

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

Refer to the CrossWise™ RF Transseptal Access System IFU for a full list of warnings.

- This device is intended for use only by physicians well-versed in angiography, percutaneous interventional procedures, cardiac TSP, and the use of electrosurgical devices.
- The CrossWise™ Multi-Use RF Adapter Cable 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.
- This device is not intended for use in children or women who are pregnant or nursing.
- The CrossWise™ Multi-Use RF Adapter Cable is validated for multiple uses only when subjected to the cleaning and sterilization methods described in the Cleaning and Sterilization Instructions section. Failure to properly clean and sterilize the device can result in patient injury and/or communication of infectious disease(s) from one patient to another.
- Exclusively use the CrossWise™ Multi-Use RF Adapter Cable with the CrossWise™ RF Transseptal Access System. Attempting to use other connector cables can pose an electrocution risk to patient or operator.



PRECAUTIONS

Refer to the CrossWise™ RF Transseptal Access System IFU for a full list of precautions.

- Before using the CrossWise™ Multi-Use RF Adapter Cable 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™ Multi-Use RF Adapter Cable for any damage before use. Do not use damaged product.
- Do not use the CrossWise™ Multi-Use RF Adapter Cable beyond the indicated “Use By” date on the label.
- The CrossWise™ Multi-Use RF Adapter Cable is only validated to be cleaned and sterilized per the instructions in this instruction for use.
- Keep all electrical connections dry to prevent the risk of electrical shock or equipment malfunction.
- Prior to initiating radiofrequency energy delivery, confirm that all connections are secure and that there are no loose or frayed wires.
- 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.
- The physician is responsible for identifying, assessing, and communicating all foreseeable risks associated with the CrossWise™ RF Transseptal Access System to each patient.
- Never use a Multi-Use RF Adapter Cable that has cracked or damaged outer insulation materials.
- Never disconnect a Multi-Use RF Adapter Cable while RF energy is being delivered.
- Never bend the Multi-Use RF Adapter Cable in a way to produce a sharp bend or kink.
- Never pull or twist on the cable to disconnect the Multi-Use RF Adapter Cable.
- 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

Refer to the CrossWise™ RF Transseptal Access System IFU for a detailed list of potential adverse events.

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

Refer to the CrossWise™ RF Transseptal Access System IFU for the Indications for Use.

CONTRAINDICATIONS

The CrossWise™ Multi-Use RF Adapter Cable is not to be used with any devices other than those listed in **Table 1**.

Refer to the CrossWise™ RF Transseptal Access System IFU for detailed list of contraindications.

DESCRIPTION

The CrossWise™ Multi-Use RF Adapter Cable (CW-1001) is used in Transseptal Puncture Procedures (TSP) to connect the CrossWise™ RF Transseptal Cannula to a 3/32" electro-surgical (ES) pencil. The cable delivers radiofrequency (RF) energy to the RF Transseptal Cannula to facilitate septal puncture.

The Multi-Use RF Adapter Cable is packaged individually in a sterile package from CIRCA Scientific, Inc. for initial use only.

The Multi-Use RF Adapter Cable is validated for up to 10 sterilization uses only when subjected to the cleaning and sterilization methods described in the Cleaning and Sterilization Instructions below.

Refer to the manufacturer's instruction manual for detailed information concerning the setup of the ValleyLab Force2 Electro-surgical Generator. Refer to the CrossWise™ RF Transseptal Access System IFU for information concerning workflow and generator settings.

The dimensions for the CrossWise™ Multi-Use RF Adapter Cable can be found on the device label. The cable is compatible with all models of the CrossWise™ RF Transseptal Access System (packaged separately), as detailed in **Table 1**.

Table 1: Compatible RF Transseptal Access Systems

Description	Reference No.
CrossWise™ 8.5Fr, 71CM, C1, Swartz	CW-1085S
CrossWise™ 8.5Fr, 97CM, C1, Agilis	CW-1085A
CrossWise™ 12Fr, 88CM, C1, Watchman	CW-1012W
CrossWise™ 12Fr, 88CM, C1, FlexCath	CW-1012C
CrossWise™ 8.5Fr, 97CM, C1, CardioCurve	CW-1085C
CrossWise™ 8.5Fr, 97CM, C1, Vizigo	CW-1085V
CrossWise™ 13Fr, 97CM, C1, Faradrive	CW-1013F

INSPECTION PRIOR TO USE

Prior to use, the CrossWise™ Multi-Use RF Adapter Cable and all equipment used in the procedure should be carefully examined for damage or defects. The cable should be inspected for any cracking or damage to the outer insulating jacket and to the two end connectors. Do not use damaged or defective equipment.

The CrossWise™ Multi-Use RF Adapter Cable is initially provided sterile and coiled inside a Tyvek pouch in a cardboard shelf carton. The pouch should be examined for any obvious damage. Do not use any product with damaged packaging.

The Multi-Use RF Adapter Cable 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 cable has been selected for the procedure and that the product has not expired. Dispose of any product found where the current date exceeds the use by date.

STORAGE AND HANDLING

The CrossWise™ Multi-Use RF Adapter Cable should be stored in a cool, dry place. Keep out of sunlight.

Any product disposal should be performed in accordance with the facility's requirements for solid biohazard waste.

PROCEDURAL CONSIDERATIONS

Refer to the CrossWise™ RF Transseptal Access System IFU for a detailed list of procedural considerations.

INSTRUCTIONS FOR USE

1. Carefully read, understand, and follow all equipment instructions to prevent complications.
2. The CrossWise™ RF Transseptal Access System and guide sheath should be properly placed in the patient prior to connecting the Multi-Use RF Adapter Cable.
3. The Patient Return Electrode (PRE) should be properly placed and plugged into the ES Generator per manufacturer's instructions prior to connecting the Multi-Use RF Adapter Cable.
4. The ES Generator should be properly set up per the manufacturer's instructions and positioned appropriately prior to connecting the Multi-Use RF Adapter Cable. Refer to CrossWise™ RF Transseptal Access System IFU for generator settings.
5. Use aseptic technique when unpackaging the Multi-Use CrossWise™ RF Adapter Cable.
6. Prior to each use, visually inspect the device to ensure that the device does not have any evidence of cracks, corrosion, excessive discoloration, or other defects. If cracks, corrosion, excessive discoloration, or other defects are observed, DO NOT USE THE DEVICE, and refer to Storage and Handling for Disposal.

7. Connect the shrouded 2mm connector to the mating connector on the RF Transseptal Cannula. Ensure that the connection is fully seated.
8. Insert the exposed 3/32" pin into the ES Pencil socket. Ensure it is fully seated, and that no metal is exposed.
9. Refer to the CrossWise™ RF Transseptal Access System IFU for instructions to perform the TSP.
10. Disconnect each side of the cable by firmly pulling on the connector. Do not pull the cable to disconnect.

CLEANING AND STERILIZATION INSTRUCTIONS

The CrossWise™ Multi-Use RF Adapter Cable is validated for multiple use only when subjected to the cleaning and sterilization instructions below.

Failure to follow these Cleaning and Sterilizing Instructions can result in patient injury and/or communication of infectious disease(s) from one patient to another.

CLEANING

1. All visual contamination should be removed to facilitate subsequent sterilization steps.
2. Special care should be taken to clean all mating surfaces and crevices during cleaning.
3. Apply a new Super Sani-Cloth to the outside surfaces of the CrossWise™ Multi-Use RF Adapter Cable. Ensure cloths are not dripping liquid as excess liquid may affect the connectors.
4. Wipe with a Super Sani-Cloth until all visual contamination has been removed. Use new Super Sani-Cloths as required.
5. Allow the device to air dry thoroughly before sterilization.
6. Visually inspect the device to ensure all visible contaminants have been removed. If visible contaminants are still present, the device may undergo the cleaning process again starting at step 1.
7. Visually inspect the device for any evidence of cracks, corrosion, excessive discoloration, or other defects. If cracks, corrosion, excessive discoloration, or other defects are observed, DO NOT USE THE DEVICE, and refer to Storage and Handling for Disposal.
8. Place the cable on a sterilization tray.
9. Consult referenced standards for proper packaging and storage of sterilized product.

STERILIZATION









1. The CrossWise™ Multi-Use RF Adapter Cable must be placed in an appropriately sized peel pouch as defined under hospital guidelines. The recommended pouch size is no smaller than 8"x10" to ensure sharp bends are not induced into the cable.
2. The pouch can be self-sealed or heat-sealed plastic and paper pouch.
3. A pre-vacuum sterilization is required.
4. A total of 4 pre-conditioning pulses are required
5. Sterilization cycle: 132°C for 4 minutes.
6. Allow the CrossWise™ Multi-Use RF Adapter Cable in pouch to dry for at least 30 minutes prior to handling.
7. The CrossWise™ Multi-Use RF Adapter Cable is validated for 10 steam sterilization cycles. Reuse beyond 10 times may cause harm to the patient or user.







CUSTOMER SERVICE AND PRODUCT RETURN INFORMATION

If you have any problems with or questions about the CrossWise™ Multi-Use RF Adapter Cable 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 use if package is damaged and consult instructions for use	ISO 15223-1	5.2.8
	Single sterile barrier system	ISO 15223-1	5.2.11

	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
	Consult instructions for use	ISO 15223-1	5.4.3
	MR Unsafe	ASTM F2503-13	7.3.3

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 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
CrossWise™ is a trademark of CIRCA Scientific, Inc.