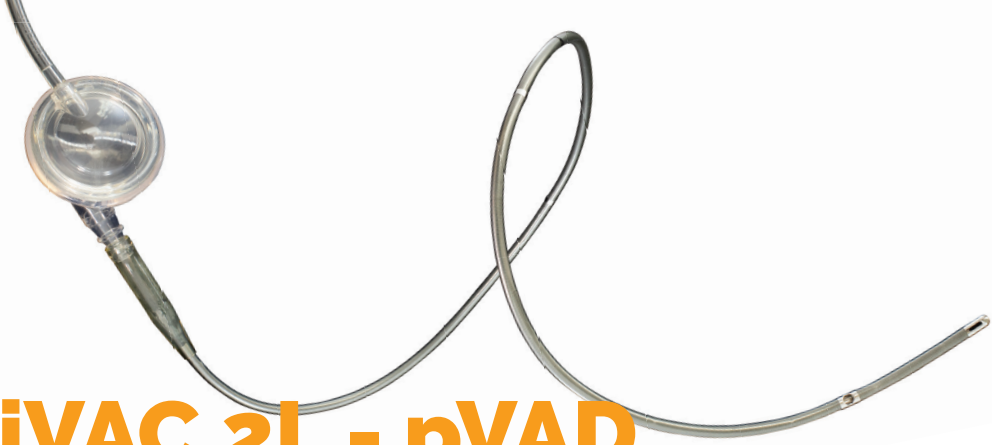

iVAC 2L - pVAD

Percutaneous Ventricular Assist Device

Natural pulsatile support for protected High-Risk PCI

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General Context

Today, Percutaneous Mechanical Circulatory Support (MCS) can be used to facilitate High-risk Percutaneous Coronary Interventions (HR-PCIs).
The in-hospital mortality rate of high-risk PCI patients is higher than usual, and may reach up to 28% after 30 days. To prevent this, the increasing use of prophylactic MCS in this setting aims to support the circulatory system from the first minutes of the intervention. This approach may reduce the risk of hemodynamic instability or circulatory collapse during coronary artery manipulation and provide sufficient time to achieve optimal and complete revascularization[1].

The main goals of Left Ventricular (LV) short-term MCS include:

- ✓ LV unloading.
- ✓ Reduction in Myocardial Oxygen Consumption (MVO_2).
- ✓ Increase in systemic pressures.
- ✓ Optimization of coronary flow and end-organ perfusion.
- ✓ Decongestion of the venous and pulmonary circulations.

Purpose of protected High-Risk PCI with pVAD

With prophylactic MCS in HR-PCI, operators can expect a reduction in major adverse events [1-9].

Body of Evidence

The efficacy of MCS has been suggested by multiple comparative studies:

- Cardiopulmonary bypass reduced intraprocedural mortality in in patients with low ejection fraction undergoing high-risk PCI (4.8% vs 18%, $p < 0.05$)[8].
- In the BCIS-1 trial, hemodynamic instability occurred in 1.3% of the group assigned for planned IABP insertion (pre-PCI) versus 12% in the group with no planned IABP insertion ($p < 0.001$), In the latter group, patients received IABP only in case of instability. The IABP is the weakest modality of MCS available[9].
- In the SHOCK trial Registry, the use of IABP significantly reduced mortality among patients with acute myocardial infarction followed by cardiogenic shock (50% vs 72%, $p < 0.001$)[10].
- The PROTECT II trial showed a 22% reduction in the relative risk of Major Adverse Events with MCS vs IABP after 90 days and a significant increase in the Cardiac Power Output (CPO) intraprocedurally. The PROTECT II trial is the largest randomized controlled trial comparing MCS with IABP in high-risk percutaneous coronary interventions[1].
- An analysis of 198 high-risk patients undergoing HR-PCI with MCS (n=69) or without MCS (n=129) at the Erasmus Medical Center (Rotterdam, NL) showed that MCS improved survival and reduced adverse events when compared with standard-of-care only[2].
- A prospective study conducted by the Erasmus Medical Center (Rotterdam, NL) documented increases in systemic pressures and reduction in pulmonary pressures when iVAC 2L was activated in elective cases of HR-PCI, with no major adverse events[6].
- A head-to-head comparison between iVAC 2L and Impella 2.5 in elective HR-PCI showed both devices are capable of significantly increasing the MAP[9].
- The PULSE trial shows LV unloading, increased mean arterial pressure (MAP) and lower myocardial oxygen consumption (MVO_2) with the use of iVAC 2L in high-risk PCI[3, 4].
- Recent experiment using porcine models of acute myocardial infarction with cardiogenic shock (AMICS) showed that iVAC 2L decreases the mean pulmonary capillary wedge pressure (mPCWP), and increases blood pressure and cardiac output at the onset of cardiogenic shock and after 12h of support[11].
- A recently published expert consensus recommends that MCS may be considered in highly selected patients undergoing HR-PCI in case of acceptable femoral access (> 6 mm in diameter of the common femoral artery with no severe tortuosity) and should be preferred instead of IABP and VA-ECMO[5].

IVAC 2L overview

iVAC 2L is a short term, fully percutaneous, 17Fr trans-femoral LVAD that effectively generates blood flow up to 2.0 L/min. By actively unloading the LV, the iVAC 2L provides critical haemodynamic support during high-risk revascularization procedures, in cases of acute myocardial infarction and in cardiogenic shock[11].

What is the labeled indication for the iVAC 2L system?

iVAC 2L is intended for use in patients with impaired left ventricular function which require mechanical circulatory support for up to 24 hours.
This includes left ventricular support in the following situations:

- ✓ Elective or emergent HR-PCIs for Coronary Heart Disease.
- ✓ Cardiogenic shock of various etiologies.
- ✓ Acute Decompensated Heart failure.
- ✓ High-risk electrophysiological procedures.

Mechanism of action

The operating mechanism of the iVAC 2L is a patented 2-way valve integrated in a 17Fr single lumen and bi-directional, 1000 mm long catheter. This catheter is connected to an extracorporeal membrane pump. The system is compatible with a standard IABP console and does not require dedicated hardware. When the heart is in the **systolic** phase, blood is aspirated from the ventricle through the tip of the catheter and transported via the lumen into the membrane pump.
During the **diastolic** phase, the membrane pump (with the IABP console as a driver) directs the blood back through the catheter to the ascending aorta by opening the 2-way valve.The pulsatile synchronization between closing of the aortic valve and the opening of the catheter valve ensures that the aortic valve function is not impaired, but supported.

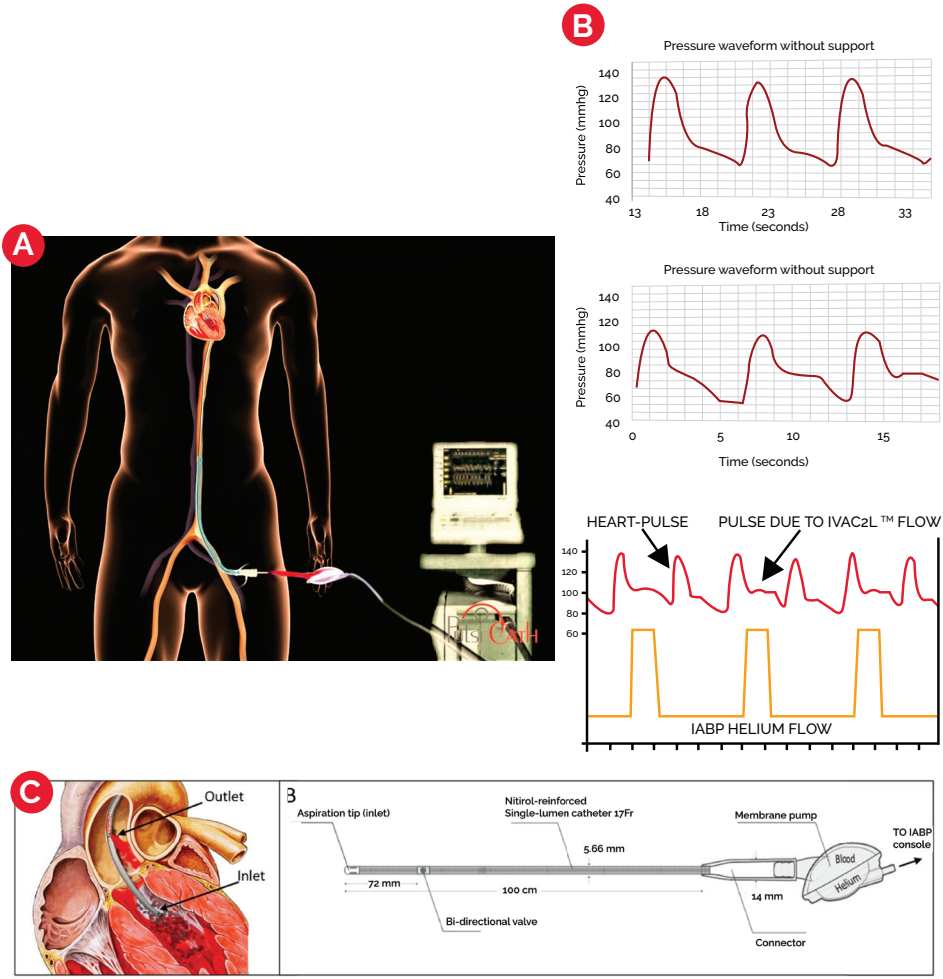
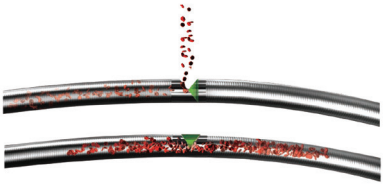


Figure 5. *(A) Implantation of iVAC 2L. The catheter is introduced through the common femoral artery and positioned with the tip inside the LV. The catheter is connected to a membrane pump which is in turn connected to a conventional IABP console. (B) Effect of iVAC 2L on the aortic pressure waveform showing diastolic augmentation and additional pulsatility in the diastolic descent. (C) Schematic view of iVAC 2L showing its main working components. Effective length of catheter as indicated by the arrows is 920 mm.*



General features:

- Trans-aortic insertion from the femoral artery.
- Designed for percutaneous use.
- Actively ejects left ventricular blood into the ascending aorta at rates up to 2.0 L/min (average: 1.5 L/min).
- Diastolic augmentation that elevates the mean arterial pressure through increases in the diastolic blood pressure, with potential benefits to the coronary flow.
- Driven by any conventional IABP consoles.

Advantages

- Pulsatile support, leading to more effective left ventricular unloading.
- Fast and easy implementation through the femoral artery.
- Fully percutaneous approach.
- Highly flexible catheter.
- Cost effectiveness: iVAC 2L has a universally adaptable design that fully integrates with a standard IABP console, but provides up to four times the support provided by the IABP.

Advantages of Pulsatile flow

Continuous flow reduces the motility of the aortic valve and has been related to worse end-organ perfusion. It may also increase the aortic impedance reducing its effectiveness in protecting the myocardium. In contrast, synchronized pulsatile flow preserves pulsatility and cyclic strain in the peripheral vasculature, potentially improving end-organ perfusion. iVAC 2L may also optimize coronary blood flow thus increasing oxygen delivery to the myocardium while sparing it by reducing the left ventricular afterload[3, 4].

References

1. O'Neill, William W et al. "A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study." Circulation vol. 126,14 (2012): 1717-27.
2. Ameloot, Koen et al. "New-generation mechanical circulatory support during high-risk PCI: a cross-sectional analysis." EuroIntervention : journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology vol. 15,5 (2019): 427-433.
3. Bastos, Marcelo B et al. "Effect of Next Generation Pulsatile Mechanical Circulatory Support on Cardiac Mechanics: The PULSE Trial." Cardiovascular revascularization medicine : including molecular interventions vol. 42 (2022): 133-142.
4. Bastos, Marcelo B et al. "PulseCath iVAC2L: next-generation pulsatile mechanical circulatory support." Future cardiology vol. 16,2 (2020): 103-112.
5. Chieffo, Alaide et al. "Joint EAPCI/ACVC expert consensus document on percutaneous ventricular assist devices." European heart journal. Acute cardiovascular care vol. 10,5 (2021): 570-583.
6. den Uil, Corstiaan A et al. "Pulsatile iVAC 2L circulatory support in high-risk percutaneous coronary intervention." EuroIntervention : journal of EuroPCR in collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology vol. 12,14 (2017): 1689-1696.
7. Tschöpe, Carsten et al. "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®." Frontiers in cardiovascular medicine vol. 7 563448. 25 Sep. 2020.
8. Dragula M, Urban L, Ságová I, Sadloňová J, Kňazeje M. High-risk PCI using Shockwave intravascular lithotripsy and iVAC2L support in a Covid-19 positive patient: a case report. Intervencni a Akutni Kardiologie [Internet]. 2022 [cited 2023 Mar 13];21(2):108–11.
9. Perera D, Stables R, Thomas M, Booth J, Pitt M, Blackman D, de Belder A, Redwood S; BCIS-1 Investigators. Elective intra-aortic balloon counterpulsation during high-risk percutaneous coronary intervention: a randomized controlled trial. JAMA. 2010 Aug 25;304(8):867-74.
10. Sanborn TA, Sleeper LA, Bates ER, Jacobs AK, Boland J, French JK, Dens J, Dzavik V, Palmeri ST, Webb JG, Goldberger M, Hochman JS. Impact of thrombolysis, intra-aortic balloon pump counterpulsation, and their combination in cardiogenic shock complicating acute myocardial infarction: a report from the SHOCK Trial Registry. SHould we emergently revascularize Occluded Coronaries for cardiogenic shocK? J Am Coll Cardiol. 2000 Sep;36(3 Suppl A):1123-9.
11. Delmas C, Porterie J, Jourdan G, Lezoualc'h F, Arnaud R, Brun S, Cavalerie H, Blanc G, Marcheix B, Lairez O, Verwaerde P, Mialet-Perez J. Effectiveness and Safety of a Prolonged Hemodynamic Support by the IVAC2L System in Healthy and Cardiogenic Shock Pigs. Front Cardiovasc Med. 2022 Feb 8;9:809143.

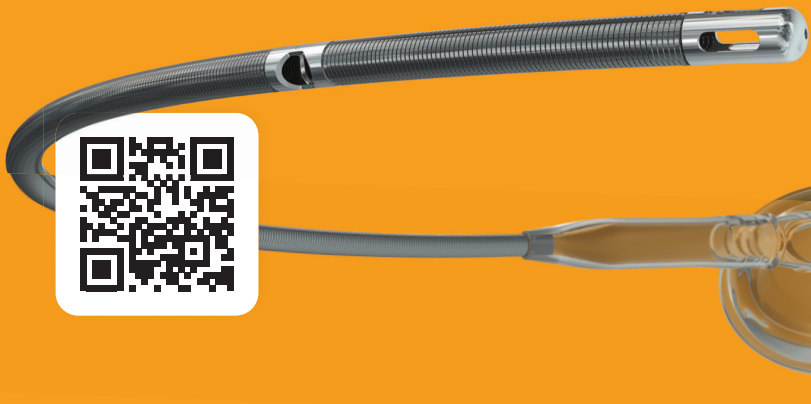
Ordering information

iVAC 2L®

Catalog number: LV17

Initial kit package contents:

- 1x LV17 catheter with insertion set
- 1x Membrane Pump
- 1x Catheter Protector
- 1x Extra PTFE Catheter Inner Tube
- Additional accessories kit: 18Fr introducer sheath, 16cm metal clamp, 50cc syringe



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