Instructions for Use
Reprocessed Eagle Eye Platinum ST RX Digital IVUS 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 Eagle Eye Platinum ST RX Digital 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 image of the coronary and peripheral vessels.

The Reprocessed Eagle Eye Platinum ST RX Digital IVUS 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 Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheters are for exclusive use with Volcano s5 Series and CORE Series of Systems. This catheter will not operate if connected to any other imaging system.

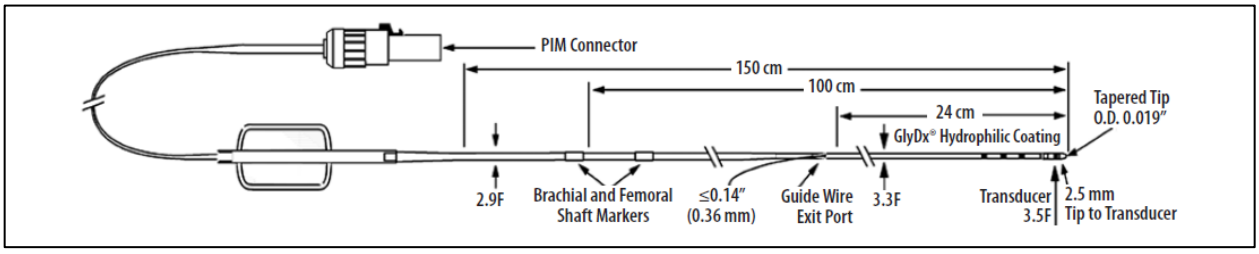

Figure 1: Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter

INDICATIONS FOR USE

The Reprocessed Eagle Eye Platinum ST RX Digital IVUS catheters are 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 the cerebral vessels.

The Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheters are 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 Reprocessed Eagle Eye Platinum ST RX Digital IVUS catheters are 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 Reprocessed Eagle Eye Platinum ST RX Digital IVUS catheters 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 physical manipulation may result in device malfunction.
- 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.
- Tactile feedback of reprocessed devices may vary during use.

PRECAUTIONS

The Reprocessed Eagle Eye Platinum ST RX Digital IVUS device 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 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
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
The Reprocessed Eagle Eye Platinum ST RX Digital IVUS 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.
- The package label is detachable and may be affixed to the medical record of the patient.
- 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**.
- Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to use.
- If using VH IVUS, review the Volcano Imaging System Operator's Manual prior to use.
- Remove the Reprocessed Eagle Eye Platinum ST RX Digital IVUS catheter from its sterile packaging when in a sterile field.
- 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.
- Remove the clear/white cap from the PIM connector (if applicable).
- Connect the PIM connector of the Reprocessed Eagle Eye Platinum ST RX Digital IVUS catheter to the Patient Interface Module as described in the Volcano Imaging System Operator's Manual. Verify that the device is imaging.
- Place the Reprocessed Eagle Eye Platinum ST RX Digital IVUS 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.
- Advance the catheter over the guide wire to the site of the vasculature to be imaged.
- 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.
- If an image is not obtained or is not satisfactory, consult the Volcano s5 Series or CORE Series of Systems Operator's Manual.

Product Specifications:

Model:	Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter
Catalog Number:	85900PST
Crossing profile at transducer:	3.5F (0.046", 1.17mm)
Maximum guide wire	0.014" (0.36mm)
Minimum guide catheter O.D.	5F (0.066", 1.67mm)
Minimum guide catheter I.D.	0.056", 1.42mm
Usable Length	150cm

Acoustic Output Parameter	B-Mode	Chromaflo
ISPTA.3 (mW/cm^2)*	2.93x10^{-3}	7.98x10^{-2}
ISPPA.3 (W/cm^2)*	7.5x10^{-3}	175.0x10^{-3}
Pr.3 (MPa)	20.0x10^{-3}	81.5x10^{-3}
PD (us)	161.0x10^{-3}	125.0x10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)	18.6	17.9
MI**	4.5x10^{-3}	1.92x10^{-2}
TI**	2.06x10^{-5}	1.56x10^{-4}

*Maximum overall uncertainty
**As estimated in tissue

Terms	Definitions
TI:	Thermal Index defined as TI=$\frac{W_{01X1fc}}{210}$
W_{01x1fc}**:**	Bounded-square Output (mW)
fc:	Center Frequency (MHz)
MI:	Mechanical Index defined as MI=Pr.3/($f_c^{1/2}$)
$I_{SPPA.3}$**:**	Derated Intensity, Spatial Peak Pulse Average (W/cm^2)
$I_{SPTA.3}$**:**	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)
W_0**:**	Total Power (mW)
PD:	Pulse Duration (μs)
PRF:	Pulse Repetition Frequency (Hz)

EXPLANATION OF SYMBOLS

Rx 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
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Use by Date
	Do Not Reuse
STERILIZE	Do Not Resterilize
	Consult Instructions for Use
	Keep Product Dry
	Keep Away from Sunlight
	Do Not Use if Package is Damaged
	Non-pyrogenic
LATEX	Not made with Natural Rubber Latex

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.