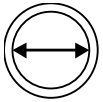
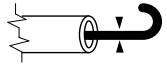
ASAHI Corsair
INSTRUCTIONS FOR USE

SYMBOLS

	Legal manufacturer		Do not use if package is damaged		Minimum GC I.D.
	Catalogue number		Caution, consult accompanying documents		Maximum injection pressure
	Batch code/LOT number		Do not reuse		Inner diameter
	Contents		Do not resterilize		Use by
	Unit		Keep away from sunlight		Keep dry
	Only sterile and non pyrogenic in unopened packages		Sterilized using ethylene oxide		Recommended guidewire diameter
	Catheter				

AMK-DT226 Ver.1.01/11TS050

ASAHI Corsair

Instructions for Use

For single use only

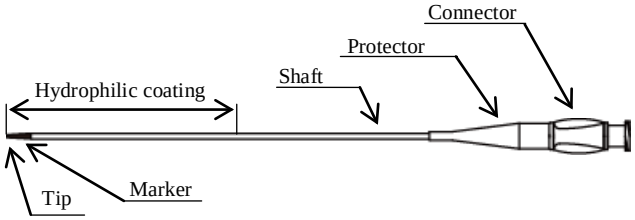
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Description

The product is composed of a microcatheter packed in a holder tube. The product is packed in a sterile pack. This sterile pack is packed in a box with this Instructions for Use.

The outer surface of this microcatheter 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 guidewire and other devices. The whole shaft is radiopaque, and the distal end is clearly distinguished by a radiopaque marker.

Shape and structure



Materials of the microcatheter

Outer layer:	Polyamide elastomer
Tip:	Polyurethane
Surface coating:	Hydrophilic coating
Inner layer:	PTFE
Reinforcing material:	Tungsten and stainless steel

Specifications

Table 1 The specifications of ASAHI Corsair

	ASAHI Corsair Microcatheter
Microcatheter O.D.	0.87 mm / 0.93 mm (2.6 Fr. / 2.8 Fr.)
Microcatheter I.D.	0.45 mm (0.018”)
Recommended Guidewire O.D.	0.36 mm (0.014”)
Minimum Guiding catheter I.D.	1.05 mm (0.041”)
Maximum Injection Pressure	2070 kPa (300 psi)
Tensile Strength	5 N (510 gf) or higher

・This microcatheter can withstand a maximum pressure of 2070 kPa (300 psi) when the distal end is open.

Indications for use

The ASAHI Corsair Microcatheter is intended to provide support to facilitate the placement of guide wires in the coronary and peripheral vasculatures, and can be used to exchange one guide wire for another.
The ASAHI Corsair Microcatheter is also intended to assist in the delivery of contrast media into the coronary, peripheral and abdominal vasculatures.

Contraindications and prohibition: Life-threatening events may occur.

This product is for single use only. Do not resterilize and/or reuse.

If this product is reused and/or resterilized, there is a strong possibility of one or more of the following adverse events occurring, and the possibility of injury to the patient even if the product is used in an appropriate manner. In the worst case, life-threatening adverse events may result.

- Infection due to inappropriate and/or insufficient sterilization
- Deterioration, breakage and/or rupture of the product due to abrasion of coating on the product's surface.
- Breakage and/or rupture of the product due to metallic fatigue.

1) Do not modify this product for any reason. Use of a modified product may occur damage to blood vessels and/or accidents.
2) It is recommended that this product 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 this product, in the worst case, life-threatening adverse events may occur.
3) This product must be used under fluoroscopy only by a physician who is fully trained in PTCA. (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 occur.)
4) Do not use this product for patients with following disorders.
   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 other causes. (In case of applying this microcatheter for the patients described above in a-i, there is a possibility that the symptom may be worsened. In the worst case, life-threatening events may occur.)
   j. Patients who have had severe and distinct reaction against the agents necessary for the intended procedure. (Side effects such as allergic symptoms or shock disease may occur. In the worst case, events may be life-threatening.)
   k. Patients who cannot lie on their back on the table for angiography because of congestive heart failure or dyspnea.
   l. Patients with mental disease or patients who do not consent to angiography.
   m. Patients who are or could be pregnant. (The fetus may be affected by X-rays under fluoroscopy.)
   n. Any other patients who are judged unsuitable for the procedure by the physician.
   o. Do not apply this product to lesions on the left main trunk, which is not protected by a bypass or collateral circulation.

p. Do not apply this product to patients with anamnesis of coronary spasm.

5) Do not use in advanced calcified lesions
6) Do not use oleaginous contrast media. (The device may be damaged.)
7) The device must not be used for drug infusion. (The device is not designed for drug infusion and its safety has not been established.)
8) Agents containing organic solvent such as alcohol must not be used either alone or concurrently. These agents must not be used for immersing or wiping the device. (The catheter may be damaged or lose its lubricity.)
9) When using a Y-connector, excessive tightening to the product with the hemostasis valve and operation with a tightened Y-connector must be avoided. (The device may be damaged.)
10) Excess rotational load must not be applied if the device is bent. (The device may be damaged or cut.)
11) The device must not be used for cerebral vessels. (The device is not designed for cerebral vessels and its safety has not been established.)
12) Medical devices used together with the microcatheter.
When this microcatheter is inserted in a guiding catheter fitted with a stopcock, do not manipulate the stopcock. Such manipulation may damage or break the microcatheter.
This microcatheter is made of tungsten and stainless steel braiding, and a combination of polyamide elastomer and polyurethane. The inner lumen of the shaft is lined with fluoropolymer. When performing a diagnostic procedure, do not use substances such as alcohol, which may damage, dissolve or swell the materials used in this microcatheter.

Warnings

Carefully read and observe all Warnings. Failure to do so may result in life-threatening events in the worst case.

- Do not use this microcatheter for cerebral blood vessels because this microcatheter is not intended for cerebral blood vessels.
- 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. (Continuing the operation while the cause of the problem is not identified may cause damage to or separation of the catheter, and damage the blood vessel. In the worst case, life-threatening adverse events may occur.)
- The device must always be operated under high-resolution fluoroscopic guidance. Particular attention should be paid when inserting or withdrawing the device into stenotic areas, stent struts, and narrower vessels than the product. (Abrasion may result in damage or separation of the device. This may cause vascular injury and perforation, possibly leading to a life-threatening adverse event.)
- Do not insert the guidewire by force or advance it rapidly when the microcatheter is bent or twisted. Such manipulations may cause breakage or damage of the microcatheter, or perforation of the blood vessel.
- Always advance the guidewire ahead of the microcatheter before attempting any manipulation of the microcatheter. (If the guidewire is not advanced ahead of the microcatheter, the blood vessel may be damaged or perforated, or the microcatheter may be damaged.)
- 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 10 consecutive turns. If resistance is felt while turning the catheter, do not proceed with further rotation even if the 10 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. (Continuing rotation may damage or break the catheter or damage the blood vessels. In the worst case, life-threatening adverse events may occur.)

- This microcatheter is coated with hydrophilic coating. Therefore, the microcatheter is highly lubricious. Always confirm the position of the distal end of this microcatheter by fluoroscopy and manipulate this microcatheter carefully.
- Do not use a power injector to infuse contrast media when the microcatheter is bent or occluded. It may cause damage to the microcatheter such as expansion or breakage.
- Injection pressure must not exceed 2070 kPa (the maximum injection pressure) when injecting contrast media by using power injector. Exceeding the injection pressure beyond the maximum injection pressure may cause damage to the microcatheter.
- When infusing contrast media, the device must be operated under high-resolution fluoroscopic guidance, with confirming that the contrast media is being infused from the tip of the device. If the contrast media is not being infused, infusion must be stopped and the device must be replaced with a new one.（If the device lumen is occluded, the device may be dilated, damaged, or ruptured even at not more than the maximum injection pressure (2070 kPa), resulting in a life-threatening adverse event due to spurting contrast media.）
- Do not 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 occur.)
- If the device is inserted into vessels and the guide wire is to be replaced, insert the guide wire carefully. If there is any resistance during operation, the operation must be discontinued immediately, and the device and the guide wire are withdrawn together. (The device may be damaged and the tip may be cut.)
- Do not wipe the surface of the microcatheter with gauze or absorbent cotton soaked with alcohols, gluconic acid chlorhexidine aqueous solution, or similar solutions. Otherwise, it may significantly deteriorate the lubricity of the surface of the microcatheter.
- The patient may suffer from subacute thrombosis, vascular complications, or bleeding complications by using this microcatheter. Therefore, it should be well examined if the intervention procedure will be applicable for the patient.
- Repeated insertion and withdrawal of the device may lead to deterioration of the hydrophilic coating. (Continuous use of the device with deteriorated hydrophilic coating may cause vascular damage. This may also increase the risk of trapped tip, resulting in a life-threatening adverse event due to a damage and/or separation of tip.)
- Comply with instructions, precautions, and warnings described in the Instructions for Use supplied with medical devices (Namely, Sheath introducer kit, Angiographic catheter, Guiding catheter, Guidewire, Power injector) used together with the microcatheter.
- Do not manipulate the stopcock of the guiding catheter when the microcatheter is inserted in the guiding catheter fitted with a stopcock. It may cause damage of the microcatheter or the guidewire.

Precautions for use

1. Contraindication and prohibition

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.

2. Important precautions

1) This product must be used under fluoroscopy only by a physician who is fully trained in interventional procedures.
2) Prior to use, check all devices, including this product, and confirm that they function normally. Check also if the product is not damaged during transportation. Do not use if the package and/or the product is suspected to be damaged.
3) Use by the expiration date indicated on the label of the product package.
4) Use immediately after opening the bag. After use, discard it respecting the disposal policies and infection controls.
5) When inserting the guidewire into the microcatheter which is already placed in the blood vessel, carefully operate the guidewire not to damage the microcatheter at the bend sections.
6) Confirm that this microcatheter does not have a kink, knot, torsion, or occlusion before injecting contrast media. The injection pressure must not exceed 2070 kPa.
7) Use the extension tube when contrast media is injected by using power injector.
8) Do not use this product for the purposes other than described in the Indications for Use written in this document.
9) Select the appropriate size of guiding catheter and guidewire to use in combination with this microcatheter. (See Table 1)
10) When using a guiding catheter fitted with a stopcock, do not manipulate the stopcock after inserting this microcatheter into the guiding catheter. (If the stopcock is manipulated during the insertion of this microcatheter, this microcatheter may be broken.)
11) Operate the microcatheter carefully to avoid damage, kinking, or bending, especially when inserting this microcatheter into the guiding catheter.
12) Check the patient's condition before the procedure. Provide appropriate anticoagulant therapy if it is necessary.
13) Manipulate the microcatheter in the blood vessel very carefully by observing it through a high-definition X-ray fluoroscopy monitor screen. If any resistance is felt, stop the manipulation and identify the cause of the resistance. Continuing the manipulation while the cause of the problem is not identified may cause damage of the blood vessel, or damage or rupture of the microcatheter.
14) When infusing contrast media, read carefully the Instructions for Use provided with such contrast media and comply with instructions, precautions, and warnings.
15) The surface of this microcatheter is coated with hydrophilic polymer. Flush the surface and the lumen of the microcatheter continuously with heparinized and sterilized saline during its use to maintain lubricity.
16) Do not wipe the surface of this microcatheter with a gauze or absorbent cotton soaked with alcohols, gluconic acid chlorhexidine aqueous solution, or the like to avoid damage of the hydrophilic polymer coating.
17) When inserting or exchanging the microcatheter, flush the lumen of the guiding catheter and the microcatheter system continuously with heparinized and sterilized saline.
18) Flush the lumen of the microcatheter sufficiently with heparinized and sterilized saline especially after injecting contrast media.
19) Discontinue injection if irregular resistance is felt at the syringe. The microcatheter may be bent or blocked. Excessive pressure may cause expansion and/or rupture of the microcatheter.

3. Other precautions

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

Malfunction and adverse events

Malfunctions and adverse events may occur from 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

   If the microcatheter is exposed to excessive force, following malfunctions may occur. Comply with precautions for use described in the above and carefully operate this microcatheter.

   - Bend
   - Sharp bend
   - Torsion
   - Separation
   - Removal difficulty
   - Damage of hydrophilic coating
   - Insertion difficulty
   - Trap with guide wire

2) Adverse events

   The interventional procedure may be accompanied with, but not limited to the following complications. If the complication occurs, appropriate treatment should be performed at the discretion of the physician. Detailed treatment for recovery should be confirmed by the physician in advance.

   A serious adverse event may lead to a severe complication or death.

   Possible adverse events include, but are not limited to:

   - Cerebral infarction
   - Other cerebral strokes
   - Myocardial ischemia
   - (Unstable) angina
   - Acute myocardial infarction
   - Other heart diseases
   - Bleeding complications
   - Ischemic complications
   - Peripheral vessel ischemia
   - Cerebral ischemia
   - Arrhythmia including ventricular fibrillation
   - Allergy
   - Hypotension/Hypertension
   - AV fistula
   - Angiospasm/Vasospasm
   - Fever
   - Bradycardia/Palpitation
   - Pulmonary embolism
   - Renal failure
   - Chill
   - Distal vascular embolism (air, tissue, thrombotic)

・Formation of Hematoma at femoral region/formation of other hematoma
・Infection or complications at the puncture site
・Vessel damage, such as dissection, perforation, rupture
・Arterial embolism, thrombosis or occlusion
・Dissecting aneurysm, false aneurysm

Performance

This product can be used directly after opening the package following sterile procedures. It is sterilized by gas sterilization with ethylene oxide before shipment. The product shall be selectively inserted in blood vessel over a guidewire.

Recommended procedure

This product can be used directly after opening the package following sterile procedures.
It is sterilized by gas sterilization with ethylene oxide before shipment. The product is for single-use only and reuse is not permitted.

<A> Instructions for use as an infusion catheter

1) Take out the holder tube containing the microcatheter from the sterile pack.
2) Inject the heparinized and sterilized saline into the holder tube through the flush connector by using a syringe. Ensure the ejection of heparinized and sterilized saline from distal end of the holder tube to make sure the holder tube is filled with heparized and sterilized saline.
3) Remove the microcatheter from the holder tube, and check the surface of the microcatheter for sufficient lubricity. If any resistance is felt when withdrawing the microcatheter from the holder tube, inject additional heparinized and sterilized saline into the holder tube to lubricate the microcatheter.
4) Flush the lumen of the microcatheter removed from the holder tube with the heparinized and sterilized saline by using a syringe. Fill the lumen of the microcatheter with the heparinized and sterilized saline.
5) Insert the appropriate guidewire (indicated on the label of product package) into the microcatheter and advance carefully.
6) Insert the guiding catheter into the patient's blood vessel according to standard catheter procedure.
7) Insert the microcatheter and the guidewire as a unit into the guiding catheter, from its hemostatic adaptor (Y-connector etc.), which is inserted in the patient's vessel. Advance the microcatheter and the guidewire until the distal end of the guiding catheter appears under fluoroscopy.
8) After loosening the hemostasis valve of the Y-connector, if this product is hindered by a stenosed area, and/or when 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 tip passes through the stenosed area.
9) The user can rotate the device when inserting, withdrawing, and passing through stenotic areas. However, do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 10 consecutive turns. If the device is trapped or suspected to be trapped, rotating operation must be avoided.
10) Before injecting contrast medium, withdraw the guidewire. Connect (a) the power injector to the connector for angiographic injection of contrast medium that according to the manufacturer's IFU and/or according to clinical practice is suitable for power injection infusion; or (b) a syringe to the connector for manual injection of contrast medium.

11)When thrombus adhesion is expected during the procedure, connect the hemostatic adaptor to the connector of the microcatheter, and inject heparinized and sterilized saline from the port of the hemostatic adaptor by using a syringe, or connect a pressured bag with heparinized and sterilized saline for continuous drip to prevent thrombus from adhering to the microcatheter.
12)After completing the procedure, withdraw the microcatheter immediately and discard.

<B> Instructions for use as a support catheter

1) Take out the holder tube containing the microcatheter from the sterile pack.
2) Inject the heparinized and sterilized saline into the holder tube through the flush connector by using a syringe. Ensure the ejection of heparinized and sterilized saline from distal end of the holder tube to make sure the holder tube is filled with heparized and sterilized saline.
3) Insert a compatible guidewire (indicated for this microcatheter) through the connector and bring the tip of the guidewire in line with the tip of this microcatheter. (If the guidewire is inserted through the tip of this microcatheter, care should be taken not to cause any damage to the microcatheter. Also, if the microcatheter is bent or kinked, discontinue its use. If the microcatheter is kinked it may cause severe damage to the patient.)
4) Loosen the hemostatic valve of the hemostatic adaptor connected to the parent guiding catheter and insert this microcatheter. (Ensure that the hemostatic valve of the hemostatic adaptor is already loosened. A tight hemostatic valve causes resistance during insertion of this microcatheter and may damage the microcatheter.)
5) Advance this microcatheter under fluoroscopy until it reaches 2 to 3 cm proximal of the tip of the parent guiding catheter.
6) Advance this microcatheter under fluoroscopy until it is close to the stenotic area. Advance the guidewire carefully until it passes the target area. Continue advancing the guidewire as distal as possible into the blood vessel, and once it is placed there, check the position by imaging from the guiding catheter. The position of the guidewire must be checked by imaging from multiple angles to confirm that the guidewire is definitely inserted into the target blood vessel.
7) After loosening the hemostatic adaptor, hold the guidewire and guiding catheter firmly. Then advance this microcatheter gradually along the guidewire until the tip has passed through the stenotic area, using the radiopaque marker on the tip of this microcatheter as a guide. (Procedures inside the blood vessel should be conducted with care, because this microcatheter is hydrophilic coated.)
8) When removing this microcatheter, loosen the hemostatic valve of the hemostatic adaptor. Remove this microcatheter while keeping the guidewire stable in the blood vessel. (When this microcatheter is removed, check the position of the guidewire under fluoroscopy. Also, if any resistance is felt during the removal of this microcatheter, remove all devices including the parent microcatheter and the guidewire.) After removal of this microcatheter, tighten the hemostatic valve of the hemostatic adaptor.
9) The user can rotate the device when inserting, withdrawing, and passing through stenotic areas. However, do not turn the catheter in the same direction, either clockwise or counterclockwise, for more than 10 consecutive turns. If the device is trapped or suspected to be trapped, rotating operation must be avoided.

Storage method

Do not keep the product in a bent condition and/or under heavy objects. 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.

Contents

One set per package

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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