WaveSelect Neurovascular Guidewire

INSTRUCTIONS FOR USE

℞ ONLY **CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Non-pyrogenic. Do not use if sterile barrier is damaged. If damage is found, call your representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Read these instructions carefully before use and observe the Indications for Use, Contraindications, Warnings, Precautions, Malfunction, Adverse Events and Directions for Use sections in the Instructions for Use. Failure to do so may result in complications, including serious injury to the patient or death.

These Instructions for Use apply to the WaveSelect Neurovascular Guidewires (hereafter called " the guidewire(s)"). For specifications of the respective product, refer to the product label.

Device Description

This product is comprised of a stainless steel core wire with distal platinum tungsten coil and proximal stainless steel coil, and includes a shaping mandrel and a torque device. The guidewire distal tip is straight and shapeable. The diameters of the guidewires are listed in the table below. The guidewires are compatible with devices with inner diameters (IDs) specified in the table below. The distal 30 mm of the guidewire tip is radiopaque. Confirm the compatibility of the guidewire diameter with the interventional device before use.

Model	Distal Diameter	Proximal Diameter	Guidewire Length, Coil Length, Coating Length	Compatible Device Minimum ID
GW1010	0.25 mm (0.010 in)	0.25 mm (0.010 in)	200 cm, 30 cm, 30 cm	0.33 mm (0.013 in)
GW1410	0.25 mm (0.010 in)	0.35 mm (0.014 in)	200 cm, 30 cm, 30 cm	0.42 mm (0.0165 in)

For lubricity, the distal 300 mm of the device is coated with hydrophilic coating and the proximal portion of the guidewire is coated with hydrophobic polytetrafluoroethylene (PTFE).

The shaping mandrel included with the guidewire can be used to shape the tip of the guidewire as appropriate. When shaping the tip, carefully crimp it while the surface is wet.

The torque device included with the guidewire attaches to the proximal end of the wire and functions as a steering guide. Rotation of the torque device facilitates guidewire placement into the target vessel by manipulation of the guidewire tip.

Indications for Use

WaveSelect Neurovascular Guidewire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guidewire is intended for use only in the neuro vasculature.

Contraindications

None known.

Warnings

- This guidewire is for single-patient use only. Do not reuse or re-sterilize. If reused or re-sterilized, the performance or quality of this guidewire may be compromised and there is a risk of complications, including infection.
- The safety and effectiveness of the WaveSelect guidewire has not been established or is unkonwn in coronary or peripheral vascular.
- Do not use the guidewire after the expiration date indicated on the label. Discard any device that exceeds the expiration date.
- This guidewire must be used only by a physician who is fully trained in neurointerventional endovascular procedures.
- This guidewire must be used in an institution where emergency surgical procedures can be performed immediately. Otherwise, in the worst case, life-threatening events may occur.
- Do not use in vessel that are not or cannot be visualized.
- Do not modify this guidewire other than shaping of the distal tip.
- The coil section of the guidewire is especially fragile. Do not excessively bend or pull it. Otherwise, the guidewire may be damaged.
- Do not use a damaged device. Using a damaged device may result in blood vessel damage and/or inaccurate torque response. Injury to the patient may result.
- Always advance and withdraw the guidewire slowly.
- Observe movement of this guidewire in the vessels. Before this guidewire is moved or torqued, the tip movement should be examined and monitored under fluoroscopy. Do not move or torque the guidewire without observing the corresponding movement of the tip. Otherwise, the guidewire may be damaged and/or vessel trauma may occur. In addition, ensure that the distal tip of this guidewire and its location in the vessel are visible during manipulation of the guidewire.
- Do not push, torque, or pull the guidewire against resistance. Pressing or pushing this guidewire against resistance may cause damage. Observe the guidewire under fluoroscopy for any signs of buckling of the tip of the guidewire. If prolapse of the guidewire tip is observed, do not allow the tip to remain in a prolapsed position. Otherwise damage to the guidewire or vessel may occur. Determine the cause of resistance under fluoroscopy and take any necessary remedial action.
- If any resistance is felt due to vasospasm or the guidewire being bent or trapped while operating the guidewire in the blood vessel or removing it, do not move or torque the guidewire. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate remedial action. If the guidewire is moved excessively, it may be damaged including separation, which may cause blood vessel injury or result in fragments being left inside the vessel.
- When torquing this guidewire inside the blood vessel, do not torque continuously in the same direction. It may result in damage including separation, which may injure the blood vessel or leave fragments inside the vessel. When torquing the guidewire, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (up to 720°) in the same direction.

- Do not push the guidewire more than necessary to advance the tip through the vessel. For example, do not push the guidewire when the distal tip of the guidewire is bent by the force of manipulation. After crossing the target area, do not excessively twist, push or pull the guidewire. If the device is moved excessively, it may be damaged including separation, which may injure the blood vessel or leave fragments inside the vessel.
- When advancing or retracting other devices over the guidewire, flush the devices with heparinized saline or other suitable solution to prevent air embolism. Perform exchange of this guidewire carefully to prevent air embolism and/or trauma. When reintroducing the guidewire, confirm that the tip is free within the vessel lumen and is not against the vessel wall. Failure to do so may result in vessel trauma. Use the radiopaque marker of the interventional device to confirm position.
- Free movement of the guidewire within the interventional device is important for a steerable guidewire system because it gives the user tactile information. Test the system for any resistance prior to use. Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit the guidewire movement.
- Before use, inspect carefully and confirm all devices and packages are undamaged.
- Before use, confirm that the guidewire is compatible with the interventional device to be used.
- Before use, confirm that the flexibility, shape, and size of the distal end of this guidewire are appropriate for the procedure.
- When manipulating the guidewire in vessels that are not fluoroscopically visible, take extreme care.
- Since the guidewire is provided with hydrophilic coating in order to increase the lubricity, handle it with extreme care.
- Failure to abide by the warnings might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Manipulation of the guidewire through the stents may damage the stent or cause breakage such as separation of the guidewire. Therefore, if it is necessary to perform such a manipulation, take extreme care.
- If it is suspected that the guidewire manipulation cannot be continued, do not forcibly manipulate the guidewire, but carefully remove the whole system. If it is deemed that removal of the whole system may cause device malfunction or adverse events, immediately stop the neurointerventional procedure, and perform an emergency surgical procedure based on judgement of a physician.
- During the procedure, provide appropriate anticoagulation while considering the condition of the patient.
- Do not use the guidewire in pregnant patients or patients who may be pregnant (X-ray may affect the fetus).
- Do not use the guidewire in patients who cannot adapt to emergency surgery or patients who have experienced a serious allergic reaction to contrast medium and other materials required for the procedure.
- The torque device and shaping mandrel are included to aid in the use of the guidewire and are not intended to enter the patient’s body at any time.
- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.

Precautions

- If the package is opened or damaged, do not use the guidewire. Do not open the package until

just prior to use. Use aseptic technique in handling and using the guidewire.

- Before using the WaveSelect guidewire with other therapeutic devices such as catheters, refer to the labeling of those devices to ensure compatibility with the guidewire.
- Maintain a constant saline flush between the catheter and the guidewire during a procedure.
- When taking the guidewire out of the protective hoop, do not handle the device roughly or pull it out abruptly.
- Inspect the guidewire carefully for bends, kinks, or other damage prior to use and whenever possible during the procedure.
- Do not use metallic needles or metallic sheaths for insertion and withdrawal of this guidewire, as this may damage the surface of this guidewire.
- Do not use catheters with a metallic part that may come into direct contact with the surface of this guidewire.
- Manipulation, advancement, and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating, which may lead to clinical adverse events, resulting in coating material remaining in the vasculature or device damage. This may result in adverse events requiring additional intervention.
- When shaping the distal end of the guidewire, use the minimum force needed so that the coil is not damaged. Inspect the coil and guidewire for damage after shaping and before use.
- Use care when shaping the tip of this guidewire. Be sure the guidewire is wet before shaping to avoid damaging the hydrophilic coating.
- Verify which is the distal end before inserting the guidewire and be sure to insert the flexible distal end (coiled end).
- Fasten the torque device to the guidewire firmly so that it may not loosen. Torquing with a loose torque device may cause the coating to come off.
- When changing the attachment position of the torque device on the guidewire, loosen the fastening of the torque device before moving it.
- If any resistance is felt during guidewire insertion into a catheter, do not use the guidewire.
- Do not manipulate the stopcock of the guiding catheter when the guidewire and/or other device is inserted in the guiding catheter fitted with a stopcock.
- Do not use liquids containing an organic solvent or an oil-based contrast medium with this guidewire.
- Do not immerse the guidewire in alcohol, chlorhexidine gluconate solution, or wipe it with gauze or absorbent cotton, soaked with these materials. In addition, do not wipe the guidewire with dry gauze or absorbent cotton.
- Do not manipulate the guidewire with a torque device other than the supplied torque device. When attaching the supplied torque device to the guidewire, or manipulating the guidewire using the supplied torque device, carefully manipulate the guidewire so that the guidewire will not be damaged. Fasten the torque device with care not to excessively fasten it.
- To activate the hydrophilic coating of the guidewire, inject heparinized saline into the guidewire protection hoop and the lumen of the catheter to be used before using the guidewire.
- Do not let the guidewire come into contact with liquids other than an intravascular contrast medium or heparinized saline.
- If bending is observed in the distal end of the guidewire during the procedure, do not manipulate the guidewire with the distal end being bent.
- Do not manipulate the guidewire while it is tightly secured with a Y-connector.
- If the guidewire is bent or deformed due to an incidental load during use, carefully remove the

guidewire.

- During the procedure, always check the distal end of the guidewire under fluoroscopy. In particular, in cases where the guidewire is not directly manipulated, such as moving the other devices used over the guidewire, always pay attention to the movement of the distal end of the guidewire so that the guidewire will not damage the vessel.
- If the guidewire meets resistance with the device used with the guidewire, do not apply an excessive force. If there is abnormal resistance, check the cause of the resistance and remove the whole system from the patient's body.
- Remove blood or contrast medium adhering to the surface of the guidewire using heparinized saline.
- Take preventive measures against infection after use. Discard this guidewire as medical waste.
- The maximum outer diameter of hydrophilic distal coil is no more than 0.29 mm (0.011 in) when exposed to heparinized saline because of swelling. Do not soak the guidewire in other solutions. The exposure time should not exceed 24hours.

Malfunction and Adverse Events

During use of this guidewire, the following malfunction and adverse events may occur. If the malfunction and adverse events are serious, it may result in death or serious complication(s). Note, however, that malfunction and adverse effects are not limited to these.

Malfunction:

Failure to cross a lesion
Breakage or bending of the guidewire Damage, such as separation
Difficulty in removal
Coating degradation or delamination

Adverse Events:

Death
Infection
Vessel dissection, trauma, perforation
Hemorrhage
Embolism (plaque, thrombus, device, tissue)
Thrombus
Infarction
Ischemia
Arrhythmia
Vasospasm
Vascular occlusion
Aneurysm rupture/perforation
Hemodynamic compromise
Aneurysm (false/dissecting)
Hypotension
Allergic reaction (to contrast, device)
Access site complications
Angina or unstable angina
Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA)
Renal insufficiency
Sterile inflammation or granulomas at access site

Tissue necrosis
Additional surgical intervention
X-Ray radiation exposure complications (e.g., alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia)

Directions for Use

1. Inspection prior to use:
   1.1 Before use, inspect carefully and confirm all devices and packages are undamaged.
2. Preparations for use:
   2.1 Remove the protecting hoop containing the guidewire from the sterile package.
   2.2 Before pulling the guidewire out of the protecting hoop, flush it with heparinized saline from the flared end of the protecting hoop to hydrate the guidewire at least for 30 seconds (Fig. 1). If it is difficult to pull the guidewire out from the hoop, flush it again with heparinized saline.

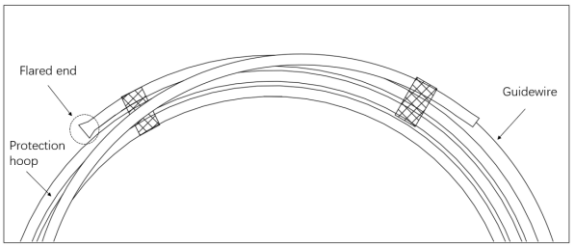

Fig. 1

   2.3 Take the guidewire's proximal end out of the hoop lock, then pull the guidewire out of the protecting loop. Do not force the guidewire out of the protecting hoop if you feel resistance when pulling. Inject heparinized saline to the hoop again, take out the guidewire for inspection to ensure that it is free of bends, kinks, or damage. If damaged, replace with another one.
   2.4 Shape the distal end of the guidewire into the intended shape using the attached shaping mandrel as needed using steps A-D below. Inspect the guidewire for damage before and after shaping the distal end.
   A. Hold the shaping mandrel in one hand, ensuring the tip of the guidewire is at a 90° angle to the shaping mandrel.
   B. Gently pinch the tip of the guidewire between the shaping mandrel and fingers.
   C. Carefully pull the mandrel towards the distal end of the guidewire to shape it.
   D. If necessary, repeat the above steps to achieve the desired shape.

   Warning: The shape configuration of the guidewire tip should not have a bend diameter of less than 2 mm or bend angle of over 90°. Do not shape the guidewire tip by methods beyond this instructed method, otherwise the coating integrity may be compromised.
   Warning: The guidewire tip can be reshaped up to 10 times. Do not reshape it more than this.
3. How to Use

   3.1 Before inserting the guidewire into an interventional device, wet it completely with heparinized saline.

   3.2 Insert the guidewire into an interventional device using inserter.

   3.3 Attach the accompanying torque device to the guidewire if necessary.

   3.4 Select the target vessel by carefully advancing or rotating the guidewire under fluoroscopy.

   3.5 After pulling the guidewire out of the body, rinse with heparinized saline to remove blood and keep the guidewire wet.

Storage Condition

Do not keep the product in a bent and/or heavily loaded condition. This product must be kept out of water. Store in a cool, dark, and dry place.

Expiration date

The expiration date is indicated on the label of the device package.

Contents

1 set per package including one neurovascular guidewire, one torque device and one shaping mandrel.

Liability Disclaimer

By no means shall "Enlight Medical Technologies (Shenzhen) Co., Ltd. and its affiliated companies" (hereinafter referred to as the "Company") be liable for accidents, personal injuries, adverse effects due to any improper use of the product(s) or any other use inconsistent with these instructions. In no event shall the Company be liable for any damage either (i) arising out of storage of the product(s) after the shipment from the Company or (ii) due to selection of patients, surgery techniques, or any other medical activities by medical institution that uses the product(s).

Symbols

	LOT number		Date of manufacture
	Do not reuse		Sterilized using ethylene oxide
	Consult instructions for use		Do not use if package is damaged
	Use by		Keep away from sunlight
	Keep dry		Do not resterilize
	Legal manufacturer		Caution, consult accompanying documents
	Catalogue number		Unit
	Rx only		Non-pyrogenic
	Shaping mandrel		Torque device

Enlight Medical Technologies (Shenzhen) Co., LTD.

5-6/F, Bldg A, Xinghui TIP, 52 Huaning Rd, Xinshi Com, Dalang St, Longhua Dist, Shenzhen, China

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