Coronary Guide Catheter

SheathLess Eaucath

SYMBOLS

	Legal manufacturer
	Do not use if package is damaged
	Do not reuse
	Do not resterilize
	Caution, consult accompanying documents
	Use by
	Keep dry
	Keep away from sunlight
LOT	LOT number
NON PYROGENIC	Only sterile and non pyrogenic in unopened packages
REF	Catalogue number
STERILE EO	Sterilized using ethylene oxide
Rx ONLY	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician
	Consult instructions for use

English

Coronary Guide Catheter
INSTRUCTIONS FOR USE

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

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

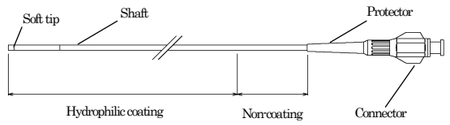
This Instructions for Use is applied to the SheathLess Eaucath Coronary Guide catheter. For specifications of each product, refer to the product label.

Descriptions

The product is composed of a guide catheter and dilator packed in a sterile pack. This sterile pack is packed in a box with this Instructions for Use.

The outer surface of this guide catheter is coated with hydrophilic polymer to provide high lubricity when the surface is wet. The inner lumen of the shaft (excluding connector portion) is lined with fluoropolymer layer to facilitate movement of the guide wire and other devices. The whole shaft is radiopaque.

3.43N (350gf) of force can be applied to this guide catheter when withdrawing the soft tip of catheter without damage, such as a separation.



Guide catheter

Dilator

Indications for Use

The SheathLess Eaucath Coronary Guide Catheter is intended to provide a pathway through which therapeutic and diagnostic devices are introduced.

The guide catheter is intended to be used in the coronary vascular system.

Contraindications

・Do not use this product in patients as follows:

a. Patients with severe heart failure.
b. Patients with hemorrhagic diathesis or renal failure.
c. Patients with intractable severe arrhythmia.
d. Patients with fever or systemic severe infection.
e. Patients with uncompensated heart failure.
f. Patients with severe pulmonary disease.
g. Patients with critical serum electrolyte disorder.
h. Patients with acute myocardial infarction.
i. Patients with blood coagulation disorder or severe change in coagulation ability due to some causes. (In case of applying this guide catheter for the patients described above in a-i, there is a possibility that the symptom may be worsened.)
j. Patients who have had any severe and distinct reaction against the agents or iodine solution necessary for the intended procedure. (Side effects such as allergic symptoms or shock disease may occur.)
k. Patients who cannot lie on their back on the table for angiography due to congestive heart failure or dyspnea.
l. Patients with mental disease or patients who do not consent to the angiography.
m. Patients who are or could be pregnant (the fetus is affected by X-rays under fluoroscopy.)
n. Patients who have undue peripheral vascular disease which inhibits the insertion of sheath introducer in appropriate size.
o. Patients with severely impaired left ventricular function.
p. Patients with gastrointestinal bleeding.
q. Any other patients who are judged unsuitable for the procedure by the physician.

Warnings

- This product and package are presterilized with ethylene oxide gas (EOG) and is intended for single use only. Do not reuse or resterilize. If reused or resterilized, the performance or quality of this product may be compromised and there is a risk of complications, including infection.
- Do not use the product after the expiration date indicated on the label. Discard any product that exceeds the expiration date.
- This product must be used under X-ray fluoroscopy only by a physician (or fully trained specialist) who is familiar with interventional procedures (PTCA).
- This product must be used in an institution where emergency surgical operation can be performed immediately.
- Do not use this product when the package is opened, damaged, or contaminated. Do not open the package until just prior to use. Use aseptic technique in handling and using this product.
- Do not use a damaged product.
- Do not use this product other than the purposes outlined in the "Indications for Use" section of this document.
- Do not modify this product for any reason. Never make new/additional side holes on the guide catheter shaft. [Making a side hole by any tool available in hospital may cause blood clot formation in the guide catheter shaft and/or deteriorate the product performance of guide catheter shaft.]
- Operate this guide catheter carefully, and if any resistance is felt, stop the manipulation and identify the cause of the resistance under X-ray fluoroscopy. Note that when using in combination with other devices, especially when inserting, for example, 5Fr device into 6.5Fr guide catheter, and the clearance between the lumen of guide catheter and the combined device is small, the combined device may be stuck in the catheter. [Otherwise, trauma and/or damage of the guide catheter may occur.]
- Do not insert the guide wire by force or advance it rapidly when the guide catheter is bent or twisted. [The guide wire may cause perforation or damage of the guide catheter, or result in trauma.]
- Torque manipulation to this guide catheter must be made only when a guide wire is inserted in. If the torque manipulation is made by only catheter, crush, bend, or twist of catheter may occur, and trauma or damage of catheter may result in.
- When torqing along the tortuous course of vessel to be inserted, take extra care and handle with caution because the manipulation may lead crush, bend, or twist of the catheter, and trauma or damage of the guide catheter may result in.
- During procedure, perform appropriate anticoagulant/antiplatelet therapy by taking the patient's condition into consideration.
- Manipulate the guide catheter in the vessel carefully by observing it under a high-definition X-ray fluoroscopy monitor screen. If any resistance is felt during operation or if torque manipulation is not transmitted to the catheter distal end, discontinue the operation and identify the cause. Catheter may be kinked and/or twisted. [Continued operation against resistance or removal of catheter by force may damage the blood vessel, or cause a separation of this guide catheter.]
- Before the insertion of the product, incise the skin at the site of angiographic guide wire insertion approximately 1-2 mm by surgical knife. [Inserting the product without making a incision may result in complication at the puncture site, trauma, or damage of the product.]

- This product is intended for percutaneous transluminal coronary angioplasty (PTCA), and should be used only for coronary arteries. Never use this product in cerebral blood vessels.
- Always refer to package inserts and/or Instructions for Use of medical devices or drugs to be used together with this product.

Precautions

- Prior to use, confirm all devices, including this product function normally. Check if the product is not damaged during transportation. Do not use if the package and/or the product is suspected to be damaged. Also, check that the specifications of the product are suitable for the indications for use and procedures.
- In case this product is inserted along an angiographic guide wire with hydrophilic polymer coating, advance this product gently, paying careful attention not to abrade the hydrophilic polymer of the guide wire by the tip of dilator of the product.
- Before use, make sure that the selected guide catheter is appropriate in size and shape, and compatible with other medical devices to be used in combination. Because the attached dilator is dedicated to this guide catheter, do not use it with other catheters regardless of manufacturer and catheter size. Do not use the guide catheter or the dilator alone.
- The maximum guide wire diameter is 0.89 mm (0.035 in.). Use only guide wires with a diameter 0.89 mm (0.035 in.) or less.
- Do not use ethiodol/lipiodol agents, or agents or organic solvents containing these drugs. [These agents may cause the erosion of the connector resin and result in fracture damage.]
- Since the tip of guide catheter is not tapered, it may cause embolization in small vessels. Use care to avoid total blockage of blood flow.
- When inserting this product into the blood vessel, pay attention not to damage the wall of vessel by the dilator and the tip of this guide catheter (the size or stiffness).
- In case the clearance between the device to be inserted in and the lumen of guide catheter is small, fully open the hemostatic valve and insert the device slowly in order not to cause air embolism.
- When taking this product out of the package, keep this product attached to the protective thick paper and take out the protective paper together with this product so as to avoid damage to the catheter and its distal tip.
- When withdrawing this guide catheter from blood vessel, it is recommended to reinsert the angiographic guide wire into the catheter, firstly, and reinsert the dilator into the catheter completely and lock it to the catheter prior to the withdrawal. Manipulating catheter alone may cause trauma or damage of catheter.
- Before injection of contrast media or drug, check this guide catheter for twist, crush or kink, and reconfirm the catheter is not occluded. Injection against anomaly may damage this guide catheter.
- When inserting or withdrawing a PTCA balloon dilation catheter, completely deflate the balloon before inserting into or removing from this product.
- Use extra care of the manipulation, if the lesion is onto the coronary ostium.
- This guide catheter is coated with hydrophilic polymer and has high level of lubricity. Consequently, always confirm the location of the tip under X-ray fluoroscopy and manipulate the guide catheter carefully.
- Prior to use this guide catheter, choose the appropriate catheter shape and size, corresponding to the anatomical shape of the ostium of target coronary artery.
- Operate slowly when inserting the dilator into the guide catheter. [Advancing it rapidly may apply excessive load onto the tip of guide catheter and result in damage of guide catheter.]
- Take preventive measures against infection after use. Discard this product as medical waste.
- According to preoperative coronary angiography, if there is a possibility the tip of guide catheter contacting plaque when engaging the guide catheter in the coronary ostium, the risk of coronary dissection is high. Avoid using guide catheter in this case.
- It is recommended to choose a catheter whose tip is coaxial to the coronary ostium. When the ostium has a steep angle which makes coaxial engagement impossible, the risk of coronary dissection is high. Avoid using guide catheter in this case.

Malfunction and Adverse effects

When using the product, the following malfunctions and adverse effects may occur. A serious adverse effects may lead to severe complication or death.

■ Malfunction

When using the product the following malfunctions may occur.

- Damage
  - ・Kink/twist
  - ・Damage of hydrophilic coating
  - ・Separation
- Withdrawal difficulty
- Insertion difficulty
- Occlusion of catheter lumen

■ Adverse effects

Possible complications and adverse effects of using this product include, but are not limited to:

- ・Cerebral infarction
- ・Subarachnoid hemorrhage
- ・Cerebral hemorrhage
- ・Other strokes
- ・Myocardial infarction
- ・(Unstable) angina
- ・Acute myocardial infarction
- ・Other heart diseases
- ・Bleeding complications
- ・Ischemic complications
- ・Vascular complications
- ・Ischemic peripheral vessel
- ・Cerebral ischemia
- ・Arrhythmia including ventricular fibrillation
- ・Allergy
- ・Hypotension/Hypertension
- ・AV fistula
- ・Angiospasm
- ・Fever
- ・Bradycardia/Palpitation
- ・Pulmonary embolism
- ・Renal failure
- ・Chill
- ・Distal vascular embolism (air, tissue, thrombus)
- ・Hematoma formation at femoral region/Other hematoma formation
- ・Pseudoaneurysm at femoral region/Other pseudoaneurysm
- ・Infection or complication of puncture site
- ・Trauma, including dissection, perforation, rupture
- ・Arterial embolism, thrombosis or embolization
- ・Convulsion
- ・Allergic reaction against contrast agent
- ・Hemorrhage or hematoma
- ・Subacute thrombosis

How to Use

The SheathLess Eaucath Coronary Guide Catheter is inserted through the aortic arch and is engaged at the coronary artery ostium only.

■ Preparation of catheter

1) When removing the product from sterile pack, take out the product with the protective thick paper, using sterile technique. In order to avoid damage to the product, remove the guide catheter and supplied dilator from the protective thick paper with care.

2) Flush the guide catheter and the dilator with heparinized and sterilized saline using syringe.

■ How to insert

1) Prepare patient for angioplasty with regular technique. Appropriate anticoagulant therapy or vasodilatory therapy is needed.
2) This guide catheter is intended to be used by inserting into radial artery or brachial artery by percutaneous means. Insertion to femoral artery is selectable at physician's preference.
3) Using sheath introducer, insert the angiographic guide wire, and then remove the sheath introducer. The combinations of guide catheter and sheath introducer are as follows:
   - Catheter: 6.5Fr ・・・Sheath introducer: 4Fr
   - Catheter: 7.5Fr ・・・Sheath introducer: 5Fr
4) Incise the skin at the site of angiographic guide insertion approximately 1-2 mm with a scalpel.
5) Insert the supplied dilator into the guide catheter completely and lock the connector of the guide catheter and the dilator. (Conduct this step immediately before insertion of the guide catheter to the patient, because leaving the dilator inserted in the guide catheter for a long time before insertion to patient may reduce the shape-memory property of the guide catheter tip.)
6) Insert the guide catheter gently and carefully along the angiographic guide wire inserted into the blood vessel. For smooth insertion of the guide catheter, add drops of heparinized and sterilized saline with a syringe to the catheter insertion to enhance the lubricity of the hydrophilic polymer of the product. If any felt, make the incision wider.
7) When the guide catheter reached aortic arch, separate the dilator from guide catheter, and then pull out the dilator from the catheter. Subsequently, remove the guide wire with regular technique. Flush the inside of catheter by aspirating with a syringe.
8) Advance the guide catheter to the target vessel and engage it.

■ Withdrawing of the catheter

Prior to withdrawing, insert the angiographic guide wire. Follow the steps below to reduce the risk of intimal injury to the artery.

1) Before withdrawing of the guide catheter after the completion of angioplasty, check for air within the catheter and aspirate as necessary.
2) When withdrawing the guide catheter, the angiographic guide wire should be inserted into the catheter.
3) When tip of this guide catheter is withdrawn to the aortic arch, insert the dilator completely along the angiographic guide wire, and lock the connector of the guide catheter and the dilator.
4) While keeping the guide catheter and the dilator locked, withdraw the catheter completely along the angiographic guide wire.

■ Replacing the catheter

While keeping the angiographic guide wire inserted in the blood vessel, withdrawing the locked catheter and dilator. For insertion of a new catheter, refer to above "How to insert" section.

Storage method

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 guide catheter package.

Contents

One piece of catheter

One piece of dilator

Liability Disclaimer

By no means shall "ASAHI INTECC 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 damages 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 the medical institution that uses the product(s).

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