CROSSROADS MG Guiding sheath

WARNINGS

Indicated Patients

- The product is a medical device and should only be used by healthcare professionals with expertise in angiography and vascular treatment.
- The product should be used only at hospitals where treatment can be provided promptly for complications that may cause disability or serious complications that may be life-threatening.
- With the use of the product, subacute thromboses, vascular or bleeding complications may occur. Therefore, patients need to be selected carefully.

CONTRAINDICATIONS/PROHIBITIONS

1. Instructions for Use

(1) The product has been sterilized. Do not re-sterilize or reuse. Re-sterilization and reuse may cause degradation of product characteristics such as shaft strength and lubricity or infection, and they may cause product failure during use.

(2) The product is a medical device and should only be used by physicians trained in percutaneous transluminal angioplasty.

(3) Do not use or use the product with drugs containing organic solvents such as ethanol for disinfection, fat emulsion, drugs containing fat emulsion, and oily contrast media.
[The catheter, connector, etc. may be damaged.]

2. Indicated Patients

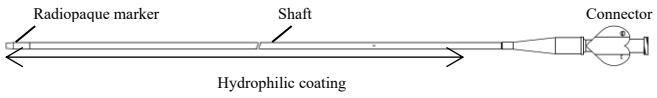
(1) Patients for whom antiplatelet treatment or anticoagulant therapy is contraindicated because of excessive prolongation of coagulation time, etc.
[Bleeding complications may occur.]

(2) Patients with serious allergy to drugs necessary for the procedure such as contrast media.
[Complications such as shock may occur.]

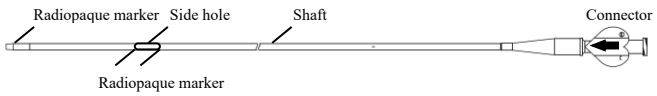
SHAPE, STRUCTURE, AND PRINCIPLE

1. Structure Diagram

Catheter



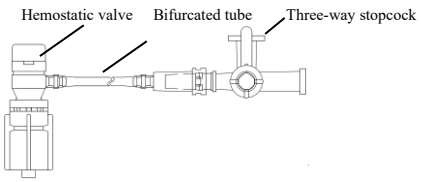
Catheter (with side hole)



Dilator

Puncture dilator

Hemostatic valve adapter



Raw materials: Polyamide elastomer
Polytetrafluoroethylene
Nylon 12
Polypropylene
Polyethylene

2. Principle

The product is a kit of instruments used to guide a catheter for intravascular surgery to the target site, and no sheath introducer is required for introduction to the blood vessel.

SPECIFICATIONS

(1) Tensile strength of joints
- Breaking strength between the catheter and the catheter connector: ≥ 15 N
- Breaking strength between the dilator and the dilator connector: ≥ 15 N
- Breaking strength of the soft tip: ≥ 5 N
- Breaking strength of the bifurcated tube: ≥ 15 N
- Breaking strength between the bifurcated tube and the joined components: ≥ 15 N

(2) Pressure resistance
- Pressure resistance of the catheter: ≥ 500 psi (3447 kPa)
- Pressure resistance with the hemostatic valve adapter connected to the catheter: ≥ 300 kPa
- Pressure resistance of the hemostatic valve: ≥ 38 kPa

(3) Connector conformance: ISO 80369-7

(4) Guidewire conformance: JIS T 3260:2012 5.5

INTENDED USE OR EFFECTS

Intended Use

The product is used to guide catheters for intravascular surgery to lesions including peripheral blood vessels in the abdomen and extremities (excluding cerebrovascular vessels, carotid arteries, and coronary arteries) and is used for infusion of various drugs including angiographic agents.

USAGE, ETC.

Instructions for Use

The following description is the explanation for the percutaneous transluminal angioplasty (PTA), etc., for which the product is mainly used. Other procedures should be performed accordingly. The product of an appropriate size with an appropriate tip shape should be selected based on the site of diagnosis and its anatomy. As for the guidewire to be used together, a guidewire of an appropriate length, the effective length of the catheter + 600 mm, should be selected. Make sure to select a guidewire with a diameter less than the maximum compatible guidewire indicated on the label.

(1) Check that the sterile package is intact, take out the product with the mount carefully, and remove the product from the mount carefully not to bend.
Caution If there is any abnormality such as damage to the sterile package, do not use the product and use a fresh product.
Caution Do not pull out the individual package bag and the mount while they are bent.

(2) Check that the hemostatic valve adapter (hereinafter referred to as the hemostatic valve) is securely connected to the catheter connector.

(3) Fill the catheter with heparinized physiological saline from the three-way stopcock of the bifurcated tube of the hemostatic valve, perform priming, and perform heparin lock.
Caution Do not rotate the plug of the three-way stopcock more than 180° (beyond the stopper). [Dislocation or disconnection of the plug may cause leakage of the drug solution, etc. or blockage of the flow path of the drug solution, etc.]
Do not bend or heat the tip of the catheter.
[The product may be damaged or broken. In addition, damage to the concomitant device or vascular damage may occur.]

(4) Prime the dilator with heparinized physiological saline using a syringe, etc. In addition, to maintain the lubricity of the tip of the catheter, wet the surface of the tip of the catheter sufficiently with heparinized physiological saline.

(5) Insert the dilator into the catheter through the center of the valve body of the hemostatic valve and fix securely by turning the dilator connector and the hemostatic valve.
Caution Insert the dilator aiming at the center of the valve body or the check valve. [If the dilator is pushed forcibly while it is not at the center, the valve body or check valve may be damaged, failing to maintain hemostasis.]

(6) Make a small incision in the skin at the puncture site with a scalpel.

(7) Insert the introduction needle into the blood vessel. Next, insert the

guidewire with the specified effective length through the introduction needle slowly avoiding vascular injury, and remove the introduction needle leaving the guidewire.

Caution Select a guidewire of an appropriate size and an introduction needle of an appropriate size according to the puncture dilator to be used.

Caution Do not use a guidewire shorter than the specified effective length. [Operation of the dilator may be impaired.]

(8) Insert the puncture dilator along the guidewire, and dilate the hole. Then, replace the guidewire according to the dilator to be used, and remove the puncture dilator.

(9) While holding the catheter and the dilator over the catheter, insert into the blood vessel along the guidewire.

(10) While checking the tip of the catheter under fluoroscopy, advance to the target site, and slowly remove the guidewire and the dilator.

Caution
- If a hemostatic valve is used, remove the dilator slowly from the catheter. [If the dilator is removed rapidly, the hemostatic valve may not close properly, resulting in leakage of blood from the valve body.]
- When inserting the product into the blood vessel, be careful not to damage the vessel wall along the path of the product.
- Since the use of the product may occlude blood vessels, operate the product carefully not to completely block blood flow.
- If the guidewire is inserted after advancing of the catheter into the blood vessel, when passing through the bent portion or the distal shaped portion of the catheter, the guidewire should be carefully manipulated not to damage the catheter.

(11) If necessary, connect the infusion line to the three-way stopcock for continuous infusion of heparinized physiological saline, etc.

(12) Insert a catheter for intravascular surgery to be used together in the specified manner carefully aiming at the center of the valve body or the check valve, advance to the target site, and perform the procedure.

(13) When replacing the device, remove the device in use, remove air from the product catheter, and repeat the operation in (11).

Caution
- When removing the balloon catheter from the body, deflate the balloon completely. [If the balloon is removed while the balloon is deflated incompletely, the balloon catheter may be caught by the tip of the catheter of the product. This may prevent removal of the balloon catheter or damage the tip of the catheter of the product.]
- When removing or re-inserting the device, perform suctioning from the three-way stopcock to remove fibrin, etc. adhered around the tip of the catheter. Suctioning should be performed slowly and gently. [If suctioning is performed rapidly with a syringe, etc., air may enter from the valve body.]
- When performing puncture, suturing, and incision operations near the catheter placement site, perform the operations carefully not to damage the catheter. [The catheter may be cut.]

(14) Upon completion of the specified procedure, insert a guidewire of an appropriate size until the guidewire protrudes approximately 5 cm from the tip of the catheter, and carefully remove the catheter with the guidewire.

(For the product type with side hole)

Before performing the following procedure, the condition of the blood vessel should be confirmed by performing imaging, etc.

(1) Take out the product together with the mount carefully from the individual package bag, and remove the product from the mount without bending.

Caution Do not pull out the individual package bag and the mount while they are bent.

(2) Check that the hemostatic valve adapter (hereinafter referred to as the hemostatic valve) is securely connected to the catheter connector.

(3) Fill the catheter with heparinized physiological saline from the three-way stopcock of the bifurcated tube of the hemostatic valve, perform priming, and perform heparin lock.

Caution Do not rotate the plug of the three-way stopcock more than 180° (beyond the stopper). [Dislocation or disconnection of the plug may cause leakage of the drug solution, etc. or blockage of the flow path of the drug solution, etc.]
Do not bend or heat the tip of the catheter.
[The product may be damaged or broken. In addition, damage to the concomitant device or vascular damage may occur.]

(4) Prime the dilator with heparinized physiological saline using a syringe, etc. Wet the entire catheter sufficiently with heparinized physiological saline.

(5) Insert the dilator into the tip of the catheter through the center of the valve body of the hemostatic valve, and fix securely by turning the dilator connector and the hemostatic valve.

Caution Insert the dilator aiming at the center of the valve body or the check valve. [If the dilator is pushed forcibly while it is not at the center, the valve body or check valve may be damaged, failing to maintain hemostasis.]

(6) Make a small incision in the skin at the puncture site with a scalpel.

(7) Insert the introduction needle into the blood vessel. Next, insert the guidewire with the specified effective length through the introduction needle slowly avoiding vascular injury, and remove the introduction needle leaving the guidewire.

Caution Select a guidewire of an appropriate size and an introduction needle of an appropriate size according to the puncture dilator to be used.

Caution Do not use a guidewire shorter than the specified effective length. [Operation of the dilator may be impaired.]

(8) Insert the puncture dilator along the guidewire, and dilate the hole. Then, replace the guidewire according to the dilator to be used, and remove the puncture dilator.

(9) While holding the catheter and the dilator over the catheter, insert into the blood vessel along the guidewire.

(10) While checking the tip of the catheter under fluoroscopy, advance to the target site, and confirm that the radiopaque marker proximal to the side hole is completely inserted into the blood vessel. Manipulate so that the arrow (→) at the connector located proximally is facing toward the treatment site. Remove the guidewire and the dilator slowly while keeping the catheter stationary.

Caution
- If a hemostatic valve is used, remove the dilator slowly from the catheter. [If the dilator is removed rapidly, the hemostatic valve may not close properly, resulting in leakage of blood from the valve body.]
- When inserting the product into the blood vessel, be careful not to damage the vessel wall along the path of the product.
- Since the use of the product may occlude blood vessels, operate the product carefully not to completely block blood flow.
- If the guidewire is inserted after advancing of the catheter into the blood vessel, when passing through the bent portion or the distal shaped portion of the catheter, the guidewire should be carefully manipulated not to damage the catheter.

(11) If necessary, connect the infusion line to the three-way stopcock for continuous infusion of heparinized physiological saline, etc.

(12) Insert a catheter for intravascular surgery to be used together in the specified manner carefully aiming at the center of the valve body or the check valve.

(13) Advance the catheter for intravascular surgery to the target site via the side hole between the radiopaque markers located proximally and distally to the side hole, and perform the procedure.

Caution
- Be careful not to move the product when manipulating the catheter for intravascular surgery. [Bleeding may occur because the side hole is located outside the blood vessel.]

(14) When replacing the device, remove the device in use, remove air from the product catheter, and repeat the operation in (11).

Caution
- When removing the balloon catheter from the body, deflate the balloon completely. [If the balloon is removed while the balloon is deflated incompletely, the balloon catheter may be caught by the side hole of the catheter of the product. This may prevent removal of the balloon catheter or damage the side hole of the catheter of the product.]
- When a device with a tip thicker than the proximal end is used, remove carefully because it may get caught in the side hole during removal.
- When removing or re-inserting the device, perform suctioning from the three-way stopcock to remove fibrin, etc. adhered around the tip and the side hole of the catheter. Suctioning should be performed slowly and gently. [If suctioning is performed rapidly with a syringe, etc., air may enter from the valve body.]
- When performing puncture, suturing, and incision operations near the catheter placement site, perform the operations carefully not to damage the catheter. [The

catheter may be cut.]

(15) Upon completion of the specified procedure, insert a guidewire of an appropriate size through the hemostatic valve until it protrudes approximately 5 cm from the tip of the catheter. Then, insert the dilator along the guidewire until it protrudes from the tip of the catheter, and carefully remove the catheter and the dilator.

Caution- When another connector is used, replace with a hemostatic valve.
[Because the dilator is not inserted for the entire length of the catheter, there is a risk of bleeding from the side hole during removal of the dilator in addition to the risks of vascular damage by the side hole and rupturing of the product.]

PRECAUTIONS

1. Important Precautions

(1) For the procedure, anticoagulant or antiplatelet therapy appropriate for the patient's condition should be performed.
(2) Do not perform processing such as heating and bending of the shaped tip, drilling of the side hole.
(3) Do not rapidly advance or forcibly insert the dilator, guidewire, or device to be used together while the catheter is kinked or twisted.
(4) Do not apply excessive rotation load when the product is kinked.
(5) Do not flush from the three-way stopcock while the catheter for intravascular surgery is inserted in the catheter.
(6) When inflating the balloon near the tip of the catheter, inflate the balloon carefully while checking the radiopaque marker at the tip of the catheter so that it is not inflated inside the tip of the catheter.
(7) Be careful not to damage the hemostatic valve with the dilator.
(8) Do not inject a contrast medium, etc. at a high pressure using an injector, etc. from the three-way stopcock.
(9) Do not apply a load of excessive pulling, pushing, or bending on the bifurcated tube and the connection to the bifurcated tube.
(10) Do not use the product if the package or its contents are damaged or contaminated.
(11) Dispose the product as medical waste and take measures to prevent spreading of infection.

2. Malfunctions/Adverse Events

< Serious Malfunctions >

The following malfunctions may occur with the use of the product. However, malfunctions are not limited to those listed below.

- Kinking or breaking of the catheter shaft
- Breaking or rupturing of the catheter shaft
- Difficulty in removal of the catheter
- Poor maneuverability or inability to manipulate the guidewire
- Cracking of the connector

< Serious Adverse Events >

The following adverse events may occur with the use of the product. However, adverse events are not limited to those listed below.

- Complications due to drugs such as contrast agents
- Subintimal injection of contrast agent
- Bleeding/hematoma
- Vascular injury/perforation
- Hypotension (severe hypotension)
- Bleeding complication
- Femoral pseudoaneurysm
- Arterial injury
- Endovascular thrombosis
- Renal failure
- Tachycardia
- Bleeding and hemorrhagic shock
- Pseudoaneurysm formation
- Fever/chill
- Palpitation
- Arterial embolism
- Puncture site hemorrhage
- Arteriovenous fistula
- Arterial dissection
- Nausea/vomiting
- Bradycardia
- Infection
- Vascular dissection
- Behavioral disorder
- Arterial perforation
- Occlusion
- Peripheral embolism
- Vasospasm

3. Use during Pregnancy, Delivery or Lactation and Pediatric Use

For the use of the product in pregnant or possibly pregnant patients, the influence of X-ray on fetus should be considered.

STORAGE METHOD AND SHELF LIFE

1. Precautions for Storage

- Store the product avoiding high temperature, high humidity, direct sunlight, and wetting.
- Store the product in a safe and stable environment, avoiding inclination, vibration, and shock (including during transportation).

2. Shelf Life

Use the product before the "Expiry date" indicated on the package label.

3. Sterilization method

The product is sterilized by exposure to ethylene oxide gas (EtO) and is not intended for re-sterilization.

MANUFACTURING SITE

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LEGAL MANUFACTURER

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SYMBOLS

REF	Model Number
LOT	Lot Number
	Use by
	Date of manufacture
	See instructions for use
STERILE EO	Sterilized using ethylene oxide
	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Manufacturer

NIPRO

GOODMAN

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