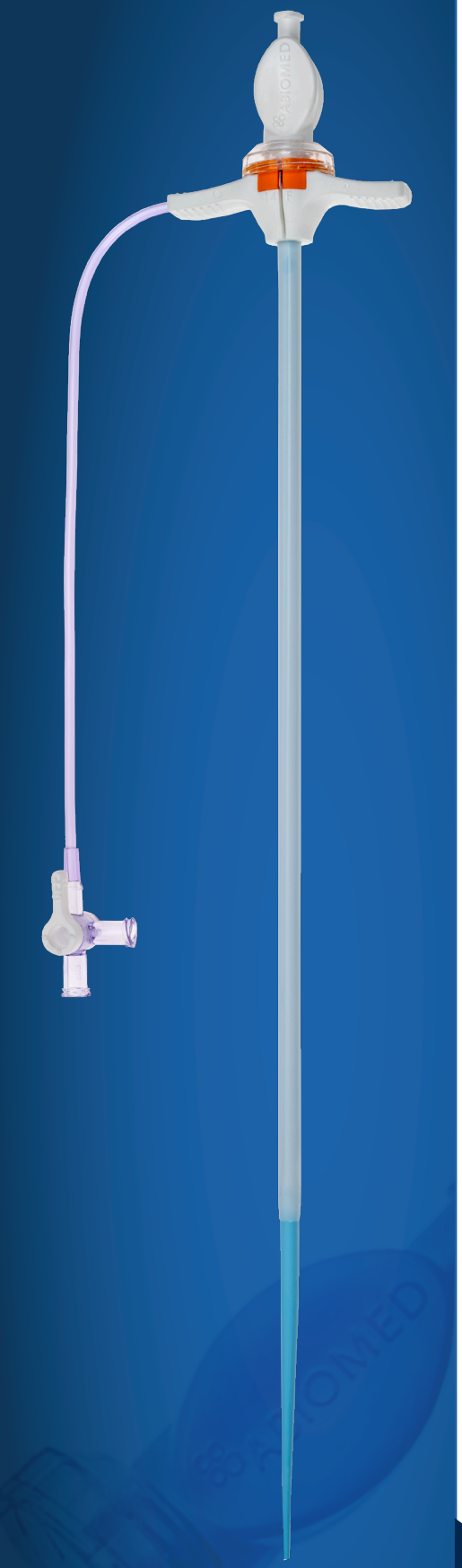


Data Sheet

Abiomed® 14 Fr Sheath

Vascular access kit used for percutaneous insertion of the Impella® catheter.

- For use with Impella CP® with SmartAssist® heart pumps
- Hemostatic valve to prevent blood loss during use
- Kink resistant sheath body and smooth tip to ease insertion
- Long tapered dilator tip facilitating insertion of the device into the femoral artery

Specifications

Valve:
Single piece, hemostatic valve prevents leaking.

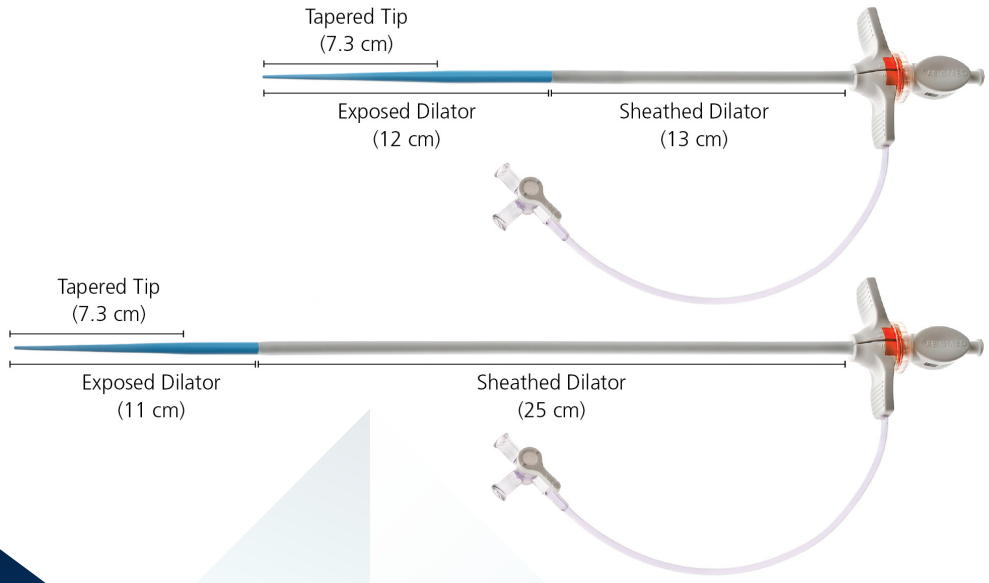
Sheath Hub:
Two wings on hub provide grip to peel sheath.

Sheath Body:
Flexible, kink resistant sheath body with two score lines to peel sheath after catheter insertion.

Dilator:
Silicone coated dilator with long tapered tip. Screws into sheath hub.

Enhanced Tip Design

Long Tapered Dilator Tip:
Elongated dilator and tapered portion of the sheath tip to provide a longer transition between the initial diameter and the final 14 Fr diameter



ABIOMED®
Recovering hearts. Saving lives.

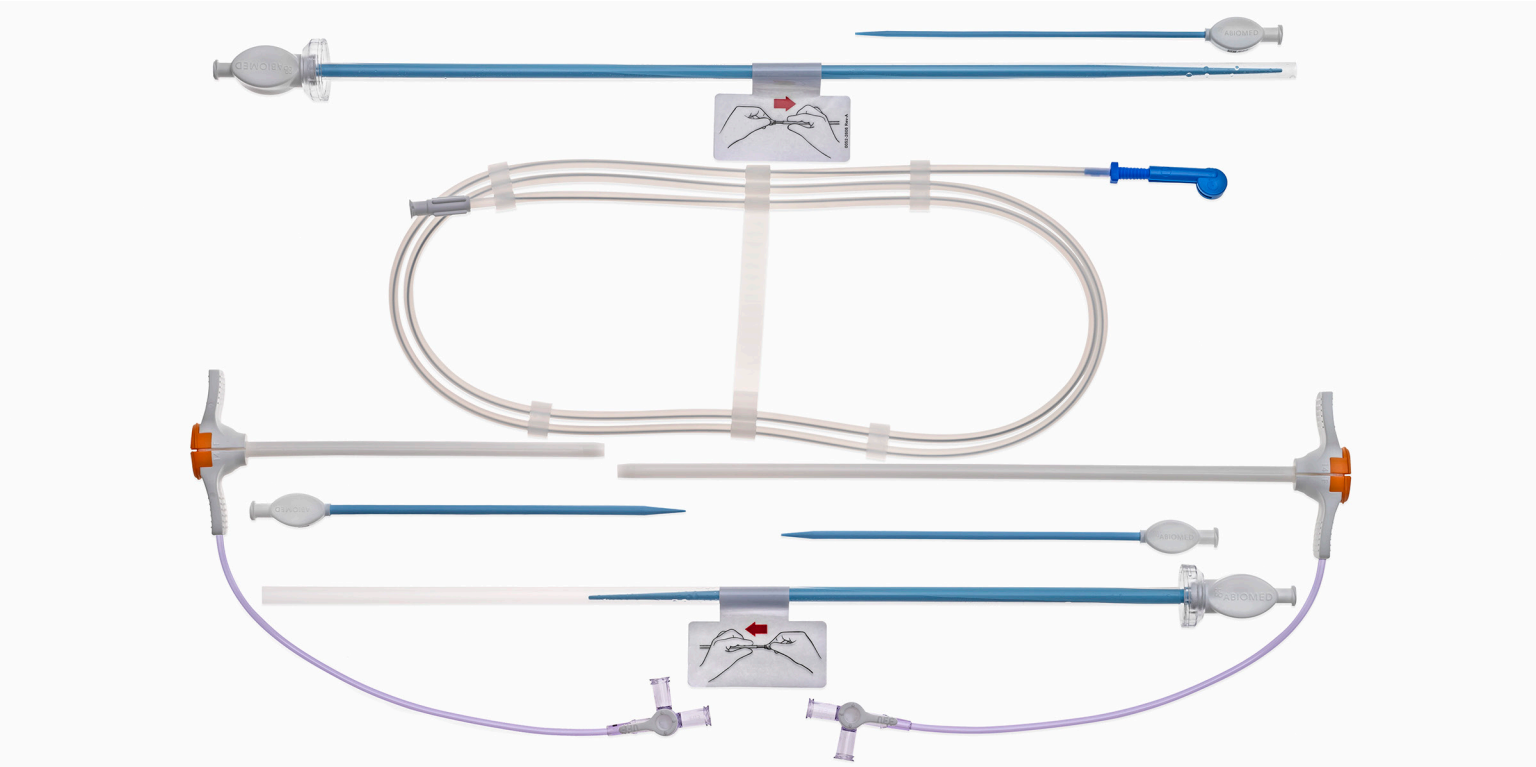
Abiomed® 14 Fr Sheath

Accessories

Introducer Kit

Part number: 0052-3046

- 14 Fr x 13 cm and a 14 Fr x 25 cm Peel-away introducer with hemostatic valve
- 8 Fr, 10 Fr, 12 Fr, and 14 Fr Dilators
- 0.035" X 150 cm Guidewire (0052-3047)



High-Risk PCI
The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Cardiogenic Shock
The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

EMERGENCY USE AUTHORIZATION:
Impella Left Ventricular (LV) Support Systems (Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, and Impella 5.5 with SmartAssist) are authorized for emergency use by HCPs in the hospital setting for providing temporary (≤ 4 days for Impella 2.5, Impella CP, and Impella CP with SmartAssist; and ≤ 14 days for Impella 5.0 and Impella 5.5 with SmartAssist) LV unloading and support to treat critical care patients (i.e. patients in the intensive care unit) with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support. The Impella LV Support Systems have neither been cleared or approved for the authorized indication for use. The Impella LV Support Systems have been authorized for the above emergency use by the FDA under an EUA. The Impella LV Support Systems have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Important Risk Information for Impella devices

CONTRAINDICATIONS:
The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade* *This condition is a contraindication for the cardiogenic shock indication only.

POTENTIAL ADVERSE EVENTS:
Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices. Visit ***http://www.abiomed.com/important-safety-information*** to learn more.

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