APT Conqueror Anchored Balloon Dilatation Catheter

“APT”CONQUEROR Trap Trapping Balloon Catheter

Ministry of Health Medical Device Land Transport No. 001394

Please read the original manual carefully before use and follow the instructions.

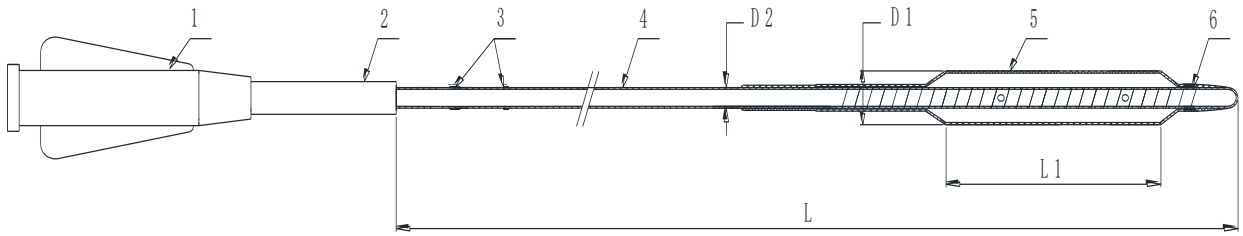
ÿ Product Description:

This product consists of a balloon, a catheter and a connector; a strain relief sleeve is set at the connection between the catheter and the connector, and a deep

The distal end of the catheter is a spiral transition structure, the distal end of the catheter is set with a radiopaque marker, and the balloon is located at the distal end of the catheter.

The product diagram is shown in Figure 1. The balloon material is polyamide; the catheter material is 304 stainless steel; the radiopaque marker material is

Platinum-iridium alloy (90Pt10Ir); The recommended expansion pressure of this product is 8-10ATM and the rated burst pressure is 14ATM.



1. Connector 2. Strain relief sleeve 3. Depth marker 4. Catheter 5. Balloon 6. Radiopaque marker

D1 balloon diameter, D2 catheter outer diameter, L1 balloon length, L catheter effective length

Figure 1 Schematic diagram of anchored balloon dilatation catheter

ÿ Model specifications: The model specifications and parameters of the anchored balloon dilatation catheter are shown in Appendix 1.

ÿ Scope of application:

During percutaneous coronary angioplasty, the guide wire in the guide catheter is fixed by balloon inflation to facilitate catheter exchange.

ÿ Warning:

1. Do not modify this product.
2. This product is sterilized with ethylene oxide and is a disposable medical device. It cannot be reused. If you reuse this device,

   May cause patient infection or cross infection.
3. This product cannot be sterilized repeatedly. If the device is sterilized and used repeatedly, its structure may be damaged or the device may become ineffective.
4. Do not use if the product packaging has been opened or damaged before use.
5. Only those who have undergone percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA)

   Only trained physicians can use this catheter.
6. Use immediately after opening the package. After the operation is completed, the product may have potential biological hazards and should be used according to the hospital, hospital, and hospital regulations.

   Dispose of products and packaging in accordance with administrative regulations or local government policies.
7. This product should be used in a guide catheter with an effective length of 100 cm or 90 cm and its proximal end

The Y-valve is connected. Insertion of this product should be confirmed under X-ray fluoroscopy to ensure that the product does not extend beyond the guide catheter. remote.

8. This product with an effective length of 102cm is recommended to be used in a guide catheter with an effective length of 90cm. When using, the insertion depth of this product cannot exceed the 90cm depth mark. Please note that the distal end of this product cannot exceed the distal end of the guide catheter. 9. This product with an effective length of 112cm is recommended to be used in a guide catheter with an effective length of 90cm.

If the depth exceeds the 90cm mark, please note that the distal end of the product cannot extend beyond the distal end of the guide catheter. In addition, when used in a guide catheter with an effective length of 100cm, the insertion depth of the product cannot exceed the 100cm mark. Please note that the distal end of the product cannot extend beyond the distal end of the guide catheter.

10. For patients who are not suitable for anticoagulant therapy, careful consideration should be given. 11. Patients who are not suitable for coronary artery bypass surgery should be carefully considered when performing PTCA, including during PTCA surgery.

Patients who may require hemodynamic support because treatment of this patient population carries particular risks.

12. When inserting this product into the guide catheter, if you feel resistance, do not force it in.

13. Do not twist the product and the wire during operation. (Twisting of the wire will increase resistance)

14. During operation, be careful not to get tangled and operate with caution. If you feel strong resistance, please stop the operation immediately and take reasonable measures after confirming the cause. (If you continue to operate, the external force applied by force may cause the product to Damaged.)

15. Do not scratch this product with a scalpel, scissors, etc. Do not clamp this product with forceps. 16. After removing this product and the exchange catheter, be sure to remove the guide catheter before the next operation.

The air inside.

17. Use the mark on the far end of this product as a reference and operate carefully under X-ray fluoroscopy.

18. Do not allow this product to come into contact with chemicals such as disinfectants. (This may damage the product.)

19. For medical devices used in conjunction, please follow the instructions that come with the medical devices. 20. Do not use this product when there are two or more catheters in the guide catheter.

21. The balloon inflation pressure should not exceed the rated burst pressure (RBP). RBP is based on in vitro test results and is less than or equal to this At least 99.9% of the balloons will not burst (95% confidence interval) when the pressure is high. To prevent over-pressurization, it is necessary to use Pressure monitoring device.

22. Only use the recommended contrast media to inflate the balloon. Never use air or any other gas to inflate the balloon.

23. Please use this product before the expiration date indicated on the package. ÿ

Notes:

1. Keep away from moisture and direct sunlight. Do not store in high temperature or high humidity environment.

2. If the catheter surface becomes dry, moisten the balloon catheter surface with heparinized saline. 3. The catheter used during surgery cannot be inserted into the packaging tube again.

4. During the operation, provide the patient with appropriate anticoagulants and coronary artery vasodilator therapy if necessary.

The duration of dilation therapy is determined by the physician.

5. The catheter should be held during operation of the entire anchored balloon dilatation catheter, including advancement and retraction of the catheter.

Potential complications :

During the use of this product, the following adverse phenomena may occur, including but not limited to: 1. Balloon rupture 2. Poor balloon expansion/contraction

3. Catheter folding/bending/breaking/ deformation 4. Difficulty in withdrawing the catheter

5. Developer leakage

During coronary artery intervention, complications may occur but are not limited to the following:

1. Acute myocardial infarction

2. Complete occlusion of the coronary artery or bypass graft

3. Dissection, perforation, rupture or injury of the coronary artery

4. Arterial dilation followed by restenosis

5. Bleeding or hematoma

6. Angina

7. Arrhythmia, including ventricular fibrillation or other conduction disorders 8. Drug reaction, contrast agent allergic reaction

9. Hypotension/hypertension

10. Infection

11. Coronary artery spasm

12. Arteriovenous fistula

13. Embolism

14. Emergency Coronary Artery Bypass Graft

15. Death

ÿ Precautionary measures:

1. For patients suspected of being allergic to contrast agents, a contrast agent allergy test should be performed before surgery to rule out the possibility of allergy.

2. Check the integrity and stability of the anchored balloon dilatation catheter before use, and prepare for foreign body capture during intravascular intervention. device.

ÿ Contraindications:

None found yet.

ÿ Storage and transportation:

Keep away from moisture and direct sunlight. Do not store in high temperature or humid environment. Avoid heavy pressure, direct sunlight and Rain.

ÿ Date of manufacture and validity period:

The manufacturing date can be found on the product packaging. This product is sterilized with ethylene oxide and has a limited shelf life of three years from the time of sterilization.

ÿ Symbols:

	Product model specifications		batch number
NAME	Nominal pressure	**RBP**	Rated burst pressure
	Date of manufacture		Shelf life
	Contents		Sterilized with ethylene oxide
	warn		No secondary use
	Do not use if packaging is damaged.		Avoid sun exposure
	Avoid rain		Hunan Apt Medical Equipment Co., Ltd. Logo

ÿ Appendix 1. Anchored balloon dilatation catheter model specifications

Model Specifications	Balloon diameter (mm)	Balloon length (mm)	Effective length of catheter (cm)	Catheter outer diameter (mm)
38250120	2.50	12	102	0.45
38250121	2.50	12	112	0.45

Manufacturer Name: APT Medical Inc.

Manufacturer Address: No.009, Xiangxiang Road, Xiangxiang Economic Development Zone,

Xiangxiang City, Hunan, 411400, China

Medical device manufacturer: Lanbowan Biotechnology Co., Ltd.

Medical equipment supplier address: According to the latest medical equipment supplier address approved by the health bureau (commercial products must be published

(Please include the actual address)

Product images