Coronary Guide Catheter

SheathLess Eaucath

INSTRUCTIONS FOR USE

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.

1. Patients with bleeding tendency or severe change in coagulation ability due to some causes. (In case of applying this guide catheter for patients described above in 1, there is a possibility that the symptoms may be worsened.)
2. Patients who have had any severe and distinct reaction against the agent or a related solution necessary for the intended procedure. (Side effects such as allergic symptoms or shock caused by the procedure may occur.)
3. Patients who cannot lie on the table for angiography due to congestive heart failure or dyspnea.
4. Patients with mental disease or patients who do not consent to the angiography.
5. Patients who could be pregnant the time is allowed by X-ray under fluoroscopy.
6. Patients who have induced peripheral vascular disease which inhibits the insertion of sheath introducer in appropriate size.
7. Patients with severely impaired left ventricular function.
8. Patients with gastrointestinal bleeding.
9. Patients with blood coagulation disorder or severe change in coagulation ability due to some causes. (In case of applying this guide catheter for patients described above in 9, there is a possibility that the symptoms may be worsened.)
10. Patients with severe heart failure.
11. Patients with severe pulmonary disease.
12. Patients with acute myocardial infarction.
13. Patients with critical serum electrolyte disorder.
14. Patients with intractable severe arrhythmia.
15. Patients with hemorrhagic diathesis or renal failure.
16. Patients with severe pulmonary disease.
17. Patients with acute myocardial infarction.
18. Patients who are judged unsuitable for the procedure by the physician.

Precautions

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 the product.

Do not use 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 result in damage of the guide catheter shaft and/or deterioration of the product performance of guide catheter shaft.]

Do not reinsert this guide catheter. Do not use this guide catheter 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 procedure (PTCA).

To insert the guide catheter carefully and, if necessary, to 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, 9Fr device into 16Fr 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 deterioration of the guide catheter may occur.]

Do not use this product as a diagnostic device. Do not use this product to perform diagnostic device procedures in combination with other devices. [Inserting the product without making a incision may result in complication at the puncture site, trauma of the guide catheter shaft and/or deteriorate the product performance of guide catheter shaft.]

Dilator

Indications for Use

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

Contraindications

Consult instructions for use

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

Only sterile and non-pyrogenic in unpackaged packages

Keep away from sunlight

Keep dry

Use by

LOT number

Only sterile and non-pyrogenic in unpackaged packages

Catalogue number

Dilator

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

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To severe complication or death.

When using the product, the following malfunctions and adverse effects may occur. A serious adverse effect may lead to the death of the patient.

**Malfunctions**

- Damage
- Kinked or twisted
- Damage of hydrophilic coating
- Separation
- Withdrawal difficulty
- Insertion difficulty
- Occlusion of catheter lumen

**Adverse effects**

- Possible complications and adverse effects of using the product include, but are not limited to:
  - Cardiac intussusception
  - Subcutaneous hematoma
  - Cardiac perforation
  - Aortic dissection
  - Myocardial infarction
  - Acute myocardial infarction
  - Other myocardial complications
  - Vascular complications
  - Renal failure
  - Bradycardia/Palpitation
  - Arrhythmia including ventricular fibrillation
  - Cerebral ischemia
  - Ischemic complications
  - Ischemic peripheral vessel
  - Subarachnoid hemorrhage
  - Cerebral hemorrhage
  - Cerebral infarction
  - A V fistula
  - Renal failure
  - Bradycardia/Palpitation
  - Arrhythmia including ventricular fibrillation
  - Cerebral ischemia
  - Ischemic complications
  - Ischemic peripheral vessel
  - Subarachnoid hemorrhage
  - Cerebral hemorrhage
  - Cerebral infarction
  - A V fistula

**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 solicited by physician's experience.
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 8Fr → Sheath introducer 6Fr
   - Catheter 7Fr → Sheath introducer 5Fr
4. Insert the 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.)
5. 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 sterilized saline with a syringe to the catheter. In case of using this guide catheter in a patient, 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.
6. 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 syringes.
7. Advance the guide catheter to the target vessel and engage it.

**How to withdraw**

1. Prior to withdrawing, insert the angiographic guide wire. Follow the steps below to reduce the risks of internal injury to the artery.
   - Before withdrawing of the guide catheter, check for abnormality in the catheter and stop 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.

**Replacement of the catheter**

- While withdrawing the angiographic guide wire inserted into the blood vessel, withdrawing the locked catheter and dilator. Formation of a new catheter is referred to above “How to insert” section.

**Storage method**

- Do not keep the product in a heat and/or humidly 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.

**Preparation of catheter**

- 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 supply dilator from the protective thick paper with care.

**Liability Disclaimer**

- By no means shall “ASAHI INTECC CO., LTD.” be held liable for any damages either arising out of misuse of the product(s) or any other use inconsistent with these instructions. In no event shall the Company be liable for any damages either arising out of misuse of the product(s) or any other use inconsistent with these instructions. In no event shall the Company be liable for any damages either arising out of misuse of the product(s) or any other use inconsistent with these instructions. In no event shall the Company be liable for any damages either arising out of misuse of the product(s) or any other use inconsistent with these instructions. In no event shall the Company be liable for any damages either arising out of misuse of the product(s) or any other use inconsistent with these instructions.