Reprocessed for

stryker

Instructions for use

Reprocessed .014 IVUS Catheters

Reprocessed device for single use

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

- Contents are sterile unless package is opened or damaged.
- For use with the Volcano Imaging System only.

WARNING: This product can expose you to chemicals, including Ethylene Oxide which is known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Note: Thoroughly read all instructions, including the Volcano Imaging System Operator's Manual, prior to using the Reprocessed .014 IVUS Catheters. Observe all warnings, precautions and cautions noted throughout these instructions. Failure to do so may result in patient complications.

Explanation of symbols

Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician.
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.1.9	3724	Distributor	Indicates the entity distributing the medical device into the locale
	ISO 15223-1 Clause 5.2.3	2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 Clause 5.1.4	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	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.
	ISO 15223-1 Clause 5.2.6	2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1 Clause 5.2.8	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Clause 5.6.3	2724	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	ISO 15223-1 Clause 5.3.2	0624	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 15223-1 Clause 5.3.4	0626	Keep dry	Indicates a medical device that needs to be protected from moisture.

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Reprocessed .014 IVUS Catheter description

The Reprocessed .014 IVUS Catheter incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The Catheter utilizes an internal lumen that allows the catheter to track over the 0.014'' (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cutdown into the vascular system. Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.

The Catheter may only be used with the Volcano s5 Series or CORE Series of Systems Operator's Manual. This catheter will not operate if connected to any other imaging system.

Indications for use

The Reprocessed .014 IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Contraindications for use

The Catheter is generally contraindicated in situations presenting a reasonable probability of tissue or organ damage. This device is not currently indicated for use in cerebral vessels.

Warnings

- Use of the Catheter should be restricted to specialists who are familiar with, and have been trained to perform, the procedures for which this device is intended.
- The product is supplied sterile; if the pouch is opened or damaged compromising the sterile barrier, please discard the product. This product cannot be re-sterilized or re- used.
- The Catheter is designed for single use only.
- In addition, VOLCANO assumes no responsibility or liability for incidental or consequential damages which may result from such re-use. Re-use including re- sterilization of unused product may result in, but is not limited, to the following:
    - Potential critical harm to patient due to Device Separation, Material Deformation or Infection/Sepsis
    - Failure to Image or other device malfunctions
- The catheter transducer is a delicate electronic assembly, deliberate misuse by bending, twisting or any other severe physical manipulation will void the warranty.
- Do not use the device for purposes other than those indicated.
- The device may not be safe in those patients who cannot be properly anticoagulated or who cannot receive anti-platelet or anti-coagulation therapies.

Precautions

The Catheter is a delicate scientific instrument and should be treated as such. Always observe the following precautions:

- Prior to use, carefully inspect the scanner and catheter body for bends, kinks or other damage. Do not use a damaged or suspected damaged catheter.
- Protect the catheter tip from impact and excessive force.
- Do not cut, crease, knot, or otherwise damage the catheter.
- Protect the electrical connections from exposure to fluid.
- Do not handle the transducer.
- The outside diameter along the entire length of the guide wire should not exceed the maximum specified
- During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.
- Clean guide wire and flush catheter thoroughly with heparinized saline before and after each insertion.

- When inserting the guide wire both catheter and wire must be straight with no bends or kinks, or damage to inner lumen may occur.
- Do not advance the guide wire against significant resistance. If binding occurs between the catheter and the guide wire while inside the patient, CAREFULLY REMOVE BOTH the wire and catheter and do not use. If binding occurs outside of the patient, remove the catheter and do not use.
- The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- During the procedure, provide appropriate anticoagulation to the patient as needed.
- When advancing or re-advancing the catheter over a guide wire and through a stented vessel, in the event that the stent is not fully apposed against the vessel wall, the guide wire and/or catheter may become entangled in the stent between the junction of the catheter and guide wire or within one or more stent struts. This may result in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation. Never use force to advance the catheter.
- Use caution when re-advancing a catheter over a guide wire and into a stented vessel. Forceful advancement of the IVUS catheter could cause entanglement between the catheter and the stent(s) resulting in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation.
- Use caution when removing the catheter over the guide wire from a stented vessel to minimize patient risk.
- If resistance is encountered during pull bade, remove the entire system (guide wire, IVUS catheter, sheath/guide catheter) at the same time.

Adverse reactions

Possible adverse effects include, but are not limited to, the following: myocardial infarction; occlusion; coronary vessel dissection; perforation, rupture or injury; restenosis; hemorrhage or hematoma; unstable angina; arrhythmias; drug reactions; allergic reaction to contrast medium; hypo/hypertension; infection; vessel spasm; arteriovenous fistula; embolism; entry puncture site bleeding; vascular wall injury; vessel thrombosis; pseudoaneurysm (at site of catheter insertion); renal failure; coronary aneurysm; vessel trauma requiring surgical repair or intervention, death.

Directions for use

1. The Catheter may be introduced into the vascular system percutaneously or surgically and advanced to the desired location. The frequency and duration of administration is subject to the discretion of the physician and depends upon the procedure and information required.
2. Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.
3. If using VH IVUS, review the Volcano Imaging System Operator's Manual prior to use.
4. Remove the Catheter from its sterile packaging when in a sterile field.
5. Remove the stylet.
6. Attach the flushing device to a 10 cc or larger syringe filled with heparinized normal saline. Insert the distal tip of the catheter into the device. Inject the saline into the lumen. Fluid should be observed flowing out of the Guide Wire Exit Port.
7. Remove the clear/white cap from the PIM connector (if applicable).
8. Connect the PIM connector of the Catheter to the Patient Interface Module as described in the Volcano Imaging System Operator's Manual. Verify that the device is imaging.
9. Place the Catheter onto the intravascular guide wire which has been previously positioned into the artery. A guide wire of 0.014# (0.36 mm) or smaller can be used.
10. Advance the catheter over the guide wire to the site of the vasculature to be imaged.
11. Check the Monitor for an image. Once the image has been obtained, the catheter can be advanced over the guide wire to image additional segments of vasculature.
12. If an image is not obtained or is not satisfactory, consult the Volcano s51M Series or CORE™ Series of Systems Operator's Manual.
13. When the procedure is completed, remove and discard the catheter in accordance with local regulations.

Storage and Handling

Products should be stored in a dry, dark, cool place in their original packaging.

Product Specifications

All Models-

Crossing profile at transducer:	Catheter 3.5F (0.046″, 1.17 mm)
Maximum guide wire:	0.014″ (0.36 mm)
Minimum guide catheter O.D.:	5F (0.066″, 1.67 mm)
Minimum guide catheter I.D.:	0.056″, 1.42 mm
Usable Length:	150 cm

Acoustic Output Parameter	B-Mode	Chromaflo
$I_{SPTA.3}$ (mW/cm^2)*	2.93×10^{-3}	7.98×10^{-2}
$I_{SPPA.3}$ (W/cm^2)*	7.5×10^{-3}	175.0×10^{-3}
Pr.3 (MPa)	20.0×10^{-3}	81.5×10^{-3}
PD (μs)	161.0×10^{-3}	125.0×10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)	18.6	17.9
MI*	4.5×10^{-3}	1.92×10^{-2}
TI*	2.06×10^{-5}	1.56×10^{-4}

*Maximum overall uncertainty +33.9% / -30.5%

**As estimated tissue

TI:	Thermal Index defined as TI = $\frac{W_{01x1fc}}{210}$
W_{01x1}:	Bounded-square Output (mW)
Fc:	Center Frequency (MHz)
MI:	Mechanical Index
ISPPA.3:	Derated Intensity, Spatial Peak Pulse Average (W/cm^2)
ISPTA.3:	Derated Intensity, Spatial Peak Temporal Average (mW/cm^2)
Pr.3:	Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)
PD:	Pulse Duration (μs)
PRF:	Pulse Repetition Frequency (Hz)

THIS PRODUCT CANNOT BE ADEQUATELY CLEANED AND/OR STERILIZED BY THE USER IN ORDER TO FACILITATE SAFE REUSE AND IS THEREFORE INTENDED FOR SINGLE USE. ATTEPMTS TO CLEAN OR STERILIZE THESE DEVICES MAY RESULT IN A BIO-INCOMPATIBILITY, INFECTION OR PRODUCT FAILURE RISKS TO THE PATIENT.

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.

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.

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.

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EL10190 Rev. A 09/2024