



## GENTUITY™ HF-OCT & VIS-RX™

IMAGING CONSOLE & MICRO-IMAGING CATHETER



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## IMAGING CONSOLE & MICRO-IMAGING CATHETER

The Genuity HF-OCT Imaging System with Vis-Rx Micro-Imaging Catheter is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures.

The Vis-Rx Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter.

The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

Unlike other intravascular imaging systems, the Genuity HF-OCT Console and Vis-Rx Micro-Imaging Catheter are indicated for the widest range of coronary arteries:

- Able to image a 100 mm vessel segment in 1 second - 33% longer than competitive systems
- 1.8F catheter can cross and clear tight stenoses; 55% smaller crossing profile than competitive catheters
- Indicated for coronary arteries 1.3 to 6.0 mm in diameter, including the left main; 3x the vessel size range of competitive systems
- Ideal for pre-intervention imaging without the need to pre-dilate
- Ideal for radial access with 1.8F catheter and 165 cm working length
- Easy to set up with catheter attachment outside the sterile field – no need for sterile bagging

## PRODUCT COMPLIANCE

- Complies with the following norms, directives, and regulations:

— CE

— MDR

— FDA

CE 2797

## MANUFACTURING DETAILS

**Legal manufacturer:** Genuity LLC

**Country of origin:** USA

Vis-Rx™ MDR 767231

Genuity™ HF-OCT MDR 767198

Vis-Rx™ Class III

Genuity™ HF-OCT Class IIb

## STERILIZATION AND SHELF LIFE : Vis-Rx™

### Sterilization

Ethylene Oxide

STERILE EO

### Single-use only





## PRODUCT DETAILS

### Vis-Rx™ Micro-Imaging catheter

#### Specifications

- 1.8 F (or 0.6 mm) rapid exchange catheter
- 165 cm working length
- 17 mm minirail tip
- Hydrophilic coating on distal 30 cm
- Three radiopaque markers
  - Tip marker 4 mm proximal to tip
  - Lens marker 5 mm distal to lens (2 mm in length)
  - Pullback marker 50 mm proximal to lens
- Indicated for coronary arteries 1.3 to 6.0 mm in diameter

## PRODUCT RANGE OVERVIEW

Reference code	Product name
CATH-OCT16-BU	Vis-Rx Micro-Imaging catheter

## PRODUCT DETAILS

### Genuity™ HF-OCT Imaging Console

#### Specifications

- Imaging speed : 250 frames per second
- Pullback length 50 or 100 mm
- Pullback speed 1 or 2 sec
- Mobile console, moves easily between multiple cath lab rooms
- Dual monitor display side-by-side angio and HF-OCT for synchronized review
- Top monitor designed for the physician, with full swivel for easy rotation
- Bottom monitor equipped with touchscreen functionality
- Genuity PIM easily mounts to the bedrail, outside the sterile field

## PRODUCT RANGE OVERVIEW

Reference code	Product name
G2-GENTCNSL-UU	Genuity™ HF-OCT Imaging Console

#### Languages

14 languages on the IFU

English (EN), Czech (CS), German (DE), French (FR), Dutch (NL), Spanish (ES), Italian (IT), Danish (DA), Latvian (LV), Norwegian (NO), Slovenian (SL), Swedish (SV), Polish (PL)

#### Label details

	HF-OCT Individual unit	Vis-Rx Individual unit
Product name	✓	✓
Product size	✓	✓
Quantity (pieces)	—	✓
REF	✓	✓
LOT	—	✓
Hourglass icon	—	✓
STERILE EO	—	✓
CE 2797	✓	✓
⊗	—	✓
⊗	—	✓
⊗	—	✓
Factory icon	✓	✓

	HF-OCT Individual unit	Vis-Rx Individual unit
EC REP	—	✓
Barcode	✓	✓
Starburst icon	—	✓
Wine glass icon	—	—
Open book icon	—	✓
Warning triangle icon	—	✓

