

# Fractional Flow Reserve (FFR) & FAME Family Studies

## Fact Sheet

### WHAT IS FRACTIONAL FLOW RESERVE (FFR)?

Coronary artery disease, also known as coronary heart disease, is the most common type of heart disease that affects millions of people worldwide. It is caused by a narrowing or blocking of the arteries due to plaque which restricts blood flow, and reduces the amount of oxygen to the heart.

There are several different tools that aid physicians in the treatment of the disease. One traditional tool is a coronary angiogram, which is an X-ray examination of the blood vessels in the heart. Other advanced tools that aid physicians in making the best treatment decisions for their patients are a next-generation imaging technology called Optical Coherence Tomography (OCT) and the measurement of Fractional Flow Reserve (FFR), which provides a more detailed, physiological analysis of blood flow blockages in the heart.

An FFR measurement indicates the severity of blood flow blockages in the coronary arteries and allows physicians to identify which specific lesion or lesions (or blockage causing blood flow restriction) are responsible for a patient's ischemia (a restriction of blood flow to the heart) and warrant stenting.

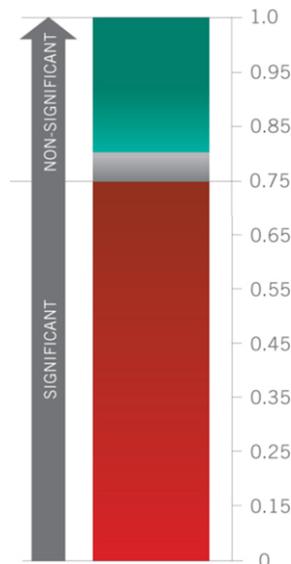
The landmark FAME family trials are sponsored by St. Jude Medical and include the original FAME Trial, and the FAME II Trial. Both trials have demonstrated that when PressureWire™ measurement technology is used in the treatment of coronary artery disease, patient outcomes are improved.

### HOW IS FFR MEASURED?

Interventional cardiologists use FFR measurement systems, such as PressureWire™ Aeris and PressureWire™ Certus to measure pressure inside the coronary arteries.

Measurements are taken by placing the PressureWire across the lesion of interest and inducing a state of maximum blood flow, thereby allowing the physician to determine if the narrowing is tight enough to cause ischemia. FFR is defined as the ratio of maximal blood flow in a stenotic (narrowed) artery to normal maximal flow, expressed as a fraction of the normal blood flow in an artery compared to the maximum achievable blood flow in the same artery.

- An FFR measurement of 1.0 indicates an artery with normal blood flow
- An FFR measurement above .80 indicates that ischemia is very unlikely, as demonstrated in the FAME study
- An FFR measurement below .75 is 100 percent specific in identifying that the blood flow blockage caused by the narrowing is responsible for a patient's ischemia



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## THE ORIGINAL FAME TRIAL

The original FAME (Fractional Flow Reserve (FFR) vs. Angiography in Multivessel Evaluation) Trial compared outcomes of patients whose treatment was guided by FFR to those whose treatment was only guided by angiography using the St. Jude Medical PressureWire Certus technology for FFR measurement. Results from the landmark trial demonstrated improved clinical outcomes in patients with stable coronary artery disease and two or three vessel disease.

The 12-month results published in the *New England Journal of Medicine* demonstrated that instances of major adverse cardiac events were reduced by 28 percent for patients whose treatment was guided by FFR rather than by standard angiography alone. Two-year results demonstrated that patients who received FFR-guided treatment continued to experience improved outcomes over time, including a 34 percent risk reduction in death or heart attack.

## THE FAME II TRIAL

The FAME II (FFR Guided Percutaneous Coronary Intervention (PCI) Plus Optimal Medical Treatment vs. Optimal Medical Treatment Alone in Patients with Stable Coronary Artery Disease) Trial examined the role of FFR in the treatment of stable coronary artery disease in one or more vessels.

The trial compared clinical outcomes, safety and cost effectiveness of percutaneous coronary intervention (PCI) guided by FFR plus the best available medical therapy (MT) to MT alone. Trial results published in the *New England Journal of Medicine* revealed that patients with FFR-guided treatment plus medical therapy experienced superior outcomes to those treated with medical treatment alone. Further, use of the PressureWire technology helped reduce the relative risk of hospital re-admission with urgent revascularization by 86 percent.

In January 2012, enrollment in the St. Jude Medical-sponsored FAME II Trial was halted after an Independent Data Safety Monitoring Board (DSMB) found a highly statistically significant reduction in unplanned hospitalizations and urgent revascularizations in patients enrolled in the PCI plus MT arm of the trial. The DSMB therefore deemed it unethical to continue to randomize patients into the arm of the trial receiving MT alone. Patients already enrolled in the trial continue to be followed, but no additional patients were added.

## PRESSUREWIRE TECHNOLOGIES

Designed to replicate the performance of standard PCI guidewires, the PressureWire technology is available in both the Aeris and Certus models. In 2012, the next generation of FFR measurement technology, the **PressureWire™ Agile Tip**, entered the market offering improved responsiveness and steerability for easy handling in difficult anatomies. The PressureWire Agile tip technology also includes a new proprietary hydrophilic coating to reduce friction; making it easier for doctors to deploy stents and coronary balloons.

The **PressureWire Aeris** is a first-of-its-kind wireless FFR system that doesn't require additional equipment or cabling in the cardiac catheterization laboratory. The system integrates FFR technology directly into a wide array of recording systems to immediately and securely display, measure and save FFR data.



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PressureWire Aeris also integrates FFR results into a patient's existing record, allowing the severity of coronary lesions to be documented together with other procedural data and angiographic imagery.

The market-leading **PressureWire Certus** provides an FFR measurement without increasing procedural time. It is the only guidewire on the market to provide a combined measurement of pressure and temperature, which enables calculations of FFR, Coronary Flow Reserve (CFR) and an Index of Microcirculatory Resistance (IMR).

## FFR AS STANDARD OF CARE

The positive outcomes of the original FAME trial resulted in the level of evidence for FFR to be upgraded to an "A" from a "B" by the American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions. Level of evidence "A" is the highest level available, requiring the most clinical evidence and is awarded only when data is derived from multiple populations and multiple randomized clinical studies or meta-analyses.

The benefits of the PressureWire technology were also recognized in guidelines from the European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) which included recommendations for the treatment of coronary artery disease that support measuring FFR before deciding to perform PCI or send the patient to surgery. The ESC guidelines gave FFR the highest recommendation possible: 1A.

FFR technologies have demonstrated significant cost savings in various health care systems. In each country where an economic analysis was conducted, the PressureWire technology was found to save resources while also improving clinical outcomes by increasing quality-adjusted life years and reducing the number of cardiac events.

In the U.S. health care system, there was a difference of about \$2,000, or 14 percent, between total health care costs for the FFR-guided cohort and the group treated by angiography alone after one year. In Europe, the savings ranged from between 500€ and 900€ per patient.

These lower health care costs were a result of reduced procedural costs, reduced follow-up costs for major adverse cardiac events and shorter hospital stays.

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