



makotoTM
INTRAVASCULAR IMAGING SYSTEM

SEE MORE – KNOW MORE



Is there a tool that can help you to identify high-risk plaques?

Introducing

Nipro's Intravascular Imaging System, **Makoto™**, together with the **Dualpro™** IVUS+NIRS catheter, offering you the tool to better diagnose your cardiovascular patients.

At the forefront of innovative technology

Intracoronary imaging can support healthcare practitioners in critical decision-making situations, both pre- and post-procedure. Working together with healthcare experts, Nipro develops the best possible tools and solutions to care for patients.



Enabling physicians to SEE MORE and KNOW MORE

Nipro is committed to providing state-of-the-art solutions to cardiologists, enabling them to diagnose and treat patients with coronary artery disease.

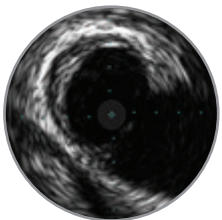
To do this, we focus on developing, manufacturing, and marketing cutting-edge technology that allows physicians to gain unparalleled insights so that they can SEE MORE and KNOW MORE.

FDA-cleared

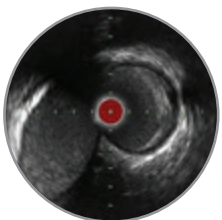
What's more, Dualpro™ IVUS+NIRS catheter and Makoto™ Intravascular Imaging System is an FDA cleared dual-modality catheter and imaging system for the detection of high-risk plaques.

SEE MORE

Delivering crisper and sharper insights



Competitor IVUS Image
20 MHz



Dualpro IVUS Image
35-65 MHz
extended bandwidth

Dualpro™ IVUS+NIRS

Imaging catheter - Best-in-class vessel structure image resolution

- Brings you high resolution without compromising depth of field.
- Allows you to identify the degree of stenosis, as well as visualize and quantify plaque burden.
- IVUS Frequency Range: 35-65 MHz, 60% Bandwidth.



Bringing valuable insights that no other system can

- Identifies unstable lipid core plaque (LCP) by using Near-Infrared Spectroscopy (NIRS).
- An intravascular imaging device cleared by the FDA for the identification of patients and plaques at increased risk of MACE.
- Distinguishes between stable plaque and vulnerable LCP.
- Generates plaque composition analysis and high-resolution structural views.
- System automatically quantifies the total lipid core in regions of interest and calculates a plaque's Lipid Core Burden Index (LCBI).
- LCBI number can be used to evaluate patient and plaque risk of MACE, gauge the effectiveness of therapies, and adjust the future treatment plan.



Proprietary Chemogram

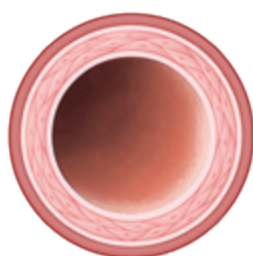
for easy-to-interpret detection of the presence of lipid core plaque

Lipid Core Burden Index

for quantification of lipid core in the scanned region

Simultaneous co-registered acquisition of IVUS and NIRS

for quick, easy, and comprehensive analysis



Normal Artery

no presence of lipid core



Fibrotic/Calcified Plaque

no presence of lipid core



Lipid Core Plaque

lipid core presence detected

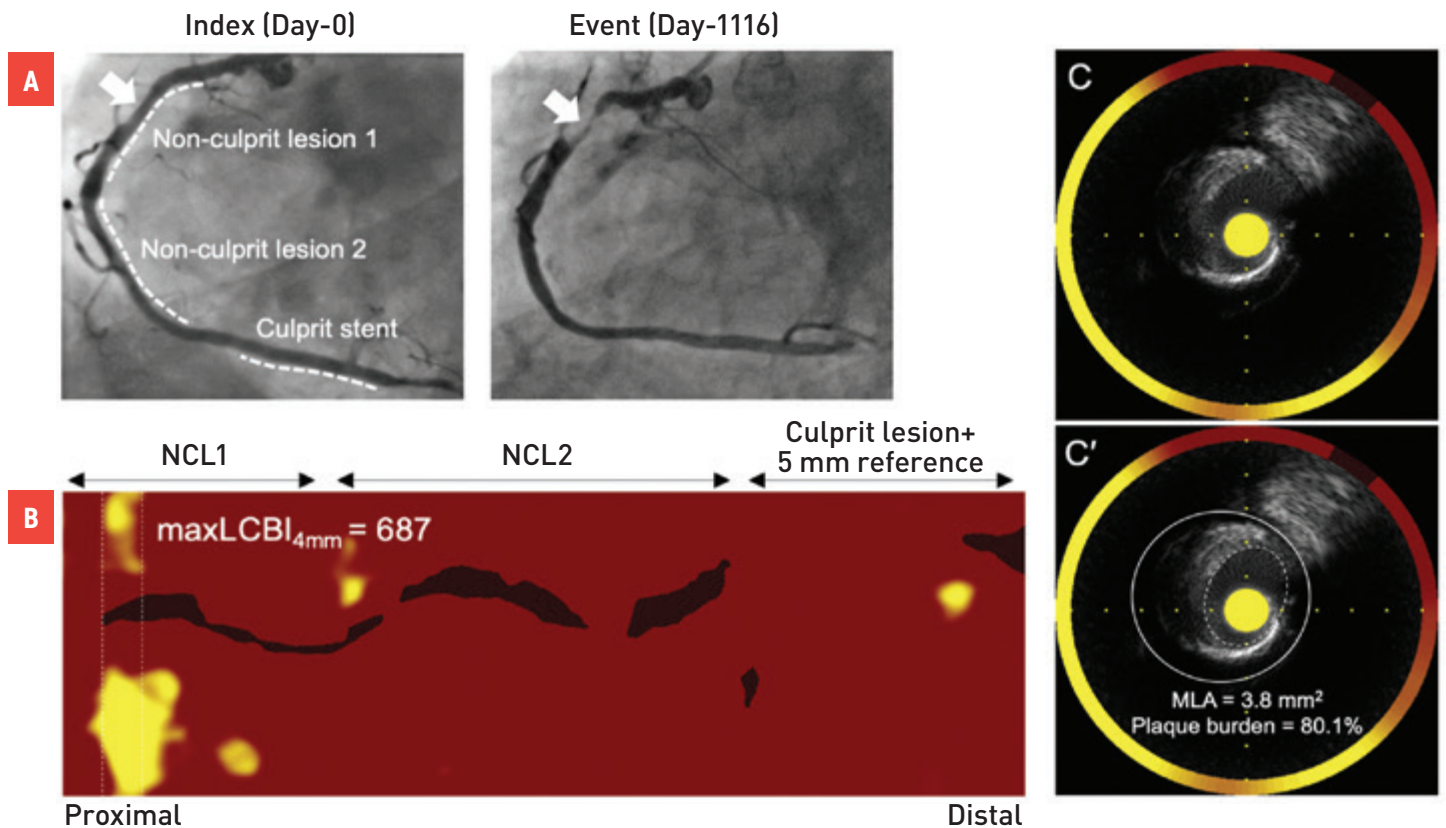
Ordering information

Product name	EU ordering code	Global product code	Asia ordering code
Makoto™ NIRS/IVUS Console	MC10-MKTCNSL-UU	TVC-MC10	IRX-TVC-MC10-CE
Dualpro™ NIRS/IVUS catheter 165cm	CATH-NI16-EU	TVC-C195-42	IRX-TVC-C195-42-ECE

Representative case example

The images below show an adverse event attributed to an untreated non-culprit-lesion (NCL), as follows:

- Angio at index day, NCL 1 without any finding and 3 years later, presenting MACE.
- NIRS Chemogram shows a high maxLCBI_{4mm} in the NCL1 area.
- The IVUS image and the related plaque burden calculation.



Product Approval and Indication

FDA, MDR, KFDA, PMDA

FDA Indications for Use:

- Detection of Lipid Core Plaques of Interest (LCP)
- Assessment of Coronary Artery Lipid Core Burden
- Identification of patients and plaques at increased risk of MACE

Ultrasound Examination of Coronary Intravascular Pathology

Images courtesy of Prof.D.Erlinge, Sweden

7

Company-sponsored clinical trials & registries addressing safety, accuracy, and prediction of outcomes

> 85

Studies at sites globally

> 6000

Studies on patients

> 15

Investigator-initiated studies

> 185

Peer-reviewed publications, including JAMA, Lancet, JACC, JACC Imaging, JACC Interventions, Circulation

Nipro Corporation Japan is a leading global healthcare company established in 1954. With over 35,000 employees worldwide, Nipro serves the Medical Device, Pharmaceutical, and Pharmaceutical Packaging industries.

Nipro is dedicated to providing interventional cardiologists and vascular surgeons with tools to perform delicate lifesaving and life-enhancing procedures to treat patients with vascular and coronary diseases.

We develop, manufacture, and market cutting-edge technology as well as the newest techniques, innovative solutions, and complex advancements to reshape the vascular space globally. Working hand in hand with physicians, we are focused on providing the best possible care for patients.

Nipro is dedicated to advancing the diagnosis and management of coronary artery disease worldwide as part of our promise to help people.

LIVE LONGER. LIVE BETTER.

