opSens

OptoWire *Deux*

Pressure Guidewire

REF F1012

en: Instructions For Use

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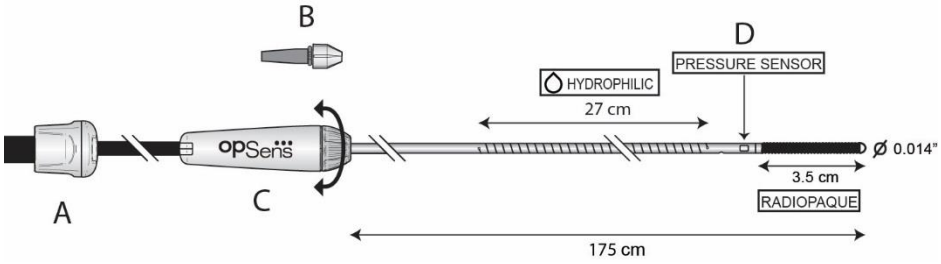
Content: One each

- Non-sterile carton box (sealed)
- Sterile pouch (sealed)
- Sterile plastic tray
- OptoWire *Deux*
- Torque device
- OptoWire Cable



A	FOIC Optical Connector
B	Torque Device
C	Handle
D	Pressure sensor

Specifications:

Operating pressure	-30 to +300 mmHg
Zero drift	<1 mmHg/h
Temperature range	15 - 42°C
Tip	Straight

U.S. Federal Law restricts this device to sale by or on the order of a physician.

Carefully read all instructions prior to use. This device should only be used by physicians trained in angiography and percutaneous transluminal coronary angioplasty (PTCA), and / or percutaneous transluminal angioplasty (PTA). Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

INDICATION OF USE:

The OptoWire *Deux* pressure guidewire is indicated for use to measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease.

DESCRIPTION:

The OptoWire *Deux* is a hybrid Nitinol/Stainless Steel pressure sensing guidewire that is a steerable guidewire with an optical pressure sensor mounted proximal to the 3.5 cm long radio opaque tip. The OptoWire *Deux* is for use in combination with Opsens' OptoMonitor system for blood pressure measurement. The OptoWire *Deux* has a diameter of 0.014" (0.36 mm) and an effective length of 175 cm. The OptoWire *Deux* is supplied preconnected to the OptoWire cable along with a torque device. The OptoWire cable is unique to each OptoWire and it must be used conjunctionally with the OptoWire supplied in the same tray. OptoWire *Deux* is supplied sterile, non-pyrogenic and is intended for single use only.

CONTRAINDICATIONS:

This OptoWire is not intended for use in crossing a total vessel occlusion, in the cerebrovascular vessels and with atherectomy devices. Refer to the device label for any additional product specific contraindications which may apply.

ADVERSE EVENTS:

Potential complications that may be encountered during coronary angiography and coronary angioplasties include but are not limited to: coronary vessel dissection, abrupt closure, occlusion, perforation, embolus, spasm, local and/or systemic infection, pneumothorax, myocardial infarction, serious arrhythmias, and death.
The physician should be familiar with the literature concerning the complications of angiography.

WARNINGS:

- OptoWire should be manipulated only under fluoroscopy. Care should be taken when manipulating a guidewire inside a vessel during device placement and removal.
- Observe OptoWire movement in the vessels. Before an OptoWire is moved or torqued, the tip movement should be examined under fluoroscopy. Do not torque an OptoWire without observing corresponding movement of the tip; otherwise, vessel trauma may occur.
- Never advance an OptoWire against resistance without first determining the reason for the resistance under fluoroscopy. Excessive force against resistance may result in damage to the wire and/or to the vessel.
- If resistance occurs and the cause of resistance cannot be determined, do not move or torque the OptoWire. Stop the procedure, determine the cause of resistance under fluoroscopy and take appropriate action.
- Do not resterilize and/or reuse this device. The OptoWire is intended for single use only. Reuse of single use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure.
- Do not use the OptoWire if any portion of the device or packaging appears damaged, if any portion of the sterile pouch has been opened or if product is expired. Return damaged units to Opsens per the Return Policy.
- Used of OptoWire in conjunction with interventional devices with a short monorail may result in folded or fracture guidewire.
- Do not use OptoWire in the ventricles if the patient has a prosthetic mechanical or biological valve. It may result in damage to both the prosthesis and OptoWire, which may cause injury or death.

PRECAUTIONS:

- Use of an OptoWire with a different OptoWire Cable than the one supplied would provide inaccurate pressure information.
- Do not use damaged OptoWire. Using a damaged OptoWire may cause vessel damage and/or inaccurate torque response and pressure reading.
- When taking the OptoWire out of the dispenser hoop, do not handle the OptoWire roughly or pull it out abruptly as this can damage the OptoWire. Inspect the OptoWire for bends, kinks or other damage prior to use.
- Do not grasp the tip of the OptoWire in taking the OptoWire out of the dispenser hoop.
- Avoid abrasion of the OptoWire coating. Do not withdraw or manipulate the coated wire in a metal cannula or sharp-edged object.
- Do not bend or pull the tip section more than necessary or the OptoWire may be damaged.
- When shaping the distal end, do not shape with a sharp edged instrument. Use the minimum force needed so that the coil is not damaged. Inspect the coil and OptoWire for damage after shaping and before using.

- Do not flex the proximal end of the OptoWire. Excessive flexing resulting kink may affect the OptoWire performance resulting in inaccurate pressure reading.
- Do not attempt to straighten a guidewire that has been kinked.
- In both diagnostic and interventional procedures clean OptoWire thoroughly with heparinized saline before and after each insertion.
- The accuracy of the diagnostic information may be affected, ensure the following but not limited to:
    - Proper selection of guide catheter size, positioning and type.
    - Ensure optimal aortic pressure waveform before FFR procedure.
    - Proper procedure and positioning of the OptoWire sensor element outside the guide catheter to achieve correct equalization.
    - Optimal maximum coronary and myocardial hyperaemia.
    - Unaffected blood flow by interventional devices, such as balloon catheters.
    - Free from contact with atrial or ventricular walls which may result in pressure artefacts.
- Confirm the compatibility of the guidewire diameter with the interventional device before actual use.
- OptoWire may become entangled in one or more stent struts when advancing into a stented vessel where the stent is not fully apposed against the vessel wall. This may result in entrapment, shredding of the OptoWire and/or stent dislocation.
- Avoid having OptoWire to come into contact with stent struts when advancing the OptoWire into a stented vessel. This may result in entrapment, shredding of the OptoWire and/or stent dislocation.
- Use caution when advancing or retracting the OptoWire through a deployed stent as use of this technique carries additional patient risks and may cause OptoWire damages, stent entanglement or stent dislocation.

INSTRUCTIONS FOR USE:

Preparation for and Initial use

- Check to ensure package has not been opened or damaged.
- Open sealed pouch and remove tray using sterile technique and place the tray flat on the sterile field.
- Connect the FOIC connector to the OptoMonitor Handle Unit.

Automatic Zero to atmosphere

- The OptoWire will ZERO automatically as soon as the OptoWire FOIC connector is inserted into the OptoMonitor Handle Unit.
- In the event of "No Signal, check OptoWire connection", verify that the proximal end of the guidewire is fully inserted into the Handle.
  Zero is not performed if the OptoWire pressure varies: OptoWire must be pulled out of guiding catheter for zeroing.
- Once zeroed, flush the working length of the OptoWire with saline solution and carefully remove the guidewire from the tray.
- If indicated, the guidewire distal tip may be shaped using standard tip-shaping practices. Do not use a shaping instrument with a sharp edge. After shaping, verify that there is no damage to the guidewire before using it.

Equalization

- Advance the OptoWire through guiding catheter using the appropriate guidewire introducer.
- Insert and position the pressure sensor (3.5 cm from tip) just outside of the guiding catheter opening in using the radiopaque marker of the interventional device to confirm position (radiopaque section is 3.5 cm of the entire tip).
- Flush the guiding catheter repeatedly with normal saline because contrast medium may dampen the catheter pressure waveform.
- Verify aortic transducer's position and ensure optimal aortic pressure waveform.
- Equalize. Verify the pressure from the guiding catheter and the OptoWire are equal.

Pressure Measurement and Induce Hyperemia

- Advance the OptoWire tip under fluoroscopy using contrast injections to verify location.
- Steer the pressure sensor to region of interest. Ensure the OptoWire tip is rotating freely and no resistance is felt when torque is applied.
- Induce maximal hyperemia according to standard clinical procedure.
- Perform pressure measurements according to standard clinical procedure. If needed, a pullback curve may be performed.

Interventional procedure

- Rotate the Handle locking mechanism to unlock position and retrieve the OptoWire gently from the Handle and remove the torque device.
- Track the interventional device over the OptoWire while taking care not to kink the proximal portion of the OptoWire.
- Proceeds according to manufacturer's instructions.
- To get post procedure pressure measurement, gently reinsert the OptoWire into its Handle and rotate the locking mechanism to the locked position to obtain pressure measurement. Clean the proximal end of the OptoWire with heparinized saline if needed.

End of procedure – Pullback signal drift check and disposal

- Carefully withdraw OptoWire after procedure. Position the pressure sensor (3.5 cm from tip) just outside of the guiding catheter opening. Verify the pressure from the guiding catheter and the OptoWire are equal.
- Handle and dispose OptoWire following standard solid biohazard waste procedures and in accordance with medical practices and applicable, local, state and federal laws and regulations.

STORAGE AND HANDLING:

Store in a dry, dark, cool place.

DISCLAIMER OF WARRANTY

Although the guidewire OptoWire *Deux* hereafter referred to as "Product" has been manufactured and designed under carefully controlled conditions, Opsens Inc. has no control over the conditions under which this Product is used. Opsens Inc., therefore disclaims all warranties, both express and implied, written or oral, with respect to the Product including, but not limited to, any implied warranty as to the condition, quality, durability, performance, merchantability or fitness for a particular purpose. Opsens Inc. shall not be liable to any person or entity for any medical expenses, any loss or injury to a party's profits or goodwill or any direct, incidental, consequential, special, punitive or exemplary damages caused by, arising from or related to any use, defect, failure or malfunction of the Product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Opsens Inc. to any representation or warranty with respect to the Product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

This product, and the use thereof, may be covered by the following U.S. and international patents: US7259862, US7689071, US 9052466, CA2576978, CA2808202, CA2591787, 100451694C, JP5264172, JP4994244. Other U.S. and international patents pending.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

Manufactured By: Opsens Inc 750 boul. du Parc Technologique, Quebec QC G1P 4S3 Canada T. :+1.418.781.0333 - www.opsens.com

en : Symbols with explanations

	Consult instructions for use
	Caution (Attention, consult accompanying document)
	For single use only. Do not reuse
	Do not resterilize
	Keep dry
	Expiry date in YYYY-MM-DD
	Do not use if package is damaged
	Sterilize using Ethylene Oxide
	Indicates that connection is adequate for cardiac application and is defibrillator proof
	System model number
	Temperature range for storage condition
	Keep away from sunlight
	USA only: Federal law restricts this device to sale by or on the order of a Physician
	Date of manufacture in YYYY-MM-DD
	Manufacturer
	LOT number
	Non pyrogenic
	Diameter - Daimètre - Durchmesser- Diametro – Diâmetro – Diámetro – Diameter.
	Length – Longeueer –Arbeitlänge – Lunghezza – Comprimento – Longitud – Lengte.
	Radiopque - radiopque –Strahlendichte – Radiopaca – Opaca de rádio – Opaca de radio – Radio-opake.
	Hydrophilic coating – Revêtement hydrophile – Hydrophile beschichtung – Revestimento idrofilico – Revestimento hidrofilico – Recubrimiento hidrofilico – Hydrofiele coating.
	Pressure sensor – capteur de pression – Optischen druksensor – Sensori di pressione – Sensor de pressão - Sensor de presión – Druksensor.