Instructions for Use
Reprocessed ViewFlex Xtra ICE
Diagnostic Ultrasound Catheter

Reprocessed Device for Single Use

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

DEVICE DESCRIPTION

The Reprocessed ViewFlex Xtra ICE is a temporary intracardiac ultrasound catheter intended for use in patients to accurately visualize cardiac structures, blood flow and other devices within the heart when connected to a compatible intracardiac ultrasound console via the compatible ViewFlex Catheter Interface Module. Examples of the types of other devices that can be visualized include, and are not limited to, intracardiac catheters, septal occluders, delivery wires, delivery sheaths, sizing balloons and transseptal needles. The use of these images is limited to visualization with no direct or indirect diagnostic use. The Reprocessed ViewFlex Xtra ICE catheter has a useable length of 90 cm, with a 9 French (F) shaft with an ultrasound transducer. A 10F introducer is recommended for use with this catheter for insertion into the femoral or jugular veins. The catheter tip has four-directional deflection allowing for Left-Right and Posterior-Anterior deflection, with an angle of at least 120 degrees in each direction.

The Reprocessed ViewFlex Xtra ICE Catheter is compatible with the ultrasound consoles listed in the table below. See table below for specifics on each ultrasound console.

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Compatible Ultrasound Console*	**ViewMate II**	**ViewMate Z or ViewMate**	**Phillips CX50**
Compatible ViewMate Catheter Interface Module	100038191	H701374 100043720	H701375 H700296
Maximum Viewing Depth	18 cm	18 cm	18 cm

*All consoles are not available in all countries.

INDICATIONS FOR USE

The Reprocessed ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

CONTRAINDICATIONS FOR USE

- The reprocessed catheter is contraindicated if there is an occurrence of conditions which create unacceptable risk during catheterization.
- The reprocessed catheter is contraindicated if the patient has a mechanical tricuspid valve (a prosthetic tissue valve is permissible).

- The reprocessed catheter is contraindicated if the patient has any condition that, in the opinion of the investigator, contraindicates the placement and use of the catheter or internal ultrasound.
- The reprocessed catheter is contraindicated if the patient has ongoing sepsis or known hypercoagulable state where the catheter could serve as a focal point or septic or bland thrombus formation.

WARNINGS

- The catheter system should be used only by or under the supervision of physicians thoroughly trained in the techniques of the cardiac catheter placement during interventional and electrophysiology procedures.
- The catheter system should be used only by or under the direct supervision of a physician thoroughly trained in sonography and ultrasound technology, or with the assistance of a sonographer or physician trained in ultrasound technology.
- The reprocessed catheter is to be used only with the ViewFlex Catheter Interface Module, the ViewMate, and the Phillips CX50 ultrasound consoles. Any other use or inappropriate electrical connection may pose a serious risk to the patient safety.
- The reprocessed catheter includes a 9F shaft. The physician should consider anatomical size restrictions if considering use of the ViewFlex Xtra ICE Catheter on pediatric patients.
- The reprocessed catheter is to be used for ultrasound imaging only.
- Do not immerse the proximal handle or cable connector in fluidof any kind. Moisture trapped between the connector and the catheter can damage the connector and/or the catheter, causing possible patient or user injury or death. Do not use the connector if the connector appears wet. Electrical performance may be affected.
- Do not use the reprocessed catheter if the packaging is open or damaged. Using a catheter that has been stored in an open or damaged package can result in patient or user injury.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

- Excessive bending, kinking, stretching or forcefully wiping the catheter can damage internal wires and/or distal tip articulating capabilities.
- Do not use forceps or any other mechanical tool to grip the catheter.
- Completely read and understand the User Manual and your ultrasound system user documentation before you attempt to connect the catheter to any ultrasound system and operate the catheter. Failure to completely read and understand the catheter User Manual and your ultrasound system user documentation can result in patient injury.
- Prior to connecting and attempting to operate the catheter, read and understand all accessory operating instructions and these Instructions for Use.
- Have antiarrhythmic drugs, an external defibrillator, and respiratory assist equipment available in case of complications during the use of this device.

ADVERSE REACTIONS / POTENTIAL COMPLICATIONS

Although temporary intracardiac catheter sonography procedures have been proven to be safe, the physician should also be aware that complications can occur with the use of any cardiac catheter.

Risks that may be associated with the use of the reprocessed catheter are those that may be encountered with the introduction and placement of any temporary cardiac catheter or pacing lead. Additional risk may also be incurred as a result of the delivery of electrical energy during internal defibrillation. Specific risks include, but are not limited to:

- Bleeding, hematoma or thrombus at the catheter introduction site
- Cardiac irritability
- Catheter kinking or excessive bending
- Infection/sepsis
- Intercostal or phrenic nerve stimulation
- Mechanical induction of arrhythmias or asystole
- Perforation of the chamber or vessel wall
- Perforation causing cardiac tamponade
- Pneumothorax
- Pulmonary Infarction

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- Thrombophlebitis
- Tricuspid valve injury
- Vasospasm

IMPORTANT ADVICE
Any alleged malfunction, deficiency, or deterioration in the characteristics and/or performance of this device, along with any alleged inadequacy in the labeling or Instructions for Use, which might lead or have led to a serious injury or death, must be brought to the attention of Innovative Health.

DIRECTIONS
The package label is detachable and may be affixed to the medical record of the patient.

Preparation
It is a recommended practice to have on hand a duplicate of each sterilized item when introducing a catheter. Thus, if aseptic technique is compromised, the procedure can continue.

Image Quality Interference (noise)
Relocate and/or shield the catheter electrical extension and Catheter Interface Module if experiencing severe RF interference during ablation procedures.

Catheter Insertion and Positioning
The following instructions are provided as a general guide and are intended for informational purposes only; the physician may alter the catheter insertion techniques based on standard clinical practice.

- Prior to the procedure, connect the patient to a vital signs monitor. Track patient vital signs throughout the procedure.
- Anticoagulation is to be used at all times during the procedure.
- Inspect the reprocessed catheter and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the catheter is damaged or if the package is compromised, do not use the catheter. Return the catheter to Innovative Health. **Do not attempt to resterilize.**
- Prepare the insertion site using cut down or percutaneous technique. Use a 10F or larger introducer sheath.
  Note: it is possible to transfix the femoral artery during percutaneous entry into the femoral vein. Follow proper femoral vein puncture technique.
- Remove the reprocessed catheter from the packaging using aseptic technique.
  - Remove catheter cable and handle from the packaging tray.
  - Carefully remove the catheter shaft and distal tip straight from protector tube without creating a sharp angle.
  - Inspect the catheter carefully for tip integrity and catheter condition.
- Connect the reprocessed ViewFlex catheter card edge connector to the ViewFlex Catheter Interface Module. Refer to the ViewFlex Catheter Interface Module instructions for use for additional instructions, precautions, and information on catheter connection.
- Prior to insertion, test the catheter for deflection function and imaging by placing the tip in sterile fluid. Movement will appear on the ultrasound console monitor.
- Hold the reprocessed catheter 1 to 2 cm from the introducer valve and feed it into the introducer slowly to prevent buckling of the catheter tip.
- Gently insert the reprocessed catheter into the selected vein and advance the catheter into the heart. If needed, confirm catheter position with the use of fluoroscopy. Do not remove and re-insert the reprocessed catheter into the introducer more than two (2) times during the procedure.
- The catheter tip may be deflected as desired during the procedure:
  - For Posterior-Anterior deflection, rotate the gray deflection knob labeled P/A clockwise/counterclockwise.

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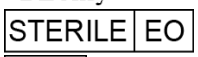
  - For Left-Right deflection, rotate the green deflection knob labeled L/R clockwise/counterclockwise.
- Secure the catheter handle at all times during the procedure. Do not allow the catheter handle or connection cable to fall or tug on the catheter body.
  Note: Do not leave the reprocessed catheter in the patient longer than 12 hours. Transducer performance and the incidence of insertion site complications increase significantly with catheters which remain indwelling longer than this period.
- Return both knobs to the neutral position to straighten the distal catheter tip before removing the catheter from the heart. Using fluoroscopy, verify that the distal catheter tip is straightened before removing the catheter from the heart.
- Do not use excessive force to advance or withdraw the reprocessed catheter. Using excessive force can result in patient injury or death.
- Manipulate the reprocessed catheter carefully in order to avoid cardiac damage, entanglement, perforation or tamponade.
- Refer to the ultrasound console Users' Manual for additional sonography instructions, precautions, and information on catheter connection.
- Upon use, please return the device per Innovative Health's instructions.

Explanation of Symbols

	Federal Law in the USA restricts this device to sale by or on the order of a physician
	Sterilized by Ethylene Oxide Gas
	Catalog Number
	Serial Number
	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Heat and Radioactive Sources
	Non-pyrogenic
	Contains or Presence of Phthalates
	Manufacturer

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

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

Please refer to www.innovative-health.com for product warranty.