

Nominee: Paul Douglas Corl, PhD, Chief Scientist, Volcano Corporation

Nominated by: Self

Product: PrimeWire, pressure measuring coronary guidewire from Volcano Corporation

Nomination:

I nominate myself as the inventor and principle developer of the PrimeWire pressure measuring guidewire, which has had a major impact on medical practice in the period from 2000 to the present. I originally developed a pressure measuring guidewire while working for Cardiometrics, Inc. in the late '90s, shortly before the company was acquired by EndoSonics (Rancho Cordova). The first patent for this device was filed in 1996 and issued in 1998. The product was introduced to the market in 1998 and I left the company shortly thereafter for geographic reasons (company moved to a new location). Several years ago, I rejoined the company, now Volcano Corporation, and thanks to a combination of engineering problem-solving and the release of several important clinical trials, this product has experienced explosive growth over the past two years, in a market that could grow to \$1B over the next decade.

A pressure measuring coronary guidewire is used to measure the blood pressure distal to a lesion or obstruction in a coronary artery. The guidewire is a thin flexible structure, just 0.014" in diameter and 185cm in length, with a tiny MEMS pressure sensor embedded near its tip. In clinical use, the guidewire is inserted into the femoral artery through a small puncture in the groin, and navigated up through the aorta into the coronary arteries. This small diameter guidewire can pass through a partial obstruction (lesion) in the coronary artery without significantly impacting the pressure drop across the lesion. The distal pressure measurement is used to calculate the Fractional Flow Reserve (FFR) as the ratio of the distal pressure to the proximal (aortic) pressure, providing a figure of merit used to quantify the functional significance of the lesion and to guide the decisions regarding the most appropriate treatment of the disease. The PrimeWire is typically used as part of a procedure called a Percutaneous Coronary Intervention (PCI), involving X-ray guided treatment of coronary artery disease using guidewires, catheters, stents, etc., inserted through the small puncture in the skin (hence percutaneous).

It is well documented and understood that angiography alone is incapable of accurately predicting the hemodynamic significance of a coronary lesion. Even with views collected from multiple angles, the limited geometric information available from the X-ray shadow-gram provides insufficient information to permit accurate modeling of the hemodynamic effects of the lesion. In contrast, a simple FFR calculation permits a robust assessment of the effect of the obstruction on the very important functional parameter of coronary blood flow. This diagnostic technology was initially embraced by only a small segment of the interventional cardiology community, but at that time there was much greater interest in developing treatment methods, particularly the stent (a small metal cage used to prop open a partially blocked coronary artery), and later the drug-coated stent. Many interventional cardiologists were satisfied with the traditional method of assessing lesion severity by X-ray angiography alone, and then applying what they considered to be a relatively safe and effective treatment wherever they saw a lesion they thought likely to be significant, based on its angiographic appearance.

Although the pressure measuring guidewire business continued to grow modestly, the growth was hampered by two important factors. The first was a low level of interest from the majority of interventional cardiologists who were satisfied with the status quo – placement of drug-coated stents, guided by the visual appearance of the lesion on the X-ray image. The second factor was a disappointingly high incidence of pressure sensor drift complaints that made the system quirky to use, and contributed to a lack of confidence among even those physicians who did embrace the functional measurement concept.

In 2003, Volcano Corporation acquired the IVUS and Functional Measurement businesses (that formerly comprised EndoSonics) from Jomed, and in 2005, they contacted me for assistance with the pressure sensor drift issue. I (re)joined the company, and found that although there had been a number of valuable improvements in the design over the intervening years, the drift complaints persisted at a frustratingly high rate.

The PrimeWire pressure measuring guidewire is conceptually simple but in terms of the physical principles that might contribute to drift, it is a complex device, incorporating a silicon MEMS device that can be affected by mechanical, thermal, electrical, and chemical influences. Over a period of 6 months, I studied a large number of drift-prone devices, attempting to isolate the various influences and identify the root cause of the complaint. I expected the problem to be found in either a mechanical or electrical effect, perhaps related to some parasitic semiconductor device, present as a part of the MEMS structure. But I was surprised to find the problem was caused by an electrochemical phenomenon, which partially explains why it had not been found sooner by the electrical and mechanical engineers who investigated the problem over many years. Once the root cause was identified, I quickly found and implemented a solution to the drift issue, eliminating that obstacle to widespread adoption of the device.

The next important development was a landmark clinical study called FAME, briefly described in the press report below:

First presented at TCT 2008, in Washington, DC, by Dr Nico Pijls (Catharina Hospital, Eindhoven, the Netherlands) and reported by **heartwire** [a medical journal] at that time, FFR-guided PCI [Percutaneous Coronary Intervention such as stent placement] reduced the risk of death, MI [Myocardial Infarction or heart attack], or repeat revascularization by 30% and death or MI by 35%, compared with the current practice of using angiography to guide stenting decisions.

More recent results from the same clinical trial not only confirm the clinical and patient benefit of FFR-guided PCI, but also demonstrate an average \$2000 savings in medical care costs, primarily by avoiding unnecessary treatment that is both expensive and increases the likelihood for negative side effects.

In today's economic climate, and with the health care system such a prominent part of the national debate, it is particularly important for the medical device industry to provide cost-effective solutions, where the patient benefit outweighs the added cost. The innovation represented by the PrimeWire takes this to another level – improving patient outcome while substantially reducing the overall cost to the health care system. This incredible value has been recognized in the marketplace, where annual sales of this product have increased by nearly 80% over the prior year, with continued high growth rates predicted for many years to come.