

# Impella Connect<sup>®</sup>

*Your Collaborative Patient Care Solution*

## Workflow Examples



**European based  
cloud**

Now you can  
**Connect with Impella**  
in a whole new way



“Impella Connect is a cloud-based data platform that can provide physicians and hospital staff with secure remote monitoring of the Automated Impella Controller (AIC). AIC data can be viewed live via mobile devices or computers. Users can view pump data from all active Impella heart pumps in use via the intuitive overview page and individually select each case to view a live video stream of the transmitted pump information.”

— **Dr. Thorsten Sieß**  
Managing Director & CTO at Abiomed



## Streamlined Patient Management

Enables timely and effective clinical care from all locations

- ▲ Direct, customizable notifications of Impella alarms and events
- ▲ Centralized dashboard provides status of all current Impella cases
- ▲ Efficiently manage ICU resources with automatic notification of new Impella cases or clinical events



## Access to Clinical Expertise

Enhances Abiomed 24/7 on-demand clinical support

- ▲ Abiomed operates a 24/7 Clinical Support Center that responds to customer calls. Many of the calls are questions regarding device operation. Adding the Impella Connect streaming capability to the AIC will allow Abiomed support to see in a dataprotection (or GDPR-)compliant way what the hospital staff are seeing in order to provide a higher level of assistance.
- ▲ In addition to live assistance, the Impella Connect System will provide the opportunity for hospital staff to review cases at any time, capturing information such as alerts, device settings, and recorded video of the AIC screen.
- ▲ Remote access to this information can enhance patient care and may improve outcomes for patients in the ICU.



**Clinical Support Center 24 hours per day, 7 days a week:**  
**00800 0 22 466 33 (EU)**



This pocket guide covers  
example workflow  
scenarios demonstrating  
the value of  
**Impella Connect®**  
for management needs of  
your Impella supported  
patients.

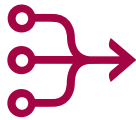


# Workflow Examples



Enhanced Response Time

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Streamlined Resources

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Data Driven Management

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Continuity of Care

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On-Demand Training

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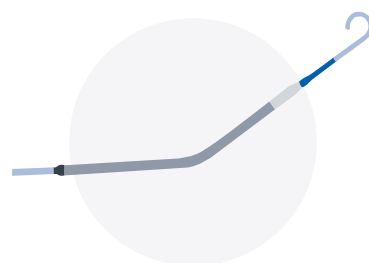
Professional Education

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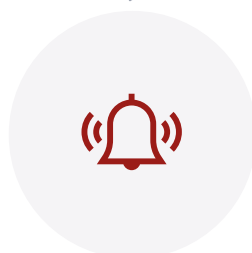


# Enhanced Response Time

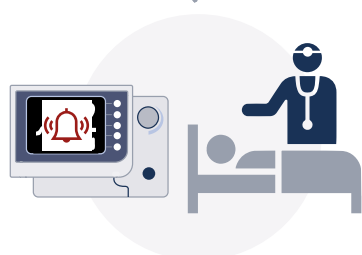
Remote access to case information  
and customized alerts enable  
timely and effective response from  
any location



Patient hemodynamically supported  
with Impella heart pump in ICU



Critical alarms overnight



Direct alert of the  
bedside physician



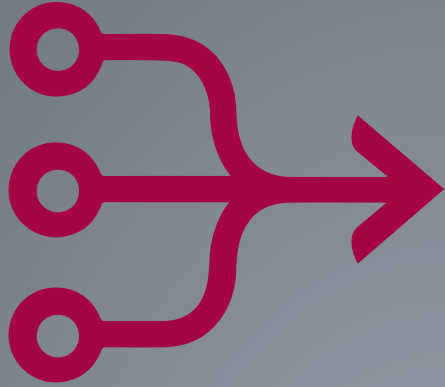
Impella Connect alerts on-call  
physician of active alarm



On-call physician remotely reviews device  
performance and case history



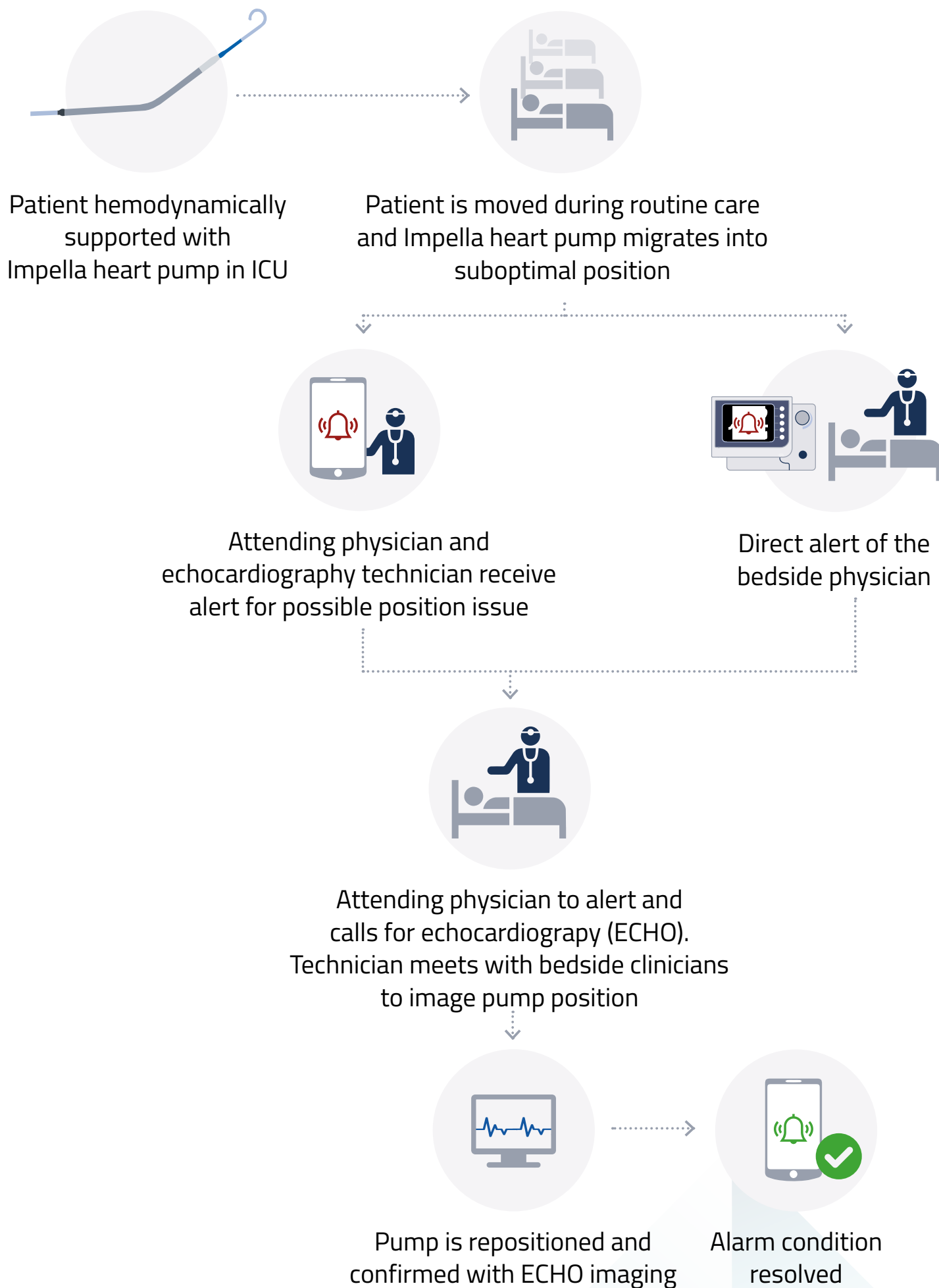
On-call physician teleconferences with bedside  
clinicians to walk through management and  
stabilizes patient remotely



# Streamlined Resources

Customized notifications enable  
timely and effective clinical care

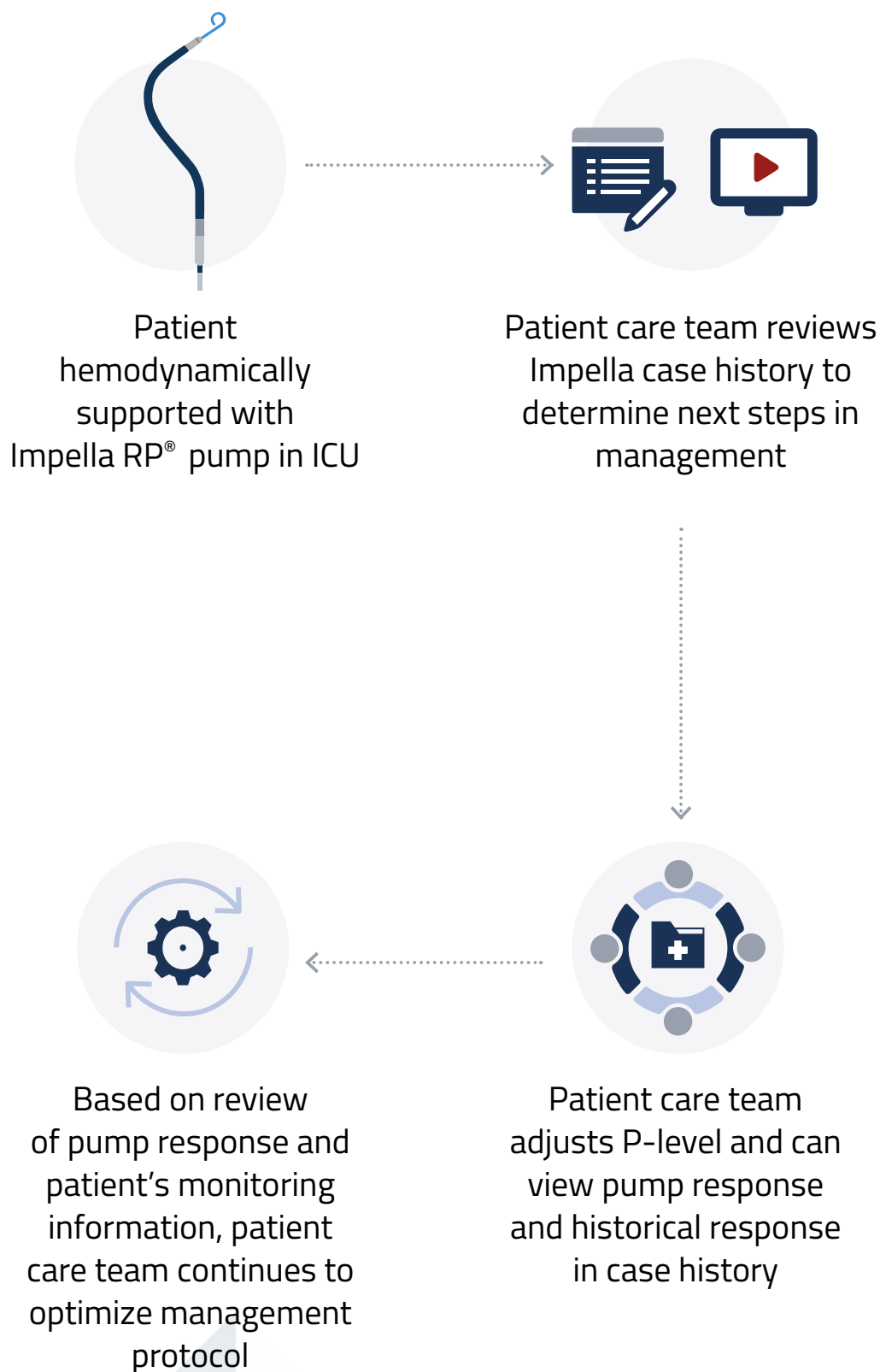






# Data Driven Management

Access to complete case history  
logs assists in patient management  
decisions and optimizing care protocols





# Continuity of Care

Efficiently manage ICU resources  
with automatic notifications of new  
Impella cases



Patient supported with  
Impella heart pump



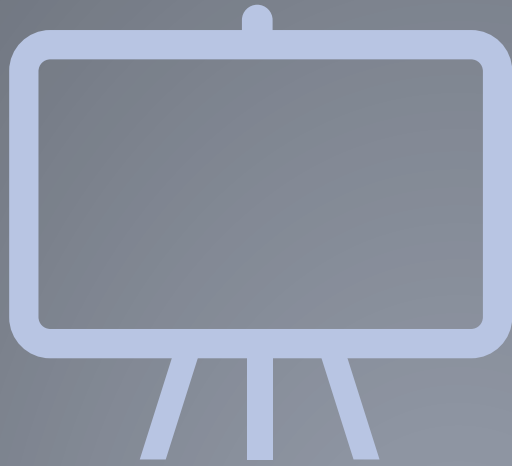
ICU charge nurse and  
coordinator receive  
notification of new  
Impella patient  
case start



Patient transferred  
to ICU from OR has a  
dedicated room and  
staff plan

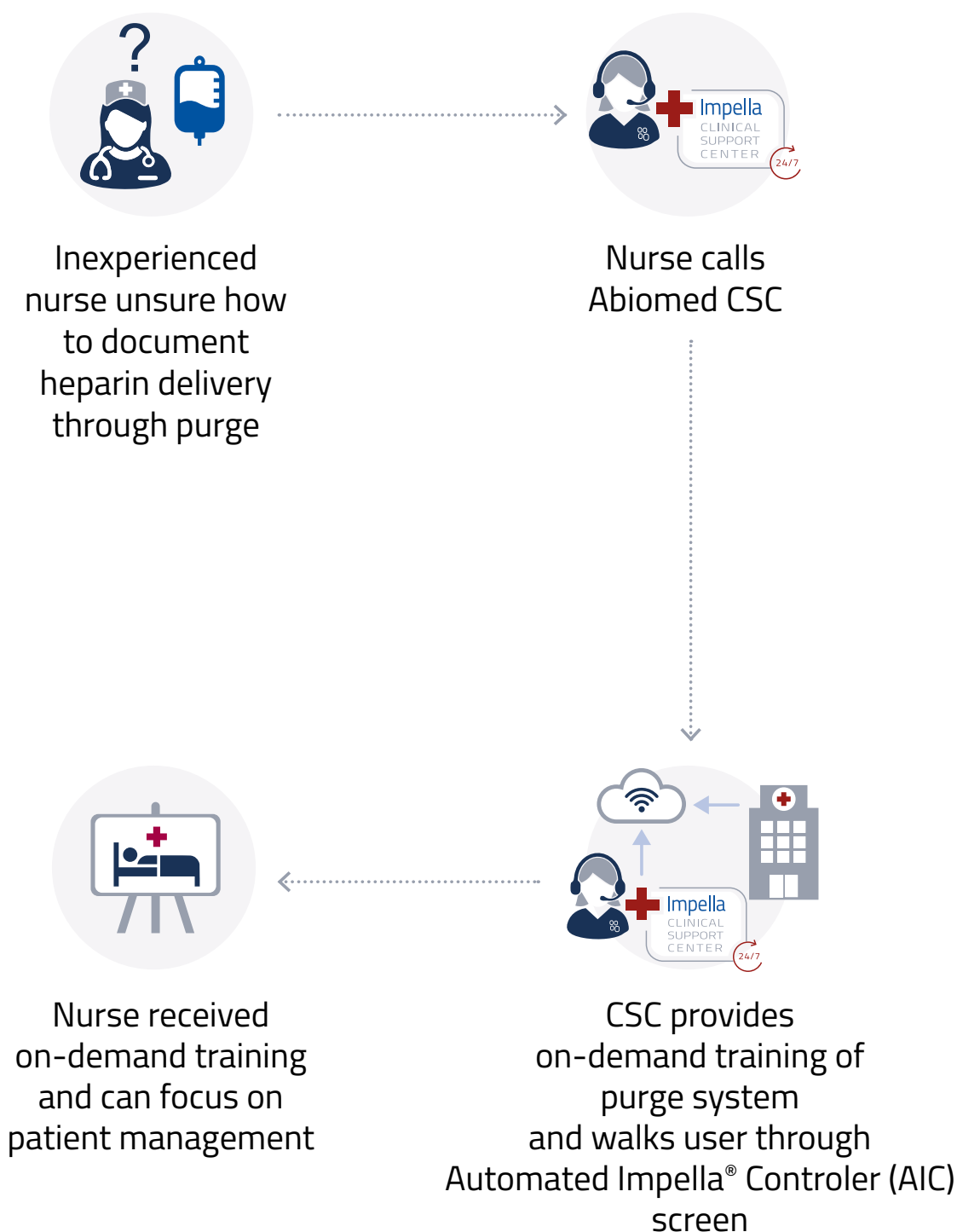


Early notification  
from Impella Connect  
allows nurse time to  
coordinate resources  
(room and staff) to  
support patient



# On-Demand Training

Remote viewing of Impella  
pump performance enhances  
Abiomed's 24/7 on-demand  
clinical support

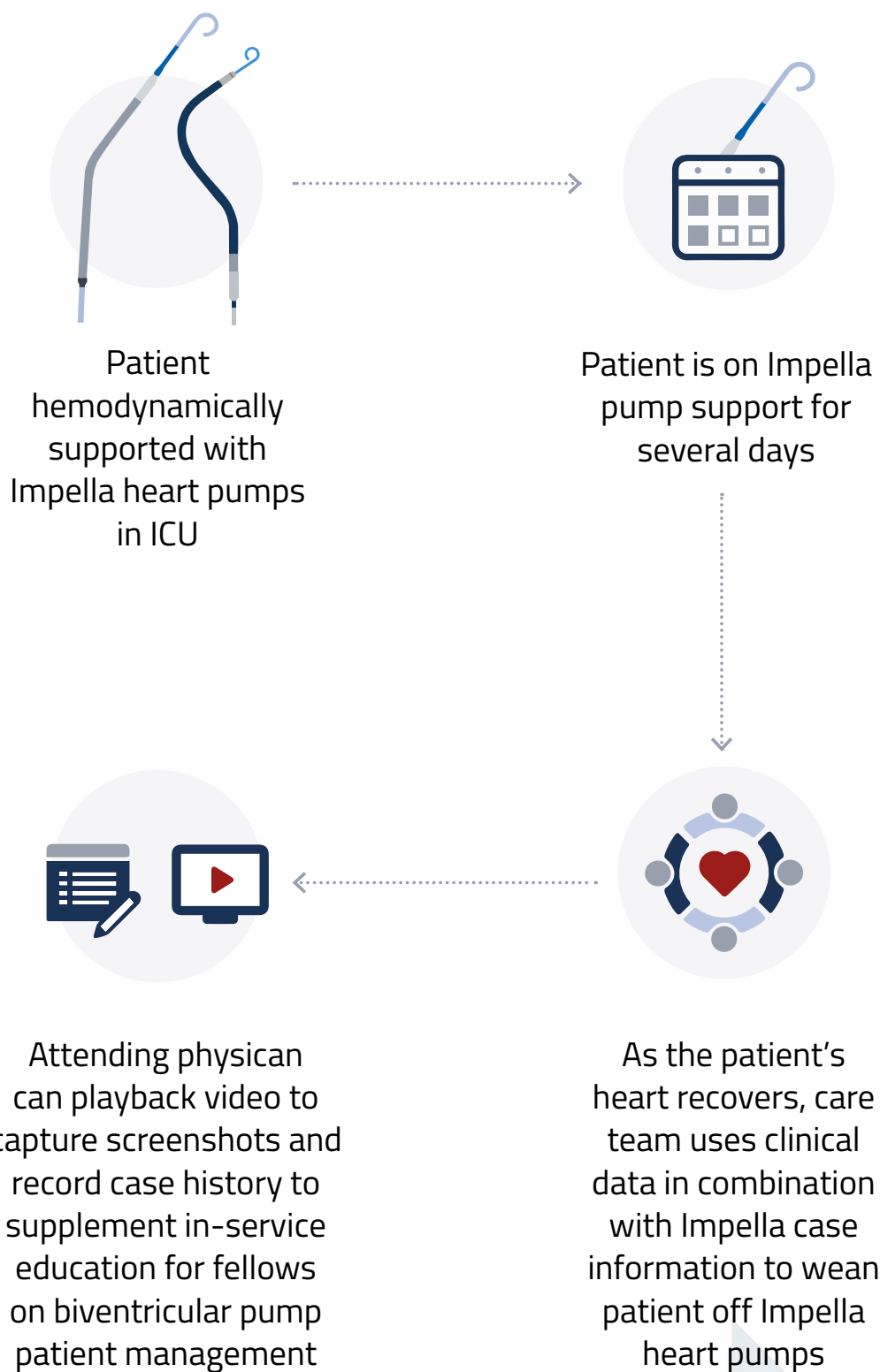




# Professional Education

Access to the complete case history logs with video playback capabilities supplements staff training and in-services





# Indications for Use

**Device: Impella 2.5®, Impella CP®, Impella CP with SmartAssist®:** The Impella (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 5 days for the following indications, as well as others:

- The Impella is a circulatory support system for patients with reduced left ventricular function, e.g., post-cardiotomy, low output syndrome, cardiogenic shock after acute myocardial infarction, or for myocardial protection after acute myocardial infarction
- The Impella 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.
- Support during high risk percutaneous coronary intervention (PCI)
- Post PCI

**Device: Impella 5.0®, Impella LD®:** The Impella (intracardiac pump for supporting the left ventricle) is intended for clinical use in cardiology and in cardiac surgery for up to 10 days for the following indications, as well as others:

- The Impella 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 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.

**Device: Impella 5.5® with SmartAssist®:** 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:

- Mechanical aortic valves, severe aortic valvular stenosis or valvular regurgitation
- 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
- Other illnesses or therapy requirements precluding use of the pump
- Severe peripheral arterial occlusion disease (PAOD) is a relative contraindication

## Possible Complications

There are risks of complications with every procedure using a blood pump. These include among others:

- Hemolysis
- Bleeding
- Immune reaction
- Embolism, thrombosis
- Vascular injury through to angionecrotomy
- Positioning problems
- Infection and septicemia
- Dislocation of the pump
- Cardiovalvular injuries due to extreme movement of the suction cannula in relation to the cardiac valve or as a result of attachment by suction of the pump to the valve system following incorrect positioning
- Endocardiac injuries as a result of attachment of the pump due to suction
- Pump failure, loss of pump components following a defect
- 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. Learn more visit: <https://www.heartrecovery.eu/products-and-services>

**Device:** The **Impella RP System** (percutaneous pump for right ventricular support) is intended for clinical use in cardiology, in cardiac surgery, and intensive care unit for up to 14 days for the following indications, as well as others:

- Acute or transient reduction of the right ventricular function (eg, postcardiotomy low output syndrome)
- Cardiogenic shock as a consequence of a posterior myocardial infarction with right ventricular heart failure
- Right heart support during coronary beating heart bypass surgery, especially for patients with a reduced preoperative cardiac output or for patients having a high risk of developing a postoperative low output syndrome for other reasons
- Right ventricular heart failure after implantation of a left ventricular assist device
- Therapy unresponsive arrhythmias with a reduction of right ventricular output
- Heart failure and/or cardiogenic shock as a consequence of refractory ventricular arrhythmias, as well as a consequence of sustained supraventricular arrhythmias, causing haemodynamic compromise.

**Contraindications:**

- Arteriosclerosis, in particular calcification or other disorders of the pulmonary artery wall
- Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid valve or pulmonary valve
- Mural thrombus of the right atrium or vena cava
- Anatomic conditions precluding insertion of the pump
- Other illnesses or therapy requirements precluding use of the pump
- Presence of a vena caval 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 Complications:**

There are risks of complications with every procedure using a blood pump. These include among others:

- Hemolysis
- Bleeding
- Immune reaction
- Embolism, thrombosis
- Vascular injury through to angionecrotomy
- Infection and septicemia
- Endocardial injuries due to attachment of the pump to the inferior vena cava
- Pump failure, loss of pump components following a defect
- Patient dependency on the pump after use for support

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella RP. Learn more visit: <https://www.heartrecovery.de/produkte-undservices/impella/impella-rp>

**Impella Connect**

Impella Connect® transfers the video image of the screen on the Automated Impella® Controller to an authorized remote user. The transmitted image can be viewed by authorized remote users. The users can include the hospital's clinicians, Abiomed local support staff, and Customer Support Center (CSC) team members.

**INTENDED USE (EU)**

Impella Connect is intended to be used to enable remote patient monitoring by providing authorized users with passive viewing of the AIC's display which includes information on alarms and data useful for troubleshooting and managing Impella devices to aid in patient management. Impella Connect transfers the video stream from the AIC (via the VGA output) and data stored by the AIC to a cloud-based remote viewing portal. Communication between the AIC and Impella Connect is one-way (AIC to Impella Connect), and the streamed information is limited to Impella device operating parameters and alarm messages with no patient identifiable information. Impella Connect is powered directly by the AIC.

**PRECAUTIONS**

- The Impella Connect is not intended to provide real-time information for monitoring patient status on the AIC.
- During use of the Impella Connect, there will be a delay between when an image appears on the AIC screen and when it is displayed at a remote viewing location.
- The Impella Connect is not a source of patient alarms, nor is its use intended as a replacement for monitoring the AIC's alarms.
- During use of Impella Connect, receipt of the displayed controller information is not confirmed by the AIC, nor is the delivery of the displayed AIC information to the authorized remote users guaranteed.
- Impella Connect is not designed for use during transport.
- When Impella Connect is configured to use the hospital's secured Wi-Fi network, signal quality and strength is dependent on the hospital's Wi-Fi.
- When Impella Connect is configured to use the hospital's secured Wi-Fi network, connection may be lost in physical locations of low Wi-Fi signal.
- No modification of this equipment is permitted.
- Radiated and conducted electromagnetic interference can affect the performance of the Impella Connect, causing a temporary loss of connectivity. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source. Any electromagnetic interference related to the Impella Connect will have no impact on any of the AIC functional specifications.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- When in use, the Ethernet cables connecting the Impella Connect to the wall could represent a tripping hazard and should be placed where foot traffic is minimal.
- Keep excess cabling on the cable wrap when not needed.
- Disconnect, when in use, the Ethernet cables from the wall outlet before moving the AIC.
- Impella Connect is not interpretive.
- Impella Connect is not intended to control or interact with any drugs.

**The Impella Connect is not designed for use during transport.**

Radiated and conducted electromagnetic interference can affect the performance of the Impella Connect, causing a temporary loss of connectivity. To clear interference, either increase the distance between system components and the EMI source or turn off the EMI source. Any electromagnetic interference related to the Impella Connect will have no impact on any of the controller functional specifications. Portable and mobile RF communications equipment can affect medical electrical equipment.

In addition to the information above, learn more about Abiomed and Impella:  
Visit <https://www.heartrecovery.de/produkte-und-services/impella>

# Impella Connect<sup>®</sup>

*Your Collaborative Patient Care Solution*

**Learn more visit**

<https://www.heartrecovery.eu/products-and-services>

**Impella Connect Technical Support**  
**EU\_ImpellaConnect@abiomed.com**

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**Clinical Support Center**

24 hours per day, 7 days a week:

**00800 0 22 466 33 (EU)**

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