STEP-BY-STEP GUIDE

Right Heart Unloading

with the Impella RP® Heart Pump

The Impella RP is the only FDA approved support device for the treatment of right heart failure. The Impella RP is most often used in the treatment of AMI-Shock. Over 30% of patient's post-transplant or VAD end up with some degree of right heart dysfunction and 37% of the SHOCK Trial and SHOCK Registry patients had RV failure when assessed by contemporary definitions.[1]

The pump is indicated for use of 14 days and provides greater than 4.0 liters/min of flow.

Device Summary

The Impella RP heart pump delivers blood from the inlet area, which sits in the inferior vena cava, through the cannula to the outlet opening in the pulmonary artery. The pump can be inserted percutaneously through the femoral vein.

Clinical support 24 hours per day, 7 days a week

1-800-422-8666 (US)

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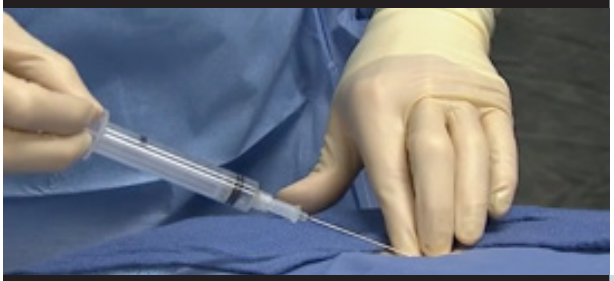
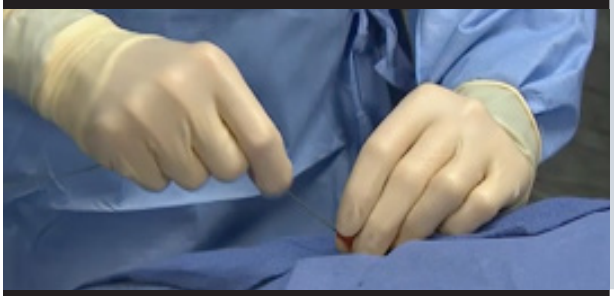
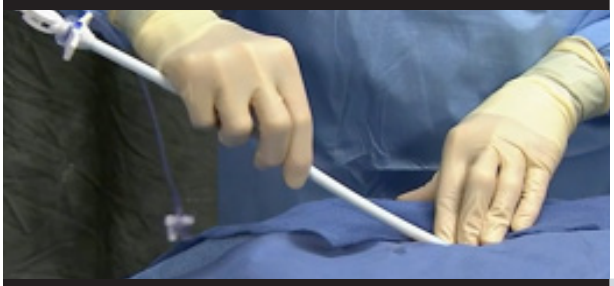
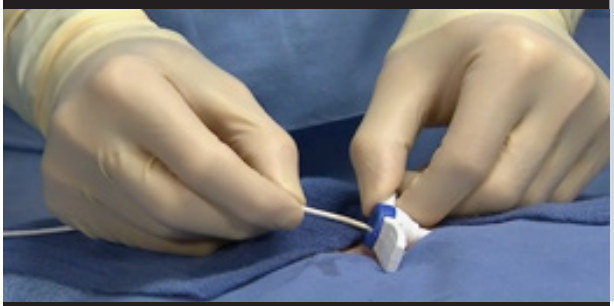
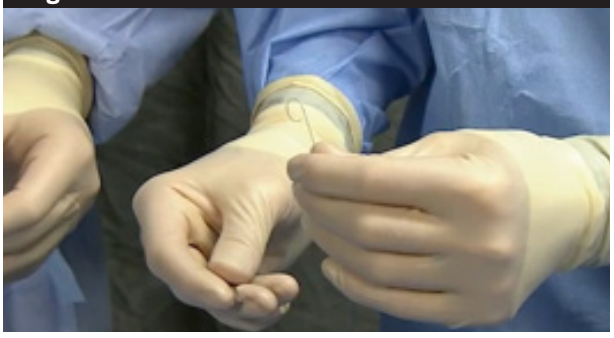
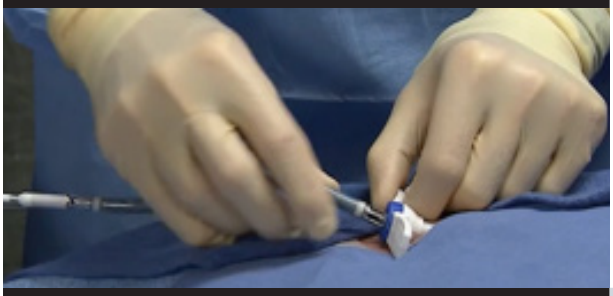
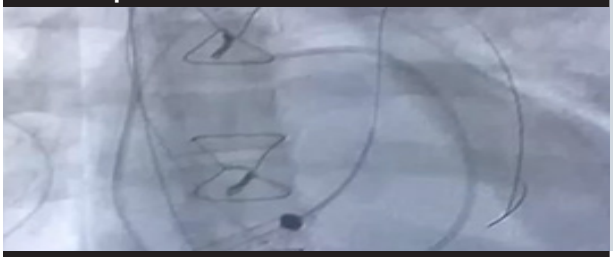
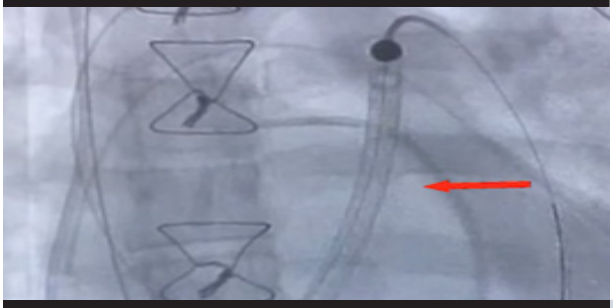
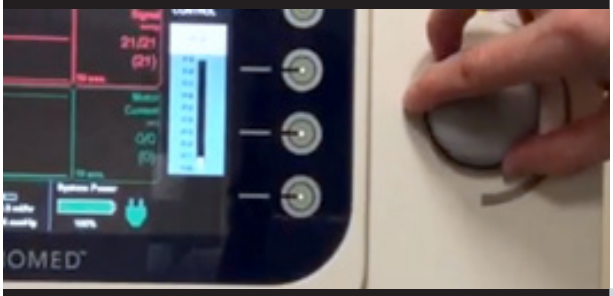
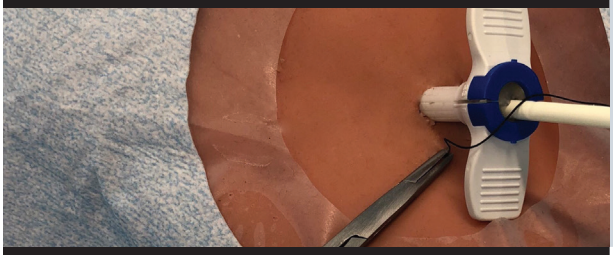
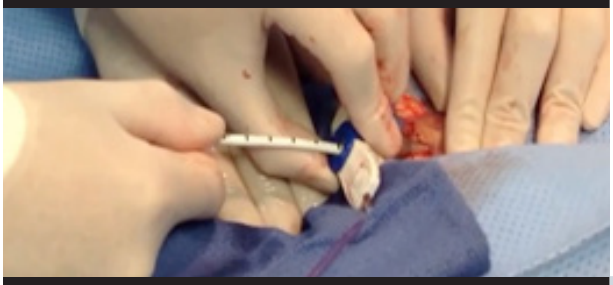
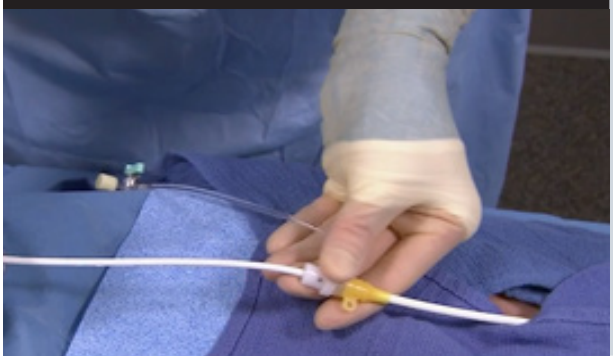
Right Heart Unloading with the Impella RP

Surgical Step	Instrumentation	Recommendations
1. Obtain femoral venous access 	▪ Impella RP Kit includes: ▪ Impella RP Catheter ▪ 0.027" x 260cm guidewire ▪ Peel away 23Fr sheath and dilator ▪ 8Fr – 20Fr sequential dilators ▪ 0.035" x 150cm stiff guidewire ▪ Impella purge cassette ▪ White connector cable	The right femoral vein is the preferred access site for this procedure.
2. Advance guidewire & introduce sheath 	▪ 0.035" x 150cm stiff guidewire ▪ Basic introducer sheath ▪ 8Fr – 20Fr sequential dilators	Insert the 0.035" guidewire for placement of the sheath. Remove the access needle and place the basic introducer sheath. Use sequential dilators to gradually expand the venotomy.
3. Insert the 23Fr peel away sheath 	▪ Peel away 23Fr ▪ Sheath and dilator	Flush the side arm of the 23Fr peel away sheath Do not wipe the dilator (coated in silicone). Under fluoroscopy insert the sheath over the 0.035" stiff guidewire, achieve an ACT of 250 sec > prior to removing the dilator and guidewire.
4. Advance a flow directed balloon tip catheter 	▪ Flow directed balloon tipped catheter ▪ Suggest a 7Fr Arrow, Medtronic or Berman catheter that can accommodate an 0.035" wire size	Insert the flow directed balloon catheter through the 23Fr sheath to the main pulmonary artery and then further advance into the left PA.
5. Curve and advance the 0.027" placement guidewire 	▪ Provided 0.027" x 260cm guidewire	Form a gentle curve/ bend on the end of the 0.027" placement guidewire. Insert through the flow directed catheter and ensure it is placed well into the distal left PA. This will create an optimal rail transition for the advancement of the Impella RP catheter across the pulmonic valve and into the PA. Once in position, pull back to remove any loops or bends in the wire to make sure it is free from any anatomical structures within the right ventricle.

Surgical Step	Instrumentation	Recommendations
6. Prepare the Impella RP 	▪ Saline ▪ Impella RP catheter	Remove the flow directed catheter Wet the cannula of the Impella RP with saline Aspirate and flush the sidearm of the 23Fr peel away sheath. Backload the Impella RP catheter over the 0.027" placement guidewire. Advance the guidewire until the wire exits any one of the 4 windows just distal of the motor. Make sure to not touch the pressure sensor.
7. Advance the Impella RP 	▪ Impella RP catheter	Slowly advance the catheter through the hemostatic valve and through the sheath. Do not touch or damage the pressure sensor on the proximal cannula upon insertion. Continue advancing the Impella RP until the pressure sensor and inflow on the catheter exits the end of the sheath into the abdominal IVC. Press the Zero Sensor soft button on the AIC to zero the sensor in the IVC. The reading should be 4/4 ± 10.
8. Visualize placement across tricuspid valve into the top of the RV 	▪ Fluoroscopy	Continue to advance the Impella RP until you visualize the pigtail and outflow across the tricuspid valve into the top of the RV. Note: Maintain the direction of the guidewire and pigtail to always point towards the pulmonic valve and not lateral or towards the apex. As the device crosses the pulmonic valve, a gentle clockwise torque on the catheter, while pulling back on the wire to straighten the distal cannula.
9. Confirm placement 	▪ Fluoroscopy	Position the outflow area of the catheter approximately 2-4cm above the pulmonic valve or above the bifurcation of the right pulmonary artery branch in the distal main pulmonary artery. Confirm that the placement of the inflow area is outside the right atrium at or below the diaphragm around the hepatic vein area of the IVC.
10. Remove the placement guidewire under fluoroscopic guidance 	▪ Fluoroscopy	Under fluoroscopy slowly remove wire while insuring catheter does not move.

Surgical Step	Instrumentation	Recommendations
11. Initiate support 	▪ AIC	Press the flow control soft key to select "performance level 2" to initiate support. Gradually increase the performance levels to achieve optimal flow and hemodynamic support. Impella Patient Management: Maintain ACT at 160-180 sec for a duration of Impella RP support (> 250 sec at time of insertion).
12. Place a mattress suture 	▪ Suture can be 0 or 2.0 silk with a CT1 surgical needle	Place a mattress suture.
13. Remove the 23Fr peel away sheath 	▪ Fluoroscopy	Apply light manual pressure just above the puncture site to control hemostasis. Use fluoroscopy to monitor the Impella RP distal positioning while removing the 23Fr peel away sheath introducer completely from the vein and skin. Grasp the 2 wings and bend forward until the hub and valve assembly comes apart. Continue to peel until the introducer is completely separated from the catheter shaft.
14. Slide the repositioning sheath into the femoral vein 	▪ Fluoroscopy	Flush the side arm of the repositioning sheath, fluoro over the inflow of the Impella RP to monitor movement. Slide the repositioning sheath over the catheter shaft into the femoral vein so that the yellow hub is at skin level. Tie the mattress suture at the venotomy site to achieve hemostasis and secure the repositioning unit to the patient by suturing the yellow hub to the skin. Manual pressure should be maintained for additional 10 minutes or as needed to achieve hemostasis. Attach the anti-contamination sleeve to the yellow hub of the repositioning sheath. Lock the anchoring ring (tuohy borst) by securing it clockwise.

References
1. Lala, Anuradha et al., 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, Journal of Cardiac Failure , Volume 22 , Issue 8 , S39

INDICATIONS FOR USE

Right-Side Support
The Impella RP® System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Important Risk Information for Impella RP System

CONTRAINDICATIONS
The Impella RP System is contraindicated for patients with the following conditions: Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device. 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 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: 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, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella RP. Learn more visit: ***www.abiomed.com/important-safety-infomation***

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