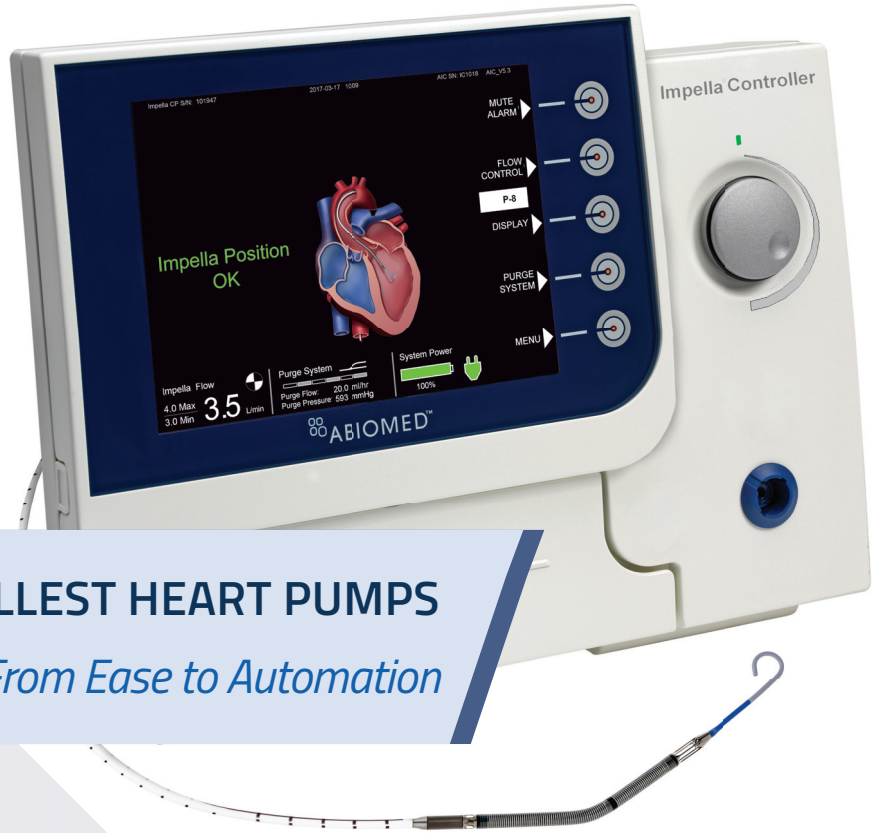


WORLD'S SMALLEST HEART PUMPS

From Ease to Automation

Impella®
Heart Pumps

ABIOMED®

Recovering hearts. Saving lives.

Make Impella® Technology Automatic

When it comes to heart muscle support every second counts.

The Impella Controller with flow control offers a new level of automation delivering personalized hemodynamic support.

One Touch Support

Unique flow control options simplify operation and patient management

- Autoflow technology provides optimal support
- Boost setting delivers maximum support

Automatic Start Up

- Automatically detects, primes, de-airs
- Automatically adjusts purge pressure

Transport Capable

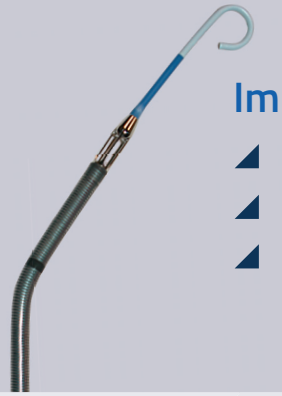
Durable cart provides easy and secure transport in the hospital

Impella® Heart Pumps

The world's smallest heart pumps deliver 2.5 to 5.0 liters of forward flow, available in a range of flow rate to provide hemodynamic support.

Impella 2.5® Heart Pump

- World's Smallest Heart Pump with up to 2.5 L/min of forward flow
- 9 Fr catheter, 12 Fr micro-axial pump
- Percutaneous insertion from femoral artery

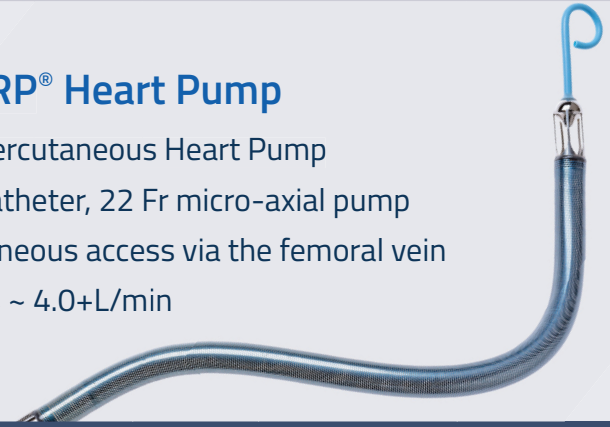


Impella CP® Heart Pump

- Up to 3.5 L/min of ventricular unloading
- 9 Fr catheter, 14 Fr micro-axial pump
- Percutaneous insertion from femoral artery

Impella 5.0® Heart Pump

- 9 Fr catheter, 21 Fr micro-axial pump
- Peripheral access from femoral artery or axillary artery
- Up to 5.0 L/min of forward flow



Impella RP® Heart Pump

- Right Percutaneous Heart Pump
- 11 Fr Catheter, 22 Fr micro-axial pump
- Percutaneous access via the femoral vein
- Delivers ~ 4.0+L/min

Clinical Guidelines for Impella® Heart Pumps

2014 ESC/EACTS Guidelines on myocardial revascularization. European Heart Journal.

Acute heart failure and cardiogenic shock: evidence class IIB

2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes. Circulation

- Revascularization in Heart Failure: Selection of a specific revascularization strategy should be based on the degree, severity, and extent of CAD; associated cardiac lesions; the extent of LV dysfunction; and the history of prior revascularization. Class I
- Large amount of ischemic territory/poor LV function, pvads can be used for support during the procedure.

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. JACC

- High risk patients: Class IIb
- PCI and Cardiogenic Shock: Class I
- CLASS III: HARM without Hemodynamic support: Primary or elective PCI without hemodynamic support capability for transfer, performed in hospitals without on-site cardiac surgery

Use of Mechanical Circulatory Support: American Heart Association. Circulation 2012

- Acutely decompensated heart failure patients: Class IIa

2013 International Society for Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support. The Journal of Heart and Lung Transplantation

- Temporary mechanical support for patients with multi-organ failure: Class I

2013 ACCF/AHA Guideline for the Management of Heart Failure, JACC

- "Bridge to Recovery" or "Bridge to Decision" for patients with acute, profound hemodynamic compromise: Class IIa

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction. Circulation

- STEMI and Cardiogenic Shock: Class IIb
- STEMI and urgent CABG: Class IIa

Product Information

REF	Description
0042-0000-EU	Automated Impella Controller
0042-0010-EU	Automated Impella Controller (optical)
0042-0020	Impella Controller Cart

Accessories

REF	Description
0042-0002	Impella Controller Connector Cable for Impella 2.5, Impella CP, Impella RP, Impella 5.0 and Impella LD
0043-0003	Impella Controller Purge Cassettes, Box of 5

Impella® Heart Pumps

REF	Description
005040	Impella 2.5 pump with 13 Fr introducer and sheath, 0.018" x 260 cm guidewire, 0.035" x 150 cm guidewire, Impella Controller connector cable, purge cassette, 10cc syringe and needle, ea.
005060	Impella 5.0 pump with Impella Controller connector cable, purge cassette, 0.018" guidewire, silicone plugs , Impella 5.0 Axillary Insertion Kit
005080	Impella LD pump with Impella Controller connector cable, purge cassette, incision template
0048-0002	Impella CP pump for use with Impella Controller, 14 Fr introducer and sheath, 0.018" x 260 cm guidewire, 0.035" x 150 cm guidewire, Impella Controller connector cable, purge cassette, ea.
0046-0011	Impella RP pump with 0.027" x 260 cm Impella RP guidewire, Impella Controller connector cable, purge cassette and 23 Fr introducer kit

DEVICE: Impella 2.5® Catheter, Impella CP® Catheter

IINDICATION FOR USE IN THE EUROPEAN UNION

The Impella (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 5 days for the following indications, aswell as others:

- The Impella is a circulatory support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction
- The Impella may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.
- Support during high risk percutaneous coronary intervention (PCI)
- Post PCI

CONTRAINDICATIONS IN THE EUROPEAN UNION

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematoolgical disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and / or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

DEVICE: Impella 5.0® & Impella LD® Catheter

INDICATION FOR USE IN THE EUROPEAN UNION

The Impella 5.0 (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 10 days for the following indications, as well as others:

- The Impella 5.0 is a cardiovascular support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction
- The Impella 5.0 may also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome.

CONTRAINDICATIONS IN THE EUROPEAN UNION

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- Hematological disorder causing fragility of the blood cells or hemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe anomaly of the ascending aorta and / or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) after myocardial infarction
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

DEVICE: Impella RP® Catheter

INDICATION FOR USE IN THE EUROPEAN UNION

The Impella RP System (percutaneous pump for right ventricular support) is intended for clinical use in cardiology, in cardiac surgery, and intensive care unit for up to 14 days for the following indications, as well as others:

- Acute or transient reduction of the right ventricular function (eg, postcardiotomy low output syndrome)
- Cardiogenic shock as a consequence of a posterior myocardial infarction with right ventricular heart failure
- Right heart support during coronary beating heart bypass surgery, especially for patients with a reduced preoperative cardiac output or for patients having a high risk of developing a postoperative low output syndrome for other reasons
- Right ventricular heart failure after implantation of a left ventricular assist device
- Therapy unresponsive arrhythmias with a reduction of right ventricular output
- Heart failure and/or cardiogenic shock as a consequence of refractory ventricular arrhythmias, as well as a consequence of sustained supraventricular arrhythmias, causing haemodynamic compromise.

CONTRAINDICATIONS IN THE EUROPEAN UNION

- Arteriosclerosis, in particular calcification or other disorders of the pulmonary artery wall
- Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid valve or pulmonary valve
- Mural thrombus of the right atrium or vena cava
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Presence of a vena caval filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter

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In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices. For more information please visit ***https://www.protectedpci.eu/en/therapy/product-variations/***

Learn more about hemodynamic support and the Impella system.

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