ACUTUS™
MEDICAL

# AcQGuide® FLEX Steerable Introducer with AcQCross™ Qx Integrated Transseptal Dilator/Needle

## Instructions for Use

### DEVICE DESCRIPTION

The AcQGuide FLEX Steerable Introducer set contains a steerable introducer, integrated vessel dilator/transseptal needle (component branded as AcQCross Qx), guidewire, ECG and Electrosurgery (ES) adapter cables. The set is designed to facilitate vascular access to the heart and then provide variable catheter positioning within the cardiac anatomy. The AcQGuide FLEX introducer is an elongated shaft with central lumen capable of accepting the AcQCross Qx dilator/needle as well as various cardiac catheters. The shaft has a proximal handle with a rotating actuator that allows the user to change the degree of curvature on the distal tip of the shaft (referred to as steerable tip, deflectable tip, or dynamic tip). Rotating the actuator can deflect the tip, in a planar fashion, +/- 180°. The handle is also fitted with a hemostasis valve to minimize blood loss during catheter introduction, and/or exchange, as well as a sideport with 3-way stopcock to allow blood aspiration, fluid infusion, and pressure monitoring. The introducer shaft features a) hydrophobic PTFE inner lumen and siloxane coated outer shaft to facilitate insertion performance, b) distal side holes to facilitate aspiration and prevent cavitation, and c) an embedded platinum radiopaque tip marker to facilitate fluoroscopic visualization.

The AcQCross Qx integrated dilator/needle combines the vessel dilator and transseptal needle of conventional devices into a single component. The AcQCross Qx consists of an elongated shaft with a tapered tip and central lumen to track over a guidewire in a similar fashion to conventional vessel dilators. The lumen of the AcQCross Qx is fitted with a hollow stainless steel transseptal needle and both the shaft and needle are connected to the same proximal handle.

The needle lumen will accept guidewire sizes up to 0.032 inches in diameter. Inside the AcQCross Qx handle, the needle is affixed to a spring-tensioned actuator that prevents needle extension until the operator purposely advances the needle via a slider button located on the outer surface of the handle. The proximal handle is fitted with a Luer connector to gain access to the central lumen of the needle. The handle is also fitted with an electrical connector in order to monitor an ECG from the needle while in the heart, utilizing the ECG adapter cable, and/or to apply radiofrequency current from an electrosurgical generator to facilitate the septal puncture utilizing the ES adapter cable.

## INDICATIONS

The AcQGuide FLEX Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

## CONTRAINDICATIONS

- Myocardial infarction within the last two weeks
- Patients with an active infection
- Patients with an atrial thrombus
- Patients with known or suspected atrial myxoma
- Patients that have experienced a recent cerebrovascular accident (CVA)
- Patients who experience unstable angina
- Patients who do not tolerate anticoagulation therapy
- Patients with an interatrial septal patch

## WARNINGS

- Only those physicians who are trained in cardiac transseptal catheterization procedures and Acutus Medical, Inc. (Acutus) catheter introducer products should use this device. If the RF current method is used, only physicians who are additionally trained in using electrosurgical devices should use this device.
- RF should be applied only under the direct control of a physician who may be expected to interrupt contact with the patient at the slightest sign of an unexpected response from the patient.
- This is a single-use device. Do Not attempt to reuse this device as it is not possible to remove all biological and/or foreign

material after use. Adverse patient reactions may occur as a result of reusing this device.

- Do Not alter this device in any way. Doing so may make its use unsafe.
- Monitor patient's hemodynamic parameters during the procedure.
- When removing devices that have been inserted into the introducer or aspirating blood, do so slowly to minimize the potential for cavitation (vacuum on the introducer walls).
- Prior to infusion of fluids through the sideport, aspirate the tube of any air that may be present.
- Fibrin may accumulate on any device leading to thrombus formation. To prevent dislodgement of any potential thrombus, aspirate through the sideport when removing the dilator or any inserted catheter.
- Prior to removing the introducer from the patient, reinsert the guidewire and dilator, straighten the introducer tip by rotating the actuator to the neutral position, and withdraw the introducer, dilator, and guidewire as an assembly.
- Not intended for use in children, or pregnant or nursing women.

## PRECAUTIONS

- **CAUTION**: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
- Read the **Instructions for Use** before using this device in order to mitigate the risks and potential complications associated with transseptal catheterization procedures, including, but not limited to, embolism and perforation.
- Use the AcQGuide FLEX introducer prior to the "**Use by**" date specified on the package label.
- Inspect all components prior to use. Do not use if the package or items in the kit appear to be damaged or defective.
- The AcQGuide FLEX Steerable Introducer is designed to interlock only with the AcQCross Qx dilator/needle included in the kit. Attempted use of a dilator other than the AcQCross Qx may result in serious complications.
- The AcQCross Qx dilator/needle contains an internal sharp point and should be handled with care.

- Prior to inserting the device into the patient, assure that the AcQGuide FLEX and AcQCross Qx components are properly assembled together.
- The French size on the label indicates the inner diameter of the introducer component. **Do Not** attempt to insert a catheter into the introducer that has a larger outer diameter than the French size of the introducer.
- **Do Not** attempt to use a guidewire larger than the maximum diameter specified on the package label.
- **Do Not** withdraw dilator, or inserted catheter, rapidly as it may result in damage to the hemostasis valve.
- **Do Not** deflect the introducer tip beyond **90°** prior to insertion of an 8 mm, or longer, tip electrode catheter.
- **Do Not** rotate the introducer shaft more than **120°** in either direction without the AcQCross Qx inserted, or another catheter device, as the hollow introducer may kink.
- If any resistance is met while advancing or withdrawing a catheter, dilator, or guidewire, determine the cause and correct it before continuing with the procedure.
- Indwelling introducers should always have the lumen supported with a catheter device or obturator.
- When aspirating, do so slowly and only from the sideport.
- Injection of fluids should only be from the sideport.
- There are certain patient conditions that require special consideration by the operator when using this product. Such conditions include, but aren't limited to, an enlarged aortic root, small left atrium, right atrial enlargement, distortion of the thorax, and congenital malformations of the heart.
- **STORE PRODUCT IN A COOL, DRY, AND DARK PLACE.**
- **STORE IN A LOCATION WITH TEMPERATURE BETWEEN -20° TO + 50° C.**

## POTENTIAL COMPLICATIONS

The following potential complications may occur during the use of this device, but are not limited to:

- Embolism, air or thrombus
- Thrombus formation
- Perforation of a vessel or heart structure
- Infection
- Hematoma at the vascular insertion site
- Pericardial effusion
- Tear in the vascular intima

Consult the respective manufacturer's labeling for potential complications associated with the use of other cardiovascular catheter devices that may be used in conjunction with this device.

## HOW SUPPLIED

The AcQGuide FLEX Steerable Introducer kit is supplied in a cardboard shelf box. Within the shelf box, the device with kit components and accessories are provided sterile mounted on a backer card and contained in a sealed Tyvek™ pouch. The contents are listed on both the pouch and box labels.

Contents

– AcQGuide FLEX steerable introducer
– AcQCross Qx length-matched dilator/needle
– 0.032", 180 cm, j-tip guidewire
– ECG adapter cable
– ES adapter cable

The **Instructions for Use** document is included inside the shelf box and is recyclable. The used product should be disposed of in accordance with the facility's standard for solid and sharps biohazard waste procedures.

## PROCEDURAL CONSIDERATIONS

Reading the **Instructions for Use** before using this device will help reduce the potential complications associated with transseptal catheterization procedures. Only those physicians specially trained in transseptal catheterization procedures should use this device. If the RF current method is used, only physicians who are additionally trained in using electrosurgical devices should use this device. Transseptal catheterization procedures should only be performed in facilities appropriately equipped and have trained personnel to perform such procedures.

The catheterization lab capabilities should include, but are not limited to:

- Fluoroscopic imaging is required, including multiplane capabilities, either by C-arm or biplane. Adjunctive imaging using intracardiac ultrasound may be useful.
- Intracardiac pressure monitoring
- Systemic blood pressure monitoring
- Contrast media injection, as well as management of adverse reactions to such
- Pericardiocentesis, to include transthoracic echocardiography
- Anticoagulation therapy and monitoring of such
- Monitoring of patient's vital signs.

Other procedural considerations include:

- Once the AcQGuide FLEX introducer has been positioned in the heart, and whenever a device is removed from the AcQGuide FLEX, aspirate until blood is seen in the sideport and then flush thoroughly with heparinized saline.
- Only use the sideport for aspiration, infusion, or pressure monitoring.
- Apply aspiration while removing dilator or catheter as the introducer tip may have formed a thrombus.
- To minimize risk of thrombus formation and/or embolus, either provide a continuous infusion of heparinized saline or periodic aspiration/saline flush while the introducer is in the body.
- **Do Not** remove dilator or catheters rapidly as this could result in damage to the hemostasis valve leading to blood leakage.

- Indwelling introducers should always be supported with an inserted cardiovascular catheter or obturator.

## SUGGESTED PROCEDURE

Device Preparation

- Remove backer card with device components and accessories from sterile pouch.
- Remove device components and accessories from backer card.
- Visually inspect each component for defects and/or foreign materials.
- Attach syringe (not included) to stopcock of sideport and flush introducer with heparinizedsaline. Failure to do so might result in increased friction when inserting devices which may result in adverse events.
- Attach syringe (not included) to Luer connector on AcQCross Qx dilator/needle and flush with heparinized saline.
- Detach J-straightener from guidewire retainer coil, attach syringe (not included) to Luer fitting on guidewire retainer coil and flush with heparinized saline.
- Gently wipe outer surfaces of AcQGuide FLEX/AcQCross Qx with gauze soaked in heparinized saline. Avoid excessive wiping of the coated device or wiping with dry gauze as this may damage the device coating. Failure to do so might result in increased friction when inserting into the patient which may result in an adverse event.
- Test the deflection of the AcQGuide FLEX introducer for appropriate function.
- Test the needle extension of the AcQCross Qx dilator/needle for appropriate function.
- Insert AcQCross Qx dilator/needle into AcQGuide FLEX introducer and lock components together in a preferred orientation (See **Figure 1**).

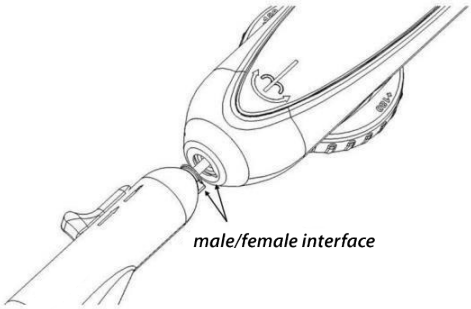


**Figure 1** – AcQCross Qx and AcQGuide FLEX keyed orienting geometries with snap-fit closure

Device Use

- Having obtained femoral venous access using a conventional percutaneous needle (not supplied), insert the included 0.032-inch guidewire into vasculature and advance tip to the superior vena cava (SVC). Remove percutaneous needle from guidewire.
- Check to make certain that the stopcock on the sideport tubing is in the closed position.
- Insert proximal end of guidewire into AcQCross Qx distal lumen and advance AcQGuide FLEX/AcQCross Qx assembly until guidewire exits proximal lumen of AcQCross Qx and is secured.
- Insert AcQGuide FLEX/AcQCross Qx assembly over guidewire into vasculature and track over guidewire to the SVC.

**The following are alternate procedure steps based on physician preference**

Alternate 1 – Guidewire method

- Withdraw the guidewire several centimeters into the AcQCross Qx lumen.
- Optional ECG monitoring
  - Connect the female end of the included ECG adapter cable to the electrical connector on the AcQCross Qx handle.
  - Connect the male end of the ECG adapter cable to the ECG monitor system.
  - Display ECG on monitor.

- Under fluoroscopic visualization (and intracardiac echocardiography, if available), withdraw device assembly from the SVC to the right atrial septum and then to the fossa ovalis (FO).
- Once the device has been confirmed to be located on the FO, advance the slider button on the handle of the AcQCross Qx to extend the needle tip and puncture into the left atrium (See Figure 2).

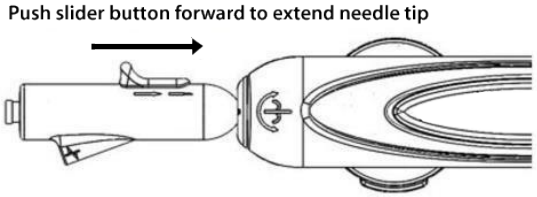


**Figure 2** – To advance needle tip, push slider button forward

- Optional RF current method

**WARNING: RF SHOULD BE APPLIED ONLY UNDER THE DIRECT CONTROL OF A PHYSICIAN WHO MAY BE EXPECTED TO INTERRUPT CONTACT WITH THE PATIENT AT THE SLIGHTEST SIGN OF AN UNEXPECTED RESPONSE FROM THE PATIENT**

**CAUTION: PRIOR TO USING RF CURRENT, TOTALLY REMOVE THE GUIDEWIRE FROM THE DEVICE AND SET ASIDE WHERE IT CANNOT COME IN CONTACT WITH ANY PART OF THE RF CIRCUIT. FOLLOWING RF CURRENT DELIVERY, THE GUIDEWIRE MAY BE REINSERTED AS NEEDED.**

- Prepare Valleylab Force 2 generator for use:
  - Connect adhesive dispersive electrode to patient and ES generator
  - Connect monopolar ES pencil to generator
    - Remove the active electrode from the pencil, if present
  - If available, user may opt to connect foot pedal switch to generator
  - Turn power on generator
  - Set to "Cut" mode

- Set output to 10 watts

- Connect the female end of the included ES adapter cable to the electrical connector on the AcQCross Qx handle.
- Connect the male end of the ES adapter cable to the ES pencil.
- While applying forward pressure and extending the needle on the AcQCross Qx at the desired puncture location, apply RF current either by the control button on the ES pencil or the optional foot pedal switch.
- RF current should only be applied for short durations per application, e.g., 1 – 2 seconds at a time
- RF current application may be repeated, in short durations as noted above, until desired transseptal puncture is achieved or a maximum of 5 attempts have been made.

**CAUTION: IF NEEDLE PUNCTURES ANY STRUCTURE OTHER THAN THE FOSSA OVALIS, DO NOT ADVANCE DILATOR AND SHEATH AND WITHDRAW THE NEEDLE.**

- With continued extension of the needle tip via the slider button, advance the guidewire through the AcQCross Qx into the left atrium.
- Once the guidewire is securely positioned in the left atrium, release the slider button to allow the needle tip to retract back into the AcQCross Qx lumen.
- With guidewire secure in left atrium, advance device assembly over the wire and through the FO until the AcQGuide FLEX introducer tip is fully inside the left atrium. (observe radiopaque tip marker on fluoroscopy)
- While holding the AcQGuide FLEX handle securely to maintain left atrial positioning, detach AcQCross Qx from device assembly and slowly withdraw the AcQCross Qx and guidewire together until totally removed from patient.
- Via the stopcock on the sideport, slowly aspirate until blood is observed in the sideport tubing.
- After aspiration, flush with heparinized saline.

Alternate 2 – Pressure recording method

- Remove the guidewire from the AcQCross Qx.
- Connect a syringe, or stopcock (neither included), to the Luer hub on the AcQCross Qx handle.
- Optional pressure recording from AcQCross Qx lumen
  - Remove syringe (or stopcock) from AcQCross Qx
  - Attach one end extension tubing (not included) to Luer hub
  - Attach opposite end of extension tubing to pressure transducer
  - Calibrate pressure recording to appropriate scale for atrial pressures
  - Zero the transducer and close to monitor pressure
- Optional ECG monitoring
  - Connect the female end of the included ECG adapter cable to the electrical connector on the AcQCross Qx handle.
  - Connect the male end of the ECG adapter cable to the ECG monitor system.
  - Display ECG on monitor.
- Under fluoroscopic visualization (and intracardiac echocardiography, if available), withdraw device assembly from the SVC to the right atrial septum and then to the fossa ovalis (FO).
- Once the device has been confirmed to be located on the FO, advance the slider button on the handle of the AcQCross Qx to extend the needle tip and puncture into the left atrium.
- Optional RF current method

**WARNING: RF SHOULD BE APPLIED ONLY UNDER THE DIRECT CONTROL OF A PHYSICIAN WHO MAY BE EXPECTED TO INTERRUPT CONTACT WITH THE PATIENT AT THE SLIGHTEST SIGN OF AN UNEXPECTED RESPONSE FROM THE PATIENT**

**CAUTION: PRIOR TO USING RF CURRENT, TOTALLY REMOVE THE GUIDEWIRE FROM THE DEVICE AND SET ASIDE WHERE IT CANNOT COME IN CONTACT WITH ANY PART OF THE RF CIRCUIT. FOLLOWING RF CURRENT DELIVERY, THE GUIDEWIRE MAY BE REINSERTED AS NEEDED.**

- Prepare Valleylab Force 2 generator for use:
  - Connect adhesive dispersive electrode to patient and ES generator
  - Connect monopolar ES pencil to generator
  - Remove the active electrode from the pencil, if present
  - If available, user may opt to connect foot pedal switch to generator
  - Turn power on generator
  - Set to "Cut" mode
  - Set output to 10 watts
- Connect the female end of the included ES adapter cable to the electrical connector on the AcQCross Qx handle.
- Connect the male end of the ES adapter cable to the ES pencil.
- While applying forward pressure and extending the needle on the AcQCross Qx at the desired puncture location, apply RF current either by the control button on the ES pencil or the optional foot pedal switch
- RF current should only be applied for short durations per application, e.g., 1 – 2 seconds at a time
- RF current application may be repeated, in short durations as noted above, until desired transseptal puncture is achieved or a maximum of 5 attempts have been made.

**CAUTION: IF NEEDLE PUNCTURES ANY STRUCTURE OTHER THAN THE FOSSA OVALIS, DO NOT ADVANCE DILATOR AND SHEATH AND WITHDRAW THE NEEDLE.**

- Observe pressure recording to confirm left atrial access.
- With the needle extended, advance device assembly until AcQCross Qx tip is fully positioned in left atrium.
- Release the slider button to retract the needle tip back into the AcQCross Qx lumen.
- With AcQCross Qx tip secure in left atrium, advance device assembly through the FO until the AcQGuide FLEX introducer tip is fully inside the left atrium (observe radiopaque tip marker on fluoroscopy).
- While holding the AcQGuide FLEX handle securely to maintain left atrial positioning, detach AcQCross Qx from device assembly and slowly withdraw the AcQCross Qx until totally removed from patient.
- Via the stopcock on the sideport, slowly aspirate until blood is observed in the sideport tubing.
- After aspiration, flush with heparinized saline.

Alternate 3 – Contrast staining/injection method

- Remove the guidewire from the AcQCross Qx.
- Optional ECG monitoring
  - Connect the female end of the included ECG adapter cable to the electrical connector on the AcQCross Qx handle.
  - Connect the male end of the ECG adapter cable to the ECG monitor system.
  - Display ECG on monitor.
- Under fluoroscopic visualization (and intracardiac echocardiography, if available), withdraw device assembly from the SVC to the right atrial septum and then to the fossa ovalis (FO).
- Optional staining of FO/contrast injection from AcQCross Qx needle
  - Connect a syringe filled with diluted contrast media (not supplied) to the Luer hub on the AcQCross Qx handle.
  - Once positioned on the FO, slightly advance the slider button in order for the needle tip to engage tissue.

- Under fluoroscopic visualization, inject contrast media through syringe to stain the FO.
- Once the device has been confirmed to be located on the FO, advance the slider button on the handle of the AcQCross Qx to extend the needle tip and puncture into the left atrium.

○ Optional RF current method

**WARNING: RF SHOULD BE APPLIED ONLY UNDER THE DIRECT CONTROL OF A PHYSICIAN WHO MAY BE EXPECTED TO INTERRUPT CONTACT WITH THE PATIENT AT THE SLIGHTEST SIGN OF AN UNEXPECTED RESPONSE FROM THE PATIENT**

**CAUTION: PRIOR TO USING RF CURRENT, TOTALLY REMOVE THE GUIDEWIRE FROM THE DEVICE AND SET ASIDE WHERE IT CANNOT COME IN CONTACT WITH ANY PART OF THE RF CIRCUIT. FOLLOWING RF CURRENT DELIVERY, THE GUIDEWIRE MAY BE REINSERTED AS NEEDED.**

- Prepare Valleylab Force 2 generator for use:
  - Connect adhesive dispersive electrode to patient and ES generator
  - Connect monopolar ES pencil to generator
    - Remove the active electrode from the pencil, if present
  - If available, user may opt to connect foot pedal switch to generator
  - Turn power on generator
  - Set to "Cut" mode
  - Set output to 10 watts
- Connect the female end of the included ES adapter cable to the electrical connector on the AcQCross Qx handle.
- Connect the male end of the ES adapter cable to the ES pencil.
- While applying forward pressure and extending the needle on the AcQCross Qx at the desired puncture

location, apply RF current either by the control button on the ES pencil or the optional foot pedal switch

- RF current should only be applied for short durations per application, e.g., 1 – 2 seconds at a time
- RF current application may be repeated, in short durations as noted above, until desired transseptal puncture is achieved or a maximum of 5 attempts have been made.

**CAUTION: IF NEEDLE PUNCTURES ANY STRUCTURE OTHER THAN THE FOSSA OVALIS, DO NOT ADVANCE DILATOR AND SHEATH AND WITHDRAW THE NEEDLE.**

- With needle extended, inject contrast under fluoroscopic visualization to confirm needle tip is located in the left atrium.

- With the needle extended, advance device assembly until AcQCross Qx tip is fully positioned in the left atrium.
- Release the slider button to retract the needle tip back into the AcQCross Qx lumen.
- With AcQCross Qx tip secure in the left atrium, advance device assembly through the FO until the AcQGuide FLEX introducer tip is fully inside the left atrium (observe radiopaque tip marker on fluoroscopy).
- While holding the AcQGuide FLEX handle securely to maintain left atrial positioning, detach AcQCross Qx from device assembly and slowly withdraw the AcQCross Qx until totally removed from patient.
- Via the stopcock on the sideport, slowly aspirate until blood is observed in the sideport tubing.
- After aspiration, flush with heparinized saline.

- The AcQGuide FLEX introducer is now ready for use in the left atrium.
- **Once the left atrium is instrumented with this device, anticoagulation therapy may be administered per physician practice.**
- During the procedure, the device should either receive continuous flush with heparinized saline or periodic aspiration/ flushing to prevent thrombus formation within the lumen.

- To deflect the tip of the introducer, the rotating actuator on the AcQGuide FLEX may be turned in either direction to achieve the desired amount of deflection.
  - Hold the handle in the left hand with the actuator positioned away from the operator (actuator on bottom side of handle, see Figure 3).
  - Use the thumb and forefinger of the left hand to operate the actuator.
  - To rotate the actuator, depress the lock button on the actuator with the fingertip to release the curve retention feature.
  - Once the desired deflection is achieved, release the lock button to retain the curve.

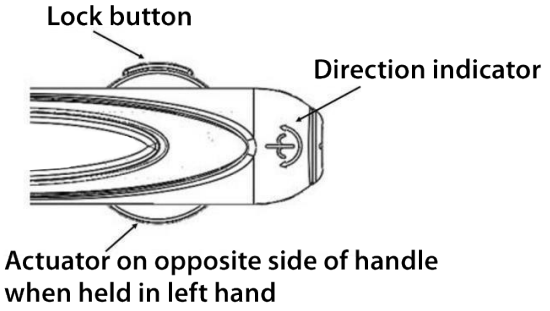


**Figure 3** – AcQGuide FLEX actuator diagram

- To remove the AcQGuide FLEX from the patient:
  - Return tip deflection to the neutral, undeflected position.
  - Aspirate/flush thoroughly.
  - Reinsert guidewire through AcQGuide FLEX into left atrium.
  - Reinsert AcQCross Qx over the guidewire and reconnect AcQCross Qx handle to AcQGuide FLEX handle.
  - Withdraw assembly slowly from patient until fully removed.
- Dispose of the device according to the facility's standard procedures for handling sharps and biohazard waste materials.

# USA ONLY

Acutus Medical, Inc. (Acutus) hereby warrants that if any Acutus product fails to perform within normal tolerances for a patient due to a defect in materials or workmanship, Acutus will provide, at no charge, a replacement Acutus product for the patient's use. This limited warranty applies only if each of the following conditions are met:

1. The product was packaged and labeled by Acutus.
2. The failed product must be returned to Acutus and becomes the property of Acutus.
3. The product has not been mishandled, reprocessed or altered in anyway.
4. The product was used before the "Use by" date marked on the packaging of the product.

No representation or warranty is made that a Acutus product will not fail. Acutus disclaims responsibility for any medical complications, including death, resulting from the use of its products. Except as expressly provided by this limited warranty, ACUTUS 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 incidental or consequential damages however, so the above limitation or exclusion may not apply to you.

Except as expressly provided by the limited warranty, ACUTUS MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

## STATE OF CALIFORNIA (USA ONLY)

**WARNING**: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

## SYMBOLS GLOSSARY

| Symbol | ISO 15223-1 Clause | Symbol Title | Explanatory Text |
|---|---|---|---|
|  | 5.1.1 | Manufacturer | Indicates the medical device manufacturer |
|  | 5.4.2 | Do not re-use | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure |
|  | 5.2.8 | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened |
|  | 5.1.4 | Use by date | Indicates the date after which the medical device is not to be used |
|  | 5.3.3 | Protect from heat and radioactive sources | Indicates medical device that needs to be protected from heat and radioactive sources |
|   | 5.1.5 | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified |
|   | 5.2.3 | Sterilized using ethylene oxide | Indicates a medical device that has been sterilized using ethylene oxide |

# SYMBOLS GLOSSARY (cont.)

| Symbol | ISO 15223-1 Clause | Symbol Title | Explanatory Text |
|---|---|---|---|
|  | 5.3.4 | Keep Dry | Indicates a medical device that needs to be protected from moisture |
|  | 5.2.6 | Do not resterilize | Indicates a medical device that is not to be resterilized |
|  | 5.4.3 | Consult Instructions for Use | Indicates the need for the user to consult the instructions for use |
|  | 5.3.2 | Keep away from sunlight | Indicates a medical device that needs to be protected from sunlight |
|  | 5.3.7 | Storage Temperature Range | Indicates the temperature limits to which the medical device can be safely exposed |
|  | 5.1.6 | Catalogue or Model number | Indicates the manufacturer's catalogue number so that the medical device can be identified |
|  | N/A; 21CFR801.109 | Prescription Only | Caution: Federal law (USA) restricts this device to sale bv or on the order of a physician |
|  | 5.6.3 | Non-pyrogenic | Indicates a medical device that is non-pyrogenic |
|  | 5.1.2 | Authorized representative in the European Community | Indicates the authorized representative in the European Community |
|  | N/A | Importer | Indicates the entity importing the medical device into the locale |

**ACUTUS MEDICAL, INC.**
2210 Faraday Ave., Suite 100
Carlsbad, CA 92008 USA
Phone: +1 442-232-6080
Fax: +1 442-232-6081
acutus.com

**ACUTUS MEDICAL NV**
Ikaroslaan 25
1930 Zaventem
Belgium
Phone: +32 2 669 75 00
Fax: +32 2 669 75 01

**MDSS GmbH**
Schiffgraben 41
30175 Hannover
Germany

CE 0297