

OmniWire

Pressure guide wire

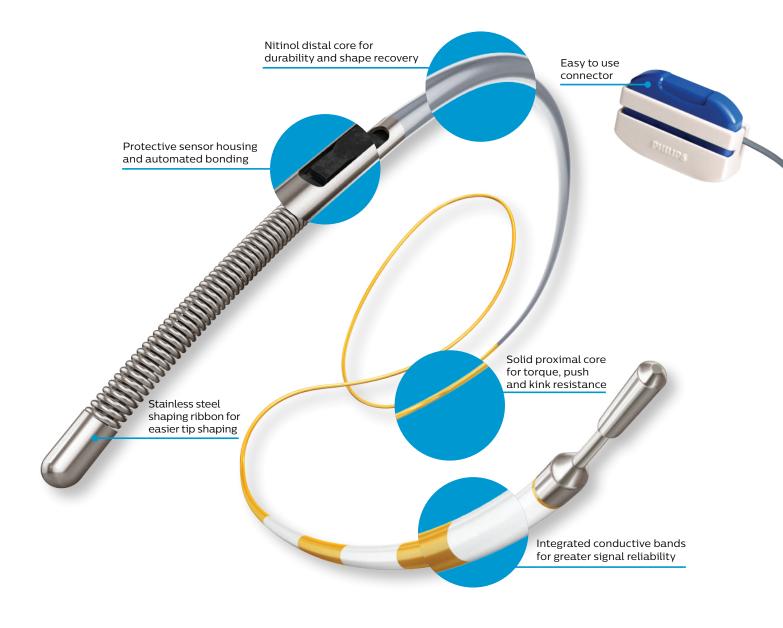
Solid core. No comprømise.

World's first solid core pressure guide wire."

Designed more like a contemporary workhorse guide wire

Only OmniWire combines reliability in wire performance with proven iFR outcomes and iFR Co-registration, making it easy to use physiology throughout the case.^{2,3,4}

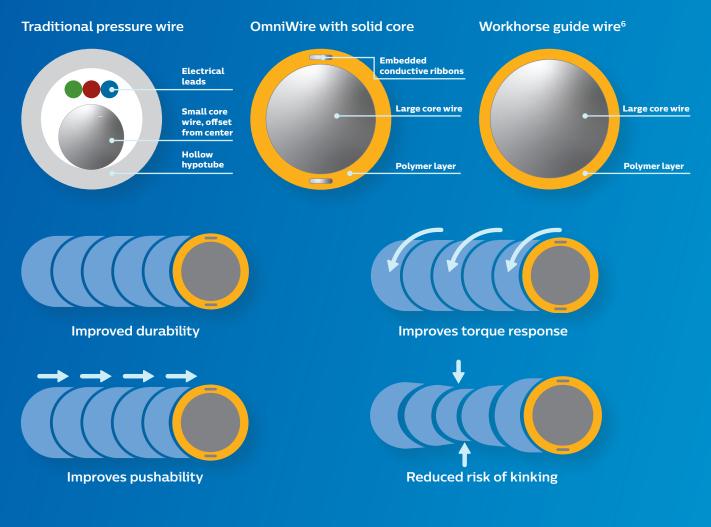
- New Nitinol distal core provides increased durability and shape recovery.
- Unique solid proximal core for improved torque, pushability and kink resistance.
- Durable, integrated conductive bands for confidence during device delivery, reconnections and post-measurements.



More core. Less hypotube.

Solid core for better performance

Until now, all pressure wires used a hollow hypotube to house electrical leads or optical fibers that carry the pressure signals. OmniWire uses a solid construction with conductive ribbons embedded in its outer layer. This innovation makes a larger solid core possible, similar to the design of your workhorse wire, providing the handling and durability needed for today's complex and multi-vessel cases.

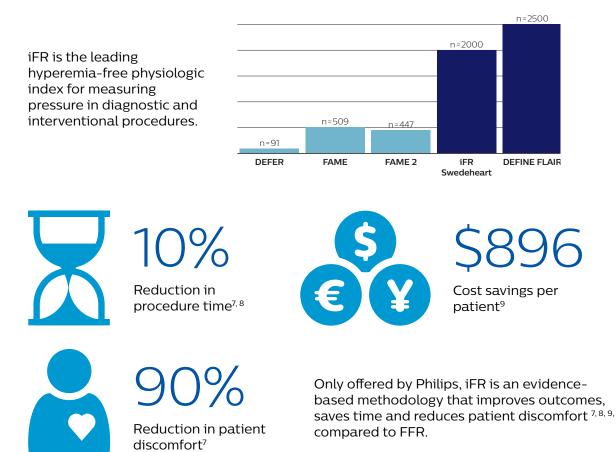


Tested to ensure reliability¹

We've rigorously tested OmniWire's design to ensure a stable signal through 30 disconnects and reconnects while navigating tortuous vessels as small as 1 mm.

iFR is in a class of its own.

Only iFR has clinically validated outcomes data in more than 4,500 patients



iFR is recognized by key industry associations

- Only iFR has been included in both the AUC (ACC Appropriate Use Criteria)¹⁰ and NCDR (National Cardiovascular Data Registry).¹¹
- Only iFR has been designated as "definitely beneficial" by SCAI (Society of Cardiac Angiography and Interventions).¹²
- Only iFR has received a Class 1A designation in the ESC (European Society of Cardiology) guidelines.¹³

Advanced physiologic guidance and PCI planning

with OmniWire, iFR Co-registration and IntraSight

OmniWire is fully compatible with Philips IntraSight platform for an outstanding user experience. IntraSight offers a comprehensive suite of clinically proven^{14,15} imaging, physiology and co-registration⁵ tools on a modern, secure platform that will help you simplify complex interventions and improve lab efficiencies.

iFR Co-registration makes it easy for you to see precisely which parts of the vessel are causing ischemia.

- Maps pressure drops onto the angiogram to better discern focal, serial or diffuse disease
- Precise lesion severity, location and length assessment without a pullback device
- Plan your treatment with a virtual stent and estimate post-PCI physiologic gain



Ordering information:

Order number	Product name	Size	Tip shape
89185	OmniWire pressure guide wire	185 cm	Straight tip
89185J	OmniWire pressure guide wire	185 cm	J-tip

OmniWire is compatible with Philips IntraSight interventional applications platform for an outstanding user experience.

Indications for use:

It can be used to measure pressure in blood vessels, including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. It can also be use to facilitate the placement of catheters as well as other interventional devices in coronary and peripheral vessels. Blood pressure measurements provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

The device is indicated for patients undergoing diagnostic angiography and/or percutaneous interventions in the coronary and peripheral vessels. iFR has been FDA cleared for ischemia testing using proven dichotomous cut-point, 0.89.

www.philips.com/OmniWire

- 2. Davies JE, et al., Use of the Instantaneous Wave-free Ratio or Fractional Flow Reserve in PCI. N Engl J Med. 2017 May 11;376(19):1824-1834.
- 3. Gotberg M, et al., iFR-SWEDEHEART Investigators. Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI. N Engl J Med. 2017 May 11;376(19):1813-1823.
- 4. Comparisons to Verrata Plus. Data/report internally on file or internal company's data on file. Verification Report, D000410086/A.
- 5. Co-registration tools available within IntraSight 7 configuration via SyncVision.
- 6. Proximal cross-sections. Not to scale, for illustration purposes only.

7. Davies JE, et al., DEFINE-FLAIR: A Multi- Centre, Prospective, International, Randomized, Blinded Comparison of Clinical Outcomes and Cost Efficiencies of iFR and FFR Decision-Making for Physiological Guided Coronary Revascularization. New England Journal of Medicine, epub March 18, 2017.

8. Gotberg M, et al., Instantaneous Wave-Free Ratio Versus Fractional Flow Reserve Guided Intervention (IFR-SWEDEHEART): A Multicenter, Prospective, Registry-Based Randomized Clinical Trial. New England Journal of Medicine, epub March 18, 2017.

9. Patel M. "Cost-effectiveness of instantaneous wave-Free Ratio (iFR) compared with Fractional Flow Reserve (FFR) to guide coronary revascularization decision-making." Late-breaking Clinical Trial presentation at ACC on March 10, 2018. 10. Patel M, et al., ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients with Stable Ischemic Heart Disease.

J Am Coll Cardiol. 2017 May 2;69(17):2212-2241.

11. ACC CathPCI Hospital Registry.

12. Lofti A, et al. Focused update of expert consensus statement: Use of invasive assessments of coronary physiology and structure: A position statement of the society of cardiac angiography and interventions. Catheter Cardiovasc Interv. 2018;1–12. 13. 2018 ESC/EACTS Guidelines on myocardial revascularization: The task force on myocardial revascularization of the European society of cardiology (ESC) and European

association for cardio-thoracic surgery (EACTS). Eur Heart J. 2018;00:1-96.

14. A. Maehara, M. Matsumura, Z.A. Ali, G.S. Mintz, G.W. Stone. IVUS-guided versus OCT-guided coronary stent implantation. J Am Coll Cardiol Img, 10 (2017), pp. 1487-1503 15. Choi K, et al. Impact of Intravascular Ultrasound-Guided Percutaneous Coronary Intervention on Long-Term Clinical Outcomes in Patients Undergoing Complex Procedures. JACC: Cardivascular Interventions. Mar 2019, 4281; DOI: 10.1016/j.jcin.2019.01.227

©2020 Koninklijke Philips N.V. All rights reserved. Approved for external distribution. D052035-00 032020



Philips 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130 USA www.philips.com/IGTdevices

^{1.} Data on file D000410086_A, D000485394_A