Lacrosse PTCA Balloon Catheter Series

- Lacrosse Coronary Dilatation Catheter, Powered Lacrosse Coronary Dilatation Catheter,
LAXA Coronary Dilatation Catheter, Powered Lacrosse2 Coronary Dilatation Catheter -

ENGLISH

WARNING

1. Intravascular manipulation of the product should be carefully performed under fluoroscopy. Movement of the product distal tip or operation without confirming its location may result in possible damage to vessel or the product.
2. Should any product resistance and abnormality in product tip movement and location occur during operation, immediately cease usage and confirm cause under fluoroscopy. Continued use may result in damage to the product.
3. Should any damage to the product be identified during use, cease the usage of the product to reduce potential adverse events such as damage to vessel.
4. With the guide wire exit port of the product placed beyond the tip of a guiding catheter, care should be taken for eliminating any slack in the guide wire to the guide wire exit port when retracting the product into the guiding catheter. Special care should also be given when performing the retrograde approach. The product or the guide wire may become inoperable or incur damage.
5. To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate to the vessel just proximal or distal to the stenosis.
6. Carefully remove the product from the protective hoop and remove stylet and the balloon protector from the product ensuring that no damage to the product is incurred. Damage to the balloon or the balloon lumen may cause balloon inflation/deflation failure or affect functionality.
7. When inserting and/or retrieving the product, use a gauze doused in heparinized saline to wipe the guide wire and remove any foreign particles from surface. Contaminant may cause damage to the product or the guide wire.
8. Care should be taken during insertion or inflation within a stent or hard lesion such as calcified lesions. Damage to the product may occur.
9. The product should only be manipulated while fully deflated. Operating while inflated may cause damage to the product.
10. During procedure, perform administration of the appropriate anticoagulants and vasodilators.

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 balloon size, shaft strength or lubricity and could result in failure of the product during use.

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

(3) 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).

(4) Do not disassemble or modify the device to avoid any unexpected incidents such as breakage of the device.

2. Inappropriate Lesions

(1) Vasculature spasm without significant stenosis.

(2) Lesions in left main trunk without protected by collateral blood flow, bypass or any other method.

3. Inappropriate Patients

(1) Not appropriate for coronary bypass surgery.

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

(3) Pregnant or potential for being pregnant.

(4) Unstable haemodynamics or shock.

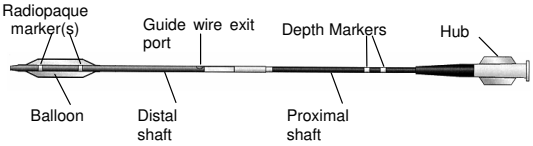
(5) Determination by a physician that use of the product is not appropriate for reasons other than those noted above.

4. Prohibition Of Use With Medicine, Medical Equipments

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

Shape/construction

1. Product Diagram



2. Product Summary

This product is a rapid-exchange (RX) balloon catheter which has a different Nominal Pressure (NP) and Rated Burst Pressure (RBP) than regular type and high pressure type balloon catheters. Furthermore, radiopaque markers are located at both ends of the balloon working length.

NOTE: LAC and LAX with a balloon working length of 5 mm and 10 mm have one marker in the center of the balloon.

PURPOSE, EFFICACY

The product is used in percutaneous transluminal coronary angioplasty (PTCA) for the purpose of dilating stenotic lesions within the coronary artery.

SPECIFICATIONS

1. Tensile Strength At Junctions

- Between Hub and Proximal Shaft: ≧10 N
- Between Proximal Shaft and Distal Shaft including around Guide wire exit port: ≧5.0 N
- Between Distal Shaft and proximal end of Balloon: ≧5.0 N

2. Recommended Inflation Pressure (NP: Nominal Pressure)

- Regular type: 6 atm (6×10^2 kPa)
- High pressure type: 12～14 atm ($12\sim14\times10^2$ kPa)

3. Maximum Inflation Pressure (RBP: Rated Burst Pressure)

- Regular type: 14 atm (14×10^2 kPa)
- High pressure type: 18～20 atm ($18\sim20\times10^2$ kPa)

  NOTE: In vitro RBP test results showed a non-rupture rate of at least 99.9% (95% reliability). Use a pressure gauge to prevent over-inflation of balloon.

4. Maximum Compatible Guide Wire Outer Diameter:
0.014 inch (0.36 mm)

5. Conformity Of Connector: ISO80369-7

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) Flush the product with heparinized saline while retaining the product in the protective hoop. Ensure the product does not become contaminated by being ejected from the hoop during flushing process.
(4) Carefully remove the product from the protective hoop.
(5) Carefully remove the balloon protector and the stylet. Confirm that there is no damage to the balloon.
(6) Prepare a inflation device and diluted contrast media (contrast : saline = 1:1), inflate to the nominal inflation pressure and confirm condition of the balloon (leakage, time required to inflate/deflate etc).
(7) Using the flushing device or the flushing needle, remove air from the guide wire lumen by flushing with heparinized saline through from the product tip (tip of the guide wire lumen).
(8) Connect the stopcock to the product hub (balloon inflation port), and secure the stopcock lever in the “off” position for the channel to the balloon.
(9) Prime an inflation device with appropriate amount of diluted contrast media into the inflation device, connect it to the stopcock and flush stopcock.
(10) Turn the stopcock lever to open the flow channel between the product and the inflation device, and with the inflation device tip facing downward, aspirate for 20-30 seconds.
(11) With the inflation device tip facing downward, cease aspiration and confirm that the product lumen is devoid of air.
(12) Repeat the above process until the product is completely devoid of residual air/bubbles.

2. Insertion Of Product

(1) Follow the package insert for 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 entry into the distal vasculature.
(3) With the balloon 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 close the hemostatic valve, locking balloon into place.
(2) Inflate the balloon to the nominal inflation pressure for appropriate length of time and deflate the balloon using the 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 angiography.
(5) Should adequate expansion not be achieved at this time, further improvement may be attained by increasing inflation pressure or length of time inflation is performed. The compliance chart for each balloon is as stated below:

＜Compliance chart＞

<Regular type Model №：LAC～、LAX～>

Bal. OD / Pressure atm [kPa]	1.00 mm	1.30 mm	1.50 mm	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm
4 [4×10²]	0.98	1.24	1.43	1.89	2.13	2.37	2.61	2.83	3.06	3.29	3.53	3.77
5 [5×10²]	0.99	1.27	1.46	1.94	2.19	2.43	2.68	2.92	3.16	3.39	3.64	3.88
6 [6×10²]	1.00	1.30	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
7 [7×10²]	1.01	1.33	1.53	2.02	2.27	2.51	2.78	3.02	3.30	3.53	3.80	4.06
8 [8×10²]	1.02	1.35	1.55	2.06	2.30	2.54	2.81	3.06	3.35	3.58	3.86	4.13
9 [9×10²]	1.03	1.38	1.59	2.10	2.34	2.58	2.85	3.10	3.39	3.64	3.92	4.20
10 [10×10²]	1.05	1.41	1.62	2.14	2.38	2.61	2.89	3.14	3.44	3.69	3.98	4.27
11 [11×10²]	1.06	1.44	1.65	2.18	2.41	2.64	2.92	3.18	3.49	3.75	4.05	4.35
12 [12×10²]	1.08	1.47	1.68	2.22	2.45	2.68	2.96	3.22	3.53	3.81	4.12	4.42
13 [13×10²]	1.09	1.50	1.72	2.26	2.49	2.71	2.99	3.26	3.58	3.86	4.18	4.49
14 [14×10²]	1.11	1.53	1.75	2.29	2.52	2.74	3.03	3.30	3.63	3.92	4.24	4.56
15 [15×10²]	1.13	1.58	1.79	2.33	2.56	2.78	3.06	3.34	3.67	3.97	4.30	4.63
16 [16×10²]	1.16	1.63	1.84	2.37	2.59	2.81	3.10	3.38	3.72	4.03	4.37	4.70
17 [17×10²]	1.19	1.69	1.90	2.41	2.63	2.84	3.13	3.42	3.77	4.09	4.43	4.77
18 [18×10²]	1.22	1.74	1.94	2.45	2.67	2.88	3.17	3.46	3.81	4.14	4.49	4.84

<High pressure type Model №：LAH～>

Bal. OD / Pressure atm [kPa]	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.25 mm	3.50 mm	3.75 mm	4.00 mm	4.50 mm
6 [6×10²]	1.88	2.06	2.27	2.53	2.73	2.96	3.27	3.54	3.77	4.21
7 [7×10²]	1.90	2.09	2.31	2.57	2.77	3.01	3.31	3.59	3.82	4.27
8 [8×10²]	1.92	2.11	2.34	2.60	2.82	3.06	3.35	3.63	3.87	4.33
9 [9×10²]	1.94	2.14	2.37	2.63	2.85	3.10	3.38	3.67	3.91	4.38
10 [10×10²]	1.95	2.16	2.40	2.66	2.89	3.14	3.42	3.70	3.95	4.43
11 [11×10²]	1.97	2.19	2.43	2.69	2.92	3.17	3.44	3.73	3.98	4.47
12 [12×10²]	1.98	2.21	2.46	2.71	2.95	3.20	3.47	3.75	4.00	4.50
13 [13×10²]	1.99	2.23	2.48	2.73	2.98	3.23	3.49	3.78	4.03	4.53
14 [14×10²]	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.80	4.06	4.56
15 [15×10²]	2.01	2.27	2.52	2.77	3.03	3.27	3.52	3.82	4.08	4.58
16 [16×10²]	2.02	2.29	2.54	2.78	3.05	3.30	3.54	3.84	4.10	4.60
17 [17×10²]	2.03	2.30	2.55	2.80	3.07	3.32	3.55	3.85	4.12	4.63
18 [18×10²]	2.04	2.32	2.57	2.81	3.09	3.34	3.57	3.87	4.15	4.65
19 [19×10²]	2.05	2.34	2.59	2.83	3.11	3.36	3.58	3.89	4.17	4.68
20 [20×10²]	2.06	2.35	2.60	2.84	3.13	3.38	3.60	3.91	4.19	4.70
21 [21×10²]	2.07	2.37	2.62	2.86	3.15	3.40	3.62	3.93	4.22	4.72
22 [22×10²]	2.08	2.39	2.64	2.88	3.17	3.43	3.63	3.94	4.24	4.75
23 [23×10²]	2.09	2.41	2.66	2.90	3.19	3.45	3.65	3.96	4.27	4.77
24 [24×10²]	2.10	2.43	2.68	2.91	3.21	3.47	3.67	3.98	4.29	4.80

■＝Nominal Pressure（NP） □＝Rated Burst Pressure（RBP）

4. Removal Of Product

After complete deflation of the balloon, carefully remove the product while ensuring that the guide wire remains in location.

5. Re-Wrapping Tool Method Of Use (Device Intended For Re-Folding the Balloon)

(1) Insert the stylet into the guidewire from the side of re-wrapping tool that is not flared.
(2) Advance the stylet through the guidewire lumen maintaining negative pressure.
(3) Carefully reshape the balloon wrapping. The balloon pleats should be twisted clockwise when seen from the tip.
(4) Care should be taken to cover the whole balloon with the re-wrapping tool. Do not rotate the re-wrapping tool nor the device when covering.
(5) Apply low pressure and reduce the pressure slowly with the balloon covered by the re-wrapping tool.
(6) Apply negative pressure and carefully remove the re-wrapping tool and stylet.
(7) Visually check the device for any damage (especially to the balloon).

NOTE : The guiding catheter, the guide wire, the hemostatic valve connector, the syringe, the inflation device and the 3-way stopcock described in METHOD OF USE are not included in the product package.

PRECAUTIONS

1. Precautions Prior To Use

(1) Refer to attached documents of all pharmaceuticals and medical devices used in relation to the target lesion and procedure.
(2) Confirm specifications of product and other devices used in relation to the target lesion and procedure.
(3) Do not use product if packaging or contents are damaged or contaminated.
(4) All product use should be undertaken in a sterile environment.

2. Precautions During Use

(1) Take care when using the guide wire or the flushing needle to ensure that any damage to the product does not occur.
(2) Do not use air when performing the balloon inflation. There is potential to cause complications associated with air embolization.
(3) When the product has not been adequately flushed with heparinized solution or when the product is used for a continuously long time, coagulation of blood within the guide wire lumen may occur and affect operation of the guide wire and the product.
(4) When the balloon can not be concentrically inflated, take care that the balloon movement does not occur. Balloon movement during inflation may cause damage to vessel.
(5) The hemostatic valve should be closed in order that the balloon positioning fixed during inflation. The balloon movement during inflation may cause damage to vessel.
(6) When closing the valve of the hemostatic valve connector, be sure not to impede the operation of the guide wire or the inflation/deflation line of the balloon.
(7) Should product incur kinking to the shaft, do not use or attempt to repair. Damage to the product may occur.
(8) When placing a number of devices into patient, operate the product and other devices carefully in order to prevent entanglement. If resistance is felt during procedure, confirm cause of resistance. Damage to the product may occur.
(9) Check the product for abnormality such as damage, loosening of connected sections or leakage of chemical solutions on a regular basis.
(10) Once the balloon has been inflated, do not re-wrap the balloon by use of the balloon protector. Damage to balloon may occur.
(11) The surface of device is covered with a hydrophilic coating and should be saturated with heparin solution at all times during use in order to avoid any inoperability that could result in damage or breakage of device.

3. Precautions After Use

Dispose the 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, restenosis following angioplasty, 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 allergenic reaction to contrast media, infection, arteriovenous fistula, air embolization, arterial dissection, blood loss from puncture site, ischemia caused by long duration inflation, intravascular thrombosis, nausea or vomiting, palpitation, tachycardia, bradycardia

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 the 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 date of “Use By” 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 balloon dilatation, such as that published by ACC/AHA.

MANUFACTURING SITE

Goodman Co., Ltd. Goodman Research Center
276-1 Idogane-cho, Seto, Aichi 489-0976 Japan

MANUFACTURING SITE

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

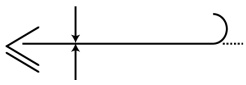
MANUFACTURER

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

SYMBOLS

Contains:
(Number of contains)

Maximum Guidewire Diameter:



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