PHILIPS

*Veri*Sight/*Veri*Sight Pro

Intracardiac echocardiography catheters

Models: VSICE2D/VSICE3D

www.philips.com/IGTdevices
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Instructions for Use

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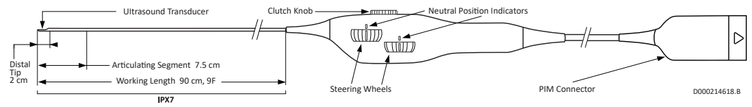
VeriSight & VeriSight Pro

Intracardiac echocardiography (ICE) catheters

English



Caution: :

1. **U.S. Federal Law restricts this device to sale by or on the order of a physician.**
2. **Prior to use, read this entire Instructions For Use.**

Indications for use:

The VeriSight/VeriSight Pro ICE catheters are intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Description:

The Philips VeriSight/VeriSight Pro ICE catheters are sterile, disposable, and licensed for single use only. The catheter's distal end has an ultrasound transducer providing 2D and/or 3D imaging capabilities. Two steering wheels manually operated from the handle control four-way articulation of the distal segment. The catheter has a 9 French (F) shaft and a usable length of 90 cm.

These catheters are for exclusive use with Philips EPIQ 7C, CVx, and CVxi series of ultrasound systems. The catheters will not operate if connected to any other imaging system. The VeriSight ICE catheter provides 2D ultrasound imaging capabilities. The VeriSight Pro ICE catheter provides 2D and/or 3D ultrasound imaging capabilities, depending on the model and configuration of your Philips EPIQ ultrasound system. Consult your Philips EPIQ ultrasound system documentation for more information about imaging transducer compatibility.

Contraindications:

Use of the catheter is contraindicated under conditions where the cardiac catheterization process would cause unacceptable risk to the patient. Contraindicated conditions include, but are not limited to, cases where vascular access is inadequate. Known contraindicated conditions include sepsis, major coagulation abnormalities, presence of any intracardiac thrombus, presence of class IV angina or heart failure, deep vein thrombosis, or significant peripheral vascular disease.

Adverse effects:

Bleeding at the entry puncture site, injury to the vascular wall, thrombosis of the vessel, and peripheral embolization has occurred with the use of percutaneous intravascular catheter devices. Adverse events related to cardiac catheterization include, but are not limited to vein injury, pseudoaneurysm, cardiac perforation, pulmonary embolism, myocardial infarction, occlusion, valve or structural cardiac damage, cardiac tamponade, pneumothorax, hemothorax, arteriovenous fistula, stroke, and death.

Warnings:

The Philips VeriSight/VeriSight Pro ICE catheters are not for use in coronary vessels or fetal tissue. Using the catheters in coronary vessels or fetal tissue can cause patient injury.

The Philips VeriSight/VeriSight Pro ICE catheters are to be used only with the Philips ICE Patient Interface Module (PIM) and compatible Philips EPIQ ultrasound systems. Any other use or inappropriate electrical connection may pose a serious risk to patient safety. Consult your Philips EPIQ ultrasound system documentation for more information about imaging transducer compatibility.

For single use only. Do not re-use, reprocess or re-sterilize. Re-use, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death.

The Philips VeriSight/VeriSight Pro ICE catheters are designed for single use only. Philips and its affiliates (collectively "Philips") makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of the catheter.

In addition, Philips assumes no responsibility or liability for any damages, including but not limited to direct, incidental, consequential or other damages which may result from such re-use. Re-use including resterilization of unused product may result in, but is not limited, to the following:

- Potential critical harm to patient due to device separation, material deformation or infection/sepsis;
- Failure to image or other device malfunctions.

Precautions:

The Philips VeriSight/VeriSight Pro ICE catheters are delicate scientific instruments and should be treated as such. Always observe the following precautions:

The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly.

Do not attempt to connect the catheter to electronic equipment other than the designated systems.

Avoid any sharp bends, pinching, or crushing of the catheter.

Do not immerse the PIM or use if the PIM appears wet. Moisture trapped between the PIM and the ICE catheter can damage the catheter and the PIM, causing a possible loss of imaging capability.

The use of an anticoagulant is recommended as per the local standard angiographic protocols and at the discretion of the physician to prevent thrombus formation.

Instructions for use:

The following instructions are provided as a general guide and are intended for informational purposes only. The physician may alter the catheter insertion techniques based on standard clinical practice.

Inspection Prior to Use

Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, contact your Philips representative to return the damaged catheter. Open a new catheter and prepare it for use per this IFU.

Warning: Do not use a device beyond the labelled expiration date.

Preparation For Use

Before you begin preparation procedures, power on the ultrasound system. Connect the patient to a vital signs monitor and track patient vital signs throughout the procedure.

To prepare the catheter and PIM for use in an ultrasound exam:

- Consult PIM User Manual for instructions on preparation and use of the PIM.
- Inspect the sterile package and the catheter prior to use.

Warning: Content is supplied STERILE using an EtO (ethylene oxide) process. Do not use if the sterile barrier is damaged. Do not use the catheter if the packaging is open or damaged. Using a catheter that has been stored in an open or damaged package can result in patient harm.

- Remove the catheter from the sterile package, and place the catheter in a sterile working area.

Caution: Ensure aseptic practice is used when transferring the catheter from the packaging to the sterile working area.

- Carefully inspect the entire catheter for damage.
- Rotate the steering wheels. The steering function should be smooth and the articulating segment of the catheter should deflect in the corresponding direction at least 120 degrees.
- Position the steering wheels in the neutral position by aligning the marks on the steering wheels to the marks on the housing.
- Connect the PIM to the EPIQ ultrasound system.
- Connect the VeriSight/VeriSight Pro ICE catheter to the PIM, and ensure a secure connection. Align the white arrows on the PIM connector and the ICE catheter connector. Then, while keeping the connectors level with each other, firmly push them together. If the connection is not done properly, an error message will occur or no reverberation is visualized. If you receive such a message or no indication a catheter is imaging, reconnect PIM or catheter and try again to ensure a tight connection. If the error persists, contact your Philips representative.

Caution: Excessively moving the PIM or ICE catheter connectors side-to-side or up and down while connecting or disconnecting the devices may damage the connectors and cause power and thermal monitoring faults.

Caution: When connecting the catheter to the PIM, ensure aseptic practice when passing the connector assembly out of the sterile field.

- Select the VeriSight/VeriSight Pro (ICE) modality on the EPIQ.
- Verify that the imaging screen appears on the EPIQ monitor.

Note: If the distal segment of the catheter is left outside the body while connected to the ultrasound system, the system may reduce imaging frame rate or enter an auto-cool mode to avoid ultrasound transducer overheating. The system will automatically revert to normal imaging mode when the catheter is inserted into the body. If the catheter must be left outside the body for an extended period, the Freeze key on the ultrasound system may be pressed to stop imaging and prevent the system from entering auto-cool mode.

Catheter placement and imaging

To conduct an ultrasound exam using the catheter:

- Create a vascular access with a hemostatic catheter introducer large enough to accommodate the catheter with heparinized saline. The Philips VeriSight/VeriSight Pro ICE catheter is compatible with a 10F or larger introducer sheath.

Caution: The Philips VeriSight/VeriSight Pro ICE catheter has a 9F shaft. The physician should consider anatomical size restrictions prior to use in patient.

Warning: Do not kink or sharply bend the catheter at any time. This can cause a pull wire failure. Do not insert the catheter into an introducer sheath at an insertion angle greater than 45º. Do not use any catheter that has been kinked or sharply bent.

- Prior to introducing the device into the vasculature, ensure the working length of the device is wiped down with heparinized saline.

Caution: Using excessive force when wiping the device down with heparinized saline can lead to catheter damage resulting in a loss of proper electrical and mechanical function.

- Before advancing or withdrawing the catheter, ensure that the steering wheels are in the neutral position and that the clutch knob is released.

Note: If the articulating segment does not return to the neutral position after releasing the steering wheels, ensure that the clutch knob is completely released. Release the deflection by rotating the clutch knob completely in the counterclockwise direction.

- Hold the catheter 1 to 2 cm from the distal tip of the device, with the clutch on the handle facing upwards, and slowly feed it into the introducer to prevent buckling of the distal segment.
- Gently advance the catheter into the vasculature. Fluoroscopy can be used to confirm the position of the catheter inside the heart. As the catheter is inserted into the body, verify that the image corresponds to the structures that the ultrasound transducer is passing.

Warning: Do not advance, manipulate or retract the catheter without fluoroscopic guidance.

Warning: Do not withdraw the catheter unless the clutch knob is released.

Warning: DO NOT advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body.

- Secure the catheter handle at all times during the procedure. Ensure the catheter handle or connection cable cannot fall or tug on the catheter body.
- When the catheter is inside the heart, use the steering wheels to direct the ultrasound transducer to visualize the target anatomy.

Warning: Do not use excessive force to articulate the catheter. If you encounter strong resistance during catheter articulation, discontinue the procedure. Identify and address the cause of the resistance before resuming the procedure.

Caution: Clean catheter thoroughly with sterile heparinized normal saline before and after each insertion.

Procedure Conclusion

To end an ultrasound exam using the catheter:

- Before you withdraw the catheter, ensure that the steering wheels are in the neutral position and that the clutch knob is released.
- Withdraw the catheter from the patient.

Warning: Do not advance, manipulate or retract the catheter without fluoroscopic guidance.

Warning: Do not withdraw the catheter unless the clutch knob is released.

- Dispose of the catheter, introducer, and sheath in accordance with local regulations.

Caution: Regard the used catheter, introducer, and sheath as biohazardous, infectious waste. Dispose of the used catheter, introducer, and sheath according to medical regulations for biohazardous waste. Observe local, state, and federal medical regulations for the disposal of electrical and electronic equipment. Wear appropriate protective gear while handling the used catheter, introducer, and sheath. Failure to dispose of the used catheter properly can result in harm to the environment and to anyone who comes in contact with the used catheter.

Warning: Do not resterilize or reuse the catheter. The catheter is disposable and is licensed for single use only. Reusing the catheter can result in loss of proper electrical and mechanical function, causing possible patient or user injury.

Troubleshooting

If your Philips EPIQ ultrasound system menu does not include the Philips VeriSight/VeriSight Pro ICE catheters, contact your Philips representative before proceeding.

Refer to your specific Philips EPIQ ultrasound system Operator's Manuals for setup, use and troubleshooting.

Storage and handling:

Products should be stored in a dry, dark, cool place in their original packaging.

Product specifications:

Model	Philips VeriSight ICE Catheter Philips VeriSight Pro ICE Catheter
Catalog number	VSICE2D VSICE3D
Outer diameter	9F
Minimum sheath size	10F
Usable length	90 cm
Articulating segment length	7.5 cm
Fixed distal segment length	2 cm

Warranty and Limitations:

The Philips VeriSight/VeriSight Pro ICE catheters have been manufactured to meet the product specifications. However, Philips has no control over the conditions of use of the VeriSight/VeriSight Pro ICE catheters. Therefore, Philips disclaims all warranties, both express and implied, including but not limited to the warranty of merchantability and the warranty of fitness for a particular purpose, with respect to the VeriSight/VeriSight Pro ICE catheters. Philips shall not be liable to any person or entity for any direct, incidental, consequential, or other damages, with respect to the VeriSight/VeriSight Pro ICE catheter, whether such claim is based upon warranty, contract, tort or otherwise. If any part of this Warranty and Limitations is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Warranty and Limitations shall not be affected, and this provision shall be construed and enforced as if this Warranty and Limitations did not contain the particular part or term held to be invalid.

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For REACH compliance status go to: www.philips.com/REACH

Additional questions regarding this product should be directed to Philips corporation in the USA.

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(800) 228-4728
IGTD.CustomerInquiry@philips.com

LOT	ISO 15223-1, 5.15.: Batch code
REF	ISO 15223-1, 5.1.6: Catalogue number
SN	ISO 15223-1, 5.1.7: Serial number
	ISO 15223-1, 5.1.1: Manufacturer/Manufactured for:
	ISO 15223-1, 5.2.8: Do not use if package damaged
STERILE EO	ISO 15223-1, 5.2.3: Sterilized using ethylene oxide
	ISO 15223-1, 5.3.4: Keep dry
	ISO 15223-1, 5.3.2: Keep away from sunlight
	ISO 15223-1, 5.4.2: Do not re-use
	ISO 15223-1, 5.2.6: Do not resterilize
	ISO 15223-1, 5.6.3: Non-pyrogenic
	IEC 60878. 2794: Use by date
	IEC 60878, 2794: Packaging unit
	IEC 60601-1, Table D.2, Symbol 10: Follow instructions for use
Rx ONLY	21 CFR 801.15(c)(1)(i)F: Prescription only
	Not made with natural rubber latex
PN	Part number
	IEC 60417, 5336: Defibrillation-proof patient connection (Type CF applied part)
IPX7	IEC 60529: Indicates that the device is protected against the effects of immersion

Refer to www.usa.philips.com/a-w/symbols/igt for complete symbol glossary.