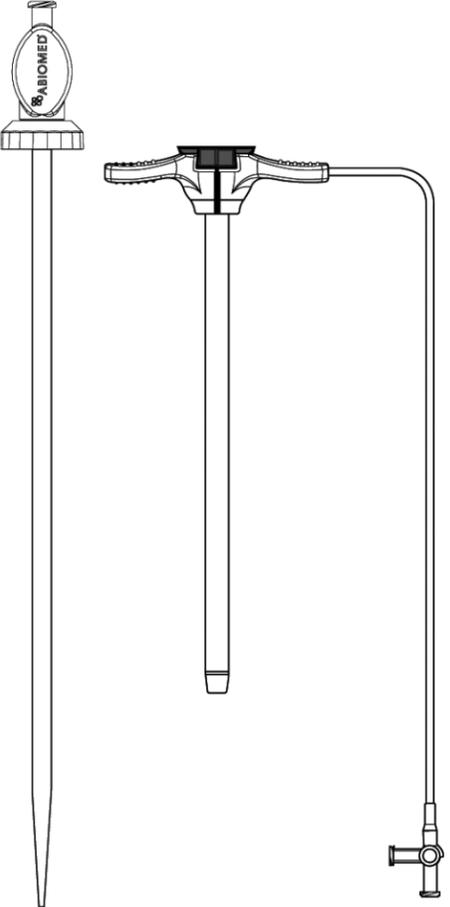




# ABIOMED 23 F INTRODUCER

Hemostatic Peel-Away Introducer System with Infusion Sideport



## 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

# ABIOMED 23 F INTRODUCER

## Hemostatic Peel-Away Introducer System with Infusion Sideport

- 1. INTENDED USE**  
 The Abiomed 23 F 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.

- 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 heavysset 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).
- 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.

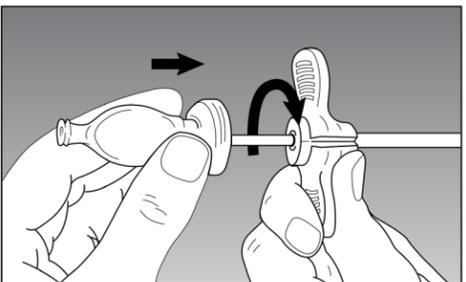


Figure 1

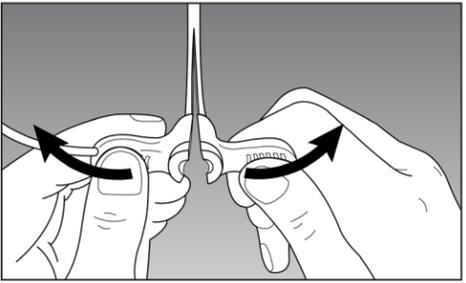


Figure 2



**Abiomed, Inc.**  
 22 Cherry Hill Drive  
 Danvers, MA 01923, USA  
 P: + 1-978-646-1400  
 E: marketing@abiomed.com  
 P: + 1-800-422-8666