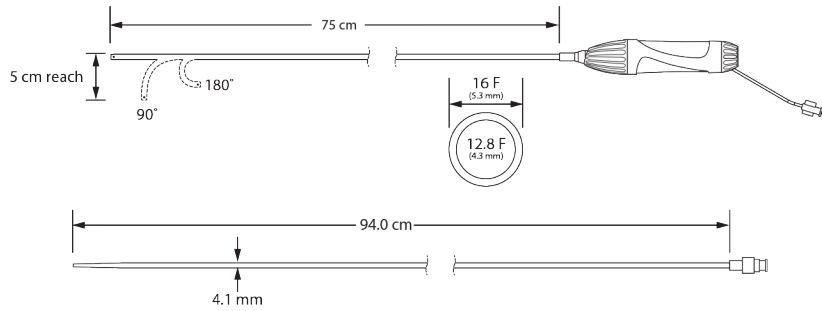


900002 AcQGuide® MAX Steerable Sheath



Instructions for Use

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

AcQGuide Steerable Sheath Description

The AcQGuide Steerable Sheath (AcQGuide) is a percutaneous catheter introducer designed to provide additional maneuverability to catheters that are advanced through the sheath and into the right or left chambers of the heart. The AcQGuide is a single use, disposable, steerable intravascular device. It is comprised of a composite structured single lumen shaft, an ergonomic handle to provide torque and active deflection, and a hemostasis valve with side flush port, to allow safe introduction of a catheter while simultaneously permitting saline to be flushed via the main shaft.

Intended Use

The AcQGuide is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The AcQGuide deflection facilitates catheter positioning.

Contraindications

Use of the AcQGuide is contraindicated for placement in the left atrium or ventricle if:

- The patient has an intra-atrial septal patch or has had other surgical intervention in or adjacent to the intra-atrial septum.
- The patient has had a previous embolic event from the left side of the heart within two months of the procedure.
- The patient has known or suspected atrial myxoma.

AcQGuide should not be used to perform the transeptal puncture.

Warnings and Precautions

Air aspiration - Remove the guide wire and dilator from the sheath or insert the catheter into the sheath before aspirating and flushing the sheath, minimizing the aspiration or air through the valve of the sheath.

Anticoagulation - Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transeptal cardiac procedures and for selected patients undergoing right-sided procedures. Administer anticoagulation therapy during and post-procedure according to institution standards to minimize bleeding and thrombotic complications.

Disposal - Dispose of used devices and sterile components in accordance with hospital procedures.

Embolism risk - Introducing any catheter or sheath into the circulatory system entails the risk of air or gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. To minimize the risk of air embolism, always advance and withdraw components slowly to minimize the vacuum created.

- Do not aspirate steerable sheath with a guidewire in place through the hemostatic valve. Aspiration with a guidewire through the valve may cause air embolism which can result in significant morbidity or death.
- For injecting or aspirating through the sheath, use the sideport only with a three-way stopcock. Prior to infusion, remove all air using the sideport.

Femoral vein damage - Take care to minimize damage to the femoral vein and access site upon sheath insertion, manipulation, or withdrawal. Complications associated with femoral vein catheterization include hematoma and thrombosis.

Fluoroscopy Guidance - Use of fluoroscopy during sheath manipulation and placement is advised. Manipulating the sheath without fluoroscopy may result in damage to cardiac and vascular structures.

Frequent flushing - Regular flushing of the sheath and dilator lumen is recommended to prevent blood stagnation, clots, air emboli, and serious patient injury. Flushing is recommended after each contrast injection to prevent contrast solution from sticking inside the lumen.

Handling and care-

- Use extreme care when manipulating the device. Lack of careful attention can result in injury such as perforation, tamponade, induction of arrhythmia or heart block.
- Do not use excessive force to advance or withdraw the device, especially if resistance is encountered. Determine cause by fluoroscopy and then take remedial action.
- Avoid positioning the device around the chordae tendineae, as this increases the likelihood of entrapment within the heart, which may necessitate surgical intervention or repair of injured tissues.
- Do not use if the sheath is kinked or damaged

Inspection - Inspect the sterile packaging and device before use. Do not use the AcQGuide if the package is open and/or the sterile barrier is broken.

Magnetic Resonance Imaging - The AcQGuide is not compatible with MRI.

Prosthetic heart valves - Do not pass the device through a prosthetic heart valve (mechanical or tissue). The device may become trapped in the valve, damaging the valve causing valvular insufficiency or premature failure of the prosthetic valve.

Power Injection - Do not connect a power injection syringe to the sideport and inject contrast solution.

Qualified Users - Only physicians thoroughly trained in electrophysiology procedures should use the AcQGuide.

Required use environment - Cardiac catheterization procedures should be performed only in a fully equipped facility.

Sheath support - Indwelling sheath should be internally supported by a catheter, electrode, or dilator to reduce the potential for the device to kink or collapse.

Side port obstruction - Prevent any obstruction of the side port to ensure continuity of the saline flush.

Significant blood leakage - Ensure there is not significant blood leakage through the hemostatic valve during the procedure.

Single Use - The AcQGuide is intended for single procedure use only. Do not attempt to reuse or re-sterilize as this may increase the risk of compromised device performance, cross-contamination from the device that could result in or patient injury, illness or death.

Storage - The AcQGuide should be stored in a cool and dry place.

Transeptal puncture - The AcQGuide Sheath and dilator have not been tested for compatibility with transeptal needles.

Use Before Date - Use prior to the "Use-by" date.

X-ray and fluoroscopic exposure - The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Extensive exposure can result in acute radiation injury and increased risk for somatic and genetic effects. Only perform procedures after giving adequate attention to the potential radiation exposure and taking steps to minimize exposure. Give careful consideration before using the device in pregnant women.

Compatibility - The AcQGuide Sheath is compatible for use with catheters up to 10.5 F in diameter. Use with catheters larger than 10.5 F has not been tested by Acutus Medical.

Potential Adverse Effects

Potential adverse effects include, but are not limited to, the following:

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| <ul style="list-style-type: none"> • Access site complications (hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage) • Air embolism • Anemia • Arrhythmias • Cardiac arrest • Chest pain/discomfort • Coronary artery spasm, dissection, thrombosis • Death • Endocarditis • Heart block, requiring permanent pacemaker • Hemothorax • Myocardial infarction | <ul style="list-style-type: none"> • Perforation or damage to vascular system • Pericardial effusion or tamponade • Pericarditis • Pleural effusion • Pneumothorax • Pseudoaneurysm • Pulmonary edema • Pulmonary embolism • Stroke • Thrombus • Transient ischemic attack (TIA) • Unintended (in)complete sinus node, AV node, or other heart block or damage • Vasovagal reactions |
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Accessories

The following supplies are not provided with the devices and need to be available and prepped per laboratory standard operating procedures prior to use of the AcQGuide:

- Introducer sheath and transeptal needle (if left atrial access is required)
- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Heparinized normal saline
- Guidewire for sheath insertion (Maximum Diameter: 0.035" [0.89mm])
- Syringe
- Three-way Stopcock
- Other supplies as needed to complete the established laboratory practice

Instructions for Use

NOTE: Before introducing the AcQGuide into the patient, test the deflection mechanism by turning the

control knob clockwise (to the right) to ensure that it is operational.

NOTE: The AcQGuide is designed for temporary use (procedure duration of eight hours or less) within the peripheral and coronary systems. Proper surgical procedures and sterile techniques are the responsibility of the medical professional.

1. Using aseptic technique, create a vascular access with an appropriate technique.
2. Insert a compatible guidewire through the vasculature and into the desired heart chamber using standard vascular access techniques.
3. Thoroughly flush the steerable sheath & dilator with either saline or heparinized saline.

NOTE: Any device/component inserted through the hemostasis valve should be wet and placed through the center of the valve to prevent tearing of the seal and leakage.

4. Wet the dilator shaft with sterile saline solution before insertion through the hemostasis valve.
5. Insert the dilator through the valve and fully into the sheath until the hub touches the back end of the hemostasis valve.
6. Thread the dilator/sheath assembly over the guidewire, using a slight twisting motion.
7. Aspirate all air from the sheath by connecting the syringe with three-way Stopcock to the side port.
8. After verifying the sheath is in neutral position, advance the dilator and sheath over the guidewire into the desired heart chamber.
9. Slowly remove the dilator and guidewire from the sheath.

CAUTION: Rapid removal may damage the valve membrane, resulting in blood flow and/or air ingress through the valve.

NOTE: Do not aspirate the steerable sheath with only a guidewire in place through the hemostatic valve.

10. Attach the sheath side port to the monitoring line. Gently aspirate blood through the side port for sampling and to make sure the sheath is clear of air. Blood should aspirate freely through the side port. Maintain anticoagulation therapy within the sheath throughout the procedure.
11. Insert the catheter through the hemostasis valve and position in the desired chamber.
12. To remove the sheath, straighten the distal section as much as possible. Turn the control knob to the left (counter clockwise) to straighten the distal section of the sheath.
13. Slowly retract the steerable sheath from the body.
14. After removal of the sheath, use standard technique to achieve hemostasis. Discard the steerable sheath after it has been removed from the body

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SERVICE

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Explanation of Symbols



Consult Instructions for Use



Do not re-sterilize



Do not re-use



Sterilized using ethylene oxide



Catalogue number



Batch code



Quantity of devices



Use-by date (YYYY-MM-DD)



Non-pyrogenic



Inner Diameter



Outer Diameter



Do not use if package is damaged



Keep dry



Keep away from sunlight



Manufacturer



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.



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