

First-in-Class Dual Modality
Intravascular Imaging System



tvc

IMAGING SYSTEM™

Sound Insight for Clinical Decision Making

TRUE VESSEL CHARACTERIZATION

In interventional cardiology today, there is the need for advanced imaging technology that provides a more accurate and complete assessment of the vessel than is possible from angiography alone.

A complete assessment of the vessel requires looking deeper than the lumen to understand both plaque composition and structure.

This complete assessment also requires identifying those clinically significant lipid core plaques (LCP) which are associated with acute coronary syndromes and other coronary events.

True vessel characterization - the accurate, reliable, rapid and simultaneous assessment of both composition and structure - can identify high-risk, lipid core plaques known to complicate stenting and associated with most coronary events. And that can provide sound insight for clinical decision-making.

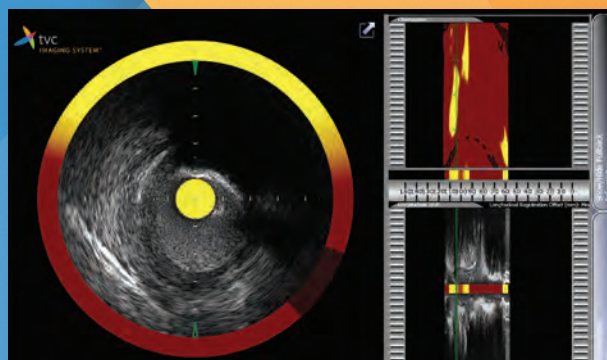
True vessel characterization holds value in:

- Improved stenting therapy
- More informed diagnosis and treatment strategies
- Detailed risk stratification
- Clearer adjustment of pharma therapy

Because information available to you right now, when you need it, can make a meaningful difference.



Angiography (Left): Angiogram from a 67 year old female with positive family history but no personal history of CAD demonstrates only a focal 75% diameter stenosis in mid segment of a large caliber RCA. A more advanced imaging technology would have the potential to reveal additional information that could help shape diagnosis and treatment strategies.



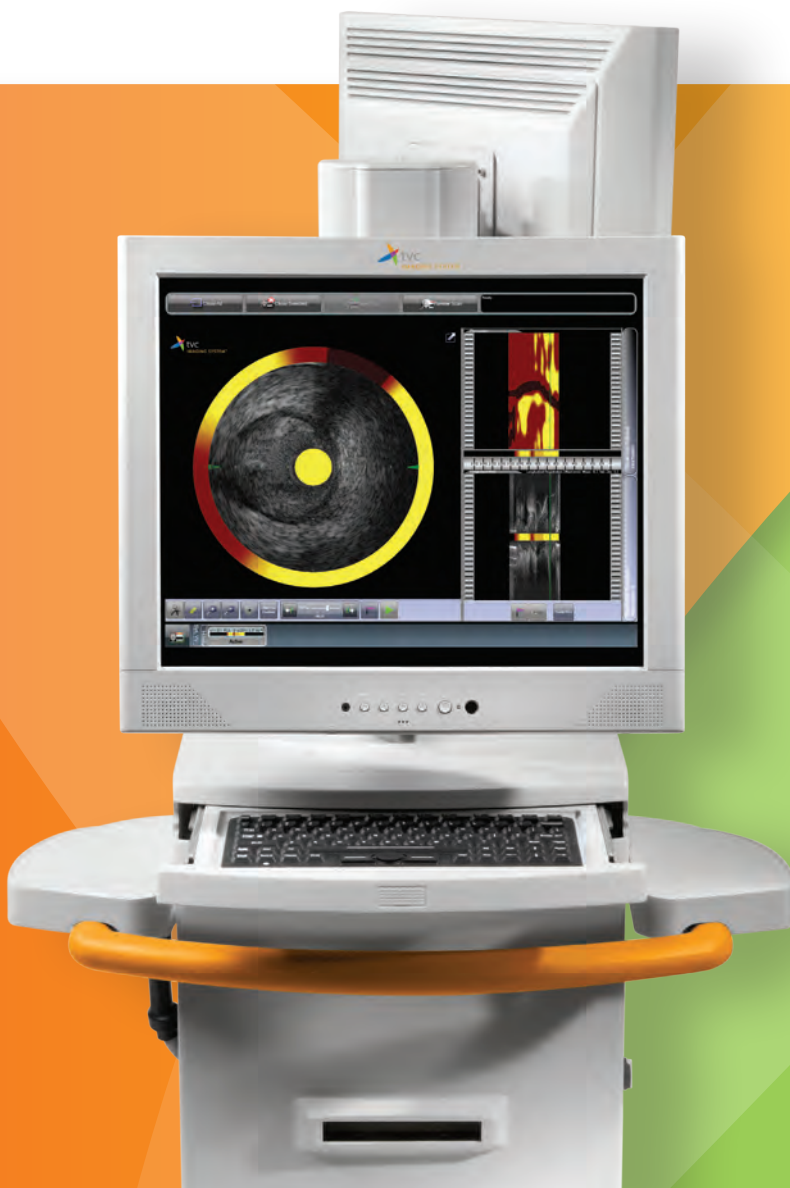
Co-registered NIRS/IVUS Image (Right): The IVUS data showing a blockage is dominated by superficial calcium. The calcium shadow artifact conceals the nature of the plaque, but the NIRS Chemogram™ reveals the lipid pool hidden from the physician's view. Both IVUS and NIRS are necessary to fully characterize the blockage.

The TVC Imaging System™ is a first-in-class intravascular imaging system with the unique ability to assess vessel composition and structure via integrated NIRS (near infrared spectroscopy) lipid core plaque detection and enhanced IVUS imaging technology.



The First and Only FDA-Cleared Device for the Detection of Lipid Core Plaques

- Lipid core plaques (LCP) are known to complicate coronary stenting. The TVC Imaging System enables the immediate, accurate, and reliable identification and location of lipid core plaque, as well as quantification of the vessel's lipid core burden.
- The TVC Imaging System provides for the immediate assessment of the lumen, vessel wall, and plaque structure. All with greater clarity and definition than ever before.
- The technology behind the TVC Imaging System is supported by extensive scientific validation in laboratory specimens and in patients, including the 2008 study by Gardner and colleagues that demonstrated LCP could be detected using NIRS.¹ Histology served as the gold standard for detection of LCP by NIRS.



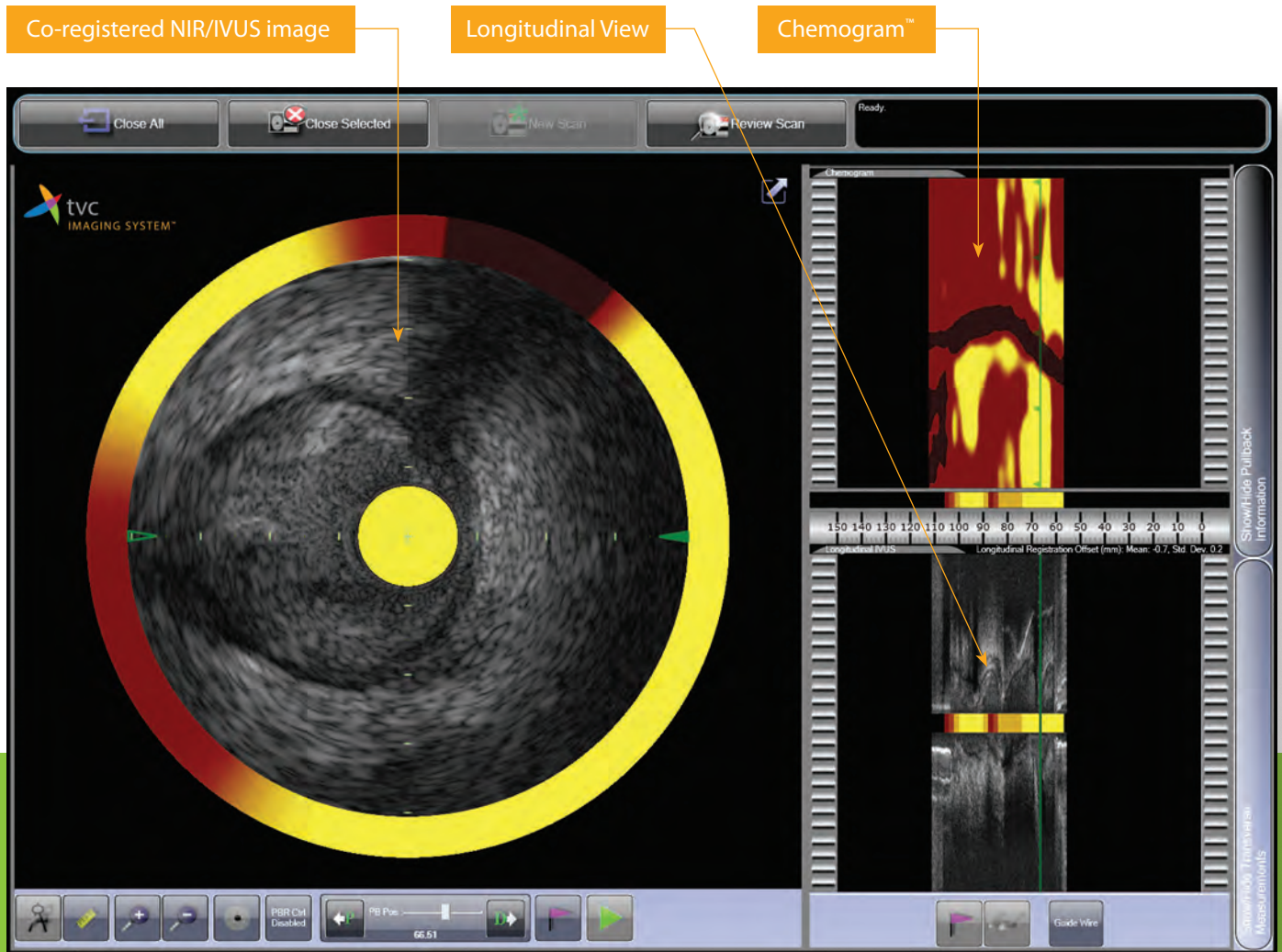
In a single pullback of the dual-modality TVC Insight™ Catheter, the TVC Imaging System enables true vessel characterization to reveal what you need to know.



1. Gardner CM, Tan H, Hull EL, et al. Detection of Lipid Core Coronary Plaques in Autopsy Specimens With a Novel Catheter-Based Near-Infrared Spectroscopy System. *J Am Coll Cardiol Img.* 2008;1(5):638-648.

First-in-Class Interventional Cardiology Imaging System

With the only dual-modality intravascular imaging catheter, the TVC Imaging System integrates NIRS for imaging vessel composition and IVUS for imaging vessel structure to bring unprecedented capability into the catheterization lab.



TVC Composite™ Image

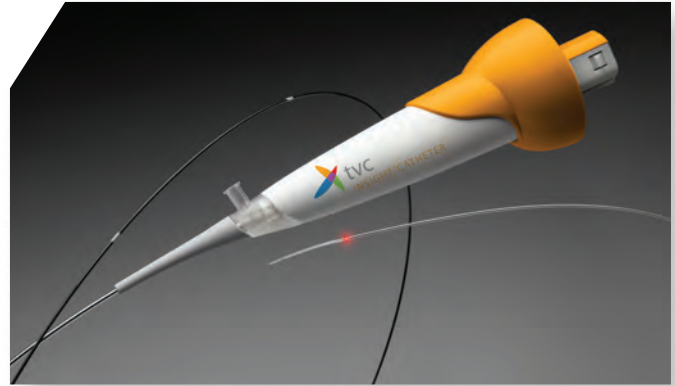
The simultaneous, co-registered NIR and IVUS image display provides true vessel characterization.

- A high resolution IVUS image and NIR Chemogram™ to support peri-procedural decision making.
- Easy to use measurement tools help optimize stent sizing and placement.

TVC Insight™ Catheter

High fidelity ultrasonics and laser-based near infrared spectroscopy work in combination to deliver clear, crisp, structural and compositional images.

- Rapid and accurate NIRS facilitates immediate lipid core plaque detection.
- 40MHz high frequency rotational IVUS enables accurate and reliable lesion assessment.
- Polished and tapered atraumatic tip allows distal access across tight anatomy.



TVC Imaging System™ Console

Highly sophisticated technology engineered into a portable system that holds utility across multiple cath labs.

- High definition monitors display imagery with superior clarity.
- Operator monitor has intuitive, touch screen graphical user interface for ease of use and optimized procedural workflow.
- Advanced system processing and data storage capabilities ensure outstanding speed and performance.



TVC Nexus™ Controller

- Provides the physician with uncompromising pullback control during an interventional procedure.
- Easy to use with pullback start, stop, flag and image review functions at the physician's control.

See for yourself the difference that TVC-guided stenting can make.
Request a demonstration from your Infraredx representative.

BACKED BY FULL INFRAREDX SERVICE & SUPPORT

The TVC Imaging System is supported by a comprehensive training and support program.

- On-site system training for physicians and staff that includes didactic and hands-on modules administered by Infraredx clinical specialists.
- Multimedia-based system training and quick reference tools.
- Dedicated customer service phone support.



Technical Specifications

TVC Imaging System™	Operating System:	Windows XP Embedded
	Processor:	Intel Quad Core i7
	Memory:	4 GB RAM
	Hard Drive Capacity:	200 GB (User)
	Digital Archiving Options:	PACS via DICOM, Local Hard Drive: 100+ cases; DVD 4.7 GB, AVI, binary data files, PDFs
	DICOM Services Supported:	DICOM Store

TVC Insight™ Intravascular Imaging Catheter	Minimum guide catheter:	6 French (2mm)
	Maximum guide wire:	0.014" (0.36mm)
	Catheter Tip Crossing Profile:	2.4 French (0.79mm)
	Maximum Imaging Diameter:	13 mm
	Catheter Working Length:	120 mm
	Operating Frequency:	40 MHz

Ordering Information

To learn more about the TVC Imaging System™ or to place an order, please contact your Infraredx representative at 888-680-REDX.

Catalog Number	Description
NIRS-MC7	TVC Imaging System™ Console
NIRC-MC7-70-3.2F	TVC Insight™ Catheter
NIRS-MC7-SA	Sterile Accessory Kit

infraredx®

www.infraredx.com

888-680-REDX (7339)