PHILIPS

Reconnaissance PV .018

Digital IVUS catheter

Model:
018OTW

Instructions for use

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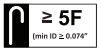
Symbol	Standard	Reference	Title	Description
	ISO 15223-1	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	5.1.6	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1	5.1.1	Manufacturer/Manufactured for	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1	5.2.8	Do not use if package damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	ISO 15223-1	5.4.2	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	5.2.6	Do not resterilize	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1	5.6.3	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	ISO 15223-1	5.1.2	Authorized representative in the European community	Indicates the authorized representative in the European Community.
	ISO 7000	3500	Electronic instructions for use	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.
	ISO 15223-1	5.1.4	Use by date	Indicates the date after which the medical device is not to be used.
	IEC 60878	2794	Packaging unit	To indicate the number of pieces in the package.
	IEC 60601-1	Table D.2, Symbol 10	Follow instructions for use	Refer to instruction manual/booklet.

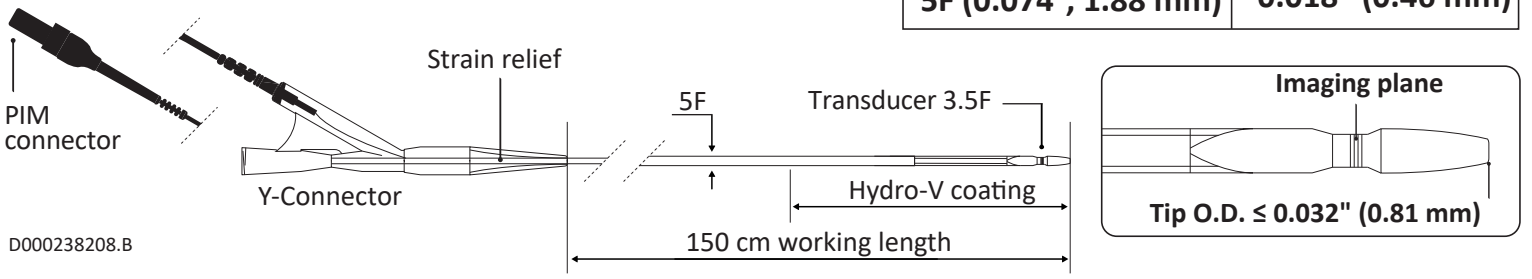
Symbol	Standard	Reference	Title	Description
	None	NA	Date of manufacture and country of origin (Costa Rica)	To identify the date of manufacture and country of origin.
	21 CFR 801.15(c)(1)(i)F	NA	Prescription only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	None	NA	Not made with natural rubber latex	Not made with natural rubber latex.
	None	NA	Part number	Part number
	None	NA	Unique device identifier	Unique device identifier
	None	NA	Medical device	Medical device
	IEC 62570 ASTM-F2503-13	7.3.3/3.1.14	MR unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR (magnetic resonance) environment.
	None	NA	Importer	Indicates the entity importing the *medical device* into the locale.
	None	NA	Length	Length
	None	NA	Tip diameter	Tip outer diameter
	None	NA	Guide wire outside diameter	Guide wire outside diameter
	None	NA	Guide sheath	Minimum compatible guide sheath size

Instructions for Use

English

Reconnaissance PV .018 Digital IVUS catheter

Minimum guide sheath **5F (0.074", 1.88 mm)**	Maximum guide wire O.D. **0.018" (0.46 mm)**



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.**

Intended use:

The Reconnaissance PV .018 Digital IVUS 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. This device is not currently indicted for use in cerebral vessels.

The Reconnaissance 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 Reconnaissance PV .018 Digital IVUS 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 Reconnaissance PV .018 Digital IVUS catheter is introduced percutaneously or via surgical cutdown into the vascular system, and is designed to track over 0.014"-0.018" (0.35-0.46 mm) guide wires.

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

THE CATHETER IS FOR EXCLUSIVE USE WITH S5, CORE SERIES OF SYSTEMS AND INTRASIGHT SYSTEMS. THIS CATHETER WILL NOT OPERATE IF CONNECTED TO ANY OTHER IMAGING SYSTEM.

Contraindications:

Reconnaissance 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:

As with all catheterization procedures, complications may be encountered with the use of the Reconnaissance .018 PV Digital IVUS 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.

Reporting of a serious incident:

If a serious incident has occurred in relation to the device, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. A serious incident means any incident that directly or indirectly led, might have led or, in case of recurrence, could lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient's, user's, fetus or other person's state of health, or a serious public health threat.

WARNINGS:

- Use of the Reconnaissance 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.
- 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 Reconnaissance PV .018 Digital IVUS catheter is designed for single use only. Philips, 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, Philips 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 Reconnaissance PV .018 Digital IVUS catheter for purposes other than those indicated.
- Do not exceed maximum pressure rating of 300 psi.

Precautions:

The Reconnaissance PV .018 Digital IVUS catheter 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 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 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.
- 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 stent 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.**
- The use of an anticoagulant is recommended as per the local standard angiographic protocols and at the discretion of the physician to prevent thrombus formation.
- Do not expose the device to a magnetic resonance environment. Device may not perform as intended and may present additional risks to patient.

Instructions for use:

The Reconnaissance 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 Philips Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.

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- Open the Reconnaissance PV .018 Digital IVUS catheter packaging using sterile technique and place the hoop in the sterile field.
- Prepare the catheter by flushing the guide wire lumen through the port at the catheter's Y-connector, and then wipe down the entire working length with sterile heparinized normal saline.
- Remove the clear/white cap from the PIM connector.
- Connect the PIM connector of the Reconnaissance PV .018 Digital IVUS catheter to the Patient Interface Module as described in the imaging system Operator's Manual. Verify that the device is imaging.
- Place the Reconnaissance PV .018 Digital IVUS catheter onto the intravascular guide wire. A guide wire of 0.014" (0.35 mm) or 0.018" (0.46 mm) can be used.
- Activate the hydrophilic coating using sterile heparinized normal saline.
- Advance the Reconnaissance PV .018 Digital IVUS 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.
- 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 Imaging System Operator's Manual.
- Once imaging has been completed, remove the Reconnaissance PV .018 Digital IVUS catheter and flush thoroughly with sterile heparinized normal saline.
- For subsequent imaging, clean guide wire and flush catheter thoroughly with sterile heparinized normal saline before re-insertion.
- When the procedure is completed, remove and discard the catheter in accordance with local regulations.

Storage and handling:

Products should be stored indoors at room temperature in their original packaging.

Product specifications :

Model	Reconnaissance PV .018 Digital IVUS catheter
Catalog Number	018OTW
Maximum shaft outer diameter	0.068" (1.73 mm)
Maximum scanner diameter	0.046" (1.17 mm)
Maximum guide wire	0.018" (0.46 mm)
Minimum guide sheath	5F (0.074", 1.88 mm)
Usable length	150 cm

Acoustic Output Parameter	B-Mode	Chromaflo
ISPTA.3 (mW/cm2)	$2.93x10^{-3}$	$7.98x10^{-2}$
ISPPA.3 (W/cm2)	$7.5x10^{-3}$	$175.0x10^{-3}$
Pr.3 (MPa)	$20.0x10^{-3}$	$81.5x10^{-3}$
PD (μs)	$161.0x10^{-3}$	$125.0x10^{-3}$
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 + 33.9%/ - 30.5%

** As estimated in tissue

TI Thermal Index defined as $TI = \frac{W01x1fc}{210}$

W01x1: Bounded-square Output (mW)

fc: Center Frequency (MHz)

MI: Mechanical Index defined as MI= Pr.3/(fc1/2)

ISPPA.3: Derated Intensity, Spatial Peak Pulse Average (W/cm2)

ISPTA.3: Derated Intensity, Spatial Peak Temporal Average (mW/cm2)

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

W0: Total Power (mW)

PD Pulse Duration (μs)

PRF: Pulse Repetition Frequency (Hz)

Limited warranty:

Subject to the conditions and limitations on liability stated herein, Philips warrants that the Reconnaissance .018 PV Digital IVUS catheter (the "catheter"), as so delivered, shall materially conform to Philips' then current specification for the catheter upon receipt for a period of one year from the date of delivery. **Any liability of Philips with respect to the catheter or the performance thereof under any warranty, negligence, strict liability or other theory will be limited exclusively to catheter replacement or, if replacement is inadequate as a remedy or, in Philips' opinion, impractical, to refund of the fee paid for the catheter. Except for the foregoing, the catheter is provided "as is" without warranty of any kind, expressed or implied, including without limitation, any warranty of fitness, merchantability, and fitness for a particular purpose of noninfringement. Further, Philips does not warrant, guarantee, or make any representations regarding the use, or the results of the use, of the catheter or written materials in terms of correctness, accuracy, reliabilty, or otherwise.** Licensee understands that Philips is not responsible for and will have no liability for any items or any services provided by any persons other than Philips'. Philips shall have no liability for delays or failures beyond its reasonable control.

Additionally, this warranty does not apply if:

1. The catheter is used in a manner other than described by Philips in the Instructions For Use supplied with the catheter.
2. The catheter is used in a manner that is not in conformance with purchase specifications or specifications contained in the Instructions For Use.
3. The catheter is re-used or re-sterilized.
4. The catheter is repaired, altered, or modified by other than Philips authorized personnel or without Philips authorization.

If claims under this warranty become necessary, contact Philips for instructions and issuance of a Return Material Authorization number if the catheter is to be returned. Equipment will not be accepted for warranty purposes unless the return has been authorized by Philips.

Patent: www.philips.com/patents

An electronic copy of these instructions can be found at: www.philips.com/IFU

The summary of safety and clinical performance will be available in the European database on medical devices (EUDAMED) at the following URL:
https://ec.europa.eu/tools/eudamed

REACH declaration:

REACH requires Philips Healthcare (PH) to provide chemical content information for "substances of Very High Concern (SVHC) if they are present above 0.1% of the product weight. The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold: www.philips.com/REACH

This product is licensed to the customer for single use only.

Additional questions regarding this product should be directed to Philips in the U.S.A.:

Manufactured for:
Philips Image Guided Therapy Corporation
9665 Federal Drive
Colorado Springs, CO 80921 USA

USA & Canada:
(800) 228-4728
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Manufactured by:
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Coyol Free Zone and Business Park
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