

FINALLY.

INTRODUCING PRESSUREWIRE WITH AGILE TIP

St. Jude Medical continues to set new standards in fractional flow reserve (FFR) measurement. With the next generation PressureWire and proprietary Agile Tip technology, physicians now have a new, more responsive pressure guidewire that provides outstanding handling — even in the most challenging anatomies.



EXCEEDING EXPECTATIONS.

FAST AND EASY FFR

- Near 1:1 torque response¹ enables exceptional performance in tortuous anatomies, matching frontline PCI guidewires
- Smooth, effortless stent/balloon delivery¹
- Better maneuverability than other pressure guidewires in vitro testing¹

TRUE FFR™

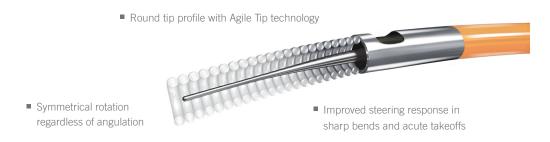
- 2.6 times lower pressure drift per hour as compared to competitive pressure guidewires in vitro testing²
- St. Jude Medical PressureWire Aeris and PressureWire Certus were the only FFR guidewires used in both FAME and FAME II studies

MORE THAN FFR

- The ultimate research tool, the only pressure guidewire on the market allowing simultaneous assessment of FFR/IMR/CFR with one wire
- The only wireless FFR system

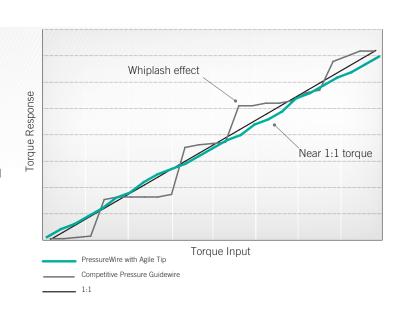
FAST AND EASY FFR - OUTSTANDING HANDLING PERFORMANCE

PressureWire with Agile Tip technology, available in both PressureWire Aeris (wireless) and PressureWire Certus models, allows physicians to more quickly and easily navigate tortuous vessels, identify hemodynamically significant stenoses and support stent deployment.



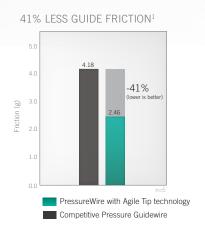
SUPERIOR STEERABILITY

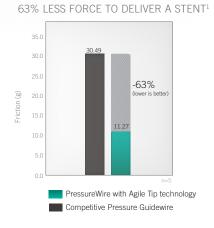
The unique new tip from St. Jude Medical features a proprietary round core-to-tip grinding profile that provides extraordinary agility and a near 1:1 torque response in sharp bends and tortuous vessels. As a result, PressureWire with Agile Tip enables smooth and accurate vessel navigation compared to competitive pressure guidewires that deliver a typical whiplash effect when torque is built up gradually before being released.¹



EASIER NAVIGATION AND BETTER DEVICE DELIVERY

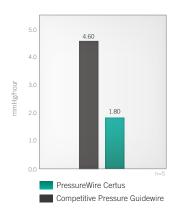
The new PressureWire features a specially developed hydrophilic coating that lowers friction between guidewire and guide catheter as well as between guidewire and stent delivery catheters. This new lubricious coating gives PressureWire superior device interaction compared to other pressure guidewires.





True FFR - The Most Reliable FFR System on the Market

The FAME trial, which demonstrated that accurate FFR measurement is crucial to improve patient outcomes, was based on exclusive use of St. Jude Medical PressureWire technology.³ Comprehensive simulation test models show that FFR measurement using PressureWire is more reliable than competitive pressure guidewires.



Simulated clinical use shows that FFR measurement using PressureWire Certus from St. Jude Medical is more reliable, with an average of 2.6 times lower pressure drift per hour as compared to competitive pressure guidewires.^{2,4}

MORE THAN FFR

- Unique multi-functionality with proprietary sensor chip technology enables assessment of multiple parameters with one wire.
- PressureWire Certus with Agile Tip is the only pressure guidewire capable of simultaneous assessment of FFR,
 CFR and IMR.
- PressureWire Aeris with Agile Tip is the only wireless FFR device with multiple platform compatibility, including all major hemodynamic recording systems and ILUMIEN™.

OUR CLAIM TO FAME

St. Jude Medical PressureWire Aeris and PressureWire Certus were the only guidewires used in both FAME and FAME II studies. The FAME two-year results affirm the advantages of using FFR to guide multivessel intervention.⁵

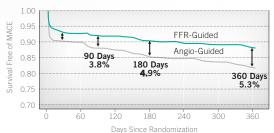
FAME STUDY RESULTS

- Reduced mortality and myocardial infarction by 34% at two years⁵
- Reduced relative risk of MI by 37% at two years follow-up⁵
- Reduced procedure and one-year follow-up costs by 14%³
- Decreased the amount of contrast agent used⁵

REDUCED COSTS

FFR-guided PCI results in reduced procedural and health care costs as demonstrated in a cost-effectiveness study presented by Professor Uwe Siebert, M.D., M.Sc., M.P.H., Sc.D., at EuroPCR 2011.

ABSOLUTE DIFFERENCE IN MACE-FREE SURVIVAL AT ONE YEAR



SUPPORTED BY GUIDELINES

FFR was awarded the highest level of evidence, Class I, Level of Evidence A, by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS).⁶ The ACC/AHA/SCAI guidelines are Class II A, Level of Evidence A, for determining whether PCI of a specific coronary lesion is warranted.⁷

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

- 1. St. Jude Medical. Data on File.
- 2. St. Jude Medical. Data on File. Average pressure drift from 25 competitive pressure guidewires and 50 PressureWire Certus during one-hour simulated clinical use in heparinized blood.
- Tonino PA, De Bruyne NH, Pijls NH, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. New Engl J Med. 2009;360(3):213-24.
- 4. 510 (K) summary. PrimeWire Prestige PLUS pressure guidewire. http://www.accessdata.fda.gov/cdrh_docs/pdf11/K111395.pdf. accessed February 2, 2012.
- 5. Pijls NH, Fearon WF, Tonino PA, et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention in patients with multivessel coronary artery disease: 2-year follow-up of the FAME (Fractional Flow Reserve versus Angiography for Multivessel Evaluation) study. J Am Coll Cardiol. 2010. 56(3):177-84.
- 6. Wijns W, Kolh P, Danchin N, et al. Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2010;31(20):2501-55.
- Kushner FG, Hand M, Smith SC Jr, et al. 2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update) a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2009;54(23):2205-41

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Product referenced is approved for CE Mark.