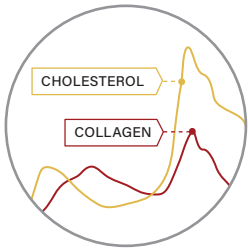


Unique NIRS Imaging Technology

For the Detection of Lipid Core Plaque (LCP)

The **Makoto™ Intravascular Imaging System**, with accompanying **Dualpro™ IVUS+NIRS Catheter**, is the only imaging system on the market today that utilizes not just intravascular ultrasound (IVUS) but also Near-Infrared Spectroscopy (NIRS) to help clinicians visualize vessel structure and gain valuable insights into plaque composition.

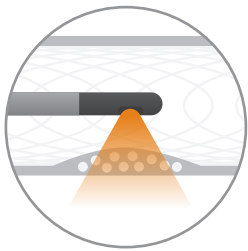
Our revolutionary technology is the **only FDA-cleared imaging technology indicated for the detection of Lipid Core Plaque (LCP)**.



Why NIR Spectroscopy?

To identify lipids such as cholesterol

Organic molecules have unique spectroscopic signatures that can be used to detect their presence in a mixture of unknown composition. NIRS allows us to **distinguish molecules, such as collagen and cholesterol**, within the vessel wall and thus identify the presence of LCP.



Where does the Light Propagate?

Through blood, tissue and interstitial spaces

The microscopic mirrors at the tip of the Dualpro™ catheter are designed to deliver near-infrared light to the vessel wall and collect the diffusely reflected light. The light propagates **through blood and tissue by scattering and absorption**, even in the presence of calcium or stents, to interrogate the plaque for its chemical fingerprint.



How are the Spectra Interpreted?

With the aid of advanced algorithms

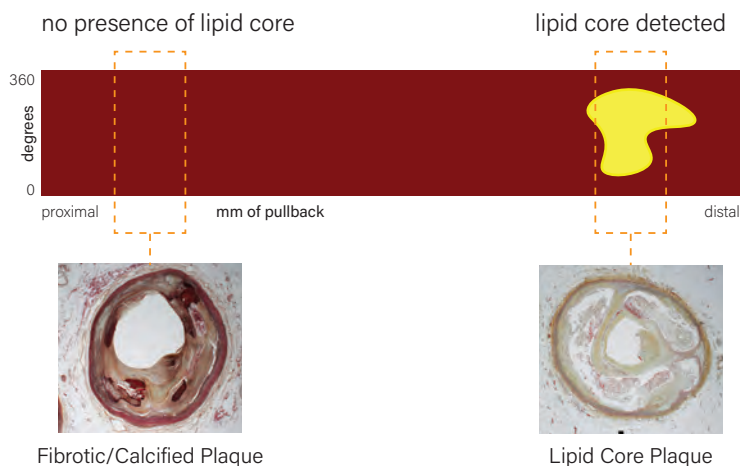
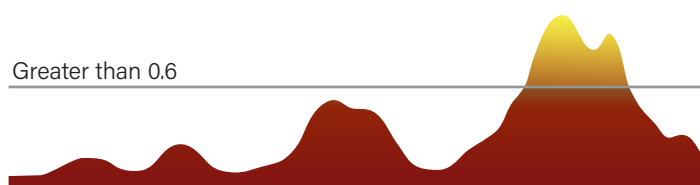
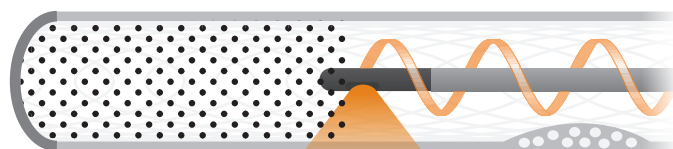
Advanced algorithms analyze the returned light and calculate the probability of the presence of a lipid core plaque. Our algorithms have been **validated in a large prospective histology study** providing you with information you can trust.

How We Create a Chemogram

A mountain of NIRS data simplified into a single image you can trust

The Makoto™ Intravascular Imaging System was designed with the primary goal of helping you make quick and informed decisions at the bedside. The easy-to-interpret chemogram provides insight into the complex plaques that complicate your interventional strategy, treatment procedures, and patient's recovery.

- 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



References: 1 In a 150mm scan at 0.5 mm/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.

infraredx™

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