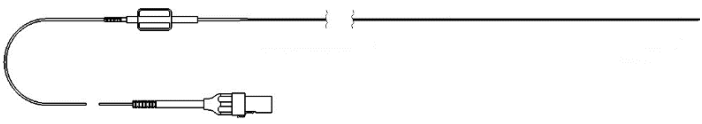
NES Reprocessed Visions PV .018 Digital IVUS Catheter

REF # R-86700

INSTRUCTIONS FOR USE



2142 Thomaston Avenue
Waterbury, CT 06704
203-756-2111
www.smarthealth-care.com

Manufacturer:
Northeast Scientific, Inc.
2142 Thomaston Avenue
Waterbury, CT 06704 U.S.A.

CAUTION:

1. U.S. Federal Law restricts this device to sale by or on the order of a physician.
2. Prior to use, read this entire package insert.

For Symbol Glossary, visit www.smarthealth-care.com

INDICATIONS FOR USE:

The NES Reprocessed Visions PV.018 Digital 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 NES Reprocessed Visions PV.018 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

DESCRIPTION·

The NES Reprocessed Visions PV.018 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 images of the coronary and peripheral vessels.
The NES Reprocessed Visions PV.018 Digital IVUS Catheter utilizes an internal lumen that allows the catheter to track over the 0.018" (0.46 mm) guide wire. The guide wire exits from the guide wire lumen approximately 31 cm proximal to the catheter tip. The NES Reprocessed Visions PV.018 Digital IVUS Catheter is introduced percutaneously or via surgical cutdown into the vascular system.
The NES Reprocessed Visions PV.018 Digital IVUS Catheter may only be used with Volcano s5™ Series and CORE™ Series of Systems. This catheter will not operate if connected to any other imaging system.

CONTRAINDICATIONS·

The NES Reprocessed Visions PV.018 Digital IVUS 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.

ADVERSE EFFECTS:

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.

WARNINGS

- Use of the NES Reprocessed Visions PV.018 Digital IVUS Catheter should be restricted to specialists who are familiar with, and have been trained to perform, the procedures for which this device is intended. Handling of reprocessed devices may vary during use.
- 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 NES Reprocessed Visions PV.018 Digital IVUS Catheter is designed for single use only.
- Volcano Corporation ("VOLCANO"), makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of the catheter.
- In addition, VOLCANO assumes no responsibility or liability for incidental or consequential damages which may result from such re-use. Re-use including resterilization 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 NES Reprocessed Visions PV.018 Digital IVUS Catheter 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 NES Reprocessed Visions PV.018 Digital IVUS Catheter device is a delicate scientific instrument and should be treated as such. Always observe the following precautions:

- 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.
- 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. e.

INSTRUCTIONS FOR USE:

The NES Reprocessed Visions PV.018 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.

- Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.
- Remove the NES Reprocessed Visions PV.018 Digital IVUS Catheter from its sterile packaging when in a sterile field. Attach the flushing device (supplied on coil in the packaging) 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.
- Connect the PIM connector of the NES Reprocessed Visions PV.018 Digital IVUS Catheter to the Patient Interface Module as described in the In-Vision Imaging System Operator's Manual. Verify that the device is imaging.
- Place the NES Reprocessed Visions PV.018 Digital IVUS Catheter onto the intravascular guide wire which has previously positioned into the artery. A guide wire of 0.018" (0.46 mm) or smaller can be used.
- Advance the NES Reprocessed Visions PV.018 Digital IVUS 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 Imaging System Operator's Manual.
- 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:

Model	NES Reprocessed Visions PV.018 Digital IVUS Catheter
Maximum shaft outer diameter	3.4F (0.044", 1.13 mm)
Maximum scanner diameter	3.5F (0.046", 1.17 mm)
Maximum guide wire	0.018" (0.46 mm)
Minimum guide catheter	6F (2.00 mm, 0.079")
Usable length	135 cm

Acoustic Output Parameter	B-Mode	Chromaflo
$I_{SPTA.3}$ (mW/cm^2)*	2.087	13.950
$I_{SPPA.3}$ (W/cm^2)*	0.2963	1.709
Pr.3 (MPa)	$132.3x10^{-3}$	$267.7x10^{-3}$
PD (µs)	$168.3x10^{-3}$	$113.8x10^{-3}$
PRF (Hz)	43008	70656
Center Freq (MHz)	20	20
MI**	3.055×10^{-2}	5.30×10^{-2}
TI**	2.698×10^{-4}	4.748×10^{-4}

* Maximum overall uncertainty +33.9% / -30.5%

** As estimated in tissue

TI: **Thermal Index defined as TI = (W_{01x1fc})/210**

W_{01x1}: **Bounded-square Output (mW)**

fc: **Center Frequency (MHz)**

MI: **Mechanical Index defined as MI=Pr.3/($fc^{1/2}$)**

$I_{SPPA.3}$: **Derated Intensity, Spatial Peak Pulse Average (W/cm^2)**

$I_{SPTA.3}$: **Derated Intensity, Spatial Peak Temporal Average (mW/cm^2) Derated**

Pr.3: **Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)**

Wo: **Total Power (mW)**

PD: **Pulse Duration (µs)**

PRF: **Pulse Repetition Frequency (Hz)**