

# Bunegin-Albin Air Aspiration Set

Instructions for Use



#### **BUNEGIN-ALBIN AIR ASPIRATION SET**

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

#### DEVICE DESCRIPTION

The Bunegin-Albin Air Aspiration Set includes a radiopaque and sideported catheter, a double-tipped (straight and curved) wire guide, an introducer needle, a dilator, a stopcock, a scalpel, and a syringe for use in venous air aspiration procedures.

### INTENDED USE

The Bunegin-Albin Air Aspiration Set is intended to aspirate venous air emboli.

## CONTRAINDICATIONS

None known

- Complications arising from the use of this device can result in serious injury or death; the catheter tip can erode or perforate vascular walls.
   Extreme caution must be used in device placement and monitoring.
  - Do not attempt to reposition this device by advancing or retracting the catheter against resistance or without fluoroscopy. Maintain visualization of the wire and catheter during and after placement under fluoroscopy.

#### PRECAUTIONS

- This product is intended for use by clinicians trained and experienced in proper positioning of catheters in the atrial-caval junction using percutaneous (Seldinger) technique. The Bunegin-Albin Set should be used in conjunction with fluoroscopic quidance.
- The catheter endhole should be positioned within the atrial-caval junction, with the most proximal sideport located just above the atrial-caval junction. This position allows for maximum removal of air emboli.

#### **POTENTIAL ADVERSE EVENTS**

- Thrombosis/occlusion
- · Vessel perforation
- · Cardiac tamponade
- Arrhythmia
- Vessel spasm
- Atrial perforation
   Death
- Myocardial infarction
- Dissection
   Emboli (air, thrombotic)
- Hemorrhage

## INSTRUCTIONS FOR USE For Antecubital Fossa Insertion

## **NOTE:** The catheter can be placed prior to any surgical procedure with a high risk for air embolism.

- Advance the introducer needle into the basilic or cephalic vein.
- Slide the wire guide straightener (positioned on the distal tip of the wire guide) over the "J tipped" portion of the wire guide.
- Under fluoroscopic visualization, pass the straightened wire guide through the introducer needle and advance it to the atrial-caval junction.
- 4. Withdraw the introducer needle, leaving the wire guide in place.
- Enlarge puncture site with a scalpel blade. If dilation is required, the dilator can be advanced over the wire guide and removed prior to insertion of the catheter.
- Advance the catheter over the wire guide until it is proximal to the atrialcaval junction. NOTE: Under fluoroscopic visualization, ensure that the wire guide always precedes the catheter tip when advancing the catheter and wire guide into the vessel.
- 7. Advance the catheter tip to the atrial-caval junction.
- 8. Confirm proper position of the catheter tip via fluoroscopy, then remove the wire guide while leaving the catheter in place.
- 9. Connect the syringe to the stopcock.
- Remove all air/saline from the syringe by opening the stopcock and pushing the plunger forward.
- Close the stopcock and attach the stopcock/syringe assembly to the catheter.
- Reconfirm correct catheter position via fluoroscopy.
- Open the stopcock and slowly advance the catheter into the air emboli.
   Pull back the syringe plunger to aspirate the emboli.
- 14. After the embolus is aspirated, turn the stopcock to the closed position and remove the air from the syringe. Repeat aspiration as necessary to remove the desired amount of air embolus.

15. Once the aspiration process is complete, turn the stopcock to the closed position and remove the Bunegin-Albin Catheter from the patient via standard hospital protocol.

### **HOW SUPPLIED**

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

A symbol glossary can be found at https://cookmedical.com/symbol-glossary



MANUFACTURER

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