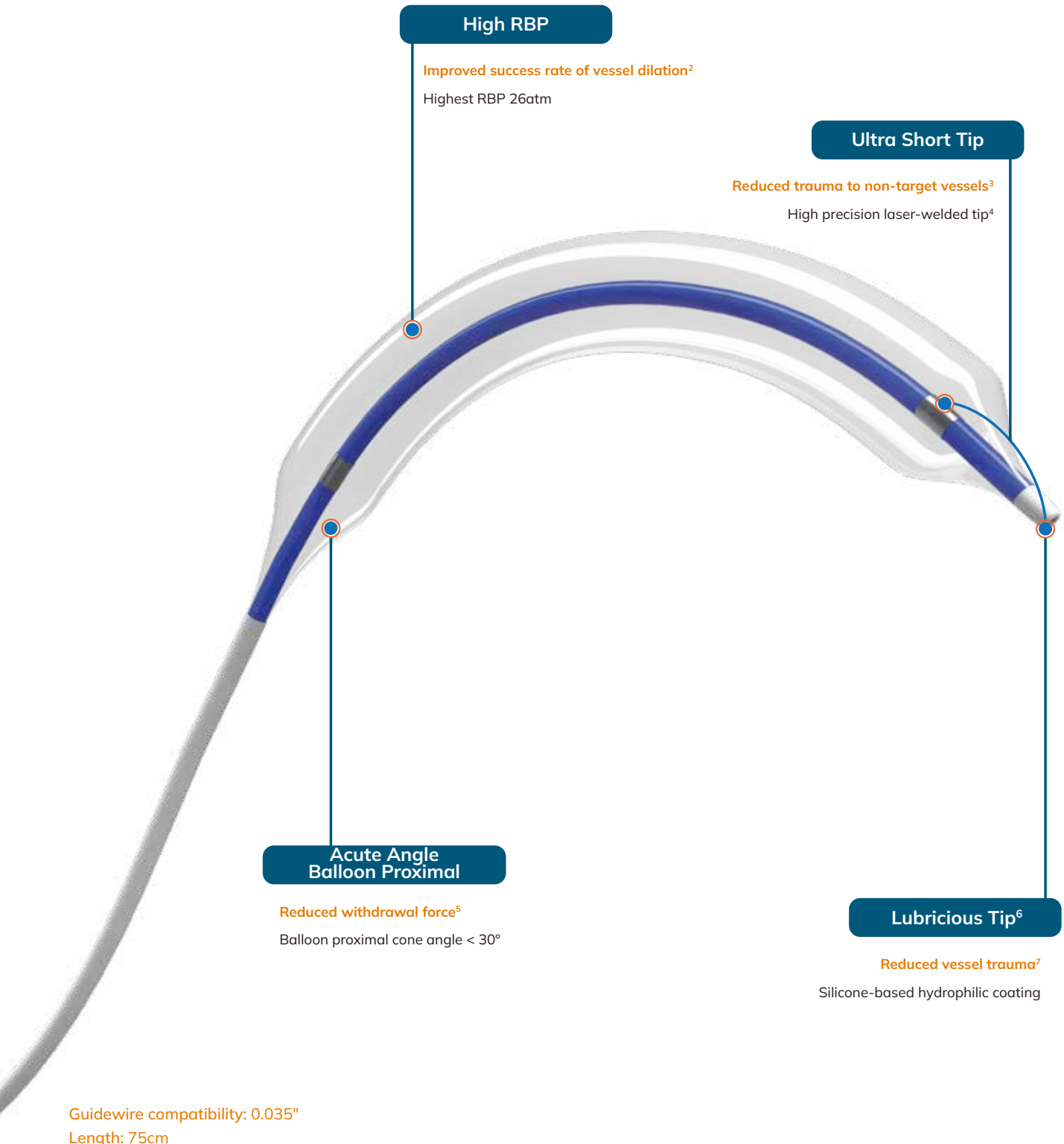


DKaptain™*

high pressure PTA balloon

High RBP¹
26 atm



Ordering Information

Model	Balloon Diameter (mm)	Balloon Length (mm)	Nominal Pressure (atm)	Rated Burst Pressure (atm)	Sheath Compatibility
HPA75-4040B5	4	40	8	26	5F
HPA75-4080B5	4	80	8	26	5F
HPA75-5040B5	5	40	8	26	6F
HPA75-5080B5	5	80	8	26	6F
HPA75-50100B5	5	100	8	22	6F
HPA75-6040B5	6	40	8	26	6F
HPA75-6080B5	6	80	8	26	6F
HPA75-60100B5	6	100	8	22	6F
HPA75-7040B5	7	40	8	22	6F
HPA75-7080B5	7	80	8	22	6F
HPA75-70100B5	7	100	8	18	6F
HPA75-70150B5	7	150	8	18	6F
HPA75-8040B6	8	40	8	22	7F
HPA75-8080B6	8	80	8	22	7F
HPA75-80100B6	8	100	8	18	7F
HPA75-80150B6	8	150	8	18	7F
HPA75-9040B6	9	40	8	18	7F
HPA75-9080B6	9	80	8	18	7F
HPA75-10040B6	10	40	8	14	7F
HPA75-10080B6	10	80	8	14	7F
HPA75-12040B7	12	40	10	14	8F
HPA75-12080B7	12	80	10	14	8F

1. Internal test report - Burst Pressure Comparisons, DKaptain. DK Medical Technology Co., Ltd; Data on File.
2. Internal test report - Vessel dilation comparisons, DKaptain. DK Medical Technology Co., Ltd; Data on File.
3. Internal test report - Substantial equivalence Annex 3 vessel trauma Comparison materials, DKaptain. DK Medical Technology Co., Ltd; Data on File.
4. Internal test report - Tip Performance, DKaptain. DK Medical Technology Co., Ltd; Data on File.
5. Internal document - BM-0001 Balloon mould dimensions drawing, Force Comparisons DKaptain. DK Medical Technology Co., Ltd; Data on File.
6. Internal technical report - DKaptain tip. DK Medical Technology Co., Ltd; Data on File.
7. Internal clinical evaluation report - Vessel Trauma Comparisons, DKaptain. DK Medical Technology Co., Ltd; Data on File.

DKaptain™* PTA high pressure balloon catheter

Important Safety Information

Please see Full Prescribing Information in the IFU.

Indications for Use

The D-Kaptain™* PTA High Pressure Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Contraindications

This catheter is not for use in the coronary vasculature.

Warnings

Single patient use only. Do not re-use, re-process or re-sterilize.

Potential Adverse Reactions

The complications that may result from a balloon dilatation procedure include, but are not limited to:

- Allergic reaction (device, contrast medium and medications)
- Arteriovenous fistula
- Embolization (air, device, plaque, etc.)
- Hematoma
- Hemorrhage, including bleeding at puncture
- Sepsis/infection
- Thromboembolic episodes
- Vessel injury, e.g. dissection, perforation, rupture, pseudoaneurysm
- Vessel occlusion
- Vessel spasm

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

DKaptain is a product of DK MedTech and sold under distribution partnership with Mozarc Medical. All claims and references are certified for U.S. standards accuracy and use by DK MedTech.

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