Goodtec Angiographic Diagnostic Catheter

ENGLISH

WARNING

- Patient selection should be considered given that use of this product may result in subacute thrombosis, cause intravascular complications or hemorrhagic complications.
- During procedure, perform administration of appropriate anticoagulant and antiplatelet therapy, as directed by lead physician.
- The product is a medical device and should only be used by physicians trained in the procedures of coronary angiography (CAG) and percutaneous transluminal coronary angioplasty (PTCA). The product should only be used in facilities capable of performing emergency coronary artery bypass grafting (CABG) as a provision against complications that may cause injury and serious complications that could prove to be life threatening.

Combination of medical devices

- Reference package insert for each medical device and pharmaceutical product used together with this product and use them with a full understanding of their characteristics to prevent damage to the product.
- Immediately cease use of any device or pharmaceutical product should any complications arise.

Method of use

- Select appropriate size and shape in consideration of the applicable case.
- All product insertion to target location and removal should be undertaken with an appropriately sized guide wire (this minimizes kinking and damage to product).
- Insertion of product through the sheath introducer should be undertaken with the guide wire inserted up to tip shape. For a pigtail product, the shape should be extended via guide wire after passing through the inducer (this eliminates damage to product shape or to catheter body).
- Care should be taken to ensure that the catheter tube tip does not cause damage to the vasculature during insertion.
- Intravascular manipulation of the product should be carefully performed under fluoroscopy, confirming both tip movement and positioning (kinking or damage may result from stress concentrated at the difference in hardness between the special soft middle tube and the adjoining tube for some types of models such as YUMIKO).
- Should any product resistance or a reduction in torque of the catheter be determined during operation, immediately cease usage and confirm cause (continued use may result in damage to vessel or the product).
- Immediately cease use and exchange product should kinking or damage to product be confirmed during use.
- Do not manipulate guide wire if kinking or damage to catheter is confirmed or guide wire is unable to advance (over manipulation may result in damage to catheter tip, body or vasculature).
- Before inserting any pharmaceutical products, confirm that there is no damage or blockage in product (damage may result due to excessive pressure).
- When removing product ensure that the guide wire has been inserted. If the guide wire is unable to be placed within product due to kinking or damage prior to removal, simultaneously remove product and sheath introducer.

CONTRAINDICATIONS FOR USE

- The product is sterilized, is not re-usable and must not be re-sterilized.

Inappropriate patients

- Patients with extensive peripheral disease which prevents the insertion of an appropriate size sheath (damage to vasculature may result).
- Patients in whom antiplatelet and/or anticoagulant therapy is contraindicated for reasons such as excessive prolongation of coagulation time (complications relating to hemorrhage may result).
- Patients with allergy to any pharmaceutical products used in the course of a PTCA procedure (complications relating to shock may develop).
- Patients who are pregnant or suspected of being pregnant (radiation exposure to fetus may occur).
- Patients with extremely low left ventricular function (outside guidelines for PTCA).
- Patients having gastrointestinal bleeding (further complications may arise).

Prohibition of use with medical devices

- Do not use any products comprising organic solvent such as ethanol, fat-based emulsions or oil-based contrast media (damage to the product or connector may result).

Prohibition of use

- Do not exceed the maximum pressure as indicated on the label when using an automated injection machine to inject contrast media or pharmaceutical product (damage to product may result).
- Do not apply heat, bend or make any additional holes to catheter tip (damage to product may result).

SHAPE / CONSTRUCTION

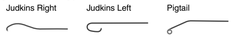
This product comprises of various catheter tubing attached to a shaped tip to form a disposable angiographic catheter. This product's tip is delivered to target location under fluoroscopic imaging to highlight the construction of the vasculature via a flushing of contrast media through the device. As a coronary sinus device, blood sampling is also performed.

1. **Catheter tube section**
   The catheter tubing is comprised from a soft tip, middle tubing and shaft, and when necessary, soft tip, middle tubing and inducer. Further, the soft tip is radiopaque, and the shaft is made of a flexible, non-braided and braided section.
2. **Proximal end**
   The proximal end comprises of a strain reliefand connector.

Maximum Pressure Resistance: 7240kPa (1050 psi)

Catheter tube material: nylon

Major catheter types



PURPOSE, EFFICACY

The following three applications of the device are performed based on type of catheter selected:

1. Coronary catheterization is achieved by intravascular insertion of the catheter and injection of contrast media in order to undertake coronary angiography (CAG), left ventriculography, abdominal angiography, diastolic aortic pressure (OAP), left ventricular pressure (LVP), and cerebral angiography.
2. Coronary catheterization can be performed via one catheter for the purpose of obtaining coronary angiography, left ventriculography and left ventricular pressure.
3. Obtain blood specimens from different locations within the coronary artery and large vessel in order to undertake blood analysis to assist with diagnosis.

SPECIFICATIONS

1. Maintains tensile strength of the catheter tubing at 9.8N (1kgf) without any separation or cracking.
2. No connector separation at 9.8N (1kgf).
3. The connection between soft tip and mid-tubing maintains integrity at 2.9N (0.3kgf).
4. The recommended guide wire diameter for 1.40mm to 2.00mm (4Fr to 6Fr) is 0.97mm (0.038"), or depending on the type may be 0.89mm (0.035") and for 1.13mm (3.4Fr) is 0.64mm (0.025").

METHOD OF USE

The following is an explanation of general use. Further steps may be required or changed as per the experience of the treating physician.

1. Preparation prior to use

- Carefully remove the product from the packaging.
- Inspect and confirm the catheter tubing and hub connector to ensure no product deformity (exchange product should any abnormality be determined).
- Using a syringe containing heparinized saline flush the inner lumen of the catheter.

2. Insertion of product

(1) Angiographic use

- Securing the sheath introducer, insert an appropriately sized angiographic guide wire.
- Placing the guide wire through the product, insert catheter through the sheath and into the vasculature.
- Advance catheter under fluoroscopy to the target vessel.
- Remove guide wire once catheter has reached target location (always ensure guide wire is inserted in product when delivering pig-tail catheter) (this minimizes the incidence of kinking and damage).
- Insert contrast media or pharmaceutical product.
- When performing co-axial technique, remove the guide wire and carefully insert the micro catheter through the product (the micro catheter size should not be larger than the guide wire size which is compatible with the product).

(2) Coronary sinus use

- Inserting an appropriately sized guide wire through the product, insert into the vasculature via a sheath introducer.
- Insert product into the right atrium using the guide wire.
- Ensuring there is no slack in the shape of the product, torque in a right direction until tip is gently placed against the right atrial posterior wall.
- With the tip placed against the wall, slowly lower the body of the catheter, placing the tip against the entry of the coronary sinus.
- With the tip placed in the coronary sinus slowly lower the catheter body, extending the shape and inserting the tip within the coronary sinus.

3. Removal of catheter

- Remove ensuring the guide wire is inserted through catheter to tip location.

PRECAUTIONS

Precautions prior to use

- Use product prior to date of expiration as noted on label.
- Confirm condition of product prior to use. If any damage or contamination is noted on product, immediately cease use and exchange product.
- When removing product from packaging, remove with the cardboard (damage to product or tip shape may otherwise occur).
- Immediately use product following removal from package.
- All use should be performed in a sterile environment.
- Ensure there is no slack between product and hub connection prior to use (leakage of contrast media may incur).
- Do not use excessive force when removing residual air through the connector (damage to connector may result).

Precautions during use

- Ensure product does not come into direct contact with scissors, surgical blades or needles during use. Further, should any leakage or abnormality of use be determined, immediately exchange the product.
- When using the inducer to place the device through a sheath introducer, secure the inducer by hand when inserting (not securing the inducer may result in inducer being inserted into the vasculature).
- Do not exceed maximum injection pressure during insertion of contract media etc. Contrast media should be maintained at 37°C.
- Ensure that connector is appropriately connected.
- Careful product manipulation should be undertaken when there is potential for a lesion in the ostial of the vessel.

Defective product

Use of product may result in the following possible defective product occurrences:

- Kinking or breaking of shaft
- Detachment or burst of shaft
- Difficulty in removing catheter
- Difficulty in guide wire manipulation and operation
- Damage to connector

Adverse event

Possible adverse events include, but are not limited to, the following:

Complications associated with medicinal products such as contrast media, infection, hemorrhage/hematoma, artery embolism/occlusion, arterial dissection, arrhythmia including ventricular fibrillation, arterial damage/perforation, stroke, subintimal injection of contrast, arteriovenous fistula, pseudoaneurysm, hypotension (severe hypotension), blood loss from puncture site, coronary arterial dissection, hemorrhagic complications, acute myocardial infarction, aortic dissection, unstable angina, distal embolization, chills/fever, intravascular thrombosis, nausea/vomiting, behavioral disorder, kidney injury, obstruction, palpitation, tachycardia and bradycardia

Precautions after use

Dispose of this product as medical waste, and take measures to prevent possible spread of infection.

STORAGE METHOD, SHELF LIFE

1. Storage method

- Store the product in a room temperature location not exposed to high temperature and humidity or direct sunlight and take proper precautions to ensure product does not contact water.
- Avoid inclinations, vibrations and impacts (including during transportation) and store in a safe, stable environment.
- Do not store near chemicals or in areas where the device may be exposed to gases.

2. Shelf life

Use this product before the "expiration date" shown on the package label.

PACKAGING

1 to 5 units / box

PRODUCT WARRANTY DISCLAIMERS AND LIMITATION OF REMEDIES

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GOODMAN

血管造影导管

禁止再次使用

【警告】

适用对象

- 由于使用本品可能会引起亚急性血栓病、血管合并症甚至出血性合并症，因此必须在选择患者上谨慎对待。
- 手术时要考虑患者的状况实施适当的抗凝或抗血小板疗法。
- 本品作为心脏导管使用时，只有精通冠脉造影法、血管内治疗的医生可以使用。另外，该病症可能引发危险现象或可能对生命造成危害，手术只能在能够迅速实施紧急冠状动脉搭桥术的医院进行。

共用医疗用具

- 共用其他药剂、器具时，请务必仔细阅读相关产品说明书，在充分了解其性能后使用以及不影响本品使用的前提下，小心谨慎使用。
- 与其他医疗药剂、用具共用有问题时，应立即停止使用。

使用方法

- 请根据病变的实际情况选择合适的尺寸及形状。
- 插入本品、将本品引导至目标部位、拔出本品时，必须先行使用适当尺寸的导引导丝。
  [防止弯曲、折断、异常扭曲等造成的破损。]
- 本品插入鞘管导引器时，将形状部顺着导引导丝慢慢伸展。另外，在使用猪尾型导管时，顺着导引器伸展形状部后再插入。
  [形状部非正常变形是造成导管破损的原因。]
- 将本品插入血管内时要特别注意导管管身部位的尖端不要损伤血管壁。
- 血管内的操作要在高清晰度的 X 线透视下谨慎实施。
  [在使用质地特别柔软的中间软管型（YUMIKO 型等）时，要根据相邻的管子的硬度差集中应力于结合部，注意可能发生弯曲、折断等情况，应谨慎操作。]
- 在操作中即使感到很小的抵抗、扭转力矩无法传达到导管管身的尖端时，应停止手术，确认其原因。
  [因为可能产生弯曲、折断、异常扭曲等，如果继续这样的强行操作，造成的破损可能会使血管损伤，本品折断，剧痛等。]
- 确认有弯曲、折断等情况时，立即停止手术，更换导管。
- 本品发生弯曲、折断等情况时，不要急剧推进或强行插入导引导丝。
  [强行插入的操作可能使导管穿孔、破损，损伤血管。]
- 操作两通旋塞的旋塞不可在导引导丝及微型导管插入时进行。
  [可能会发生导引导丝及微型导管的破损、折断。]
- 在注入造影剂、药剂之前，确认本品无结节形成、弯曲、折断、无闭塞。
  [如果不确认上述情况就注入造影剂，即便是在最大耐受压下使用也可能造成破损。]
- 拔出本产品时，一定要插入导丝。如果由于产品的扭结、弯折等导致导丝无法插入时，将鞘管与本品一同拔出。

【禁忌 · 禁止】

禁止再次使用

- 本品已灭菌，仅限一次性使用。（包括拔出的部件）不可再灭菌及再使用。

有关适用对象的禁忌事项

- 有助即适合尺寸的鞘管插入的过度未精血管疾病的患者。
  [可能会使血管损伤。]
- 有凝血时间过度延长、抗血小板治疗、抗凝治疗禁忌的患者。
  [可能会出现出血性合并症。]
- 对于造影剂等手术必要的药剂有重度过敏反应的患者。
  [可能会出现休克等合并症。]
- 妊娠或有妊娠可能的患者。
  [X 线可能会对胎儿有影响。]
- 左心室功能极度低下的患者。
  [基于心脏导管法的禁忌。]
- 消化道出血的患者。
  [可能会引起恶心或呕吐等合并症。]

有关共用医疗用具的禁止事项

- 绝对不可以使用或共用含有消毒用酒精等有机溶剂在内的药剂、脂肪乳酸及含有脂肪乳酸的药剂、油性造影剂。
  [可能会使导管及转接端子破损。]

有关使用方法的禁止事项

- 用注射器（自动注入器）注入药剂、造影剂时，必须在最大耐受压范围内（产品标签标示）使用。
  [一旦超过最大耐受压注入，可能会破损。]
- 不可进行尖端形状的加热及扭曲、打开侧孔等的加工。
  [可能会引起本品破损等不测事故。]

【形状 · 构造及原理等】

本品为一次性使用的管状血管造影用导管，由尖端被加工成各种形状的导管管身部和末端部构成。导管尖端部实施了不透 X 射线加工，能够安全引导到目标部位。血管造影时，通过转接口及本导管的内腔注入造影剂，形成不透 X 射线的影像，从而得到血管等造影影像。用于冠状窦时，通过导管的内腔可采集冠状窦内的血液。

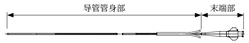
（1）导管管身部分

导管管身部由软质尖端、中间软管及管杆构成，软质尖端、中间软管，导引器按照需要设置。另外，软质尖端经过不透 X 线加工，管杆由无偏织部及有偏织状的编织部构成。

（2）末端部

末端部由增强管子、转接端子构成，按照需要配置两通旋塞。另外，根据规格不同，也有由增强管子、两通旋塞构成的情况。

＜构造图＞



最大耐受压 =7240kPa（1050psi）

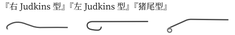
最大耐受压 =4137kPa（600psi）
导管管子部分材质：尼龙

适用范围

该产品为血管造影及脏器内血液采取为目的使用的导管。

＜代表形状＞

『右 Judkins 型』『左 Judkins 型』『猪尾型』



产品规格型号一览表

型号	尺寸	形状	有效长度 (mm)
GCB4-APL1	4.2F	AL	1000
GCB4-APL2	4.2F	AL	1000
GCB4-APL1SH	4.2F	AL	1000
GCB4-APL2SH	4.2F	AL	1000
GCB4-APR1	4.2F	AR	1000
GCB4-APR2	4.2F	AR	1000
GCB4-APR1SH	4.2F	AR	1000
GCB4-APR2SH	4.2F	AR	1000
GCB4-BRF35B	4.2F	BR	1000
GCB4-BRF40B	4.2F	BR	1000
GCB4-BRH35	4.2F	BR	1000
GCB4-BRH40	4.2F	BR	1000
GCB4-BRI3SS	4.2F	BR	1000
GCB4-BRI40S	4.2F	BR	1000
GCB4-BRT35B	4.2F	栓动脉	1000
GCB4-BRT40B	4.2F	栓动脉	1000
GCB4-CGL	4.2F	JR	1000
GCB4-CGR	4.2F	JR	1000
GCB4-CP155	4.2F	PIG	1100
GCB4-INT-MB	4.2F	内胸动脉	1100
GCB4-JL10	4.2F	JL	1000
GCB4-JL35	4.2F	JL	1000
GCB4-JL3SSH	4.2F	JL	1000
GCB4-JL40	4.2F	JL	1000
GCB4-JL40SH	4.2F	JL	1000
GCB4-JL45SH	4.2F	JL	1000
GCB4-JL50	4.2F	JL	1000
GCB4-JL50SH	4.2F	JL	1000
GCB4-JR35	4.2F	JR	1000
GCB4-JR3SSH	4.2F	JR	1000
GCB4-JR40	4.2F	JR	1000
GCB4-JR40SH	4.2F	JR	1000
GCB4-JR50	4.2F	JR	1000
GCB4-JR50SH	4.2F	JR	1000
GCB4-MPE30	4.2F	MP	1100
GCB4-MPE35	4.2F	MP	1100
GCB4-MPK5	4.2F	MP	1100
GCB4-P145D	4.2F	PIG	1100
GCB4-P155D	4.2F	PIG	1100
GCB4-P155FL	4.2F	PIG	1100
GCB4-P180D	4.2F	PIG	1100
GCB4-SAPL1	4.2F	AL	1000
GCB4-SF1553	4.2F	PIG	1100
GCB4-SF155A	4.2F	PIG	1100
GCB4-SF1803	4.2F	PIG	1100
GCB4-W145	4.2F	PIG	1100
GCB4-W155	4.2F	PIG	1100
GCB4-W155A	4.2F	PIG	1100
GCB4-W155GL	4.2F	PIG	1300
GCB4-W180	4.2F	PIG	1100
GCB4-W180GL	4.2F	PIG	1300
GCB4-YUMIKO	4.2F	内胸动脉	1100
GCB4-ZMPK9B	4.2F	MP	900
GCB4-ZMPK9L	4.2F	MP	1100
GCB5-APL1	5F	AL	1000
GCB5-APL15	5F	AL	1100
GCB5-APL1SH	5F	AL	1000
GCB5-APL2	5F	AL	1000
GCB5-APL2SH	5F	AL	1000
GCB5-APR1	5F	AR	1000
GCB5-APR2	5F	AR	1000
GCB5-BRB	5F	BR	1000
GCB5-BRD35	5F	BR	1000
GCB5-BRD40	5F	BR	1000
GCB5-BRF35B	5F	BR	1000
GCB5-BRF40B	5F	BR	1000
GCB5-BRH35B	5F	BR	1000
GCB5-BRH40B	5F	BR	1000
GCB5-BRI3SS	5F	栓动脉	1000
GCB5-BRI40S	5F	栓动脉	1000
GCB5-CGL	5F	JR	1000
GCB5-CGR	5F	JR	1000
GCB5-CS	5F	MP	1000
GCB5-CSF3	5F	AR	1000
GCB5-INT-MB	5F	内胸动脉	1100
GCB5-JL10A	5F	JL	1000
GCB5-JL35	5F	JL	1000
GCB5-JL35A	5F	JL	1000
GCB5-JL3SSH	5F	JL	1000
GCB5-JL40	5F	JL	1000
GCB5-JL40A	5F	JL	1000
GCB5-JL40SH	5F	JL	1000
GCB5-JL45	5F	JL	1000
GCB5-JL45A	5F	JL	1000
GCB5-JL45SH	5F	JL	1000
GCB5-JL50	5F	JL	1000
GCB5-JL50A	5F	JL	1000
GCB5-JL50SH	5F	JL	1000
GCB5-JR35	5F	JR	1000
GCB5-JR3SSH	5F	JR	1000
GCB5-JR40	5F	JR	1000
GCB5-JR40A	5F	JR	1000
GCB5-JR40SH	5F	JR	1000
GCB5-JR45	5F	JR	1000
GCB5-JR50	5F	JR	1000
GCB5-JR50A	5F	JR	1000
GCB5-JR50SH	5F	JR	1000
GCB5-MP	5F	MP	1100
GCB5-MPE30	5F	MP	1100
GCB5-MPE35	5F	MP	1100
GCB5-MPK10	5F	MP	1300
GCB5-SAPL1	5F	AL	1000
GCB5-YUMIKO	5F	内胸动脉	1100
GCB5-ZMPK9B	5F	MP	900
GCB5-ZMPK9L	5F	MP	1100
GCB5-P145	5F	PIG	1100
GCB5-P145SS	5F	PIG	1100
GCB5-P155	5F	PIG	1100
GCB5-P155C	5F	PIG	1100
GCB5-P155GL	5F	PIG	1300
GCB5-P155SS	5F	PIG	1100
GCB5-P180	5F	PIG	1100
GCB5-P180C	5F	PIG	1100
GCB5-P180GL	5F	PIG	1300
GCB5-W145	5F	PIG	1100
GCB5-W155	5F	PIG	1100
GCB5-W155A	5F	PIG	1100
GCB5-W155GL	5F	PIG	1300
GCB5-W180	5F	PIG	1100
GCB5-W180GL	5F	PIG	1300
GCS5-BRT35B	5F	BR	1000
GCS5-BRT40B	5F	BR	1000
GCB6-APL1	6F	AL	1000
GCB6-APL1A	6F	AL	1000
GCB6-APL2	6F	AL	1100
GCB6-APL2A	6F	AL	1000
GCB6-APR1	6F	AR	1000
GCB6-APR2	6F	AR	1000
GCB6-BRF35B	6F	BR	1000
GCB6-BRF40B	6F	BR	1000
GCB6-CSF3	6F	AR	1000
GCB6-INT-MB	6F	内胸动脉	1100
GCB6-JL35	6F	JL	1000
GCB6-JL40	6F	JL	1000
GCB6-JL45	6F	JL	1000
GCB6-JL50	6F	JL	1000
GCB6-JL35A	6F	JL	1000
GCB6-JL40A	6F	JL	1000
GCB6-JL50A	6F	JL	1000
GCB6-JR35	6F	JR	1000
GCB6-JR40	6F	JR	1000
GCB6-JR45	6F	JR	1000
GCB6-JR50	6F	JR	1000
GCB6-JR35A	6F	JR	1000
GCB6-JR40A	6F	JR	1000
GCB6-JR50A	6F	JR	1000
GCB6-MP	6F	MP	1100
GCB6-P145	6F	PIG	1100
GCB6-P155	6F	PIG	1100
GCB6-P155SS	6F	PIG	1100
GCB6-P180	6F	PIG	1100
GCB6-ZMPK9B	6F	MP	900
GCB6-ZMPK9L	6F	MP	1100

【使用目的、效果或效能】

使用目的

本品按照不同形状，具有以下三种使用目的。

① 在心脏导管检查中，插入血管内，推进至目标部位后注入造影剂，进行左右冠状动脉造影或心室造影、腹部血管造影、测定大动脉压力、测定左心室、脑部血管造影。

② 在心脏导管检查中，插入血管内，推进至目标部位后注入造影剂，单一进行左右冠状动脉造影、心室造影、测定左心室压力。

③ 采集心内以及大血管各部位的血液，进行血液气体分析，用作辅助诊断的脏器内血液采集导管。

【产品规格等】

性能

① 导管管身的拉伸强度，在 9.8N（1kgf）载荷下应不折断或龟裂。

② 转接端子的连接强度，在 9.8N（1kgf）载荷下应不脱落。

③ 软质尖端及中间软管的连接强度，在 2.9N（0.3kgf）载荷下应不折断或龟裂。

④ 适用导丝的直径，在 1.40mm ～ 2.00mm（4 ～ 6Fr）时为 0.97mm（0.038 英寸）。或者，根据型号不同为 0.89mm（0.035 英寸）。1.13mm（3.4Fr）时为 0.64mm（0.025 英寸）。

【操作方法或使用方法】

下述的说明为通用方法。按照需要根据各医生的临床经验可追加、变更操作顺序。

1. 导管（本品）的准备

- 将本品和衬纸从灭菌包装袋中取出，之后再从衬纸上小心地取出本产品。
- 从包装中取出后确认导管管身部无损伤、转接端子部无松动。本品有异常情况时应更换导管。
- 使用注射器等，用肝素生理盐水冲洗本品。

2. 插入方法

（1）血管造影用

- 用鞘管法确保血管时要留置鞘管导引器。让尺寸合适的导引导丝从鞘管导引器内先行移动。
- 将该导丝通过本产品，从鞘管内向血管内送入。若附带插入器的话，使用插入器伸展导管，将导管前端送入鞘管后，拆除插入器。
- 在 X 线下将本品推到目标血管。
- 直到本品的尖端部位推送到目标位置后再拔去导引导丝。但是使用猪尾型导管时，必须插入导引导丝引导到目标位置后再拔去。
  [防止弯曲、折断、异常扭曲。]
- 如果操作本品选择目标血管，通过转接端子或两通旋塞向目标血管注入造影剂或药剂。
- 用同轴法实施手术时，要谨慎地拔出导引导丝、将所使用的微导管插入本品的内腔里。
  [要使用的微导管需在本品最大适应的导引导丝直径之内。]

（2）冠状动脉实用

- 通过尺寸适当的导引导丝、使用鞘管导引器将本品插入血管内。
- 使用导引导丝向右心房内引导导管的尖端部。
- 用不致变形的力度向右旋转扭矩，使尖端温柔地触到右心房后壁。
- 在尖端触壁状态下慢慢地降低导管整体，挂于右心房后壁打开着的冠状动脉窦口处。
- 在尖端挂于冠状动脉窦口的状态下慢慢地降低导管整体，扩展形状将尖端向冠状动脉窦内插入。

3. 拔出导管

- 拔出本品时，必须将导引导丝插入形状部位伸展后，再拔出本品。

【使用注意事项】

1. 重要的基本的注意

（1）使用前的注意

- 请在包装上注明的“失效日期”前使用本产品。
- 使用前要确认本品无损伤等异常情况再使用。万一，包装材料有破损、污染，或者确认产品有破损等情况，禁止使用，请更换新品。
- 从包装中取出时，请将衬纸一同取出。切勿直接单独取出本产品。
  [否则可能损伤导管或软质尖端。]
- 打开包装后要立即使用。
- 所有操作都要无菌进行。
- 使用前确认转接端子部无松动。
  [转接端子部的松动是造成药液泄漏的原因。]
- 排出空气时，请勿过度敲打转接端子。
  [否则，转接端子可能损害。]

（2）使用中的注意

- 使用中，注意手术刀、剪子、针等不要损伤本品。另外，使用中如确认有药液泄漏、堵塞等异常情况要停止使用，更换新品。
- 使用插入器将本产品插入鞘管内时，请用手紧握插入器进行操作。
  [否则插入器会顺势进入体内。]
- 用注射器（自动注入器）注入药剂、造影剂时，必须在最大耐受压以下使用。造影剂必须加温到 37℃使用。
- 造影时、采血时，确认连接部确实连接着再使用。
- 在进行目标部位入口处有病变的操作时要特别谨慎。

2. 不良情况 · 有害现象

（1）不良情况

使用本品可能会有以下不良情况。

- 导管管杆的弯曲、折断、异常扭曲
- 导管管杆的断裂、破裂
- 导管拔出困难
- 导引导丝的操作不良、不能操作
- 转接端子的龟裂

（2）有害现象

使用本品可能会有以下有害现象情况，但不仅限于以下表述。

- 造影剂等药物引起的并发症
- 感染
- 出血或血肿
- 动脉栓塞
- 血管夹层
- 包括室侧在内的各种心律失常
- 血管损伤或穿孔
- 脑梗塞
- 造影剂注入内膜下
- 动静脉瘘
- 假性动脉瘤
- 低血压（重症低血压）
- 穿刺部位出血
- 冠状动脉夹层
- 出血性合并症
- 急性心肌梗塞
- 大动脉夹层
- 不稳定型心绞痛
- 末梢血管栓塞
- 发烧或恶寒
- 血管内血栓症
- 恶心或呕吐
- 行动障碍
- 肾功能不全
- 闭塞
- 心悸
- 心律过速
- 心律过缓

3. 其他的注意

使用后要注意防止感染，用安全的方法将其作为医用废有物处理。

【贮藏 · 保管方法及使用期限等】

1. 保管方法

保管本品时注意事项如下。

（1）避免高温多湿、阳光直射及水淋。

（2）避免倾斜、振动、冲撞（包括搬运时），要在非常稳定的状态下保管。

（3）避开化学药品保管场所或煤气发生场所保管。

2. 有效期

本品有效期为3年，请在包装标签所示的 [失效日期] 前使用。

3. 生产日期及失效日期

请见产品标签。

【灭菌方法】

环氧乙烷灭菌

【包装】

1 根 -5 根 / 盒

【注册人 / 生产企业名称及地址等】

注册人 / 生产企业名称：　戈德曼株式会社
株式会社グッドマン
Goodman Co., Ltd.

注册人 / 生产企业住所：　爱知县名古屋市中区荣四丁目 5 番 3 号
KDX 名古屋荣大厦 5 楼
愛知県名古屋市中区栄四丁目5番3号
KDX名古屋栄ビル 5 階 ,
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【中国境内代理人及售后服务机构】

代理人名称：　尼普洛贸易（上海）有限公司

代理人住所：　中国（上海）自由贸易试验区冰克路 500 号 1006 室

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