Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed ViewFlex™ Xtra ICE Catheter

Reprocessed Device for Single Use

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

- **STERILE**

Explanation of Icons

℞ Only	Federal Law in the USA restricts this device to sale by or on the order of a physician.

STERILE EO	Sterilized by Ethylene Oxide Gas
	Use by Date
PHT BBP	Contains or Presence of Phthalate: benzyl butyl phthalate (BBP)
REF	Catalogue Number
	Do Not Reuse
	See Instructions For Use
	Do Not Use If Package Is Damaged
	Keep Away from Sunlight
	Keep Dry
	Protect from heat and radioactive sources
	Do not resterilize

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Reprocessed ViewFlex™ Xtra ICE Catheter Description
The Reprocessed ViewFlex™ Xtra ICE Catheter 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 compatible intracardiac ultrasound console via the compatible ViewFlex™ Catheter Interface Module. Examples of the types of 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 consoles.

Compatible Ultrasound Consoles*	ViewMate™ II	ViewMate™ Z or ViewMate™	Phillips CX50[a]
Compatible ViewFlex™ 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.
[a] CX50 is a trademark of Koninklijke Philips Electronics.N.V.

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
Reprocessed ViewFlex™ Xtra Ice Catheter are contraindicated:
- If there is an occurrence of conditions that create unacceptable risk during catheterization.
- If the patient that has a mechanical tricuspid valve (a prosthetic tissue valve is permissible).
- If the patient has ongoing sepsis or known hypercoagulable state where the catheter could serve as a focal point for septic or bland thrombus formation.
- If the patient has any condition that, in the opinion of the investigator, contraindicates the placement and use of the cardiac catheter or internal ultrasound.

Warnings
- The Reprocessed ViewFlex™ Xtra ICE catheter and 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 ViewFlex Xtra™ ICE catheter and system should be used only by or under the direct supervision of a physician thoroughly trained in the techniques of cardiac placement during interventional and electrophysiology procedures.
- The Reprocessed ViewFlex Xtra™ ICE 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 patient safety.
- The Reprocessed ViewFlex Xtra™ ICE 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 ViewFlex™ Xtra ICE catheter is to be used for ultrasound imaging only.
- Do not immerse the proximal handle or cable connector in fluid. Electrical performance may be affected.
- Do not use the Reprocessed ViewFlex™ Xtra ICE catheter if the packaging is opened or damaged.
- Do not use the Reprocessed ViewFlex™ Xtra ICE catheter if it is damaged.

- Tactile feedback of reprocessed devices may vary during use.

Precautions
- Do not attempt to use the Reprocessed ViewFlex™ Xtra ICE Catheter prior to completely reading and understanding the Directions for Use.
- The Reprocessed ViewFlex™ Xtra Ice catheters are supplied sterile only if packaging is not damaged or open.
- Inspect the packaging and catheter for damage or defects prior to use.
- The Reprocessed ViewFlex™ Xtra ICE Catheters have been sterilized using EtO. Do not attempt to sterilize the catheters by autoclave, gamma or ultraviolet radiation, or liquid sterilizing solutions.
- Do not bend, kink, stretch, or forcefully wipe the catheter. These actions may damage the catheter.
- Do not use mechanical tools or forceps to grip the catheter.
- Have antiarrhythmic drugs, an external defibrillator, and respiratory assist equipment available in case of complications during the use of this device.
- The device should only be used in patients that have received anticoagulation prior or during the procedure.

Adverse Reactions
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 ViewFlex™ Xtra ICE catheter are those that may be encountered with the introduction and placement of temporary cardiac catheter or pacing lead. As a result of the delivery of electrical energy during internal defibrillation additional risk may result.

Adverse events related to cardiac catheterization have been documented and 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
- Thrombophlebitis
- Tricuspid valve injury
- Vasospasm

Important Advice
Any alleged malfunctions, deficiencies, or deterioration in the characteristics and/or performance of this device, along with any alleged inadequacy in the labeling or Instruction for Use, which might lead or have led to a serious injury or death must be brought to the attention of Stryker Sustainability Solutions.

Directions for Use

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

Image Quality Interference (noise)
If severe RF interference is experienced during ablation procedures, relocate and/or shield the Reprocessed ViewFlex™ Xtra ICE catheter electrical extension and Catheter Interface Module.

Catheter Insertion and Positioning
1. Follow a suitable surgery protocol. The instruction are provided as a general guide and are intended for information purposes only, the physician may alter the catheter insertion techniques based on standard clinical practice.
2. The Reprocessed ViewFlex™ Xtra ICE catheter is intended for use during single patient procedure.

3. Do not attempt to resterilize. Stryker will not accept Reprocessed ViewFlex™ Xtra ICE Catheters for reprocessing that have been reprocessed and sterilized by other facilities.
4. The package label is detachable and may be affixed to the medical record of the patient.
5. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
6. Connect the patient to a vital signs monitor. Track patient vital signs throughout the procedure.
7. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised.
8. Do not use the Reprocessed ViewFlex™ Xtra ICE Catheter if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the Reprocessed ViewFlex™ Xtra ICE Catheter and the package to Stryker.
9. Prepare the insertion site using cutdown or percutaneous entry 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.
10. Using proper sterile technique, remove the Reprocessed ViewFlex™ Xtra ICE Catheter from the package and place it in a sterile work area.
11. Carefully inspect the catheter for tip integrity and catheter condition. Do not use the catheter if any damage is noted. Return the Reprocessed ViewFlex™ Xtra ICE Catheter and packaging to Stryker if it is not in acceptable condition for the procedure.
12. Connect the Reprocessed ViewFlex™ Xtra ICE Catheter connector edge 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.
13. Prior to insertion, test that the catheter is imaging by placing the tip in sterile fluid. Movement will appear on the ultrasound console monitor.
14. Hold the catheter 1 to 2 cm from the introducer valve and feed it into the introducer slowly to prevent buckling of the catheter tip.
15. Gently insert the catheter into the selected vein and advance the catheter into the heart. Confirm catheter position with the use of fluoroscopy, if needed. Do not remove and re-insert the catheter into the introducer more than two (2) times during the procedure.
16. The Reprocessed ViewFlex Xtra ICE Catheter tip may be deflected as desired during the procedure:
    - For Posterior – Anterior deflection, rotate the gray deflection knob labeled P/A clockwise or counterclockwise
    - For Left – Right deflection, rotate the green deflection knob labeled L/R clockwise or counterclockwise
17. The catheter handle should be secure 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 catheter in the patient longer than 12 hours. Transducer performance or incidence of insertion site complications increase significantly with catheters which remain in dwelling longer than this specified time.
18. Return both knobs to the neutral position to straighten the distal tip of the catheter before removing the catheter from the heart. Using fluoroscopy, verify that the distal tip of the catheter is straightened before removing the catheter from the heart.
19. Refer to the ultrasound console Users' Manual for additional sonography instructions, precautions, and information on catheter connection.

Hospital Storage

- Room Temperature: 18°C to +26°C (64°F to 79°F)
- Use product on a first-in, first-out basis prior to expiration or use by date on the label

Transport

- Temperature: -20°C to +50°C (-4°F to 122°F)
- Relative Humidity: 25% to 90%

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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

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.

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