

iVAC2L

Percutaneous Ventricular Assist Device

PRODUCT SPECIFICATION



ORDERING INFORMATION

iVAC2L® - single pack

An initial kit package contains an LV17 catheter, an extra PTFE catheter inner tube, an extension tube and an 18 Fr Sheath Access System.

Code: LV17

iVAC2L - pVAD

Percutaneous Ventricular Assist Device

**NATURAL PULSATILE SUPPORT
FOR PROTECTED PCI**

PULSECATH

PulseCath BV
Nieuwe Stationsstraat 20,
6811 KS Arnhem,
The Netherlands

www.eukon.it

Numero Verde
800-134964

CE 2409

EUKON
Future Healthcare Now

PULSECATH

THE TRANSFEMORAL PULSATILE pVAD*

PRODUCT FEATURES:

- Transfemoral 17 Fr pVAD system
- Inserted through an 18 Fr sheath
- A 17 Fr single lumen, bi-directional flow catheter providing pulsatile support
- ECG- or AP-triggered counterpulsation
- Driven and compatible with standard IABP consoles

PRODUCT ADVANTAGES:

- Swift percutaneous approach, also in emergency situations ^(1, 2)
- Provides up to 2.0L/min additional diastolic flow
- Improves coronary artery and end-organ perfusion ^(1, 2)
- Non-significant hemolysis, fHb <10 µmol/L ^(1,2)
- No additional cost for a console; compatible with a standard IABP console
- Easy to operate, time-efficient

CLINICAL INDICATION:

The iVAC2L is intended for use in patients with impaired left ventricular function, which require left ventricular mechanical circulatory support for up to 24h. The iVAC2L is found to be effective in high-risk PCI procedures. ^(1, 2)

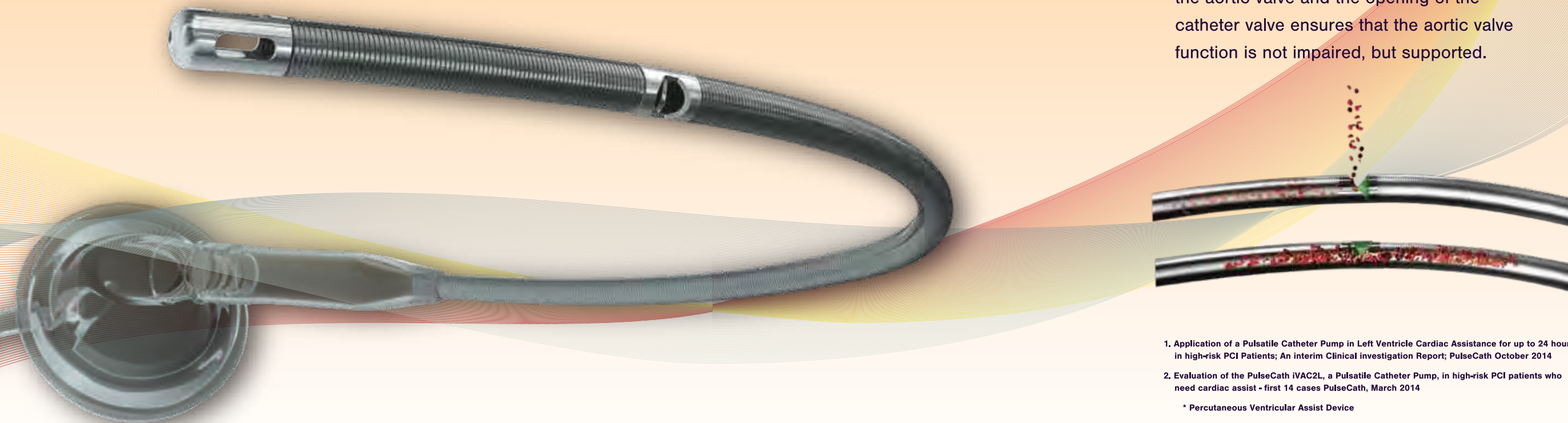
MECHANISM OF ACTION:

The operating mechanism of the iVAC2L is a patented 2-way valve integrated in a 17 Fr single lumen and bi-directional, 1000 mm long catheter. This catheter is connected to an extracorporeal 40cc 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.



1. Application of a Pulsatile Catheter Pump in Left Ventricle Cardiac Assistance for up to 24 hours in high-risk PCI Patients; An interim Clinical investigation Report; PulseCath October 2014

2. Evaluation of the PulseCath iVAC2L, a Pulsatile Catheter Pump, in high-risk PCI patients who need cardiac assist - first 14 cases PulseCath, March 2014

* Percutaneous Ventricular Assist Device