

Impella® 5.0 and LD

Part Number	Description
005060	Impella® 5.0 pump with Impella® Controller connector cable, purge cassette, 0.025" guide-wire, silicone plugs
005080	Impella® LD pump with Impella® Controller connector cable, purge cassette, incision template

Accessories

0042-0002	Impella® Controller Connector Cable for Impella® 2.5, Impella CP®, Impella® 5.0 and Impella® LD
0043-0003	Impella® Controller Purge Cassettes, Box of 5

Technical Specifications

Impella® 5.0	
Flow Rate	0 – 5.0 L/min
Speed	0 – 33,000 rpm
Voltage	18V DC maximum
Power Consumption	< 1.07 W
Rinsing (purge) Solution	5 – 40% glucose + 50 IU heparin/mL unless contraindicated
Purge Rate	2 – 30 mL/hr
Purge Pressure	300 – 1100 mmHg
Catheter Length (Invasive)	121 cm +/- 4 cm
Diameter	Maximum: 7.2 mm (nominal 6.4 mm)
Storage Temperature	10 – 25° C (50 – 77° F)
Storage Humidity	75% relative

Impella® LD	
Flow Rate	0 – 5.0 L/min
Speed	0 – 33,000 rpm
Voltage	18V DC maximum
Power Consumption	< 1.07 W
Rinsing (purge) Solution	5 – 40% glucose + 50 IU heparin/mL unless contraindicated
Purge Rate	2 – 30 mL/hr
Purge Pressure	300 – 1100 mmHg
Catheter Length (Invasive)	129 cm +/- 4 cm
Diameter	Maximum: 7.2 mm (nominal 6.4 mm)
Storage Temperature	10 – 25° C (50 – 77° F)
Storage Humidity	75% relative



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Clinical support 24 hours per day,
7 days a week:

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HCS-EM00883-EN rA

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Impella® 5.0 and LD

STABILIZE | UNLOAD | RESTORE



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Impella® 5.0 and LD

The World's Smallest 5.0 L/min Heart Pump

Micro-axial Blood Pump

Delivers forward flow from the left ventricle to the aorta

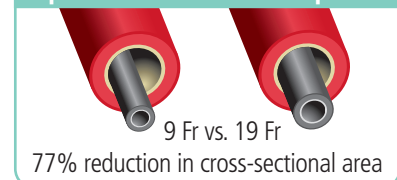
- 9 Fr catheter-based platform
- 21 Fr micro-axial pump
- Low anticoagulation regime
- Minimal bedside support

Single Access Point

Minimally Invasive Placement through a single artery and into the left ventricle

- Several options for access site
- No septal puncture
- No priming / no blood outside the body
- Multiple large bore cannula not required

Impella Catheter vs. Competitor

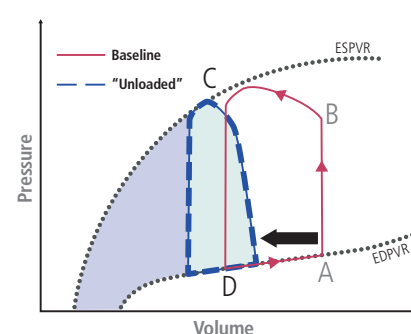


Direct Ventricular Unloading

Actively unloads up to 5 L/min from left ventricle

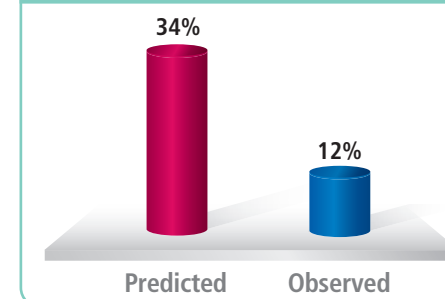
- Reduces wall tension and myocardial O_2 demand^{1,2,3,4,5,6}
- Increases O_2 supply^{6,10}
- Reduces inotrope dependence⁷
- Provides ventricular unloading unlike ECMO⁸

PV Loop of the Cardiac Cycle



RECOVER I : FDA Safety Study⁷

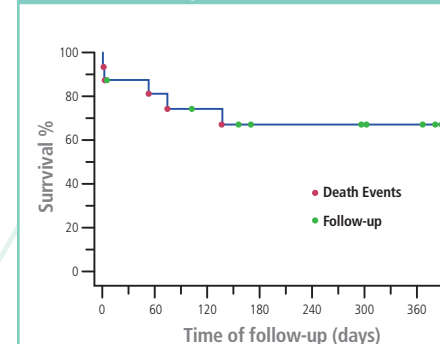
In-hospital Mortality⁹



Patients and Methods (N=17)

- Postcardiotomy patients
- Baseline EF 22% ($\pm 7\%$)
- 62% NYHA Class III/IV
- 93% Multi-vessel disease
- 70% either emergent or urgent

30 Day Survival = 88%



Clinical Results

- 4.2 ± 0.8 L/min pump flow during support
- Less inotropes required post implant
- Low adverse events
- Bleeding – 3 (17%)
- Neurological Dysfunction – 1 (6%)
- Limb ischemia – 0 (0%)
- Site Infection – 1 (6%)
- Survival 88% at 30 days

Initial Experience with Impella® Patients with Cardiogenic Shock

	Pre-Implantat	6 hours of support	24 hours of support
Cardiac output (L/min)	4.1 ± 1.3	$5.5 \pm 1.3^*$	$5.9 \pm 1.9^*$
Mean Blood Pressure (mmHg)	57 ± 13	$75 \pm 13^*$	$81 \pm 17^*$
PCWP (mmHg)	29 ± 10	$17 \pm 5^*$	18 ± 7

*p ≤ 0.01 compared to pre-implant

Impella® Support for Severe Cardiogenic Shock¹¹

- 4.2 ± 0.3 L/min initial pump flow
- Significant improvement in cardiac output and mean blood pressure(cf. table)
- Significant reduction in pulmonary capillary wedge pressure (cf. table)
- 61% successfully wean after a mean of 4 days (2 to 8 days)
- Survival 46% at 30 days

Conclusion: "Left ventricular unloading with the Impella® pump via the transthoracic or femoral approach is feasible and effective."

1. Burzotta et al, Journal of Card Vasc Med, 2008
2. Dixon et al, JACC, 2009
3. Sjaauw et al, MACH II, JACC, 2008
4. Valgimigli et al, Cath Cardio Interventions, 2005

5. Reesink et al., CHEST, 2004
6. Sauren et al., Artificial Organs, 2007
7. Recover I Trial Summary, 2008 TCT; N=17
8. Kawashima, D, et.al., ASAIO, 2010

9. Roques F et al. Eur Heart J., 2003 May; 24(9):882-3
10. Remmelink, Cath Cardio Interventions, 2007
11. Meynes B, Thorac Cardiovasc Surg, 2003