

Company Profile

Industry Sector: Medical Devices

Intra-operative measurement of blood flow provides critical vessel specific guidance to interventions for coronary artery stenosis, peripheral artery disease and dialysis access graft thrombosis.

DVX's patented V-HELIX™ blood flow measurement device has been demonstrated by our clinical research partners to be accurate, reliable and durable in analogous pre-clinical models.

PCI clinical practice (stenting) has not embraced Fractional Flow Reserve (FFR) as a standard for assessing functional severity of coronary artery stenosis. Extensive clinical investigations of FFR and multi-site patient studies (FAME) have all established benefits to patient outcome and healthcare cost. However interventional cardiologist and cardiac catheterization labs have been wary of increased procedure time and cost and increased patient risk (crossing stenosis).

To overcome the hurdles to FFR adoption, by incorporating FFR on a cardiac angiography catheter, the interventional cardiologist can use their guide wire of choice, not require extra procedure steps or time (angiography is current standard of care) and not incur significant increase in device cost (such as with IVUS).

The company's V-HELIX™ flexible thin film ultrasound sensor is the only technology that can be incorporated on cardiac angiography catheters for FFR without degrading their clinical ergonomics.

The very recent American College of Cardiology "2012 Appropriate Use Criteria for Coronary Revascularization" establishes a large category of coronary lesions that demand FFR (or IVUS) to determine whether PCI is appropriate or inappropriate. Clinicians will adopt DVX's multi-function catheter because it does not impact the economics of the cath lab yet offers compliance with FAME; becoming the best demonstrated practice and a criterion for reimbursement.

Target Markets: Interventional Cardiologist, Catheterization labs

Management

David Vilkomerson, Ph.D. and John Turner, Ph.D., MBA

Co-Principle Investigators:

John Blebea MD, Vascular Surgery, Case Western, now Chair Dept of Surgery, Univ. Oklahoma (HL071359, HL095195)

Joseph Gorman III MD, Cardiovascular Surgery, Penn School of Medicine, (HL104812)

Robert Wilensky MD, Interventional Cardiology, Penn School of Medicine, (HL104812)

Key Value Driver

Technology: Intra-coronary measurement of blood flow by Doppler ultrasound proximal to a stenosis is preferable to a distal measurement of pressure requiring sensor to cross a stenosis (e.g. St. Jude Medical PressureWire). The original research in assessing functional stenosis severity (Pijls 1993) determined the Coronary Flow Reserve (CFR) using Doppler ultrasound) and deduced the Fractional Flow Reserve (FFR) using readily available pressure sensor technology. Now with DVX's unique ultrasound flow sensor, the functional assessment of a specific stenosis is straight forward.

DVX's split-phase sensor (US [6,346,081](#)) creates a Doppler ultrasound beam that has been demonstrated to produce reliable and accurate intravascular flow measurements independent of its orientation to the vessel walls (HL095195). Volcano's FloWire® Doppler Guide Wire INSTRUCTIONS FOR USE specify "Manipulate guide wire tip to insonify peak velocities"; orientation dependent reading limits its diagnostic utility.

The V-HELIX™ spiral geometry (US [7,902,722](#)) generates a unique in-vessel circumferential ultrasound beam around a catheter to best insonify an irregular aperture (US [7,963,920](#)). The thin film piezo-polymer applied in a flexible layered construction (US [8,052,608](#)) allows this device to conform to existing catheters without degrading their clinical ergonomics. DVX has extensive experience (4 NIH grants) in producing sensors (pending 61/532,643), measuring blood flow by attaching to catheters or vessels (pending 61/437,945) with pre-clinical verification completed by our clinical partners.

DVX's piezo-polymer operates in an ultrasound frequency range (distinct from existing products) that provides superior blood vessel Doppler returns (SNR), extremely low power requirements and simpler electrical interface characteristics.

Competitive Advantage: Versatile thin film sensors for accurate, repeatable Doppler ultrasound measurements significantly improve and simplify the clinical verification of blood flow to sustain viable tissue. DVX is focused on products that minimally change clinical practice and cost, yet provide diagnostic information for better patient outcomes.

Plan & Strategy: DVX expects to either partner with an existing medical device company or work with a contract catheter developer. DVX will maintain the skill and art in manufacturing piezo-polymer medical sensors under QLP.

Product Development Pipeline

Angiography catheter with FFR: Pre-clinical testing in 6 months after funding/partner V-HELIX catheter device (5 Fr) already verified in live animal testing, HL095195
Select clinically preferred angiography catheter suitable for sensor integration.
Scale to 4 Fr with sensor & interconnect without impeding angiographic function
Undertake pre-clinical study (similar to Pijls 1993) once under QLP process.
FDA 510(k) clearance process acknowledging similar predicate devices
DVX will pursue improving other catheters where blood flow measurements lead to clinically significant outcomes.