PRODUCT DATA SHEET

MAKOTO™ AND DUALPRO™ IVUS+NIRS CATHETER

A DUAL-MODALITY INTRAVASCULAR IMAGING DEVICE

NIPRO

MAKOTO™ AND DUALPRO™ IVUS+NIRS CATHETER

A dual-modality intravascular imaging device with the ability to assess vessel structure and plaque composition via IVUS imaging and Near-Infrared Spectroscopy (NIRS), and Lipid Core Plaque detection technologies.

- Imaging system that uses ultrasound and near-infrared light to characterize plaque.

- The only intravascular imaging device cleared by the FDA for the identification of patients and plaques at increased risk of MACE.

- The only dual modality intravascular imaging device on the market capable of detecting both plaque structure and composition using IVUS and NIRS

- 35-65 MHz extended bandwidth image gives a crisp HD-IVUS image quality to bring HD resolution and depth of penetration.

- Used before, during, and after PCI.

PRODUCT COMPLIANCE

- Complies with the following norms, directives, and regulations:
  - FDA
  - KFDA
  - MDR
  - PMDA

CE 2797
Dualpro™ Sterile
Dualpro™ Class III
Makoto™ System IIb

MANUFACTURING DETAILS

Legal manufacturer: Infraredx, A Nipro Company

Country of origin: USA

STERILIZATION AND SHELF LIFE

Sterilization	Single-use only	Shelf life
Ethylene Oxide	②	36 months
STERILE EO		

PRODUCT DETAILS

Dualpro™ IVUS+ NIRS Catheter, 35-65 MHz Rotational

Specifications

- 160 cm Working Length
- 150 mm Imaging Range
- 16 mm Tip to IVUS Image Distance
- 16 mm IVUS Image Diameter
- 6F Interventional Guide Compatible
- 0.014˝ Guide Wire Compatible
- 3.2F Crossing Profile

PRODUCT RANGE OVERVIEW

Reference code	Product name
CATH-NI16-EU	Dualpro™ IVUS+NIRS catheter 165cm

PRODUCT DETAILS

Makoto™ Intravascular Imaging System

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 RANGE OVERVIEW

Reference code	Product name
MC10-MKTCNSL-UU	Makoto™ Intravascular Imaging System

Languages

16 languages on the IFU

English (EN), Czech Republic (CZ), German (DE), French (FR), Russian(RU), Dutch (NL), Spanish (ES), Italian (IT), Korean(KO), Japanese(JP), Danish (DK), Latvian (LV), Norwegian (NO), Portuguese (PT), Slovak (SK), Swedish (SV)