Version: D

Effective date:2026-07-13

V-BALLEX® Peripheral balloon dilatation catheter

Instruction for Use

(Please read this manual carefully before use, paying special attention to all warnings and precautions)

Shanghai EndoVas Medical Technology Co., Ltd.

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CE 2764

Instruction for use for Peripheral balloon dilatation catheter

Please read the instruction carefully before using this product. If not operated correctly according to instructions, warnings, and precautions, it may result in serious surgical consequences or cause serious harm to patients.

【Product Components】

This product is an OTW peripheral balloon dilation catheter, which is composed of a tip, radiopaque maker, balloon, inner lumen, outer sheath, anti-kinking protector and catheter hub. The balloon is made of polyamide (Pa12) and polyether block polyamide (Pebax7233), see Figure 1, and the balloon is designed to reach a specific diameter at a specific pressure (see Table 1).

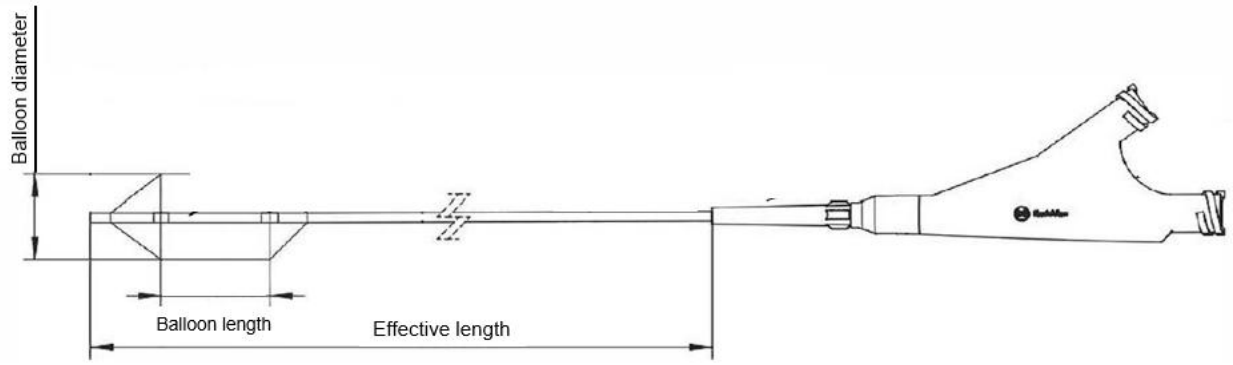

Figure 1. Peripheral balloon dilatation catheter

Figure 2: The distal components of the Peripheral balloon dilatation catheter

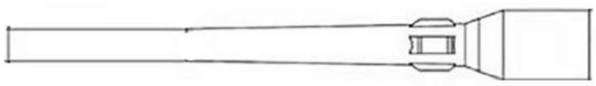

Figure 3: Anti-kinking protector

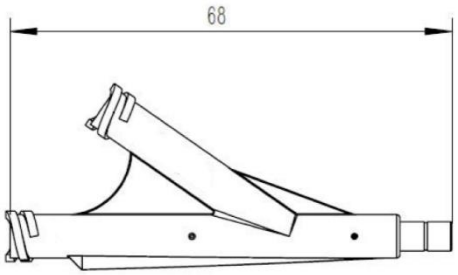

Figure 4: Catheter hub

Figure 5: Sectional view of distal components of the Peripheral balloon dilatation catheter

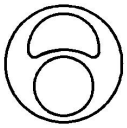

Figure 6: Cross-sectional view of outer sheath

【Specification】

The Peripheral balloon dilatation catheter is divided according to the balloon diameter, balloon length, and catheter length.Product specification list is shown below:

Name	Available size (mm)	Tolerance
Balloon length	40、60、80	±10%
Effective length	750、1150	±20mm
Balloon diameter at nominal pressure	8、10、12、14、16、18	±10%
Outer sheath outer diameter	1.75	±0.05mm
	2.08	±0.1mm

This product contains a total of 36 specifications according to the length of the catheter and the size of the balloon, and the specific specifications and models are shown in Annex 1.

【Intended Purpose】

The Peripheral Balloon Dilatation Catheter is intended for use in percutaneous transluminal

angioplasty (BDC) of the peripheral vascular system and balloon dilation stents or posterior expansion of self-expanding stents.

【Limitation】

This balloon catheter is intended for use exclusively in peripheral arterial and/or venous vessels outside the central circulation system.

【Intended user】

This product shall be used by skilled surgeon and trained nurses. The qualified surgeons trained on the operation of Peripheral Balloon Dilatation Catheter, experienced in surgical operation and fully understood the Instructions for use prior to operate.

【Indication】

Percutaneous transluminal angioplasty (PTA) is performed on the peripheral vascular system, including the iliac artery, femoral artery, popliteal artery, tibial artery, fibular artery, subclavian artery, and renal artery, and is suitable for treating obstructive lesions of arteriovenous fistulas for autologous or artificial dialysis. It is also suitable for post dilation of balloon or self expanding stents in the peripheral vascular system.

【Patient target groups/patient population】

Peripheral balloon dilatation catheter is mainly suitable for patients with peripheral vascular diseases, as well as some patients who require vascular angioplasty or stent implantation assistance. For patients who are sensitive to medication such as anticoagulants and antiplatelet drugs, please communicate with your physician to decide whether to use the medication.

【Contraindications】

- Severe infection
- Severe vascular stenosis or occlusion prevents the guidewire from passing through the lesion
- Coagulation disorders (bleeding diseases)
- High-risk aneurysm
- Allergic reactions

【Warnings】

- This instrument is for one-time use only, do not sterilize and reuse. Reuse of catheters may affect the performance and safety of catheters, and incomplete sterilization may lead to malignant cross-infection between different patients. Weakening of the catheter due to re-sterilization and reuse can lead to serious consequences. Read the instruction carefully before use and follow the intended use.
- Do not use if the package is opened, cracked, leaking, or beyond the sterilization expiration date before use.
- The device use only peripheral vascular system, and cannot be used in central circulation and aorta system.
- Balloon size selection is critical, and to reduce the likelihood of vascular injury, the nominal diameter of the peripheral balloon dilatation catheter should be close to the diameter of the blood vessel anterior and posterior to the narrowed lesion.
- When the catheter is placed in the body, it should be performed under adequate and/or high-quality fluoroscopy. Before the peripheral balloon dilatation catheter can be withdrawn from the lesion site, the balloon must be fully contracted under vacuum aspiration. If resistance is encountered during operation, the cause of resistance should be clarified before proceeding.
- Do not use air or any gaseous medium to dilate the balloon, and only use the recommended liquid for pressurization (usually a 50% :/50% mixture of contrast medium and sterile saline).
- The balloon pressure cannot be higher than the rated burst pressure (RBP). In vitro studies have confirmed that the balloon may rupture at bursting pressures higher than the rated burst pressure. When the balloon pressure is less than or equal to the balloon's rated burst pressure, 99.9% of the balloon or balloon bonding will not leak (95% confidence). It is recommended to use a balloon compression device for expansion to prevent overpressure, as dilation beyond the rated burst pressure may result in balloon rupture. Failure to use a visual guide when advancing, withdrawing, or manipulating a Peripheral Vascular Snare in the cardiovascular system may result in foreign body displacement or damage to the peripheral vascular system.
- While the balloon is in dilation, under no circumstances should the guidewire be moved.
- Use the product before the expiration date.

- Use in severely calcified vessels may reduce the success rate of surgery (60% to 80%) and increase the risk of obstruction, vascular injury, balloon rupture, and associated complications.

【Clinical side effects/Possible complications/Undesirable effects】

Complications that may arise from balloon dilatation procedures include the following

- Allergic reaction (to device, contrast medium or medication)
- Arteriovenous fistula
- Embolization (air, device, plaque, etc.)
- Hematoma
- Hemorrhage, including bleeding at the site of operation
- Pseudoaneurysm
- Sepsis/infection
- Thromboembolic events
- Vascular damage, e.g. dissection, perforation or rupture
- Vascular occlusion
- Vascular spasm

In addition, the following complications may arise from balloon dilatation procedures within the biliary system:

- Angiocholitis
- Hemobilia
- Pancreatitis
- Trauma to ducts (vessel dissection, perforation, rupture, etc.)
- Occlusion ofducts
- Ductal spasm

【Main performance criteria】

- Balloon dilatation catheter components should not show signs of corrosion
- Capable of passing 0.035” (0.89mm) diameter guidewire
- Balloon filling time to nominal pressure ≤ 60 seconds
- Balloon depressurization time should be ≤120 seconds

- There should be no liquid leakage from the seat (luer fitting) or connection assembly or other parts of the tubing
- No air should enter the seat (luer fitting) assembly during continuous suction

【Summary of the product's safety criteria】

When the balloon diameter is 8~12mm, the filling pressure should be 10atm;
when the balloon diameter is 14~18mm, the filling pressure should be 6atm;
when the balloon diameter is 8mm, the rated burst pressure should be 18atm;
when the balloon diameter is 10~12mm, the rated burst pressure should be 14atm;
when the balloon diameter is 14~18mm, the rated burst pressure should be 8atm;
The catheter effective length is 75cm or 115cm.

【Accessories not included but necessary for use】

There are no accessories for Peripheral Balloon Dilatation Catheter.

【Devices related to the surgical technique】

- Contrast agent;
- Stroke-physiological saline solution;
- Syringe with a Luer lock interface;
- Three-way valve;
- Haemostatic valve;
- The balloon filling device;
- Sheath / guide catheter of appropriate size (8F sheath recommended for 8,10,12mm, 12F sheath recommended for 14,16,18mm);
- 0.89mm (0.035 ") guide wire;
- Appropriate size of the peripheral balloon dilatation catheter.

【Application steps】

Carefully inspect all devices that will be used, including the peripheral balloon dilatation catheter, before use to ensure that it is functioning well. Confirm that the peripheral balloon dilatation catheter and sterile pouch have not been damaged during transportation and that the specifications

of the peripheral balloon dilatation catheter are suitable for the appropriate procedure.

1. Preparation of balloon compression device

Prepare the balloon filling device according to the manufacturer's instruction.

2. Select a peripheral balloon dilatation catheter

The selected peripheral balloon dilatation catheter size must be less than or equal to the internal diameter of the proximal and distal veins of the lesion. If the intended peripheral balloon dilatation catheter does not pass through the stenotic lesion site, a smaller catheter is used to pre-dilate the lesion site to provide access to a more appropriately sized catheter.

3. Preparation of peripheral balloon dilatation catheter

a. Carefully remove the catheter from the package.

b. Remove the protective sleeve from the balloon.

c. A constricted balloon contains a small amount of air that should be expelled before being inserted into a blood vessel. To do this, aspirate the contrast agent diluted with sterile saline with a syringe with a luer locking interface, connect the syringe to the three-way valve, and flush the three-way valve to the filling port of the peripheral balloon dilatation catheter. Pull the syringe piston back with the distal end of the peripheral balloon dilatation catheter and the balloon vertically downward, and aspirate for 15 seconds until the air is completely expelled, and release the piston. Remove the syringe, drain the air from the syringe, reconnect the syringe, and repeat until the balloon is completely free of air. Do not use air or any gaseous medium to expand the balloon.

d. Attach the syringe to the balloon catheter guidewire mouth and flush the guidewire cavity with normal saline.

4. The connection between the balloon compression device and the catheter

a. The balloon compression device is used to draw the contrast medium diluted with sterile normal saline and expel the air in the balloon compression device.

b. The balloon compression device is attached to the filling port of the peripheral balloon dilatation catheter.

5. The use of peripheral balloon dilatation catheter

a. A guidewire is inserted from the distal end of the peripheral balloon dilatation catheter. While the balloon is fully contracted, slowly advance the peripheral balloon dilatation catheter through the hemostatic valve. It should be noted that the hemostatic valve should be closed to the extent that it prevents blood from backing up while allowing easy movement of the peripheral balloon dilatation catheter. If resistance is encountered, do not push the catheter forward.

b. Under X-ray fluoroscopy, the balloon's radiopaque marker is used to locate the balloon to the lesion to be inflated and to the appropriate pressure.

c. Negative pressure is applied to completely shrink the balloon. Withdraw the contracted peripheral balloon dilatation catheter from the guide catheter while tightening the hemostatic valve.

d. Peripheral balloon dilatating catheter of different balloon types and sizes can be replaced if needed, but they are all performed through a guide wire located in the blood vessels.

e. The recovery and disposal of peripheral balloon dilatation catheter must be in accordance with national and local laws.

【Shelf life and storage condition】

- This product is sterilized by ethylene oxide and is valid for two years.
- Manufacture date and expiration date refer to label
- Avoid sunlight and store at room temperature in a dry place
- Storage temperature: 10℃~30℃; Storage humidity: 10%~60% .

【Packaging】

The product is provided in a sterile state. The product components are fixed and protected inside the coil, and sealed in double-layer special Tyvek® dialysis bags.

【Sterilization】

This product is sterilized by ethylene oxide and shall not undergo secondary sterilization. The sterilization method of this product is ethylene oxide sterilization, Tyvek® bag is recognized in the industry suitable for ethylene oxide sterilization packaging materials. The Tyvek® bag is suitable to ethylene oxide sterilization method.

【Post sale service】

Contact with our company if there are any questions.

【Declaration】

The peripheral balloon dilatation catheter is for single use and should not be reused. The Company shall not be responsible for any damage to the product or failure of the procedure due to reuse, improper selection of product specifications, operational errors, or any other human-caused accidents.

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Explanation of graphics, symbols, abbreviations, etc. used in the label of medical devices

	Manufacturer
	Date of manufacture
	No secondary sterilization
	Do not re-use
	Batch code
	Consult instructions for use
	Use-by date
	Do not use if package is damaged
	Medical Device
	Sterilized using ethylene oxide
QTY:1	Quantity
	Keep Dry
	Avoid Sunshine
	Product model and specification
	Notified Body, and product meet the basic requirements of MDR 2017/745

Annex 1. Product specification list

Model	Balloon size (mm)	Balloon diameter at nominal pressure (mm) (±10%)	Balloon Length (mm) (±10%)	Effective Length (cm) (±2cm)	Models suitable for guide wires	Nominal Pressure (NP) （atm）	Burst Pressure Rating (RBP) （atm）
BDC-0840-075	8.0×40	8.0	40	75	Fits 0.89mm (0.035 inch) guide wire	10	18
BDC-0840-115	8.0×40	8.0	40	115		10	18
BDC-0860-075	8.0×60	8.0	60	75		10	18
BDC-0860-115	8.0×60	8.0	60	115		10	18
BDC-0880-075	8.0×80	8.0	80	75		10	18
BDC-0880-115	8.0×80	8.0	80	115		10	18
BDC-1040-075	10.0×40	10.0	40	75		10	14
BDC-1040-115	10.0×40	10.0	40	115		10	14
BDC-1060-075	10.0×60	10.0	60	75		10	14
BDC-1060-115	10.0×60	10.0	60	115		10	14
BDC-1080-075	10.0×80	10.0	80	75		10	14
BDC-1080-115	10.0×80	10.0	80	115		10	14
BDC-1240-075	12.0×40	12.0	40	75		10	14
BDC-1240-115	12.0×40	12.0	40	115		10	14
BDC-1260-075	12.0×60	12.0	60	75		10	14
BDC-1260-115	12.0×60	12.0	60	115		10	14
BDC-1280-075	12.0×80	12.0	80	75		10	14
BDC-1280-115	12.0×80	12.0	80	115		10	14
BDC-1440-075	14.0×40	14.0	40	75		6	8
BDC-1440-115	14.0×40	14.0	40	115		6	8
BDC-1460-075	14.0×60	14.0	60	75		6	8
BDC-1460-115	14.0×60	14.0	60	115		6	8
BDC-1480-075	14.0×80	14.0	80	75		6	8
BDC-1480-115	14.0×80	14.0	80	115		6	8

BDC-1640-075	16.0×40	16.0	40	75		6	8
BDC-1640-115	16.0×40	16.0	40	115		6	8
BDC-1660-075	16.0×60	16.0	60	75		6	8
BDC-1660-115	16.0×60	16.0	60	115		6	8
BDC-1680-075	16.0×80	16.0	80	75		6	8
BDC-1680-115	16.0×80	16.0	80	115		6	8
BDC-1840-075	18.0×40	18.0	40	75		6	8
BDC-1840-115	18.0×40	18.0	40	115		6	8
BDC-1860-075	18.0×60	18.0	60	75		6	8
BDC-1860-115	18.0×60	18.0	60	115		6	8
BDC-1880-075	18.0×80	18.0	80	75		6	8
BDC-1880-115	18.0×80	18.0	80	115		6	8

NOTE: The peripheral balloon dilatation catheter does not have the function of distal perfusion or pressure measurement