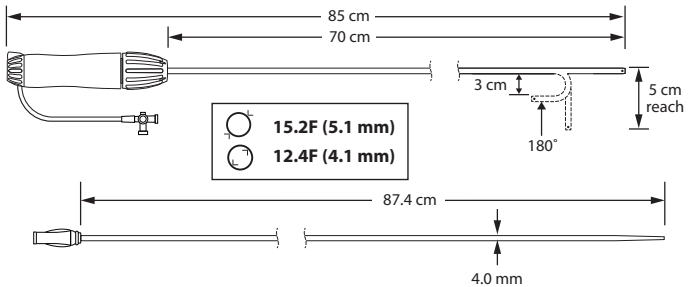
ACUTUS®
MEDICAL

900200 AcQGuide® MAX Steerable Sheath



Instructions for Use

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

Contents of Package:
The AcQGuide® MAX Steerable Sheath is supplied sterile. The contents include:

- One (1) Acutus Medical AcQGuide MAX Steerable Sheath
- One (1) Acutus Medical AcQGuide Dilator
- Product Information/Documentation (Instructions for Use)

AcQGuide Steerable Sheath Description
The AcQGuide MAX Steerable Sheath is a single use, percutaneous catheter introducer designed to provide additional maneuverability to interventional catheters that are advanced through the sheath and into the right or left chambers of the heart. The distal portion of the sheath is comprised of a composite structured single lumen shaft. At the proximal end, an ergonomic handle provides torque and active deflection, a hemostasis valve allows safe introduction of an interventional catheter, and a side port provides access for aspiration, fluid flushes and fluid/medication infusions.

Intended Use
The AcQGuide MAX Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The AcQGuide MAX deflection facilitates catheter positioning.

Contraindications
Use of the AcQGuide MAX 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.

Use of the AcQGuide MAX is contraindicated for placement in any chamber if:

- The patient has known or suspected sepsis.
- The patient has known atrial thrombus.
- The patient has known history of hematologic disorders (bleeding/clotting).
- The patient has contraindications to IV anticoagulation.
- There is venous access through graft material.

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 transseptal cardiac procedures and for selected patients undergoing right-sided procedures. Current guidelines recommend an activated clotting time (ACT) >350 seconds. To minimize thromboembolic complications, administration of anticoagulation therapy during and post-procedure should follow the institution's standard practice and anticoagulation labeling of other devices used during the procedure.

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 embolism, which can occlude vessels and lead to tissue infarction with serious consequences. To minimize the risk of air embolism:

- Always aspirate and flush the sheath from the side-port once inserted.
- Always advance and withdraw components slowly to minimize the vacuum created.
- Do not aspirate the steerable sheath with a guidewire in place and inserted 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 fluids/medications or aspirating through the sheath, use the side port with a three-way stopcock in place.
- Prior to any infusion, remove all air with aspiration and flushing using the side port.

Femoral vein damage - Take care to minimize damage to the femoral (femoral venous access) vasculature and access site upon sheath insertion, manipulation, or withdrawal. Complications associated with femoral vessel cannulation include hematoma, thrombosis, AV fistula, and pseudoaneurysm.

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, thrombus, 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 valve leaflets or 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 MAX if the package is open and/or the sterile barrier is broken.

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

Patient – Not intended for children, nursing women, or pregnant women.

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 side port and inject contrast solution.

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

Required use environment - Interventional cardiology 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.

Single Use - The AcQGuide MAX 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, or cross-contamination from the device that could result in patient injury, illness or death.

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

Transseptal puncture - The AcQGuide MAX Sheath has been tested for compatibility with the Acutus Medical AcQCross™ Qx.

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. Limit exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible. Give careful consideration before using the device in pregnant women.

Compatibility - The AcQGuide MAX Sheath is compatible for use with catheters up to 12F in diameter. Use with catheters larger than 12F has not been tested by Acutus Medical.

Potential Adverse Effects
When used in an interventional procedure, risks may include:

- Access site complications (hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage)
- Acute Respiratory Distress Syndrome
- Air embolism
- Allergic reaction/anaphylaxis
- Anemia
- Arrhythmias
- AV Fistula
- Cardiac arrest/tamponade
- Cardiac thromboembolism
- Cerebral infarct (hemorrhagic/thrombotic)
- Chest pain/discomfort
- Congestive heart failure
- Coronary artery spasm, dissection, thrombosis
- Death
- Elevated cardiac enzymes
- Endocarditis
- Exacerbation of pre-existing atrial fibrillation
- Expressive aphasia
- Femoral nerve injury
- Heart block (complete/transient)
- Heart failure
- Hemothorax
- Hypotension
- Infection/sepsis
- Laceration
- Life threatening arrhythmias/cardiac arrest
- Major bleeding requiring surgery/blood products
- Myocardial infarction
- Obstruction or perforation or damage to vascular system
- Pericardial effusion or tamponade
- Pericarditis
- Phrenic nerve damage
- Pleural effusion

- Pneumonia
- Pneumothorax
- Pseudo aneurysm
- Pulmonary edema
- Pulmonary embolism
- Radiation injury
- Respiratory depression
- Skin burns
- Thromboembolism
- Transient ischemic attack (TIA)
- Vascular bleeding
- Vascular damage/insufficiency
- Vasovagal reactions
- Ventricular tachycardia
- Worsening chronic obstructive pulmonary disease
- X-ray radiation exposure may cause adverse events including, but not limited to, alopecia, burns, cataracts, or delayed neoplasia (cancers).

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 MAX:

- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Heparinized normal saline
- Guidewire for sheath insertion (Maximum Diameter: 0.035" [0.89mm])
- Syringe
- Other supplies as needed to complete the established laboratory practice

Instructions for Use

NOTE: Before introducing the AcQGuide MAX into the patient, test the deflection mechanism by turning the control knob clockwise (to the right) to ensure that it is operational. The handle is equipped with the following graphic showing the direction of deflection/actuation of the distal tip  .

NOTE: The AcQGuide MAX is designed for temporary use (procedure duration of six 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 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 locks onto the proximal end of the handle assembly. Full engagement is achieved when an audible click is heard.
6. Thread the dilator/sheath assembly over the guidewire until the guidewire exits the proximal end of the dilator
7. After verifying the distal curve of the sheath is in neutral position, while securing the guidewire, advance the dilator and sheath over the guidewire into the desired heart chamber.
8. To unlock the dilator hub from the proximal end of the handle assembly, deflect the dilator hub downward from the proximal end of the handle assembly, then 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.

9. Attach the syringe to the 3-way stopcock on the sheath side port and gently aspirate blood to ensure there is no air in the system. If desired connect a continual flush line to the 3-way stopcock, ensure there is no air in the system.
10. Insert the catheter through the hemostasis valve and position in the desired chamber.
11. 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.
12. Any catheters within the sheath should be fully retracted into the sheath prior to removing 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.

LIMITED WARRANTY AND DISCLAIMER
Acutus Medical, Inc. warrants that reasonable care has been used in the design and manufacture of its products. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, and cleaning of a device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Acutus Medical's control directly affect the device and the results obtained from its use. Acutus Medical's obligation under this warranty is limited solely to the repair or replacement of a device and Acutus Medical shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of the device. Acutus Medical neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with a device. Acutus Medical assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.

SERVICE
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Symbol Glossary

	Manufacturer		Caution
	Date of Manufacturer		Non-pyrogenic
	Authorized representative in the European Community		Quantity of devices
	Use-by date (YYYY-MM-DD)		MR Unsafe
	Batch code		Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Catalogue number		Single sterile barrier system with protective packaging inside
	Sterilized using ethylene oxide		Medical Device
	Do not re-sterilize		Importer
	Do not use if package is damaged		Inner Diameter
	Keep away from sunlight		Outer Diameter
	Keep dry		Sheath deflection indicator
	Do not re-use		Dilator
	Consult Instructions for use	CH REP	Authorized representative in Switzerland.

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