



## MAKOTO™ IMAGING SYSTEM AND DUALPRO™ IVUS+NIRS CATHETER

A DUAL-MODALITY INTRAVASCULAR IMAGING DEVICE



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

- Imaging system that uses ultrasound and near-infrared light to characterize plaque.
- An 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 regulations:
  - FDA
  - MDR
  - KFDA
  - PMDA

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

## MANUFACTURING DETAILS

**Legal manufacturer:** Infraredx, A Nipro Company

**Country of origin:** USA

## STERILIZATION AND SHELF LIFE

### Sterilization

Ethylene Oxide



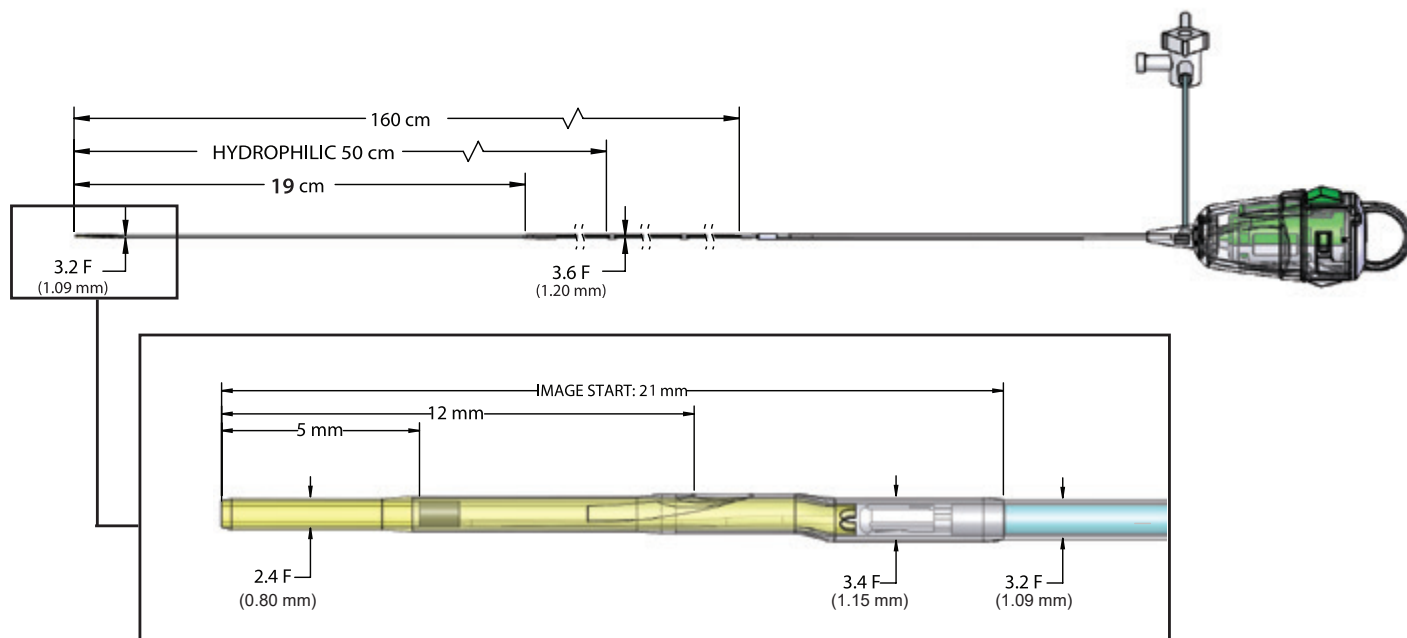
### Single-use only



### Shelf life

36 months





## PRODUCT DETAILS

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

#### Specifications

- IVUS Frequency Range: 35-65 MHz, 60% Bandwidth
- 160 cm Working Length
- 150 mm Imaging Range
- 16 mm Tip to IVUS Image Distance
- 16 mm IVUS Image Diameter
- 6 F Interventional Guide Compatible
- 0.014" Guide Wire Compatible
- 3.2 F Crossing Profile
- 3.4 F Tracking Reinforcement Sleeve (TRS) Outer Diameter

## PRODUCT RANGE OVERVIEW

**Product name :** DUALPRO™ IVUS-NIRS IMAGING CATHETER, 3.2 F 35-65 MHZ, ETO,CE

**Global product code**

TVC-C195-42

**EU ordering code**

CATH-NI16-EU

**Asia ordering code**

IRX-TVC-C195-42-ECE





## PRODUCT DETAILS

### Makoto™ Intravascular Imaging System

#### Specifications

- IVUS Axial Resolution: 20  $\mu\text{m}^*$
- **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

**Product name :** MAKOTO™ NIRS/IVUS CONSOLE

Global product code
TVC-MC10

EU ordering code	Asia ordering code
MC10-MKTCNSL-UU	IRX-TVC-MC10-CE

### Languages

14 languages on the IFU

English (EN), Czech (CS), German (DE), French (FR), Dutch (NL), Spanish (ES), Italian (IT), Korean (KO), Japanese (JP), Danish (DA), Latvian (LV), Norwegian (NO), Slovak (SK), Swedish (SV)

\* Theoretical resolution based on transducer design, data on file

