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.

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<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tr>
<td>Grant/Research Support</td>
<td>Opsens, Edwards Lifesciences, Medtronic</td>
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<td>Consulting Fees/Honoraria</td>
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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

Tip: Anchoring & Electrical contact in LV
- Anchor zone
- XS: 32 mm
- Small: 42 mm

Shaft Stiffness
- Safari < SavvyWire < Confida

Fiber-optic sensor for LV pressure

Pacing connection zones

Shaft: Support & Electrical insulation

SavvyWire™ is not cleared for sales in the US
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

OptoMonitor™ TAVI interface is not cleared for sales in the US
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

Example from FIM: Hemodynamic comparison pre and post procedure

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

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 ≥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