

# **A Pressure Wire for Valve Implantation and Continuous Hemodynamic Monitoring During TAVR Procedures: Initial Experience with the SavvyWire**

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# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

Grant/Research Support

Consulting Fees/Honoraria

## Company

Opsens, Edwards Lifesciences,  
Medtronic

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# SavvyWire™ (Opsens Inc.)



**Structural Pre-Shaped Guidewire with Pressure Measurement and Rapid Pacing capabilities**

- 0.035" stiff guidewire
- Exchange length for valve catheters, 280cm
- Pre-Shaped tip, 2 sizes available (XS & Small)
- PTFE coating

## OptoWire technology

- Optical pressure sensor
- Optical connector

**Shaft Stiffness**  
Safari < SavvyWire < Confida



**Tip:  
Anchoring &  
Electrical  
contact in LV**

**XS: 32 mm  
Small: 42 mm**

**Pacing connection zones**

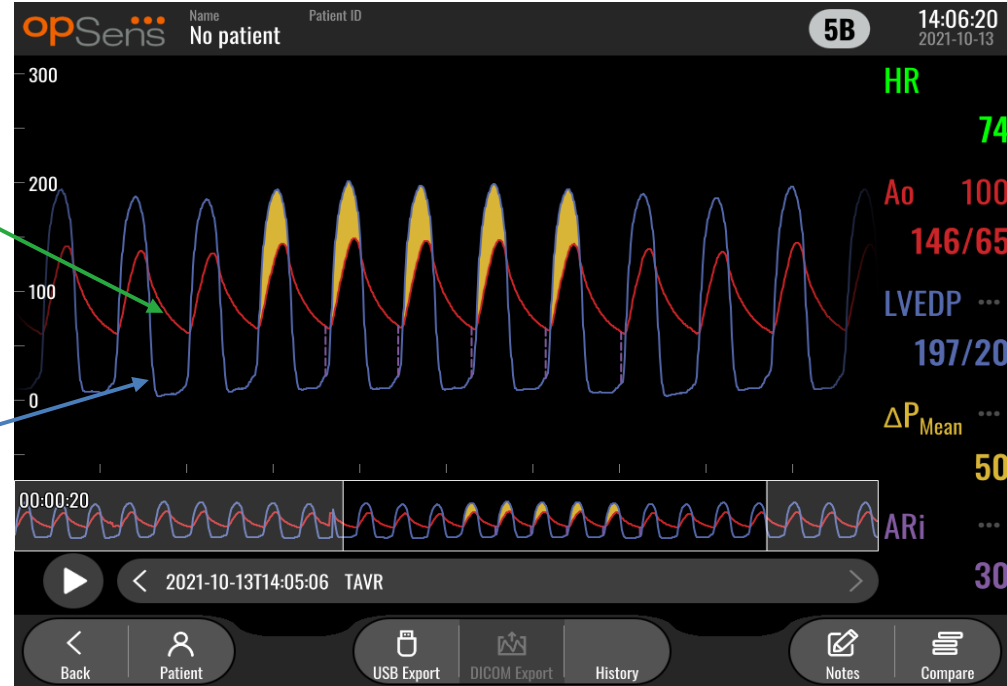
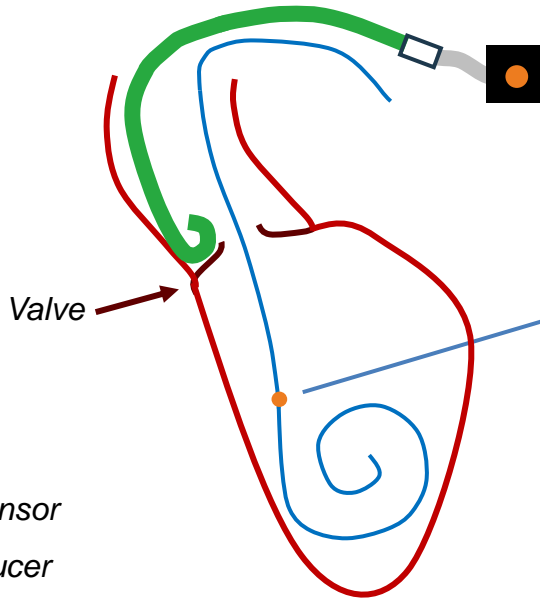
**Fiber-optic sensor  
for LV pressure**

**Shaft: Support & Electrical insulation**

# OpSens OptoMonitor™ TAVI interface

- Live hemodynamics feedback without catheter exchange
  - Gradient (mean, max, P2P)
  - Regurgitation indices (ARi, TIARi)

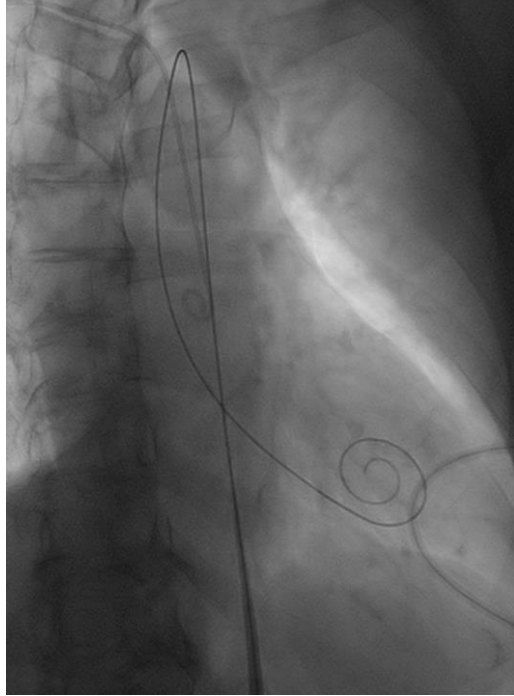
Example from FIM: Gradient at baseline



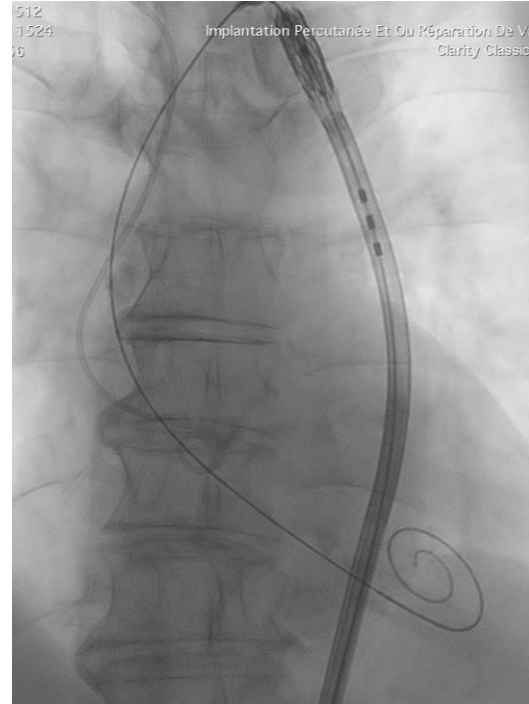
Note: Data from FIM was imported in OpM-TAVI interface

# Guidewire Support – FIM example

## Ventricular positioning

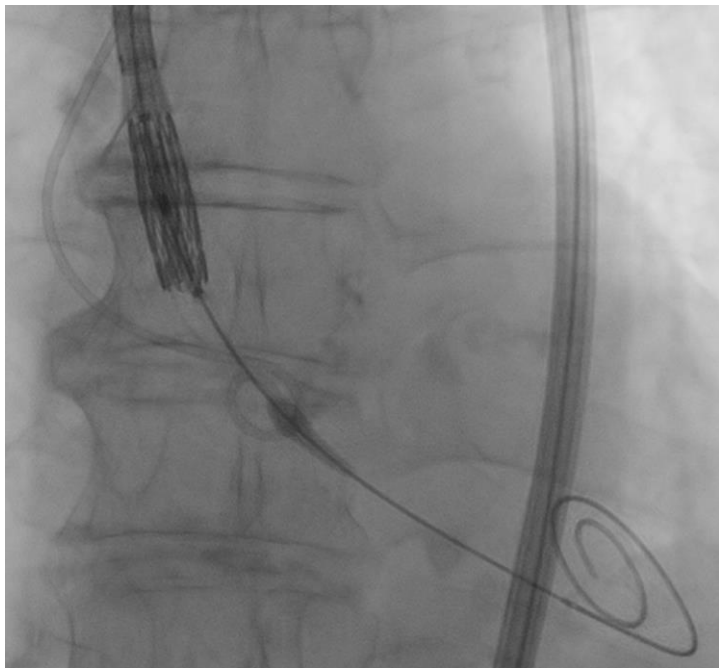


## Valve delivering

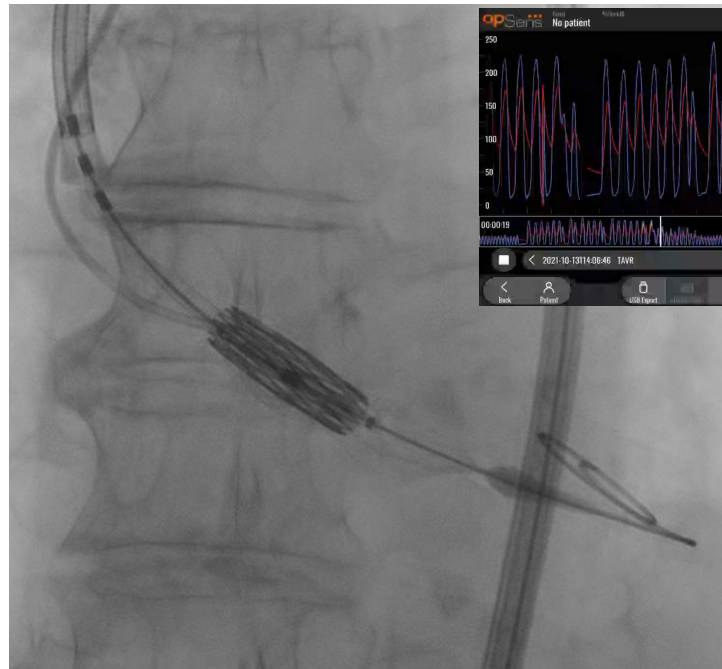


# Guidewire Support – FIM example

## Valve crossing

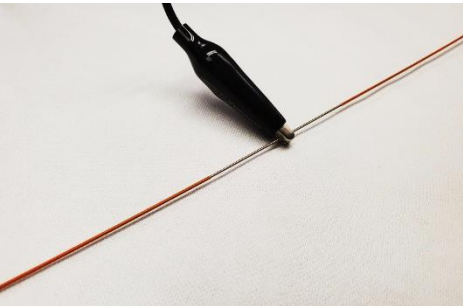


## Valve deployment



# Rapid pacing

- Unipolar left ventricular pacing
- Built-in shaft insulation
  - LV pacing at anytime, without catheter
- Eliminates RV access for eligible patients
- Pacing cables from external pacemaker



Example from FIM: Pacing test just before valve deployment



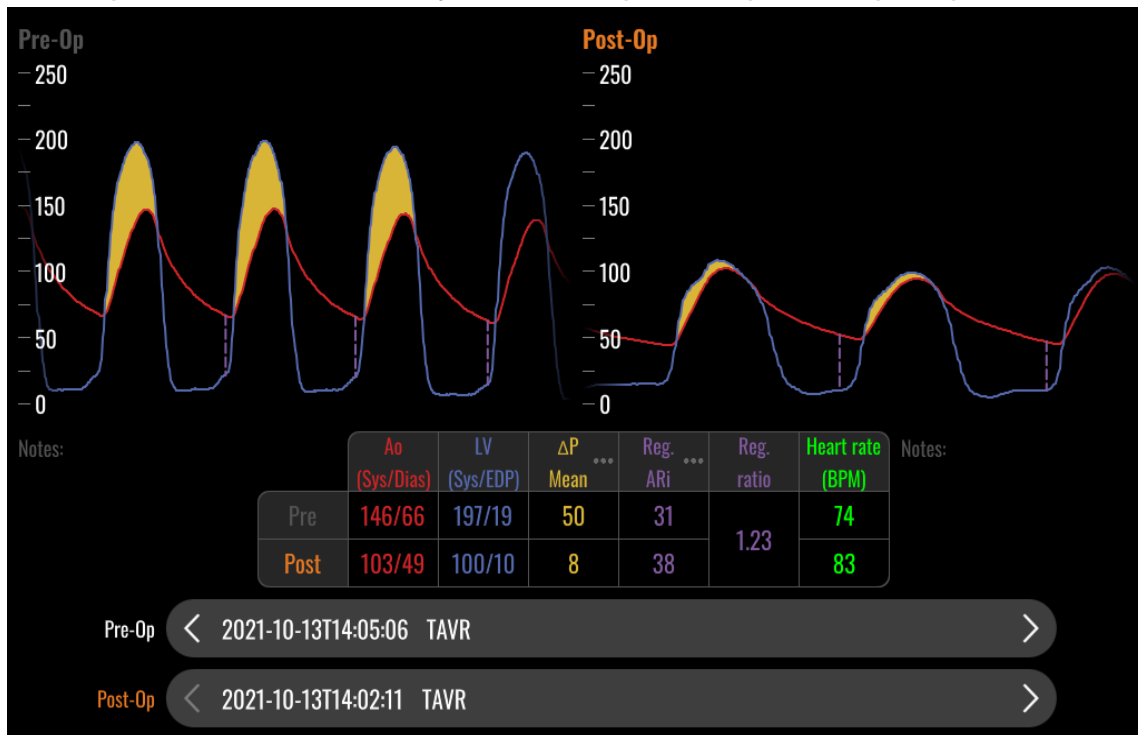
Note: Data from FIM was imported in OpM-TAVI interface

# Hemodynamics report

Immediate pre and post comparison report on OptoMonitor

- Pressure (Sys, Dias, LVEDP)
- Gradient (Mean, Max, P2P)
- Regurgitation (ARi, TIARI, Ratio)
- Heart Rate
- Export to DICOM
- Export to USB

Example from FIM: Hemodynamic comparison pre and post procedure



Note: Data from FIM was imported in OpM-TAVI interface



# SAVVY Study – Early Feasibility Trial

- Prospective observational feasibility study
- 20 patients with severe symptomatic AS undergoing TAVR
- Principal investigators
  - Dr. Josep Rodés-Cabau, Quebec Heart & Lung Institute, Quebec City, Canada
  - Dr. Reda Ibrahim, Montreal Heart Institute, Montreal, Canada
- Endpoints
  - Safety: Absence of major complications related to guidewire
  - Efficacy:
    - Effective rapid pacing capture with significant pressure drop (mean Pa decrease  $\geq 50\%$  or  $< 60$  mmHg)
    - Accurate ventricular pressure measurements (within 5 mmHg compared to pigtail catheter)

# Conclusions – SavvyWire

## 1. Transcatheter Valve Implantation

- Stiff pre-shaped guidewire

## 2. Hemodynamics

- Evaluate valve performance

## 3. Heart Stimulation

- Rapid pacing capabilities

4. FIM experience: positive results. Ongoing early feasibility trial.

# SavvyWire: FIM Teams

Quebec Heart & Lung Institute  
PI: *Dr. Josep Rodés-Cabau*



Montreal Heart Institute  
PI: *Dr. Reda Ibrahim*

