SavvyWire™

Pre-Shaped Pressure Guidewire

X-Small Pre-Shaped Pressure Guidewire REF F3001

Small Pre-Shaped Pressure Guidewire REF F3002

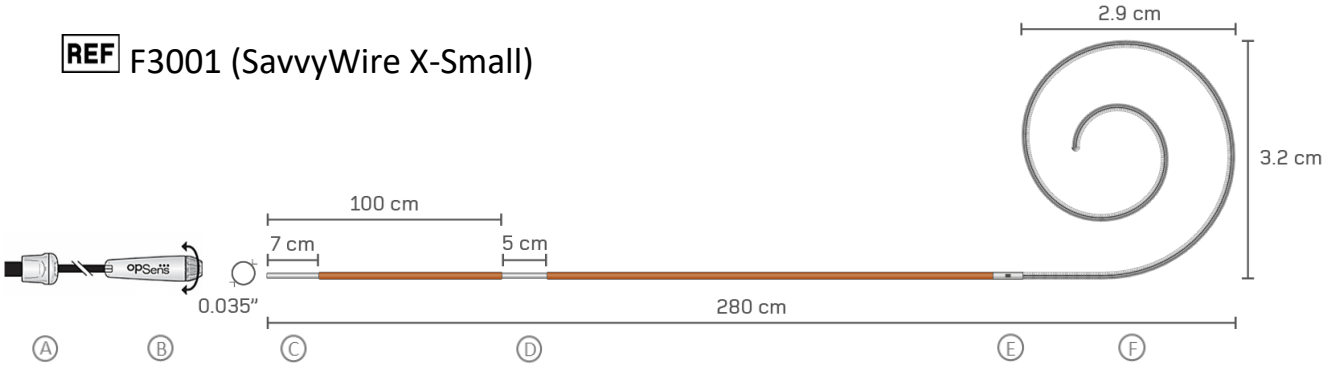
Content: One each

- Non-sterile carton box (sealed)
- Sterile pouch (sealed)
- Hoop and plastic clips
- SavvyWire
- Hemostasis Valve
- Insertion tube
- Fiber Optical Interface Cable (FOIC)

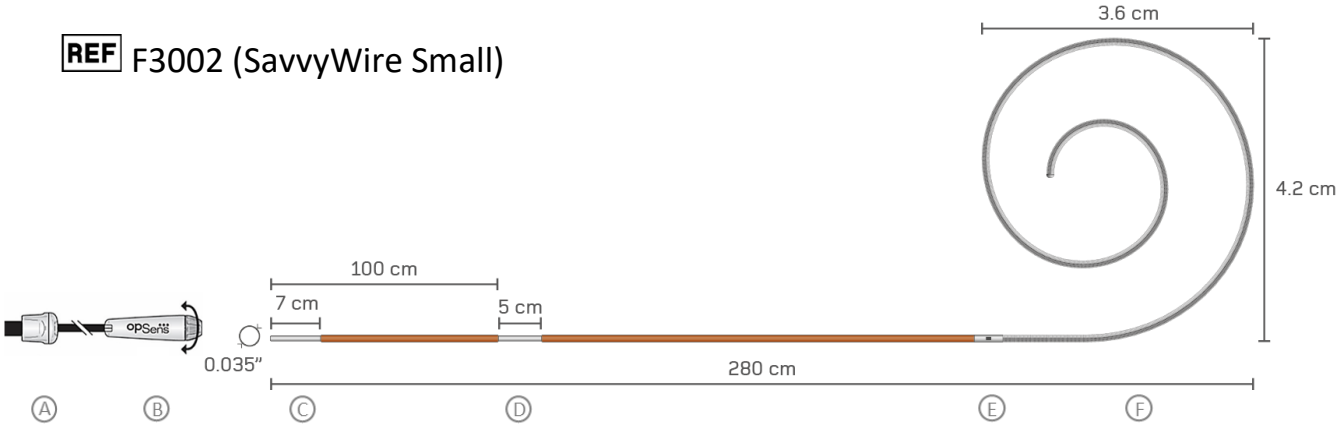
A	Fiber Optical Interface Cable (FOIC)
B	FOIC Handle
C	Proximal optical connector and Alternative pacing connection zone
D	Pacing connection zone
E	Pressure sensor housing
F	Tip
G	Hemostasis valve
H	Insertion tube

en: Instructions for Use

REF F3001 (SavvyWire X-Small)



REF F3002 (SavvyWire Small)

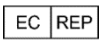
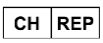


Hemostasis valve and insertion tube

Accuracy*:
± 1 mmHg plus ± 1 % of reading (over the pressure range -30 to 50 mmHg)
± 3 % of reading (over the range 50 to 300 mmHg)
***Includes the effect of both the OptoMonitor 3 and OpSens Pressure Guidewire**

en: Symbols with explanations

	Consult Instructions for Use or Consult electronics 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.
	Sterilized using Ethylene Oxide.
	Indicates that connection is adequate for cardiac application and is defibrillator proof.
	System model number.
	Temperature range for storage condition. Upper limit of 54°C.
	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
	Outer diameter
	Contains Hazardous Substances: Cobalt
	Length
	Radiopaque
	Pre-Shaped Pressure Guidewire
	Medical Device
	Unique Device Identifier
	Single sterile barrier system
	Indicates equipment not to be used in MRI scanner room
	Authorised European Representative.
	Australian sponsor.
	Authorised representative for Switzerland.
	Importer

Carefully read all instructions prior to use. This device should only be used by physicians trained in the introduction and placement of interventional devices including those used within transcatheter aortic valve procedure. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

DESCRIPTION

The SavvyWire™ is a stainless-steel guidewire with an optical pressure sensor and a pre-shaped spiral tip. The SavvyWire is intended to be used in combination with OpSens' OptoMonitor system for blood pressure measurement. The SavvyWire has a diameter of 0.035" (0.89 mm) and a length of 280 cm. See the instructions front page and product label for tip dimensions. The SavvyWire is supplied with a tip insertion tube to help the insertion of the guidewire into a catheter and with a hemostasis valve to flush the pressure sensor. A PTFE sleeve (orange) covers the whole length of the guidewire shaft except for two zones left exposed, both allowing connection of surgical pacing cables (not provided). The proximal zone also allows connection of the SavvyWire to the FOIC handle (delivered preconnected). The SavvyWire is supplied sterile, non-pyrogenic and is intended for single use only.

INTENDED PURPOSE/INTENDED USE

The SavvyWire is intended for use to introduce and position interventional devices within the chambers of the heart, including those used for transcatheter aortic valve procedures, while measuring the pressure within the heart allowing calculation of hemodynamic parameters. Additionally, the SavvyWire can be used for temporary intracardiac pacing by transmitting an electrical signal from an external pulse generator to the heart.

TARGET POPULATION

The SavvyWire is intended to be used in adult populations who do not meet contraindications and regardless of gender. Clinical data showing use of this device in pregnant/breastfeeding women and pediatric children is not available.

INDICATIONS FOR USE/MEDICAL CONDITIONS TO BE TREATED

Structural heart diseases

CONTRAINDICATIONS

The SavvyWire is not intended for use in the cerebrovasculature or coronary arteries. The SavvyWire is contraindicated in the absence of anticoagulation therapy. Refer to the device label for any additional product specific contraindications which may apply.

ADVERSE EVENTS

Adverse events that may result from the use of this device include, but are not limited to: access site or vessels complications, additional surgical procedure, allergic reactions, amputation, aneurysm, angina, arrhythmia, bleeding, cardiac or vessel perforation/dissection, coronary obstruction, death, embolism, fibrillation, foreign body/wire fracture, heart block, hematoma, hypotension/hypertension, infection, kidney injury/failure, myocardial infarction, need for permanent pacemaker, pericardial effusion, pneumothorax, stroke or other neurologic event, spasm, tamponade, thrombus, valve dysfunction or complications, valve malpositioning or embolization, vasospasm, vessel occlusion, wire entrapment/entanglement, X-Ray radiation exposure complications.

WARNINGS

- The SavvyWire is intended for single use only. Do not resterilize and/or reuse this device. 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 SavvyWire 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.
- Administer appropriate level of anticoagulation throughout the procedure, according to hospital protocol.
- The SavvyWire is not meant to be deployed in other anatomy than heart chambers. The safety and effectiveness of the device has not been established or is unknown in vascular regions other than those specifically indicated
- The SavvyWire should only be introduced in, and pulled out from, the ventricle through a catheter already positioned in the ventricle. A diagnostic pigtail catheter is recommended.
- Unipolar rapid pacing with the SavvyWire should only be performed using a dedicated external pacemaker. Use of electrical current generator other than dedicated pacemaker may result in injury to the patient or user.
- Inadequate electrode placement during rapid pacing and valve deployment may result in valve displacement and patient injury. Always test pacing capture prior to proceeding with intervention. Maintain SavvyWire tip position during device deployment when rapid pacing.
- Some patients are not receptive to left ventricular rapid pacing (e.g., history of infarct). It is up to the physician to decide if unipolar left ventricular pacing is appropriate, depending on the patient state.
- Contains Cobalt. Cobalt may be present in the stainless-steel components of the device at or above 1000 ppm, and should be taken into consideration for the treatment of pregnant and breastfeeding patients.
- Persons allergic to Cobalt-Chromium or Nickel may suffer an allergic reaction. Care should be exercised in patients with hypersensitivity to nickel.

PRECAUTIONS

- Confirm the compatibility of the guidewire diameter with the interventional device before actual use.
- Inspect the SavvyWire for bends, kinks or other damage prior to use.
- Do not attempt to straighten a guidewire that has been kinked.
- Proceed with care when pulling the SavvyWire out of the hoop. Do not grasp the tip. The stiffness of the guidewire may cause it to uncoil unexpectedly if pulled out or manipulated abruptly.
- The tip of the SavvyWire is pre-shaped for compatibility with ventricles. Do not manually shape the tip.
- Avoid abrasion of the SavvyWire orange PTFE sleeve. Do not withdraw or manipulate the orange sleeve in a metal cannula or sharp-edged object.
- Always use the FOIC provided along with each SavvyWire. A FOIC contains unique calibration factors and should not be interchanged with another SavvyWire.
- Clean SavvyWire thoroughly with heparinized saline before and after each insertion or exchange of catheter.
- Always use the provided insertion tube to retract the tip prior to inserting the SavvyWire in a catheter or other device. If the insertion tube is taken off the SavvyWire , reinsert the tube by the proximal end of the wire.
- Never advance, pull or torque a SavvyWire 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 anatomy.
- Fluoroscopic guidance should be used during manipulations of the SavvyWire. Care should be taken when the tip of the SavvyWire is positioned, moved or torqued in the ventricle.
- Use special care when positioning SavvyWire tip in small, hyperdynamic ventricles.
- Clinical operators should be adequately protected against radiation when using fluoroscopy.
- Rapid pacing can induce patient discomfort or muscle contraction.
- Consider the following precautions to ensure accuracy of the signals from both the SavvyWire and aortic catheter:
    - Flow restrictions caused by interventional devices (e.g. delivery system or guidewire blocking valve leaflet) should be taken into account when interpreting hemodynamics provided by the SavvyWire and OptoMonitor.
    - Tubing and catheter connected to the external transducer (i.e. for aortic pressure) should be chosen appropriately and flushed prior to pressure measurement, with all valves properly closed.
    - External transducer should be zeroed and positioned at heart level.
    - SavvyWire zero, flush and equalization steps should be executed as indicated in the instructions below.
    - Catheter extremity and sensor housing should not be in contact with cardiac or vessels walls, as it could result in pressure artefacts.

STORAGE AND HANDLING: Store in a dry, dark, cool place. Shelf-life of the product is 2 years from its date of manufacture, as indicated on the label.

DEVICE LIFETIME: SavvyWire is a single-use and single-procedure device.

CLINICAL BENEFITS

The clinical benefits associated with the use of the device are as follows:

- Successfully deliver and position interventional devices during structural heart procedures.
- Provide important information for determining the stage of structural heart disease. This data helps to determine the course of patient management.
- Facilitate structural heart procedures by stabilizing the heart rhythm through delivery of electrical current (pacing).

REPORTING ADVERSE EVENTS

The user and/or patient should report any serious incident that has occurred in relation to SavvyWire to the manufacturer. Contact information is located at the end of this IFU.
Member State in which the user and / or patient is established: Contact information is located at the end of this IFU
Kingdom of Saudi Arabia Market: Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the Saudi Food and Drug Authority

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

A summary of the safety and clinical performance for this device will be available on the European Database on Medical Devices / EUDAMED at ec.europa.eu/tools/eudamed. Search for the device using the Basic UDI-DI: 07540184F3000ZW.

INSTRUCTIONS FOR USE

Preparation

- Ensure package has not been opened or damaged.
- Open sealed pouch and take the hoop out using sterile technique and place the hoop flat on the sterile field.

Zero and flush

- Connect the FOIC connector to the OptoMonitor Handle Unit.
  - The SavvyWire will ZERO automatically as soon as the SavvyWire FOIC connector is inserted into the OptoMonitor Handle Unit.
  - In the event of "No Signal, check SavvyWire connection", verify that the proximal end of the guidewire is fully inserted into the FOIC Handle. Note that SavvyWire must be at atmospheric pressure (out of patient) for zeroing (Zero is not performed if the pressure varies).
- Once ZERO is done, advance the insertion tube over the tip to straighten it and position the sensor (end of orange coating) in line with the injection port of the hemostasis valve. Tighten the valve and connect a syringe filled with saline to the injection port.
- Vigorously flush the sensor of the SavvyWire.

Insertion in ventricle

- Connect the insertion tube to the ventricular catheter.
- Untighten the hemostasis valve. Advance the SavvyWire through the catheter and carefully deploy its tip into the ventricle under fluoroscopic guidance.

Rapid pacing

- If temporary unipolar rapid pacing is desired, place an electrode on the patient. An example of electrode is a subcutaneous needle in the patient groin.
- Using surgical pacing cables with alligator clamps, connect the negative terminal of an external pulse generator to one of the SavvyWire pacing zones (zones C and D). Connect the positive terminal to the electrode on the patient.
- Always ensure tip is stable while pacing, maintaining wire position and contact with the ventricular wall.
- Test capture using standard cardiac pacing verification procedure. Ensure that temporary pacemaker is set at asynchronous and current output is at max output (at least 20 mA).
- For more information on common unipolar pacing practice, refer to *May A, et al., Pacing Over the Guidewire in Cardiac Structural Intervention: A Practical Guide, Heart, Lung and Circulation (2020), https://doi.org/10.1016/j.hlc.2020.06.007*

Interventional procedure

- Disconnect the FOIC and the pacing clamps from the SavvyWire to insert the interventional device.
- Maintain wire position and monitor the tip under fluoroscopy while advancing device over the wire.
- Connect the pacing clamp to allow rapid pacing and the FOIC to monitor ventricular pressure signal during intervention.
- Proceed with intervention according to manufacturer's instructions.

Equalization

- Verify that the aortic transducer is zeroed and level with the heart.
- Flush the aortic transducer line and catheter with saline. Ensure there is no air bubble.
- Position the SavvyWire sensor and the tip of the aortic catheter at the same location. Verify the presence of two corresponding pressure waveform on the OptoMonitor
- Equalize. Verify that the pressure waveforms are superimposed on the OptoMonitor.

Pressure Measurement

- Confirm under fluoroscopy that the SavvyWire pressure sensor is positioned in the ventricle.
- Use the OptoMonitor to evaluate hemodynamic measurements from the SavvyWire and from the aortic catheter.
- If the SavvyWire is removed from the patient and intended to be reintroduced, flush the sensor to clean blood and store it in the insertion tube, filled with saline.

End of procedure

- A catheter must be used over the SavvyWire to retract its tip prior to pulling it out of the ventricle.
- Handle and dispose SavvyWire following standard solid biohazard waste procedures and in accordance with medical practices and applicable, local, state and federal laws and regulations.

ELECTRONIC LABELING

Per European Regulation (EU) 2017/745, this Instruction for Use (IFU) can be found on the OpSens eLabeling website at **https://opsensmedical.com/products**

DISCLAIMER OF WARRANTY

Although the guidewire SavvyWire 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 U.S. and international patents.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

Manufacturer: Opsens Inc, 750 Boulevard du Parc Technologique, Quebec City, QC, G1P 4S3, Canada. www.opsensmedical.com

Authorized European Representative: MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany

Australian Sponsor: Emergo Australia, 201 Sussex Street, Darling Park, Tower II, Level 20, Sydney NSW 2000, Australia

Authorized representative for Switzerland: MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug, Switzerland