PM-09750

2025-02 Rev.1

DualView®

Imaging Catheter

+MDU Cover

Rx ONLY

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

DU34M002-01

TERUMO



Catalogue number



Batch code



Use-by date



Do not use if package is damaged and consult instructions for use



Contents



Consult instructions for use or consult electronic instructions for use



Sterilized using ethylene oxide



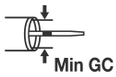
Do not re-use



Manufacturer



Do not resterilize



Guiding Catheter minimum inner diameter



Manufacturing site



Non-pyrogenic



Medical device



Unique Device Identifier



Date of manufacture



Single sterile barrier system



Hydrophilic coating length



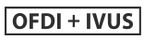
Keep dry



Keep away from sunlight



Caution



OFDI + IVUS



MDU Cover



+MDU Cover



Ultrasound Frequency



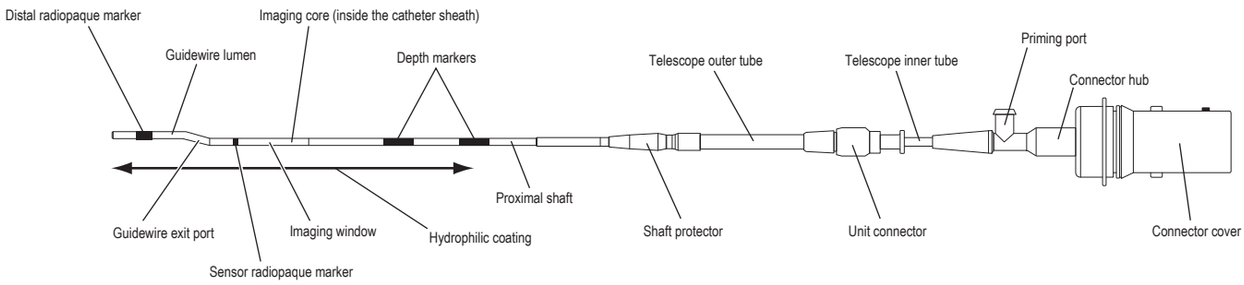
Do not wet the connector. Failure of system could occur.

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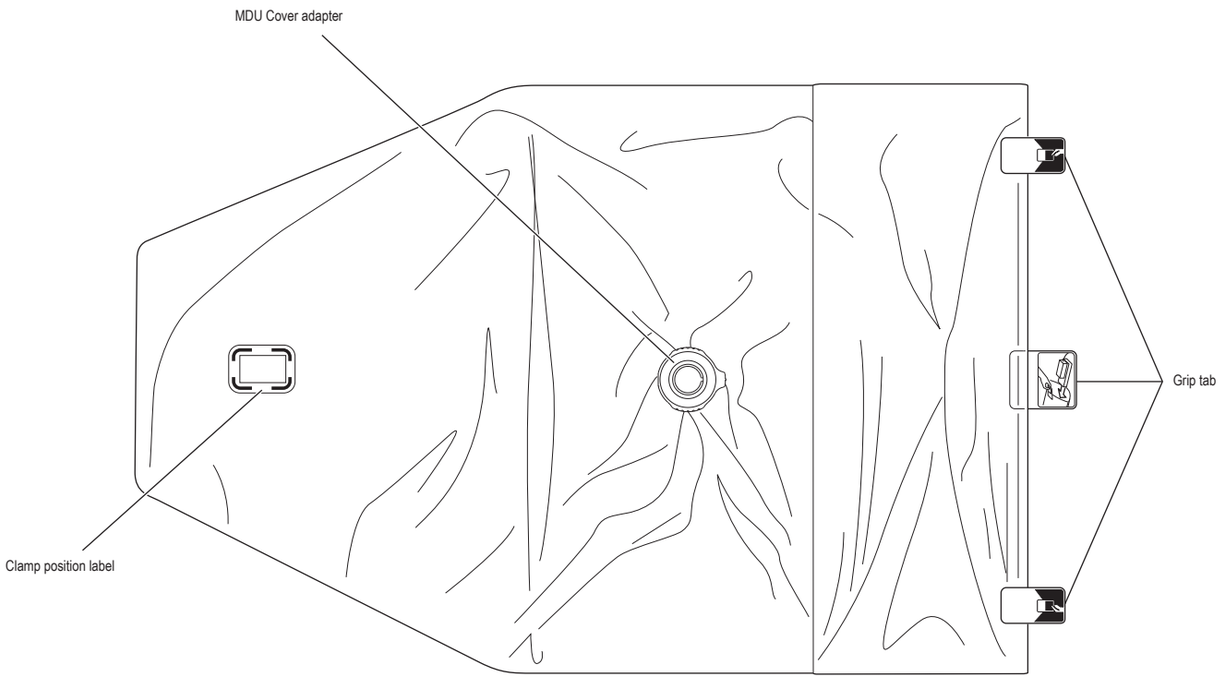
SPECIFICATIONS

<NAME OF EACH PART>

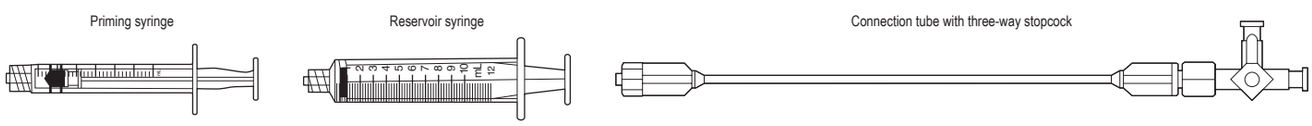
CATHETER



Motor Drive Unit (MDU) Cover



Accessories



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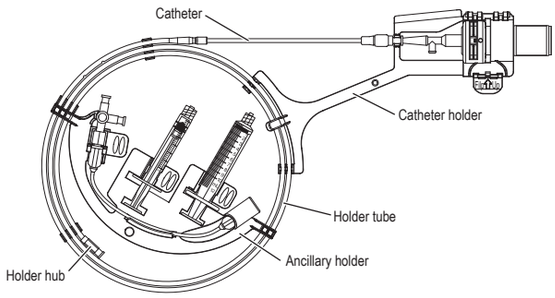
ENGLISH

Please read all instructions prior to use.

DESCRIPTION

This catheter consists of two assemblies: the catheter sheath and the imaging core (consisting of lens and transducer). During imaging, the imaging core rotates inside the catheter sheath to obtain a 360°image of the surface layer of the vessel wall by irradiating with near-infrared light and ultrasound. By pulling back the imaging core inside the catheter sheath, an image in the long axis direction can be obtained.
This is a rapid exchange (RX) design (short monorail) catheter with a 0.014" (0.36 mm) guidewire. The catheter is 2.6 Fr (0.86 mm) in the imaging window section and 3.0 Fr (1.01 mm) in the shaft section with an effective length of 137 cm.
The catheter has a 100 cm hydrophilic coating starting from the distal end, which becomes highly lubricious when wet. There are two radiopaque markers. The distal radiopaque marker is located 7 mm from the distal end of the catheter sheath, and the sensor radiopaque marker is located where the near-infrared light and ultrasound are emitted. Those markers allow a user to confirm the positional relationship between the distal end of the catheter and the sensor position (imaging point). There are two depth markers, one at 90 cm and the other at 100 cm from the distal end of the catheter sheath, which serves as a guide for insertion.
The transducer has an IPX7 ingress rating in accordance with IEC 60529.
This catheter is intended for use with OPUSWAVE.
The catheter is stored in the holder tube and is secured to the catheter holder (see Fig. 1).

Fig. 1 Packaging form



The catheter comes with the Motor Drive Unit (MDU) Cover and accessories. The MDU Cover consists of an adapter and a cover sheet to maintain the sterility of the catheter and clean field. The catheter accessories consist of a connection tube with a three-way stopcock, a priming syringe, and a reservoir syringe for priming the catheter lumen with heparinized saline solution.

INTENDED USE / INDICATION

DualView is intended for the intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

TARGET PATIENTS

Patients who need coronary angioplasty or percutaneous diagnosis of the coronary artery.

INTENDED USERS

This catheter must be used by professionals trained in Percutaneous Coronary Intervention (PCI) procedures and intravascular Optical Frequency Domain Imaging (OFDI) and Intravascular Ultrasound (IVUS) imaging techniques.

CLINICAL BENEFIT

Imaging of the vascular surface layer using near-infrared light and ultrasound provides morphological and tissue characteristic information.
This allows for optimization of coronary intervention procedures and appropriate selection of interventional devices.

COMPLICATIONS

Possible complications include, but are not limited to, the following.
Should these complications occur, be aware of the treatment before use.
- Coronary dissection, perforation, rupture or injury
- Coronary artery spasm
- Thrombus formation, coronary total occlusion
- Distal emboli, cerebral infarction (with air, tissue, and/or thrombus)
- Myocardial ischemia
- Arrhythmia including ventricular fibrillation
- Infection
- Hemorrhagic complications
- Renal insufficiency or failure
- Allergic reaction to the contrast media

WARNINGS AND PRECAUTIONS

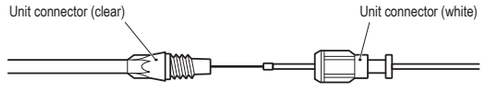
WARNINGS

- This catheter, MDU Cover, and accessories are for single use only. **Do not** reuse, resterilize, or reprocess. Reprocessing may compromise the sterility, biocompatibility, and functional integrity of the device.
- **Do not** use the catheter if the expiration date has passed, or if the expiration date is missing.
- Carefully look at each individual package to ensure that no damage has occurred to the sterile barrier.
- Sterility is maintained in an unopened and undamaged individual package. **Do not** use if the individual package or the catheter or the MDU Cover are damaged or soiled.
- The entire operation should be carried out aseptically. Always cover the MDU with the provided MDU Cover before operation.
- Use appropriate anti-platelet and anti-coagulation therapy while using the catheter.
- Carefully advance the catheter into the artery. If resistance is felt, stop manipulating the catheter and determine the cause of resistance under fluoroscopy.
- Failure to follow the warnings in the labeling may damage the coating. This may result in serious adverse events requiring additional intervention.

PRECAUTIONS

- OFDI and IVUS procedures should be carried out only at institutions where emergency coronary artery surgery can be performed in case of severe complications.
- This device should only be used in patients who are pregnant or suspected pregnant if the therapeutic benefit is determined to exceed the risks.
- This device should be applied or manipulated carefully when used in patients with;
  - serious allergies to contrast media or other drugs required for the procedure
  - congenital heart disease, severe valve disease, and/or myocardial disorder
  - a history of coronary artery spasm
  - severe thrombosis was found in the target vessel during angiography
  - severe left main disease
  - totally occluded vessels
  - pseudoaneurysms and contiguous lesions
- Do not use under Magnetic Resonance Imaging (MRI).
- This catheter is intended for use with OPUSWAVE and should never be connected with any other device.
- The catheter, MDU Cover, and accessories have been sterilized by ethylene oxide gas.
- Use the catheter and MDU Cover immediately after opening the package, and dispose of it safely and properly after use in accordance with local regulations. The used catheter and MDU Cover are biohazardous because they are contaminated with blood.
- Do not wet the connector cover of the catheter or apply any medical agents to it. The MDU may become wet and damaged.
- Do not turn the handle of the three-way stopcock more than 180 degrees.
- Do not use the catheter with chemical solutions containing organic solvents or oil-based contrast. This may damage the catheter including the coating.
- Do not bend, or apply excessive force, torque, or twist. This may cause the catheter damage, which may result in the vessel injury. If there is any change in shape, stop the operation.
- Do not leave the catheter in the blood vessel for an extended period of time.
- Do not connect or remove the catheter to/from the MDU while the MDU scanner motor is running. Do not manipulate or prime the catheter while the MDU scanner motor is running. These may damage the catheter and MDU.
- Carefully operate the catheter under fluoroscopy. Always observe the position and movement of the distal radiopaque marker of the catheter and the tip of the guidewire when manipulating it intravascularly.
- Use a guidewire with a maximum outer diameter of 0.014" (0.36 mm) and a guiding catheter with a minimum inner diameter of 0.070" (1.78 mm).
- Always engage the guidewire when inserting this catheter into the body. Do not advance the catheter to the floppy portion of the guidewire when manipulating it in the blood vessel. The floppy portion of the guidewire may not adequately support the catheter and it may damage the vessel.
- Do not use with the kinked or damaged guiding catheter or guidewire. Use with damaged devices may result in vessel injury.
- The catheter should be manipulated carefully to avoid entanglement when multiple guidewires are used.
- Do not use a guiding catheter with side holes.
- Avoid air bubbles in this catheter. Bubbles may interfere with near-infrared light and ultrasound transmission from the sensor and prevent images from being obtained.
- Do not prime the catheter inside the body. If air bubbles exist in the catheter, they may be introduced into the vessel.
- Do not use the distal radiopaque marker and sensor radiopaque marker for measurements.
- Do not insert the catheter into a branch via a stent strut.
- Carefully and slowly manipulate, advance, or withdraw this device through stents or other devices with sharp edges, or through tortuous or calcified vessels. This may cause separation of the surface coating and/or device damage, which may lead to clinical adverse events.
- Do not force the catheter into a lumen narrower than the catheter body, or into a stenotic or heavily calcified lesion.
- If the image is distorted, the scan should be stopped and check the condition of the catheter under fluoroscopy. If the distortion continues, withdraw the catheter for replacement.
- If the telescope inner tube does not go into the outer tube completely and the sensor is not positioned at the most distal end, carefully remove the catheter under fluoroscopy to determine the cause.
- When evaluating acquired images, it is recommended that Optical Coherence Tomography (OCT) images be reviewed only for vessels with a diameter of 2.0 to 3.5 mm. OCT images of the left main coronary artery or of a vessel that has previously undergone bypass surgery should not be relied upon for image assessment.
- When removing the catheter from the vessel, observe the movement of the distal guidewire tip under fluoroscopy to ensure that the guidewire is not deflected. If the catheter is removed with the deflected guidewire, the guidewire may break or bend, and it may be difficult to remove.
- Do not remove the catheter with force if the catheter is trapped in the scaffold of a stent or in a blood vessel, and is difficult to remove. Follow the steps below to remove the catheter.
  - Slowly advance the catheter to free the catheter from entrapment.
  - If not resolved by the above technique, separate the unit connector portion by rotating it counterclockwise (separating the white and clear parts) and remove the imaging core (see Fig. 2).

Fig. 2 Separation of the unit connector



If the unit connector cannot be separated, cut the telescope inner tube with a sharp instrument (scalpel, scissors, etc.) and remove the imaging core. Be careful not to cut the imaging core at this time.
  - Wet the guidewire (maximum outer diameter of 0.021" [0.53 mm] and minimum total length of 180 cm) with heparinized saline solution and insert it into the lumen where the imaging core was removed by rotating it from the tip.
  - Insert the guidewire until it reaches the tip of the catheter, reinforcing the catheter sheath. Slowly advance the catheter along the inserted guidewire again to free it from entrapment.
- The safety and efficacy of coated devices have not been established or are unknown in vascular regions other than those specifically indicated.

DIRECTIONS FOR USE

1. Preparation

1-1 By following the instructions for OPUSWAVE, power on the system and make sure the initial screen appears on the monitor.

1-2 Using the position lever, move the MDU scanner unit to the white line located on the MDU base.

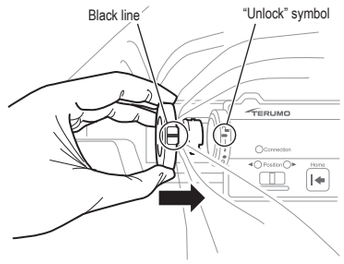
1-3 Following sterile technique, carefully open the MDU Cover package and hand the contents to the sterile operator.

CAUTION

- Keep the MDU Cover sterile. Do not drop on the floor.

1-4 Cover the MDU with the MDU Cover, align the black line on the MDU Cover adapter to the "unlock" symbol on MDU and insert the MDU Cover adapter into the MDU (see Fig. 3).

Fig. 3 Insert MDU Cover adapter to the MDU



CAUTIONS

- Excessive pulling may damage the MDU Cover.
- When connecting the MDU Cover adapter to the MDU, make sure the MDU Cover is not pinched between the MDU and the MDU Cover adapter. If the MDU Cover is pinched at the connection, it may interfere with the movement of the MDU.

1-5 Place the MDU on a stable, flat surface within the sterile field.

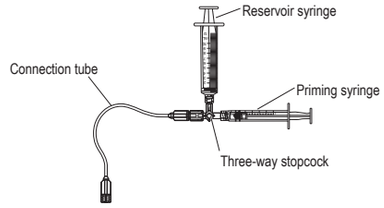
1-6 Following sterile technique, carefully open the catheter package and hand the contents to the sterile operator.

CAUTION

- When taking out the catheter from its individual package, pay special attention to the connector area where it interfaces with the MDU. Keep the catheter sterile. Do not drop on the floor.

1-7 Detach the two types of the syringes and the connection tube with the three-way stopcock from the ancillary holder. Fill the two syringes with heparinized saline solution, assemble the two types of syringes and the three-way stopcock as shown in Fig. 4, and fill the connection tube and three-way stopcock with heparinized saline solution.

Fig. 4 Assembly of syringes



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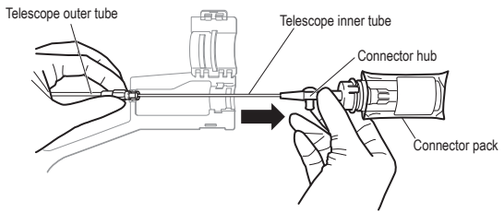
CAUTION
- Ensure that the connection tube and syringes are secured to the three-way stopcock before use. Do not allow air bubbles to enter the connection tube, syringes, and/or the three-way stopcock. Air bubbles may enter the catheter.

1-8 Keep the catheter in the holder tube and inject heparinized saline solution into the holder hub using a syringe to fill the holder tube and lubricate the catheter surface.

CAUTIONS
- Carefully inject the heparinized saline solution into the holder tube. Do not allow the catheter to come out of the holder tube.
- Only use heparinized saline solution. Do not use contrast media for flushing the holder tube.

1-9 Unlatch the catheter holder and detach the connector cover from the catheter holder. Keep the catheter inside the holder tube, grasp the connector hub and extend the telescope inner tube slowly and completely from the telescope outer tube in the direction of the arrow in Fig. 5.

Fig. 5 Extend the telescope inner tube from telescope outer tube



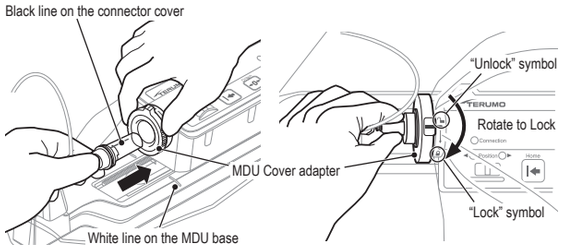
CAUTION
- Do not extend the telescope inner tube with force. This may result in damage to the catheter.

1-10 Connect the connection tube to the priming port of the catheter. Slowly inject heparinized saline solution into the catheter twice using the priming syringe. Close the catheter side of the three-way stopcock.

CAUTIONS
- Do not use other than heparinized saline solution for priming. This may result in low image quality or catheter damage.
- When priming the catheter, do not use any other device other than the supplied accessories. This may result in damage to the catheter or its accessories, or a failure of the MDU scanner unit due to the ingress of heparinized saline solution.
- Ensure that the catheter telescope is fully extended when priming the catheter. If priming is done with the telescope in halfway position, air bubbles may remain in the catheter.
- Always use the reservoir syringe as a reservoir to replenish the priming syringe. If priming is done with a reservoir syringe, air bubbles may remain in the catheter.
- Ensure that the connection tube is secured to the priming port of the catheter before use. Do not allow air bubbles to enter the connection tube. Air bubbles may enter the catheter.
- Ensure the three-way stopcock is closed on the catheter side except when priming. Do not remove the connection tube from the catheter. Leaving the priming port of the catheter released or failure to close the priming port could allow air or blood to be introduced via the catheter tip.

1-11 Carefully remove the connector pack from the connector cover. Line up the black line on the connector cover with the "unlock" symbol on the MDU. Carefully insert the catheter connector into the MDU Cover adapter until it stops at the end of the MDU Cover adapter. Turn the MDU Cover adapter clockwise to align with the "lock" symbol on the MDU. Ensure that the MDU "Connection" indicator LED turns ON (see Fig. 6).

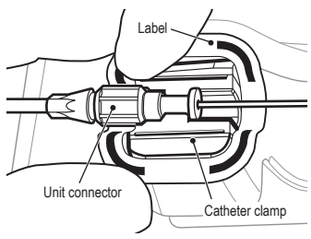
Fig. 6 Inserting and locking the catheter in place



CAUTIONS
- If resistance is felt during insertion, slightly twist the catheter connector hub and reinsert. Do not insert the catheter with force. This may result in damage to the catheter.
- Do not touch the portion where the connector pack was attached with wet hands. The inside of the MDU may get wet and damaged.

1-12 Align the clamp position label on the MDU Cover with the catheter clamp on the MDU, and clamp the unit connector of the catheter to the catheter clamp by snapping it in place (see Fig. 7).

Fig. 7 Clamp the Unit Connector



CAUTION
- Firmly secure the unit connector and the catheter clamp on the MDU in place prior to performing the operation. If not firmly secured, it may prevent normal movement of the MDU causing patient harm.

1-13 Press the home button "|←" on the MDU to move the MDU scanner unit forward.

CAUTION
- Do not touch the MDU while moving the MDU scanner unit forward.

1-14 According to the instructions for OPUSWAVE, keep the catheter in the holder tube and perform the auto calibration of the OFDI image. After auto calibration, confirm that the outer ring of the catheter is aligned with the blue line on the screen. If the outer ring of the catheter is not aligned with the blue line, perform a manual calibration. After calibration of the OFDI image, make sure that the IVUS image is appropriate (see Fig. 8 and Fig. 9).

Fig. 8 Image after the auto calibration

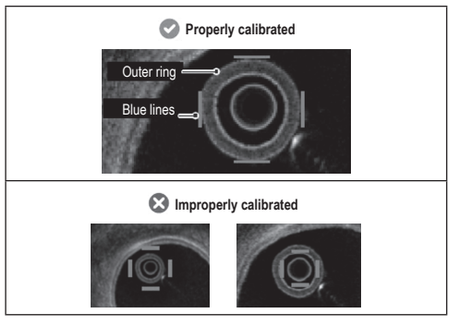
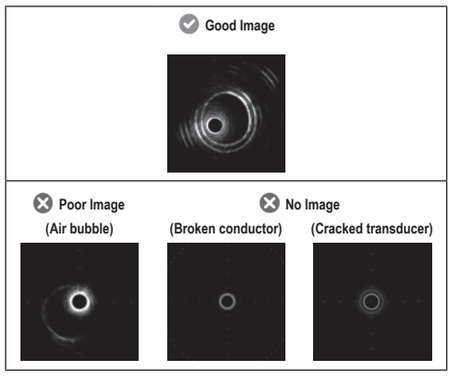


Fig. 9 Examples of appropriate and inappropriate IVUS images



CAUTIONS
- Keep the catheter in the holder tube during calibration. This will allow for calibration accuracy.
- If there is vibration or abnormal audible noise, check the catheter connection to the MDU scanner unit. If there is no improvement, discontinue use and replace the catheter with a new one.
- If there is no image or the image is unclear or unstable, inject heparinized saline solution from the priming port of the catheter as needed. If there is no improvement, discontinue use and replace the catheter with a new one.

1-15 Carefully remove the catheter from the holder tube.

CAUTIONS
- If resistance is felt when removing or re-inserting the catheter, do not apply excessive force. Carefully inject the heparinized saline solution into the holder tube and try again.
- Do not scratch the catheter with the edge of the holder tube. This may damage the catheter and its hydrophilic coating.
- Do not move the MDU scanner unit back while the catheter tip is outside the holder tube. Air bubbles will enter through the catheter tip.
- If the catheter is not immediately inserted into the guiding catheter, keep it inside the holder tube filled with heparinized saline solution.

1-16 Remove the catheter holder and the ancillary holder from the holder tube.

2. Imaging

2-1 Prior to use, follow the instructions for OPUSWAVE and select pullback configuration menu.

2-2 Thoroughly wipe the guidewire with gauze soaked in heparinized saline solution to remove any blood on the surface of the guidewire. If the catheter is dry, moisten it with gauze soaked in heparinized saline solution to enhance lubrication.

CAUTIONS
- If the guidewire is used while the surface of the guidewire is contaminated with blood, a blood clot may form and interfere with the movement of the guidewire and this catheter.
- The catheter is lubricious only when it is wet.

2-3 First, ensure that the MDU scanner motor is not running and the MDU scanner unit is in the HOME position. Use the priming syringe to re-inject heparinized saline solution into the catheter to purge the air around the sensor.

CAUTION
- Do not prime the catheter while the MDU scanner motor is running.

2-4 After inserting the guidewire into the guidewire lumen of the catheter, advance the catheter over the guidewire. Open the hemostasis valve so as not to interfere with the operation of the catheter, insert the catheter into the guiding catheter. Stop advancing the catheter in the guiding catheter and press the "Scan" button on the MDU or click "Scan" on the system screen to activate the MDU scanner motor. Verify the image is displayed on the monitor. After confirming the image, press the "Scan" button on the MDU or on the system screen to stop the MDU scanner motor and resume advancing the catheter.

CAUTIONS
- Avoid deforming the catheter tip when inserting the guidewire.
- If the image does not appear or the image is unclear or unstable, or there is vibration or abnormal audible noise, refer to the contents of caution in step 1-14.
- Excessive tightening of the hemostasis valve may disturb the imaging core rotation, leading to image distortion or catheter damage.
- When manipulating the catheter, pay special attention to the position of the MDU. The catheter may be damaged if it is pulled or bent sharply.

2-5 Carefully advance the catheter to the lesion under fluoroscopy.

CAUTION
- If the distal radiopaque marker does not move as the catheter is manipulated, carefully pull the catheter to see if the distal radiopaque marker moves. If the distal radiopaque marker does not move, the catheter may be stuck in an implanted stent or stuck in a stenosis.

For the following steps, see 2-6 through 2-13 for OFDI+IVUS mode and OFDI only mode, and 2-14 through 2-17 for IVUS only mode. ("3. Removing Imaging Catheter" is applicable to all modes.)

<OFDI+IVUS mode and OFDI only mode>

2-6 Fill the injector with the contrast solution (contrast agent, isotonic solution, or a mixture of two). Set the flush rate to 4 mL/s, the total volume to 16 mL, and the pressure limit to 300 psi (2068 kPa).

CAUTIONS
- Refer to the flushing media usage instructions for flushing media injection.
- Do not apply an excessive flow rate or pressure during flushing. This may result in vessel injury or damage to materials used with the catheter.
- If the flow rate or pressure during flushing is not sufficient, it may result in an unclear OFDI image.
- Ensure no air is introduced during flushing with the solution.

ENGLISH

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2-7 Fill the guiding catheter with the flushing solution via the hemostasis valve.

CAUTION

• Ensure the guiding catheter is oriented so that the flushing solution will be directed toward the target artery.

2-8 Press the "Scan" button on the MDU or click “Scan” on the system screen, and verify the image on the monitor. If necessary, follow the instructions for OPUSWAVE to apply manual calibration to the OFDI image.

CAUTION

• If there is no image or the image is unclear or unstable, or there is vibration or abnormal audible noise, refer to the contents of caution in step 1-14.

2-9 Press the "Ready" button on the MDU or click “Ready Pullback” on the system screen to get ready for image capture.

2-10 Inject flushing solution via the hemostasis valve within 30 seconds of activating image acquisition.

2-11 If "Manual Start" was selected, the pullback is triggered manually by the operator when a clear image appears (typically 1-2 seconds after injecting the flushing solution). Press the "Pullback" button on the MDU or on the system screen to trigger pullback and acquire the image. If "Auto Start" was selected, the system will automatically trigger a pullback after the flushing solution is injected and a clear image is detected.

CAUTION

• If a clear image is not obtained, flushing media or blood may have entered the sheath. Inject the heparinized saline solution to prime the catheter, according to the appropriate procedure. If a clear image is still not obtained, discontinue use and replace the catheter with a new one.

2-12 If "Manual Stop" was selected, press the "Pullback" button on the MDU or click "Stop" on the system screen to end the pullback manually. If "Auto Stop" was selected, the pullback will end when the MDU scanner unit has traveled the predetermined length.

2-13 Press the home button “|←” on the MDU and move the sensor to the distal end.
If further imaging is needed, return to step 2-5.

<IVUS only mode>

2-14 Press the "Scan" button on the MDU or click “Scan” on the system screen, and verify the image on the monitor.

CAUTION

• If there is no image or the image is unclear or unstable, or there is vibration or abnormal audible noise, refer to the contents of caution in step 1-14.

2-15 Press the "Pullback" button on the MDU or click “Pullback” on the system screen to initiate the pullback and perform the imaging. If starting a manual pullback, use the position lever on the MDU to manually scrub the vessel, moving distal and proximal and click “Record” on the system screen to recording.

CAUTION

• If a clear image is not obtained, flushing media or blood may have entered the sheath. Inject the heparinized saline solution to prime the catheter, according to the appropriate procedure. If a clear image is still not obtained, discontinue use and replace the catheter with a new one.

2-16 If "Manual Stop" was selected, press the "Pullback" button on the MDU or click "Stop" on the system screen to end the pullback manually. If "Auto Stop" was selected, the pullback will end when the MDU scanner unit has traveled the predetermined length. To stop recording in manual pullback, click “Record Stop” on the system screen.

2-17 Press the home button “|←” on the MDU and move the sensor to the distal end. If further imaging is needed, return to step 2-5.

3. Removing Imaging Catheter

3-1 Under fluoroscopy, verify whether the sensor is located at the distal end of the catheter.

3-2 Open the hemostasis valve and carefully remove the catheter while monitoring any movement of the catheter, guidewire, or guiding catheter under fluoroscopy. If the catheter is to be re-inserted into the patient for additional imaging, gently wipe the surface with gauze soaked in heparinized saline solution to remove any blood and place the catheter in the holder tube and set aside.

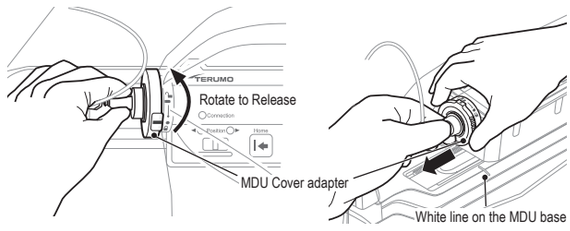
CAUTIONS

• If the catheter cannot be pulled back properly, stop manipulating the catheter and determine the cause under fluoroscopy.
• Do not accidentally advance the guiding catheter in the blood vessel while removing the catheter. This may result in vessel injury or damage to the catheter.
• Avoid wiping the surface on the catheter with dry gauze. This may damage the coating.

3-3 Using the position lever, move the MDU scanner unit to the white line located on the MDU base.

3-4 Grasp the unit connector of the catheter secured in the MDU catheter clamp, and pull it up to release. Rotate the MDU Cover adapter counterclockwise to unlock the catheter. The black line on the MDU Cover adapter should be aligned with the "unlock" symbol on the MDU. The MDU Green connection indicator LED should turn off to indicate that the catheter is not connected. Remove the catheter from the MDU Cover adapter (See Fig. 10).

Fig. 10 Detach the catheter from the MDU



3-5 Remove the MDU Cover from the MDU and dispose of the catheter and the MDU Cover following proper safety procedures.

3-6 By following the instructions for OPUSWAVE, turn off the system main power supply.

PRECAUTION FOR STORAGE

Avoid exposure to water, direct sunlight, extreme temperature, or high humidity during storage.

REPORTING OF INCIDENTS

If a serious accident occurs during or as a result of the use of the catheter, report it to the manufacturer and/or its authorized representative and to your national authority.

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