makoto™
INTRAVASCULAR IMAGING SYSTEM

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EUKON
Future Healthcare Now

The evidence is clear

The value of IVUS in improving outcomes

The use of IVUS imaging has been proven to achieve optimal intravascular treatment and durable results in both the coronary and peripheral settings.

Coronary IVUS-guided PCI

Target Vessel Failure at 3-Years[1]

6.6% IVUS — VS — p=0.01 — **10.7%** Angiography

Peripheral IVUS-guided PCI

Primary Patency at 5-Years[2]

89%

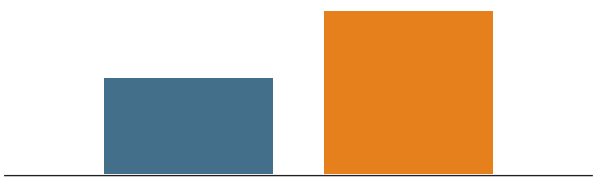
The value of NIRS in detecting risk of MACE

Multiple studies have demonstrated that assessment of the coronary artery with the Makoto IVUS+NIRS Intravascular Imaging System is unmatched in its ability to identify the risk of MACE. The results of the landmark LRP study provided clinical evidence that intravascular NIRS imaging can accurately identify both vulnerable patients and vulnerable plaques that are at significantly higher risk for subsequent NC-MACE during a 24-month period.

Vulnerable **Patient Risk** Identified by NIRS

89%

Increased risk of NC-MACE[3]

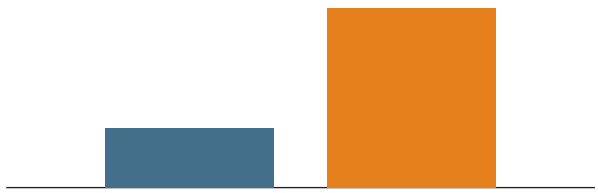


for patients with overall $maxLCBI_{4mm}$>400

Vulnerable **Plaque Risk** Identified by NIRS

322%

Increased risk of NC-MACE[3]



for each 30mm Ware segment with $maxLCBI_{4mm}$>400

References:

1. Kumakura H, et al. 15-Year Patency and Life Expectancy After Primary Stenting Guided by Intravascular Ultrasound for Iliac Artery Lesions in Peripheral Arterial Disease. JACC Cardiovasc Interv. 2015 Dec 21;8(14):1893-901. doi: 10.1016/j.jcin.2015.08.020. Epub 2015 Nov 18. PMID: 26604061.
2. Gao XF, et al; ULTIMATE Investigators. 3-Year Outcomes of the ULTIMATE Trial Comparing Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation. JACC Cardiovasc Interv. 2021 Feb 8;14(3):247-257. doi: 10.1016/j.jcin.2020.10.001. Epub 2020 Oct 29. PMID: 33541535.
3. Waksman R, et al; LRP Investigators. Identification of patients and plaques vulnerable to future coronary events with near-infrared spectroscopy intravascular ultrasound imaging: a prospective, cohort study. Lancet. 2019 Nov 2;394(10209):1629-1637. doi: 10.1016/S0140-6736(19)31794-5. Epub 2019 Sep 27. Erratum in: Lancet. 2019 Nov 2;394(10209):1618. PMID: 31570255.

See more with
Extended Bandwidth HD-IVUS

Best-in-class vessel structure image resolution without compromising depth of field

Unlike other HD-IVUS technologies that sacrifice clarity for depth, Infraredx Clarispro HD-IVUS and Dualpro IVUS+NIRS are the only intravascular imaging catheters on the market utilizing Extended Bandwidth HD-IVUS technology. By emitting and carefully processing a broad band of frequencies, the Infraredx Clarispro HD-IVUS and Dualpro IVUS+NIRS imaging catheters bring 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.

Know more with
Unique NIR Spectroscopy

The only intravascular imaging modality proven to identify LCP and risk of MACE

Dualpro IVUS+NIRS is the only dual-modality intravascular imaging catheter equipped with Near-Infrared Spectroscopy (NIRS) delivering intel on plaque composition and giving you the power to make highly informed decisions right in the Cath lab. 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 Dualpro IVUS+NIRS, you can identify patients and plaque at a higher risk of MACE and readily distinguish between stable plaque and vulnerable LCP.

Heal more with
Makoto Intravascular Imaging

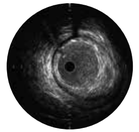
Delivering unprecedented treatment insights through the power of plaque composition analysis and high-resolution structural views

The Makoto Intravascular Imaging System is 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. The system automatically quantifies the total lipid core in regions of interest and calculates a plaque's Lipid Core Burden Index (LCBI). Multiple studies have confirmed that the LCBI number can be used to evaluate patient and plaque risk of MACE, gauge the effectiveness of current therapies, and adjust future treatment plans.

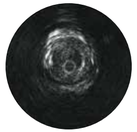
The Makoto Intravascular Imaging System brings you valuable insights that no other system can.

Get Crisp Vessel Structure Visualization with Infraredx Clarispro HD-IVUS and Dualpro IVUS+NIRS

PERIPHERAL

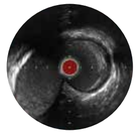


Infraredx Clarispro HD-IVUS
35-65 MHz extended bandwidth

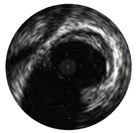


Competitor IVUS Image
20 MHz

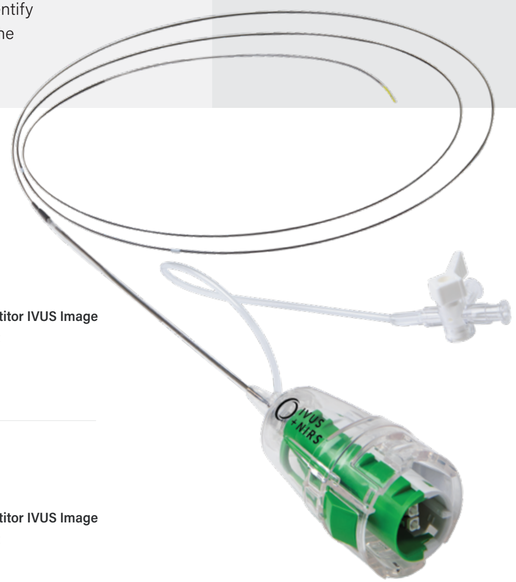
CORONARY



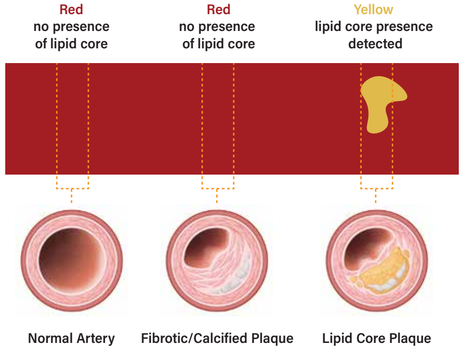
Dualpro IVUS+NIRS
35-65 MHz extended bandwidth



Competitor IVUS Image
20 MHz



Proprietary Chemogram Displays Lipid Core Plaque



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 plaque

Expand your imaging capabilities

The Makoto Intravascular Imaging System is compatible with our two state-of-the-art catheters:

Dualpro IVUS+NIRS – indicated for coronary procedures

Infraredx Clarispro HD-IVUS – indicated for coronary and peripheral procedures

Catalog Number	Description	Coronary Use	Peripheral Use
TVC-MC10	Makoto™ Intravascular Imaging System	✓	✓
TVC-C195-42	Dualpro™ IVUS+NIRS Catheter	✓	
TVC-E195-42	Infraredx Clarispro™ HD-IVUS Catheter	✓	✓

References:

1 Madder RD, et al. Detection by near-infrared spectroscopy of large lipid core plaques at culprit sites in patients with acute ST-segment elevation myocardial infarction. JACC Cardiovasc Interv. 2013 Aug;6(8):838-46. doi: 10.1016/j.jcin.2013.04.012. Epub 2013 Jul 17. PMID: 23871513.

2 Goldstein JA, et al. Detection of lipid-core plaques by intracoronary near-infrared spectroscopy identifies high risk of periprocedural myocardial infarction. Circ Cardiovasc Interv. 2011 Oct 1;4(5):429-37. doi: 10.1161/CIRCINTERVENTIONS.111.963264. Epub 2011 Oct 4. PMID: 21972399.

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