PTA Balloon Dilatation Catheter
(KPTA Series)
Instruction for Use

Kossel Medtech (Suzhou) Co., Ltd.

Contents

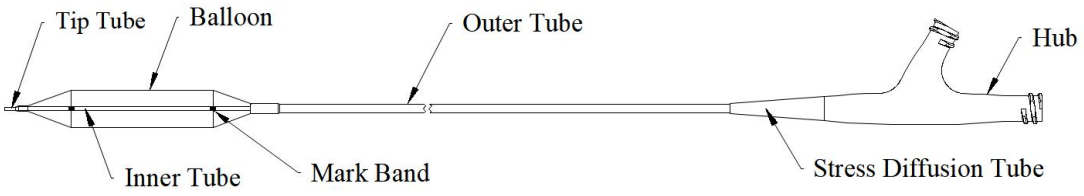
Caution: Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications.

Device Name

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

Device Description

The 0.0180″ PTA balloon dilatation catheter is mainly composed of tip tube, inner tube, balloon, marker bands, outer 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 difference dimension by inflating different pressure. The soft tip at the end of the balloon is to make the balloon catheter more easily to push to the stenosis position. The inner tube which connects to the tip tube is for guide wire passage and the pushing road. The two marker bands wrapping on the inner tube are for positioning the balloon location by cooperating in vitro monitoring equipment. The distal of the outer tube is connected with the balloon by a variable-diameter stretching structure, which can make the balloon get smaller winding diameter. The proximal of the outer tube is connected with the hub as the inflation passage and the pushing shaft. The hub is used to connect with the external pressure equipment for balloon filling. The stress diffusion tube can prevent the outer tube from being folded.



Contents

One PTA balloon dilatation catheter (KPTA series).

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

List of Type, Sizes, Configurations, Variants

Table 1: PTA Balloon Dilatation Catheter (KPTA series)

REF numbers	Specification	Balloon Diameter D1(mm)	Balloon Length L1(mm)	Outer Tube Diameter D2(mm)	Catheter Effective Length L2（cm）
KPTA20020L	2.0×20×1500	2.00±0.20	20±2	1.32±0.05	150±3
KPTA20030L	2.0×30×1500	2.00±0.20	30±3	1.32±0.05	150±3
KPTA20040L	2.0×40×1500	2.00±0.20	40±4	1.32±0.05	150±3
KPTA20060L	2.0×60×1500	2.00±0.20	60±6	1.32±0.05	150±3
KPTA20080L	2.0×80×1500	2.00±0.20	80±8	1.32±0.05	150±3
KPTA20100L	2.0×100×1500	2.00±0.20	100±10	1.32±0.05	150±3
KPTA20120L	2.0×120×1500	2.00±0.20	120±12	1.32±0.05	150±3
KPTA20150L	2.0×150×1500	2.00±0.20	150±15	1.32±0.05	150±3
KPTA20200L	2.0×200×1500	2.00±0.20	200±20	1.32±0.05	150±3
KPTA20250L	2.0×250×1500	2.00±0.20	250±25	1.32±0.05	150±3
KPTA20300L	2.0×300×1500	2.00±0.20	300±30	1.32±0.05	150±3
KPTA25020L	2.5×20×1500	2.50±0.25	20±2	1.32±0.05	150±3
KPTA25030L	2.5×30×1500	2.50±0.25	30±3	1.32±0.05	150±3
KPTA25040L	2.5×40×1500	2.50±0.25	40±4	1.32±0.05	150±3
KPTA25060L	2.5×60×1500	2.50±0.25	60±6	1.32±0.05	150±3
KPTA25080L	2.5×80×1500	2.50±0.25	80±8	1.32±0.05	150±3
KPTA25100L	2.5×100×1500	2.50±0.25	100±10	1.32±0.05	150±3
KPTA25120L	2.5×120×1500	2.50±0.25	120±12	1.32±0.05	150±3
KPTA25150L	2.5×150×1500	2.50±0.25	150±15	1.32±0.05	150±3
KPTA25200L	2.5×200×1500	2.50±0.25	200±20	1.32±0.05	150±3
KPTA25250L	2.5×250×1500	2.50±0.25	250±25	1.32±0.05	150±3
KPTA25300L	2.5×300×1500	2.50±0.25	300±30	1.32±0.05	150±3
KPTA30020L	3.0×20×1500	3.00±0.30	20±2	1.32±0.05	150±3
KPTA30030L	3.0×30×1500	3.00±0.30	30±3	1.32±0.05	150±3
KPTA30040L	3.0×40×1500	3.00±0.30	40±4	1.32±0.05	150±3
KPTA30060L	3.0×60×1500	3.00±0.30	60±6	1.32±0.05	150±3
KPTA30080L	3.0×80×1500	3.00±0.30	80±8	1.32±0.05	150±3
KPTA30100L	3.0×100×1500	3.00±0.30	100±10	1.32±0.05	150±3
KPTA30120L	3.0×120×1500	3.00±0.30	120±12	1.32±0.05	150±3
KPTA30150L	3.0×150×1500	3.00±0.30	150±15	1.32±0.05	150±3
KPTA30200L	3.0×200×1500	3.00±0.30	200±20	1.32±0.05	150±3
KPTA30250L	3.0×250×1500	3.00±0.30	250±25	1.32±0.05	150±3
KPTA30300L	3.0×300×1500	3.00±0.30	300±30	1.32±0.05	150±3
KPTA35020L	3.5×20×1500	3.50±0.35	20±2	1.32±0.05	150±3

REF numbers	Specification	Balloon Diameter D1(mm)	Balloon Length L1(mm)	Outer Tube Diameter D2(mm)	Catheter Effective Length L2（cm）
KPTA35030L	3.5×30×1500	3.50±0.35	30±3	1.32±0.05	150±3
KPTA35040L	3.5×40×1500	3.50±0.35	40±4	1.32±0.05	150±3
KPTA35060L	3.5×60×1500	3.50±0.35	60±6	1.32±0.05	150±3
KPTA35080L	3.5×80×1500	3.50±0.35	80±8	1.32±0.05	150±3
KPTA35100L	3.5×100×1500	3.50±0.35	100±10	1.32±0.05	150±3
KPTA35120L	3.5×120×1500	3.50±0.35	120±12	1.32±0.05	150±3
KPTA35150L	3.5×150×1500	3.50±0.35	150±15	1.32±0.05	150±3
KPTA35200L	3.5×200×1500	3.50±0.35	200±20	1.32±0.05	150±3
KPTA35250L	3.5×250×1500	3.50±0.35	250±25	1.32±0.05	150±3
KPTA35300L	3.5×300×1500	3.50±0.35	300±30	1.32±0.05	150±3
KPTA40020L	4.0×20×1500	4.00±0.40	20±2	1.32±0.05	150±3
KPTA40030L	4.0×30×1500	4.00±0.40	30±3	1.32±0.05	150±3
KPTA40040L	4.0×40×1500	4.00±0.40	40±4	1.32±0.05	150±3
KPTA40060L	4.0×60×1500	4.00±0.40	60±6	1.32±0.05	150±3
KPTA40080L	4.0×80×1500	4.00±0.40	80±8	1.32±0.05	150±3
KPTA40100L	4.0×100×1500	4.00±0.40	100±10	1.32±0.05	150±3
KPTA40120L	4.0×120×1500	4.00±0.40	120±12	1.32±0.05	150±3
KPTA40150L	4.0×150×1500	4.00±0.40	150±15	1.32±0.05	150±3
KPTA40200L	4.0×200×1500	4.00±0.40	200±20	1.32±0.05	150±3
KPTA40250L	4.0×250×1500	4.00±0.40	250±25	1.32±0.05	150±3
KPTA40300L	4.0×300×1500	4.00±0.40	300±30	1.32±0.05	150±3
KPTA50020L	5.0×20×1500	5.00±0.50	20±2	1.32±0.05	150±3
KPTA50030L	5.0×30×1500	5.00±0.50	30±3	1.32±0.05	150±3
KPTA50040L	5.0×40×1500	5.00±0.50	40±4	1.32±0.05	150±3
KPTA50060L	5.0×60×1500	5.00±0.50	60±6	1.32±0.05	150±3
KPTA50080L	5.0×80×1500	5.00±0.50	80±8	1.32±0.05	150±3
KPTA50100L	5.0×100×1500	5.00±0.50	100±10	1.32±0.05	150±3
KPTA50120L	5.0×120×1500	5.00±0.50	120±12	1.32±0.05	150±3
KPTA50150L	5.0×150×1500	5.00±0.50	150±15	1.55±0.05	150±3
KPTA50200L	5.0×200×1500	5.00±0.50	200±20	1.55±0.05	150±3
KPTA50250L	5.0×250×1500	5.00±0.50	250±25	1.55±0.05	150±3
KPTA50300L	5.0×300×1500	5.00±0.50	300±30	1.55±0.05	150±3
KPTA60020L	6.0×20×1500	6.00±0.55	20±2	1.32±0.05	150±3
KPTA60030L	6.0×30×1500	6.00±0.55	30±3	1.32±0.05	150±3
KPTA60040L	6.0×40×1500	6.00±0.55	40±4	1.32±0.05	150±3
KPTA60060L	6.0×60×1500	6.00±0.55	60±6	1.32±0.05	150±3
KPTA60080L	6.0×80×1500	6.00±0.55	80±8	1.32±0.05	150±3
KPTA60100L	6.0×100×1500	6.00±0.55	100±10	1.32±0.05	150±3

REF numbers	Specification	Balloon Diameter D1(mm)	Balloon Length L1(mm)	Outer Tube Diameter D2(mm)	Catheter Effective Length L2（cm）
KPTA60120L	6.0×120×1500	6.00±0.55	120±12	1.32±0.05	150±3
KPTA60150L	6.0×150×1500	6.00±0.55	150±15	1.55±0.05	150±3
KPTA60200L	6.0×200×1500	6.00±0.55	200±20	1.55±0.05	150±3
KPTA60250L	6.0×250×1500	6.00±0.55	250±25	1.55±0.05	150±3
KPTA60300L	6.0×300×1500	6.00±0.55	300±30	1.55±0.05	150±3
KPTA70020L	7.0×20×1500	7.00±0.60	20±2	1.32±0.05	150±3
KPTA70030L	7.0×30×1500	7.00±0.60	30±3	1.32±0.05	150±3
KPTA70040L	7.0×40×1500	7.00±0.60	40±4	1.32±0.05	150±3
KPTA70060L	7.0×60×1500	7.00±0.60	60±6	1.32±0.05	150±3
KPTA70080L	7.0×80×1500	7.00±0.60	80±8	1.32±0.05	150±3
KPTA70100L	7.0×100×1500	7.00±0.60	100±10	1.32±0.05	150±3
KPTA70120L	7.0×120×1500	7.00±0.60	120±12	1.32±0.05	150±3
KPTA70150L	7.0×150×1500	7.00±0.60	150±15	1.55±0.05	150±3
KPTA70200L	7.0×200×1500	7.00±0.60	200±20	1.55±0.05	150±3
KPTA70250L	7.0×250×1500	7.00±0.60	250±25	1.55±0.05	150±3
KPTA70300L	7.0×300×1500	7.00±0.60	300±30	1.55±0.05	150±3
KPTA20020S	2.0×20×900	2.00±0.20	20±2	1.32±0.05	90±2
KPTA20030S	2.0×30×900	2.00±0.20	30±3	1.32±0.05	90±2
KPTA20040S	2.0×40×900	2.00±0.20	40±4	1.32±0.05	90±2
KPTA20060S	2.0×60×900	2.00±0.20	60±6	1.32±0.05	90±2
KPTA20080S	2.0×80×900	2.00±0.20	80±8	1.32±0.05	90±2
KPTA20100S	2.0×100×900	2.00±0.20	100±10	1.32±0.05	90±2
KPTA20120S	2.0×120×900	2.00±0.20	120±12	1.32±0.05	90±2
KPTA20150S	2.0×150×900	2.00±0.20	150±15	1.32±0.05	90±2
KPTA20200S	2.0×200×900	2.00±0.20	200±20	1.32±0.05	90±2
KPTA20250S	2.0×250×900	2.00±0.20	250±25	1.32±0.05	90±2
KPTA20300S	2.0×300×900	2.00±0.20	300±30	1.32±0.05	90±2
KPTA25020S	2.5×20×900	2.50±0.25	20±2	1.32±0.05	90±2
KPTA25030S	2.5×30×900	2.50±0.25	30±3	1.32±0.05	90±2
KPTA25040S	2.5×40×900	2.50±0.25	40±4	1.32±0.05	90±2
KPTA25060S	2.5×60×900	2.50±0.25	60±6	1.32±0.05	90±2
KPTA25080S	2.5×80×900	2.50±0.25	80±8	1.32±0.05	90±2
KPTA25100S	2.5×100×900	2.50±0.25	100±10	1.32±0.05	90±2
KPTA25120S	2.5×120×900	2.50±0.25	120±12	1.32±0.05	90±2
KPTA25150S	2.5×150×900	2.50±0.25	150±15	1.32±0.05	90±2
KPTA25200S	2.5×200×900	2.50±0.25	200±20	1.32±0.05	90±2
KPTA25250S	2.5×250×900	2.50±0.25	250±25	1.32±0.05	90±2
KPTA25300S	2.5×300×900	2.50±0.25	300±30	1.32±0.05	90±2

REF numbers	Specification	Balloon Diameter D1(mm)	Balloon Length L1(mm)	Outer Tube Diameter D2(mm)	Catheter Effective Length L2（cm）
KPTA30020S	3.0×20×900	3.00±0.30	20±2	1.32±0.05	90±2
KPTA30030S	3.0×30×900	3.00±0.30	30±3	1.32±0.05	90±2
KPTA30040S	3.0×40×900	3.00±0.30	40±4	1.32±0.05	90±2
KPTA30060S	3.0×60×900	3.00±0.30	60±6	1.32±0.05	90±2
KPTA30080S	3.0×80×900	3.00±0.30	80±8	1.32±0.05	90±2
KPTA30100S	3.0×100×900	3.00±0.30	100±10	1.32±0.05	90±2
KPTA30120S	3.0×120×900	3.00±0.30	120±12	1.32±0.05	90±2
KPTA30150S	3.0×150×900	3.00±0.30	150±15	1.32±0.05	90±2
KPTA30200S	3.0×200×900	3.00±0.30	200±20	1.32±0.05	90±2
KPTA30250S	3.0×250×900	3.00±0.30	250±25	1.32±0.05	90±2
KPTA30300S	3.0×300×900	3.00±0.30	300±30	1.32±0.05	90±2
KPTA35020S	3.5×20×900	3.50±0.35	20±2	1.32±0.05	90±2
KPTA35030S	3.5×30×900	3.50±0.35	30±3	1.32±0.05	90±2
KPTA35040S	3.5×40×900	3.50±0.35	40±4	1.32±0.05	90±2
KPTA35060S	3.5×60×900	3.50±0.35	60±6	1.32±0.05	90±2
KPTA35080S	3.5×80×900	3.50±0.35	80±8	1.32±0.05	90±2
KPTA35100S	3.5×100×900	3.50±0.35	100±10	1.32±0.05	90±2
KPTA35120S	3.5×120×900	3.50±0.35	120±12	1.32±0.05	90±2
KPTA35150S	3.5×150×900	3.50±0.35	150±15	1.32±0.05	90±2
KPTA35200S	3.5×200×900	3.50±0.35	200±20	1.32±0.05	90±2
KPTA35250S	3.5×250×900	3.50±0.35	250±25	1.32±0.05	90±2
KPTA35300S	3.5×300×900	3.50±0.35	300±30	1.32±0.05	90±2
KPTA40020S	4.0×20×900	4.00±0.40	20±2	1.32±0.05	90±2
KPTA40030S	4.0×30×900	4.00±0.40	30±3	1.32±0.05	90±2
KPTA40040S	4.0×40×900	4.00±0.40	40±4	1.32±0.05	90±2
KPTA40060S	4.0×60×900	4.00±0.40	60±6	1.32±0.05	90±2
KPTA40080S	4.0×80×900	4.00±0.40	80±8	1.32±0.05	90±2
KPTA40100S	4.0×100×900	4.00±0.40	100±10	1.32±0.05	90±2
KPTA40120S	4.0×120×900	4.00±0.40	120±12	1.32±0.05	90±2
KPTA40150S	4.0×150×900	4.00±0.40	150±15	1.32±0.05	90±2
KPTA40200S	4.0×200×900	4.00±0.40	200±20	1.32±0.05	90±2
KPTA40250S	4.0×250×900	4.00±0.40	250±25	1.32±0.05	90±2
KPTA40300S	4.0×300×900	4.00±0.40	300±30	1.32±0.05	90±2
KPTA50020S	5.0×20×900	5.00±0.50	20±2	1.32±0.05	90±2
KPTA50030S	5.0×30×900	5.00±0.50	30±3	1.32±0.05	90±2
KPTA50040S	5.0×40×900	5.00±0.50	40±4	1.32±0.05	90±2
KPTA50060S	5.0×60×900	5.00±0.50	60±6	1.32±0.05	90±2
KPTA50080S	5.0×80×900	5.00±0.50	80±8	1.32±0.05	90±2

REF numbers	Specification	Balloon Diameter D1(mm)	Balloon Length L1(mm)	Outer Tube Diameter D2(mm)	Catheter Effective Length L2（cm）
KPTA50100S	5.0×100×900	5.00±0.50	100±10	1.32±0.05	90±2
KPTA50120S	5.0×120×900	5.00±0.50	120±12	1.32±0.05	90±2
KPTA50150S	5.0×150×900	5.00±0.50	150±15	1.55±0.05	90±2
KPTA50200S	5.0×200×900	5.00±0.50	200±20	1.55±0.05	90±2
KPTA50250S	5.0×250×900	5.00±0.50	250±25	1.55±0.05	90±2
KPTA50300S	5.0×300×900	5.00±0.50	300±30	1.55±0.05	90±2
KPTA60020S	6.0×20×900	6.00±0.55	20±2	1.32±0.05	90±2
KPTA60030S	6.0×30×900	6.00±0.55	30±3	1.32±0.05	90±2
KPTA60040S	6.0×40×900	6.00±0.55	40±4	1.32±0.05	90±2
KPTA60060S	6.0×60×900	6.00±0.55	60±6	1.32±0.05	90±2
KPTA60080S	6.0×80×900	6.00±0.55	80±8	1.32±0.05	90±2
KPTA60100S	6.0×100×900	6.00±0.55	100±10	1.32±0.05	90±2
KPTA60120S	6.0×120×900	6.00±0.55	120±12	1.32±0.05	90±2
KPTA60150S	6.0×150×900	6.00±0.55	150±15	1.55±0.05	90±2
KPTA60200S	6.0×200×900	6.00±0.55	200±20	1.55±0.05	90±2
KPTA60250S	6.0×250×900	6.00±0.55	250±25	1.55±0.05	90±2
KPTA60300S	6.0×300×900	6.00±0.55	300±30	1.55±0.05	90±2
KPTA70020S	7.0×20×900	7.00±0.60	20±2	1.32±0.05	90±2
KPTA70030S	7.0×30×900	7.00±0.60	30±3	1.32±0.05	90±2
KPTA70040S	7.0×40×900	7.00±0.60	40±4	1.32±0.05	90±2
KPTA70060S	7.0×60×900	7.00±0.60	60±6	1.32±0.05	90±2
KPTA70080S	7.0×80×900	7.00±0.60	80±8	1.32±0.05	90±2
KPTA70100S	7.0×100×900	7.00±0.60	100±10	1.32±0.05	90±2
KPTA70120S	7.0×120×900	7.00±0.60	120±12	1.32±0.05	90±2
KPTA70150S	7.0×150×900	7.00±0.60	150±15	1.55±0.05	90±2
KPTA70200S	7.0×200×900	7.00±0.60	200±20	1.55±0.05	90±2
KPTA70250S	7.0×250×900	7.00±0.60	250±25	1.55±0.05	90±2
KPTA70300S	7.0×300×900	7.00±0.60	300±30	1.55±0.05	90±2

Note: Balloon diameter D1: The diameter when the balloon is inflated to the nominal pressure (NP) (6atm); Balloon Length-L1: The length of balloon inflated at the pressure of nominal pressure.

Intended Purpose

The PTA balloon dilatation catheter (KPTA series) is intended for dilatation of stenosis in the peripheral vasculature.

Intended Patient Population

Adult patients need PTA during treatment. They have the stenosis in peripheral vessels and indicated for the treatment as determined by competent physicians.

Indications for Use

The PTA balloon dilatation catheter (KPTA series) is indicated for the treatment of obstructive lesions in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications

It should not be used for lesion that cannot be passed by the guide wire.

Performance Characteristics

The balloon diameter range: 2.0-7.0mm; balloon length: 20-300mm;
Nominal pressure: 6atm
Rated burst pressure:
14 atm for balloon diameter 2.0-4.0mm (balloon effective length 150-300mm);
16 atm for balloon diameter 2.0-4.0mm (balloon effective length 20-120mm);
12 atm for balloon diameter 5.0-6.0mm (balloon effective length 150--300mm);
14 atm for balloon diameter 5.0-6.0mm (balloon effective length 20-120mm);
10 atm for balloon diameter 7.0mm (balloon effective length 150--300mm);
12 atm for balloon diameter 7.0mm (balloon effective length 20--120mm);

Sterilization Method

Sterilized with ethylene oxide gas. Non-pyrogenic.

Handling and Storage

Store the device in an area away from sunlight.

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 PTA balloon dilatation catheter (KPTA series) is 3 years.

Precautions

- This product should be used only by physicians with experience in angiography and percutaneous transluminal angioplasty. A thorough understanding of the technical principles, clinical applications and risks associated with percutaneous transluminal angioplasty is essential prior to the use of this product.
- 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 will reactivate the coating.
- 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.

Potential Complications and Adverse Effects

Potential complications and adverse effects due to the use of this product include, but are not limited to the following:

- Abrupt vessel closure
- Additional intervention
- Acute myocardial infarction
- Allergic reaction(device,contrast medium and medications)
- Amputation
- Arrhythmias
- Arteriovenous fistula
- Bradycardia
- Death
- Embolism

- Hematoma at puncture site
- Hemorrhage
- Hypotension /hypertension
- Inflammation/infection/sepsis
- Ischemia
- Necrosis
- Organ failure(single,multiple)
- Pain
- Paralysis
- Potential for balloon burst and potential complications(rated burst pressure)
- Potential for separation and potential complications(integrity to be checked before and after use)
- Procedural complications:bleeding,hypotension,access site complications
- Pseudoaneurysm
- Renal failure
- Restenosis of the dilated vessel
- Thrombosis
- Vascular complications(e.g. intimal tear, dissection, pseudoaneurysm, perforation, rupture, spasm, occlusion)

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

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 PTA balloon dilatation catheter (KPTA Series) for use:

1. Take out the device from the packaging and gently withdraw the dilatation catheter from the protection ring.
2. Remove the stylet from the distal tip of the dilatation catheter, slide the protective sheath off the balloon.
3. Flush the PTA balloon dilatation catheter (KPTA Series). Attach a syringe filled with heparinized normal saline to the flushing tool, gently insert the flushing tool into distal end of the catheter, 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 to activate the coating.

4. Prepare the inflation device with the recommended contrast medium according to the product instructions.
5. Clear the air from the tube filling cavity by following the steps:

a) Attach a 3-way stopcock to the inflation port.

b) Attach a partially filled syringe with heparinized saline to the stopcock, open the stopcock to the balloon and induce negative pressure.

c) Hold the syringe and proximal end of the catheter above the distal end of the catheter, and hold the balloon vertically with the balloon tip pointing down.

d) While maintaining negative pressure close the stopcock to the inflation port. Remove the syringe and purge the air.

e) To ensure air contained in the balloon and inflation lumen is removed, apply negative pressure twice as instructed and repeat steps.

f) Without twisting, slide the forming tube off the balloon.

g) Prepare an angioplasty inflation system with a 50% solution of contrast medium in sterile saline or similar solution.

h) Purge the air from the inflation device.

i)Connect the inflation device to the 3-way stopcock that is connected to the catheter inflation port, open the stopcock to the catheter and slowly fill the inflation lumen and the balloon will slowly fill with diluted contrast medium.

Note: Before entering the human body, all air in the balloon must be emptied and the catheter cavity filled with contrast agent. Do not apply positive or negative pressure to the balloon at this time.

Instructions for Use

Note: Percutaneous introduction techniques and arteriotomy are both suitable when using introduction sets and guide wires.

1. Insert the sheath fitted with a hemostatic adapter using standard technique. If necessary, the inner cavity of the sheath can be rinsed with normal saline.
2. According to the manufacturer's instructions, under x-ray fluoroscopy, the guide wire is pushed to the designated vascular position and then passed through the narrow area.
3. Place the prepared catheter over a prepositioned guide wire and advance the tip to the introduction site.When loading or changing the Catheter, it is recommended that the guide wire be cleaned thoroughly so that the catheter can move more smoothly on the guide wire.

Note: Balloon inflation should be performed with the guide wire extended beyond the catheter tip. It is strongly recommended that the guide wire, the balloon catheter, or both, remain across the lesion until the procedure is completed and the dilatation system is to be removed from the vessel.

Note: To preserve the folded balloon shape during insertion and catheter manipulation, maintain a vacuum on the inflation lumen.

Caution: Fully deflate the balloon by inducing negative pressure with the inflation system whenever the PTA balloon dilatation catheter is advanced or withdrawn. Do not advance or withdraw the PTA balloon dilatation catheter within the vasculature unless the catheter is preceded by a guide wire.

4. Carefully advance the catheter through a sheath or guide catheter through the percutaneous entry site.

Note: Gentle counterclockwise rotation of the balloon may ease introduction through the sheath or percutaneous entry site.

Note: To avoid kinking, push the catheter slowly, inch by inch, until the proximal end of the wire is exposed.

Note: Perform all further catheter manipulations under fluoroscopy.

5. Carefully advance the catheter to the selected stenosis. If the expandable catheter cannot pass through the expandable area, use a smaller balloon to pass through the area and predilate the area to make it easier to pass through the expandable catheter.

Caution: If strong resistance is met during advancement or withdrawal of the catheter, discontinue movement and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, withdraw the entire system.

6. Using fluoroscopy and the radiopaque marker bands, position the catheter at the appropriate location.
7. When an acceptable position has been obtained, inflate the balloon to achieve the desired dilatation.

Caution: If resistance is encountered during balloon expansion, do not continue to expand, the catheter should be removed.

Caution: Do not exceed the rated burst pressure. Higher pressures may damage the balloon or catheter or over distend the selected artery. The RBP and compliances of catheter (KPTA Series) are

list in the table 2

Warning: Inflation at a high rate may damage the balloon.

8. Deflate the balloon by pulling vacuum on the inflation syringe or inflation device.
9. Remove the vacuum (do not apply pressure) and carefully withdraw and remove the catheter.

Note: Gentle counterclockwise rotation of the balloon may ease withdrawal from the sheath or from the percutaneous entry site.If the balloon cannot be withdrawn through the sheath, withdraw the catheter and sheath as a unit.

Dispose of all used devices in accordance with hospital policy for bio hazardous materials.

Table 2: Compliance of PTA Balloon Dilatation Catheter (KPTA Series)

Balloon Diameter	Balloon Diameter Under Corresponding Pressure					
	6atm	8atm	10atm	12atm	14atm	16atm
2.0	2.00●	2.04	2.08	2.12	2.16■	2.20▲
2.5	2.50●	2.54	2.58	2.62	2.66■	2.70▲
3.0	3.00●	3.05	3.10	3.15	3.20■	3.25▲
3.5	3.50●	3.56	3.62	3.68	3.74■	3.80▲
4.0	4.00●	4.06	4.12	4.18	4.24■	4.30▲
5.0	5.00●	5.07	5.14	5.21■	5.28▲	/
6.0	6.00●	6.09	6.18	6.27■	6.36▲	/
7.0	7.00●	7.10	7.20■	7.30▲	/	/

Notice：

●indicates Nominal pressure;

▲Indicates the nominal length of the balloon 20-120mm, rated burst pressure (Do not exceed RBP);

■ Indicates the length of the balloon is 150-300mm, rated burst pressure (Do not exceed RBP).

The tolerance of balloon diameter under corresponding pressure refers to balloon diameter column in section ‘List of type, sizes, configurations, variants’ in this document.

Clinical Benefits

The PTA balloon dilatation catheter (KPTA series) is indicated for the treatment of obstructive lesions in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Kossel claims that the PTA Balloon Dilatation Catheter (KPTA Series) has direct clinical benefit:

1. Effective vascular lesion dilation and luminal patency restoration
2. Reduced vascular injury and complication risk

References

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

Serious Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Graphical Symbols for Medical Device Labeling

1		Manufacturer
2		Batch code
3		Use -by date
4		Sterilized using ethylene oxide
5		Caution
6		Consult instructions for use or consult electronic instructions for use
7		Do not re-use
8		Keep away from sunlight
9		Keep dry
10		Do not use if package is damaged and consult instructions for use
11		Do not resterilize
12		Catalogue number

13		Date of manufacture
14		Authorized Representative in the European Community
15		Single sterile barrier system with protective packaging inside
16		Medical Device
17		Unique device identifier

Information on Sterilization, Storage, Date of Manufacture and Expiry

Sterile Sterilized with ethylene oxide gas.
Storage Store the device in an area away from sunlight.
Expiry Date The shelf life of the PTA balloon dilatation catheter (KPTA Series) is 3 years
Date of Manufacture Reference to label

 **Manufacturer:**

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