

The next generation  
**Impella 5.5<sup>®</sup>**  
with SmartAssist<sup>®</sup>

*Minimally Invasive Heart Pump Providing  
Full Support with Maximum Unloading*



# SmartAssist<sup>®</sup> 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 5.5<sup>®</sup> with SmartAssist<sup>®</sup> 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<sup>®</sup> System

Cloud-based mobile view of the Impella device status for remote patient monitoring and collaborative patient management to optimize patient outcomes.

\* For ventricularized pumps

# Impella 5.5<sup>®</sup> with SmartAssist<sup>®</sup>

## New Features to Improve Hemodynamic Support

### Full Support with Maximum Unloading

Reduces the heart's oxygen demand and workload

- ▲ Forward flow provides coronary and end organ perfusion
- ▲ Provides flows up to 5.5 L/min

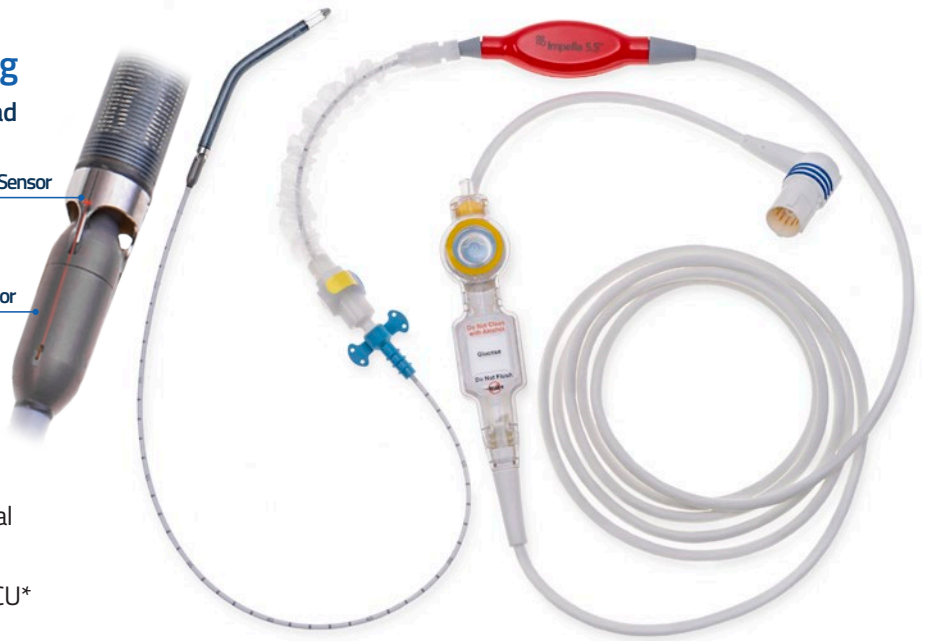
Optical Sensor

Microaxial Motor

### Confident Positioning

New hemodynamic sensors to intelligently position, manage, and wean

- ▲ New always-locked catheter
- ▲ Optical sensor providing aortic placement signal for improved position detection
- ▲ Enables repositioning without imaging in the ICU\*



### Even More Simplified Set-up

Improved ease of use and faster set-up time

- ▲ New integrated purge filter unit improves patient management and mobility
- ▲ New user-friendly three-point fixation
- ▲ New integrated tubing for optimal purge line setup and management
- ▲ Streamlined single fluid line management in ICU

### Ease of Insertion

Insert via axillary artery or anterior aorta using familiar surgical skills

- ▲ Directly unloads the left ventricle reducing ventricular work for up to 29 days for indications including support during cardiogenic shock
- ▲ Enhanced deliverability and torque response
- ▲ New sodium hydrogencarbonate compatible luer for heparin-free purge alternative

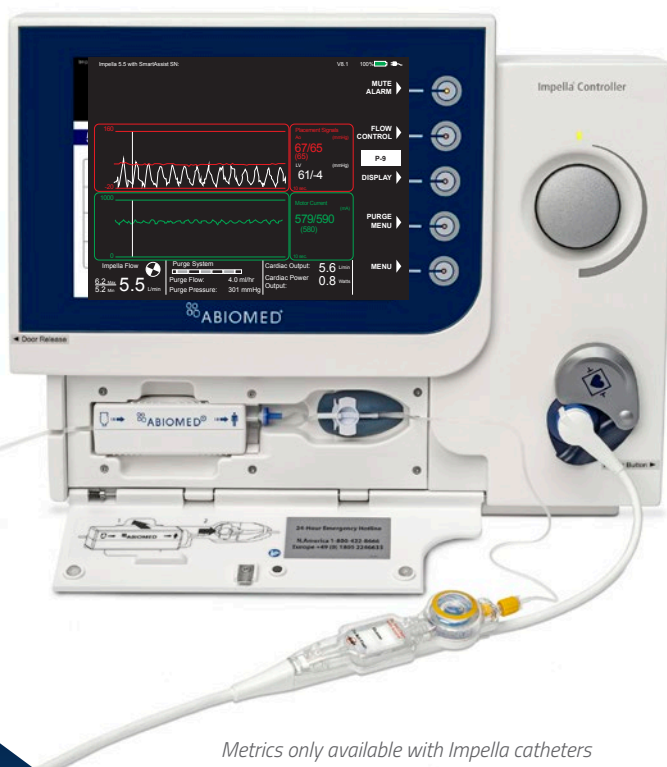
### Advanced Pump Metrics

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<sup>1</sup>
- ▲ Designed to optimize survival and native heart recovery
- ▲ Clear, concise alarms for improved troubleshooting

Cardiac Power Output: #1 Correlation to Mortality in AMI Cardiogenic Shock<sup>2</sup>

- ▲  $CPO \text{ (in watts)} = (MAP \times \text{Cardiac Output}) / 451$



Metrics only available with Impella catheters with SmartAssist Technology.

1. These trends are informational, do not use for diagnostic purposes. Refer to section 9 of IFU for information on accuracies.

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

# Impella 5.5<sup>®</sup> with SmartAssist<sup>®</sup> Heart Pump Specifications

PART NUMBER	DESCRIPTION
1000482	Impella 5.5 with SmartAssist Kit <ul style="list-style-type: none"><li>▪ Impella Catheter</li><li>▪ Purge Cassette</li><li>▪ Introducer and Graft Locks</li><li>▪ 0.018" x 260cm placement guidewire</li></ul>
1000200	Impella Controller Purge Cassette, 5 Package
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 Flow:** 5.2 L/min

**Speed Range:** 0 to 33,000 rpm

**Learn more. Visit** [www.heartrecovery.eu](http://www.heartrecovery.eu)

## INTENDED USE (EU)

The Impella 5.5<sup>®</sup> 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 29 days for the following indications, as well as others:

- The Impella 5.5<sup>®</sup> with SmartAssist is a cardiovascular support system for patients with acutely reduced left ventricular function, e.g., low output syndrome, cardiogenic shock after acute myocardial infarction.
- The Impella 5.5 with SmartAssist heart pump is also a temporary support system for patients in need of circulatory support due to chronically reduced left ventricular function, e.g. for bridging patients with chronic heart failure to implantable assist device, heart transplantation, or myocardial recovery / stabilization.
- The Impella 5.5 with SmartAssist heart pump may also be used as a cardiovascular support system during cardiological interventions or heart surgery (e.g. coronary bypass surgery), particularly in patients with limited preoperative ejection fraction with a high risk of postoperative low output syndrome, or in cases of difficulties to wean from heart-lung machine support.

## CONTRAINDICATIONS (EU)

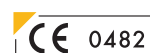
The Impella 5.5<sup>®</sup> with SmartAssist heart pump is contraindicated for the following situations:

- 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, causing hemolysis or reduced haemodynamic support 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 [heartrecovery.eu](http://heartrecovery.eu)



**Clinical Support 24 hours per day, 7 days a week:**  
**+800 022 466 33 (EU & APAC)**

