



ACQCROSS™ QX INTEGRATED TRANSSEPTAL DILATOR/NEEDLE

Instructions for Use

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DEVICE DESCRIPTION

The AcQCross Qx Integrated Transseptal Dilator/Needle contains an integrated vessel dilator/transseptal needle, guidewire, and adapter lead wires for electrogram monitoring (EGM) for connection to an electrosurgery (ES) pencil. When used with a compatible transseptal vascular introducer, the set is designed to facilitate vascular access to the heart with or without utilizing radiofrequency current from an electrosurgical generator to facilitate the septal puncture.

The AcQCross Qx Integrated Transseptal Dilator/Needle combines the vessel dilator and transseptal needle 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 EGM from the needle while in the heart, utilizing the EGM adapter cable, and/or to apply radiofrequency current from an electrosurgical generator to facilitate the septal puncture utilizing the ES adapter cable. The distal tip of the handle is configured to mate with specific compatible transseptal vascular introducers, providing secure attachment during use. AcQCross Qx is intended to facilitate transseptal puncture when delivered through the introducers in the following table.

AcQCross Qx Models		Compatible Introducer	
Product	Model #	Description	Model #
AcQCross Qx – AG 61 cm	900300	Abbott Agilis NxT 8.5F steerable sheath – 61 cm	G408318
			G408319
AcQCross Qx – AG 71 cm	900301	Abbott Agilis NxT 8.5F steerable sheath – 71 cm	G408320
			G408321
			G408324
AcQCross Qx – SL 63 cm	900302	Swartz SL1 8.5F fixed curve guiding sheath – 63 cm	407453
AcQCross Qx – VZ 71 cm	900303	BSW Vizigo 8.5F bi-directional guiding sheath – 71 cm	D138501
			D138502
			D138503
AcQCross Qx – FC 65 cm	900304	Medtronic FlexCath Advance 12F steerable sheath – 65 cm	4FC12
AcQCross Qx – MAX 70 cm	900305	AcQGuide MAX 12F steerable sheath – 70 cm	900200

INDICATIONS

The AcQCross Qx Integrated Transseptal Dilator/Needle is indicated to puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.

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 fully trained in cardiac transseptal access 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.
- 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.
- 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 access procedures, including, but not limited to, embolism and perforation.
- Use the AcQCross Qx 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 set appear to be damaged or defective.
- The AcQCross Qx is designed to be length matched with specific compatible vascular introducers. Make certain the proper model has been selected for the vascular introducer to be used. Attempted use of a non-length matched 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 compatible introducer and AcQCross Qx components are properly assembled.

- The French size on the label indicates the outer diameter of the device. Do Not attempt to insert the device into an introducer that has a smaller inner diameter than the French size of the dilator/needle.
- Do Not attempt to use a guidewire larger than the maximum diameter specified on the package label.
- 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.
- 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
- Cerebral infarct / stroke (embolic or hemorrhagic)
- Cardiac perforation / tamponade

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 MINI Catheter 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

- AcQCross Qx length-matched dilator / needle
- 0.032", 180 cm, j-tip guidewire
- EGM 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 transeptal catheterization procedures. Only those physicians specially trained in transeptal 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. Transeptal catheterization procedures should only be performed in facilities appropriately equipped and have trained personnel to perform such procedures.

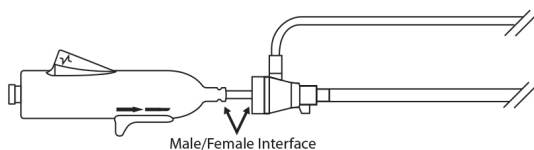
The catheterization lab capabilities should include, but are not limited to:

- 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

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 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 AcQCross Qx with gauze soaked in heparinized saline to assist with insertion into introducer.
- Test the needle extension of the AcQCross Qx dilator/needle for appropriate function.
- Insert AcQCross Qx dilator/needle into compatible, length-matched vascular introducer. See **Figure 1**.



Panel A

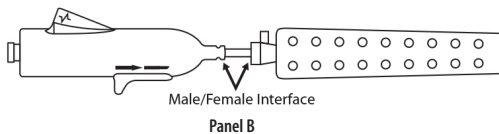


Figure 1

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.
- Insert proximal end of guidewire into AcQCross Qx distal lumen and advance introducer / AcQCross Qx assembly until guidewire exits proximal lumen of AcQCross Qx and is secured. (Refer to compatible sheath IFU for additional procedural instructions.)
- Insert introducer / AcQCross Qx assembly over the guidewire into the vasculature and track over the 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 EGM monitoring
 - Connect the female end of the included EGM adapter cable to the electrical connector on the AcQCross Qx handle.
 - Connect the male end of the EGM adapter cable to the EGM monitor system.
 - Display EGM 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).

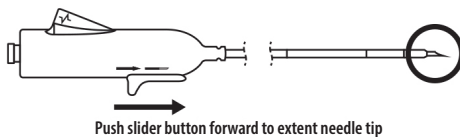


Figure 2

- 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.

- Attach syringe to Luer connector on AcQCross Qx and aspirate until blood is present in the syringe
- Exchange syringe with new one filled with heparinized saline and fully flush needle
- Leave syringe attached to Luer hub or attach a stopcock to Luer connector and turn to off position
- 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 transeptal 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 introducer tip is fully inside the left atrium.
- While holding the introducer 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.
- Follow manufacturer's Instructions for Use for proper operation of the vascular introducer.

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.
- Aspirate until blood is present in the syringe
- Exchange syringe with new one filled with heparinized saline and fully flush needle
- Leave syringe attached to Luer hub or attach a stopcock to Luer connector and turn to off position
- Optional pressure recording from AcQCross Qx lumen
 - If using syringe, remove syringe from AcQCross Qx and attach one end of extension tubing (not included) to Luer hub (or stopcock if desired)
 - 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 EGM monitoring
 - Connect the female end of the included EGM adapter cable to the electrical connector on the AcQCross Qx handle.
 - Connect the male end of the EGM adapter cable to the EGM monitor system.
 - Display EGM 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.

- Continue monitoring pressure from the AcQCross Qx lumen
- 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 transeptal 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 INTRODUCER 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 introducer tip is fully inside the left atrium.
- While holding the introducer securely to maintain left atrial positioning, detach AcQCross Qx from device assembly and slowly withdraw the AcQCross Qx until totally removed from patient.
- Follow manufacturer's Instructions for Use for proper operation of the vascular introducer.

Alternate 3 – Contrast staining/injection method

- Remove the guidewire from the AcQCross Qx.
- Attach syringe to Luer connector on AcQCross Qx and aspirate until blood is present in the syringe
- Exchange syringe with new one filled with heparinized saline and fully flush needle
- Leave syringe attached to Luer hub or attach a stopcock to Luer connector and turn to off position
- Optional EGM monitoring
 - Connect the female end of the included EGM adapter cable to the electrical connector on the AcQCross Qx handle.
 - Connect the male end of the EGM adapter cable to the EGM monitor system.
 - Display EGM 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.
 - Once puncture is made, inject additional contrast to confirm position in 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.

- Attach syringe to Luer connector on AcQCross Qx and aspirate until blood is present in the syringe
- Exchange syringe with new one filled with heparinized saline and fully flush needle
- Leave syringe attached to Luer hub or attach a stopcock to Luer connector and turn to off position
- 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 transeptal puncture is achieved or a maximum of 5 attempts have been made.
- With needle extended, inject contrast under fluoroscopic visualization to confirm needle tip is located in the left atrium.

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

- 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 introducer tip is fully inside the left atrium.
- While holding the introducer securely to maintain left atrial positioning, detach AcQCross Qx from device assembly and slowly withdraw the AcQCross Qx until totally removed from patient.
- Follow manufacturer's Instructions for Use for proper operation of the vascular introducer.

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,
















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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.

SYMBOL 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
	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 by or on the order of a physician
	5.6.3	Non-pyrogenic	Indicates a medical device that is non-pyrogenic

SYMBOL GLOSSARY (cont.)

Symbol	ISO 15223-1 Clause	Symbol Title	Explanatory Text
	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
	N/A	MR Unsafe	N/A

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