Summary of Safety and Clinical Performance (SSCP)

Vis-Rx® Micro-Imaging Catheter

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List of Abbreviations

CE	Conformité Européene
CIL	Clear Image Length
EU	European Union
EUDAMED	European Database Medical Device
HF-OCT	High Frequency Optical Coherence Tomography
IFU	Instructions for Use
MRI	Magnetic Resonance Imaging
OCT	Optical Coherence Tomography
PMCF	Post-market Clinical Follow-Up
SSCP	Summary of Safety and Clinical Performance
IVUS	Intravascular Ultrasound

Introduction

This Summary of Safety and Clinical Performance (SSCP) is related to the Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter. The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of this medical device. The Gentuity HF-OCT Imaging System is regulated as a Class IIb with Vis-Rx Micro-Imaging Catheter being regulated as a Class III per Rule 6.

This SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of this medical device. It is also not intended to provide direct diagnosis or or monitoring of vital physiological processess as well as not intended to be used for therapeutic suggestions to intended users or patients. The device is intended for imaging of the coronary artery.

The information provided in this SSCP is intended for the users of this device as well as healthcare professionals. A supplemental SSCP with information for patients is not provided since the medical device is not intended to be used directly by patients.

The English version of this SSCP document has been validated by BSI who is the Notified Body (#2797) for this medical device.

1. Device Identification

Device Trade Name/Product	Gentuity HF-OCT Imaging System with Vis-Rx Micro-Imaging Catheter ("Gentuity HF-OCT Imaging System")
Manufacturer's Name and Address	Gentuity, LLC 142 North Road, Suite G Sudbury, MA 01776 United States
Manufacturer's Single Registration Number (SRN)	US-MF-000022757
Basic UDI-DI	0859910007G30SN (Vis-Rx Micro-Imaging Catheter) 0859910007G105G (Gentuity HF-OCT Imaging System)
Medical Device Nomenclature	EMDN Code: C019004 Category Description: Cardiovascular Monitoring Systems
Device Classification	Class III (Vis-Rx Micro-Imaging Catheter) Class IIb (Gentuity HF-OCT Imaging System)
Year When First Certificate (CE) Was Issued	2022
Authorized Representative and SRN	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands SRN: NL-AR-000000116
Notified Body Name & Single Identification Number	BSI Group The Netherlands B.V. CE 2797

2. Intended Purpose

2.1 Intended/Indications for Use

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.

2.2 Intended Patient Population

The intended patient population for the Gentuity HF-OCT Imaging System includes patients who are being evaluated in a catheterization laboratory for suspected coronary artery disease and who are suitable candidates for transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

2.3 Intended User(s)

The device is intended to be used by physicians and technicians trained in the performance of catheter based intracoronary interventional procedures. These physicians are interventional cardiologists. The interventional cardiologist will frequently be assisted by an interventional cardiology fellow, catheterization laboratory technician, or nurse.

2.4 Contraindications & Limitations

Listed below are the contraindications related to the use of the device. There are no limitations to its use.

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Coronary artery spasm
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA

3. Device Description

3.1 Description of the Device

The Vis-Rx Micro-Imaging Catheter, as shown in Image 1, is a 1.8F sterile, single-use catheter. The Vis-Rx Micro-Imaging Catheter is sterilized by electron beam radiation.

Image 1: Vis-Rx Micro-Imaging Catheter

The Vis-Rx Micro-Imaging Catheter is sold pre-packaged with a 3 mL sterile syringe. A sterile 3 ml purge syringe is provided with the Vis-Rx Micro-Imaging Catheter and is used to prepare the catheter by flushing the lumen between the external and inner sheaths with saline.

The Vis-Rx Micro-Imaging Catheter can only be used with the Gentuity HF-OCT Imaging System (Image 2), which is mobile system and is equipped with a large display monitor, touch screen display monitor, keyboard, mouse, host computer, software, hardware, and firmware. The HF-OCT System is a Class IIb device.

Image 2: Gentuity HF-OCT Imaging System

The device uses optical coherence tomography (OCT) which is an imaging modality that is comparable to ultrasound imaging but uses light instead of sound. Coronary OCT systems uses an optical fiber and lens that delivers near-infrared light to the tissue and where the light reflects from the tissue to create the artery images. The tissue penetration of the light is in the range of 1 to 3 mm depending on the type of tissue and disease.

Table 1 provides a list of the Vis-Rx Micro-Imaging Catheter materials that come into contact with the patient, either directly through contact with the blood or indirectly in that it contacts a solution that then contacts the blood.

Table 1: Vis-Rx Micro-Imaging Catheter Materials in Direct and Indirect Contact with Blood

Name of Component	Patient Contact
Minirail	Direct
Pullback Marker	Indirect
Catheter Sheath	Catheter Coating Direct (distal 30 cm)
	Catheter Sheath Direct (OD of sheath) Indirect (ID of sheath)
90 cm Insertion Depth Marker	Direct
100 cm Insertion Depth Marker	Direct
Side Arm Luer and Tubing	Indirect
Purge Handle	Indirect

3.2 Previous Device Generations

This is the first and only available variant of the device.

3.3 Accessories and Device Combinations

The Gentuity HF-OCT Imaging Catheter is kitted with a CE Marked 3 ml syringe in a procedure pack.

Other accessories or device combinations that are required to use the Gentuity HF-OCT Imaging System per its intended use are a guide catheter with a minimum ID of 0.068" (1.73mm), a guidewire with a maximum OD of 0.014" (0.36mm), a sheath introducer matched to the guide catheter and a hemostatic y-adapter/connector. The procedure also requires use of heparinized saline for hydrophilic catheter preparation and catheter purging, power injector pump for coronary angiography or coronary control syringe (minimum of 10 ml), and contrast media indicated for coronary use, for flush. The Gentuity device may also be connected to an angiography system.

The Gentuity console does not require any additional accessories, but provides a video input port for connection to the angiography system and a video output port for connection to an external monitor. Additionally, the console has a DICOM port which is enabled via a standard cable.

4. Risks and Warnings

4.1 Residual risks and Undesirable Effects

The risks involved in intravascular cardiology imaging include those associated with all catheterization procedures. The following complications (listed alphabetically) may occur as a consequence of intravascular imaging and may necessitate additional medical treatment including surgical intervention. Table 2 presents these risks along with the estimated probability of occurrence rates of harm. There have not been any safety incidents reported with use of the Gentuity device based on clinical investigation and customer feedback. Occurrence rates were estimated based on clinical investigation, customer feedback, and the Vis-Rx Micro-Imaging risk analysis. There has not been any safety incidents with the product reported.

Table 2: Intravascular Cardiology Imaging Risks and Estimated

Risk	Probability of Occurrence of Harm
Acute myocardial infarction or unstable angina	< 0.1%
Allergic reaction to contrast media	< 0.1%
Arterial dissection, injury, or perforation	< 0.1%
Cardiac arrhythmias	< 0.1%
Coronary artery spasm	< 0.1%
Death	< 0.001%
Embolism	< 0.1%
Myocardial ischemia	< 0.1%
Renal insufficiency from contrast media use	< 0.1%
Thrombus formation	< 0.1%

4.2 Warnings and Precautions

The following Warnings, Precautions and Complications for the Gentuity HF-OCT Imaging System are listed below. These statements are located throughout the Gentuity High-Frequency OCT

Imaging System User Manual (Item Number 003907) and the Instructions for Use (IFU) for the Vis-Rx Catheter (Item Number 003906).

Warning Statements (User Manual)

- The Gentuity High-Frequency OCT Imaging System is intended for use only by medical personnel trained in its operation and skilled in the clinical procedures to be used.
- Medical personnel who use the Gentuity High-Frequency OCT Imaging System must be aware of the system's limitations. Only trained operators can determine if the use of the Gentuity High-Frequency OCT Imaging System is appropriate.
- Always use controls, make adjustments, and perform procedures as specified in this User Manual.
- Always read and follow the Instructions for Use supplied with the Vis-Rx Micro-Imaging Catheter.
- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Refer to the contrast media’s instructions for general warnings and precautions relating to contrast media.
- The catheter is sterilized by irradiation and is intended for one time use only. Do not reuse, re-sterilize, or reprocess. Reuse or re-processing could result in a degradation of catheter material or patient infection.
- Non-pyrogenic. Do not use the catheter if the package is opened or damaged.
- Do not use the catheter after the expiration date, or if there is not a date on the package.
- Make sure to use the contrast media and injectors according to injection specifications given by the manufacturers. Excessive flow rate and pressure may damage the blood vessel or devices used with the catheter. Low flush rate may result in a faint image.
- Selecting the wrong flush media can cause measurement errors which could lead to incorrect treatment. Prior to acquisition, make sure the media identified in the Pullback Settings window matches the media you are using.
- The system weighs up to 70 kg (154 lb). Use caution when moving the system.
- To avoid a potential tripping hazard and possible equipment damage, before beginning a system move, make sure the system is off, the Ethernet cable is disconnected from the console (if applicable), the system’s power cord is disconnected from the wall outlet, and the power cord is secured on the cord wrap on the back of the system.
- To avoid a potential tripping hazard and possible equipment damage, position the PIM cable appropriately before moving the system.
- To eliminate the potential danger of the system tipping over, make sure that the system’s wheels roll freely before beginning the move. Resolve any wheel problems before you move the system. Be sure the system brakes are in the up position (unlocked).
- To eliminate the potential danger of the system tipping over, avoid ramps that are steeper than 10 degrees. Wheelchair ramps usually have an incline of less than 5 degrees.

- To eliminate the potential danger of the system tipping over, use two people if you must move the system up or down ramps with an incline of more than 10 degrees.
- The catheter is intended for one time use only. Do not reuse, re-sterilize, or reprocess.
- Observe sterile technique when connecting the catheter to the PIM, which is outside of the sterile field.
- Observe all advancement and movement of the Vis-Rx Micro-Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- If resistance is encountered during advancement or withdrawal of the Vis-Rx Micro-Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- Always advance and withdraw the imaging catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- The catheter should never be forced into lumens that are narrower than the catheter body.
- When advancing or withdrawing a catheter with a minirail tip through a stented vessel, the catheter may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- To avoid vessel damage or catheter damage, do not push the guide catheter further into the blood vessel when removing the catheter.
- Before injecting flush media, be sure that the hemostasis valve is tightened to reduce the risk of unintended catheter movement or leaking of flush media during injection.
- Excessive flush rate and pressure may damage the blood vessel or devices used with the Vis-Rx Micro-Imaging Catheter. Low flush rate may result in a faint image.
- If the imaging catheter becomes kinked, stop manipulating it to avoid vessel injury or imaging catheter damage.
- To avoid vessel damage, leave the guidewire engaged with the catheter at all times during use.
- To avoid vessel damage, maintain the position of the guidewire when manipulating the imaging catheter in the vessel.
- Do not disconnect the Vis-Rx Micro-Imaging Catheter from the PIM until the procedure is complete to avoid a sterility breach.
- Do not remove system covers. Only personnel qualified by Gentuity should service the system. Accidentally contacting the electrical circuits inside the housing could cause serious injury or death.
- Failure to follow the electrical connection warnings below causes the system and its use to be out of compliance with regulations and places the patient and the operator at risk of injury or death and may damage the equipment.

- Connect the system only to properly grounded (three-hole) hospital-grade AC outlets.
- Do not use extension cords.
- The circuit must accommodate an additional load of up to 600 VA.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The Gentuity High-Frequency OCT Imaging System was not tested for compatibility with HF Surgical Equipment or Magnetic Resonance Imaging Systems and should not be used near this equipment without first testing for proper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Gentuity High-Frequency OCT Imaging System, including cables specified by Gentuity. Otherwise, degradation of the performance of this equipment could result.
- Leave the guidewire engaged with this catheter at all times during use.

Warning Statements (Vis-Rx Catheter IFU)

- Before using the Vis-Rx Micro-Imaging Catheter, review the Gentuity High-Frequency OCT Imaging System User Manual for additional warnings and cautions.
- The Gentuity High-Frequency OCT Imaging System is intended for use only by medical personnel trained in its operation and skilled in the clinical procedures to be used.
- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Observe all advancement and movement of the Vis-Rx Micro-Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- If resistance is encountered during the advancement or withdrawal of the Vis-Rx Micro-Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- The catheter should never be forced into lumens that are narrower than the catheter body.
- When advancing or withdrawing a catheter with a minirail tip through a stented vessel, the catheter may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- The catheter is sterilized by irradiation and is intended for one time use only. Do not reuse, re-sterilize, or reprocess. Reuse or re-processing could result in a degradation of catheter material or patient infection.
- Non-pyrogenic. Do not use if the package is opened or damaged.
- Do not use the catheter after the expiration date, or if there is not a date on the package.

- The catheter is not compatible with magnetic resonance imaging (MRI).
- Observe all advancement and movement of the Vis-Rx Micro-Imaging Catheter under fluoroscopy.
- If the imaging catheter becomes kinked, stop manipulating to avoid vessel injury or imaging catheter damage.
- Leave the guidewire engaged with the catheter at all times during use.
- To avoid blood vessel damage, maintain the position of the guidewire when manipulating the imaging catheter in the vessel.
- Selecting the wrong flush medium can cause measurement errors which could lead to incorrect treatment. Prior to acquisition, make sure the flush medium identified in the Pullback Settings window matches the flush medium you are using.
- Excessive flush rate and pressure may damage the blood vessel or devices used with the Vis-Rx Micro-Imaging Catheter. Low flush rate may result in a faint image.
- Before injecting flush media, be sure that the hemostasis valve is tightened to reduce the risk of unintended catheter movement or leaking of flush media during injection.
- To avoid vessel damage or catheter damage, do not push the guide catheter further into the blood vessel when removing the catheter.
- Do not disconnect the Vis-Rx Micro-Imaging Catheter from the PIM until the procedure is complete to avoid a potential sterility breach.

Caution Statements (User Manual)

- The system components are integral parts of the Gentuity High-Frequency OCT Imaging System. The Gentuity High-Frequency OCT Imaging System hardware and software must not be modified in any way by the user. Making such modifications may interfere with correct operation and will void system warranties. Contact Gentuity Support for more information.
- The Gentuity High-Frequency OCT Imaging System can only be connected to angiography systems that have been set up by Gentuity Support.
- The purge must be performed prior to insertion and imaging. The syringe should be left attached to the side-arm to allow repeated purging throughout the imaging procedure.
- Do not remove the syringe from the catheter purge port to prevent air from entering the purge lumen and to allow repurging as necessary.
- Use a guidewire with a maximum outer diameter of 0.014" (0.36 mm) and a guide catheter with a minimum inner diameter of 0.068" (1.73 mm).
- To avoid catheter damage, make sure the PIM motor is NOT running when inserting the Vis-Rx Micro-Imaging Catheter into the guide catheter.
- To help ensure successful imaging, the guide catheter should be oriented to preferentially direct the flush media flow to the target artery.
- To help ensure successful imaging, do not use a guide catheter with side holes.

- To ensure imaging of selected anatomy, do not move the guidewire after the imaging catheter is in position.
- If the optical imaging core encounters resistance while returning to the distal position within the sheath (due to a kink or breakage), the Advance Force Limiter will buckle to absorb the forward motion. If this occurs, carefully remove the imaging catheter from the guide catheter. Replace with a new catheter if further imaging is required.
- When there is no catheter connected to the PIM, be sure the PIM connector cover is securely in place to protect from dirt and damage.
- Always store the PIM with the PIM connector cover facing down.
- Do not touch the internal optics of the optical connector on the catheter or on the PIM.
- Protect the PIM connection ports and the catheter connectors from fluids.
- Cardiac motion relative to the catheter can cause lengthening and shortening of longitudinal segments of the Lumen Profile and L-Mode, or can create a jagged appearance of the reconstructed image. Do not rely solely on the Lumen Profile or L-Mode for longitudinal measurements.
- Use caution when interpreting the low confidence slices. If measurements are present, you can manually adjust the lumen trace to more accurately identify the lumen boundary.
- Because image data is displayed centered around the catheter, off-center catheter locations can make the lumen appear significantly smaller than actual diameter in some L-Mode views. When viewing in L-Mode, rotate the cut-plane to avoid image misinterpretation.
- Deleting files from the system frees up storage space on the system but the deleted files cannot be imported back into the system.
- Do not use images that have been exported in standard formats (such as MP4, JPEG, and PDF) for clinical decision making. This format uses compression methods that may degrade the image quality.
- Files exported using the Gentuity format have .g2raw and .patient file extensions. Changing the filename or extension of files exported using the Gentuity format may result in the loss of exported information. Gentuity recommends not changing these filenames or extensions.
- Using non-OCT software to measure standard format images will not produce accurate measurements.
- If you want to make measurements on files which will be exported in standard formats (such as MP4, JPEG, and PDF), you must make the measurements BEFORE exporting the images.
- If you believe that your system has been compromised by a cybersecurity breach, stop using the system and contact Gentuity immediately at support@gentuity.com.
- To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.
- To prevent unauthorized access, do not use a password that can be easily guessed. Use a combination of letters, numbers, and symbols when creating a password.

- Passwords are encrypted and cannot be recovered once they are set. If necessary, contact Gentuity Support to help reset the password.
- Gentuity makes no representation or warranty that use of the Gentuity High-Frequency OCT Imaging System complies with applicable privacy, security and confidentiality laws, but encourages you to assess your own risk as you use, disclose, control, process or transfer patient health information with the Gentuity High-Frequency OCT Imaging System.
- Do not use personally identifiable information in annotations. Annotations do NOT get anonymized.
- Deleting a patient record deletes all pullback data for that patient, and cannot be recovered.
- To help protect the system from unauthorized access, Gentuity strongly recommends the use of the lock screen feature.
- When there is no catheter connected to the PIM, be sure the PIM connector cover is securely covering the connectors to protect from dirt and damage. Always store the PIM with the PIM connector cover facing down.
- Refer to the contrast media's instructions for general warnings and precautions relating to contrast media.
- Make sure to use the contrast media and injectors according to injection specifications given by the manufacturers.
- Do not use personally identifiable information in annotations. Annotations are not changed for an anonymized export.
- Observe sterile technique when connecting the catheter to the PIM, which is outside of the sterile field.
- Always advance and withdraw the imaging catheter slowly.

<u>Caution Statements (Vis-Rx Catheter IFU)</u>

- Prior to use and for more detailed information, please review the Gentuity High-Frequency OCT Imaging System User Manual.
- Refer to the contrast media's instructions for general warnings and precautions relating to contrast media.
- Make sure to use the contrast media and injectors according to specifications given by the manufacturers.
- Protect the PIM connection ports and the catheter connectors from fluids.
- Do not touch the internal optics of the optical connector on the catheter or on the PIM.
- Observe sterile technique when connecting the catheter to the PIM, which is outside of the sterile field.
- Do not remove the syringe from the catheter purge port to prevent air from entering the purge lumen and to allow repurging as necessary.
- Use a guidewire with a maximum outer diameter of 0.014" (0.36 mm) and a guide catheter with a minimum inner diameter of 0.068" (1.73 mm).

- To avoid catheter damage, make sure the PIM motor is NOT running when inserting the Vis-Rx Micro-Imaging Catheter into the guide catheter.
- Always advance and withdraw the imaging catheter slowly.
- To ensure imaging of the selected anatomy, do not move the guidewire after the imaging catheter is in position.
- To help ensure successful imaging, the guide catheter should be oriented to preferentially direct the flush media flow to the target artery.
- To help ensure successful imaging, do not use a guide catheter with side holes.
- If the optical imaging core encounters resistance while returning to the distal position within the sheath (due to a kink or blockage), the Advance Force Limiter will buckle to absorb the forward motion. If this occurs, carefully remove the imaging catheter from the guide catheter. Replace with a new catheter if further imaging is required.
- When there is no catheter connected to the PIM, be sure the PIM connector cover is securely in place to protect from dirt and damage.
- When not in use, always store the PIM in the PIM cradle with the PIM connector cover facing down.

4.3 Other Relevant Aspects of Safety & Summary of Field Safety Corrective Action

The Gentuity device has not been subject to any field safety corrective action or field safety notices.

5. Summary of Clinical Evaluation and Post-Market Follow-Up

The clinical data used to support the Vis-Rx Micro Imaging Catheter was gained from published literature and a post market clinical investigation as described below.

5.1 Equivalence

Equivalence was not used to support the safety and performance of the Gentuity device.

5.2 Clinical Investigation

The clinical investigation summary includes the initial clinical data used to support the Vis-Rx Micro Imaging Catheter and the additional subjects enrolled as part of the PMCF plan.

Study Identification	Post-Market Clinical Evaluation of the Gentuity High-Frequency Optical Coherence Tomography Imaging System and Vis-Rx Micro-Imaging Catheter (Vis-Rx PME) The study was conducted in the United States of America from February 2021 through January 2023. This phase includes the subjects enrolled to support the PMCF plan.
Device Identification	Gentuity HF-OCT Imaging System (G10-01) Vis-Rx Micro-Imaging Catheter Kit, includes Vis-Rx Micro-Imaging Catheter with syringe (G30-03)

Intended Use	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.
Study Objectives & Methods	The study objectives include clinical and technical performance of the Gentuity High-Frequency Optical Coherence Tomography Imaging System and Vis-Rx Micro-Imaging Catheter in a target population as outlined in the 510(k) cleared labeling.
Study Design	The study design includes a single arm, unblinded, multi-center, post-market clinical evaluation performed at 3 clinical centers in the United States in subjects who are candidates for transluminal interventional procedures undergoing HF-OCT imaging.
Duration of Follow-up	Subjects followed through the end of the interventional procedure. No further follow-up assessments or visits were required.
Number of Subjects	Total of 257 subjects were consented of which 75 participants underwent HF-OCT imaging with the Gentuity device.
Technical Endpoint	A median Clear Image Length for the acquired HF-OCT pullback images greater than 35 mm, as evaluated by an independent core lab.
Safety Endpoint	Safety monitoring through the interventional procedure and adverse event reporting.
Clinical Performance Endpoint	The clinical performance endpoint includes the following four categories: 1) Catheter Preparation, 2) Catheter Deliverability, 3) Image Quality and 4) Overall Performance. Subjective criteria within these categories were evaluated and rated using the 5-point Likert scale by the interventional cardiologist with the objective of a mean score of greater than 3 for each category, where 3 is acceptable. The Likert scale was defined as (5) Excellent, (4) Good, (3) Acceptable, (2) Poor, and (1) Unacceptable. The evaluation was conducted following completion of the PCI procedure for each subject that completed HF-OCT imaging.
Inclusion Criteria	• Patients 18 years of age or older • Patients willing and able to provide written informed consent to participate in evaluation • Patients who are candidates for transluminal interventional procedures for their coronary arteries (also known as PCI)
Exclusion Criteria	• Bacteremia or sepsis • Major coagulation system abnormalities

	• Severe hemodynamic instability or shock • Acute renal failure • Disqualified for Coronary Artery Bypass Graft surgery • Disqualified for Percutaneous Coronary Intervention • Patients currently enrolled in another study to evaluate an investigational device or medication The following lesion-specific exclusion criteria applied during the catheterization laboratory visit, which was assessed during angiography and prior to HF-OCT imaging: • Total occlusion • Coronary artery spasm • Large thrombus (as visible under angiography) • Any target vessel which has undergone a bypass procedure
Study Population	Patients in the cardiac catheterization laboratory who were candidates for transluminal interventional procedures were included in the study.
Study Results	<u>Safety</u> There were no safety incidents (0%) reported in the study. <u>Clinical Performance</u> The objective of the clinical performance endpoint was met with mean rating of greater than 3 for each of these four categories. The mean scores for each category are as follows: • Mean catheter preparation score of 5.0 • Mean catheter deliverability score of 4.8 • Mean image quality score of 4.7 • Mean overall performance score of 4.3 <u>Technical Endpoint</u> Achieving a median Clear Image Length (CIL) of 35 mm was met, with the median CIL measured as 67.2 mm (p-value <0.0001).
Study Limitations	Enrollment took longer than expected due to impact of COVID-19 from hospitals in the United States postponing elective interventional cardiology procedures.
Device Deficiencies	One subject was not imaged due to catheter malfunction. The physician elected not to replace catheter to complete vessel imaging.

5.3 Summary of Clinical Data from Other Sources

There are no other sources of clinical data using the Gentuity device.

5.4 Overall Summary of the Clinical Performance & Safety

During percutaneous coronary interventions, HF-OCT can be used as a diagnostic tool in providing detailed vessel and lesion information to the treating physician. The Gentuity device provides images of the coronary arteries in patients who are candidates for transluminal interventional procedures. This clinical study evaluated the use of the device in a real-world setting.

The results of the study demonstrated that all study endpoints were successfully achieved. The clinical performance endpoint evaluated investigator responses to system performance in catheter preparation and deliverability, image quality and overall performance on a 5-point Likert scale. The objective was a mean score of greater than 3 in all categories. The clinical performance endpoint was met for all four categories. In addition, the mean score for each variable was greater than 3, with a range of 3.9 – 4.4, indicating a high level of satisfaction across all aspects of the device. The technical endpoint evaluated Clear Image Length (CIL) for the acquired HF-OCT pullback images. The endpoint was a median CIL of greater than 35 mm. CIL was assessed using 144 collected HF-OCT images from the 75 subjects. The primary endpoint of achieving a median CIL of 35 mm was met, with the median CIL measured as 67.2 mm (p-value <0.0001).

As expected, the study demonstrated an impressive safety endpoint with no adverse events occurring throughout the duration of the study. The completion of the study supports that there is an acceptable benefit-risk ratio. Furthermore, there were no systematic misuse or off-label use of the device based on review of the deviations which supports that the intended purpose is correct.

In summary, the trial demonstrated that the Gentuity device was found to be easy to use with good image quality and performance as evidenced by the investigators using the system. All clinical and performance endpoints were met with no device- or procedure-related adverse events. The benefit of using the Gentuity device are greater than the risks associated with its use. The device remains clinically relevant as a diagnostic tool during percutaneous coronary procedures and continues to meet state-of-the-art.

5.5 Post-market Clinical Follow-up

Gentuity expanded the products AI-based software features to include two new features (i.e., stent detection and guide catheter detection). The existing AI feature (i.e., lumen segmentation) and the new AI-based features will continue to be evaluated as part of PMCF. Data collection of HF-OCT images from multiple hospitals in the United States will be used to ensure the AI features are performing per their performance requirements. The sample size of the HF-OCT images for the AI software features will be met in order to complete the post-market evaluation. A minimum of N=40 HF-OCT pullbacks will be collected for the evaluation of the lumen segmentation and a minimum of N=15 HF-OCT pullbacks will be collected for the evaluation of the stent detection and guide catheter detection. The acceptance criteria are based on the software requirements for AI performance. These objectives will ensure the Gentuity device continues to meet state-of-the art and overall safety and performance expectations of the new software features.

6. Possible Diagnostic or Therapeutic Alternatives

A possible diagnostic tool alternative to the Gentuity HF-OCT imaging device includes intravascular ultrasound (IVUS). IVUS can be a useful tool during percutaneous coronary interventional procedures. IVUS uses ultrasound waves where the Gentuity device uses infrared light to see inside the vessels. HF-OCT has significantly greater image resolution compared with

IVUS. However, HF-OCT requires clearing of blood during imaging with use of contrast media. Both HF-OCT and IVUS are associated with low complaint rates.

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

7. Suggested Profile and Training of Users

The users of the Vis-Rx Micro-Imaging Catheter are physicians and technicians trained in the performance of catheter based intracoronary interventional procedures. These physicians are interventional cardiologists. The interventional cardiologist will frequently be assisted by an interventional cardiology fellow, catheterization laboratory technician, or nurse.

The Gentuity device is intended for use only by medical personnel trained in its operation and skilled in the clinical procedures to be used. Gentuity and/or its trained distributors provide on-site customer training for the device. Training is provided after installation of the device and as requested by its customers.

8. References

Quality Standards	Title
EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes
Risk Management Standards	**Title**
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
Clinical Standards	**Title**
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good clinical practice
Biocompatibility Standards	**Title**
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
Sterilization Standards	**Title**
EN ISO 11137-1:2015+A2:2019	Sterilization of health care products - Radiation-Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices – Amendment 2: Revision to 4.3.4 and 11.2

EN ISO 11137-2:2015+A1:2023	Sterilization of health care products - Radiation-Part 2: Establishing the sterilization dose
EN ISO 11737-1:2018+A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products – Amendment 1
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
Packaging Standards	**Title**
EN ISO 11607-1:2020**+A1:2023**	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020**+A1:2023**	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
ASTM F1980:2021	**Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices**
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F1886/F1886M:2016	**Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection**
ASTM F88/F88M:2021	**Standard Test Method for Seal Strength of Flexible Barrier Materials**
ASTM F2096:2011: R2019	**Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)**
ASTM F2203:2013: R2022	**Standard Test Method for Linear Measurement Using Precision Steel Rule**
EN 868-5:2018	Packaging for terminally sterilized medical devices Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods
ASTM D5276-19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
ASTM D4728:2017: R2022	Standard Test Method for Random Vibration Testing of Shipping Containers
ASTM D642-20	Standard Test Method of Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
ASTM D6653/D6653M:2013: R2021	Standard Test Methods for Determining the Effects of High Altitude on Packaging Systems by Vacuum Method
ASTM D999:2008: R2015	Standard Test Methods for Vibration Testing of Shipping Containers
Labeling Standards	**Title**
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
ISO 15223-2:2010	Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation
ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
IEC TR 60878:2015	Graphical symbols for electrical equipment in medical practice

ISO 7010:2019	Graphical symbols — Safety colours and safety signs — Registered safety signs
ISO IEC 15415:2011	Information technology – Automatic identification and data capture techniques – Bar code symbol print quality test specification – Two-dimensional symbols
ISO IEC 15416:2016	Automatic identification and data capture techniques – Bar code print quality test specification – Linear symbols
ISO IEC 15417:2007	Information technology – Automatic identification and data capture techniques – Code 128 bar code symbology specification
ISO IEC 15420:2009	Information technology – Automatic identification and data capture techniques – EAN/UPC bar code symbology specification
ISO IEC 16022:2006	Information technology – Automatic identification and data capture techniques – Data Matrix bar code symbology specification
Usability Standards	**Title**
EN 62366-1:2015+A1:2020	Medical devices – Application of usability engineering to medical devices
EN 60601-1-6:2010+A1:2013+A2:2021	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
Electrical Safety Standards	**Title**
IEC 60601-1:2005+A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020	Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Software Standards	**Title**
IEC 62304:2006+A1:2015	Medical device software – Software life cycle processes – Amendment 1
ISO 12052:2017	Health informatics — Digital imaging and communication in medicine (DICOM)
AAMI/TIR57:2016 R(2019)	Principles for Medical Device Security Risk Management
ANSI-NEMA HN 1-2019	Manufacturer Disclosure Statement for Medical Device Security (MDS2)
IEC 81001-5-1:2021	Health software and health IT systems safety, effectiveness and security — Part 5-1: Security — Activities in the product life cycle
Performance Standards	**Title**
EN 60601-2-52:2010+A1:2015	Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
ISO 10555-1:2013+A1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements – Amendment 1
ASTM F2394:2007: R2022	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System
ASTM F2743-11 (2018)	Standard Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems
IEC 60825-1:2014	Safety of laser products – Equipment classification and requirements
Environmental Standards	**Title**
EN 60601-1-9:2008+A2:2020	Requirements for Environmentally Conscious Design

EN 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

9. Revision History

Revision	ECO Number/Date Issued	Release Date	Description of Changes	Revision validated by the Notified Body?	Validation Language
A	E02590	Oct 24, 2022	Initial Release	☒ Yes ☐ No	English
B	E02743	Feb 3, 2023	Revised authorized representative address, added new caution statement, clarified multiple caution/warning statements	☒ Yes ☐ No	English
C	E04087	09/12/2023	3.3 Added DICOM port information, 4.2 revised warning/caution statements for clarification, and 8.0 updated standards.	☒ Yes ☐ No	English
D	E04215	9/29/2023	Updated Standards Information to align with GSPR Updated Warnings and Cautions section to ensure all IFU / UM items are documented in SSCP.	☒ Yes ☐ No	English

Revision	ECO Number/Date Issued	Release Date	Description of Changes	Revision validated by the Notified Body?	Validation Language
E	E04511	9/30/2024	Updated 5.2 and 5.4 with PME PMCF data. Updated 5.5 with additional PMCF information. Updated 8.0 standards.	☒ Yes ☐ No	English