

TORNUS

INSTRUCTIONS FOR USE

SYMBOLS



Legal manufacturer



Catalogue number



Batch code/LOT number



Do not reuse



Do not re-sterilize



Consult instructions for use



Do not use if package is damaged



Caution, consult accompanying documents



Keep away from sunlight



Keep dry



Number of units

RX
ONLY

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



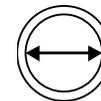
Sterilized using ethylene oxide



Only sterile and non pyrogenic in
unopened packages



Use by



Inner diameter

TORNUS

INSTRUCTIONS FOR USE

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

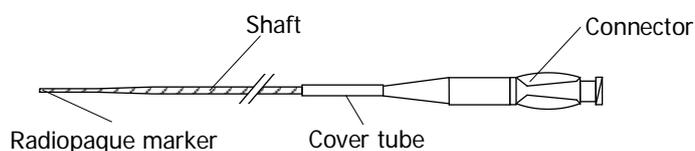
Read these instructions carefully before using the product and observe the Indications for Use, Warnings, Precautions and How to Use sections in the Instructions for Use. Failure to do so may result in complications, including serious injury to the patient or death.

Description

The product is composed of a catheter packed in a holder tube. The product is packed in a sterile pack. This sterile pack is packed in a box with this Instruction for use.

This product is composed of shaft, cover tube and connector. The both inner lumen and outer surface of the shaft is coated with silicone coating. The distal end of the shaft is clearly distinguished by a radiopaque marker.

Shape and structure



[Materials]

Shaft:	Stainless steel
Coating:	Silicone coating (both inner and outer surfaces of the shaft)
Radiopaque marker:	Platinum

Specifications

Tensile strength: 3.0 N (306 gf) or higher

Recommended guidewire diameter: 0.36 mm (0.014 inch)

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.

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 or peripheral arteries. 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 on the left coronary artery main trunk, which is not protected by a bypass or collateral circulation.
- Do not apply this product to patients with anamnesis of coronary spasm.
- Do not apply this product to lesions where this catheter needs to pass through stent struts.

Warnings

Carefully read and observe all Warnings.

- This catheter 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. If reused or resterilized, the performance or quality of the product may be compromised and there is a risk of complications, including infection.
- If any resistance or something abnormal is felt when operating this catheter, 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) or the percutaneous transluminal angioplasty (PTA), 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 breakage 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 break 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 breaking 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 break 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 or guide wire 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 or PTA. (Unskillful 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 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) or the percutaneous transluminal angioplasty (PTA). 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.)

Precautions for Use

- Important precautions
 - 1) Prior to use, always confirm that the product is compatible with peripheral equipment pertinent to PTCA or PTA.
 - 2) Do not modify the product for whatever purpose.
 - 3) Prior to use, the catheter must be soaked in a vat filled with sterile heparinized saline prepared in advance. Make sure the entire surface of the catheter is wet before taking it out from the vat, then insert the catheter in the vessel.
 - 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 guidewire(s) (including polymer-covered guidewire), carefully manipulate the

guide wire and the catheter to avoid abrasion of the hydrophilic coating (and/or polymer cover) 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) Before insertion of the guidewire into the catheter and/or advancing the catheter over the guidewire, wipe the blood and contrast medium adhering to the surface of the guidewire (section out of body) with gauze or absorbent cotton wetted with sterile heparinized saline.
- 12) Use an inserter to insert a guidewire through the connector of the product. Make sure to remove the inserter after insertion. In addition, never use a metallic inserter.
- 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) Before re-inserting the catheter into the body, make sure to keep this catheter in a vat filled with sterile heparinized saline prepared in advance, rinse the catheter in the vat by flushing the sterile heparinized saline into the catheter by syringe in order to remove the blood and adhered contrast medium. Gently wipe blood or contrast medium particles adhering to the surface of the product with gauze or absorbent cotton soaked with sterile heparinized saline. However never use gauze or absorbent cotton wetted with drugs or other kinds of solvents.
- 15) Carefully manipulate this catheter and the guide wire used in conjunction. The distal end of the guide wire can get stuck inside this catheter, depending on the shaping condition. If advanced by force, it is possible for the guide wire to suddenly come out of the distal end of this catheter. Damage to the vessel may result.

- 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.

- Other precautions

Take preventive measures against infection after use. Discard this product as medical waste.

Malfunction and adverse events

Malfunctions 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 malfunctions and adverse events from occurring by carefully reading this document and complying with the directions contained in it.

- 1) Malfunction

- Twist and sharp bend
- Damage
- Separation
- Removal difficulty, etc

If a malfunction arises, avoid excessive manipulation, and carefully remove the entire catheter system while paying full attention to avoid complications.

Note: If the catheter is damaged, this catheter 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

How to Use

- This catheter can be used immediately 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 catheter aseptically from the package paying attention not to cause bend or kink. Keep this catheter in a vat filled with sterile heparinized saline and remove the bubbles inside the catheter.

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 artery of interest.
- 2-6 When additional support is required for the insertion of a guidewire, advance this catheter along a guidewire. The tip of this device contains radiopaque markers to assist in positioning and aiming the device.
- 2-7 When this catheter is not advanced by a stenoses, and 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 proximal end of the guidewire or exchanging with a longer guidewire.)

Storage method and expiration date

Storage method

- Do not keep the product in a bent and/or heavily-loaded condition. This catheter 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) 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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