Mogul Coronary Micro Catheter

ENGLISH

WARNING

1. 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.
2. The product is a medical device and should only be used by physicians trained in the procedures of percutaneous transluminal coronary angioplasty (PTCA).
3. Intravascular manipulation of the product should be carefully performed under fluoroscopy, confirming both tip movement and positioning. Movement of catheter tip or operation without confirming location may result in possible damage to vessel or the product.
4. Ensure that the guiding catheter is securely engaged within the vasculature (damage to product may result if the guiding catheter becomes disengaged during product insertion).
5. Do not operate valve attached to guiding catheter during product insertion (damage to product or guide wire may result).
6. Should any product resistance or abnormality in catheter tip movement during operation, immediately cease usage and confirm cause under fluoroscopy. Continued use may result in damage to vessel or the product.
7. Immediately cease use of product should kinking or damage to product be confirmed during use (a reduced inner lumen may affect device and/or guide wire manipulation).
8. Do not manipulate guide wire if kinking or damage to catheter be confirmed.
9. Do not rapidly advance catheter (damage to vessel may result).
10. Do not rotate catheter.
11. Do not open or close y-connector valve during manipulation of device (damage to device or guide wire may occur).
12. When using other medical devices or pharmaceutical products together with the product, use them carefully and with a full understanding of their characteristics to prevent damage to the product.
13. Before inserting any pharmaceutical products, confirm that there is no damage or blockage in product.
14. Confirm flow of any pharmaceutical product from catheter tip and immediately cease use and replace product should flow be impeded.
15. Should resistance be felt during insertion of pharmaceutical products, immediately cease use.
16. Do not excessively force any embolic material should an increase in resistance during delivery occur (damage to catheter may result).
17. Carefully manipulate catheter when crossing stent struts and during removal across a stent and immediately cease use and remove product with guide wire should resistance occur.
18. Do not use excessive force when removing product.
19. Should any problem arise due to use in conjunction with another device or pharmaceutical product, immediately cease use.
20. Reference package insert for each medical device and pharmaceutical product used together with this product.
21. Patient selection should be made in consideration of the potential for complications associated with use of this product (i.e. thrombus, hemorrhaging etc).
22. During procedure, perform administration of the appropriate anticoagulants and vasodilators, as directed by lead physician.
23. All product use should be undertaken in a sterile environment.

CONTRAINDICATIONS

1. Contraindications for Use

(1) The product is sterilized, is not re-usable and must not be re-sterilized. Resterilization and/or reuse could result in infection or degradation of product characteristics such as shaft strength or lubricity and could result in failure of the product during use.

(2) This product is for intravascular use only.

2. Inappropriate Patients

(1) Allergy to any pharmaceutical products used in the course of a PTCA procedure, or unable to undergo local anesthesia.

(2) Serious allergy to medication required during the procedure (contrast, etc).

(3) Low left ventricular function.

(4) Pregnant or potential for being pregnant.

(5) Severe disease of other internal organs.

3. Prohibition of Use

(1) Do not use any products comprising organic solvent, fat-based emulsions or oil to prevent damage to the product and/or hydrophilic coating deterioration.

(2) Do not undertake any product modification (damage to product may occur as a result).

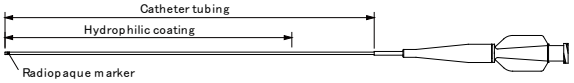
(3) Do not exceed the maximum injection pressure (as noted on the label) when introducing pharmaceutical products through the product.

SHAPE / CONSTRUCTION

1. Construction

This product is a microcatheter with a transition in stiffness from tip to hub. The catheter is coated in a hydrophilic property and contains a radiopaque marker at tip.

2. Product Diagram



PURPOSE, EFFICACY,

1. For intravascular flushing of contrast media during intravascular diagnosis, as well as the injection of pharmaceutical drugs during intravascular treatment.
2. For delivery of medical devices used in the process of a PTCA procedure.

SPECIFICATIONS

1. Tensile Strength Of Catheter:
   - Proximal and Distal Shaft: >5N
   - Hub and Proximal Shaft: >5N
   - Radiopaque Marker at tip: >1N

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

(1) Remove the product from the packaging (still in the protective hoop).

(2) Flush the product with heparinized saline through a syringe attached to the hoop tip, while retaining the product in the protective hoop (flushing for a period of over 30 seconds in order to ensure full product saturation due to hydrophilic coating).

(3) Carefully remove the product from the protective hoop. Inspect and confirm each device for correct functionality ensuring no product deformity.

(4) Using a syringe containing heparinized saline flush the inner lumen of the catheter.

(5) Insert appropriate guide wire into device. .

2. Insertion of Product

(1) Using standard procedures to insert guiding catheter and following connection of y-connector and appropriate flushing advance product through the guiding catheter to target location along the guide wire.

(2) Following completion of preparation for pharmaceutical product, completely remove the guide wire, attach the syringe to catheter hub and inject through the catheter.

3. Removal of product

(1) Carefully remove product following completion of the procedure.

PRECAUTIONS

1. Precautions prior to Use

(1) Use product prior to date of expiration as noted on label.

(2) Confirm condition of product. If any damage or contamination is noted on product, immediately cease use and exchange product.

(3) Confirm specifications of the product and other devices used in conjunction for compatibility with use and procedure.

(4) Immediately use product following removal from package

(5) All use should be performed in a sterile environment

(6) Due to hydrophilic coating ensure that product has been completely saturated in heparinized saline prior to use.

(7) Should any resistance be encountered when removing product from protective hoop, re-perform flushing with heparinized saline.

(8) When removing any residual air, do not forcibly over-tighten the y-connector (damage to y-connector may result).

2. Precautions during Use

(1) If any resistance is incurred during insertion through the guide catheter, immediately remove product and confirm the condition of both product and guide wire.

(2) Do not torque device during delivery or use (damage to both vessel and product may result).

(3) If resistance is felt during removal of the guide wire, remove product to the location whereby the resistance is eliminated (excessive force may damage product)

(4) Immediately exchange out product should any leakage or blockage occur during use.

(5) Only use an automated injector for flushing of contrast media and not other pharmaceutical products.

(6) Intermittent flushing of both guiding catheter and product is required during the procedure (eliminates potential for coagulation of blood particles and potential embolization).

3. Precautions after Use

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

4. Adverse Event

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

Death, myocardial infarction, internal hemorrhage, hematoma, ventricular fibrillation including arrhythmia, hypertension, hypotension, hemorrhagic complications, arterial spasm, stroke, distal embolization, arterial or bypass graft occlusion, arterial dissection or perforation or damage, unstable angina, medicinal reaction or allergic reaction to contrast media, infection, arteriovenous fistula, air embolization, arterial dissection, blood loss from puncture site, ischemia, intravascular thrombosis, nausea or vomiting, palpitation, tachycardia, bradycardia.

5. Defective product

The following occurrences may occur:

- Kinking/breakage of shaft
- Damage to shaft
- Separation of shaft
- Difficulty in removing product/guide wire
- Difficulty in guide wire manipulation
- Damage to connector
- Difficulty in injecting contrast/pharmaceutical product

STORAGE METHOD, SHELF LIFE AND OTHER

1. Storage Method

(1) 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.

(2) Avoid inclinations, vibrations and impacts (including during transportation) and store in a safe, stable environment.

(3) 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.

3. Sterilization Method

The product package has been sterilized by exposure to Ethylene Oxide Gas (EtO) and not intended to be re-sterilized.

PRODUCT WARRANTY DISCLAIMERS AND LIMITATION OF REMEDIES

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REFERENCES

The physician should consult current medical practice literature on PTCA procedures, such as that published by ACC/AHA.

MANUFACTURING SITE

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SYMBOLS

REF	Model Number
LOT	Lot Number
	Contains
	Maximum Guidewire Diameter
	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

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