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

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

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

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

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<th>PRODUCT &amp; ACCESSORIES</th>
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<tr>
<td>Impella 5.0*</td>
<td>005062</td>
<td>Impella 5.0 pump with Impella Controller connector cable, 0.025” guidewire, purge cassette, silicone plugs, axillary kit.</td>
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<tr>
<td>Impella LD*</td>
<td>005082</td>
<td>Impella LD pump with Impella Controller connector cable, purge cassette, incision template.</td>
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<td>Axillary Kit</td>
<td>0052-0011</td>
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<td>Purge Cassettes</td>
<td>0043-0003</td>
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Clinical support 24 hours per day, 7 days a week
1-800-422-8666 (US)
Simple, direct aortic surgical placement
- Single vascular insertion point via ascending aorta
- No septal puncture
- No priming / no blood outside the body
- Multiple large bore cannulas NOT required
- No repositioning sheath

After the closing of the sternum, patients can be ambulated with the Impella LD while resting their left ventricle

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

INDICATIONS FOR USE
Cardiogenic Shock
The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, and Impella LD® Catheters, in conjunction with the Automated Impella Controller (collectively, “Impella® System Therapy”), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5 and Impella CP, and ≤ 6 days for the Impella 5.0, and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

Important Risk Information for Impella devices
CONTRAINDICATIONS
The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0 and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm² or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*, Combined cardiopulmonary failure*, Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*, Left ventricular rupture*, Cardiac tamponade*.

* This condition is a contraindication for the cardiogenic shock indication only.

POTENTIAL ADVERSE EVENTS
Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices. Learn more visit: www.abiomed.com/important-safety-information