

Pioneer the Next Advancement in CAD Treatment

with our unique IVUS+NIRS innovation

Technology that makes you
look twice at heart disease.



It's a pursuit that starts very near the human heart.
Exactly like courage.

Infraredx is an intravascular imaging company committed to advancing the diagnosis and management of coronary artery disease around the world.

We harness 30 years of research into the association between heart attacks and lipid core plaques because we believe in the promise and power of intelligent insights. Infraredx commands a bold vision, pioneering the design, manufacture and distribution of technologies that address the needs of practitioners and improve outcomes for patients with coronary artery disease.

With ongoing investment in several landmark global clinical trials, Infraredx's mission to help cardiologists predict and prevent heart attacks continues. We applaud your courage to push these vital discoveries forward and we are committed to supporting you every step of the way.

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References:

1 Detection by NIRS of LCPs at Culprit Sites in Patients with Acute STEMI, Madder et al, *JACC Cardiovasc Interv.* 2013

2 Detection of LCPs by intracoronary NIRS Identifies High Risk of Periprocedural MI, Goldstein et al, *Circ Cardiovasc Interv.* 2011

MK0335rE

Catalog Number	Description
TVC-MC10	Makoto™ Intravascular Imaging system
TVC-C195-42	Dualpro™ IVUS+NIRS Catheter

It's time to chart
the uncharted territories
of Coronary Artery Disease

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makoto™
INTRAVASCULAR IMAGING SYSTEM

Gain Unparalleled Insights into Heart Disease

with the Makoto™ Intravascular Imaging System

There are still broad swaths of uncharted territories concerning the role lipid core plaques play in heart disease. Now you can achieve unparalleled insights with the Makoto Intravascular Imaging System and its accompanying Dualpro™ IVUS+NIRS catheter, the only FDA-cleared imaging system indicated for the detection of lipid core plaque (LCP) and the identification of plaque and patients at increased risk of MACE.

By analyzing both structural and compositional data you can learn about the effects of specific treatments on plaque size and lipid core content, develop novel preventative

approaches for plaque stabilization, study regression of plaque size and composition, or guide the use of existing therapies.

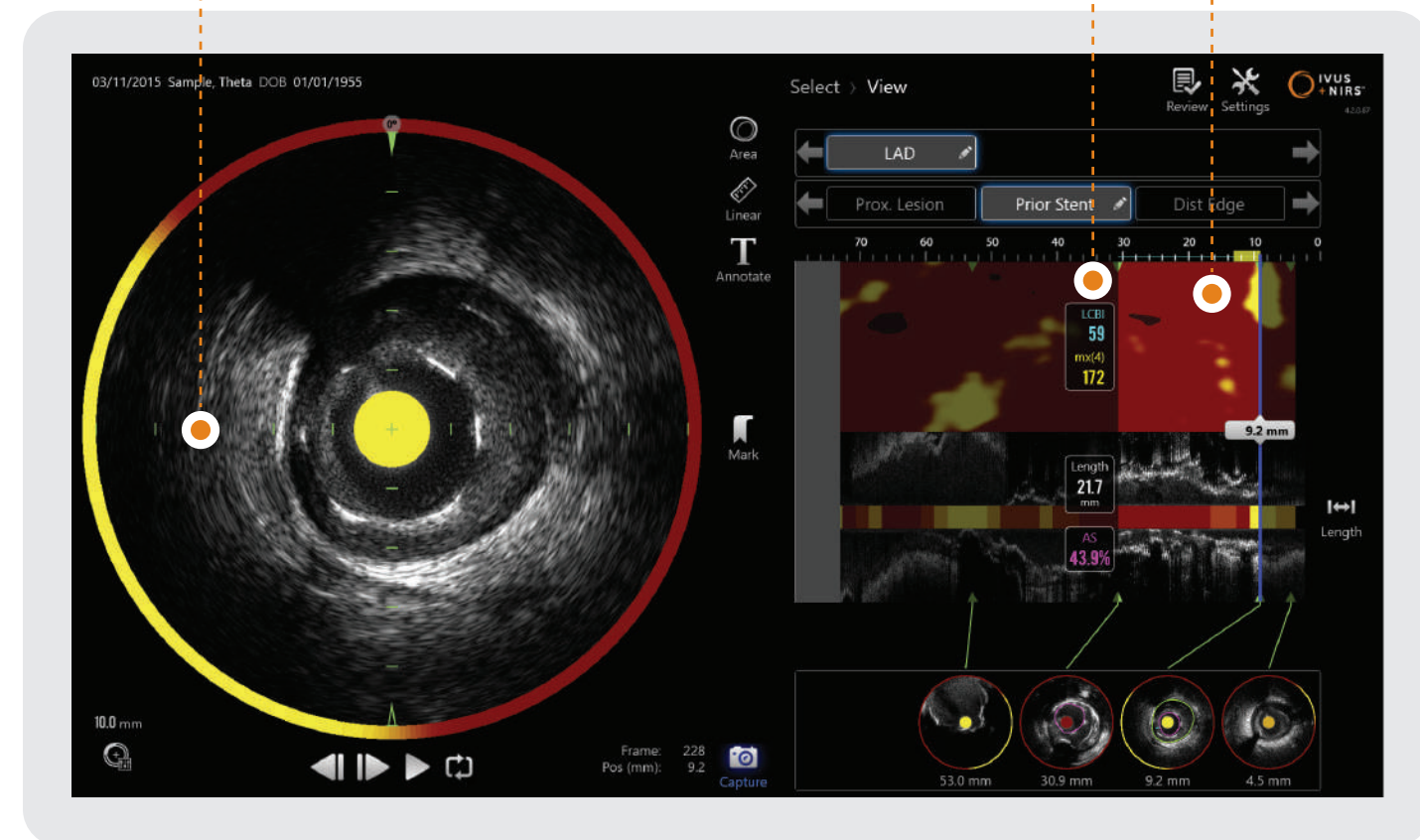
The system automatically quantifies the total lipid core in regions of interest as the lipid core burden index (LCBI). LCBI numbers can be directly compared with prior validation studies for greater understanding of the underlying tissue pathology and to make associations with the published literature for outcomes related to LCBI.

Anything else and you are leaving valuable data on the table.

Simultaneous co-registered acquisition of IVUS and NIRS for quick, easy and comprehensive analysis

Lipid Core Burden Index (LCBI) for quantification of lipid core in the scanned region

Proprietary Chemogram for easy-to-interpret detection of the presence of lipid core



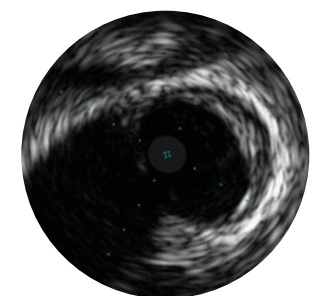
See a Crisper Image of Vessel Structure

with the Dualpro IVUS

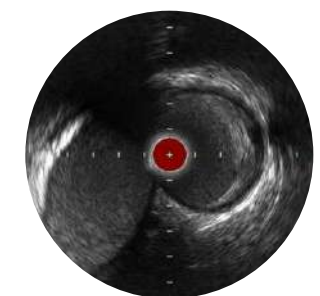
Dualpro is the only intravascular imaging catheter on the market today utilizing extended bandwidth IVUS technology. By emitting and carefully processing a broad band of frequencies, the Dualpro IVUS brings you best-in-class image resolution without compromising depth of field.

With a crisper IVUS image of the vessel structure you can more easily identify the degree of stenosis, visualize and quantify plaque burden, determine the landing zone for a stent and assure proper stent deployment.

Unique Extended Bandwidth IVUS Technology



Competitor IVUS Image
20 MHz



Dualpro IVUS Image
35-65 MHz extended bandwidth



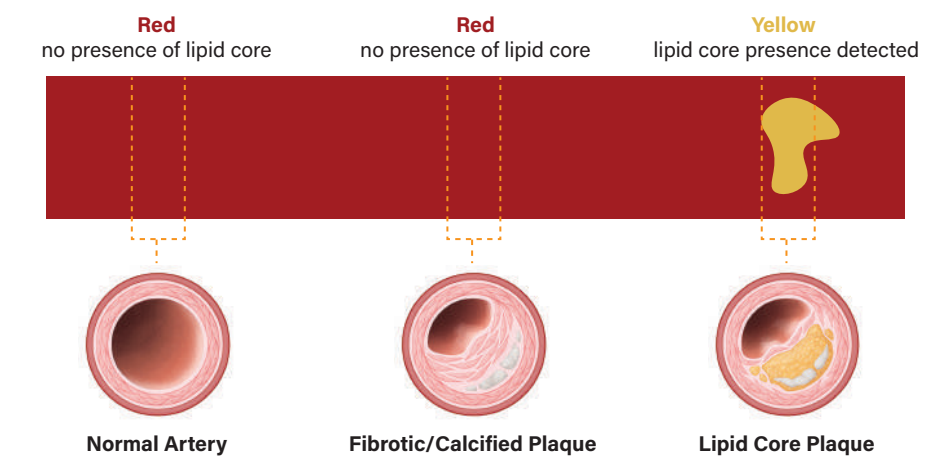
Reveal the Value of Plaque Composition

with the Dualpro NIRS

Dualpro is the only intravascular imaging catheter equipped with Near-Infrared Spectroscopy (NIRS) technology. Now you can easily identify unstable lipid core plaque (LCP) - a well-documented culprit in heart disease associated with 95% of STEMIs and an increased risk of peri-procedural complications.^{1,2}

With the power of NIRS, you can gain insights into a plaque's composition and can readily distinguish between stable plaque and dangerous LCP.

Proprietary Chemogram Displays Lipid Core Plaque



THE EVIDENCE IS CLEAR:

NIRS-identified lipid core plaque has been clinically shown to predict MACE

Identification of Patients and Plaques Vulnerable to Future Coronary Events with Near-infrared Spectroscopy Intravascular Ultrasound Imaging: a Prospective, Cohort Study
Waksman et al
Published online. *The Lancet*. 2019 Sept 27
Visit www.infraredx.com/lrp to learn more

Near-Infrared Spectroscopy Predicts Cardiovascular Outcome in Patients with Coronary Artery Disease
Oemrawsingh RM, Cheng JM, Garcia-Garcia HM, et al
CONCLUSION: CAD patients with an LCBI equal to or above the median of 43.0, as assessed by NIRS in a nonculprit coronary artery, had a four-fold risk of adverse cardiovascular events during one-year follow-up.
J Am Coll Cardiol. 2014 Dec 16;64(23):2510-8.

Large Lipid-Rich Coronary Plaques Detected by Near-Infrared Spectroscopy at Non-Stented Sites in the Target Artery Identify Patients Likely to Experience Future Major Adverse Cardiovascular Events
Madder RD, Husaini M, Davis AT, et al.
CONCLUSION: Detection of large LRP by NIRS at non-stented sites in a target artery was associated with an increased risk of future MACCE.
Eur Heart J Cardiovasc Imaging. 2016 Apr;17(4):393-9.

Near-Infrared Spectroscopy-Derived Lipid Core Burden Index Predicts Adverse Cardiovascular Outcome in Patients with Coronary Artery Disease During Long-Term Follow-Up
Schuurman A-S, Vroegindewey M, Kardys I, et al.
CONCLUSION: NIRS-derived LCBI is associated with adverse cardiac outcome in CAD patients during long-term follow-up independent of clinical risk factors and plaque burden.
Eur Heart J 2017; ehx247, Epub ahead of print.

Long-Term Follow-Up after Near-Infrared Spectroscopy Coronary Imaging: Insights From the Lipid Core Plaque Association with Clinical Events (ORACLE-NIRS) Registry
Danek BA, Karatasakis A, Karacsonyi J, et al.
CONCLUSION: During long-term follow-up of patients who underwent NIRS imaging, high LCBI in a non-PCI target vessel was associated with increased incidence of MACE.
Cardiovasc Revascularization Med Mol Interv 2017;18(3):177-81.