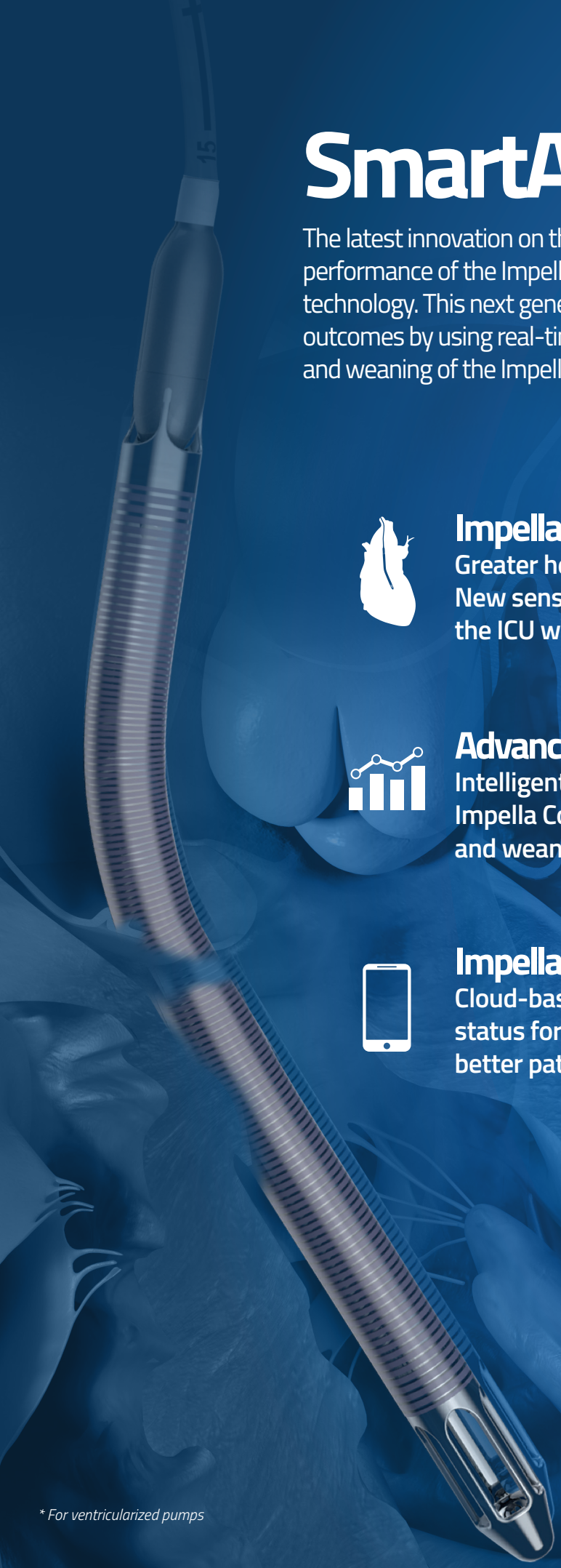
Impella 5.5® with SmartAssist®

Minimally Invasive Heart Pump
Delivering Full Forward Flow

ABIOMED®
Recovering hearts. Saving lives.

SmartAssist® Platform

The latest innovation on the Impella platform integrates the trusted performance of the Impella heart pump with state-of-the-art SmartAssist technology. This next generation heart pump is designed to improve patient outcomes by using real-time intelligence to optimize positioning, managing and weaning of the Impella device for better patient care.



Impella® Heart Pump

Greater hemodynamic support and ease of use. New sensor technology allows for repositioning in the ICU without the need for imaging.*

Advanced Pump Metrics

Intelligent pump metrics on the Automated Impella Controller assist in positioning, managing and weaning the Impella device.

Impella Connect® *READY*

Cloud-based, remote view of the Impella device status for collaborative patient management and better patient outcomes.

** For ventricularized pumps*

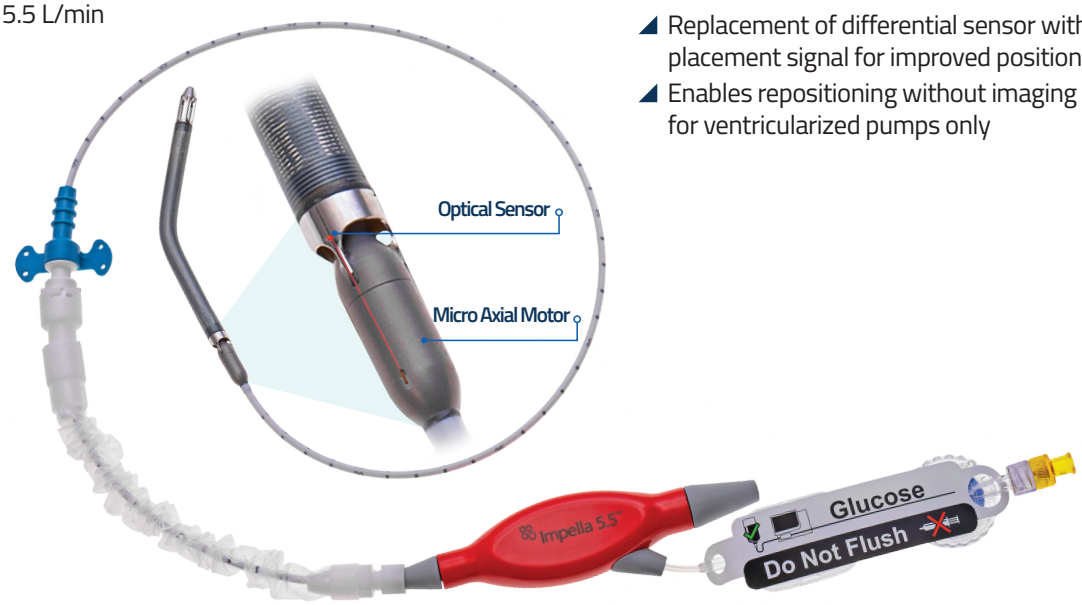
Impella 5.5 with SmartAssist

New Features to Improve Hemodynamic Support

Full Hemodynamic Support

Forward flow provides coronary and end organ perfusion

- Peak flows up to 5.5 L/min



Confident Positioning

New sensors to intelligently position, manage, and wean

- Replacement of differential sensor with aortic placement signal for improved position detection
- Enables repositioning without imaging in the ICU for ventricularized pumps only

Designed for Heart Surgeons

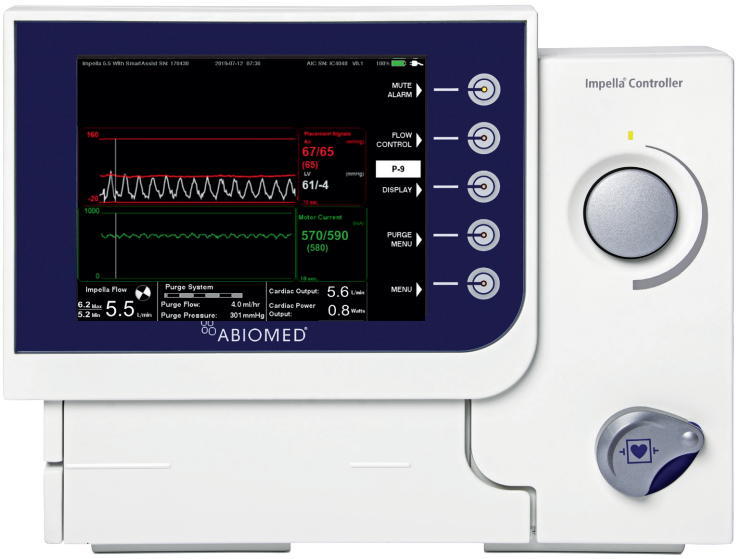
Insert via axillary artery using familiar surgical skills

- Directly unloads the left ventricle reducing ventricular work for up to 30 days for indications including support during cardiogenic shock
- Enhanced deliverability and torque response

Simplified Set-up

Improved ease of use and faster set-up time

- Reduction in set-up steps with fewer connections
- Single fluid line management in ICU



Advanced Pump Metrics

Designed to optimize pump management and assist in weaning

- Left ventricular placement signal
- Less invasive heart pump with the ability to display Cardiac Power Output
- Designed to provide weaning algorithms to optimize survival and native heart recovery
- Clear, concise alarms for improved troubleshooting

Cardiac Power Output: #1 Correlation to Mortality in AMI Cardiogenic Shock[1]

- CPO (in watts) = (MAP x Cardiac Output) / 451

1.Fincke, et. al. JACC, 2004 SHOCK TRIAL

Impella 5.5 Heart Pump Specifications

PART NUMBER	DESCRIPTION
0550-0002	Impella 5.5 with SmartAssist Kit
0043-0003	Impella Controller Purge Cassettes, Box of 5
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, and 8 Fr silicone-coated dilator
0052-3005	0.018" x 260 cm PTFE guidewire with a radiopaque, shapable tip used for placement of Impella catheter into left ventricle

Maximum Flow: 5.5 L/min | **Maximum Mean: 5.2 L/min** | **Spead Range: 0 to 33,000 rpm**

Learn more. Visit www.impella.eu/smartassist

INTENDED USE (EU)

The Impella 5.5® 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® 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® 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)

The Impella 5.5® 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.*

IMP-1074 EU-EN (v1.0)

Impella® CLINICAL SUPPORT CENTER 24/7

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