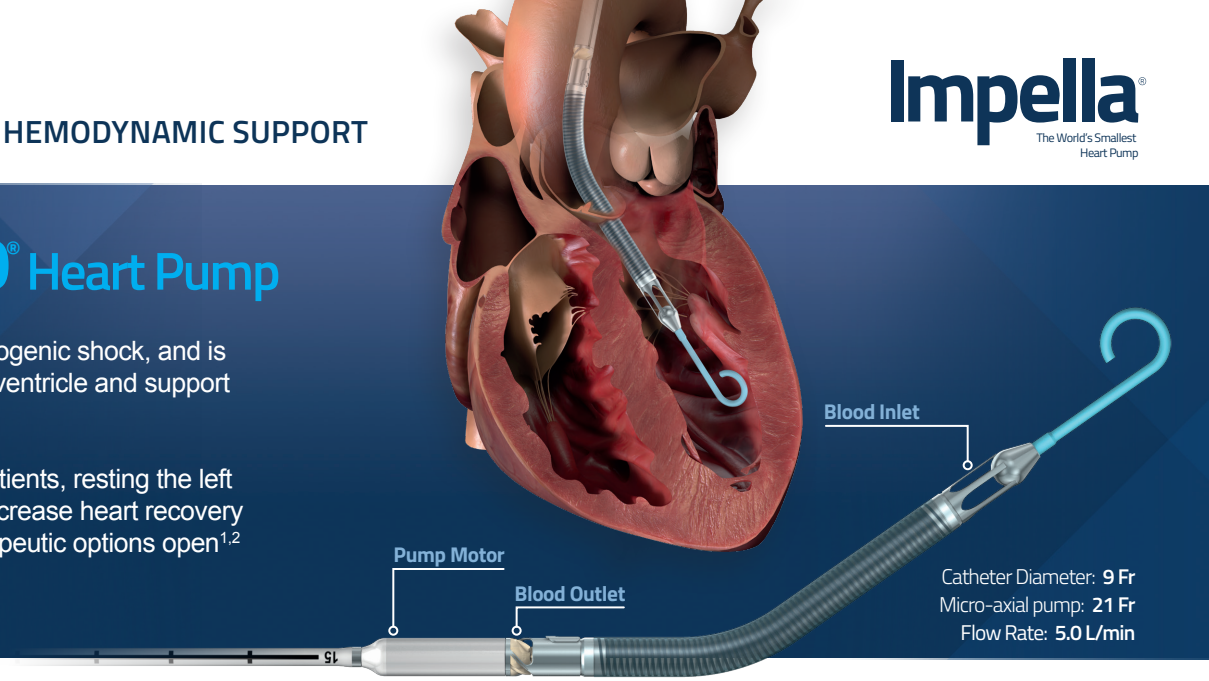
Stabilize. Unload. Recover.

MINIMALLY INVASIVE HEMODYNAMIC SUPPORT

Impella®
The World's Smallest Heart Pump

Impella 5.0® Heart Pump

- Approved for use in cardiogenic shock, and is proven to unload the left ventricle and support the systemic circulation[1]
- Immediately ambulate patients, resting the left ventricle has proven to increase heart recovery while keeping other therapeutic options open[1,2]



Micro-axial Blood Pump
Delivers forward flow from the left ventricle to the aorta

Single Access Point
Minimally invasive placement through a single artery and into the left ventricle

Direct Ventricular Unloading
Actively unloads up to 5.0 L/min from the left ventricle

Who is the Intended User?

- Impella 5.0 is for surgeons who need full left ventricular unloading and full systemic flow.

Who is the Patient?

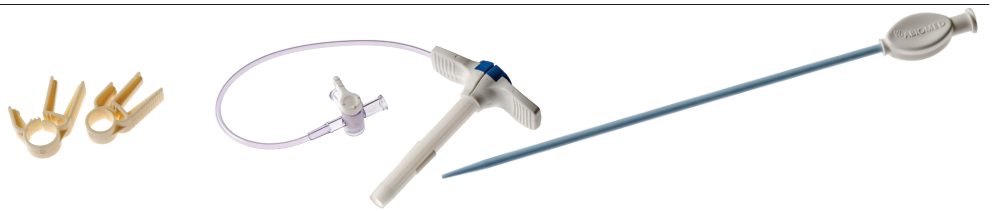
- Postcardiotomy
- AMI Cardiogenic Shock
- MCS Escalation
- Acute Decompensated Heart Failure
- Cardiomyopathy
- Postpartum
- Myocarditis

Product Overview

- Inserted through the axillary or femoral artery
- Integrated microaxial impeller pulls blood from the ventricle into the aorta
- Uses a differential pressure sensor
  - An electronic sensor that measures the pressure difference between the inside and outside of the cannula
  - Flexible membrane integrated into the cannula
  - Generates the placement signal used to monitor position and calculate flow
- Over 10 years experience and 5,000 patient use
- Currently the only acute MCS therapy with full PMA approval

Surgical Accessories

- 2 Graft locks
- 23 Fr x 6 cm Peel-away introducer with hemostatic valve
- 8 Fr Silicone-coated dilator



PRODUCT & ACCESSORIES	PART NUMBERS	DESCRIPTION
Impella 5.0®	005062	Impella 5.0 pump with Impella Controller connector cable, 0.018" guidewire, purge cassette, silicone plugs, axillary kit.
Impella LD®	005080	Impella LD pump with Impella Controller connector cable, purge cassette, incision template.
Axillary Kit	0052-0011	Axillary Kit for Impella 5.0
Purge Cassettes	0043-0003	Impella Purge Cassettes, Box of 5

Clinical support 24 hours per day, 7 days a week
+49 (0) 1805 2246633 (EU)

ABIOMED®

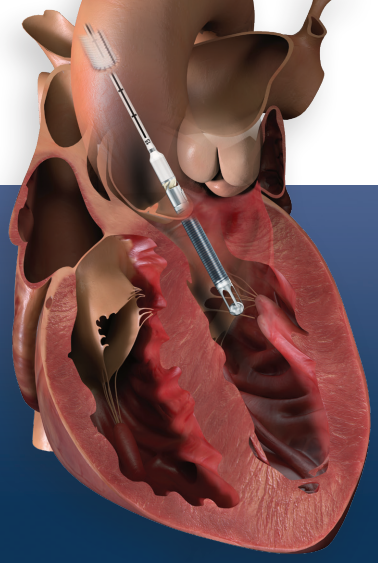
Stabilize. Unload. Recover.

LEFT DIRECT VENTRICULAR UNLOADING

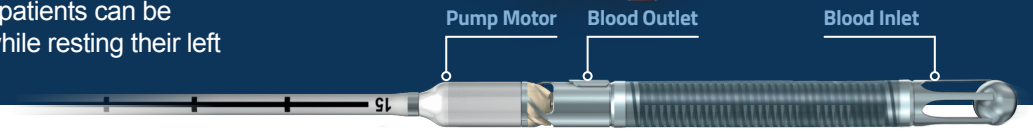
Impella®
The World's Smallest Heart Pump

Impella LD® Heart Pump

- A left ventricular microaxial blood pump that delivers up to 5.0 L/min of forward flow from the LV to the aorta
- The Impella LD can be an open-chested, direct support option with 5.0 liters of flow, when PCCS is unanticipated and fluoroscopy is not available
- After the closing of the sternum, patients can be ambulated with the Impella LD while resting their left ventricle[1]



Catheter Diameter: **9 Fr**
Micro-axial pump: **21 Fr**
Flow Rate: **5,0 L/min**



Micro-axial Blood Pump
Delivers forward flow from the left ventricle to the aorta

Single Access Point
Single aortotomy access

Easy to Use
No fluoro needed or wires, TEE guidance

Who is the Intended User?

- Impella LD is for surgeons who need full left ventricular unloading and full systemic flow.

Who is the Patient?

- Postcardiotomy
- Difficult or failure to wean from bypass
- Ideal for unplanned post-op support

Product Overview

- Simple, direct aortic surgical placement
  - Single vascular insertion point via ascending aorta
  - No septal puncture
  - No priming / no blood outside the body
  - Multipe large bore cannulas NOT required
  - No repositioning sheath
- Straight Cannula
- No Pigtail
- Silicone plugs
- No fluoro or wires

References::
1. Griffith, B et al. The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support. J of TCS 2013; 145(2):548-554
2. Perme, C et al. Early Mobilization of LVAD Recipients. Texas Heart Institute Journal 2006; 33:130-133

INDICATIONS FOR USE
Impella 5.0®, Impella LD®: The Impella (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 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 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.

Important Risk Information for Impella devices

CONTRAINDICATIONS
- 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
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

POSSIBLE COMPLICATIONS
There are risks of complications with every procedure using blood pump. These include among others:
- MechHemolysis
- Bleeding
- Immune reaction
- Embolism, thrombosis
- Vascular injury through to angionecrotomy
- Positioning problems
- Infection and septicemia
- Dislocation of the pump
- Cardiovalvular injuries due to extreme movement of the suction cannula in relation to the cardiac valve or as a result of attachment by suction of the pump to the valve system following incorrect positioning
- Endocardiac injuries as a result of attachment of the pump due to suction
- Pump failure, loss of pump components following a defect
- Patient dependency on the pump after use for support

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.
For more information please see the Instructions for Use Manual.

ABIOMED®

ABIOMED, Inc.
22 Cherry Hill Drive, Danvers, MA 01923 USA
Tel.: +1-978- 646-1400
Fax: +1-978- 777-8411
E-Mail: marketing@abiomed.com

Clinical Support Center
24 hours per day, 7 days a week:
+49 (0)1805 2246633 (EU)
+1- 800- 422- 8666 (USA)

Abiomed Europe GmbH
Neuenhofer Weg 3
52074 Aachen, Deutschland
Tel.: +49 (0) 241 8860-0
Fax: +49 (0) 241 8860-111
E-Mail: europe@abiomed.com

www.abiomed.com

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