KOSSEL

HP PTA Balloon Dilatation Catheter
Instruction for Use

Kossel Medtech (Suzhou) Co., Ltd.

【Contents】

℞ Only

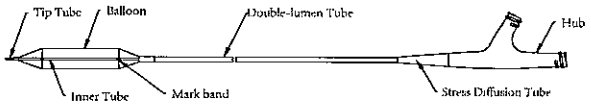
Caution: Federal (USA) law restricts this device to sale by or on order of a physician. Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications.

[Device Name]

The device is manufactured by Kossel Medtech (Suzhou) Co., Ltd. The generic device name is HP PTA Balloon Dilatation Catheter.

[Device Description]

The 0.0350"HP PTA balloon dilatation catheter is mainly composed of tip tube, inner tube, balloon, marker bands, double-lumen tube, stress diffusion tube and hub. Among them the balloon is the most important part of the catheter. In order to dilate different stenosis, the balloon should be dilated to different dimensions by inflating to different pressures. The soft tip at the end of the balloon is intended to make the balloon catheter more easy to push to the stenosis position. The inner tube which connects to the tip tube is for guide wire passage and the pushing rod. The two marker bands wrapped around the inner tube are for positioning the balloon location with the use of in vitro monitoring equipment. The proximal end of the double-lumen tube is connected with the hub, which is used as the balloon filling channel and also as the push rod of the catheter. The hub is used to connect with the external pressure equipment for balloon filling. The stress diffusion tube can prevent the double-lumen tube from being folded.



[Contents]

One HP PTA balloon dilatation catheter.

[How Supplied]

Packaging is designed to maintain sterility according to expiration date on the label. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

[Sterilization Method]

Sterilized with ethylene oxide gas. Nonpyrogenic.

[Handling and Storage]

Store in a dry, dark, cool place.

[Transport Conditions]

The device should be protected from heavy pressure, direct sunlight and rain and snow immersion during transportation.

[Expiry Date]

The shelf life of the HP PTA balloon dilatation catheter is 2 years.

[Indications]

The HP PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
This catheter is not for use in coronary arteries.

[Contraindications]

· It should not be used for lesion that cannot be passed by the guide wire.
· This product is not recommended for patients with certain diseases, conditions or specific populations (such as children, pregnant and lactating women, and those with liver and kidney dysfunction).

[Precautions]

· This product should be used only by physicians with experience in angiography and percutaneous transluminal angioplasty.
· Inspect the products carefully prior to use. Do not use if the package is open or damage.
· It is possible to rinse the guide wire lumen in a sterile/isotonic saline solution.
· Prior to angioplasty the balloon dilatation catheter should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.
· Do not inflate the balloon prematurely. The recommended inflation pressure of the balloon must not be exceeded. It is also recommended that a pressure gauge is used to measure the inflation pressure.
· During the procedure, provide appropriate anticoagulant and vasodilator therapy to the patient as needed. Anticoagulant therapy should be continued for a period of time as determined by the physician after the procedure.
· If the surface of the dilatation catheter becomes dry, wetting with heparinized normal saline.

·The inflated diameter of the balloon should correspond to the lumen of the artery, never use a balloon with a larger diameter.
·Care should be taken not to apply excessive force during preparation or use, as this may damage the device.

[Warnings]

When using this type of device, the following warnings should be observed:
·The catheter is only sterilized with ethylene oxide gas and non-pyrogenic, do not use if the package is opened, damaged or broken.
·This device is designed and intended for single use only. Do not resterilize or reuse it. Reuse of device or non-sterile device may result in patient infection.
·To reduce the potential for vessel damage, the inflate diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
·PTA operation should only be performed at hospitals, and the catheter system is to be used only by physicians thoroughly trained in the performance of PTA operation.
·Use only the recommended balloon inflation medium, Never use air or any gaseous medium to inflate the balloon.
·Balloon pressure should not exceed the rate burst pressure (RBP) indicated on the package label for each balloon. The RBP is based on results of in vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or burst at or below their RPB. To prevent over-pressurization, use a pressure-monitoring.
·When the catheter is exposed to the vascular system, it should be manipulated while under high quality X-ray fluoroscopic. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and/or damage/separation of the catheter.
·Do not use, or attempt to straighten, a catheter if the shaft has become bent or kinked, this may result in the shaft breaking. Instead, prepare a new catheter.
·Use the catheter prior to the "Use By" date specified on the package and labels.

[Complications]

Potential complications and adverse effects due to the

use of this product include, but are not limited to the following:
·Abrupt vessel closure
·Acute myocardial infarction
·Hematoma
·Pseudoaneurysm
·Arterial perforation
·Infections
·Embolism
·General bleeding
·Arterial rupture
·Thrombus formation
·Hypotension
·Ischemia
·Arterio-venous fistulas
·Palpitations
·Drug reaction, allergic reaction to contrast medium
·Arrhythmia
·Bradycardia
·Vessel trauma requiring surgical repair or re-intervention
·Vascular complication which necessitate a surgical intervention
·Restenosis of prior treated target vessel segment

[Materials Required]

·Sterile heparinized normal saline
·Hemostatic valve(s)
·Appropriate guide catheter and contrast catheter
·contrast medium
·Inflation device
·Luer-lock syringe (optional)
·Appropriately-sized guide wire(diameter not to exceed the maximum guide wire for the dilatation catheter; see product label)
·Guide wire torque device
·Guide wire introducer
·Primary flushing tool

[Preparation for Use]

Prior to use, it is essential to examine all equipment carefully for defects. Examine the dilatation catheter for bends, kinks, or other damage. Do not use if the package is open or damaged, or the product is damaged.
Prepare equipment to be used following manufacture's instruction or standard procedure.
Complete the following steps to prepare the HP PTA catheter for use:

1.Take out the device from the packaging and gently withdraw the dilatation catheter from the hoop dispenser.
2.Take the balloon protection tube from the distal of the balloon dilatation catheter.
3.Flush the HP PTA balloon dilatation catheter. Attach a syringe filled with heparinized normal saline to the flushing tool, gently insert the flushing tool into guide wire lumen of hub, and inject heparinized normal saline into the lumen. Follow this procedure for subsequent flushing. Flush solution should be seen coming out of the guide wire port.
Note: Submerge the balloon in sterile heparinized normal saline during balloon preparation.
4.Prepare the inflation device with the recommended contrast medium according to the product instructions.
5.Use the following steps to remove the air from the inner cavity filled by the catheter:
a) Fill a 20cc syringe or inflation device with about 15cc of the recommended contrast medium.
b) After connecting the syringe or inflation device to the balloon filling lumen, adjust the catheter distal to make the balloon vertically downward.
c) Apply negative pressure and keep it for 15s. Slowly release the pressure to normal pressure and allow the contrast medium to fill the dilatation catheter shaft.
d) Remove the syringe or inflation device from the dilatation catheter inflation port.
e) Discharge all air from the syringe or inflation device cavity, and reconnect it with the dilatation catheter inflation port. Keep the negative pressure of the balloon until no air returns to the inflation device.
f) Slowly release the instrument pressure to normal pressure.
g) Remove the 20cc syringe (if used), connect the inflation device with the inflation port of the dilatation catheter, and prevent air from entering the balloon system.
Note: Before entering the human body, all air in the balloon must be drained and filled with contrast medium (diluted 1:1 with normal saline) (if necessary, repeat the steps of 5a to 5g). Otherwise, it may cause complications.

[Instructions for Use]

Note: Percutaneous introduction techniques and arteriotomy are both suitable when using introduction sets and guide wires.
1.Insert a guiding catheter fitted with a hemostatic adapter using standard technique. If necessary the guide wire lumen can be irrigated with physiological saline solution.
2.Insert a guide wire through the hemostatic valve following the manufacturer' s instructions. Advance the guide wire carefully into and through the guiding catheter.
3.Attach a torque device to the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.
4.Carefully introduce the balloon-tipped catheter over the proximal end of the guide wire until it approaches the hemostatic valve. Open the hemostatic valve insert the dilatation catheter while maintaining guide wire position and tighten the hemostatic valve. To facilitate insertion, the balloon must be fully deflated to negative pressure.
5.Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting movement of the dilatation catheter. This will allow continuous recording of proximal coronary artery pressure.
Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the dilatation catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.
6.Slide the PTA catheter forwards the lesion, position the usable section of the balloon across the lesion using the balloon radiopaque markers as reference points.
7.Inflate the balloon to perform PTA per standard procedure. Maintain negative pressure on the balloon between inflations. The inflation should be kept for a period of at least 30 seconds.
Note: Do not exceed the rated burst pressure (RBP) printed on the package label. The RBP and compliances of HP PTA catheter are list in the table 1.
8.Withdraw the deflated dilatation catheter and guide wire from the guide catheter through the hemostatic valve. Tighten the hemostatic valve.
9.Dispose of the catheter per institutional standard for biohazardous materials.

Table 1. HP PTA dilatation catheter compliance

Balloon Diameter (mm)	Diameter of balloon under each pressure (tolerance ± 10%)											
	8atm 811 Kpa	10atm 1013 Kpa	12atm 1216 Kpa	14atm 1419 Kpa	16atm 1621 Kpa	18atm 1824 Kpa	20atm 2026 Kpa	22atm 2229 Kpa	24atm 2432 Kpa	26atm 2634 Kpa	28atm 2837 Kpa	30atm 3040 Kpa
3	2.98	3.02●	3.05	3.09	3.12	3.15	3.18	3.21	3.24◆	3.27	3.30	3.35
4	3.97	4.02●	4.07	4.12	4.17	4.22	4.27	4.32	4.37◆	4.42	4.45	4.53
5	4.95	5.02●	5.07	5.12	5.17	5.22	5.26	5.32◆	5.37	5.42	/	/
6	5.92	6.00●	6.04	6.10	6.15	6.20	6.25	6.31◆	6.37	6.44	/	/
7	6.95	7.02●	7.09	7.16	7.23	7.30▲	7.37▼	7.44	7.53	/	/	/
8	7.96	8.07●	8.17	8.27	8.38	8.50◆	8.62	8.76	/	/	/	/
9	9.02●	9.11	9.20	9.29	9.38	9.47◆	9.56	10.21	/	/	/	/
10	10.05●	10.15	10.25	10.35◆	10.45	/	/	/	/	/	/	/
12	11.93	12.05●	12.17	12.29◆	12.41	/	/	/	/	/	/	/

Notice: ● Nominal pressure 8ATM (φ9-φ10), 10ATM (φ 3-φ8, φ12)
◆ Indicates the rated blasting pressure of all specifications of the diameter
▼ Indicates the length of the balloon 20-100mm rated blasting pressure
▲ indicates the length of the balloon is 120-200mm, rated blasting pressure

[References]

The physician should consult recent literature on current medical practice on balloon dilatation.

[Graphical Symbols for Medical Device Labeling]

1		Manufacturer
2	LOT	Batch code
3		Use by
4	STERILE EO	Sterilized using Ethylene Oxide
5		Warning
6		Consult instructions for use
7		Do not reuse
8		Keep away from sunlight
9		Keep dry
10		Do not use if package is damaged
11		Do not re-sterilize
12	REF	Catalogue number
13		Date of manufacture
14	Rx only	Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

[Supply, Storage and Expiry date]

Sterile	Sterilized with ethylene oxide gas.
Storage	Store in a dry, dark, cool place.
Expiry date	The shelf life of the PTA balloon dilatation catheter is 2 years
date of manufacture	Reference label

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