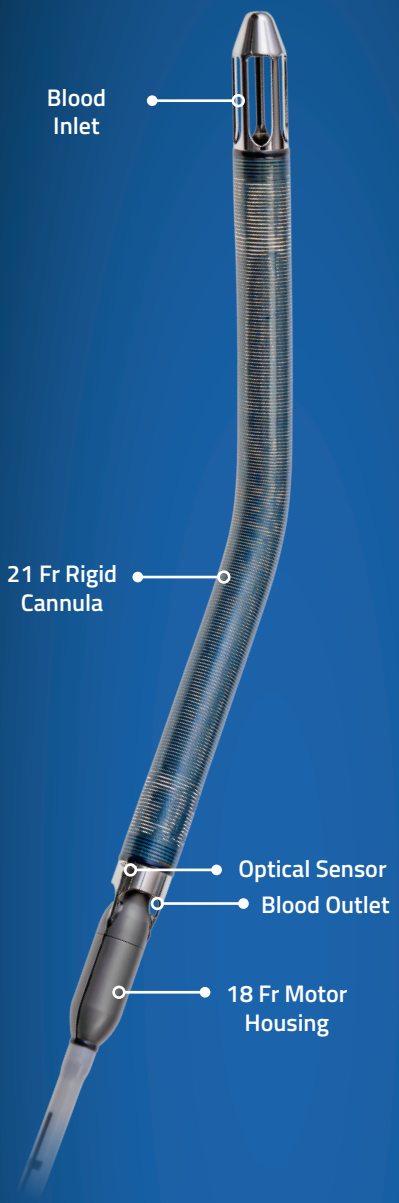
Data Sheet

Impella 5.5® with SmartAssist®

A minimally invasive heart pump delivering peak flows up to 5.5 L/min of forward flow, enabling heart recovery.

- The Impella 5.5 with SmartAssist can be inserted into the left ventricle through the axillary artery across the valve
- Directly unloads the left ventricle reducing ventricular work for up to 30 days for indications including support during cardiogenic shock
- Provides peak flow of up to 5.5 L/min for systemic perfusion
- Supports coronary perfusion
- Enables repositioning in the ICU without imaging*
- 70 cm catheter length ease patient mobilisation

** For ventricularized pumps only*



Specifications

Cannula:
Polyurethane coated nitinol with a 145-degree angle. Rigid cannula improves deliverability

Motor Housing:
A decrease in motor housing size allows for ease of vascular navigation around the innominate artery

Catheter Shaft:
Polyurethane catheter with reinforced steel coil and triple internal lumens for pressure, purge and electrical signal

Position Sensor:
Optical pressure sensor located immediately distal to the outlet, provides a pressure reading indicating aortic pressure only when both the outlet and sensor are located within the aorta

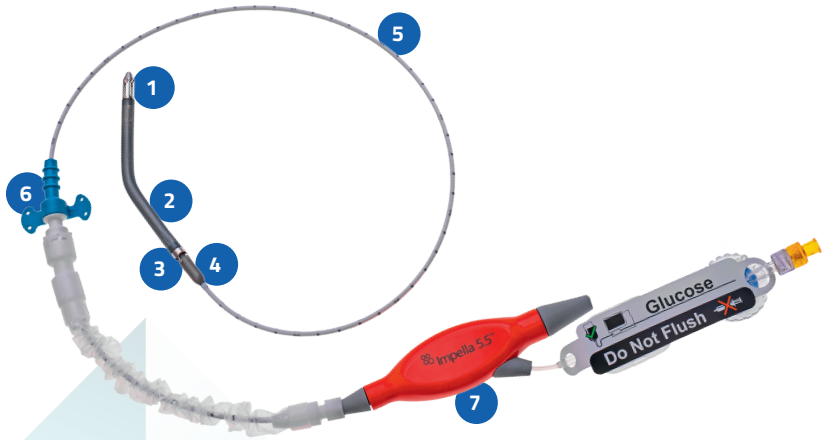
Blue Suture Hub
Graduated shaft from 9 Fr to 13 Fr with StatLock® compatible suture pads and anti-contamination sleeve

Red Impella Plug:
Connections - 1 luer connection for purge fluid, 1 electrical connection direct to Automated Impella Controller

Electronics - electronic memory for retention of operating parameters

Overview

1. Inlet
2. Cannula
3. Outlet
4. Motor Housing
5. Catheter Shaft
6. Blue Suture Hub
7. Red Impella Plug



Maximum Flow: 5.5 L/min

Maximum Mean: 5.2 L/min

Speed Range: 0 to 33,000 rpm

Diameter: 9 Fr Catheter, 18 Fr pump, 21 Fr cannula

For additional information about flow rates see the Instructions For Use manual.

ABIOMED®
Recovering hearts. Saving lives.

Impella 5.5® with SmartAssist®

Accessories

Impella 5.5 Kit

Part number: 0550-0002

- Impella Catheter (0550-0007)
- Purge Cassette (0043-0001)
- Axillary Insertion Kit (0052-3009)
- 0.018" x 260cm placement guidewire (0052-3005)

Automated Impella® Controller

Part number: 0042-0010-EU

The controller provides an interface for monitoring and controlling the function of all Impella catheters.

- 10.4" color display for easy viewing
- Mounts to Controller Cart (not shown) for transport within hospital
- 60 minutes of battery back-up power for mobile transport

Axillary Insertion kit

Part number: 0052-3009

Vascular access kit used for axillary insertion of the Impella catheter.

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

0.018"x 260cm Placement Guidewire

Part number: 0052-3005

Guidewire with a radiopaque, shapable tip used for placement of Impella catheter into left ventricle.

Purge Cassette

Single Package: 0043-0002

5 Package: 0043-0003

The purge cassette delivers rinsing fluid to the Impella catheter. The purge fluid flows from the purge cassette through the catheter to the microaxial blood pump to prevent blood from entering the motor.

INTENDED USE (EU)

INTENDED USE IN THE EUROPEAN UNION

The Impella 5.5 with SmartAssist heart pump is an intracardiac pump for supporting the left ventricle. It is intended for clinical use in cardiology and in cardiac surgery for up to 30 days for the following indications, as well as others:

- The Impella 5.5 with SmartAssist heart pump 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 5.5 with SmartAssist heart pump 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 (EU)

CONTRAINDICATIONS IN THE EUROPEAN UNION

The Impella 5.5 with SmartAssist heart pump is contraindicated for the following situations:

- Mechanical aortic valves, severe aortic valvular stenosis
- 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

POTENTIAL ADVERSE EVENTS

Hemolysis, Bleeding, Immune reaction, Embolism, Thrombosis, Vascular injury, Positioning problems Infection and septicemia, Dislocation of the pump, Cardiovalvular injuries, Endocardiac injuries, Pump failure, Loss of pump components, 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. Please visit **impella.eu**.

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IMP-998 EU-EN (v1.0)

CE 0482

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

EC REP
Abiomed Europe GmbH
Neuenhofer Weg 3 | 52074 Aachen, Germany
Phone: **+49 (0) 241 8860-0**
Fax: +49 (0) 241 8860-111
europe@abiomed.com

Abiomed, Inc.
22 Cherry Hill Drive, Danvers, MA 01923 USA
Phone: **+1 978-646-1400**
Fax: +1 978-777-8411
marketing@abiomed.com

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