Powered3 NC Coronary Dilatation Catheter

Not for reuse

Warning

1. Appropriate patients

(1) Excluding emergent patients, discussions between surgical and interventional cardiologists should be undertaken in consideration of the patient risk factors for treatment of unprotected left main lesions, with treatment confined to those patients determined to be high risk for coronary bypass and with anatomically appropriate lesions determined to be low risk for treatment with a percutaneous transluminal coronary angioplasty (PTCA) procedure.

2. Method of use

(1) This 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 or serious complications that could prove to be life threatening.

(2) Be careful to avoid slack in the guide wire when retrieving this device with the guide wire port advanced beyond the tip of the guiding catheter (damage to product and guide wire may result).

Contraindications for use

1. Method of use

(1) Not for reuse

2. Inappropriate lesion

(1) Coronary spasm without significant stenosis (there is no efficacy in regards to coronary spasm).

3. Inappropriate patient

(1) Serious allergy to medication required during the procedure (contrast media etc).

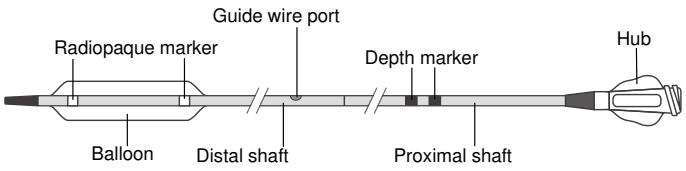
(2) Unstable haemodynamics or shock (aggravation to haemodynamic flow may incur).

4. Inappropriate combination use

(1) Do not use in combination with products comprising of organic solvent, fat-based emulsions or oils (in order to prevent damage to product components such as hub, and/or deterioration to hydrophilic coating).

SHAPE / CONSTRUCTION

1. Product Diagram



<Accessories>
Flush device, rewrap tool, catheter clip

2. Product overview

This product is a rapid exchange (RX) type balloon catheter, with radiopaque markers positioned at both ends of the balloon.

PURPOSE, EFFICACY

The product is used in percutaneous transluminal coronary angioplasty (PTCA) for the purpose of expanding stenotic lesions within an artery or for post inflation immediately following stenting.

METHOD OF USE

1. Preparation

(1) Inspect and confirm each device for correct functionality.
(2) Remove the product from the packaging (remaining in the protective hoop).
(3) Carefully remove the product from the protective hoop.
(4) Carefully remove the balloon protector and the stylet. Confirm that there is no damage to the product.
(5) Dip the entire catheter body into heparinized saline.
(6) Connect the stopcock to the product hub.
(7) Prime an inflation device with an appropriate amount of diluted contrast media (contrast: heparinized saline = 1:1) and connect the stopcock to the inflation device.
(8) With the inflation device tip facing downward, create negative pressure and remove any residual air from within the balloon lumen. Repeat this process until balloon lumen is devoid of air.
(9) Using the flushing device contained as an accessory, remove any air from within the guide wire lumen by flushing with heparinized saline.

2. Insertion Of Product

(1) Follow the package insert of each medical device and complete preparation of the devices prior to insertion of the product.
(2) Cross the target lesion with the guide wire and confirm its placement into the distal vasculature.
(3) Confirming the balloon is completely deflated, carefully insert the tail end of the guide wire into the distal tip of the product and advance the product to the target lesion.

3. Balloon Inflation

(1) Confirm position of the balloon in relation to the target lesion and lock the balloon position by closing the y connector valve.
(2) Confirming condition under fluoroscopy, inflate the balloon to nominal pressure for an appropriate length of time and deflate the balloon using an inflation device.
(3) Perform multiple inflations as deemed necessary.
(4) Upon completion of dilatation, ensure the balloon is completely deflated, return the product to within the guiding catheter and evaluate improvement to stenotic site via fluoroscopy.
(5) Should adequate expansion not be achieved at this time, further improvement may be attained by increasing the inflation pressure or length of time.

4. Removal Of Product

(1) After complete deflation of the balloon, carefully remove the product whilst ensuring that the guide wire remains in position.

5. Rewrap tool (reference)

The rewrap tool is used for re-wrapping the balloon folds. When undertaking re-wrapping using the rewrap tool included as an accessory, follow the procedure described below.

(1) Insert the stylet through the side of the rewrap tool that does not have a flair.
(2) With the balloon held in negative pressure, insert the stylet into the guide wire lumen.
(3) Being careful not to damage product, use fingers to gently roll the balloon wrapping. Looking directly at the fold from the tip, the folds are wrapped in a clock wise direction.
(4) Carefully insert the balloon body into the rewrap tool. In order to avoid damaging product do not rotate product or tool during insertion.
(5) While inside the rewrap tool, apply low inflation pressure and slowly reduce pressure.
(6) Under negative pressure, carefully remove rewrap tool and stylet.
(7) Visually confirm condition of product (including balloon).

6. Precautions During Use

(1) Do not apply excessive force when removing the product from the protective hoop and removing the stylet and balloon protective sheath (damage may affect inflation and deflation functionality).
(2) Be careful when using products with sharp edges such as guide wires to ensure that damage to product does not incur.

(3) All product manipulation should be undertaken with the balloon completely deflated (damage to vasculature or product may result).
(4) When inserting and removing the product, use a gauze soaked in heparinized saline solution to remove any particles from the guide wire (deliverability of product and/or guide wire may be affected).
(5) All device manipulation (including tip movement and balloon positioning) should be conducted under fluoroscopy (damage to vasculature or product may result).
(6) All device insertion and inflation in either a stent or hard plaque such as calcification should be performed carefully (damage to vasculature or product may result).
(7) Do not rotate product (damage to product may result).
(8) When the product has not been adequately flushed with heparinized saline or when the product is used for extended periods of time, coagulation of blood with the guide wire lumen may occur and affect manipulation of both product and guide wire.
(9) Balloon inflation diameter should be determined in consideration of both distal and proximal sites to the lesion (damage to vasculature may result).
(10) During inflation ensure that the y connector valve is adequately closed, ensuring fixation of the product (damage to vasculature may result).
(11) Do not over tighten y connector valve (guide wire manipulation, balloon inflation and deflation functionality as well as contrast media leakage may be affected).
(12) All balloon inflation should utilize a contrast media and never be performed with air (air embolism may result).
(13) Balloon inflation should be used in reference to the compliance chart included in packaging to ensure appropriate sizing (to avoid damage to vasculature and ensure optimal lesion expansion).
(14) When concentric expansion of the balloon is unable to be achieved, ensure that balloon movement does not incur during balloon expansion (damage to the vasculature may result).
(15) When utilizing multiple devices, ensure that products do not become entangled. Should any resistance be encountered, confirm cause before proceeding (damage to product may result).
(16) Should device become kinked immediately cease use (product may become detached).
(17) Regularly confirm condition of product to ensure no damage, lose connection, leakage is occurring.
(18) Once the balloon protective sheath is removed, do not reinsert product (damage to product may result).

Precautions During Use

1. Important fundament precautions

(1) During product usage, ensure appropriate administration of antiplatelet agents and anticoagulants (potential for thrombus formation may occur).
(2) Do not exceed the Rated Burst Pressure (RBP) of the product (damage to product may result).

2. Product defect

This product may incur (but not limited to) the following product defects.
- Balloon rupture
- Inability to inflate/deflate balloon
- Stretching/breakage of tip
- Kinking/damage/separation of catheter shaft
- Unable to remove product
- Resistance due to combined use with other medical products
- Leakage of contrast media used for balloon inflation

3. Adverse Events

Possible adverse events include (but not limited to) the following:
- death
- acute myocardial infarction
- restenosis following angioplasty
- internal hemorrhage/hematoma
- arrhythmia including ventricular fibrillation
- unstable angina
- hypotension/hypertension
- hemorrhagic complications
- coronary spasm
- stroke
- rupture, perforation, damage of coronary artery
- distal embolization
- complete occlusion of coronary artery or bypass graft
- medicinal reaction, allergic reaction to contrast media
- infection
- arteriovenous fistula
- air embolization
- arterial dissection
- blood loss from puncture site
- ischemia from long inflation duration
- intravascular thrombosis
- nausea or vomiting
- palpitation
- tachycardia, bradycardia

4. Applicability for pregnant, parturient, breast-feeding females, pediatrics and others

(1) Effect of radiation on the fetus should be taken into consideration for pregnant or potentially pregnant women.

Shelf Life and Storage

1. Storage Method

Do not store in areas with high temperature and humidity, avoid direct sunlight and contact with water.

2. Shelf Life

Use this product before the date of 'Use By' indicated on product packaging.

MANUFACTURING SITE

Goodman Medical Ireland Ltd
Mervue Business Park, Galway H91 H9CK Ireland

LEGAL MANUFACTURER

Goodman Co., Ltd.
5F KDX Nagoya Sakae Building
4-5-3 Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan

GOODMAN

11th April , 2024 / Rev.3 / GM104 / L9F890003X