PRODUCT DATA SHEET

VASCULAR





GENTUITY™ HF-OCT & VIS-RX™

IMAGING CONSOLE & MICRO-IMAGING CATHETER

NIPRO

GENTUITY™ HF-OCT & VIS-RX™

IMAGING CONSOLE & MICRO-IMAGING CATHETER

The Gentuity 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 Gentuity 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
Vis-Rx™ MDR 767231
Gentuity™ HF-OCT MDR 767198
Vis-Rx™ Class III
Gentuity™ HF-OCT Class IIb

MANUFACTURING DETAILS

Legal manufacturer: Gentuity LLC

Country of origin: USA

STERILIZATION AND SHELF LIFE : Vis-Rx™

Sterilization	Single-use only	Shelf Life
E-beam STERILE R		12 months



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

Product name	EU ordering code	Global product code
Vis-Rx Micro-Imaging catheter	CATH-OCT16-BU	G30-03 (EU) / G30-01(US)

PRODUCT DETAILS

Gentuity™ 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
- Gentuity PIM easily mounts to the bedrail, outside the sterile field

PRODUCT RANGE OVERVIEW

Product name	EU ordering code	Global product code
Gentuity™ HF-OCT Imaging Console	G2-GENTCNSL-UU	G10-01

Languages

13 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	—	✓
	—	✓
STERILE R	—	✓
CE 2797	✓	✓
	—	✓
	—	✓
	—	✓
	✓	✓

	HF-OCT Individual unit	Vis-Rx Individual unit
EC REP	—	✓
	✓	✓
	—	✓
	—	—
	—	✓
	—	✓

MM-3980 - Datasheet - HF-OCT_Vis-Rx - EN - 13 Nov 2023