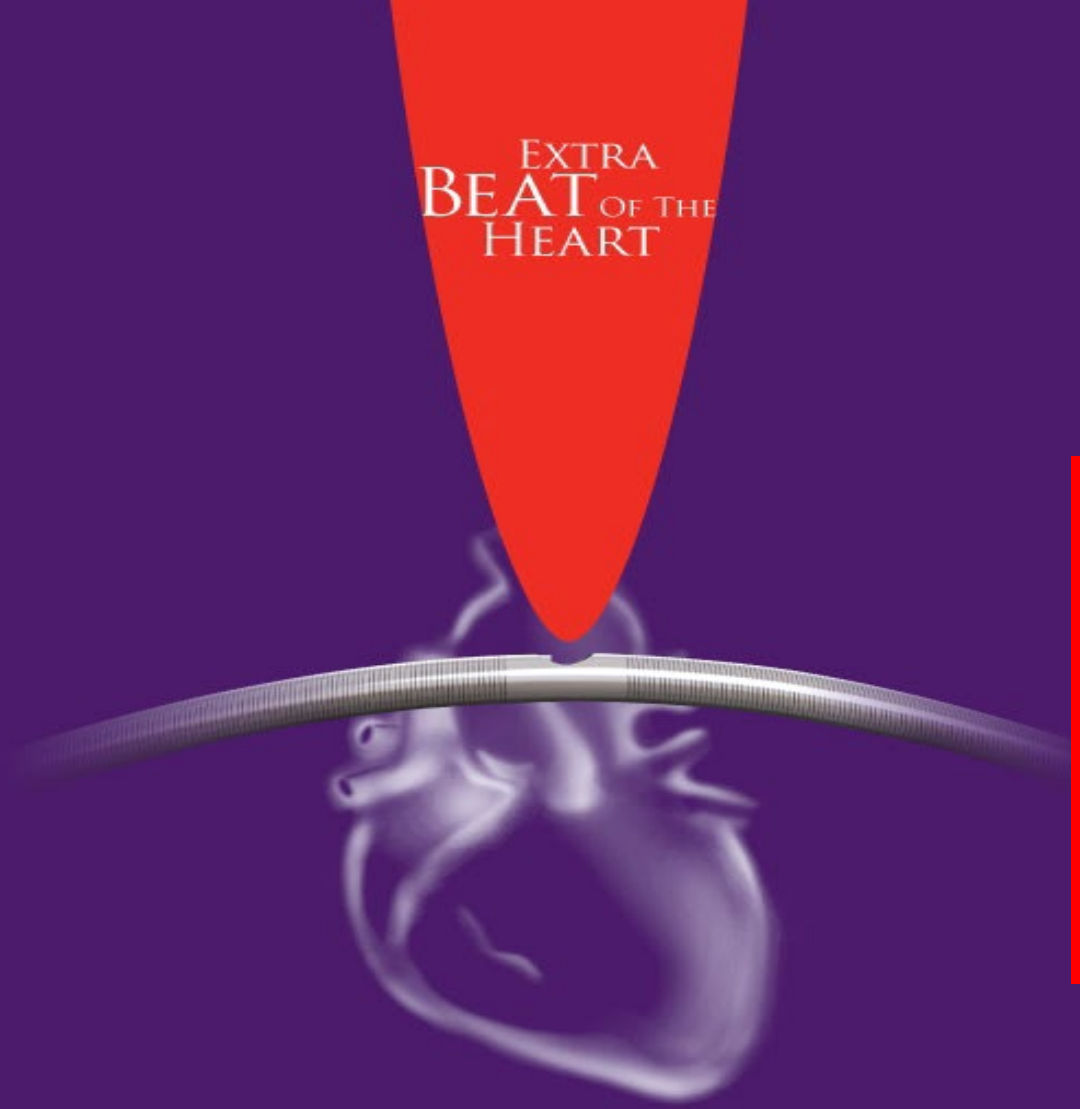


iVAC 2L
Product Presentation

PulseCath

V112022_001

PulseCath

A Netherlands based medical device company that develops, manufactures and markets mechanical circulatory support (MCS) system.

Our Mission

To provide effective circulatory support systems to the cardiologist and the cardiac surgeon that address a wide range of patients through novel solutions that reduce healthcare costs and improve patient outcomes.

PulseCath milestones

Before 2007

IntraVasc

Before PulseCath: original idea for a pulsatile pump came from founder Dr. Gerard Rakhorst, University Medical Center Groningen & IntraVasc, The Netherlands and was called the PUCA (PUlsatile Catheter pump)

2007

PulseCath was established

2007 – 2009 - 2011

2010 - 2011

iVAC 2L

Product development 17Fr, pVAD

2009

CE Mark iVAC 3L

First version of iVAC, 21 Fr version, Subclavian approach

2012 – 2014

2012 - 2014

iVAC 2L

Start clinical study

2014

CE Mark iVAC 2L

2015 – 2019

2015 - 2018

iVAC 2L

Clinical evaluations

2019

Commercialisation iVAC 2L & First Award

Best medical device company start-up EU Business News

2020 – 2022

2021

Strategic Alliance

Huadong Medicine

2022

PULSE trial

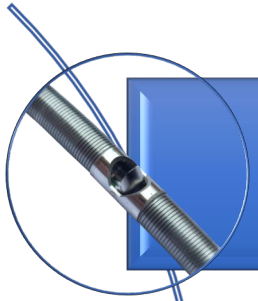
Publication

Today

> 600 iVAC 2L sold
> 400 iVAC 2L performed procedures
> 35 countries registered
> 30 distributor agreements
> 30 publications
> 7 Centers of Excellences
> 3 medical advisors

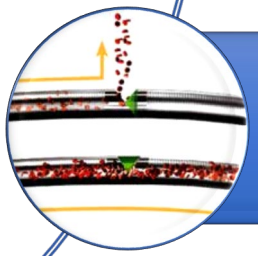
iVAC 2L 16Fr Sheathless

iVAC 2L



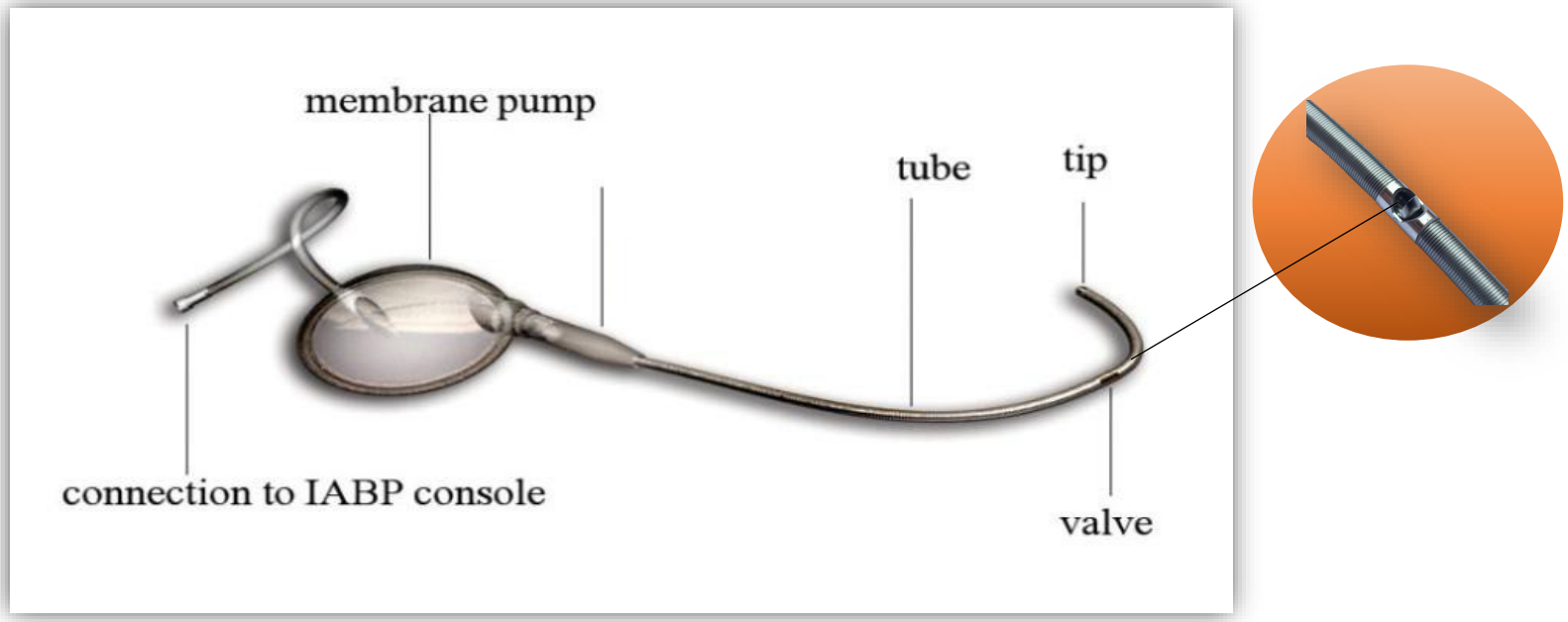
iVAC 2L is a short term Pulsatile Mechanical Circulatory Support System in the form of a pVAD (Percutaneous Ventricular Assist Device) that effectively generates blood flow of up to 1.5 liters per minute

It works by actively unloading the left ventricle to provide critical hemodynamic support for patients being treated for acute myocardial infarction and cardiogenic shock



Its application as hemodynamical backup may also result in more extensive treatment of the coronary lesions and improved long-term clinical outcomes and improve myocardial perfusion and optimize the cardiac workload, thus reducing the likelihood of peri- and post-procedural adverse events

What does it consist of?



- 17Fr flexible thin-walled catheter
- Bi-directional valve
- Single port 40cc membrane pump
- Delivered via 18Fr braided, hydrophilic delivery sheath
- Run by an IABP console

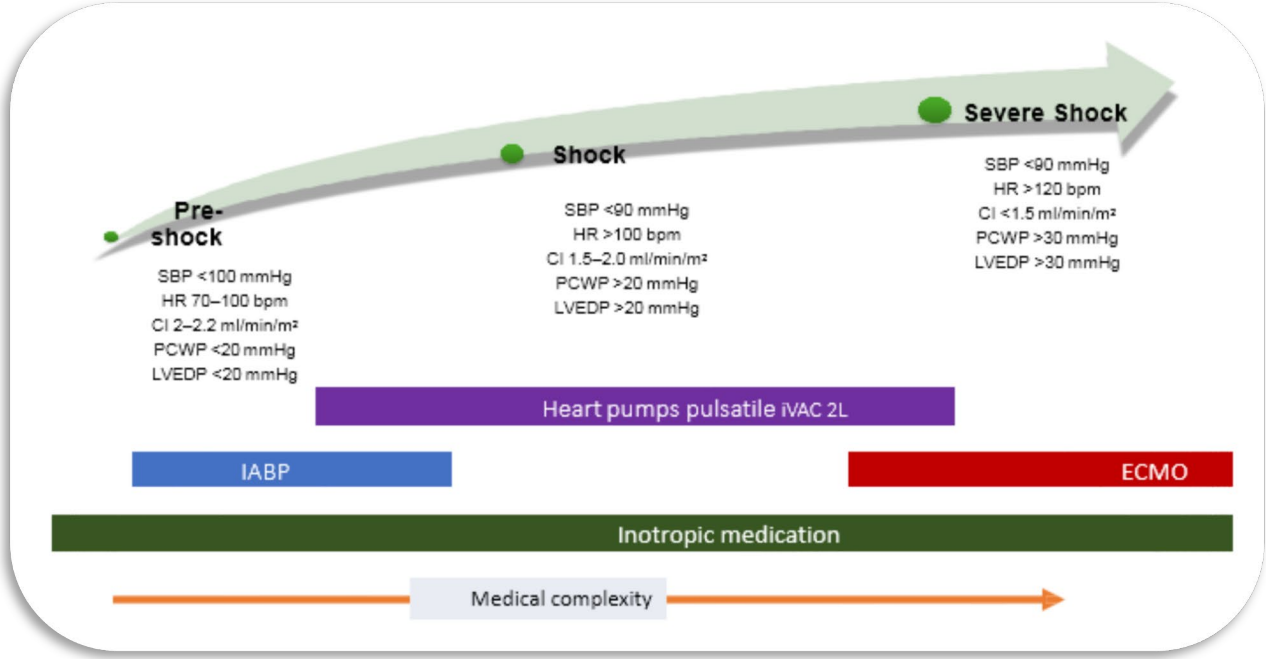
Bastos, Marcelo B et al. “PulseCath iVAC2L: next-generation pulsatile mechanical circulatory support.” Future cardiology vol. 16,2 (2020): 103-112.

Where can it be used?

Indications

Protected high-risk PCI*

Cardiogenic shock - In patients where IABP isn't enough and ECMO is too severe



*

1 Clinical characteristic + 1 Angiographic characteristic

Clinical Characteristic	Angiographic Characteristic
• LVEF < 35%	• Diffuse CAD
• Hemodynamic Instability	• Multivessel Disease
• Diabetes Mellitus	• Unprotected LM involving bifurcation
• Acute Coronary Syndrome	• Severe Coronary Total Occlusion
• Previous Cardiac Surgery	• Rotational Atherectomy
• Chronic Kidney Disease	• Late Patent Conduit

Contra indications include*: Femoral artery diameter <6mm, Severe Aortic stenosis, Thrombus in LV, Presence of a mechanical aortic valve

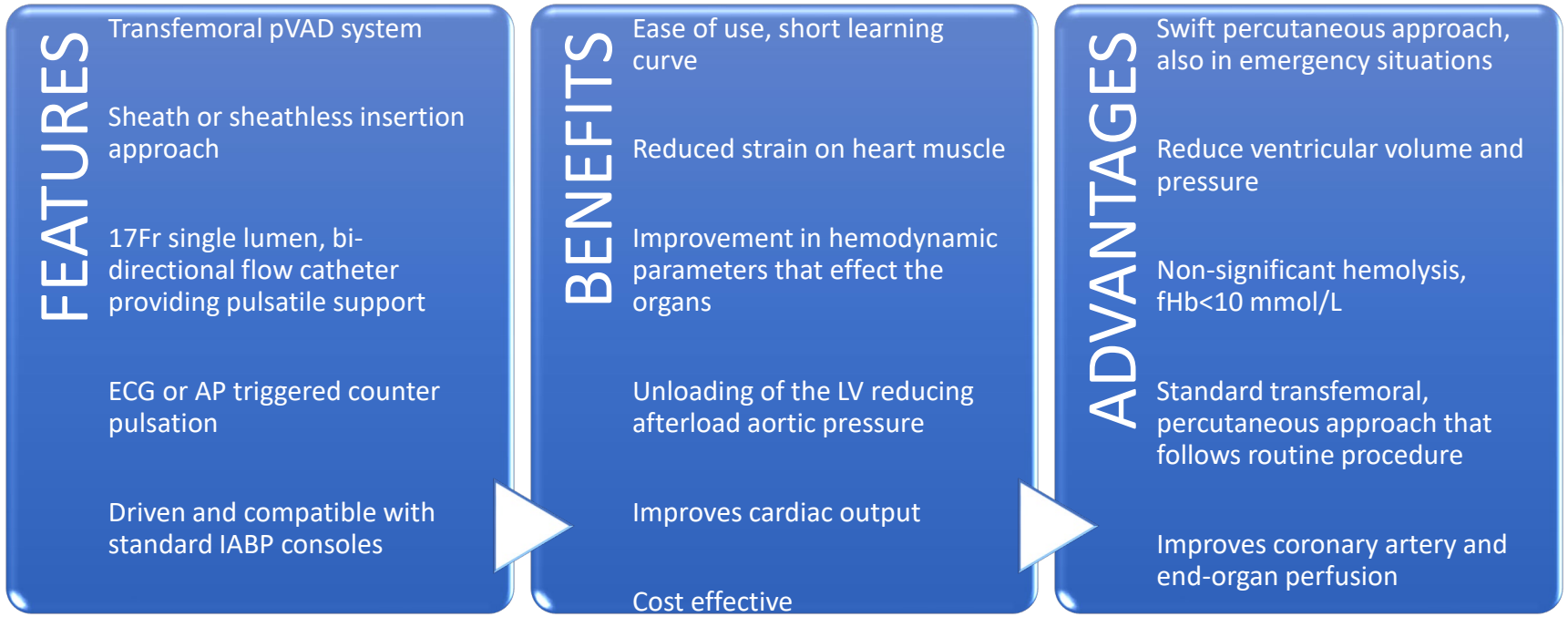
*please check the PulseCath iVAC 2L Instructions for Use for other contra indications

Arri, Satpal S et al. "Myocardial revascularisation in high-risk subjects." Heart (British Cardiac Society) vol. 104,2 (2018): 166-179.

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

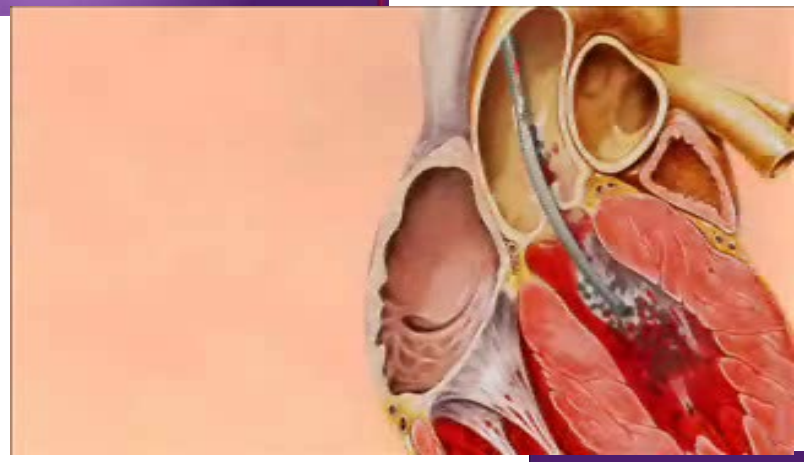
J Am Coll Cardiol. 2015 May 19;65(19):e7-e26

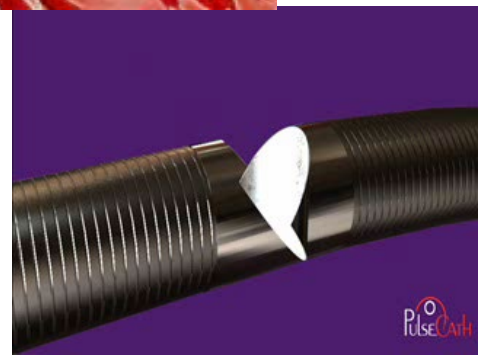
iVAC 2L: Features – Benefits - Advantages



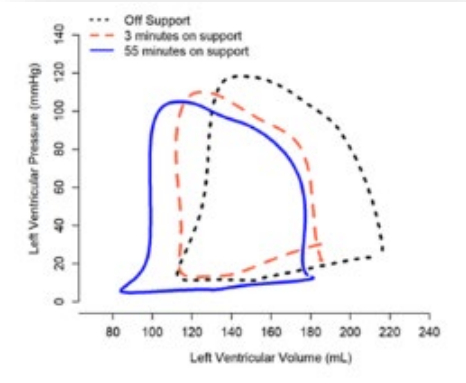
How does it work?

- The iVAC 2L is activated by standard IABP console that is triggered by ECG /AP
- The helium from IABP console is “pushing and pulling” the iVAC 2L membrane pump synchronized with heart beats
- During systole, blood enters the catheter through its tip located at the left ventricular and is aspirated into the membrane pump
- The membrane pump pushes the blood back in the catheter, the valve at the side hole opens, and ejects the blood out sideways to aorta during diastole



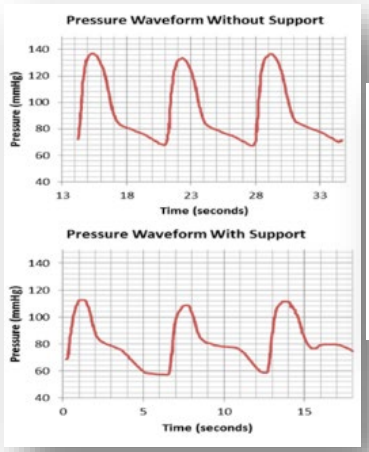


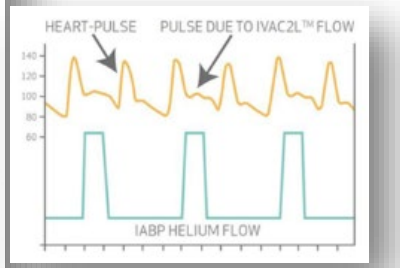
Impact of iVAC 2L as seen on PV Loop, Waveform and Mechanical unloading



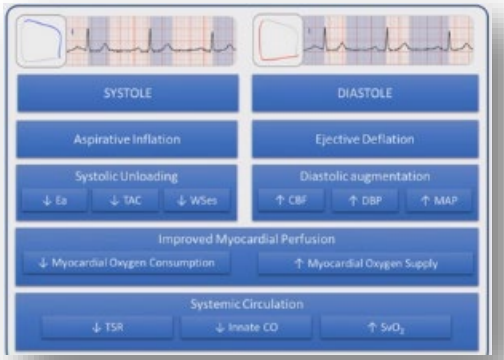
A significant shift to the left and south is observed on use of iVAC 2L

iVAC 2L increases pressure diastolic providing additional diastolic flow without taking over LV ejection fraction volume





- Impact of iVAC 2L in heart failure patients
  - Improvement in heart work efficacy
  - Improvement in systematic hemodynamics



- LV volumes and pressure show significant increase
- The Arterial Elastance (Ea), reflecting the forces opposing blood ejection by the LV, is reduced significantly and consistently after activation of iVAC 2L
- Total systemic resistance is significantly reduced after iVAC 2L activation as the blood reaches the peripheral circulation more easily
- The global cycle efficiency is significantly improved

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

Clinical Studies

- Over 30 articles and trials published
- 15 since 2017
- PULSE Trial* most recently published in the CRM

*Effect of next generation pulsatile mechanical circulatory support on cardiac mechanics - The PULSE trial. Cardiovascular Revascularization Medicine, March 2022
Marcelo B. Bastos , Hannah McConkey, Oren Malkin, Corstiaan den Uil, Joost Daemen, Tiffany Patterson, Quinten Wolff, Isabella Kardys, Jan Schreuder, Mattie Lenzen, Felix Zijlstra, Simon Redwood, Nicolas M. Van Mieghem

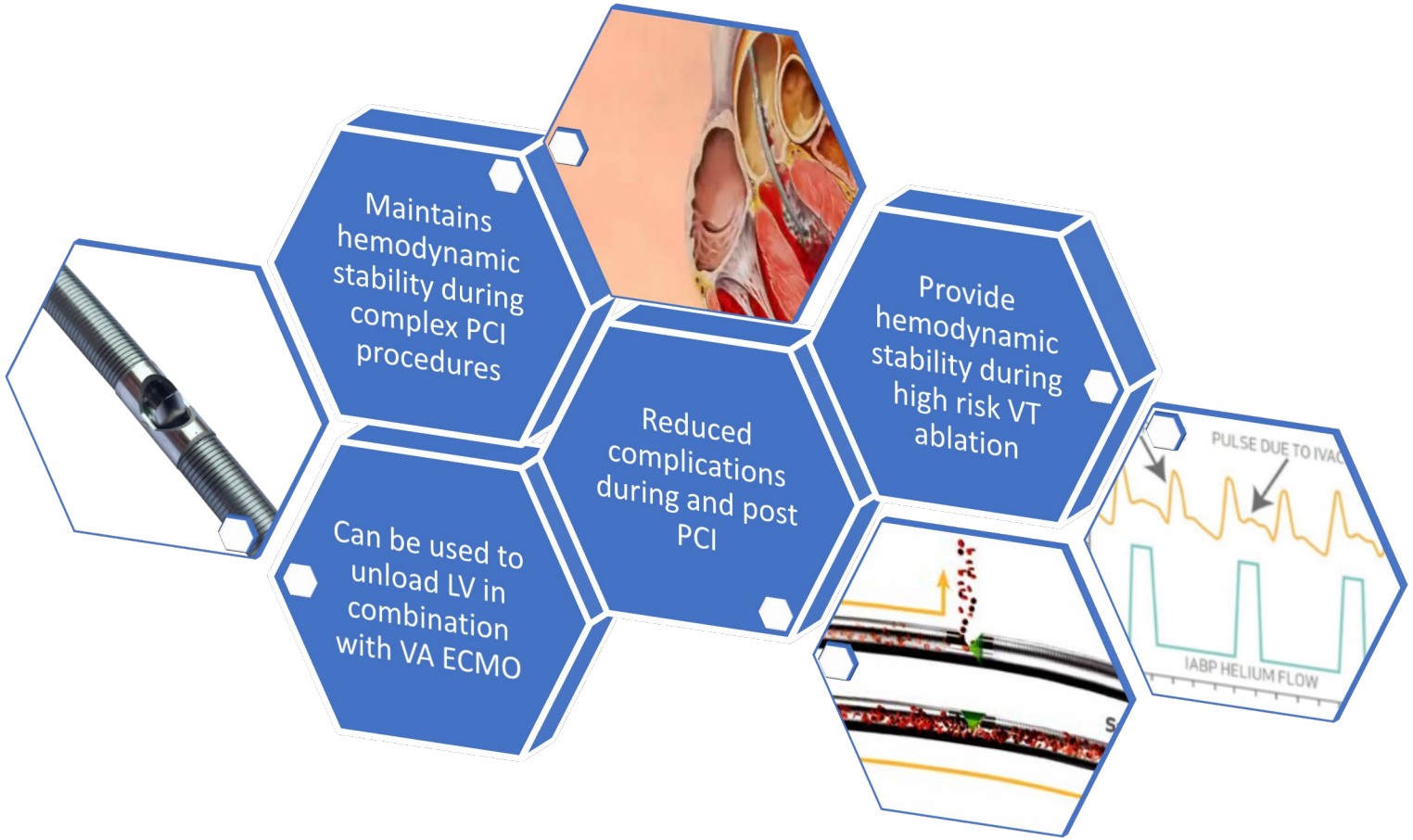
Why use a Short Term Mechanical Circulatory Device during high-risk PCI?

Performing high-risk PCI's normally create heart deuteriation during blocking LM coronary with balloon

In many cases this can force to stop procedure in order to let myocardial to recover

In order to get to maximum outcome from one procedure the iVAC 2L can prevent patient collapsing and give the "safety net" needed to continue for next steps

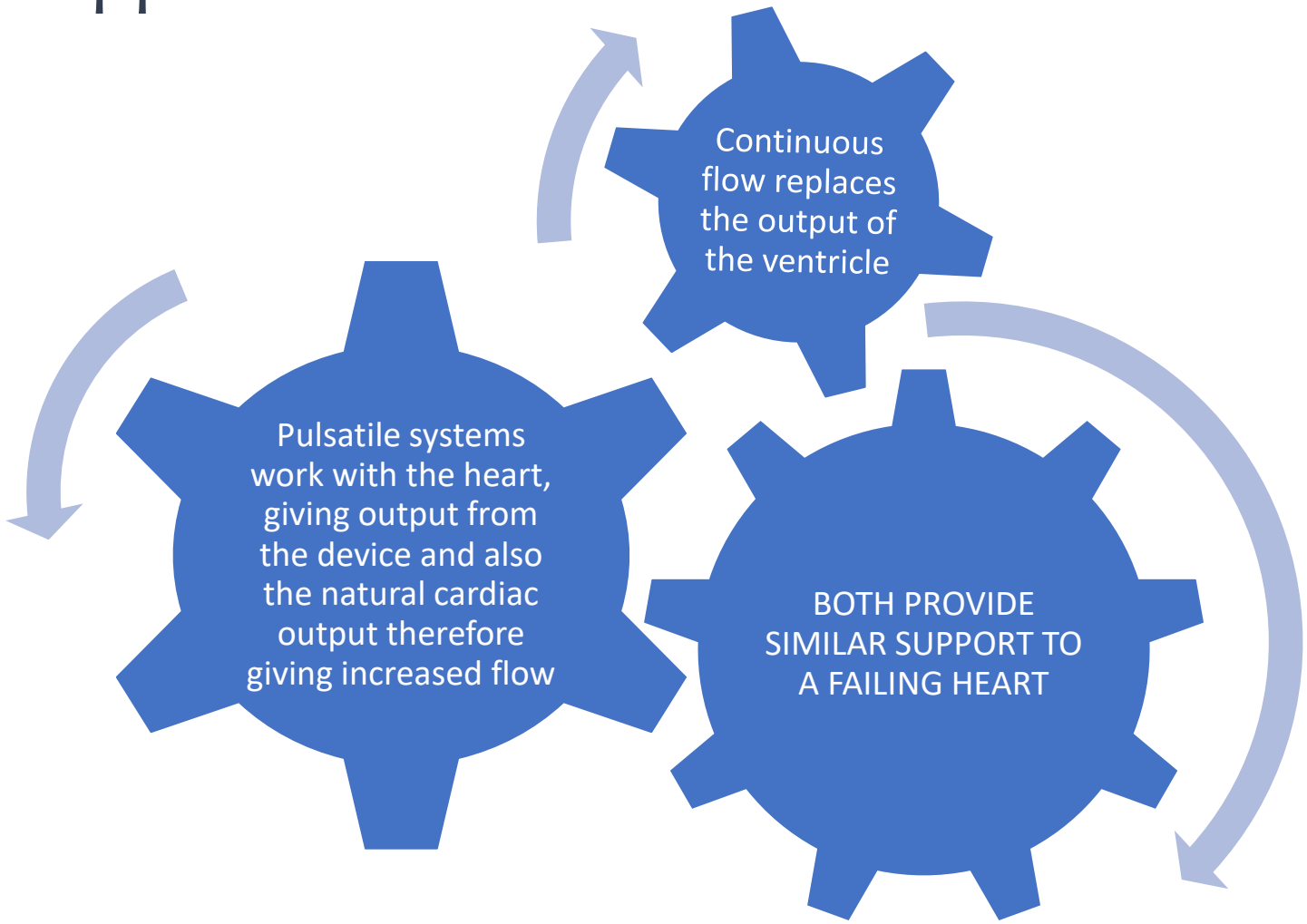
Not using safety net pump during these cases force you to preform the procedure in high speed only by senior and well experienced doctors



* Ameloot K, B Bastos M, Daemen J, Schreuder J, Boersma E, Zijlstra F, Van Mieghem NM.Top of Form New Generation mechanical circulatory support during high-risk PCI: a cross sectional analysis. EuroIntervention 2019.

The effect of pulsatile support over continuous flow?

Stroke volume of heart + stroke volume of device ≈ pumping greater volume of blood through the body



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

Comparison of iVAC 2L to Impella CP

- iVAC 2L although a smaller pump generates equivalent results to Impella CP
- Works with the heart
- No significant hemolysis in comparison to Impella CP
- Easy to operate and time efficient
- Cost effective

Clinical Effect	IVAC 2L	Impella CP
Cardiac output and systematic pressure changes*	LV volumes and pressures showed a significant increase.	LV volumes and pressures showed a significant increase.
The Effective Arterial Elastance (Ea)*	Decrease	Increase
Total Systemic Resistance*	Decrease	Increase
Global Cycle Efficiency*	Increase	No change
Aortic Afterload*	Decrease	Increase
PV Loop Changes*	Shifting to left and down	Shifting to right and Up
Hemolysis (fHb)*	<10 mg/dL	>50 mg/dL
Principle of action	Pulsatile	Continuance flow
Indications		
	High risk PCI, Unloading LV during ECMO (CS), High risk Ablation and Mapping	High risk PCI, Unloading LV during ECMO (CS)
Use and complications		
Bleeding complications*	Very low	High
Procedure steps	Easy and intuitive	Complicated and involve high skill user
Learning time	Short	long
Learning new procedure and console	Not needed	needed
Economics		
Cost (Europe)	++	++++
Console	Standard IAB console	Dedicated Impella console

Based on clinical studies and publications

Alexander Samol, Marcus Wiemer, Sven Kaese. Comparison of a pulsatile and a continuous flow left ventricular assist device in high-risk PCI. International Journal of Cardiology May 2022

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

Thank you for Listening

PulseCath