Impella®
Product Catalogue 2020

ABIOMED®
Recovering hearts. Saving lives.

Ordering Guide

More than
140,000
patients
treated
worldwide

www.impella.de

Impella®
Heart pumps for greater safety

Impella heart pumps are used in emergency medicine and for complex coronary interventions. More than 140,000 patients have been treated with them worldwide. Impella® was invented, developed and produced in Aachen: German engineers and technicians are working there together with US experts continuously, to develop the system further.

If you require any further information or clinical protocols, please visit **www.impella.de** or visit **www.abiomed.de**

The Impella® product family

Impella heart pumps offer haemodynamic support and greater safety, among other benefits, in the event of cardiogenic shock or percutaneous coronary intervention (Protected PCI). Different product variants are available depending on the indication. This ordering guide presents the different product variants and the corresponding accessories.

Overview
Product variants and part numbers

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Automated Impella Controller (AIC)

We will be happy to advise you in person

Would you like to learn more about Impella heart pumps or are you interested in one of our training courses? We will gladly answer your questions and deal with your inquiries as soon as possible.

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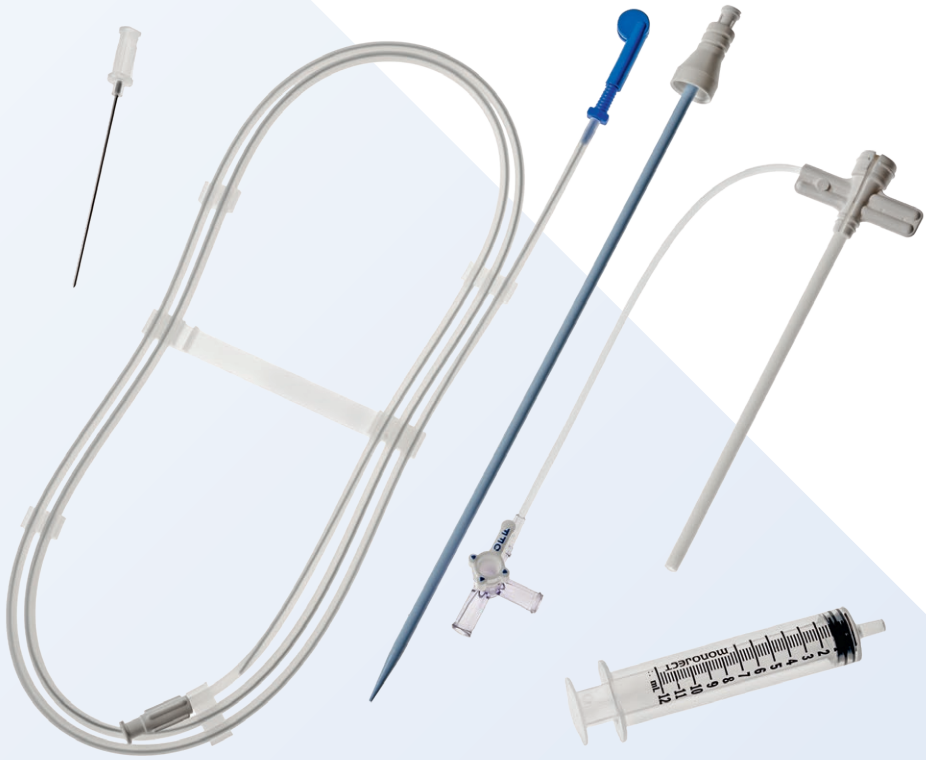
Impella 2.5® heart pump

Smallest heart pump in the world



Introducer kit

Impella 2.5®
heart pump

Part number: 005040
Product description: Impella 2.5 with 13 Fr sheath introducer including 0.035" x 150 cm guide wire, 0.018" x 260 cm guide wire, Automated Impella Controller connector cable, purge cassette

Accessories

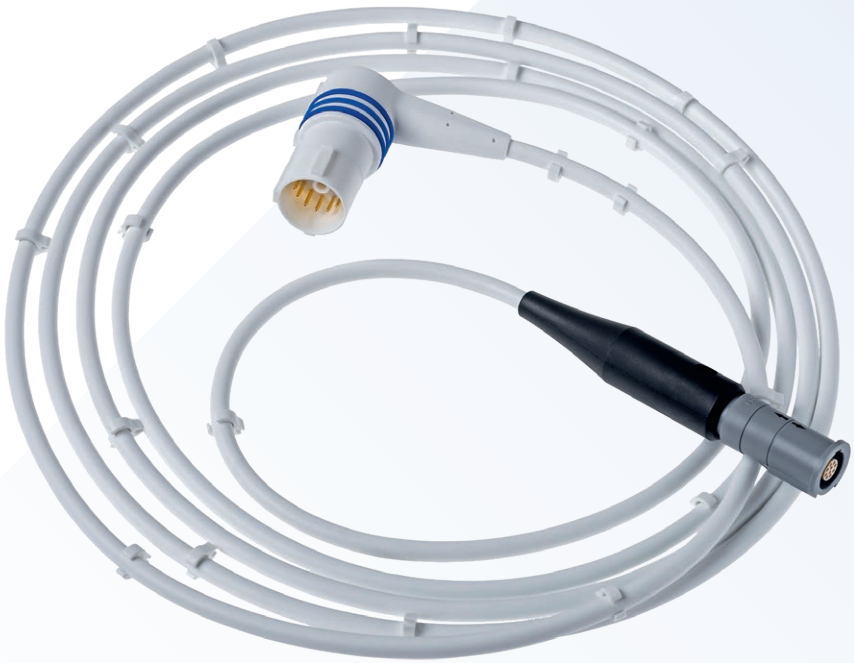
◢ 0042-0002
Automated Impella Controller connector cable for Impella 2.5, Impella CP, Impella 5.0, Impella LD and Impella RP

◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

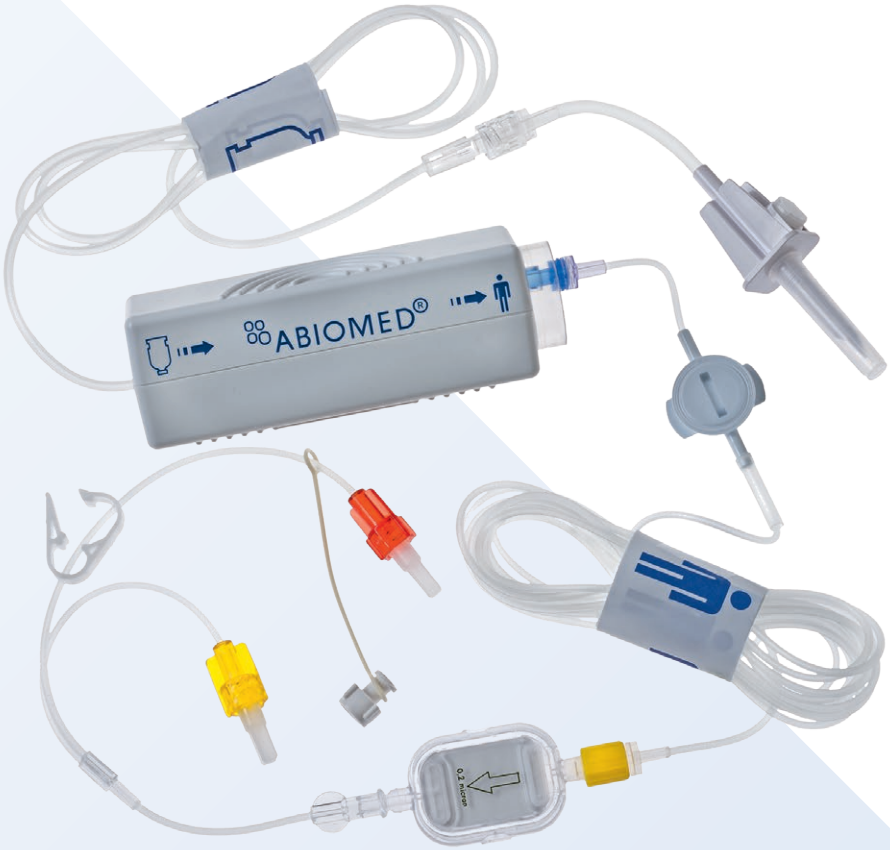
◢ 0052-0007
Introducer kit:
13 Fr (splittable) sheath introducer, dilator, guide wire, puncture cannula, 10 ml syringe

◢ 0052-3005
Guide wire for placement of Impella 2.5, 0.018" (0.47 mm) diameter, 260 cm long, PTFE coated



◢ Automated Impella Controller connector cable

Impella CP® heart pump



Purge cassette

Impella CP®
heart pump

Part number: 0048-0002
Product description: Impella CP with 14 Fr x 13 cm sheath introducer incl. 0.035" x 150 cm guide wire, 0.018" x 260 cm guide wire, Automated Impella Controller connector cable, purge cassette

Accessories

◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

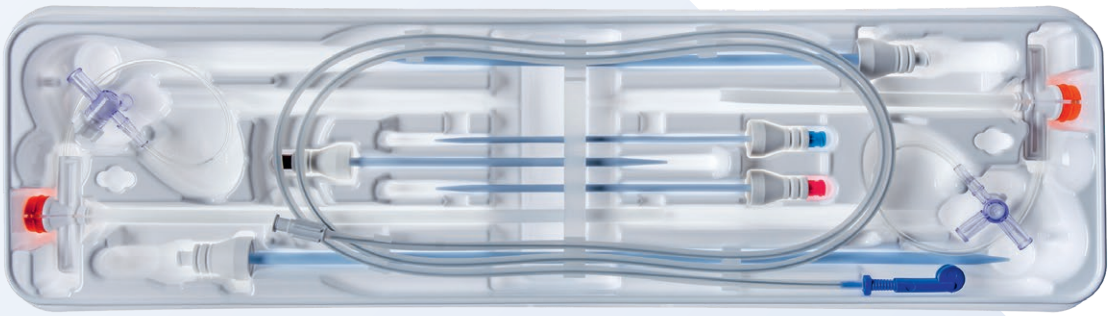
◢ 0052-0016
Introducer kit:
14 Fr x 13 cm sheath; 8, 10, 12 Fr dilators; 0.035" x 150 cm guide wire

◢ 0052-0017
Introducer kit: 14 Fr x 25 cm sheath introducer; 8, 10, 12, 14 Fr dilators; 0.035" x 150 cm guide wire

◢ 0052-3005
Guide wire for placement of Impella CP, 0.018" (0.47 mm) diameter, 260 cm long, PTFE-coated

◢ 14 Fr x 13 cm sheath introducer

Impella CP® with SmartAssist®



Combo introducer kit, 14 Fr with 13 cm and 25 cm long sheaths (only supplied with pump set)

Impella CP®
with SmartAssist®

Part number: 0048-0014
Product description: Impella CP with SmartAssist, with 14 Fr Combo introducer kit (13 cm and 25 cm sheath introducers), purge cassette, 0.018" x 260 cm guide wire

Accessories

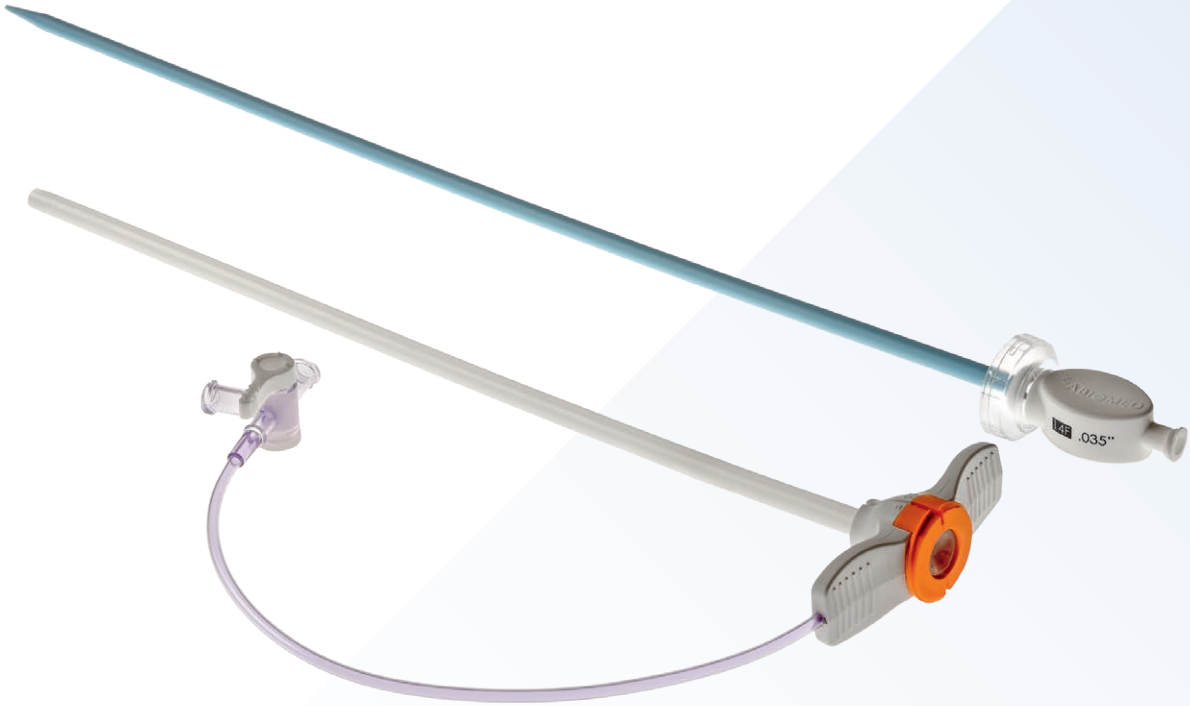
◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

◢ 0052-0016
Sheath introducer includes:
14 Fr x 13 cm; 8, 10, 12, 14 Fr dilators;
0.035" x 150 cm guide wire

◢ 0052-0017
Introducer kit: 14 Fr x 25 cm sheath introducer; 8, 10, 12, 14 Fr dilators;
0.035" x 150 cm guide wire

◢ 0052-3005
Guide wire for for placement of Impella CP with SmartAssist, 0.018" (0.47 mm) diameter, 260 cm long, PTFE-coated



◢ 14 Fr x 25 cm sheath introducer

Impella 5.0®

Impella LD®

Impella 5.0® and **Impella LD®** heart pumps

Part number: 005060
Product description: Impella 5.0 with Automated Impella Controller connector cable, purge cassette, 0.025" guide wire, silicone plugs and introducer kit (23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator)

Part number: 005080
Product description: Impella LD with Automated Impella Controller connector cable, purge cassette, 1 incision template, silicone plugs

Accessories

◢ 0042-0002
Automated Impella Controller connector cable

◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

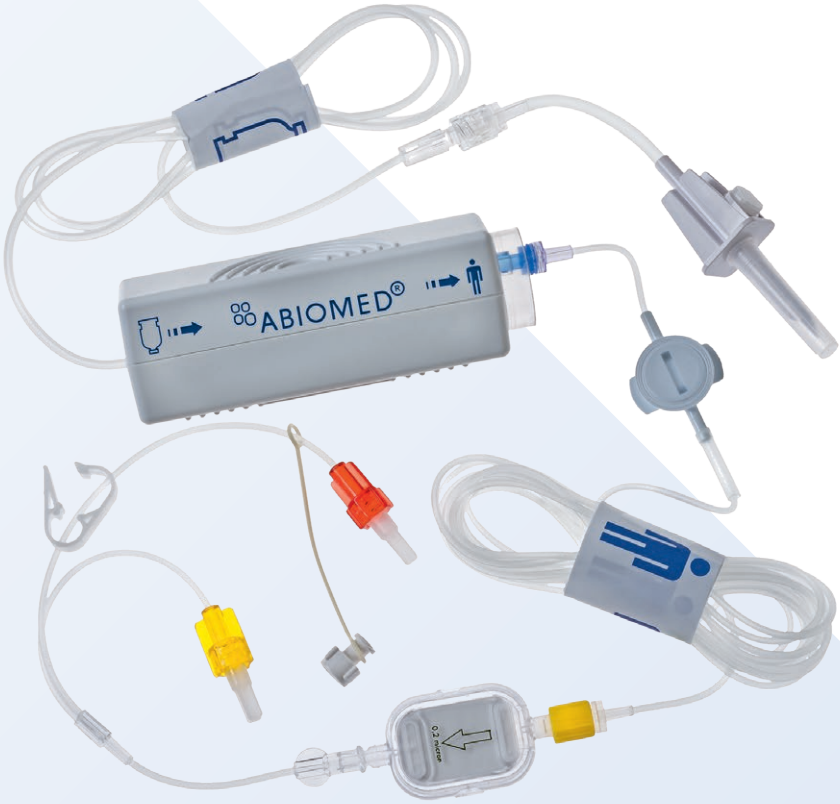
◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

◢ 0052-0011-EU
Introducer kit: 23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator

Only for Impella 5.0:
◢ 0052-3005
Guide wire for placement of Impella 5.0, 0.018" (0.47 mm) diameter, 260 cm length, PTFE-coated

◢ Introducer kit with graft locks

Impella RP®



Purge cassette

Impella RP®
heart pump

Part number: 0046-0011
Product description: Impella RP with 0.027" guide wire, 23 Fr introducer kit, Automated Impella Controller connector cable, purge cassette

Accessories

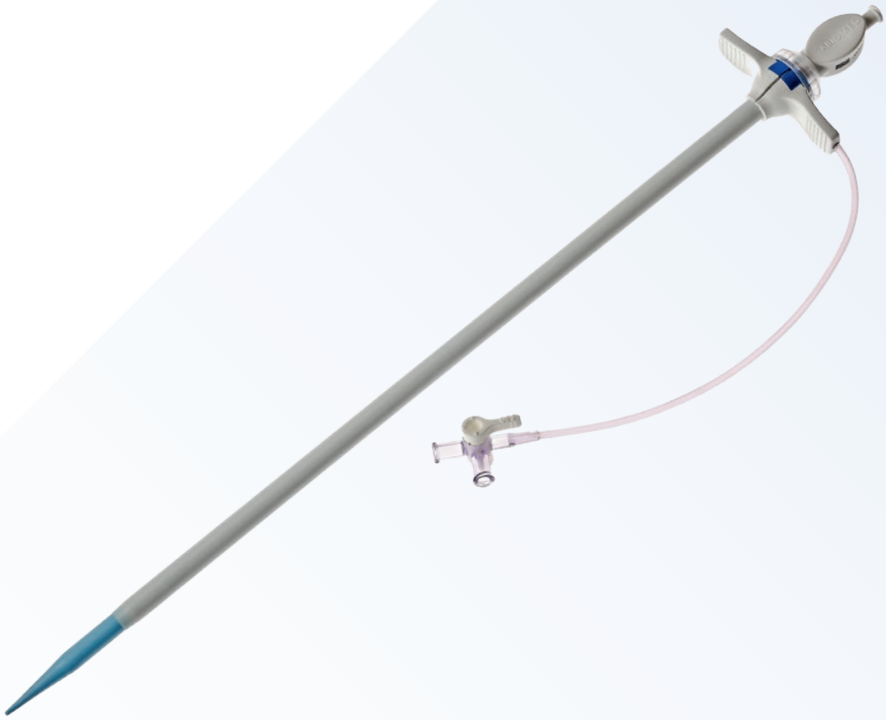
◢ 0042-0002
Automated Impella Controller connector cable for Impella 2.5, Impella 5.0, Impella CP, Impella LD and Impella RP

◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

◢ 0052-0002-EU
Introducer kit: 23 Fr sheath introducer; 8, 12, 16, 20 Fr dilator; 0.035" x 150 cm guide wire

◢ 0052-3018
Guide wire 0.027" x 260 cm



◢ 23 Fr introducer sheath

Impella 5.5® with Smart Assist®

Silicone plugs

Impella 5.5®
with SmartAssist®

Part number: 0550-0002
Product description: Impella 5.5 with SmartAssist with 0.018" x 260 cm guide wire, purge cassette, silicone plugs and introducer kit (23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator)

Accessories

◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

◢ 0052-0011-EU
Introducer kit: 23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator

◢ 0052-3005
Guide wire for placement of Impella 5.5 with SmartAssist, 0.018" (0.47 mm) diameter, 260 cm long, PTFE coated

◢ Introducer kit with graft locks

Automated Impella Controller

Automated Impella Controller Cart

Automated Impella® Controller (AIC)

Part number: 0042-0000-EU
Product description: Automated Impella Controller

Part number: 0042-0010-EU
Product description: Automated Impella Controller with SmartAssist (visual)

Part number: 0042-0020
Product description: Automated Impella Controller Cart

Accessories

◢ 0042-0002
Automated Impella Controller connector cable for Impella 2.5, Impella CP, Impella RP, Impella 5.0 and Impella LD catheters

◢ 0042-0012
Automated Impella Controller connector cable for Impella CP (not required for Impella with SmartAssist pumps)

◢ 0043-0002
Automated Impella Controller purge cassette (1 piece)

◢ 0043-0003
Automated Impella Controller purge cassettes (5 pieces)

◢ Purge cassette

The Impella® product family

Impella® heart pumps

Impella 2.5 **Part number:** 005040
Product description: Impella 2.5 with 13 Fr sheath introducer including 0.035" x 150 cm guide wire, 0.018" x 260 cm guide wire, Automated Impella Controller connector cable, purge cassette

Impella CP **Part number:** 0048-0002
Product description: Impella CP with 14 Fr x 13 cm sheath introducer incl. 0.035" x 150 cm guide wire, 0.018" x 260 cm guide wire, Automated Impella Controller connector cable, purge cassette

Impella CP with SmartAssist **Part number:** 0048-0014
Product description: Impella CP with SmartAssist, with 14 Fr Combo introducer kit (13 cm and 25 cm sheath introducers), purge cassette, 0.018" x 260 cm guide wire

Impella 5.0 **Part number:** 005060
Product description: Impella 5.0 with Automated Impella Controller connector cable, purge cassette, 0.025" guide wire, silicone plugs and introducer kit (23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator)

Impella LD **Part number:** 005080
Product description: Impella LD with Automated Impella Controller connector cable, purge cassette, 1 incision template, silicone plugs

Impella RP **Part number:** 0046-0011
Product description: Impella RP with 0.027" guide wire, 23 Fr introducer kit, Automated Impella Controller connector cable, purge cassette

Impella 5.5 with SmartAssist **Part number:** 0550-0002
Product description: Impella 5.5 with SmartAssist with 0.018'' x 260 cm guide wire, purge cassette, silicone plugs and introducer kit (23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator)

The ABIOMED logo, ABIOMED, Impella, Impella 2.5, Impella 5.0, Impella 5.5 with SmartAssist, Impella LD, Impella CP, Impella RP and Recovering Hearts. Saving Lives. are registered trademarks of ABIOMED, Inc. in the USA and certain other countries

Impella® heart pump accessories

Part number	Product	For the following heart pumps
0042-0002	Automated Impella Controller connector cable	Impella 2.5 Impella CP Impella 5.0 Impella LD Impella RP
0043-0002	Automated Impella Controller purge cassette (1 piece)	Impella 2.5 Impella CP Impella CP with SmartAssist Impella 5.0 Impella LD Impella RP Impella 5.5 with SmartAssist
0043-0003	Automated Impella Controller purge cassettes (5 pieces)	Impella 2.5 Impella CP Impella CP with SmartAssist Impella 5.0 Impella LD Impella RP Impella 5.5 with SmartAssist
0052-0002	23 Fr Introducer kit with sheath, introducer dilators and guide wire	Impella RP
0052-0007	Introducer kit: 13 Fr (splittable) sheath introducer, dilator, guide wire, puncture cannula, 10 ml syringe	Impella 2.5

Impella® heart pump accessories

Part number	Product	For the following heart pumps
0052-0011-EU	Introducer kit: 23 Fr x 6 cm sheath introducer, 2 graft locks, silicone-coated 8 Fr dilator	Impella 5.0 Impella 5.5
0052-0016	Sheath introducer includes: 14 Fr x 13 cm, 8, 10, 12, 14 Fr dilators, 0.035" x 150 cm guide wire	Impella CP Impella CP with SmartAssist
0052-0017	Introducer kit: 14 Fr x 25 cm sheath introducer; 8, 10, 12, 14 Fr dilators; 0.035'' x 150 cm guide wire	Impella CP Impella CP with SmartAssist
0052-3005	Guide wire for placement of Impella 5.5 with SmartAssist, 0.018" (0.47 mm) diameter, 260 cm long, PTFE coated	Impella 2.5 Impella 5.0 Impella 5.5 with SmartAssist Impella CP Impella CP with SmartAssist
0052-3018	Guide wire 0.027" x 260 cm	Impella RP

ABIOMED®

Recovering hearts. Saving lives.

Impella 2.5®, Impella CP® & Impella CP with SmartAssist®

INDICATIONS EU

The Impella System (intracardiac pump for support of the left ventricle) is intended for clinical use in cardiology and cardiac surgery for up to five days for the following indications, among others:

- The Impella System is a circulatory support system for patients with reduced left ventricular function, e.g. low-power postcardiotomy syndrome or cardiogenic shock following acute myocardial infarction, or for myocardial protection following acute myocardial infarction
- The Impella System can also be used as a cardiovascular support system during coronary artery bypass surgery on the beating heart, especially in patients with reduced preoperative ejection fraction and high risk of postoperative low output syndrome
- Support during high-risk percutaneous coronary intervention (PCI)
- Post-PCI

CONTRAINDICATIONS EU

- Mechanical aortic valves, severe aortic valve stenosis or valve regurgitation
- Haematological disorders causing blood cell fragility or haemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrosis or severe abnormality of the ascending aorta and/or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) following acute myocardial infarction
- Anatomical conditions that preclude the pump from being inserted
- Other diseases or therapy requirements that preclude the use of a pump
- Severe peripheral arterial occlusive disease (PAD) is a relative contraindication

Impella 5.0® & Impella LD®

INDICATIONS EU

The Impella System (intracardiac pump for support of the left ventricle) is intended for clinical use in cardiology and cardiac surgery for up to ten days in the following indications, among others:

- The Impella System is a cardiovascular support system for patients with reduced function of the left ventricle, e.g. after cardiotomy, low output syndrome or cardiogenic shock after acute myocardial infarction
- The Impella System can also be used as a cardiovascular support system during coronary artery bypass surgery on the beating heart, especially in patients with reduced preoperative ejection fraction and high risk of postoperative low output syndrome

CONTRAINDICATIONS EU

- Mechanical aortic valves, severe aortic valve stenosis or valve regurgitation
- Haematological disorders causing blood cell fragility or haemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrosis or severe abnormality of the ascending aorta and/or the aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) following myocardial infarction
- Anatomical conditions that preclude the pump from being inserted
- Other diseases or therapeutic requirements that preclude the use of a pump
- Severe peripheral arterial occlusive disease (PAD) is a relative contraindication

Impella 5.5® with SmartAssist®

INDICATION (EU) The Impella 5.5 with SmartAssist heart pump is an intracardiac pump for left ventricular support. It is intended for clinical use in cardiology and cardiac surgery for up to 30 days for the following indications, among others: The Impella 5.5 is a cardiovascular support system for patients with reduced left caridac function, e.g. postcardiotomy, low output syndrome or cardiogenic shock after acute myocardial infarction. ▪ The Impella 5.5 can also be used as a cardiovascular support system during coronary bypass surgery on the beating heart, especially in patients with a preoperatively reduced ejection fraction and a high risk of postoperative low output syndrome.

CONTRAINDICATIONS (EU)

Impella 5.5 with SmartAssist heart pump is contraindicated in the following situations:

- Artificial aortic valves, severe aortic valve stenosis
- Haematological disorders that causes instability of the blood cells or haemolysis
- Hypertrophic obstructive cardiomyopathy (HOCM)
- Aneurysm or necrotomy or severe abnormality of the ascending aorta and/or aortic arch
- Mural thrombus in the left ventricle
- Ventricular septal defect (VSD) following myocardial infarction
- Anatomical conditions that preclude the pump from being inserted

Impella RP®

INDICATIONS EU

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 EU

- 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 ADVERSE REACTIONS

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
- Endocardiac injuries due to attachment by suction 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 mentioned above, there are other WARNINGS and PRECAUTIONS related to Impella equipment. Visit the website **www.impella.de**.

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