Reprocessed for

stryker

Instructions for use

Reprocessed Visions PV .035 Digital IVUS 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.

- 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 NES Reprocessed Visions PV .035 Digital IVUS Catheter. 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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Visions PV .035 Digital IVUS Catheter description

The Reprocessed Visions PV .035 catheter is an over-the-wire intravascular imaging catheter with a digital ultrasound transducer at the distal end. The transducer utilizes a 64-element cylindrical array that 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 peripheral vessels.

The catheter is introduced percutaneously or via surgical cutdown into the vascular system, and it is designed to track over 0.035″-0.038″ (0.89-0.97mm) guide wires.

The catheter has body markers 1 cm apart along the working length. There are 25 radiopaque markers on the distal end of the catheter, starting 1cm from the imaging plane, with the 25th RO marker overlapping the distal most wide inked marker. Inked markers (non-radiopaque) continue along the shaft, spaced 1 cm apart, middle-to-middle, with wider marks indicating 5 cm intervals (See Figure 1).

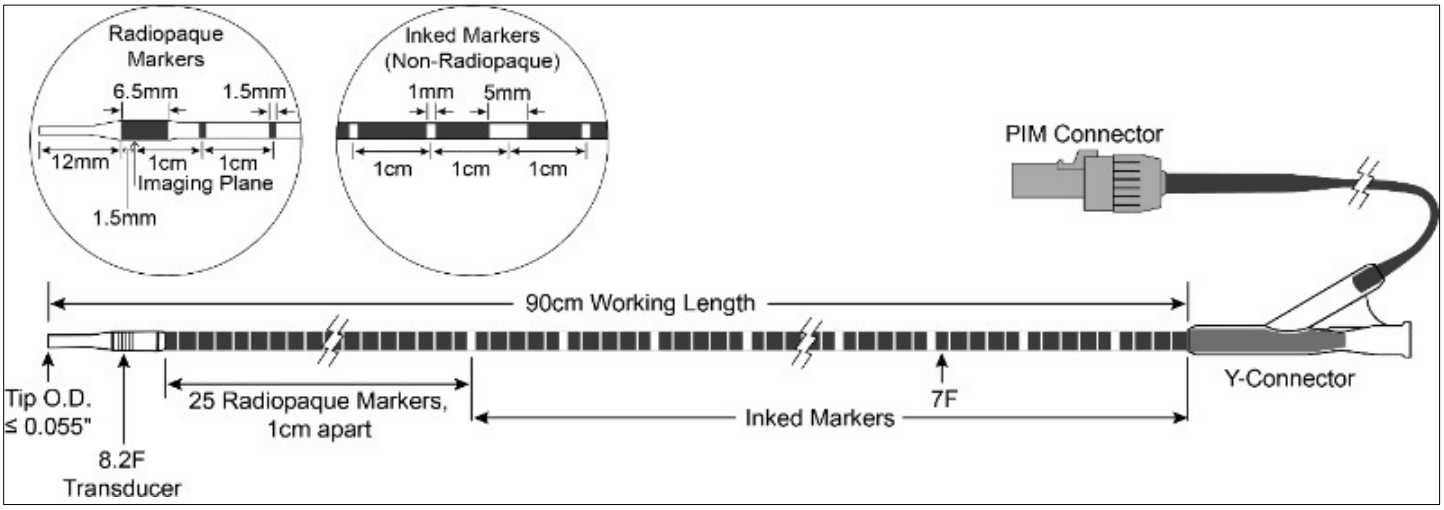

Figure 1: Visions PV .035 Catheter

A hydrophilic coating is applied externally to a distal portion of the catheter.

The Visions PV .035 catheters may only be used with Volcano s5 Series and CORE Series of Systems.

Indications for use

The Reprocessed Visions PV .035 catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Visions PV .035 ultrasound imaging catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Contraindications for use

The Reprocessed Visions PV .035 catheter is contraindicated for:

- Use in cerebral vasculature
- Situations presenting a reasonable probability of tissue or organ damage
- Vessel spasm
- Severe calcification
- Angiographic evidence of thrombus
- Severe vessel tortuosity
- The catheter should not be used in patients unable to receive heparin or an acceptable alternative to achieve the adequate anticoagulation.

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 catheter transducer is a delicate electronic assembly. Deliberate misuse by bending, twisting, or any other severe manipulation may result in device malfunction.
- Do not use the device for other purposes other than those indicated.
- Tactile feedback of reprocessed devices may vary during use.

Precautions

- Do not attempt to operate the catheter prior to completely reading and understanding these directions for use.
- 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 the placement of the catheter does not preclude blood flow through the vessel.
- Clean guide wire and flush catheter thoroughly with sterile heparinized normal saline before and after each insertion.
- Keep the exterior of the catheter wiped down with sterile heparinized normal saline during prolonged use.
- 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 guidewire against significant resistance. If binding occurs between the catheter and the guidewire while inside the patient, CAREFULLY remove both the wire and the catheter and do not use. If binding occurs outside the patient, remove the catheter and do not use.
- 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, in the event that the catheter may come in contact with one or more stents struts. Subsequent 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.
- The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- If resistance is encountered during pullback, remove the entire system (guide wire, IVUS catheter, sheath/guide catheter) at the same time.
- Store in a cool, dark, dry place

Adverse reactions

As with all catheterization procedures, complications may be encountered with use of the catheter. Possible adverse effects include, but are not limited to, the following: occlusion; vessel spasm; vessel dissection; perforation; rupture or injury; restenosis; hemorrhage or hematoma; drug reactions; allergic reaction to contrast medium; hypo/hypertension; infection; arteriovenous fistula; embolism; entry puncture site bleeding; vascular wall injury; vessel thrombosis; pseudoaneurysm (at site of catheter insertion); renal failure; aneurysm; vessel trauma requiring surgical repair or intervention; death.

Directions for use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect the 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.
3. 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.

4. Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.
5. Open the catheter packaging using sterile technique and place the hoop in the sterile field.
6. Prepare the catheter by flushing the guide wire lumen through the port at the catheters Y-connector, and then wipe down the entire working length with sterile heparinized normal saline.
7. Connect the PIM connector of the catheter to the patient Interface Module as described in the imaging system Operator's Manual. Verify that the device is imaging.
8. Place the catheter onto the intravascular guide wire. A guide wire of 0.035" (0.89 mm)- 0.038" (0.97 mm) can be used).
9. Activate the hydrophilic coating using the sterile heparinized normal saline.
10. Advance the catheter over the guide wire to the site of the vasculature to be imaged. The guide wire should always be advanced ahead of the IVUS catheter.
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 not satisfactory, consult the Volcano Imaging System Operator's Manual.
13. Once imaging has been completed, remove the catheter and flush thoroughly with sterile heparinized normal saline.
14. For subsequent imaging, clean guide wire and flush catheter thoroughly with sterile heparinized normal saline before re-insertion.

Product Specifications

Model:	Visions PV .035
Maximum shaft outer diameter	7.0F (0.092", 2.33mm)
Maximum scanner diameter:	8.2F (0.108", 2.73mm)
Maximum guide wire:	0.038" (0.97 mm)
Minimum Introducer Sheath:	8.5F (0.111", 2.83 mm)
Usable Length:	90 cm

Acoustic Output Parameter	B-Mode
ISPTA.3 (mW/cm^2)	0.0534
ISPPA.3 (W/cm^2)	0.0680
Pr.3 (MPa)	0.0482
PD (μs)	0.333
PRF (Hz)	2.09x10^4
Center Freq (MHz)	9.00
MI*	0.0162
TI*	6.18x10^{-5}

Maximum overall uncertainty ±20.4%

*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.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

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:

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