XXX 2019

Kaneka Micro Catheter C/P-N1

Do not re-use

STERILE EO

Sterilized using ethylene oxide

[Warnings]

[Usage Methods]

- Before performing a procedure with the product, conduct appropriate anticoagulation or antiplatelet therapy according to the patient's condition. Otherwise, the procedure may induce complications such as thrombotic embolism.
- Intravascular manipulation must be performed carefully under high resolution X-ray fluoroscopy. If any resistance is sensed during the procedure, stop the procedure to identify and resolve the cause of the resistance. If continuing the procedure with the resistance, it may damage the blood vessel, and/or may cause damage or breakage of the product.
- The product must be entered into or removed from a strut of a stent carefully under high resolution X-ray fluoroscopy. Otherwise, it may lead to damaging the blood vessel, or causing damage or breakage of the product as a result of friction with the stent.
- Do not rotate the product while performing any manipulation during the procedure such as advancing in a stent or crossing a stenotic lesion. If doing so, it may cause damage or breakage of the product.
- When exchanging a guidewire while the product is inserted in the blood vessel, insert a guidewire carefully and if any resistance is sensed during the procedure, stop the procedure and remove the product and the guidewire together. If continuing the procedure, it may cause damage or breakage of the product.
- Before exchanging the product, wipe the guidewire with a piece of gauze or similar material moistened with saline to clean the surface of the guidewire. If anything is adhered, there is a contamination on to the guidewire surface or it is not sufficiently moistened, removal or insertion of the product along the guidewire may cause damage or breakage of the product.
- Do not manipulate the product without a guidewire-guidance. If conducting manipulation of the product without a guidewire-guidance, it may lead to damaging or perforating the blood vessel, and/or damaging the product.
- Repeated insertion and removal of the product may deteriorate the performance of the hydrophilic coating. If continuing using the product with deteriorated hydrophilic coating, it may lead to damaging the blood vessel, and/or causing damage or breakage of the product as a result of becoming trapped.
- When injecting contrast media or drugs, make sure that they are flowing out from the distal tip of the product. If they do not flow out, immediately stop injection and replace the product with a new one as there may be a kink, breakage or other abnormalities. Do not inject additional contrast media or drugs or use the guidewire to open the lumen as this may damage the product.
- Do not advance the guidewire swiftly or forcibly if any kink or bending exists in the product. If conducting insertion or manipulation of the product forcibly, it may cause perforation/damage of the product, or damage to the blood vessel.

[Contraindications and Prohibitions]

- Do not re-use.
- Do not resterilize.

[Patients in Whom the Use is Contraindicated]

- Patients with past history of coronary artery spasm. This procedure may cause acute coronary occlusion.
- Pregnant or possibly pregnant patients. X-ray may affect fetus to the patients
- Patients who are not applicable to undergo coronary artery bypass graft (CABG). In the event of an acute-phase ischemic complication, it may be necessary to perform emergency CABG.
- Patients with severe cardiac failure.
- Patients with hemorrhagic diathesis or renal failure.
- Patients with refractory severe arrhythmia.
- Patients with severe systemic infection or pyrexia.
- Patients with decompensated heart failure.
- Patients with severe pulmonary diseases.
- Patients with serious abnormalities of serum electrolytes.
- Patients with coagulation disorder or serious coagulative changes from any cause. Symptoms may be aggravated.
- Patients who have experienced and shown serious reactions to contrast media, iodine solution, or any other drugs required for procedures. If using the above drugs, such patients may be prone to adverse reactions, such as allergic reactions or shock.

[Contraindicated Conjunctive Medical Devices]

- Do not use or use in conjunctive with any drug containing organic solvents and oil-based contrast media. If using these agents, it may damage the product.
- When using an injector (automatic injection device, power injector), the injection pressure must be set at 1000 psi (6895 kPa) or less (in an open system). If conducting an injection at a pressure that exceeds the maximum Injection pressure, it may damage the product.
- Do not use any guidewire with a diameter exceeding the maximum guidewire diameter specified in the product specifications or other documents. If using a guidewire with a diameter exceeding the maximum guidewire diameter, it may cause resistance when inserting and removing the guidewire, and in some cases, it may cause damage or breakage of the product, and/or damage to the blood vessel.

- When using a guide catheter with stopcock, do not manipulate the stopcock while the product remains inserted in the blood vessel. If doing so, it may cause damage or breakage of the product.
- Do not use the product for delivering a detachable embolization coil.

[Contraindicated Usage]

- Do not use the product for severe calcified lesions.
- Do not use the product for the left main trunk that is not protected by bypass graft or collateral circulation. If using the product, this may result acute coronary occlusion.
- Do not use the product in the cerebral or carotid vessel.
- The product must be used only by physicians who are well trained in procedures, such as percutaneous transluminal coronary angioplasty (PTCA), coronary stent placement, angiography, and endovascular diagnosis/treatment, and are knowledgeable about associated problems and adverse events. If the product is used by physicians not sufficiently skilled in the procedure, serious problems associated with inappropriate use of the product may occur.
- Do not use the product in medical institutions where emergency CABG cannot be performed promptly. In the event of problems or complications, prompt action cannot be taken.
- Do not attempt to reshape the product. If doing so, it may cause damage or breakage of the product.
- Do not immerse the product in alcohol for disinfection or use other chemicals containing organic solvents. Also, do not wipe the product with any chemical agents. If doing so, it may cause damage or breakage of the product, or deteriorate the lubricity.

[Form and Structure]

[Intended Use, Indications]

The product is used for intravascular diagnosis/treatments to inject contrast media or drugs into a target lesion in a blood vessel. The product is a single-lumen catheter designed to facilitate vascular access by being used in combination with a guide catheter and a guidewire, and is capable of injecting drugs through the hub into the target lesion selectively in the blood vessel.

In addition, the product is used to secure the passage of a guidewire in patients with stenotic vessels (arteries, veins or shunts) into which guidewire penetration is difficult.

However, the carotid artery and intracranial cerebral vessels are excluded from the scope of use.

[Product Specifications]

Tensile strength: Catheter outside diameter < 0.75 mm: ≥ 3N
Catheter outside diameter ≥ 0.75 mm: ≥ 5N

Maximum guidewire diameter: 0.36 mm (0.014 inches)

[Usage or Operation Methods]

1. Preparation of the Product

1-1. Take the product as packed in the carrier tube out of the sterile package.

1-2. Place the product with the carrier tube in a tray and immerse them in heparinized saline.

1-3. Inject heparinized saline into the carrier tube through the flush connector using a syringe until the solution comes out from the end of the carrier tube.

Caution

- Inject heparinized saline slowly into the carrier tube. Take care to prevent the product falling out of the carrier tube.

1-4. Remove the product from the carrier tube, and inspect the product to make sure whether the surface is lubricated. If resistance is sensed when removing the product from the carrier tube, inject heparinized saline into the carrier tube again to make the product surface lubricated.

Caution

- Do not bend the product at the end of the carrier tube to remove the product. If doing so, it may cause damage or breakage of the product.

2. Insertion of the Product

2-1. Inject heparinized saline through the hub to fill the catheter lumen with heparinized saline.

2-2. Insert a guidewire with a diameter smaller than the maximum guidewire diameter through the hub into the catheter lumen, and advance it till the guidewire tip is aligned with the distal tip of the product.

Caution

- If inserting the guidewire from the distal tip of the product, do it carefully to avoid damaging the product.

2-3. Unfasten the hemostasis valve of the Y-connector connected to the guide catheter and insert the product.

Caution

- Ensure that the hemostasis valve has been unfastened. If the hemostasis valve is not sufficiently unfastened, this may cause resistance when inserting the product.
- Do not manipulate the product while the hemostasis valve is unfastened. Also, do not fasten the hemostasis valve excessively. If doing so, it may damage the product.

2-4. Under high resolution X-ray fluoroscopy, advance the product until it reaches 2–3 cm proximal to the distal end of the guide catheter. Then, fasten the hemostasis valve to hold the product.

Caution

- Insert the product carefully if other device has already been inserted in the guide catheter. The other device may be pushed forward accompanied by inserting the product, and may damage the blood vessel.

2-5. Under high resolution X-ray fluoroscopy, insert the guidewire into the target blood vessel and advance it as distal as possible or to the appropriate position in the target vessel.

2-6. Inject contrast media through the guide catheter to confirm that the guidewire has reached or passed through the target lesion. View the angiogram from multiple angles to ensure that the guidewire is inserted into the target blood vessel.

2-7. Unfasten the hemostasis valve and then, with securely holding the guidewire and the guide catheter, advance the product forward gradually along the guidewire until the catheter tip reaches or passes through the target lesion using the radiopaque marker on the distal tip of the product as a guide. Then, fasten the hemostasis valve to hold the product.

Caution

- As the product has a hydrophilic coating, be careful when manipulating the product inside the blood vessel.
- If the blood vessel is smaller than the outside diameter of the catheter tip, the product must be inserted into the blood vessel with utmost care at the discretion of a physician. If conducting the insertion carelessly, it may cause the blood vessel injury.
- If the blood vessel is severely tortuous, insert the product into the blood vessel carefully at the discretion of a physician.
- Do not rotate the product if it is trapped or seems to be trapped in the blood vessel. If doing so, it may cause damage or breakage of the product.

2-8. Remove the guidewire carefully not to introduce air bubbles in the catheter lumen, and then inject the contrast media, drug, or embolization material as needed. After injection, make sure to insert back the guidewire into the catheter lumen.

3. Removal of the Product

3-1. Unfasten the hemostasis valve.

3-2. With the guidewire remained in the blood vessel, remove the product by pulling straight back along the guidewire.

3-3. After removing the product, fasten the hemostasis valve.

Caution

- Confirm the position of the guidewire under high resolution X-ray fluoroscopy when removing the product from the blood vessel.
- If resistance is sensed while removing the product, withdraw together with the guide catheter and the guidewire.
- When removing the product with remaining the guidewire in the blood vessel, be careful not to injure the blood vessel by the guidewire.

[Precautions for Use related to the Usage Methods]

- When placing the product in a tray filled with heparinized saline, be careful as it may spring out owing to catheter shaft resilience.
- Handle the product carefully not to damage the tip as it is very soft.
- Do not add excessive stress to the catheter hub. If doing so, it may cause damage or breakage of the product.

[Precautions for Use]

[Important, Basic Precautions]

- Consult the prescribing information of drugs, the instructions for use and/or the operation manuals of medical devices to be used in conjunction with the product.
- After removing the product from the patient's blood vessel, rinse away blood on its surface by immersing and rinsing the product in a tray filled with heparinized saline. When it is difficult to rinse away the blood, gently wipe the surface once with a piece of gauze or similar material moistened with heparinized saline. Rinse away blood in the catheter lumen of the product by flushing with heparinized saline.
- Carefully handle the product not to kink it. When the product is kinked, stop using it. If conducting manipulation of the product with kinking, it may cause damage or breakage of the product.
- When inserting an angled guidewire into the product inserted in the blood vessel, insert the guidewire carefully into the product. Under high resolution X-ray fluoroscopy, stop advancing the guidewire just before the tip of the guidewire comes out from the tip of the product, and withdraw the product carefully so that the guidewire comes out from the tip of the product. If the guidewire spring out from the tip of the product, it may cause the blood vessel injury.
- If the physician chooses to use a stiff tip guidewire, insert the guidewire into the product carefully, and manipulate gently while confirming its movement under high resolution X-ray fluoroscopy. Otherwise, the guidewire may penetrate through the shaft of the product and may cause the blood vessel injury.
- Before commencing the procedure, make sure that all devices and instruments are in good condition.
- Do not use the product in the event of any abnormalities, such as any damage or stain of the package, or damage of the product.
- All the procedures must be carried out under aseptic conditions.
- Use the product immediately after opening the package and dispose of the product in a safe and proper manner after use.
- Inspect the product to make sure that there is no focal collapse, kink, distortion, or occlusion, before injecting contrast media or drugs.
- Do not inject drugs or contrast media using the injector (automatic injection instrument, power injector) when the product is kinked or occluded. In such the situation, even when injection is performed under the maximum injection pressure, the product may be damaged.
- Before using the product, fill heparinized saline in the carrier tube and make sure that the entire surface of the product is wet.
- If the surface of the product becomes dry, immerse the product in heparinized saline again to recover the surface lubricity.
- If any resistance is sensed when taking the product out of the carrier tube, do not pull out the product forcibly. Instead, infuse more heparinized saline into the carrier tube and then, attempt to pull out the product.
- Do not tap the hub excessively to purge air. If doing so, the hub may be damaged.
- When inserting or removing the product, perfuse sufficiently with heparinized saline and connect an extension wire to the guidewire or insert a long guidewire for catheter exchange before insertion or removal of the product. Handle carefully when connecting the extension wire to the guidewire as there may be resistance when the distal tip of the product passes through the connection.
- During the procedure, perfuse the catheter lumen of the product and the guide catheter lumen with heparinized saline. Perfuse thoroughly, especially after injecting contrast media or embolization materials. Residual contrast media or blood clots may deteriorate the lubricity performance.

- Inject only contrast media when using the injector (automatic injection device, power injector) in conjunctive with the product. Do not use the injector for other drugs.
- If resistance is sensed while advancing the product into the guide catheter, do not attempt to advance the product forcibly but remove the product and inspect both the product and the guidewire for any abnormality.
- Do not attempt to bend the product excessively and focally during manipulation. If doing so, it may cause the blood vessel injury or damage of the product.
- Do not use the product when any abnormalities are found. In the event an abnormality such as leakage or occlusion occurs during the procedure, stop using the product and replace it with a new one.
- Do not attempt to damage the product with a scalpel, scissors, or forceps.
- When there is a case that the catheter lumen is occluded or resistance is sensed from any cause while manipulating the guidewire or an embolization coil, stop manipulation, remove and replace it with a new one.
- When the product is kinked during procedure, stop advancement or manipulation, remove and replace it with a new one.
- During the use of the product, pay attention to the patient's vital signs such as body temperature, pulse, and respiration**.** When any abnormality in the patient's condition is observed, stop the procedure immediately or take appropriate measures at the discretion of the physician depending on the patient's condition.
- Do not manipulate the product swiftly or forcibly. If doing so, it may damage the intima of the blood vessel.
- If the maneuverability of the product is deteriorated while the product is in the blood vessel, remove the product together with the guide catheter and the guidewire.

[Device Failure]

Since the product is precisely manufactured, applying abrupt force to the product during a procedure may result in the following device failure. Therefore, the product must be used carefully in accordance with the precautions for use.

- Kinking
- Distortion
- Damage
- Breakage
- Difficulty in removal
- Difficulty in insertion

[Adverse Events]

The following adverse events may occur in association with procedures. If a serious adverse event occurs, it may lead to the death of the patient or serious complications. In the event of a complication, appropriate remedial action must be taken at the discretion of the physician. (Adverse events are not limited to the following. Read the instructions for use carefully to prevent such events.)

- Acute myocardial infarction
- Complete coronary occlusion
- Vascular dissection, perforation, rupture, and injury
- Hemorrhagic complication
- Myocardial ischemia
- (Unstable) Angina
- Arrhythmia including ventricular fibrillation
- Arterial embolism/thrombosis/occlusion
- Allergic reaction to drugs
- Hypotension/hypertension
- Infection and puncture-site complication
- Vascular spasm
- Arteriovenous fistula
- Bradycardia/palpitation
- Cerebrovascular disorder
- Ischemic complication
- Peripheral vascular ischemia
- Other heart diseases
- Pyrexia
- Pulmonary embolism
- Chill
- Renal failure
- Internal bleeding or hematoma
- Aortic dissection
- Femoral pseudoaneurysm
- Death
- Device breakage resulting in remaining broken parts in the blood vessel
- (Air, tissue, thrombotic) Embolism in distal sites

[Storage Method and Expiration Period]

1. Store in a clean and cool place avoiding getting wet and direct sunlight, extreme temperature, or high humidity.
2. The expiration date is indicated on the box.
   Do not use after the expiration date.

[Package]

1 piece / box

[Name and Address of Manufacturer and Manufacturing Site]

[Manufacturer]

Name: KANEKA CORPORATION
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[Manufacturing Site]

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