

Makoto™ Intravascular Imaging System

A dual-modality intravascular imaging device with the ability to assess vessel structure and plaque composition via IVUS imaging and near infrared spectroscopy (NIRS) **Lipid Core Plaque detection technologies.**

Mechanism of operation	NIRS, Near-Infrared Spectroscopy & IVUS, 35-65 MHz Rotational
Specifications	IVUS Frequency Range: 35-65 MHz, 60% Bandwidth IVUS Axial Resolution: 20 µm Pullback Speed: 0.5, 1.0, 2.0 mm/s, 1800 rpm Live IVUS Speeds: 0.0, 2.0, 10.0 mm/s, Bi-directional, 960 rpm
Product Approval and Indication	FDA, CE, KFDA, PMDA FDA Indications for Use: Detection of Lipid-Core Plaques of Interest (LCP) Assessment of Coronary Artery Lipid Core Burden Ultrasound Examination of Coronary Intravascular Pathology



Dualpro™ IVUS+NIRS Catheter

Intravascular Imaging catheter for detection of lipid core plaques (LCP) and assessment of vessel structure and plaque composition.



IVUS

for plaque structure
visualization

NIRS

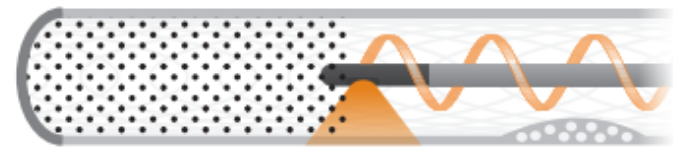
for plaque composition
analysis

Mechanism of operation	NIRS, Near-Infrared Spectroscopy & IVUS, 35-65 MHz Rotational
Specifications	160 cm Working Length 150 mm Imaging Range 16 mm Tip to IVUS Image Distance 6F Interventional Guide Compatible 0.014" Guide Wire Compatible 3.2F Crossing Profile
Features	Tracking Reinforcement Sleeve (TRS) Dual Layer Hydrophilic Coating Extended Bandwidth IVUS transducer (XB)

Creating a Chemogram

The Makoto™ Imaging System uses a proprietary **Chemogram** for easy detection of the presence of lipid core plaque.

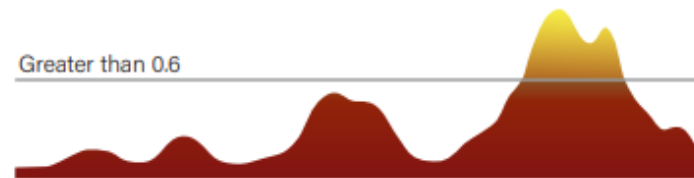
① **200,000 NIRS Spectra**
Approximately **1,300 NIRS spectra per millimeter** are acquired as the catheter scans the vessel.¹



② **Analysis of Acquired Data**
The acquired NIRS signals are analyzed and **each spectrum is assigned a probability score, from 0 to 1**, based on the likelihood of the presence of LCP.



③ **Color Based on Probability**
All probability scores, low to high, are mapped on a **continuous color scale from red to yellow**. Scores above 0.6 appear orange to yellow in the chemogram and contribute to the Lipid Core Burden Index (LCBI).

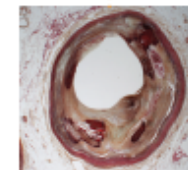


④ **Chemogram Display**
The chemogram is automatically generated within seconds, creating a **map of the LCP location** within the vessel wall. This color-coded map can be interpreted quickly, permitting informed treatment decisions.

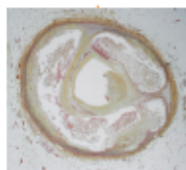


Data you can trust:

Nearly 2,500 artery cross-sections were histologically and spectrally analyzed to validate lipid core plaque detection by NIRS. The red and yellow colors on the chemogram help differentiate normal or fibrotic plaque that is presumed to be stable (left) from those that contain lipid core plaques (right).²



Fibrotic/Calcified Plaque



Lipid Core Plaque

References:

1 in a 150mm scan at 0.5mm/s

2 Detection of lipid core coronary plaques in autopsy specimens with a novel catheter-based near-infrared spectroscopy system, Gardner et al, *JACC Cardiovasc Imaging*, 2008