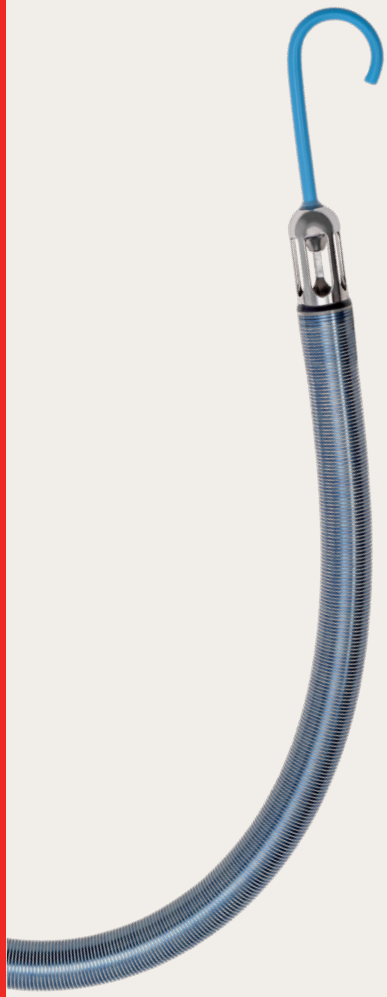
Impella RP Flex™ with SmartAssist®

The standard of care for right heart failure

FDA approved for acute right ventricular failure



Johnson&Johnson MedTech

Heart Recovery

Impella RP Flex with SmartAssist

Unload the right ventricle with continuous hemodynamic support.

- First dual sensor, IJ or femoral access, percutaneous heart pump approved by the FDA as safe and effective for right heart failure
- Internal jugular vein insertion allows for increased patient mobility
- Integral part of Abiomed's comprehensive heart recovery product portfolio, that provides immediate hemodynamic benefit for patients with ventricular dysfunction
- Pumps blood from the SVC or IVC and right atrium directly to the pulmonary artery
- May enable right ventricular recovery in patients

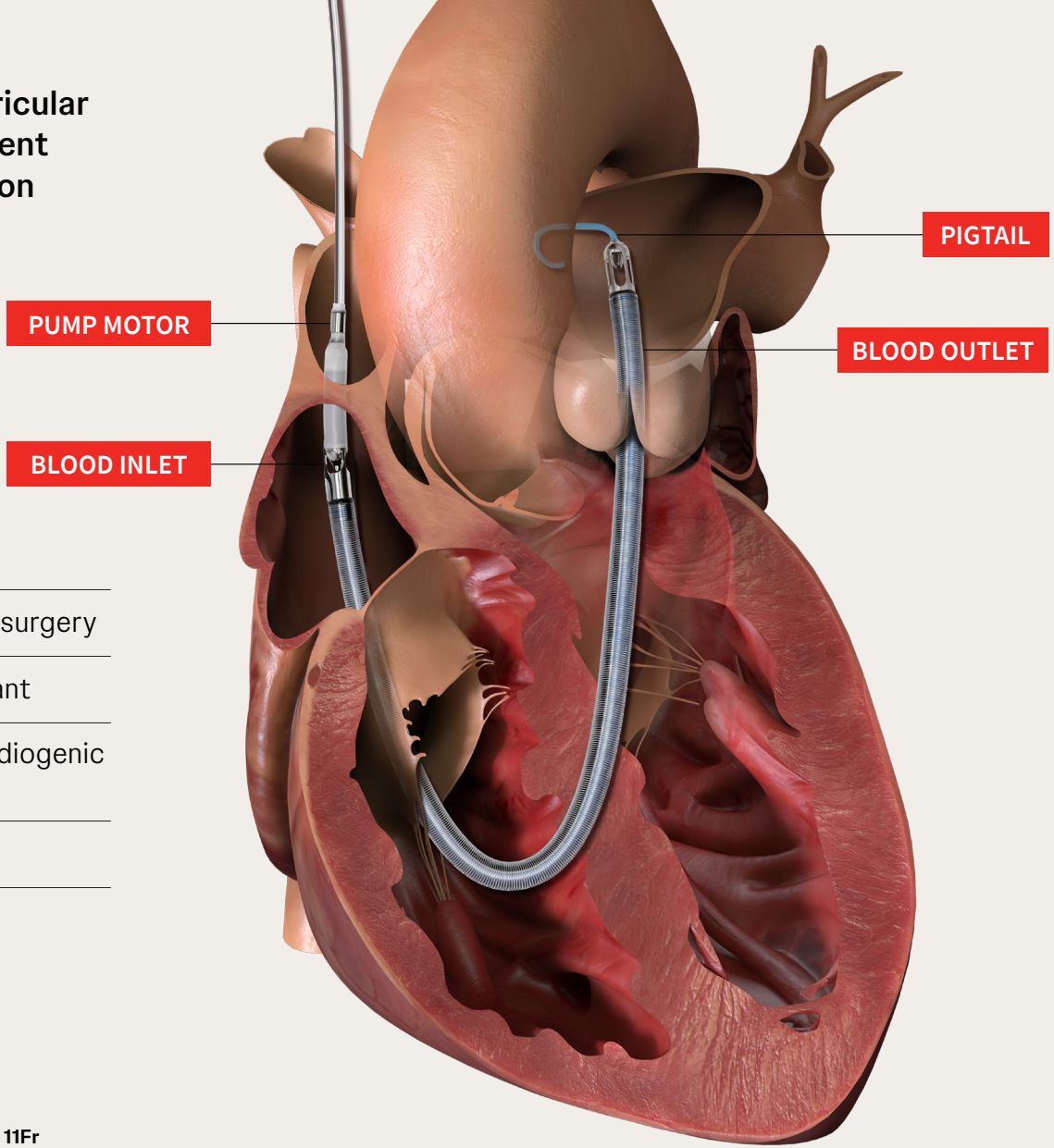
Safe and effective for right heart failure

- Provides right ventricular unloading with 4.0+ L/min of peak flow for immediate improvement in hemodynamic performance*
- Indicated for use for up to 14 days in patients with a body surface area of ≥1.5 m2
- Enables biventricular support**

*As demonstrated in the RECOVER RIGHT clinical trial

**When used in conjunction with a durable LVAD system or if Impella has already been placed for left heart support

Right ventricular failure patient identification



- Post-cardiac surgery
- Post-Transplant
- Post-AMI cardiogenic shock
- Post-LVAD

Catheter Diameter: **11Fr**
Flow Rate: **4.0+L/min**

Easy to deliver

- Percutaneous, single venous access gained through familiar internal jugular or femoral techniques
- Anatomically optimized, low-profile catheter for easy placement and flexible positioning in right heart anatomy
- Quick set-up and lack of circuit prep enables rapid initiation of hemodynamic support
- EasyGuide Lumen for quicker insertion of the guidewire
- 23 Fr introducer sheath and small indwelling catheter size of 11Fr

Automated Impella Controller™

Built on the proven Impella® platform

- More than 350,000 patients treated with the Impella device
- Low complication rate^
- Low anticoagulation profile^^
- Utilizes same console as left-sided Impella devices

Patient care features

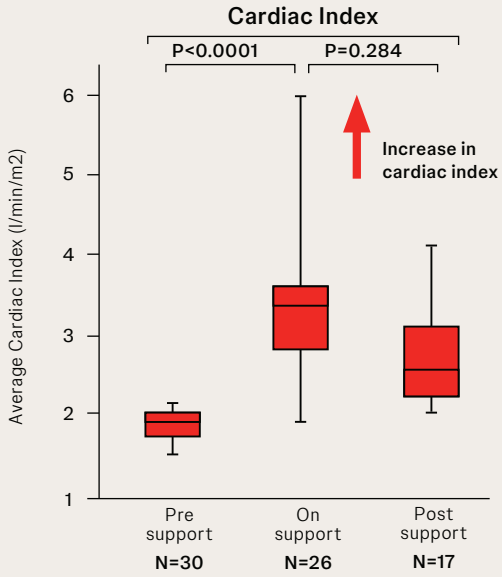
- Essential real-time insights and trends of Pulmonary Artery Placement Signal and Pulmonary Artery Pressure Index (PAPi)
- Dual sensors for placement and flow monitoring
- New sodium bicarbonate compatible luer for heparin-free purge alternative

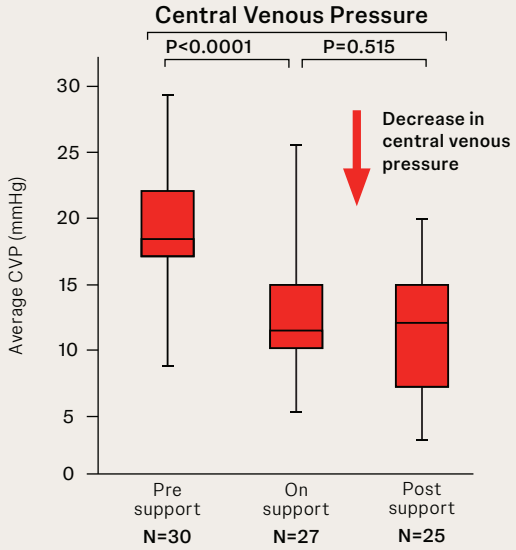
37%

Incidence of right ventricular failure in cardiogenic shock[2]

Many patients experience right heart failure when in cardiogenic shock. Impella RP Flex with SmartAssist can support patients and may enable recovery

^RECOVER RIGHT / Impella RP with SmartAssist Prospective PAS ^^As compared to LVAD and ECMO procedures





Impella RP Flex heart pump specifications

PMA APPROVED INDICATION

The Impella RP® System, Impella RP® with SmartAssist® and Impella RP Flex™ with SmartAssist® are indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation for less than 48 hours following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery, without the presence of profound shock, end organ failure, or acute neurologic injury.

Important Risk Information for Impella RP System, Impella RP with SmartAssist and Impella RP Flex with SmartAssist

CONTRAINDICATIONS

The Impella RP System, Impella RP with SmartAssist and Impella RP Flex with SmartAssist are contraindicated for patients with the following conditions: Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP devices. Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve. Mural thrombus of the right atrium or vena cava. Anatomic conditions precluding insertion of the pump. Presence of a vena cava filter or caval interruption device, unless there is clear access from the internal jugular or femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

POTENTIAL ADVERSE EVENTS

The potential adverse effects (eg, complications) associated with the use of the Impella RP System, Impella RP with SmartAssist and Impella RP Flex with SmartAssist: Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device malfunction, Hemolysis, Hepatic failure, Insertion site infection, Perforation, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Cardiac or vascular injury (including ventricular perforation), Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella RP, Impella RP with SmartAssist and Impella RP Flex with SmartAssist.

Visit **www.abiomed.com/important-safety-information** to learn more.

See how the Impella device provides hemodynamic support for your highest-risk patients. To learn more visit **www.abiomed.com**

PART NUMBER	DESCRIPTION
1000323	Impella RP Flex with SmartAssist Heart Pump Kit, U.S.
1000185 (Single Package) 1000200 (5 Package)	Purge Cassette delivers rinsing fluid to the Impella catheter.
2000342	Introducer Kit used for percutaneous insertion of the Impella catheter.
0052-3018	0.027", 260cm Placement Guidewire with a radiopaque, shapeable tip used for placement of Impella catheter into pulmonary artery via the femoral vein or internal jugular.

References

1. Anderson, M. et al. (2015). Benefits of a novel percutaneous ventricular assist device for right heart failure: The prospective RECOVER RIGHT study of the Impella RP device. J Heart Lung Transplant, 34(12), 1549-1560

2. Lala, A. et al. (2018). Right Ventricular Dysfunction in Acute Myocardial Infarction Complicated by Cardiogenic Shock: A Hemodynamic Analysis of the Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial and Registry. J Card Fail, 24(3), 148-156

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