ACUTUS™
MEDICAL
ACQREF™
INTRODUCER SHEATH

IFU-022 Rev. C (10/2021)

# AcQRef® Introducer Sheath

## Instructions for use

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

### AcQRef Introducer Sheath Description

The Acutus Medical AcQRef Introducer Sheath is a sterile, single use venous access device that consists of a straight shaft with lumen, hemostasis valve, flush port, electrode, and attached extension cable for electrode connectivity.

The AcQRef Introducer Sheath consists of the following components:

One (1) 7Fr Introducer Sheath with electrode and connection cable

One (1) 7Fr Vessel Dilator
One (1) Guide wire - 0.038 in, J-tip

The electrode is connected to the yellow cable and connector. The Introducer Sheath is compatible for use with the AcQMap® High Resolution Imaging and Mapping System Model 900000/900100.

### Intended Use

The Acutus Medical AcQRef Introducer Sheath is indicated for use in percutaneous procedures to facilitate venous access from the lower extremities for introduction of catheters and other devices and may be used to sense intravenous signals.

### Contraindications

Use of the AcQRef Introducer Sheath is contraindicated in children, nursing or pregnant women and patients with:

- A known or suspected obstruction in the vessel to be cannulated
- Hypercoagulopathy or an inability to tolerate anticoagulation therapy
- Presence of bleeding disorders that would contraindicate an electrophysiology procedure

### Potential Complications

The potential complications related to the use of the introducer include, but are not limited to the following: Air embolism, wound infection, intimal tear, and perforation of the vessel wall.

### Warnings and Precautions

**Anticoagulation** - Before insertion of the AcQRef Introducer, appropriate anticoagulation therapy should be administered to attain an activated clotting time (ACT) of >250 seconds. To minimize risk of thromboembolic events, ACT monitoring should be performed during the procedure to maintain an ACT value at or above the target clotting time.

**Damage** - Damage to the valve assembly may occur under the following circumstances:

- Dilator or catheter in valve assembly for extended periods.
- Inner catheter is withdrawn too rapidly.

**Device compatibility**- Use the AcQRef Introducer Sheath only with compatible transvenous devices. Use the appropriate size sheath for the size of the transvenous device being utilized. Consequences of using the AcQRef Introducer Sheath with incompatible devices may include the inability to deliver the transvenous device or result in damage to the transvenous device during delivery. The AcQRef Introducer Sheath is compatible for use with the AcQMap High Resolution Imaging and Mapping System.

**Disposal** - Dispose per local biohazard standards.

**Handling** - The AcQRef Introducer Sheath should be handled with care. Prior to use and during the procedure, inspect the packaging and introducer sheath for bends, kinks, or other damage. Use of a damaged sheath or guidewire may result in damage to the venous structures. Discontinue use if the introducer sheath becomes damaged. Because of the delicate and fragile nature of guidewires, extra care in handling must be taken. Do not alter this device in any way.

**Inspection** - Do not use the AcQRef Introducer Sheath if the package is open and/or the sterile barrier is broken, as this may create a risk of contamination from the device that could result in patient injury, illness, or death.

**Magnetic Resonance Imaging** - The AcQRef is not compatible with MRI. Use with MRI may create risk of patient injury.

**Organic Solvents** - Do not expose to organic solvents.

**Procedure** - Individual patient anatomy and physician technique may require procedural variations.

**Qualified Users** - Only physicians thoroughly trained in this procedure should use the AcQRef Introducer Sheath.

**Removal** - Rapid withdrawal of the dilator from the AcQRef Introducer Sheath may create a vacuum which may result in air in.

**Resistance** - Do not advance or rotate the introducer sheath or guidewire if significant resistance is met, as it may result in damage to venous structures. If resistance is met when advancing the sheath or guidewire, determine the cause by fluoroscopy and correct before continuing with the procedure.

**Single Use** - The AcQRef Introducer Sheath 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 or patient injury.

**Storage** - The AcQRef Introducer Sheath should be stored in a cool and dry place to reduce the risk of compromised device performance.

**Support** - Do not leave a catheter introducer sheath in place for extended periods of time without a catheter or a dilator to support the introducer wall.

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

### Accessories

The following supplies are not provided with the devices and should be available and prepped per laboratory standard operating procedures prior to use of the AcQRef Introducer Sheath:

- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Heparinized normal saline
- Other supplies as needed to fulfill the established laboratory practice

### Product Preparation

1. Remove the AcQRef Introducer Sheath and components from the sterile packaging and inspect for damage or defects. Do no use defective or damaged devices.

2. Unwrap the electrical connection cables.
3. Thoroughly flush the introducer sheath and dilator with either saline or heparinized saline.
4. Insert the sheath dilator through the hemostasis valve and into the body of the sheath.
5. Advance dilator until the hub of dilator snaps into the back end of the hemostasis valve.
6. To disengage locking feature, gently push hub of dilator in any direction, then pull straight out of sheath.
7. The introducer sheath can be set aside within the sterile field.

## Product Operation

### AcQRef Introducer Sheath Placement

**NOTE:** The AcQRef Introducer Sheath is designed for temporary use (procedure duration of eight hours or less) within the peripheral veins. Proper surgical procedures and sterile techniques are the responsibility of the medical professional.

1. In a sterile field and using institutional standard practice (e.g. Seldinger technique), obtain femoral venous access.
2. Advance the provided .038", J-tip guidewire through the needle into the femoral vein.
3. Thread the dilator/sheath assembly over the guidewire, using a slight twisting motion. Maintain control of the middle of the introducer sheath during insertion to avoid buckling.

**NOTE:** Any device/component inserted through the hemostasis valve should be moistened with sterile and/or heparinized saline and placed through the center of the valve to prevent leakage and/or tearing of the seal.

4. Under fluoroscopy, position the electrode per standard protocol.
5. Slowly remove the dilator and wire from the sheath.

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

6. Aspirate all air from the sheath by connecting a syringe to the luer connector on the three-way stopcock on the side port.
7. Introduce the selected catheter or other device into the sheath using the instructions provided by the manufacturer of the catheter or other device and standard hospital practice.

**CAUTION:** When removing the catheter, aspirate via the sideport extension to collect fibrin that may have been deposited at the tip of the sheath.

**For use with the AcQMap® High Resolution Imaging and Mapping System, Model 900000**

1. Ensure that the electrode is positioned below the base of the diaphragm.
2. Connect the yellow connector to the yellow (9) Unipolar Reference receptacle on the AcQMap Patient Interface Unit (PIU) when using Model 900000.

**For use with the AcQMap® High Resolution Imaging and Mapping System, Model 900100**

1. Ensure that the electrode is positioned below the base of the diaphragm.
2. Connect the yellow connector to the AcQRef receptacle on the AcQMap front panel when using Model 900100.

### AcQRef Introducer Sheath Removal

1. Remove the introducer sheath using standard institutional practice.
2. After removal of the introducer sheath, use standard technique to achieve hemostasis.
3. Discard the introducer sheath after it has been removed from the body.

## Symbol Glossary

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| | Manufacturer | | Consult instructions for use |
| | Use-by date (YYYY-MM-DD) | | Caution |
| LOT | Batch code | | Non-pyrogenic |
| REF | Catalogue number | MD | Medical Device |
| STERILE EO | Sterilized using ethylene oxide | Rx only | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician |
| | Do not resterilize | 1 | Quantity of Devices |
| | Do not use if package is damaged | | Single Sterile Barrier |
| | Keep away from sunlight | | Inner diameter |
| | Keep dry | | Outer diameter |
| 2 | Do not re-use | | |

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