# Initiator Angiographic Catheter

## A Caution

The Initiator Angiographic Catheter should be used by a physician who is well trained in manipulation and observation under fluoroscopy.

## B Description

The Initiator Angiographic Catheter has a large lumen to allow contrast media to be injected at high flow rates and is designed to exhibit good torque control. The Initiator Angiographic Catheter is comprised of a two-layer construction featuring stainless steel mesh sandwiched between layers of polyamide elastomers. The shaft inner layer and outer layer contain barium sulfate for visibility and contrast under fluoroscopy. The device is offered in lengths of 65-125 cm. French sizes and shaft inner diameters are as follows:

| French Size | Shaft Inner Diameter |
|---|---|
| 4 | 1.03 |
| 5 | 1.20 |
| 6 | 1.40 |

It is a disposable device intended for single use only. This device is individually packaged and sterilized by ethylene oxide gas.

## C Indication for use

The Initiator Angiographic Catheter is intended for use in the delivery of radiopaque contrast media to selected sites in the coronary and peripheral vasculature. This device is not intended for use in the neurovasculature

## D Contraindications

In certain medical conditions, angiography may be contraindicated or, special precautionary measures may need to be taken prior to and/or during the procedure. The following is a list of some of these medical conditions.

- The acute phase of myocardial infarction
- A serious heart failure
- A serious arrhythmia
- A serious systemic infection or fever
- A serious disease other than coronary disease
- Serious serum electrolyte imbalance
- An allergy to or reaction to from the contrast medium
- Renal dysfunction
- Blood coagulopathies
- Some Respiratory Disorders
- Mental Disease
- Pregnancy

## E Direction for use

1. Carefully open the sterile pouch and gently remove the catheter from the package. Flush it by injecting heparinized saline solution through the catheter hub using a syringe.

⚠CAUTIONS
- Do not use if the catheter has been damaged or any other anomaly is observed.
- Employ an aseptic technique during removal from the package and use.

2. Insert a guide wire of appropriate size into the catheter through its hub and advance the wire to approximately 5cm beyond the catheter's distal tip.

⚠CAUTIONS
- The Initiator can accommodate a maximum guide wire size of 0.038" (0.97 mm) diameter.

3. Gain access to the artery by using the Seldinger technique.

⚠WARNING
- Consider the use of systemic heparinization.

4. Insert the guide wire alone into the artery. Then proceed to advance the catheter into the artery over the guide wire.

⚠CAUTIONS
- To avoid damage to the catheter after it has been advanced into the vessel, manipulate the guide wire carefully, particularly when negotiating a bend in the catheter and/or when passing through the catheter's tip.

5. Manipulate the catheter slowly and carefully in the artery.

⚠WARNING
- Never advance or withdraw an intraluminal device against resistance until the cause of resistance is determined by fluoroscopy. Failure to exercise proper caution may result in damage to the vessel or catheter. Separation of the catheter may occur requiring retrieval in some cases.

6. When the catheter tip has reached the branch of the desired vessel, remove the guide wire through the catheter.
7. While confirming the location of the catheter tip under fluoroscopy, advance the catheter to the desired site and perform angiography.

⚠WARNINGS
- Reinforce the catheter shaft with a guide wire while torque is given to the catheter. Excessive torque without use of a guide wire may result in kinking or twisting of the catheter, which may cause difficulty in catheter retrieval.
- Before starting infusion, verify that the catheter has not been kinked or blocked. Failure to abide by this warning may cause the catheter to break / rupture / separate, resulting in damage to the vessel.

8. When using the catheter to guide a micro catheter, insert the micro catheter carefully into the lumen of the catheter.

⚠CAUTIONS
- Use a micro catheter that is below the maximum guide wire size compatible to this catheter.

9. After the procedure is completed, draw the catheter back from the site. Insert the guide wire into the catheter until it extends slightly beyond the distal end of the catheter. Carefully remove the catheter and guide wire together.

## F Warning

- Do not use after the "Use by" date specified on the label.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross contamination.
- Do not heat or bend the catheter tip. Damage to the catheter may result.
- Consider the use of systemic heparinization to prevent or reduce the possibility of thrombus formation on the surface of the catheter.
- Do not advance the guidewire or any other component if resistance is met, without first determining the cause and taking remedial action. This may cause breakage/separation of the catheter, resulting in damage to the vessel.
- Do not advance the Initiator angiographic independent from the guidewire.
- Take care to avoid completely blocking the blood flow.
- Do not use if the unit package or the product has been damaged or soiled. Use immediately after the unit package is opened. Dispose of safely after single use to avoid risk of infection.
- Do not store at extreme temperatures and humidity. Avoid direct sunlight.

## G Precaution

Avoid damaging the tip of the catheter during removal from the packaging.
- The Initiator angiographic catheter procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Select the catheter of optimal tip shape and size, taking into account the site in which it is to be advanced to, as well as the patient's anatomy.
- When using a drug or a device with the Initiator, the operator should have a complete understanding of the properties/characteristics of the drug or device and exercise due caution to avoid damage to the catheter.
- If strong resistance is met during manipulation, stop the procedure and the cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem before proceeding.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.
- Contrast media should be injected at 37°C.
- Performance data for Initiator is provided below. Do not exceed the maximum permissible injection pressure.

| French size | Flow rate | | Maximum permissible Pressure(psi/kPa) |
|---|---|---|---|
| | Flow rate(mL/sec) | Pressure(psi/kPa) | |
| 4Fr. (1.38mm) | 12 | 800psi / 5,516kPa | 800psi / 5,516kPa |
| 5Fr. (1.70mm) | 21 | 1,000psi / 6,895kPa | 1,000psi / 6,895kPa |
| 6Fr. (2.0mm) | 30 | 1,000psi / 6,895kPa | 1,000psi / 6,895kPa |

※ All measurements were taken using 125cm length Initiator samples using the glycerin water mix injections of 23°C.

## H Complications

Potential complications related to the introduction of the catheter into the body include, but are not limited to, the following:
- Arterial embolism or obstruction
- Artery dissection
- Artery injury
- Pseudoaneurysm
- Acute myocardial infarction
- Unstable angina pectoris
- False aneurysm
- Ventricular fibrillation/arrhythmia
- Artery perforation
- Arteriovenous fistula
- Distal embolism
- Spasm
- Vascular thrombosis
- Infection and pain at the puncture site.
- Hematoma
- Bradycardia
- Hemorrhage
- Necessity of blood transfusion
- Limb ischemia

## I Package & Storage

Store at room temperature (1°C~30°C) to avoid direct sunlight and humidity.

## J Limited warranty

GENOSS Co., Ltd. warrants that the Initiator Angiographic Catheter is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by GENOSS Co., Ltd. to be defective in workmanship or materials. GENOSS Co., Ltd. shall not be liable for any incidental, special, or consequential damages arising from the use of the Initiator Angiographic Catheter. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty. No employee, agent, or distributor of GENOSS Co., Ltd. has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against GENOSS Co., Ltd.
THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER OBLIGATION OF GENOSS CO., LTD.

## K Symbols

| | | | |
|---|---|---|---|
| | Manufacturer | | Keep away from sunlight |
| | Date of manufacture | | Keep dry |
| | Use by date | 1°C 30°C | Temperature limit |
| LOT | Batch code | | Do not re-use |
| REF | Catalogue number | | Consult instructions for use |
| STERILE EO | Sterilized using ethylene oxide | | Caution |
| | Do not resterilize | MD | Medical device |
| | Do not use if package is damaged | EU REP | Authorized representative in the European Union |
| | Single Sterile barrier system with protective packaging outside | | |

MS-P2659/IFU-DS1502(Rev.6,2512)

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