



opSenS



Louis Laflamme
President and CEO



Forward Looking Statement

This corporate presentation contains forward-looking statements, which reflect the Company's current expectations regarding future events. The forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors, including the successful and timely completion and the commercialization of the products herein. The reader of this document is forewarned concerning the inherent variability and risk associated in terms of strategies or deliverables stated herein by the Company and is cautioned prior to considering these forward-looking statements. The Company disclaims any obligation to update these forward-looking statements.

Opsens Overview



Key player in cardiovascular medical devices

- Innovative fiber optic pressure guidewire
- Products **OptoWire** and **OptoMonitor**

Physiological measurement (FFR or dPR) to assess coronary blockages

- Assessment helps select appropriate treatment
- OptoWire can be used to deliver stents in the treatment of blockages.

Opsens at a Glance

Market

\$1B

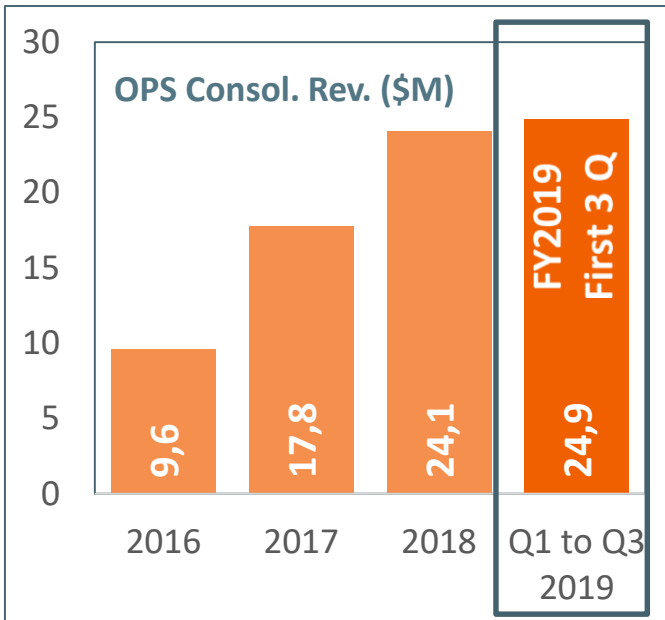
Future FFR market opportunity

FFR

- 70,000 patients treated
- 30+ countries
- Recognized in medical publications

Strategic Value

- **Expanding to structural heart**
- OPS sensing technology applications



OPS - It's Time to Buy Now

- **Stock price**
 - OPS – Ratio Enterprise Value vs Sales
 - OPS - Strategic in cathlab
- **Business and market growth**
 - Cardiology – Aging population
 - Abiomed - LT supply agreement
- **Financial performance**
 - Growth and margin potential
- **Innovation**
 - New generation of FFR products (OW3, OM3 and dPR)
 - Improvement – Products and COGS
 - New area of interest:
 - Fast-growing structural heart market, Trans Aortic Valve Replacement (TAVR)
 - New product to enhance Company portfolio



What is Fractional Flow Reserve (FFR)

- FFR used for **diagnosis** of patients

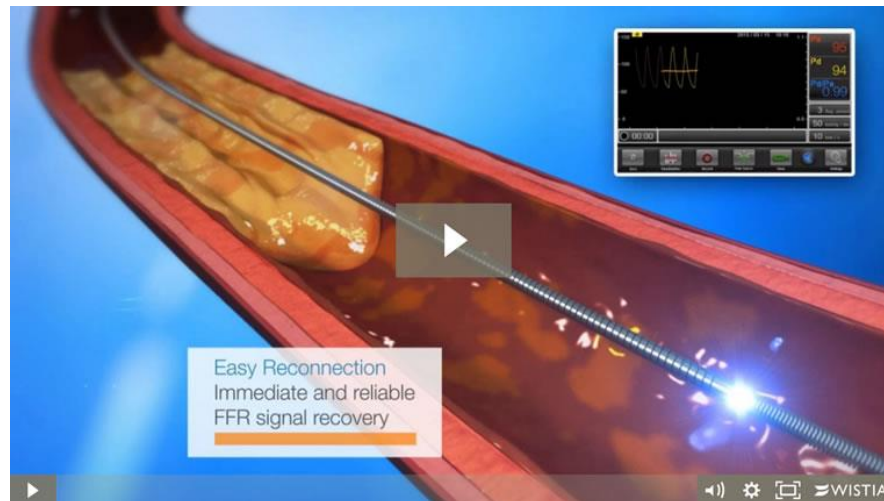
Evaluation of the **severity of a coronary artery blockage**

Cardiologists measure blood pressure before / after a blockage, **obtain a ratio**

Ratio helps in **selecting treatment** (angioplasty, stenting, bypass, etc.)

- FFR used for **treatment** of patients

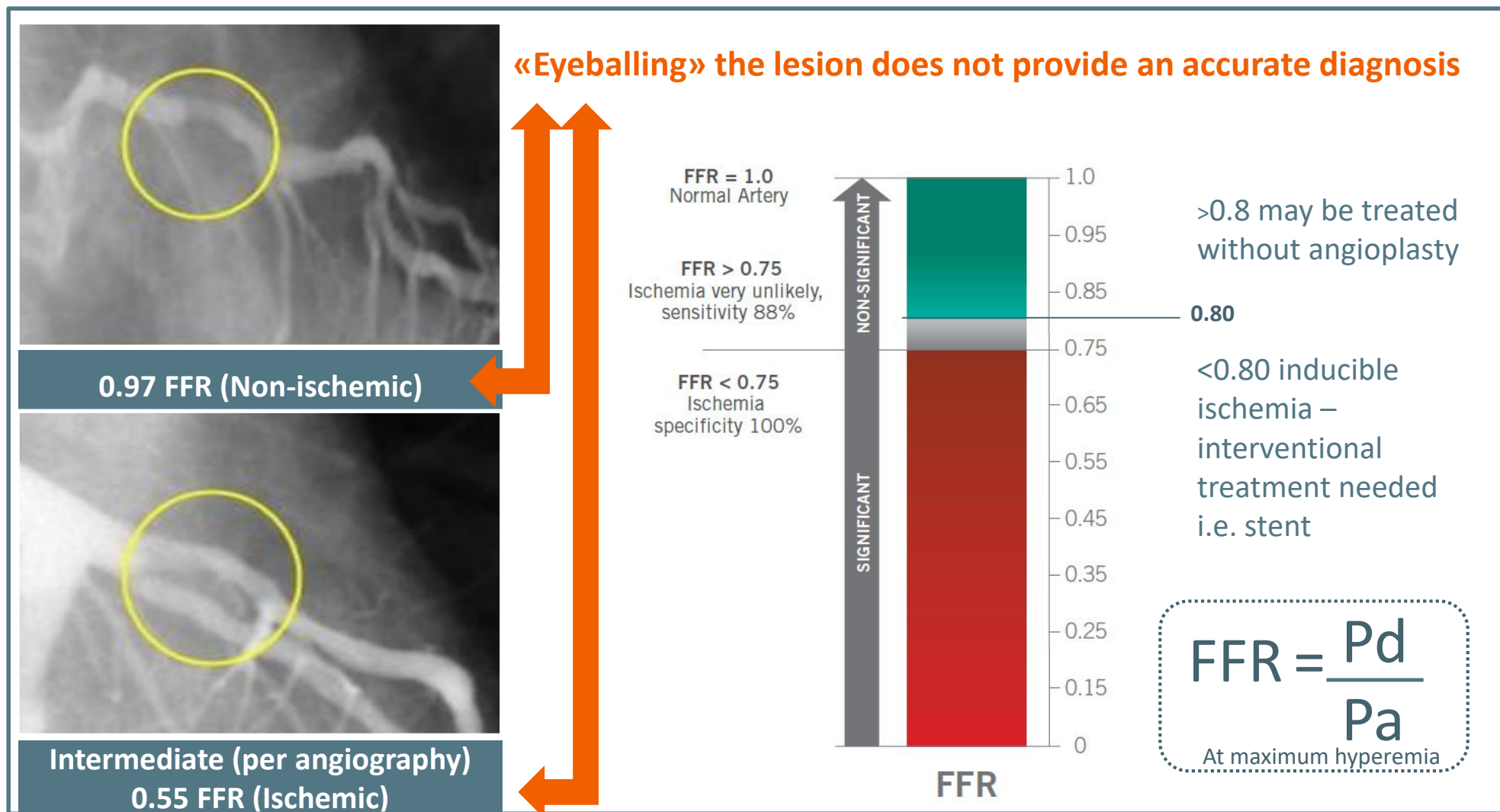
Once cardiologist selects treatment, he can stent the lesion immediately.



[Opsens Video](#)

Fractional Flow Reserve (FFR)

Max achievable blood flow in stenotic coronary artery divided by
Max blood flow in the same artery without stenosis



FAME Study – FFR-guided therapy improves clinical outcomes of patient resulting in significant decrease of major adverse cardiac events.

FFR Market Overview

As FFR becomes more mainstream, the pressure guidewire market is poised for disruption

Backdrop

- Studies prove FFR superior to angiography to guide Percutaneous Coronary Interventions (PCI)
- 2017 - New Appropriate Use (AUC) Criteria shows patients with acute myocardial infarction (STEMI) benefit from FFR-guided treatment as it lowers incidence of Major Adverse Cardiovascular and Cerebrovascular Event
- FFR used to assess **increasingly complex lesions**
- Hospitals now **acutely sensitive to costs** and **appropriate PCI**
- FFR guidewire market - **large growing market** in cath lab as it **improves patient outcomes** and can **lower costs**

Penetration

- Despite strong outcome data, **FFR guidewires are still underutilized**
- Performance** of conventional pressure guidewires is **an obstacle** to market penetration.

FFR Market

Year	Milestones	Outcome
2009	FAME I Study	Angiography + FFR + Stent <u>superior</u> to Angiography + Stent
2010	EU: ESC Class I Level of Evidence A	Highest class & level: Procedure beneficial, useful & effective
2011	US: ACC/AHA Class IIA Level of Evidence A	Benefits of FFR outweigh risks & can be useful as a tool
2012	FAME II Study	Angiography + FFR + Stent + OMT <u>superior</u> to Angiography + OMT
2012 cont'd	Reimbursement Code for FFR	Several countries have codes Japan, France, UK, Germany, etc.
2017	AUC Revision Compare-Acute Study	FFR growing use and importance (STEMI)
2018	AUC Revision	Inclusion of other physiological measurements without hyperemia
2018	Change in Regulation Japan Key market for Opsens	New: Evaluation of all coronary stenosis. Mention: FFR a preferred method

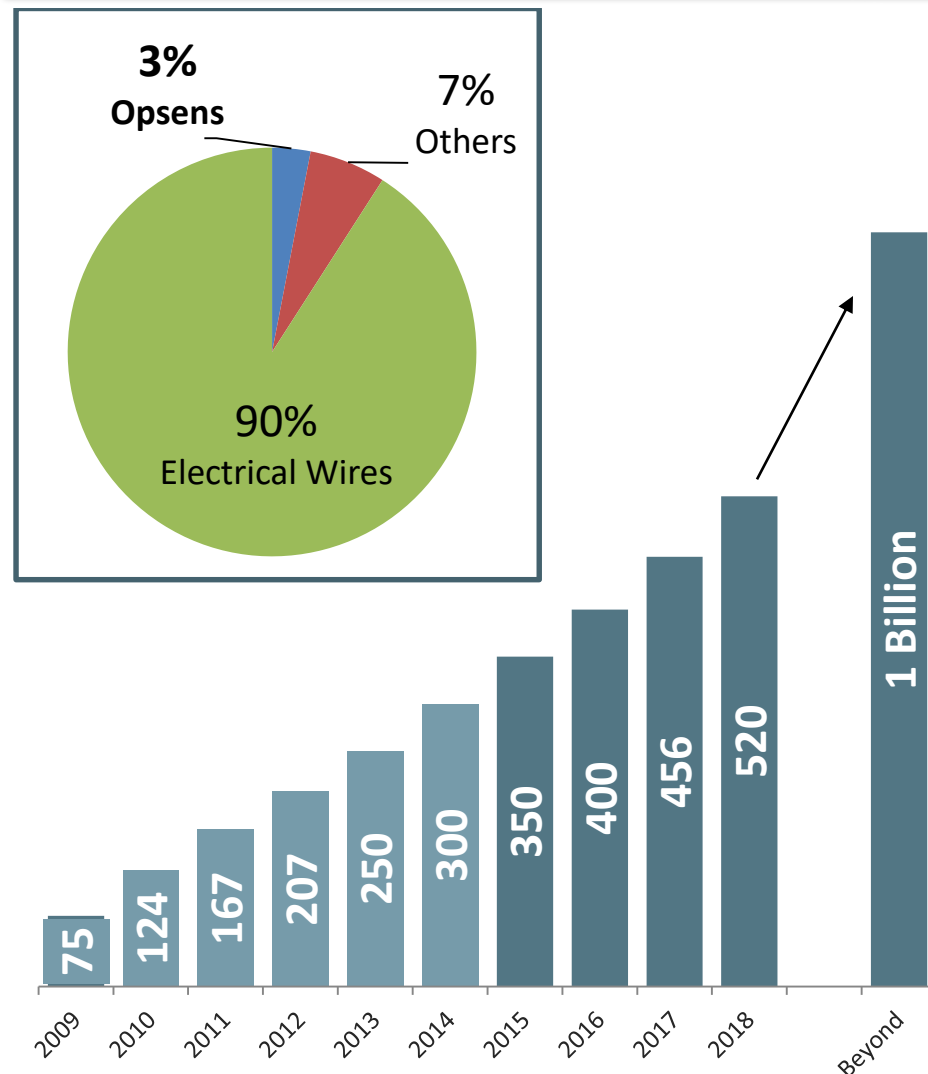
FFR: Growing Market with Upside

Potential for significant market share capture through product innovation and differentiation

Key Market Drivers

- FFR procedure penetration: ~15%¹
- Industry players estimate potential procedure penetration closer to 45%²
- FFR-guided PCI improves patient outcomes
- Better FFR devices, easier to use
- Increased confidence in procedure
- New Appropriate Use Criteria
- Increasing need to control costs
- FFR could facilitate reimbursement by hospitals and third-party payers
- Increased indications of use
 - Left-main, Bifurcation, Non-Stemi.

FFR Market (US\$ M)*



Opsens' Products



OptoWire (disposable)

- Exceptional handling
- Reliable strength and support
- Revolutionary consistency and accuracy
- Worry-free reconnect



OptoMonitor (capital)

- Seamless and simple integration
- Intuitive workflow
- Small footprint
- FFR data output options

OptoWire Advantage – One Wire from Start to Finish

Best-in-class technology overcomes limitations of conventional pressure guidewires

Current FFR Products Limitations

- Limitations in steerability, support, drift and connectivity prevent products from being used from start to end of procedure (diagnostic and treatment)
- Measurement reliability affected by length of procedure (impact on drift)
- Highly sensitive electrical contact, unreliable connectivity result in uncertainty to reconnect and loss of signal, affecting workflow and ability to perform post-PCI FFR.

OptoWire

- 2nd gen fiber optic guidewire designed to provide lowest drift in the industry and excellent lesions access
- Nitinol-based guidewire delivers workhorse performance to reach lesions – **One wire from start to finish**
- Patented optical sensor eliminates drift and thermal shift
- Sensor stability, connection reliability provides more accurate diagnostic for **increased operator confidence.**

"The arrival of an optical FFR guidewire such as the OptoWire on the market is positive for interventional cardiologists and will be helpful to promote the use of FFR."

—Dr. Nico Pijls, Catharina Hospital, Netherlands

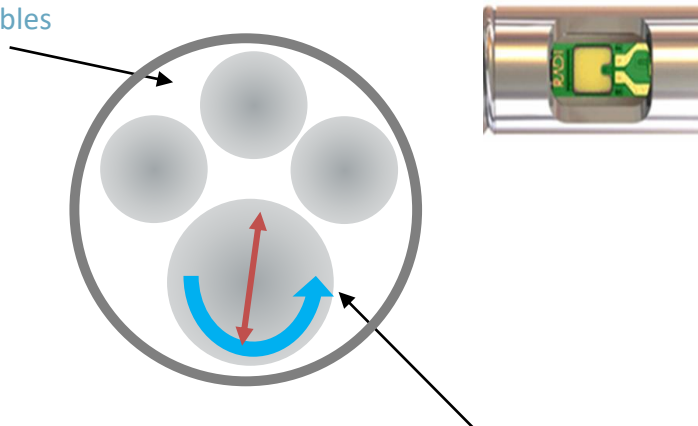
OptoWire - Guidewire Performance

Fiber Optic vs Piezoelectric Pressure Guidewires

Traditional FFR wire

- Older piezoelectric technology requires three electrical wires offsetting corewire from center, resulting in whipping and limited torqueability

3 electrical cables



Small Stainless Steel Core

FFR assessment unreliability

Limited vessel access - No current electrical guidewire provides workhorse wire performance

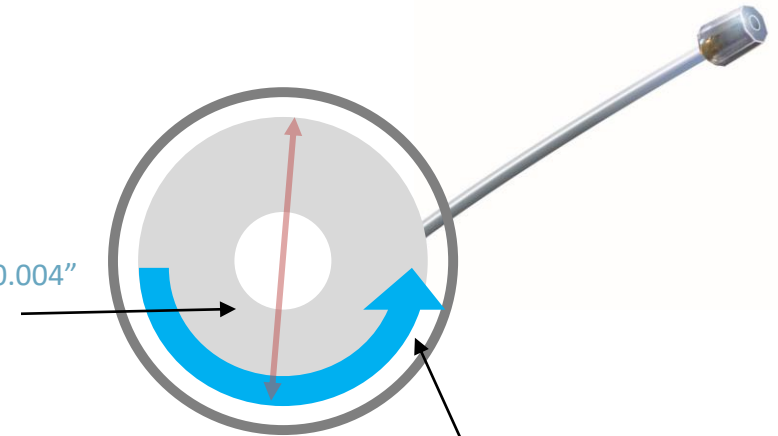
Drift - Moisture sensitive

Unreliable connection - Hinders multi-vessels and post-stent FFR assessment.

OptoWire – 2nd Gen Fiber Optic guidewire

- Single central fiber-optic eliminates whipping, yielding space for larger, stronger nitinol

Optical fiber 0.004"



Large Central Nitinol Core

FFR assessment reliability

Performance - Pressure guidewire design

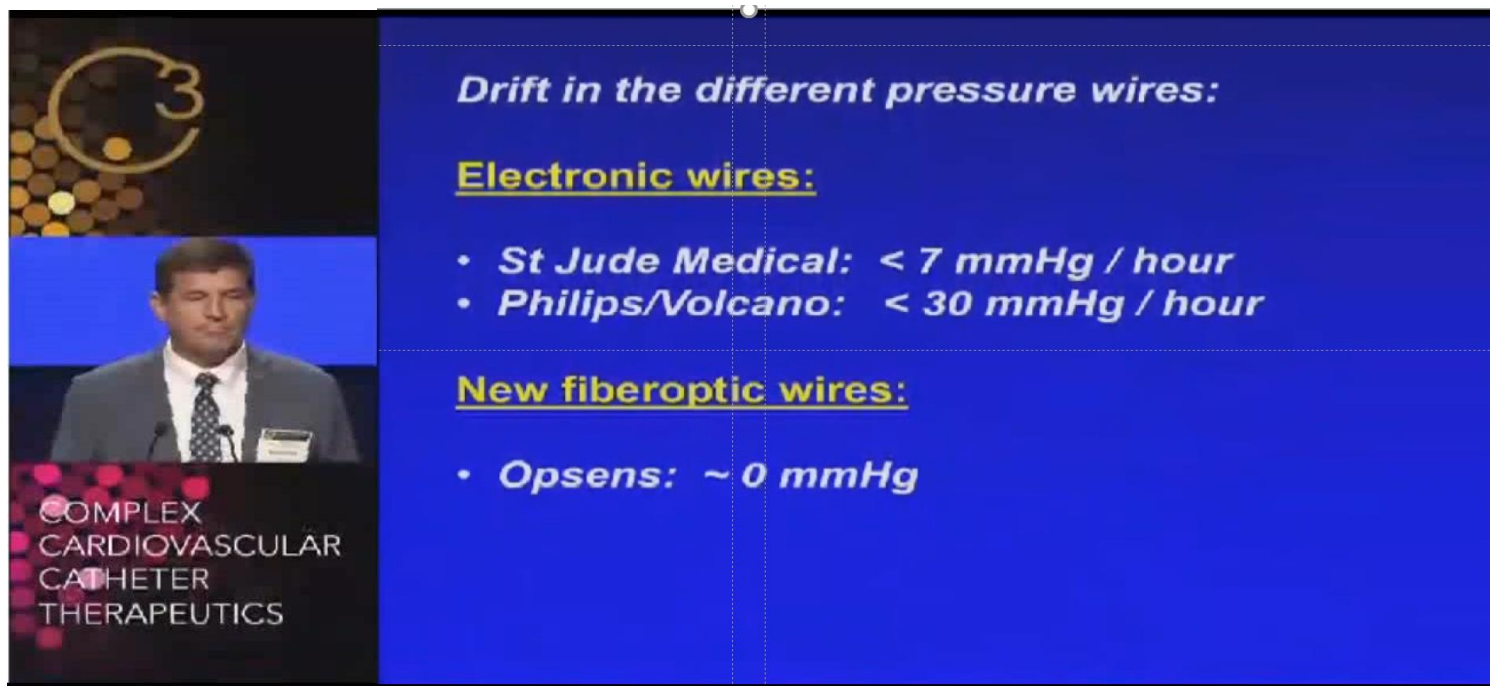
Accuracy - Pressure measurement with minimal drift

Choice – FFR or Resting Indices

Freedom – Saves time, costs - Same guidewire for diagnostic, treatment - Reconnect-disconnect: Quick, Reliable, Easy.

OptoWire - 2nd gen Fiber Optic Pressure Guidewire

Designed to provide lowest drift in the industry and excellent lesions access



Drift in the different pressure wires:


Electronic wires:

- *St Jude Medical:* < 7 mmHg / hour
- *Philips/Volcano:* < 30 mmHg / hour

New fiberoptic wires:

- *Opsens:* ~ 0 mmHg

COMPLEX
CARDIOVASCULAR
CATHETER
THERAPEUTICS

	Next-Gen FFR	Traditional FFR			
		Boston Scientific COMET ²	St. Jude PressureWire Aeris ³	Acist Navvus Microcatheter ⁴	Volcano Verrata
Drift from zero (mmHg/h)	<1	<3	<7	<7	Not specified

1) Opsens Medical. Data on File


13 2) Chambers, Jeff. Electric or Optical Fibers Based Pressure Measurements. Presentation sponsored by Boston Scientific, 19th Tremblant Interventional Cardiology Meeting. 2016

3) St. Jude. PressureWire Aeris, Instructions for Use, 20828 Rev 0F

4) Acist. Rapid Exchange (Rx) System and Navvus Catheter. 510(k) Filing, K132474. Jan 2014

Medical Publications

Opportunities to Create Value with Additional Clinical Work



Circulation Journal
Official Journal of the Japanese Circulation Society
<http://www.j-circ.or.jp>

EDITORIAL

Fractional Flow Reserve, Coronary Pressure Wires, and Drift
 Nico HJ Pijls, MD, PhD; Bernard De Bruyne, MD, PhD

Circulation Journal
Official Journal of the Japanese Circulation Society




COLUMBIA UNIVERSITY
IRVING MEDICAL CENTER

DRIFT Study
 Drift-Reduction for Improved FFR using Fiberoptic Technology
 Manish A Parikh, MD - Columbia University Medical Center, May 2019

Columbia University Irving Medical Center
Cardiovascular Research foundation

Cardiovasc Interv and Ther
 DOI 10.1007/s12928-017-0481-x


 CrossMark

ORIGINAL ARTICLE

Frequency of a large drift caused by pressure wire using optical fibers
 Yoshiaki Kawase¹ • Toru Tanigaki¹ • Akihiro Hirakawa² • Hiroyuki Omori¹ •
 Tetsuo Hirata¹ • Syuuichi Okamoto¹ • Hideaki Ota¹ • Jun Kikuchi¹ •
 Munenori Okubo¹ • Hiroki Kamiya¹ • Masanori Kawasaki³ • Takahiko Suzuki¹ •
 Hitoshi Matsuo¹

Received: 26 April 2017 / Accepted: 21 June 2017
 © Japanese Association of Cardiovascular Intervention and Therapeutics 2017

Cardiovascular Intervention and Therapeutics

Drift (% of cases with > 3 mm/hg of drift)	Country	OptoWire	Competition
Circulation (2016)	Europe	0%	30%
Drift (Columbia) (2019)	US	5,8%	
Cardiovasc Interv (2017)	JPN	4%	

OptoWire Performance – Worry-Free Reconnect

Strong Distinction Between Optical and Electrical Technology

Optical contact unaffected by procedural contaminant

- Competitor's electrical technology sensitive to contact resistance

Workflow freedom with FFR reliability

- Disconnect, handle like standard PCI wire
- Reconnect and perform post-PCI FFR
- May save time and money with improved effectiveness.



"It was a pleasure to use the OptoWire in several patients, some of them with complex disease. It allowed me to appreciate its impressive zero drift performance during all cases performed while also acknowledging the constant connection reliability as well as its support during percutaneous coronary intervention."

—Dr. Bernard de Bruyne, Cardiovascular Center Aalst, Belgium

BACKGROUND

Physiological lesion assessment by FFR after successful PCI (post-PCI FFR) related to long-term outcomes in retrospective studies with the highest values showing the lowest MACE rate.

Recently, it has been shown in a retrospective study that post-PCI FFR may be in the ischemic range in as high as 20% of cases after angiographically optimized PCI and that FFR can be improved by further intervention in a majority of cases.

Findings suggest modifying current PCI paradigm to use FFR routinely for all lesions with measurement of FFR post-PCI to determine "functional optimization". This approach requires a pressure wire with characteristics simulating a workhorse wire.

We used a new generation pressure wire (OptoWire, Opsens, QC, CA) with excellent handling characteristics to measure pre- and post-PCI FFR for all routine non-CTO interventions. We developed a prospective registry to study this clinical approach.

STUDY PURPOSE

To determine:

- 1) frequency of ischemic FFR post-PCI after angiographic optimization
- 2) ability to increase low FFR by further intervention after angiographic optimization
- 3) performance of the OptoWire wire for severe as well as intermediate lesions.

METHODS

Prospective registry of FFR-guided PCI as routine clinical approach using OptoWire as a workhorse guidewire with FFR measured pre- and post-PCI. Post-PCI transducer was placed in the distal artery with a stereotyped pullback on all patients. For the cohort enrolled from Mar 1, 2017 – May 8, 2018.

Exclusion criteria: STEMI culprit vessel - "High risk" ACS lesions - Hemodynamic instability - Chronic total occlusion - Saphenous vein PCI - Operator preference.

RESULTS

177 patients, 218 lesions. FFR was >0.80 in 57 lesions - no PCI performed
PCI group = 145 patients, 161 lesions. SIHD 86 (59%), ACS 59 (41%)
PCI lesion success rate 99.4% (160/161); stenosis pre-83+11%, post 2+10%, $p<0.0001$

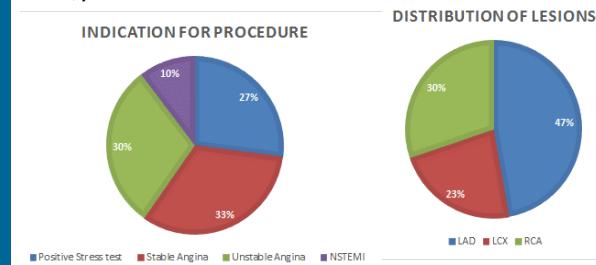


Fig 1: Indication for PCI and coronary artery distribution

FFR Pre- and Post-PCI

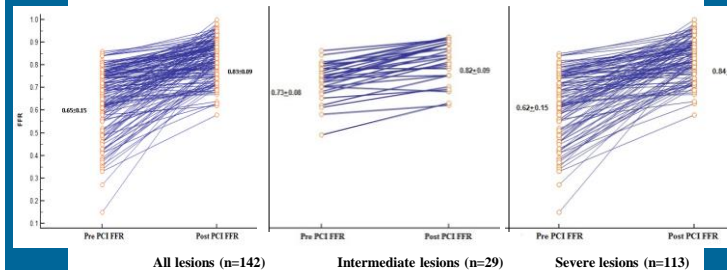


Fig 2: Improvement in FFR post PCI in entire cohort and by angiographic

After angiographic optimization, FFR showed ischemic value (<0.80) in 32.4% (46/142) of stented vessels. Of these, 14 (30%) underwent further intervention w/ significant improvement in FFR. The other 32 had diffuse disease considered not amenable to further intervention.

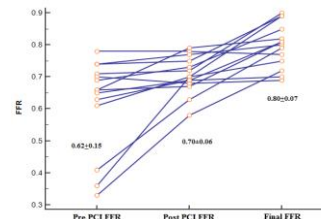


Fig 3: Further intervention improved FFR by 0.10 on average.

Pressure wire performance:

1) Ability to cross lesion with OptoWire (buddy wire support in 2 lesions)	95.6%
Crossing with other wires	3.7%
Pilot 200	1
Fielder XT	2
Runthrough	3
Not able to cross lesion w/ any wire	1 0.6%

2) Characteristics of lesions not crossed with OptoWire (n=7)

Moderate/heavy	100%
Moderate/severe tortuosity	71%
Stenosis severity	94+7%

3) Performing entire case w/ pressure wire (pre-PCI FFR, intervention, post-PCI FFR) 88.2%

Extent of drift
0.02+0.02

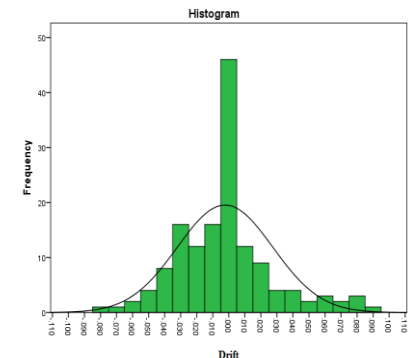
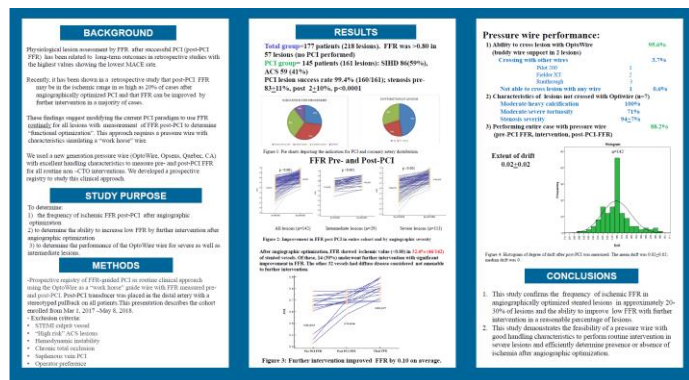


Fig 4: Degree of drift after post-PCI was measured. The mean drift was 0.02+0.02; median drift was 0.02+0.02.

CONCLUSIONS

1. Study confirms the frequency of ischemic FFR angiographically optimized stented lesions in approximately 20-30% of lesions and the ability to improve low FFR with further intervention in a reasonable percentage of lesions.
2. Study demonstrates the feasibility of a pressure wire with good handling characteristics to perform routine intervention in severe lesions and efficiently determine presence or absence of ischemia after angiographic optimization.

Functional Optimization of Coronary Intervention Using Post-PCI FFR: A Prospective Registry*



Goal

1. Frequency of <0.8 FFR after stent
2. Ability to ↑ FFR by additional intervention
3. Performance of OW for severe, intermediate lesions.

Benefits of performing post-PCI FFR

- ↓ rate of major cardiac events with post-PCI FFR
- FFR can guide optimization
- Results suggest using post-PCI FFR for functional optimization (all lesions). Need for a pressure guidewire with Workhorse features.

OptoWire (OW) to measure pre and post-PCI FFR

- Excellent handling characteristics
- Precision of measure
- Capacity to disconnect and reconnect.

Performance, Results and Conclusions

1. Frequency <0.8 after stent: ≈ 20-30%
2. Possible to ↑ FFR by 0.08 with additional intervention
3. Cases performed with OW only: 95.6% of cases
Extent of drift OW: 0.01± 0.025

With a guidewire with good mechanical characteristics it possible to perform a routine intervention in severe lesions and to determine the presence/absence of ischemia after angiographic optimization.

Strong IP (more than 10 patents) – Potential for Partnerships

- Freedom to operate is challenging to obtain in FFR and significantly limits potential for newcomers
 - **Electrical pressure sensing:** Extensive IP owned by Phillips / Volcano and Abbott / St. Jude
 - **Optical pressure sensing:** Opsens is the first-comer and IP leader
- Opsens' IP may prohibit FTO and any other companies using optical pressure sensing.



Guidewire - 1 patent

- Guidewire with internal pressure sensor



Optical Sensor - 3 patents

- Optical sensor using low-coherence interferometry
- Fiber-optic pressure sensor for catheter use
- Miniature high sensitivity pressure sensor



Optical Connector - 4 patents

- Method for disposable guidewire optical connection



Microcatheter / Equalization - 2 patents

- Eccentric pressure catheter with guidewire compatibility
- Method for pressure guidewire equalization
- Pressure based blood vessel assessment systems and methods

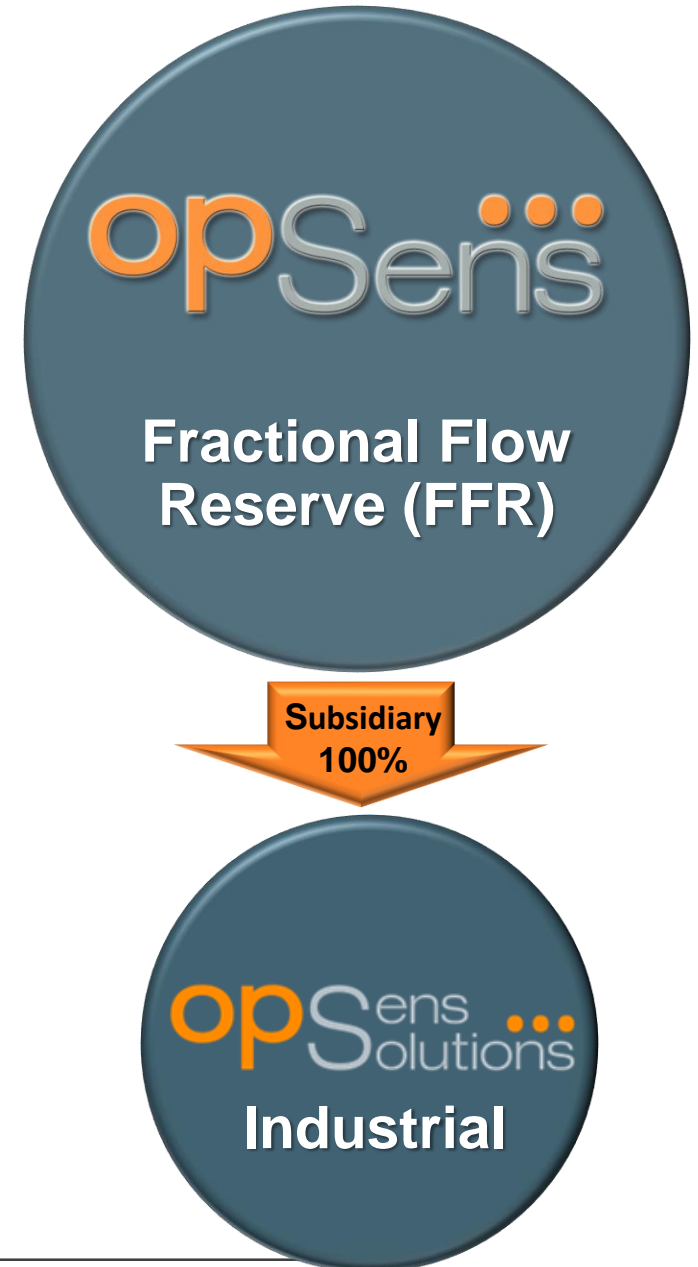


Protected by more than 10 Patents

Applications Beyond the Medical Industry

Opsens: Focus on medical devices.

Opsens Solutions: Applications include laboratories, aerospace, semiconductors and other industries.



Industrial: Large Growing Markets, Recuring Revenues

Opsens' Versatile WLPI Technology: To meet the needs of industrial markets

Unique and differentiated product capabilities

- Positive buzz around our technology

Full range of sensing solutions

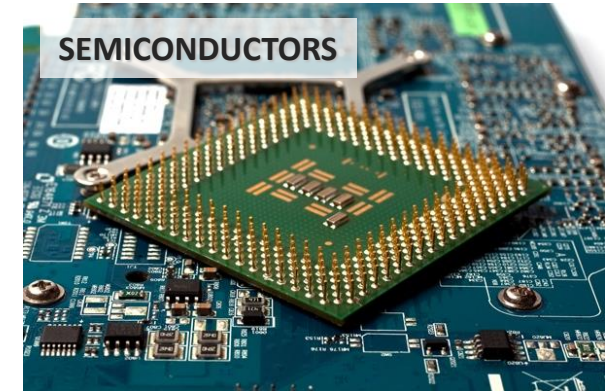
- Pressure
- Temperature
- Displacement
- Strain

Lead markets

- Laboratories, aerospace, semiconductors

Strategy

- Capitalize on technologies and on product range
- Develop marketing network.



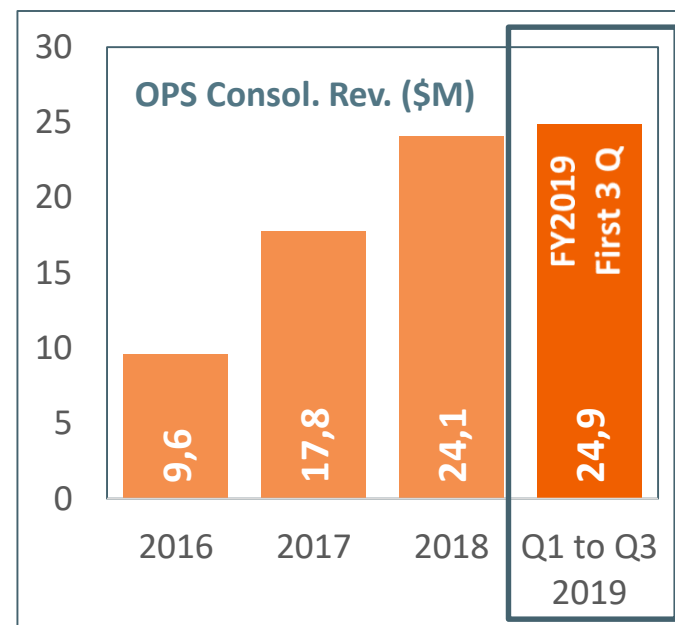
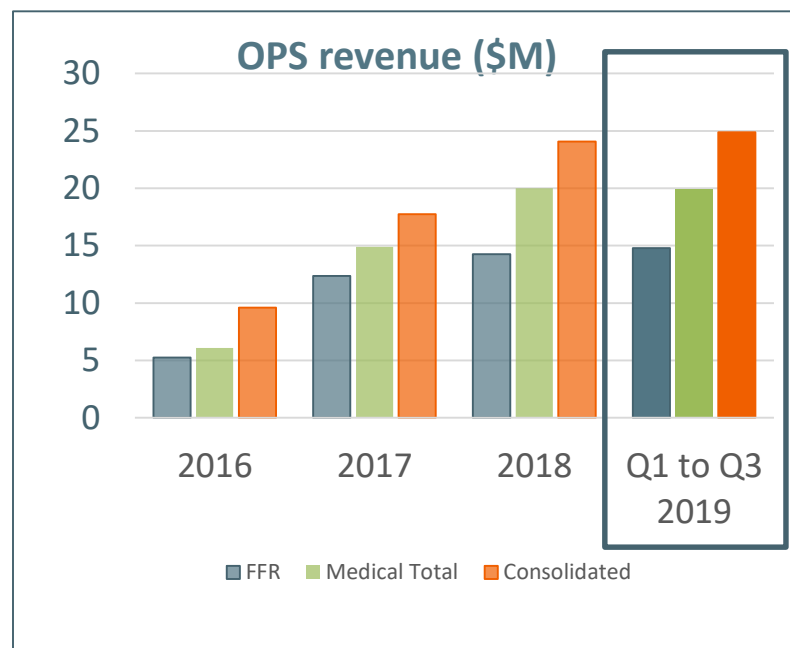
Creating Value for Shareholders

Key Considerations

- Product performance recognized by key opinion leaders
- Growing markets: US, EU, JPN, CAN
- Building clinical data
- 70,000 cases performed*
- Improvement of production processes
- Sales channels in >30 countries

Value Drivers

- Market share gain – Revenue growth
- Expansion in structural heart
- Clinical data
- Innovation – OWIII, OMIII and dPR
- Applications in exciting markets (Abiomed, Monteris, US Army, others).



Opsens Operations (TSX:OPS – OTCQX:OPSSF)

Operations & finance

- 184 employees
- Lean manufacturing approach - increasing gross margin
- 32% Revenue growth (Q3 2019 vs Q3 2018 – 9 month-period) – Q4: Nov 14
- Cash - \$17,1 M
- Shares - 90 M (96 M diluted)
- 52-week High / Low - \$1.05 / \$0.62.



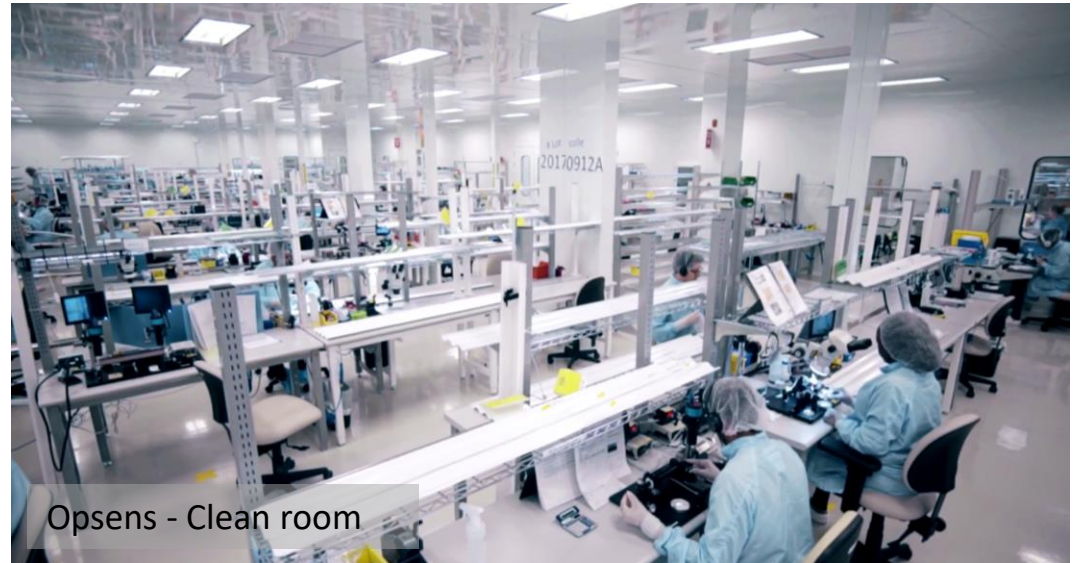
Opsens Operations (TSX:OPS – OTCQX:OPSSF)

Sales & Marketing

- Sales channels around the world
- US market penetration to increase as adoption rates grow
- Opsens' technology is used in other exciting applications
e.g. licensing agreement with Abiomed (NASDAQ:ABMD).



Opsens headquarters, QC Canada



Opsens - Clean room

Opsens has the Capability to Win Big

Worldwide Market

- >US\$500 M
- Increased confidence in physiology (FFR and dPR)

Product

- Advanced technology in pressure guidewire
- Workhorse-type guidewire, no drift

Sales

- FY 2019 – Improvement in sales channels

R&D

- dPR, OptoWire III and OptoMonitor III
- Expansion in fast-growing structural heart market

IP

- Strong IP portfolio leading to business opportunities

Manufacturing Plant

- Continuous improvement leading to improved gross margin

Team

- Capability to expand in cardiology + Experts in fiber optic

Vision: to become a leader within a few years