iVAC 2L® TECHNOLOGY FACT SHEET

PulseCath BV is a Netherlands based medical device company that develops, manufactures and markets mechanical circulatory support (MCS) systems. The company, formed in 2007, has developed unique and proprietary platform technology to provide a short-term circulatory support system for cardiologists and cardiac surgeons.

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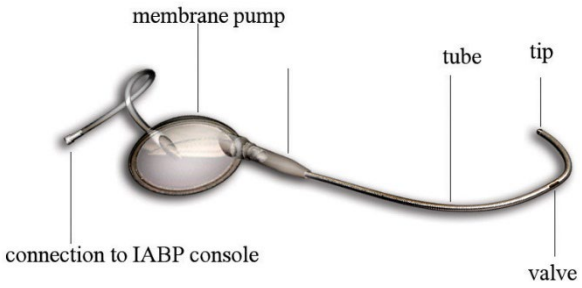
WHAT IS MECHANICAL CIRCULATORY SUPPORT?

Percutaneous MCS can be used to facilitate high risk percutaneous coronary interventions (PCI). MCS may assure hemodynamic stability and enhance coronary and end-organ perfusion. In parallel, it may also reduce myocardial oxygen consumption and left ventricular (LV) afterload. There has been a significant increase in the use of short-term percutaneous ventricular assist devices (pVADs) as acute circulatory support in cardiogenic shock and to provide haemodynamic support during interventional procedures, including high-risk PCI[1].

HOW DOES THE IVAC 2L TECHNOLOGY WORK?

The iVAC 2L system is a CE marked next generation pulsatile left ventricular assist device that consists of an extracorporeal pump driven by a standard IABP console. It is capable of delivering an output flow of up to 1.5L/min which is in synchrony with the native heart.

The iVAC 2L has three essential components: 1) the membrane pump, 2) a bi-directional flow catheter and 3) a patented rotational 2-way valve. The transparent extracorporeal membrane pump contains a blood chamber and an air chamber divided by a thin flexible membrane. The blood chamber is connected to a bi-directional flow catheter and the air chamber to a genuine Intra-Aortic Balloon Pump (IABP) console, which acts as pneumatic driver for the pump. The total chamber volume is 40cc, and the pump can expel 1.5L/min of blood/beat. The bi-directional flow catheter is composed of nitinol-wire-reinforced polyurethane, measures 100cm and has a 17Fr (5.9mm) outer diameter. The inlet tip is made of stainless steel.



The catheter has an **integrated two-way valve** at 6cm from the inlet. A connector piece at the other end of the catheter connects to the membrane pump. The bidirectional flow catheter is percutaneously inserted through the CFA and advanced across the aortic valve.

When the heart is in the systolic phase, blood is aspirated from the LV through the catheter tip into the membrane pump.

During the diastolic phase the IABP console inflates the gas chamber, compressing the blood chamber. As a result, blood is ejected back through the catheter, subsequently opening the two-way valve and delivering the blood to the ascending aorta. This leads to diastolic augmentation, generating an“extra beat of the heart”.

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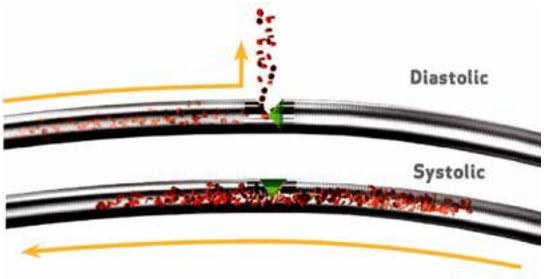
The iVAC 2L directly unloads the heart by active aspiration of left ventricular blood, which simultaneously creates a counter pulsating flow in the ascending aorta. This effect is also known as diastolic augmentation and may enhance blood flow to the coronaries. Moreover, the **pulsatile synchronization** between the closing of the aortic valve and the opening of the catheter valve favors the motility of the aortic valve by increasing the pressure gradient between the LV and the ascending aorta in diastole[2, 3].



WHAT IS THE POTENTIAL IMPACT OF THE IVAC 2L SYSTEM?

Recent technological developments in Interventional Cardiology have enabled PCI in patients with complex coronary artery disease. 30-days mortality can reach 28%[4, 5]. The iVAC 2L System aims to reduce the risk of hemodynamical deterioration and myocardial injury during manipulation of the coronary vessels. Furthermore, the streamlined insertion technique allows for prompt initiation of MCS in emergent cases.

WHAT IS THE LABELED INDICATION FOR THE IVAC 2L SYSTEM?

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

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

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