

WARNING: When re-accessing the sheath body prior to sheath removal, the guidewire may dislodge thrombus from the sheath body lumen.
Note: The presence of thrombus may be observed in the syringe following aspiration.

- Remove the entire sheath from the vessel.
WARNING: Do NOT apply manual pressure while removing the sheath as this could result in trauma to vessel or arteriotomy leading to bleeding complications.

- Obtain hemostasis with manual pressure or with vascular closure device per physician discretion.

Pump & Sheath Removal: Additional Techniques

WARNING: Thrombus formation is possible when using an indwelling sheath. Consider the risk of thrombus dislodgement throughout the patient's course of treatment, including sheath flushing, use as an arterial line, catheter manipulation, and device removal.

To minimize the risk of thrombus dislodgment at the time of Impella CP with SmartAssist pump removal or the removal of the 14Fr Low Profile Sheath, consider the following steps during product use.

- During prolonged sheath use, reduce or eliminate all sheath lumen flushing.
- When ready to remove the Impella CP with SmartAssist pump, aspirate the sheath body. Aspirations may be repeated, if clinically reasonable, when thrombus remains present within the syringe.
- Prior to Impella CP with SmartAssist pump removal, attach a syringe to the sheath sidearm and open the stopcock. Leave the stopcock open during pump removal.
Note: The syringe plunger may retract during pump removal, filling the syringe with blood and/or thrombus.
- Prior to replacement of the guidewire, remove any visible thrombus from the outer hub. Consider aspiration of the outer hub with a slip tip syringe, placed through and around the valve.
- Advance a guidewire cheater approximately 2cm through the sheath valve, to allow brief back bleeding before placing the re-access guidewire through the sheath.
- Remove the Impella CP with SmartAssist and 14Fr Low Profile Sheath together as a single unit.
Note: Consider the implications of wire access and vascular closure strategy prior to removing the system.

HANDLING AND STORAGE

- The device should be stored at temperatures between 10° C and 25° C (50° F and 77° F).

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SYMBOL	SYMBOL TITLE	REFERENCE	STANDARD TITLE	EXPLANATORY TEXT
	Consult instructions for use	ISO 15223-1:2016 and ISO 15223-1:2020 Reference no. 5.4.3. (ISO 7000-1641) Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates the need for the user to consult the instructions for use.
	Prescription only	N/A	N/A	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Do not resterilize	ISO 15223-1:2016 Reference no. 5.2.6. (ISO 7000-2608)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that is not to be resterilized.
	Temperature Limit	ISO 15223-1 Reference no. 5.3.7 (ISO 7000-0632)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if package is damaged	ISO 15223-1:2016 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that should not be used if the package has been damaged or opened.
	Date of manufacture	ISO 15223-1:2016 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates the date when the medical device was manufactured.
	Manufacturer	ISO 15223-1:2016 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates the medical device manufacturer
	Non-pyrogenic	ISO 15223-1:2016 Reference no. 5.6.3. (ISO 7000-2724)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that is non-pyrogenic.
	Use-by date	ISO 15223-1:2016 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates the date after which the medical device is not to be used.
	Do not reuse	ISO 15223-1:2016E Reference no. 5.4.2. (ISO 7000-1051)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Keep dry	ISO 15223-1:2016 and ISO 15223-1:2020 Reference no. 5.3.4. (ISO 7000-0626)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight	ISO 15223-1:2016 Reference no. 5.3.2. (ISO 7000-0624)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that needs protection from light sources.
	Sterilized using ethylene oxide.	ISO 15223-1:2016 Reference no. 5.2.4. (ISO 7000-2501)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates a medical device that has been sterilized using ethylene oxide.
	Batch code	ISO 15223-1:2016 ISO 7000-2492	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Indicates the manufacturer's batch code so that the batch or lot can be identified.



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For U.S.-California Only.
 Proposition 65, a State of California voter initiative, requires the following notice:
WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm

Mat: 3000140 Rev. D
 Doc: 10002086 Rev. D
 August 2025

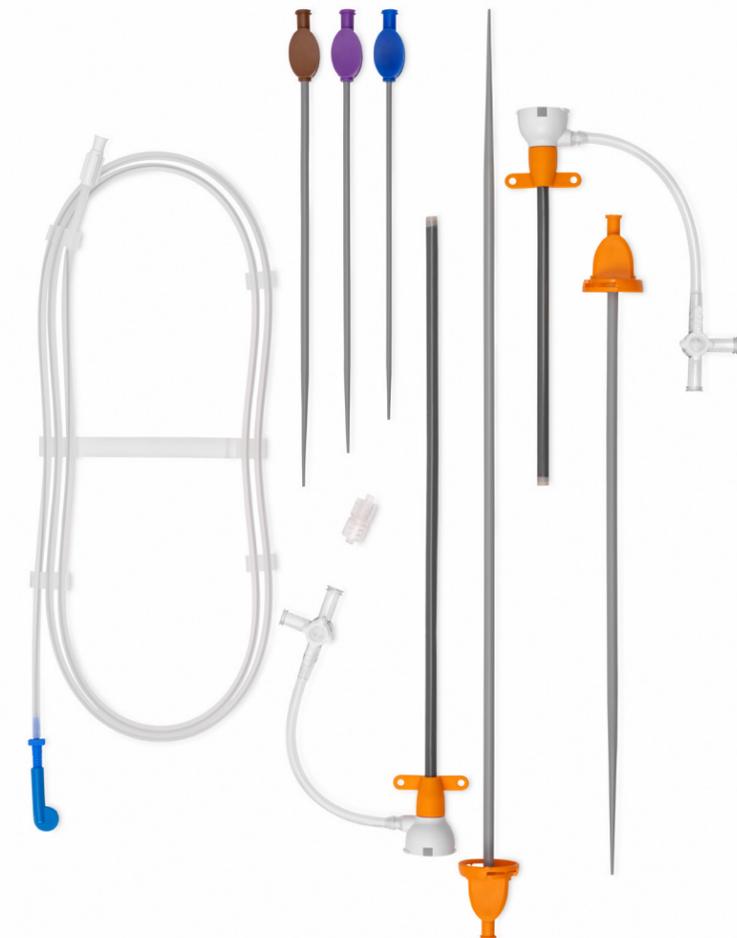
14Fr Low Profile Introducer Kit
 for the Impella CP® with SmartAssist®
 INSTRUCTIONS FOR USE



Kit Contents:

- 1 or 2* - Sheath(s), 14Fr, 13 cm and/or 25 cm, ID 4.9 mm
- 1 or 2* - Hydrophilic Coated Dilator(s), 14Fr, 25 cm and/or 37 cm, OD 5.0 mm
- 1 - Supplemental Dilator, 8Fr, 15 cm
- 1 - Supplemental Dilator, 10Fr, 16.5 cm
- 1 - Supplemental Dilator, 12Fr, 18 cm
- 1 - Guidewire, 0.035 in, 150 cm, 3 mm Modified J Tip
- 1 - Male-to-Male Luer Connector

Rx Only



* Configurations vary. One or two sheaths with accompanying dilators will be placed within the kit



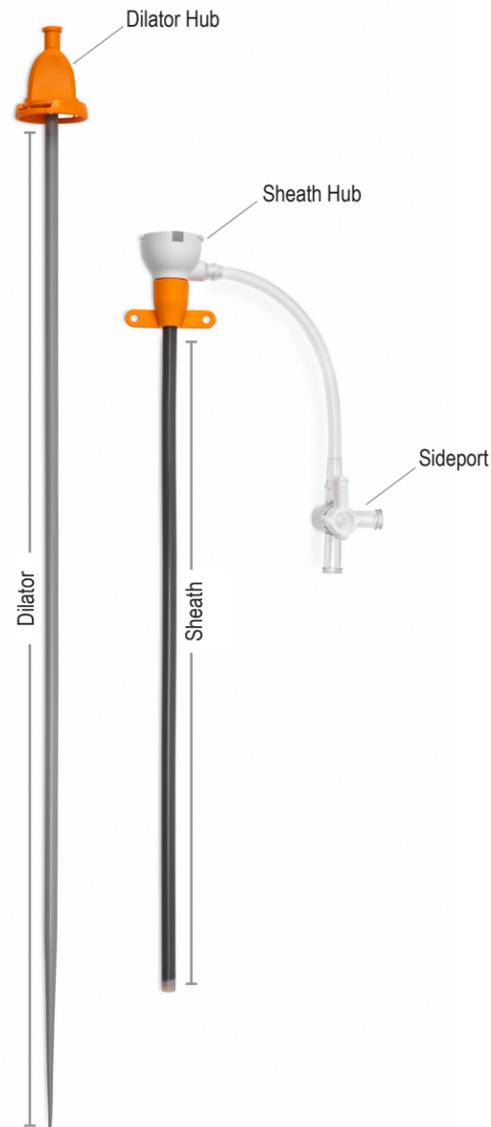


Figure 2: 14 Fr Low Profile Introducer



Figure 3: Sheath and Dilator assembly

en English - Instructions for Use

INDICATIONS FOR USE

The 14Fr Low Profile Introducer Kit is intended to facilitate access to the vascular system for the introduction and removal of the Impella Impella CP with SmartAssist and ancillary devices.

DEVICE DESCRIPTION

The 14Fr Low Profile Introducer Sheath consists of a sheath hub with a hemostasis valve, sideport with three-way stopcock, and a radiopaque sheath body. The 14Fr Low Profile Introducer Kits consist of:

- One (1) or two (2) 14Fr Low Profile sheath(s) (13 cm and/or 25 cm)
- One (1) or two (2) 14Fr hydrophilic coated, tapered dilator(s) (25 cm and/or 37 cm)
- Three (3) optional supplemental dilators (8Fr, 10Fr, 12Fr)
- One (1) 0.035" delivery guidewire
- One (1) male to male luer connector

WARNINGS

- Before inserting the sheath into the patient, flush the sheath and dilator to remove air bubbles and any potential particulate.
- Do not attempt to insert a catheter or interventional device having a diameter larger than the introducer sheath size. Device damage or breakage may result.
- Do not attempt to place a guidewire with a maximum diameter greater than 0.035" (0.89 mm) through the dilator.
- Do not advance or withdraw guidewire or sheath when resistance is met. Evaluate with fluoroscopic imaging prior to taking additional action.
- Thrombus formation is always possible when using an indwelling sheath. Consider the risk of thrombus dislodgement throughout product use including sheath flushing, use as an arterial line, catheter manipulation, and device removal.
- The 14Fr Low Profile Introducer Kit is supplied in sterile packaging. To ensure the sterile barrier has been maintained, do not use the device if the package has been opened or damaged.
- [During Single Access procedure] When blood return is observed, stop advancing the needle. Needle puncture too deep or too close to the valve center may damage the Impella CP with SmartAssist or hemostatic valve.
- Do NOT kink the Impella CP with SmartAssist catheter or sheath.
- To reduce the risk of limb ischemia, consider pre, peri, or post-procedural limb assessments to prevent or identify limb ischemia when clinically feasible. Given the multiple anatomic and physiological situations which may cause limb ischemia, if limb ischemia is identified and if clinically appropriate, consider adjusting medical therapy (including vasoactive medications), repositioning the procedural sheath, placement of an antegrade perfusion sheath, or device removal, as necessary. Other access locations for the use of Impella may be considered for patients requiring continued mechanical circulatory support.
- Infusion through the sideport can be done only after all air is removed from the unit.
- The sheath stopcock must remain in the closed position when not in use. Significant blood loss can occur if left open.
- Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve membrane resulting in blood flow through the valve.
- Do not use the 14Fr Low Profile Sheath if there are signs of device damage. Damage may include, but is not limited to, other kit contents, sheath body kinks or buckling, cracks, broken components, and excess or missing components.
- Placing an occlusive dressing over the anticontamination sleeve may cause the sleeve to tear during dressing management.
- Avoid or minimize contact with exposed sections of catheter that could be snagged or place pressure on the catheter, which may result in Impella CP with SmartAssist catheter movement.
- Thrombus may form within the sheath body lumen and the possibility of thrombus dislodgement should be considered when determining aspiration and flush protocols.
- Aspiration and flush, continuous infusion, or other techniques may not totally prevent thrombus formation within the sheath body lumen.

- Flushing the sheath body may increase the risk of thrombus dislodgment.
- When re-accessing the sheath body prior to sheath removal, the guidewire may dislodge thrombus from the sheath body lumen.
- Do NOT apply manual pressure while removing the sheath as this could result in trauma to vessel or arteriotomy leading to bleeding complications.

ADVERSE EFFECTS

Adverse effects and possible complications that may be associated with use of the 14Fr Low Profile Introducer Kit include, but are not limited to: Embolism, Major Bleed, Death, Ischemia, Sepsis, Stroke, Toxic reaction, Hemorrhagic Shock, Vessel damage, Allergic Reaction, Arterial Spasm, Surgical Intervention, Catheter Damage/Malposition, Peripheral Vascular Occlusion, X-ray radiation exposure may cause adverse events including, but not limited to, alopecia, burns, cataracts, or delayed neoplasia (cancers).

CAUTIONS

- Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.
- Procedure must be performed by medical personnel trained in anatomical landmarks, safe techniques, and potential complications.
- Do not alter this device, including cutting to alter length. Alterations may impair device function.
- Handle with care. The components of The 14Fr Low Profile Introducer Kit can be damaged during removal from packaging, or during preparation, insertion, and/or removal. Do NOT bend, pull, or use excess force on the components of the Introducer Kit at any time.
- Do not use after the expiration date printed on the label.
- Limit exposure to X-ray radiation doses to patients and physicians; reduce fluoroscopy time and use shielding where possible.
- The product is designed for single use only. Do not resterilize or reuse.
- If planning to exchange for a new Impella CP with SmartAssist device, replace the 14Fr Low Profile Sheath.

Table 1: 14 Fr Low Profile Introducer Kit Dimensions

14 FR LOW PROFILE INTRODUCER KIT	
Sheath	
Sheath Size	14Fr
Effective Length(s)	13 cm and/or 25 cm
Sheath Dilator	
Dilator Length(s)	25 cm and/or 37 cm
Hydrophilic Coating Length	12.5 cm
Supplemental Dilator	
Dilator Size	8Fr, 10Fr, 12Fr
Dilator Length	15 cm, 16.5 cm, 18 cm
Compatible Stiff Guidewire	
Diameter	0.035"
Guidewire Length	150 cm

14Fr Low Profile Introducer Preparation

Always use sterile technique. The suggested procedural steps are:

1. Peel open the pouch and place contents on the sterile field. Do not use if damaged or defective.
 - Caution:** Do not use the 14Fr Low Profile Sheath if there are signs of device damage. Damage may include, but is not limited to, other kit contents, sheath body kinks or buckling, cracks, broken components, and excess or missing components.
2. Flush the central lumen of the sheath via the side arm, then turn the stopcock to the off position.
3. Flush the central lumen of the 14Fr tapered dilator with saline.

4. Wet the distal 20 cm of the 14Fr tapered dilator with saline deposited on the outside of the device by a syringe to activate the hydrophilic coating.
5. Insert 14Fr tapered dilator into sheath. Align the arrows on the dilator with the gray regions marked on the sheath hub and push the dilator until the orange cap meets the sheath hub. To secure the dilator to the sheath, rotate the hub of the dilator clockwise 1/4 turn until a "click" is felt.

14Fr Low Profile Introducer Use

For all procedural steps, consider the use of fluoroscopy.

1. Obtain access to the femoral artery following accepted clinical practice for vessel puncture or incision and guidewire insertion. Refer to the Impella CP with SmartAssist Instructions for Use (SPEC-4552) on heartrecovery.com/ifu for recommended best practices.
2. If necessary, pre-dilate the vessel using the supplied supplemental dilators by threading the dilator over the guidewire and advancing into the vessel.
 - Note:** Rotate the sidearm of the sheath to the desired side prior to insertion.
3. Insert 14Fr Low Profile Sheath over the provided 0.035" wire, advancing into the vessel under fluoroscopic guidance until the orange suture pad is flush with the surface of the skin.
 - WARNING:** Do NOT advance or withdraw guidewire or sheath when resistance is met. Evaluate with fluoroscopic imaging prior to taking additional action.
4. The dilator should be left in place until the administered systemic anticoagulation achieves an ACT greater than 250 seconds.
5. To remove the dilator, rotate the hub of the dilator counterclockwise 1/4 turn to unlock, then slowly retract the guidewire and dilator, leaving the sheath in position.
 - WARNING:** Dilators and catheters should be removed slowly from the sheath. Rapid removal may damage the valve membrane resulting in blood loss through the valve.
6. Aspirate and flush the sheath lumen using a syringe connected to the side port.
 - WARNING:** Infusion through the sideport can be done only after all air is removed from the unit.
7. Perform a femoral angiogram to evaluate distal flow.
8. Introduce and advance the Impella CP with SmartAssist through the sheath. For these steps, refer to the Impella CP with SmartAssist Instructions for Use (SPEC-4552) on heartrecovery.com/ifu.
9. If desired, suture the sheath to the patient's skin using the suture pad and a forward suture technique.

Single Access with 7Fr Low Profile Companion Sheath

Always use sterile technique. Below is a suggested procedure for secondary access through the 14Fr sheath with a 9Fr Impella CP with SmartAssist catheter inserted through its valve. Refer to the 7Fr Low Profile Companion Sheath IFU for setup instructions.

1. Aspirate and flush 14Fr Low Profile sheath using a syringe connected to the sideport.
2. Utilizing the guide markers in the foam, place a 18G needle through the diaphragm of the 14Fr Low Profile Sheath at the 2 o'clock or 10 o'clock position parallel to the 9 Fr Impella CP with SmartAssist catheter until blood return is observed.
 - WARNING:** When blood return is observed, stop advancing the needle. Needle puncture too deep or too close the valve center may damage the SmartAssist catheter or hemostatic valve.
3. Insert J-tip of 0.035" guidewire to the required depth.
 - Note:** At no time should the guidewire be advanced or withdrawn when resistance is met.
4. With the Impella CP with SmartAssist secured, insert the 7Fr Low Profile Companion Sheath over 0.035" guidewire.
 - Note:** While performing Single Access, if bleeding is observed, remove all devices in the secondary access location and assess for hemostasis. If hemostasis is

- observed, regain access at a position not previously used in initial access.
5. Prior to inserting intervention equipment, flush the 7Fr Low Profile Companion Sheath by using a syringe connected to the sideport.
6. Complete Percutaneous Coronary Intervention procedure per physician discretion.
7. Remove the 7Fr Low Profile Companion Sheath at the end of the PCI procedure while securing the Impella CP with SmartAssist.

Prepping the 14Fr Low Profile Sheath and Impella CP with SmartAssist for Transfer to the Intensive Care Unit

Please refer to the Impella CP® with SmartAssist® Instructions for Use (SPEC-4552) on heartrecovery.com/ifu for management instructions of the Impella CP with SmartAssist in the ICU setting. Prior to transferring the patient out of the procedure room, confirm blood flow in the distal limb by repeating angiography through the sheath and assessing pedal pulses are present using manual palpation or the use of Doppler ultrasound.

1. Secure the 14Fr Low Profile sheath to skin at groin site utilizing forward tension sutures through the orange suture pad.

Managing the 14Fr Low Profile Sheath with Impella CP with SmartAssist in the ICU

While the 14Fr Low Profile Sheath dwells in the ICU, maintain sheath patency per hospital protocol.

The 14Fr Low Profile Sheath sidearm can be used for invasive arterial pressure monitoring when connected to a pressure transducer. Maintain arterial line patency per hospital protocol.

WARNING: Thrombus may form within the sheath body lumen, and the possibility of thrombus dislodgment should be considered when determining aspiration and flush protocols.

WARNING: Aspiration and flush, continuous infusion, or other techniques may not prevent thrombus formation within the sheath body lumen.

When managing the Impella CP with SmartAssist pump, refer to the Impella CP with SmartAssist Instructions for Use (SPEC-4552) on heartrecovery.com/ifu.

Removing the Impella CP with SmartAssist & 14Fr Low Profile Sheath

Pump Removal

Additional equipment such as fluoroscopy and/or vascular closure devices may be utilized to remove the 14Fr Low Profile Sheath. The decision to remove the device in the ICU or procedure room should be based on the availability of equipment and personnel to optimize patient safety. Prior to explant:

1. Refer to the Impella CP with SmartAssist Instructions for Use (SPEC-4552) on heartrecovery.com/ifu for weaning and removal procedures.
2. If necessary, remove access site dressings and sutures from the Impella CP with SmartAssist.
3. Use a 20mL syringe to fully aspirate through sheath sidearm.
 - WARNING:** Flushing the sheath body may increase the risk of thrombus dislodgment.
 - Note:** The presence of thrombus may be observed in the syringe following aspiration.
4. Fully remove the Impella CP with SmartAssist catheter through the sheath.
 - Note:** Ensure P-Level is at P-0 prior to Impella CP with SmartAssist catheter removal.

Sheath Removal

5. Prior to sheath removal, ensure the ACT is below 150 seconds or in accordance with hospital protocol.
6. Aspirate using a 20ml syringe.
 - WARNING:** Flushing the sheath body may increase the risk of thrombus dislodgment.