RX ONLY

Caution: Federal (U.S.A.) law restricts the use of this device for sale by or on the order of a physician.

For U.S.-California Only. Proposition 65, a State of California voter initiative requires the following notice:

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

Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these instructions. Failure to do so may result in patient complications.

GENERAL WARNINGS & CAUTIONS

WARNINGS

- The CrossWise™ RF Transseptal Cannula is not recommended for use with conditions that do not require cutting or coagulation of soft tissue.
- Other patient conditions that require physician consideration prior to use include:
  - Myocardial infarction within the last two weeks
  - Active infection
  - Atrial thrombus
  - Known or suspected atrial myxoma
  - Recent cerebrovascular accident (CVA)
  - Unstable angina
  - Intolerance of anticoagulation therapy
  - Interatrial septal patch
- This device is intended for use only by physicians well-versed in angiography, percutaneous interventional procedures, cardiac Transseptal Puncture (TSP), and the use of electrosurgical devices. The CrossWise™ RF Transseptal Cannula is supplied sterile using an ethylene oxide process. Do not use if the packaging is damaged.
- Do not modify this device in any way. Doing so may make its use unsafe.
- Apply RF energy under the direct control of a physician who can promptly discontinue contact with the patient in response to unexpected patient reactions.
- Monitor patient hemodynamic parameters throughout the procedure.

- This device is not intended for use in children or women who are pregnant or nursing.
- Laboratory staff and patients can be exposed to significant X-ray radiation during fluoroscopic imaging in radiofrequency puncture procedures. Follow the facility policy for personal protection equipment (PPE) to minimize this exposure to prevent acute radiation injury and reduce the risk of somatic and genetic effects.
- The CrossWise™ RF Transseptal Cannula is designed for single-patient use only. Do not attempt to re-sterilize and reuse it, as this can lead to patient injury or transmission of infectious diseases. Failure to comply may result in patient complications.
- Exclusively use the CrossWise™ RF Transseptal Cannula with the provided CrossWise™ RF Adapter Cable. Attempting to use other connector cables can pose an electrocution risk to patient or operator.
- Do not apply RF energy for longer than 5 seconds. Attempting to deliver energy for longer than 5 seconds can pose a risk to the patient.

PRECAUTIONS

- Before using the CrossWise™ RF Transseptal Access System or any associated equipment, thoroughly review the provided Instructions for Use.
- Radiofrequency puncture procedures require experienced physicians operating in fully equipped catheterization laboratories.
- Maintain strict sterility throughout the procedure and ensure that all personnel involved are appropriately attired to minimize the risk of contamination.
- Prior to use, visually inspect the sterile packaging for signs of compromise or damage. Do not use devices with compromised packaging.
- Examine the CrossWise™ RF Transseptal cannula, dilator, and guidewire for any damage before use. Do not use damaged product.
- Do not use the CrossWise™ Transseptal System beyond the indicated “Use By” date on the label.
- Utilize the CrossWise™ Transseptal System only with devices listed in section “Ancillary Devices Required But Not Provided.”
- The CrossWise™ RF Transseptal Access System is designed to be length-matched with specific compatible guide sheaths. Make certain the proper model has been selected for the guide sheath. Attempted use of a non-length matched sheath may result in risk to the patient.
- Prior to use, refer to the Valleylab Force 2 generator Instructions for Use (IFU) for detailed information on proper operation, emission class, immunity test level, recommended separation distances from other portable RF communications equipment, and other safety precautions related to IEC 60601-1-2.

- The CrossWise™ Transseptal Access System is not tested for use with diathermy devices. The application of diathermy in proximity to the CrossWise system could result in unintended electrical conduction and cause device malfunction.
- Adhere to the manufacturer's instructions for using the Patient Return Electrode, and always use electrodes meeting or exceeding IEC 60601-2-2 requirements.
- Placing the dispersive electrode on the thigh or hip may result in higher impedance.
- Confirm proper placement of the guidewire within the vascular system before advancing the CrossWise™ RF Transseptal Cannula to prevent inadvertent vessel injury.
- Use caution when manipulating the guidewire to avoid kinking or fracturing, which could lead to complications.
- Maintain adequate filtering to enable continuous surface electrocardiogram (ECG) monitoring during radiofrequency power applications.
- Keep all electrical connections dry to prevent the risk of electrical shock or equipment malfunction.
- Exercise caution in manipulating the cannula to avoid cardiac damage or tamponade. Use fluoroscopic or Intracardiac Echocardiography (ICE) guidance for cannula advancement and refrain from applying excessive force when encountering resistance.
- Refrain from attempting puncture until the active tip is securely positioned against the atrial septum.
- Do not attempt to deliver RF energy while the tip of the RF Transseptal Cannula is within the dilator. Observe the status of the indicator sleeve to ensure that the cannula is properly positioned prior to delivering RF energy.
- Prior to initiating radiofrequency energy delivery, confirm that all connections are secure and that there are no loose or frayed wires.
- Do not exceed five (5) radiofrequency power applications per CrossWise™ RF Transseptal Cannula.
- Handle the CrossWise™ RF Transseptal Cannula with care, avoiding improper bending or kinking of the cannula shaft, which can damage it and pose risks to the patient.
- Exercise caution when operating the generator, as it can deliver significant electrical power. Improper handling of the cannula and return electrode during device operation may result in patient or operator injury.
- During power delivery, ensure the patient is not in contact with grounded metal surfaces.
- Troubleshoot apparent low power output or equipment malfunctions at standard settings by checking for issues such as improper application of the return electrode, electrical lead failure, or poor tissue contact at the active tip. Investigate obvious equipment defects or misapplications, and only increase power if low output persists after addressing these issues.

- Certain patient conditions require special consideration by the physician when using this product. Such conditions include, but are not limited to, an enlarged aortic root, small left atrium, right atrial enlargement, distortion of the thorax, and congenital malformations of the heart.
- The physician is responsible for identifying, assessing, and communicating all foreseeable risks associated with the CrossWise™ RF Transseptal Access System to each individual patient.
- Adhere to all applicable local, regional, and national regulations and guidelines governing the use of medical devices and radiofrequency procedures to ensure compliance and patient safety.

POTENTIAL COMPLICATIONS

The following potential complications may occur while using the CrossWise™ RF Transseptal Access System:

- Cardiac Tamponade
- Vessel perforation
- Hematoma
- Sepsis/Infection
- Embolism, air or thrombus
- Atrial Fibrillation
- Thrombus Formation
- Thromboembolic Episodes
- Myocardial Infarction
- Cardiac Perforation
- Ventricular Tachycardia
- Pericardial Effusion
- Cerebral Infarct / Stroke (embolic or hemorrhagic)

Consult the respective manufacturer's labeling for potential complications associated with the use of other cardiovascular catheters, generators, and ancillary devices that may be used with the CrossWise™ RF Transseptal Access System.

***Notice**: any serious incident that occurs in relation to this device should be reported to CIRCA Scientific and the US Food & Drug Administration.*

INDICATIONS FOR USE

The CrossWise™ RF Transseptal Cannula and accessories are used to create an atrial septal defect in the heart. Secondary indications include infusing solutions including heparinized saline and mixtures of 50% contrast media and 50% saline.

CONTRAINDICATIONS

There are no known contraindications for use of the CrossWise™ RF Transseptal Access System.

DEVICE DESCRIPTION

The CrossWise™ RF Transseptal Access System is used to puncture the Fossa Ovalis (FO) to establish transcatheter access from the right atrium to the left atrium. Monopolar radiofrequency (RF) energy is delivered between the CrossWise™ focal force electrode and a patient return electrode. The unique design of the focal force electrode minimizes trauma to cardiac tissue, unless RF energy is applied. A colored

sleeve is provided on the CrossWise™ RF Transseptal Cannula handle to indicate to the user when the tip of the catheter is still within the dilator.

The CrossWise™ RF Transseptal Cannula is supplied with a compatible dilator and a Super Stiff 0.032” PTFE-Coated Fixed Core J-Tip guidewire for vascular introduction using an over-the-wire technique, as outlined in the Instructions for Use section. The RF Transseptal Cannula is connected to a ValleyLabs Force2 Electrosurgical Generator (Medtronic, Inc) via the CrossWise™ RF Adapter Cable (packaged separately) and a commercially available Electrosurgical Pencil.

The CrossWise™ RF Transseptal Cannula is designed to facilitate injection of heparinized saline and/or contrast solution.

The dimensions for the CrossWise™ RF Transseptal Cannula can be found on the device label. The CrossWise™ RF Transseptal Access System offers multiple configurations compatible with various commercially available guide sheaths, as detailed in **Table 1.**

Table 1: Compatible Systems

CrossWise™ Product Configuration		**Compatible Guide Sheath**	
Description	**Reference Number**	**Description**	**Reference Number**
CrossWise™ 8.5Fr, 71CM, C1, Swartz	CW-1085S	St. Jude Medical Swartz Braided Transseptal Guiding Introducer, 8.5Fr x 63cm, SL0, SL1, SL2 Models	407451 407453 407455
CrossWise™ 8.5Fr, 97CM, C1, Agilis	CW-1085A	St. Jude Medical Agilis NxT Steerable Introducer, 8.5Fr, 71cm, Small, Med, Large Curl	408309 G408320 408310 G408321 G408324
CrossWise™ 12Fr, 88CM, C1, Watchman	CW-1012W	Boston Scientific WATCHMAN	M635TU70010 M635TU70020 M635TU70040 M635TU80010 M635TU80020 M635TU90050
CrossWise™ 12Fr, 88CM, C1, FlexCath	CW-1012C	Medtronic FlexCath Advance Steerable Sheath, 12Fr	4FC12
CrossWise™ 8.5Fr, 97CM, C1, CardioCurve	CW-1085C	Circa Scientific CardioCurve	CC-1071S CC-1071M CC-1071L
CrossWise™ 8.5Fr, 97CM, C1, Vizigo	CW-1085V	Biosense Webster Vizigo	D138501 D138502 D138503
CrossWise™ 13Fr, 97CM, C1, Faradrive	CW-1013F	Boston Scientific Faradrive	M004PF21M402

ANCILLARY DEVICES REQUIRED BUT NOT PROVIDED

Intracardiac puncture procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit and/or Intracardiac echo (ICE) imaging, radiographic table, physiologic recorder, emergency equipment, and instrumentation for gaining vascular access. The following ancillary devices may be used by the clinician and are commercially available from other manufacturers:

- CrossWise™ Multi-use RF Adapter Cable, REF CW-1001
- Conventional percutaneous needle for initiating vascular access
- Syringe for flushing devices with heparinized saline and contrast media administration
- Transseptal introducer sheath (see **Table 1** for compatible guide sheath)
- ValleyLabs Force 2 Electrosurgical Generator
- Patient Return Electrode, such as the Covidien Polyhesive Adult Patient Return Electrode, REF E7507

INSPECTION PRIOR TO USE

Prior to use of the CrossWise™ RF Transseptal Access System, the individual components, including the CrossWise™ RF Transseptal Cannula and the CrossWise™ RF Adapter Cable, should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use damaged or defective equipment.

The CrossWise™ RF Transseptal Access System is provided in a cardboard shelf carton. Within the carton, the sterile device is mounted on a backer card inside a Tyvek pouch. The pouch should be examined for obvious damage. Do not use any product with damaged packaging.

The RF Transseptal Cannula is labeled on both the cardboard shelf box and the Tyvek pouch. The contents of the package are clearly identified on both labels along with other information concerning the contents of the package. A careful review of the label is required to ensure the proper RF Transseptal Access System has been selected for the procedure and that the product is not expired. Dispose of any product found where the current date exceeds the use by date.

STORAGE AND HANDLING

The CrossWise™ RF Transseptal Access System should be stored in a cool, dry place. Keep out of sunlight.

The used product should be disposed of in accordance with the facility’s requirements for solid and sharps biohazard waste.

PROCEDURAL CONSIDERATIONS

Read the Instructions for Use before using this device to reduce the potential complications associated with Transseptal Puncture (TSP) procedures. Only physicians trained in TSP procedures and in using electrosurgical equipment should use this device. TSP procedures should only be performed in appropriately equipped facilities that have trained personnel to perform such procedures.

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

- Fluoroscopic imaging or echocardiographic imaging is required
- 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

INSTRUCTIONS FOR USE

1. Carefully read, understand, and follow all equipment instructions to prevent complications.
2. When handling the sterile CrossWise™ RF Transseptal Access System, use aseptic technique.
3. Before use, thoroughly flush the CrossWise™ Transseptal Cannula and CrossWise™ Dilator with heparinized saline.
4. Insert the CrossWise™ Transseptal Cannula into the CrossWise™ Dilator until it is fully seated with the cannula tip exposed.
5. Prepare the ValleyLab Force2 Generator.
    a. Attach the Patient Return Electrode (PRE) to the patient and connect the cable to the generator by following the electrode instructions for use.
    b. Connect the monopolar Electrosurgical Pencil to the generator.
    c. Power on the generator and set it to "Cut" mode with an output setting of 25.
6. Gain access through the femoral vein and navigate the 0.032" guidewire, provided with CrossWise™, into the Superior Vena Cava (SVC).
7. Advance the compatible transseptal sheath (refer to **Table 1**) over the guidewire using the dilator provided with the sheath.
8. Remove the dilator from the compatible transseptal sheath.
9. Insert the CrossWise™ Transseptal Cannula and CrossWise™ Dilator through the compatible transseptal sheath (refer to **Table 1**)until the dilator hub meets the sheath hub. Snap-in features can be used for convenience.
10. Once the CrossWise™ Dilator reached the hub of the compatible transseptal sheath, retract the CrossWise™ Transseptal Cannula tip within the dilator before repositioning.

    Note: The indicator sleeve on the CrossWise™ Transseptal Cannula handle may be used to verify whether the tip of the cannula is advanced past the end of the dilator. If any portion of the indicator sleeve has entered the hub of the dilator, the tip of the cannula is exposed and should be retracted.

11. Connect the CrossWise™ RF Adapter Cable to the CrossWise™ RF Transseptal Cannula and the Electrosurgical Pencil, and ensure connections are secure.
12. Retract the guidewire into the CrossWise™ Transseptal Cannula.
13. With the cannula tip still retracted, move the CrossWise™ Transseptal Cannula, CrossWise™ Dilator, and compatible sheath inferiorly into the right atrium.
14. Position the tip of the assembly onto the interatrial septum at the Fossa Ovalis (FO) using fluoroscopic and/or echocardiographic guidance.
15. Maintain the position of the compatible transseptal sheath and CrossWise™ Dilator and apply firm forward pressure on the CrossWise™ RF Transseptal Cannula to tent the FO. Verify that there is contact between the tip of the cannula and the FO. While maintaining forward pressure, apply RF energy via the control button on the Electrosurgical Pencil. Stop RF energy after advancing the cannula into the left atrium.

    Warning: Apply RF energy briefly (e.g., 1-2 seconds at a time) and use the minimum energy necessary. Do not deliver RF energy for more than five (5) seconds.

    Note: Confirm left atrium access through fluoroscopy, echocardiographic guidance, or contrast media injection.
16. If septal puncture is not achieved, reapply RF energy until successful. Do not exceed five (5) RF power applications.

    Note: If unsuccessful after five (5) attempts, it is recommended to use an alternate method.
17. Once a successful puncture into the left atrium is confirmed, enlarge the puncture by advancing the guidewire followed by the CrossWise™ Transseptal Cannula, CrossWise™ Dilator, and compatible sheath into the left atrium.
18. Slowly remove the CrossWise™ Transseptal Cannula and CrossWise™ Dilator. The sheath and guidewire may be left in place.

CLEANING AND STERILIZATION INSTRUCTIONS

The CrossWise™ RF Transseptal Access System is intended for single use only. Do not clean or re-sterilize the devices.

CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION

If you have any problems with or questions about the CrossWise™ RF Transseptal System, contact CIRCA Scientific customer service.

- In order to return any product, you must have a return authorization number before shipping the product back to CIRCA Scientific.
- CIRCA Scientific will not accept any used devices without proper decontamination being performed under the guidelines of the hospital where the device was used. Ensure that any product being returned to CIRCA Scientific has been cleaned and decontaminated in compliance with any local or organization guidelines.

LABELING AND SYMBOLS

Symbol	Definition	Standard	Reference
	Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician	21 CFR 801	N/A
	Manufacturer	ISO 15223-1	5.1.1
	Use By Date	ISO 15223-1	5.1.4
	Batch code	ISO 15223-1	5.1.5
	Catalogue number	ISO 15223-1	5.1.6
	Sterilized using ethylene oxide	ISO 15223-1	5.2.3
	Do not resterilize	ISO 15223-1	5.2.6
	Do not use if package is damaged and consult instructions for use	ISO 15223-1	5.2.8
	Single sterile barrier system with protective packaging inside	ISO 15223-1	5.2.13
	Single sterile barrier system with protective packaging outside	ISO 15223-1	5.2.14
	Keep away from sunlight	ISO 15223-1	5.3.2
	Keep dry	ISO 15223-1	5.3.4
	Temperature limit	ISO 15223-1	5.3.7
	Do not re-use	ISO 15223-1	5.4.2
	Consult instructions for use	ISO 15223-1	5.4.3
	Non-pyrogenic	ISO 15223-1	5.6.3
	Medical device	ISO 15223-1	5.7.7
	MR Unsafe	ASTM F2503-13	7.3.3
	Packaging unit (number inserted into symbol indicates the number in the package	ISO 7000	2794

LIMITED WARRANTY – DISPOSABLES AND ACCESSORIES

CIRCA Scientific, Inc. (CSI) warrants its Disposable and Accessory products against defects in materials and workmanship. Warrants that sterile products will remain sterile for a period of time as shown on the label, as long as the original package remains intact. Under this Limited Warranty, if any covered product is proven to be defective in materials or workmanship, CSI will replace or repair, in its absolute and sole discretion, any such product, less any charges to CSI for transportation and labor costs incidental to inspection, removal or restocking of product. The length of the warranty is:

(i) for the Disposable products, the shelf life of the product, and (ii) for the Accessory products, 90 days from shipment date. This Limited Warranty applies only to new original factory delivered products that have been used for their normal and intended uses. CSI's Limited Warranty shall not apply to CSI products that have been re-sterilized, repaired, altered, or modified in any way and shall not apply to CSI products that have been improperly stored or improperly cleaned, installed, operated or maintained contrary to CSI's instructions.

DISCLAIMER AND LIMITATION OF LIABILITY

THE LIMITED WARRANTY ABOVE IS THE SOLE WARRANTY PROVIDED BY THE SELLER. SELLER DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

THE REMEDY SET FORTH HEREIN SHALL BE THE EXCLUSIVE REMEDY FOR ANY WARRANTY CLAIM, AND ADDITIONAL DAMAGES, INCLUDING CONSEQUENTIAL DAMAGES OR DAMAGES FOR BUSINESS INTERRUPTION OR LOSS OF PROFIT, REVENUE, MATERIALS, ANTICIPATED SAVINGS, DATA, CONTRACT, GOODWILL OR THE LIKE (WHETHER DIRECT OR INDIRECT IN NATURE) OR FOR ANY OTHER FORM OF INCIDENTAL, OR INDIRECT DAMAGES OF ANY KIND, SHALL NOT BE AVAILABLE. SELLER'S MAXIMUM CUMULATIVE LIABILITY RELATIVE TO ALL OTHER CLAIMS AND LIABILITIES, INCLUDING OBLIGATIONS UNDER ANY INDEMNITY, WHETHER OR NOT INSURED, WILL NOT EXCEED THE COST OF THE PRODUCT(S) GIVING RISE TO THE CLAIM OR LIABILITY. SELLER DISCLAIMS ALL LIABILITY RELATIVE TO GRATUITOUS INFORMATION OR ASSISTANCE PROVIDED BY, BUT NOT REQUIRED OF SELLER HEREUNDER. ANY ACTION AGAINST THE SELLER MUST BE BROUGHT WITHIN EIGHTEEN (18) MONTHS AFTER THE CAUSE OF ACTION ACCRUES. THESE DISCLAIMERS AND LIMITATIONS OF LIABILITY WILL APPLY REGARDLESS OF ANY OTHER CONTRARY PROVISION HEREOF AND REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, AND FURTHER WILL EXTEND TO THE BENEFIT OF SELLER'S VENDORS, APPOINTED DISTRIBUTORS AND OTHER AUTHORIZED RESELLERS AS THIRD-PARTY BENEFICIARIES. EACH PROVISION HEREOF THAT PROVIDES FOR A LIMITATION OF LIABILITY, DISCLAIMER OF WARRANTY, OR CONDITION OR EXCLUSION OF DAMAGES IS SEVERABLE AND INDEPENDENT OF ANY OTHER PROVISION AND IS TO BE ENFORCED AS SUCH.

IN ANY CLAIM OR LAWSUIT FOR DAMAGES ARISING FROM AN ALLEGED BREACH OF WARRANTY, BREACH OF CONTRACT, NEGLIGENCE, PRODUCT LIABILITY, OR ANY OTHER LEGAL OR EQUITABLE THEORY, THE BUYER SPECIFICALLY AGREES THAT CSI SHALL NOT BE LIABLE FOR DAMAGES OR LOSS OF PROFITS, WHETHER FROM BUYER OR BUYER'S CUSTOMERS. CSI'S LIABILITY SHALL BE LIMITED TO THE PURCHASE COST TO THE BUYER OF THE SPECIFIED GOODS SOLD BY CSI TO BUYER, WHICH GIVES RISE TO THE CLAIM FOR LIABILITY.

No agent, employee, or representative has the authority to bind the Company to any other warranty, affirmation, or representation concerning the product.

This warranty is valid only to the original purchaser of CrossWise™ products directly from a CIRCA Scientific authorized agent. The original purchaser cannot transfer the warranty.

Use of any CIRCA Scientific product shall be deemed acceptance of the terms and conditions herein. The warranty periods for CrossWise™ products are as follows:

Disposable Products	The shelf life of the product
Accessory Products	90 days from the shipment date

Patent www.circascientific.com/en-us/patents