Warnings:

Carefully read and observe all Warnings.

- If any resistance or something abnormal is felt when operating this product, do not continue the operation while the causes are unclear. If it is suspected that the product is not operating correctly, avoid excessive manipulations, and carefully remove the entire catheter system while paying full attention to avoid complications. If there are complications as a result of the removal of the entire system, stop immediately the percutaneous transluminal coronary angioplasty (PTCA), and perform appropriate treatment at the discretion of the physician. (Continuing the operation while the cause of the problem is not identified may cause damage to or rupture of the catheter, and damage the blood vessel. In the worst case, life-threatening adverse events may result.)

- Always hold the connector with one hand and turn the catheter carefully while regularly releasing the accumulated torsion of the catheter. Never turn the catheter continuously while holding the connector with both hands or use any other means to apply force. When releasing the accumulated torsion, be sure to open the hemostatic valve on the Y connector. Do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 20 consecutive turns. If resistance is felt while turning the catheter, do not proceed with further rotation even if the 20 turn limit has not been reached. Identify the cause of resistance under fluoroscopy, and take an appropriate action. Never continue the operation without identifying the cause. While rotating the catheter, carefully observe the proximal end of the cover tube (the section of 5cm length from the protector). If any breakage is recognized in this section during rotation, stop the rotation and remove and exchange the catheter while paying full attention. (Continuing rotation may damage or rupture the catheter or damage the blood vessels. In the worst case, life-threatening adverse events may result.)

- Exercise due caution when turning the catheter continuously in the same direction, either clockwise or counterclockwise, as it may increase the risk of damaging or rupturing the catheter or the blood vessels. (In the worst case, life-threatening adverse events may result.)

- If a strong reaction is felt in the opposite direction of rotation when the catheter is advanced toward or withdrawn from the lesion, the catheter may be caught. Operate the catheter carefully and do not forcefully continue the procedure. (It may damage or rupture the catheter or damage the blood vessels. In the worst case, life-threatening adverse events may result.)

- Closely observe to ensure that the guidewire is tightly secured and not following the catheter movement during catheter operation. If the guidewire follows and moves in concert with the push, pull, or rotation of the catheter, stop the operation immediately and avoid further operation while the causes are unclear. In such a situation, avoid excessive manipulations, and carefully remove the catheter together with the guidewire while paying full attention to avoid complications. If the removal of the catheter together with the guidewire is impractical, stop immediately the procedure, and perform appropriate treatment at the discretion of the physician. (Continuing the operation may cause the guidewire to break or become damaged, which may injure the blood vessel. In the worst case, life-threatening adverse events may result.)

- Never use guidewires larger than the recommended size. (Resistance may be felt while advancing or withdrawing a guidewire larger than the recommended size, which may cause the catheter to become damaged or break, or the blood vessel to become damaged. In the worst case, life-threatening adverse events may result.)

- This catheter must be used under fluoroscopy only by a physician who is fully trained in PTCA. (Unskilful procedure may cause an error in operation or misjudgment, leading to damage to the blood vessel. In the worst case, life-threatening adverse events may result.)

- It is recommended that this catheter only be used at a medical institution capable of promptly performing an emergency coronary bypass operation. If the emergency operation is not performed promptly when needed, for example, in the case of an accidental patient injury during a procedure using TORNUS, in the worst case, life-threatening adverse events may result.

- Always confirm that the guidewire is advanced ahead of the catheter before attempting any manipulation of the catheter, such as advancement, withdrawal and rotation. (If the guidewire is not advanced ahead, the blood vessels may be damaged. In the worst case, life-threatening adverse events may result.)

- During the procedure, the patient needs an appropriate anticoagulant or antiplatelet treatment depending on the patient's clinical conditions. (In the absence of an appropriate treatment, thrombi may form, leading to complications. In the worst case, life-threatening adverse events may result.)

- In the same way as advancing the catheter toward the lesion, operate the catheter carefully when withdrawing the catheter. If any abnormal resistance is felt and occurrence of complication is likely, immediately stop the percutaneous transluminal coronary angioplasty (PTCA). If the procedure is required to be stopped, the physician should evaluate the possible need to perform an emergency bypass surgery or other appropriate procedure at the discretion of the physician. (In the worst case, life-threatening adverse events may result.)
Contraindications and prohibition: Life-threatening adverse events may ensue.

• This product is intended for single use only. Do not resterilize and/or reuse.
• This product should not be used if the package is damaged or open.
• This product must be used exclusively for coronary artery. Never use it for other kinds of blood vessels.
• Do not perform procedures using the catheter on patients who are or could be pregnant. (The fetus is affected by X-rays under fluoroscopy.)
• Do not apply this product to patients who are not eligible for coronary bypass operation, or have exhibited a severe allergic reaction to operation-related drugs, such as contrast media.
• Do not apply this product to patients who are considered by the physician in attendance to be ineligible.
• Do not apply this product to lesions where this catheter needs to pass through stent strands stent struts.

Precautions for use

• Warning
This product is intended for single use only. Do not resterilize and/or reuse. Do not use if the package is opened or damaged. Always open the package just prior to use.

• Important precautions
1) Prior to use, always confirm that the product is compatible with peripheral equipment pertinent to PTCA.
2) Do not modify the product for whatever purpose.
3) Prior to use, flush the inside of the holder and of the catheter with heparinized and sterilized saline, and confirm that all the surfaces are wet before taking out the product for the insertion procedure.
4) If the product is distorted, for example, bent or broken, due to accidental damage during operation, discontinue the use of the catheter.
5) Be sure to use the product before the expiration date indicated on the label.
6) When using hydrophilic-coated guidewires, carefully manipulate the guidewire and the catheter to avoid abrasion of the hydrophilic coating on the guidewire.
7) Do not wet the surface of the product with alcohols, gluconic acid chlorhexidine aqueous solution, or the like, nor wipe the surface with gauze or absorbent cotton soaked with such solvents.
8) Do not use the product for drug solution injections because the product shaft is not tight enough to seal liquid; and the product connector is made of polycarbonate, which may come in contact with and eroded by some kind of drug solution.
9) If any crack is detected on the connector, immediately replace the catheter with a new one.
10) Either attach an extension wire to the guidewire or use a longer guidewire before inserting or removing the product. Do not adopt the catheter removal method (commonly known as Nanto method) in which the catheter is removed by making use of the injection pressure of heparinized and sterilized saline.
11) When the catheter is reinserted into the body, be sure to flush the catheter again to remove thrombosis on the surface.
12) Use an inserter to insert a guidewire through the connector of the product.
13) It may happen that the catheter advances too far toward periphery over the target area of the operator’s aim. The manipulation of the product demands careful attention to the position and movement of the catheter tip under fluoroscopy.
14) Gently wipe blood or contrast medium particles adhering to the surface of the product with gauze or absorbent cotton soaked with heparinized and sterilized saline. However, never use gauze or absorbent cotton wetted with drugs or other kinds of solvents.

• Interaction
<Precautions for combined use of other devices>
Comply with instructions, precautions, and warnings described in the user’s manuals supplied with each guidewire, catheter, or medical device, used together with the product.

Shape and structure

[Materials]
Shaft: Stainless steel
Coating: Silicon coat (both inner and outer surfaces of the shaft)
Radiopaque marker: Platinum
Performance and indication for use

Indication for use
- This product is intended to be used in conjunction with a steerable guidewire to access discrete region of the vasculature, and for guidewire exchange.

Specifications
- Tensile strength: 3.0 N (306 gf) or higher
- Recommended guidewire diameter: 0.36 mm (0.014 inch)

How to use
- This product can be used directly by aseptically opening the package, because it is sterilized by gas sterilization with ethylene oxide before shipment. Notice, however, that the product is disposable and its reuse is not allowed.
- Prior to use, inspect carefully and confirm that the product and its package are not damaged during transportation. Never use any one of the products, for whatever reason, if it is suspected of being contaminated or damaged.

1. Preparation of the product
Take out the product from the sterile pack aseptically and cautiously to avoid twisting it or bending it sharply, and soak it in the container filled with heparinized and sterilized saline.

2. Insertion of the product
2-1 Flush the product through its connector with heparinized and sterilized saline to remove bubbles.
2-2 Insert in advance a guidewire having a diameter of 0.36 mm or less through the product connector, until the guidewire tip meets the product tip.
2-3 Loosen the hemostatic valve on the Y connector that is connected to the guiding catheter, and insert the product into the guiding catheter.
2-4 Under fluoroscopy, advance the product slowly toward 2 to 3 cm short of the guiding catheter tip.
2-5 Under fluoroscopy, advance only the guidewire through the coronary artery of interest.
2-6 When additional support is required for the insertion of a guidewire, advance this product along a guidewire. The tip of this device contains radiopaque markers to assist in positioning and aiming the device.
2-7 When this product is not advanced/hindered by a stenosed area, and/or when an enough guidewire support is not obtained, secure tightly both the guidewire and the guiding catheter. Then, advance the product slowly along the guidewire and observe the movement of the radiopaque markers to determine if the product tip passes through and over the stenosed area.
2-8 Repeat steps 2-5 to 2-7 as necessary, and confirm ultimately that the product traverses the stenosed area.

3. Removal of the product
3-1 Loosen the hemostatic valve on the Y connector.
3-2 Remove the product while keeping the guidewire left inserted in the blood vessel.
    (Remove the product after either attaching an extension wire to the back end of the guidewire or exchanging with a longer guidewire.)

4. Defects and adverse events
Defects and adverse events may ensue from the improper use of the product. A serious adverse event may lead to a severe complication or death. Prevent such defects and adverse events from occurring by carefully reading this document and complying with the directions contained in it.

1) Defects
   - Twist and sharp bend
   - Damage
   - Rupture
   - Removal difficulty, etc

If these defects arise, avoid excessive manipulation, and carefully remove the entire catheter system while paying full attention to avoid complications.

Note: If the catheter is damaged, this product may cut into a blood vessel wall. Extreme caution needs to be taken when removing a damaged device.

In the case of complications resulting from the removal of the entire system, stop immediately the procedure, and perform appropriate treatment at the discretion of the physician.

2) Adverse events
   - Acute myocardial infarction
   - Unstable angina
   - Arrhythmia including ventricular fibrillation
   - Blood vessel damage, etc
Storage method and expiration date

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 product package (by in-house certification).

Content
・ One catheter

Liability Disclaimer

By no means shall “ASAHI INTECC CO., LTD.” (hereinafter referred to as the “Company”) be liable for accidents, personal injuries, adverse effects due to any improper use of the product(s) disobedient to 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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