GENTUITY

Vis-Rx™ PRIME

Micro-Imaging Catheter
High-Frequency OCT

Instructions for Use

Intended Use

The Gentuity® HF-OCT Imaging System with Vis-Rx™ Prime 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 Prime Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Prime Micro-Imaging Catheter is also intended for use prior to or following transluminal interventional procedures. The Vis-Rx Prime Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

Contraindications

Contraindications for use of the Gentuity High-Frequency OCT Imaging System include:

- 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

WARNINGS: GENERAL

- Before using the 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.
- 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).
- Refer to the contrast media's instructions for general warnings and precautions relating to contrast media.

WARNINGS: PREPARATION

- Observe sterile technique when connecting the catheter to the PIM, which is outside of the sterile field.
- Do not disconnect the imaging catheter from the PIM until the procedure is complete to avoid a potential sterility breach.
- To avoid risk of air embolism, the catheter lumen must be purged prior to insertion and imaging.

WARNINGS: USING THE CATHETER

- Observe all advancement and movement of the 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 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.
- If the imaging catheter becomes kinked, stop manipulating to avoid vessel injury or imaging catheter damage.
- The catheter should never be forced into lumens that are narrower than the catheter body.
- To avoid blood vessel damage, maintain the position of the guidewire when manipulating the imaging catheter in the vessel.
- 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.
- 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 flush media identified in the **Pullback Settings** window matches the flush media you are using.
- 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.

CAUTIONS

- Prior to use and for more detailed information, please review the *Gentuity High-Frequency OCT Imaging System User Manual*.
- Federal law restricts this device to sale by or on the order of a Physician licensed by law of the state in which he or she practices to use or order the use of the device.

NOTE: Additional cautions are included with the relevant usage instructions in this document.

Complications

The risks involved in vascular 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.

- Acute myocardial infarction or unstable angina
- Allergic reaction to contrast media
- Arterial dissection, injury, or perforation
- Cardiac arrhythmias
- Coronary artery spasm
- Death
- Embolism
- Myocardial ischemia
- Renal insufficiency from contrast usage
- Thrombus formation

Intended Users

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.

Description

The Vis-Rx Prime Micro-Imaging Catheter is a rapid exchange (RX) catheter with a 17 mm minirail tip designed for compatibility with a 0.014" (0.356 mm) guidewire. The catheter is 1.8 Fr in size, allowing compatibility with 5F and larger guide catheters. The effective length of the catheter is 165 cm. The distal 62 cm has a hydrophilic coating applied to improve lubricity.

The Vis-Rx Prime Micro-Imaging Catheter consists of two assemblies: an external catheter sheath and an imaging core (housing an optical fiber and lens assembly).

Proximal to the minirail tip is the imaging area. During image acquisition, the lens rotates within the imaging core to obtain a 360° image of the surface layer of the artery wall. The imaging core is automatically retracted within the external catheter sheath to obtain a continuous pullback image of the arterial segment.

Markers

The catheter has three radiopaque markers:

- The most distal marker, the **tip marker**, is located 4 mm proximal to the tip of the catheter and is affixed to the catheter sheath.
- The **lens marker** is located 4 mm distal to the lens on the imaging core.
- There is an additional **pullback marker** placed 100 mm proximal to the lens on the imaging core which frames the imaging region.

Together, these markers enable confirmation of the catheter distal end, lens location, and imaging region. The lens and pullback marker move with the pullback, while the tip marker remains stationary.

The catheter sheath has two insertion depth markers at 90 cm and 100 cm from the distal tip that provide an indication of insertion depth.

Purging

A luer fitting on the side-arm at the proximal end of the catheter facilitates purging the central catheter lumen of the imaging catheter with heparinized saline prior to use. A 3 ml syringe is provided to perform the catheter purge.

Probe Interface Module (PIM)

The PIM provides both automated rotation and longitudinal pullback of the imaging core within the imaging catheter. The PIM is rail-mountable and can be placed outside of the sterile field so that a non-sterile technician can connect the catheter to the PIM and operate it during the procedure.

The imaging catheter connects to the Gentuity High-Frequency OCT Imaging System through the PIM. All imaging core rotation and translational pullback is driven by the PIM and occurs inside the catheter sheath. For more details on the PIM, see the *Gentuity High-Frequency OCT Imaging System User Manual.*

USING THE CATHETER

The system provides illustrated instructions for connecting the catheter to the PIM. The instructions are displayed when you select the **Acquire** button if the catheter is not yet connected to the PIM.

Preparing the Catheter

Note: SO indicates Sterile Operator. **NSO** indicates Non-Sterile Operator.

1. **NSO:** Carefully open the catheter and syringe pouches and transfer the contents into the sterile field using sterile techniques.
2. **SO:** When ready to perform imaging, activate the hydrophilic coating by injecting heparinized saline into the hoop or wiping the distal segment with gauze moistened with heparinized saline.
3. **SO:** Fill the provided 3 ml syringe with heparinized saline and attach to the catheter purge port. Purge the lumen of the catheter with saline until 3-5 drops exit the distal purge exit.
4. **SO:** Leave the purge syringe connected so that the catheter lumen can be repurged if necessary.

CAUTIONS

- 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 and to maintain a static pressure to prevent backflow.
- Purge the catheter lumen only with saline to ensure optimal image quality.
- Do not remove the syringe from the catheter purge port to prevent air from entering the purge lumen and to allow repurging as necessary.

Connecting the Catheter to the PIM

1. **NSO:** Attach the PIM to the surgical bed rail by hooking the top of the clamp to the rail and tilting downward.
2. **SO:** Using sterile techniques, pass the catheter connector to the NSO near the PIM.
3. **NSO:** Remove the cover from the PIM connector and the cover from the catheter optical connector.
4. **NSO:** Align the catheter connectors to the connection ports on the PIM and insert the catheter into the PIM until it snaps into place.
5. **NSO:** Rotate the optical connector lock clockwise to the LOCKED position.

NOTE: When properly connected, a red light is displayed at the lens of the catheter and the system progresses to the next stage of readiness.

Inserting and Positioning the Imaging Catheter

1. **SO:** Insert the guidewire into the guidewire lumen of the imaging catheter and advance the imaging catheter over the guidewire. Use the insertion depth gauges at 90 cm and 100 cm as guides.
2. **SO:** Using fluoroscopy, position the imaging catheter in the region of interest. The lens marker is located 4 mm distal to the imaging lens, so should be positioned distal to the area of interest. The pullback marker 100 mm proximal to the lens frames the imaging region.

CAUTIONS

- Use a guidewire with a maximum outer diameter of 0.014" (0.36 mm) and a guide catheter with a minimum inner diameter of 0.056" (1.42 mm).
- To help ensure successful imaging, do not use a guide catheter with side holes.
- To avoid catheter damage, make sure the PIM motor is NOT running when inserting the 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 ensure imaging of the selected anatomy, do not move the guidewire after the imaging catheter is in position.

Confirming Imaging Settings

1. **NSO:** When ready, select **Acquire** on the touchscreen. If the catheter has not yet been connected, the system provides guidance.
2. **NSO:** Specify the following in the **Imaging Settings** window:
   - Select the **Pullback Settings**.
   - Confirm the default **Flush Media** type or select another **Flush Media** type.
   - In the **Automatic Flush Detection** section, select **ON** for automatic detection, or **OFF** for manual detection.

Notes:

- **Automatic Flush Detection (ON)** is the setting in which the system triggers a pullback automatically when a brief sequence of clearing is detected as a result of contrast injection. If clearing is not detected within 15 seconds after being enabled, the system displays a **Timeout** message. You can initiate pullback manually when in Automatic mode by selecting **Acquire** on the touchscreen or the **GO** button on the PIM.
- **Automatic Flush Detection (OFF)** is the manual setting. After clearing is observed, you select the **Acquire** button or press **Go** on the PIM to start the pullback. If you do not initiate pullback within 15 seconds after the system is enabled, the system displays a **Timeout** message.

3. **NSO:** When ready, select **Confirm Settings** on the touchscreen.

Preparing the Flush Media

SO: Depending on the type of flush media injection, do one of the following:

- If using an **automated injector**, ensure the selected flush media is loaded in the injector and set the flush rate to 4 ml/sec or less, with a total volume of 16 ml or less and pressure limit of 300 psi (2068 kPa).
- If using a **manual injection**, prepare a coronary control syringe capable of injecting up to 4 ml/sec for 3 to 4 seconds.

Beginning Preview (Optional)

Perform the *optional* steps in Preview to confirm the position of the catheter within the vessel.

1. **NSO:** When the catheter is in position, select **Preview**. The PIM will activate and the OCT image is displayed. A **Calibration** window is also displayed for approximately 5 seconds.
2. **SO:** If necessary, use the 3 ml purge syringe to eliminate any blood from the catheter lumen.

Delivering 5 ml Flush Media to Confirm Alignment

Optionally, you can deliver flush media to confirm alignment of the guide catheter with the vessel.

1. **SO:** Deliver approximately 5 ml of flush media via the Y-connector to fill the guide catheter with flush media and to ensure proper guide catheter alignment with the ostium under fluoroscopic guidance.
2. Proceed to **Enable** step, or press **STOP** on the touchscreen (or on the PIM) to exit **Preview** mode.

Enabling the Start of High-Speed Rotation

NSO: With confirmation of proper guide position and imaging catheter position, select **Enable** on the touchscreen or press the green **Go** button on the PIM to start high-speed PIM rotation.
When the PIM reaches full speed and the catheter is calibrated, the system is ready for pullback. The 15-second clock begins, and the system prompts for injection of the flush media.

Note

If you do not inject the flush media and initiate pullback within the 15 seconds, the PIM rotation stops completely and a **Timeout** message is displayed. Select **OK** and then select **Enable** to enable the system when ready to image.

Injecting Flush Media and Initiating Pullback

1. **SO:** Inject the flush media into the target artery via the Y-connector on the guide catheter.
2. **NSO:** Depending on the selected **Automatic Flush Detection** setting, do one of the following:
   - **Automatic Flush Detection (ON)**: The system automatically initiates pullback when clearing is detected. Alternatively, you can manually initiate pullback prior to the automatic trigger by selecting **Acquire** on the touchscreen or by pressing the green **Go** button on the PIM.
   - **Automatic Flush Detection (OFF)**: Select **Acquire** on the touchscreen or press the green **Go** button on the PIM to initiate the pullback and start capturing images once the blood is removed and a clear image displays (1-2 seconds after injecting the flush media).

The image displays after completion of the pullback. The optical imaging core returns to the distal position within the sheath for further imaging.

CAUTION

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.

Notes:

- **SO:** Do not remove the catheter until you confirm the image is acceptable.
- **NSO:** Do not disconnect the catheter from the PIM until you are completely finished with the system.

REMOVING THE CATHETER

After confirming that the image or images are acceptable, perform the following steps to remove the catheter:

1. **SO:** Under fluoroscopy, carefully remove the catheter from the guide catheter, checking the condition of the catheter, guidewire, and guide catheter during withdrawal.
2. **SO:** After removing the catheter from the patient, use the 3 ml purge syringe to purge the imaging catheter until 3-5 drops of saline exit the purge exit. Keep the purge syringe connected throughout the procedure.
3. **SO:** Wipe the distal section of the catheter with saline to remove external blood and flush media.

When the catheter is removed from the guide catheter and no further imaging is required, it may be disconnected from the PIM.

DISCONNECTING THE CATHETER FROM THE PIM

1. **NSO:** Hold the catheter connector and unlock the optical connection by turning it counter-clockwise to the UNLOCKED position.
2. **NSO:** Grasp the pullback connector (by squeezing both sides) to remove the catheter from the PIM.
3. **NSO:** Place the protective port cover on the PIM to prevent damage to the catheter and pullback connection ports on the PIM.
4. **NSO:** Dispose of the catheter in accordance with accepted medical practice and applicable laws and regulations.

CAUTIONS

- 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.
- Protect the PIM connection ports and catheter connectors from fluids.
- Do not touch the internal optics of the optical connector on the catheter or on the PIM.

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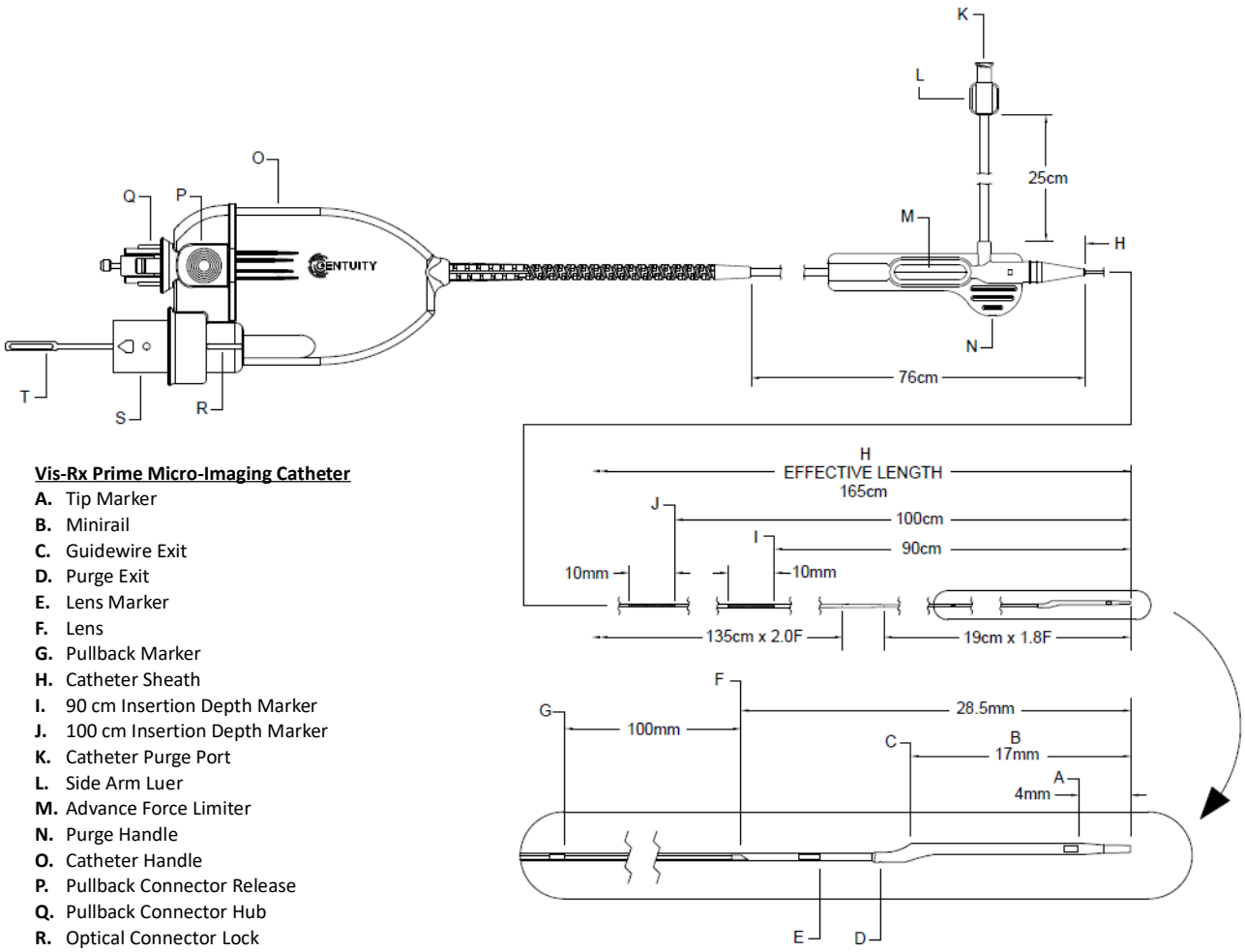
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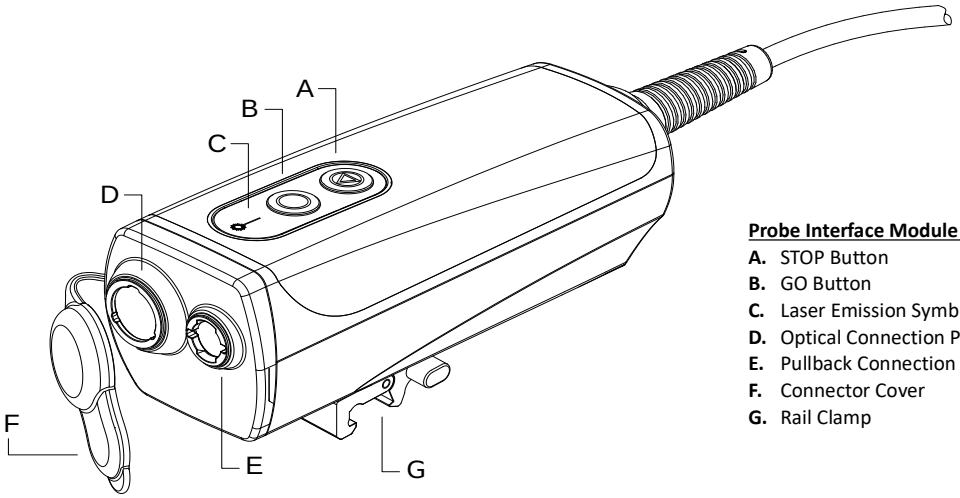
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Figure: Vis-Rx Prime Micro-Imaging Catheter and Probe Interface Module (PIM)



Vis-Rx Prime Micro-Imaging Catheter

- **A.** Tip Marker
- **B.** Minirail
- **C.** Guidewire Exit
- **D.** Purge Exit
- **E.** Lens Marker
- **F.** Lens
- **G.** Pullback Marker
- **H.** Catheter Sheath
- **I.** 90 cm Insertion Depth Marker
- **J.** 100 cm Insertion Depth Marker
- **K.** Catheter Purge Port
- **L.** Side Arm Luer
- **M.** Advance Force Limiter
- **N.** Purge Handle
- **O.** Catheter Handle
- **P.** Pullback Connector Release
- **Q.** Pullback Connector Hub
- **R.** Optical Connector Lock
- **S.** Optical Connector Hub
- **T.** Optical Connector Cover (remove before use)



Probe Interface Module (PIM)

- **A.** STOP Button
- **B.** GO Button
- **C.** Laser Emission Symbol
- **D.** Optical Connection Port
- **E.** Pullback Connection Port
- **F.** Connector Cover
- **G.** Rail Clamp