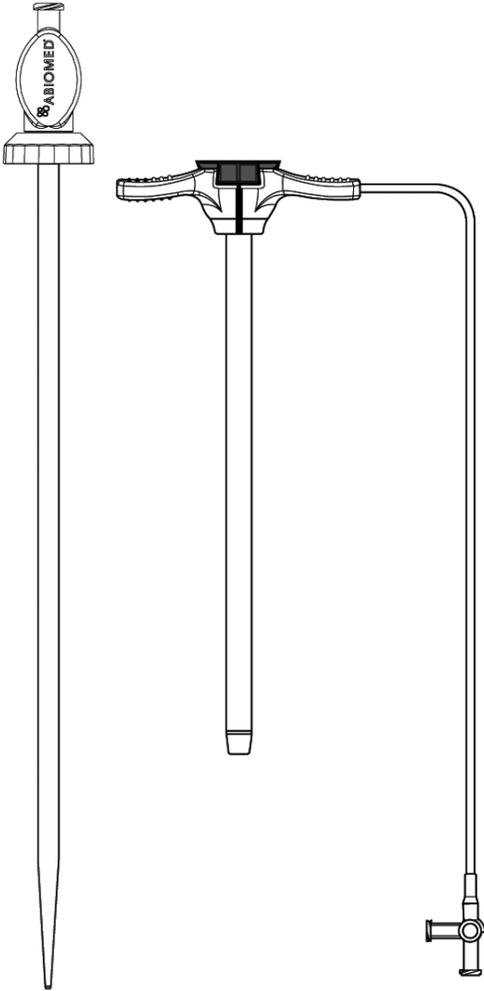


INSTRUCTIONS FOR USE



Explanation of symbols on package labeling

Refer to the outer package label to see which symbols apply to this product.



ATTENTION! Consult the accompanying documentation



Single use only



Use before date



Method of sterilization using ethylene oxide gas



Lot number



Model number



Store in a cool, dark, dry place



Temperature limitation



Date of manufacture



Manufacturer



European representative



Do not resterilize!



Do not use if packaging is damaged!



By prescription only



Sterilization lot



Length



Inside diameter



Quantity

IMPELLA CP INTRODUCER

Hemostatic Peel-Away Introducer System with Infusion Sideport

1. INDICATIONS FOR USE

The Impella CP Introducer is intended for introduction of pacing leads or catheters into the body.

2. DEVICE DESCRIPTION

The introducer set is composed of sheath, dilator(s) and guidewire.

3. CAUTIONS

- Device is supplied sterile. Do not use if package has been previously opened or damaged.
- Prior to use, read all package inserts, warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
- Procedure must be performed by trained medical personnel well versed in anatomical landmarks, safe technique, and potential complications.
- The product is designed for single use only.
- Do not resterilize or reuse. Do not alter the product in any way.
- If you have any questions, please call Abiomed Inc. at (800) 422-8666.

4. ADVERSE EFFECTS/POSSIBLE COMPLICATIONS

- Air embolism
- Bleeding
- Hematoma formation
- Vessel damage

5. PRECAUTIONS

- When assembling the sheath and dilator, care must be taken to insert the dilator tip straight through the center of the valve membrane in order to prevent inadvertent puncturing of the membrane.
- Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation.
- Infusion through the sideport can be done only after all air is removed from the unit.
- Indwelling introducer sheaths should be internally supported by a catheter, lead, or dilator.
- Dilators, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve membrane resulting in blood flow through the valve.
- Never advance or withdraw guidewire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action.
- When injecting or aspirating through the sheath, use the sideport only.

IMPELLA CP® INTRODUCER

Hemostatic Peel-Away Introducer System
with Infusion Sideport

6. DIRECTIONS FOR USE

Always use sterile technique.

Below is a suggested procedure:

1. Peel open package and place contents on sterile field.
2. Prep skin and drape in area of anticipated puncture as desired.
3. The angle of the needle should be adjusted depending on the patient's build: shallow in a thin person, deeper in a heavyset person.
4. Insert needle into vessel. The needle position should be verified by blood return.
5. Aspirate the puncture needle using the syringe.
6. Remove the syringe and insert soft tip of guidewire through the introducer needle into the vessel. Advance the guidewire to the required depth. Leave an appropriate amount of guidewire exposed.

At no time should the guidewire be advanced or withdrawn when resistance is met.

Determine the cause of resistance before proceeding. Fluoroscopic verification of the guidewire's entrance into the vessel is suggested.

7. Hold guidewire in place and remove introducer needle. Do not withdraw the guidewire back into the cannula as this may result in separation of the guidewire. The cannula should be removed first.
8. If necessary, pre-dilate the vessel using the supplied supplemental dilators by threading the dilator over the guidewire and advancing into the vessel.
9. Insert vessel dilator into sheath and rotate the dilator cap over valve housing to secure the dilator onto sheath assembly (see Figure 1).
10. Thread the dilator/sheath assembly over the guidewire.
11. Advance the dilator and sheath together with a twisting motion over the guidewire and into the vessel. Fluoroscopic observation may be advisable. Attaching a clamp or hemostat to the proximal end of the guidewire will prevent inadvertently advancing the guidewire entirely into the patient.
12. Once assembly is fully introduced into the vascular system, separate the dilator cap from the sheath valve housing by rotating the dilator cap off the hub.
13. Slowly retract the guidewire and dilator, leaving the sheath in position. The hemostasis valve will reduce the loss of blood and the inadvertent aspiration of air through the sheath.
14. Aspirate all air from the sheath valve assembly by using a syringe connected to the sideport. Flush the introducer through the sideport. If the introducer is to remain in place during catheter positioning and testing, flushing the introducer via the sideport periodically with saline is advised.
15. Introduce the catheter through the hemostasis valve/sheath and advance it into position.

Introducer Removal

16. Flush the sheath with 5 cc of saline immediately before peeling the sheath away in order to minimize backbleeding.
17. First, completely **withdraw the sheath from the vessel**.
18. Then remove the sheath by sharply snapping the tabs of the valve housing in a plane perpendicular to the long axis of the sheath to split the valve and peel the sheath apart (see Figure 2).

Always use sterile technique. Below is a suggested procedure for secondary access through the 14F sheath with a 9 F catheter inserted through its valve:

1. Aspirate and flush the sheath using a syringe connected to the sideport.
2. Pierce the valve with an access needle (18 or 21 gauge) at the 2 or 10 o'clock position until blood return (see Figure 3).
3. Insert soft tip of 0.018" guidewire through the access needle and advance to required depth. Remove needle and insert assembled 4F sheath and dilator.
4. Remove 4F dilator and insert soft tip of 0.035" guidewire to required depth through the 4F sheath. At no time should the guidewire be advanced or withdrawn when resistance is met.
5. Remove 4F sheath and insert assembled secondary sheath (up to 7F) and dilator over 0.035" guidewire. **Secure primary catheter when inserting second introducer.** At no time should the sheath be advanced or withdrawn when resistance is met. It is recommended that the secondary sheath have a hydrophilic coating.
6. Aspirate and flush the sheath using a syringe connected to the sideport. If the introducer is to remain in place during catheter positioning and testing, flushing the introducer via the sideport periodically with saline is advised.
7. **When removing secondary sheath, primary catheter must be secured.**

7. HANDLING AND STORAGE

Avoid subjecting the device to unusual stresses. The device should be stored at temperatures between 5° C and 30° C (41° F - 86° F).

8. U.S. LIMITED WARRANTY AND DISCLAIMER:

Abiomed Inc. hereby warrants that if any Abiomed Inc. product fails to perform within normal tolerances due to a defect in materials or workmanship, Abiomed Inc. will provide, at no charge, a replacement of Abiomed Inc. product. This limited warranty applies only if each of the following conditions are met:

- A. The product was designed, manufactured and distributed by Abiomed Inc.
- B. The product has not been mishandled, reprocessed, or altered in any way.
- C. The product was used before the "USE BEFORE" date marked on the packaging of the product.
- D. The failed product must be returned to Abiomed Inc. and becomes the property of Abiomed Inc.

No representation or warranty is made that an Abiomed Inc. product will not fail. Abiomed Inc. disclaims responsibility for any medical complications, including death, resulting from the use of its products.

Except as expressly provided by this limited warranty, Abiomed Inc. is not responsible for any direct, incidental, or consequential damages based on any defect, failure, or malfunction of its products whether the claim is based on warranty, contract, tort, or otherwise. Some states do not allow the exclusion or limitation of consequential damages and so the above limitation or exclusion may not apply to you.

Except as expressly provided by the limited warranty, Abiomed Inc. makes no warranty, express or implied, including but not limited to, any implied warranty of merchantability, or fitness for a particular purpose.

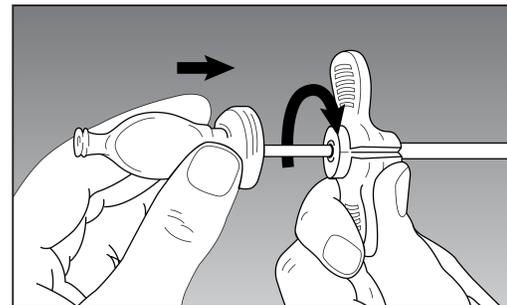


Figure 1

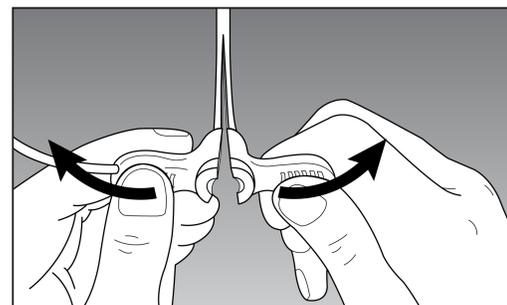


Figure 2

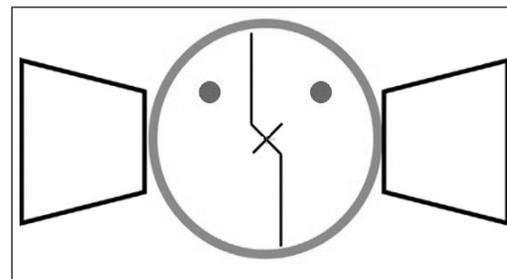


Figure 3

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