

TECHNICAL SPECIFICATIONS

DESCRIPTION:

BioPath™ 035 is a second generation paclitaxel eluting PTA over the wire (OTW) catheter specifically designed for Peripheral Interventions, with a guidewire diameter of 0.035" (0.91 mm).

BioPath™ 035 PTA balloon is coated with Paclitaxel ($3\mu\text{g}/\text{mm}^2$). The outer lumen is used for balloon inflation and the inner lumen has a guidewire 0.035 to facilitate the advancement of the catheter.

BioPath™ 035 has the benefit of delivering paclitaxel locally in a short time in a procedure as simple to do as a standard PTA balloon inflation.

BioPath™ 014 has a low crossing profile, low tip entry profile and a hydrophilic shaft coating.

Pre-dilation is required before using BioPath™ 035.

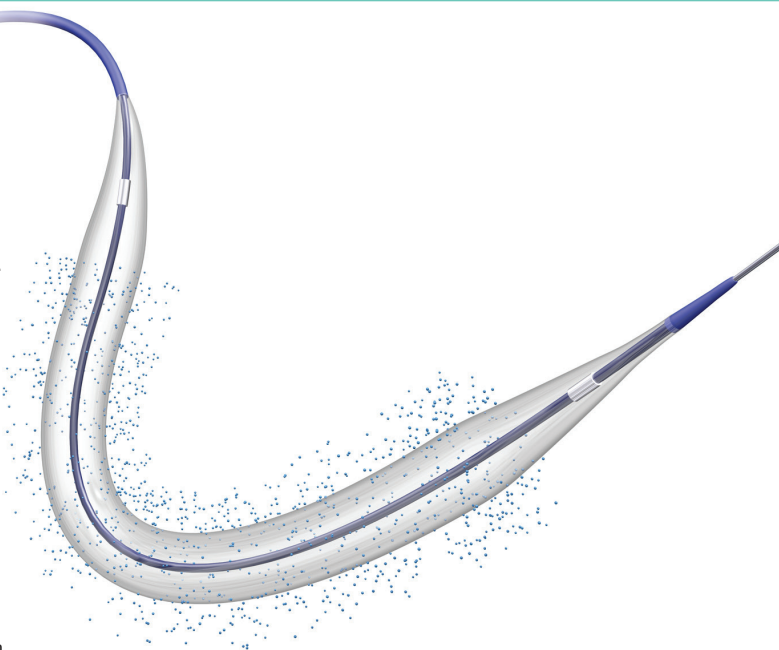
Paclitaxel prevents restenosis by blocking microtubular formation, inhibiting cell division and migration. Paclitaxel effectively inhibits the natural inflammatory process started post balloon dilatation. The injury caused to the arterial wall by dilatation stimulates an inflammatory reaction; specifically the production of growth factors. Paclitaxel inhibits platelet derived growth factor (PDGF).

Paclitaxel also inhibits extracellular matrix secretion and breakdown.

Paclitaxel selectively inhibits the proliferation of smooth muscle cells and does not influence non- proliferating cells.

BioPath™ 035 PTA catheter delivers a smooth re-endothelialization process.

Shellac is a natural resin composed of shellolic and alleuritic acid. The coating is a 1:1 mixture of Paclitaxel and shellac applied by micro-pipetting in a clean room under sterile conditions. Shellac is EMEA and FDA approved (GRAS) as a food additive under E 904.



INDICATIONS:

1. De-Novo lesions
2. Restenosis after implantation of balloon and / or stent PTA
3. Pre- and post-dilatation when implanting a peripheral stent

TECHNICAL DATA:

Design	Bilumen design - over the wire catheter		
Balloon diameter	4.0 / 5.0 / 6.0 / 7.0 and 8.0 mm		
Balloon length	20-150 mm		
Usable catheter length (tip to strain relief)	80 cm and 135 cm		
Guide wire diameter	0.035" (0.91 mm)		
Coating	Hydrophilic coating		
Balloon material	PA, Polyamid/Nylon		
Balloon folding	4-folding for 4 and 5 mm 5-folding for 6 to 8 mm		
Balloon characteristic	Semi-compliant		
Recommended introducer sheath	5F for 4.0 to 6.0 mm diameter 6F for 6.0 and length ≥ 100 mm 6F for 7.0 and 8.0 mm diameter		
Nominal pressure	6 atm		
Rated burst pressure	Balloon length:	Diameter:	Pressure:
	20/40/60 mm	4-6 mm	16 atm
	20 /40/60 mm	7-8 mm	14 atm
	80/100/120/150 mm	4 mm	16 atm
	80/100/120/150 mm	5-6 mm	14 atm
	80/100/120/150 mm	7-8 mm	12 atm
Packaging unit	1 unit		

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COMPLIANCE CHART:

Inflation pressure		Balloon Diameter (mm)				
atm/bar	kPa	4.00	5.00	6.00	7.00	8.00
4	400	3.78	4.80	5.68	6.67	7.45
6*	600*	4.00*	5.00*	6.00*	7.00*	8.00*
8	800	4.15	5.15	6.16	7.19	8.31
10	1000	4.28	5.26	6.30	7.33	8.53
12***	1200	4.40	5.37	6.44	7.48***	8.77***
13	1300	4.46	5.43	6.52	7.55	8.89
14**	1400	4.53	5.49***	6.59***	7.63**	9.00**
15	1500	4.60	5.58	6.67	7.70	9.12
16***	1600	4.67***	5.64**	6.79**	7.78	9.25
17	1700	4.75	5.72	6.84		
18	1800	4.83	5.80			

* Nominal Pressure

** Rated burst pressure (RBP) for Balloon length 20-60 mm

*** Rated burst pressure (RBP) for Balloon length 80-150 mm

Class III device, Rules 8, 13: MDD 93/42/EC

Sterilization method: Ethylene Oxide Gas

Single use product.

One unit per box.

Do not bend or squeeze the balloon area before the procedure.

Sterile unless package is open or damaged.

Do not reuse or resterilize.

Use before the expiry date indicated on the label.

CE certification: 1434

Shelf Life: 24 months

Storage Conditions:

Store in a dry place between 0 °C and 25 °C.

Store away from light.

ORDERING INFORMATION:

Balloon diameter (mm)	Balloon lengths (mm)						
	20	40	60	80	100	120	150
4.0	BPTH-35-4020 S	BPTH-35-4040 S	BPTH-35-4060 S	BPTH-35-4080 S	BPTH-35-40100 S	BPTH-35-40120 S	BPTH-35-40150 S
	BPTH-35-4020 L	BPTH-35-4040 L	BPTH-35-4060 L	BPTH-35-4080 L	BPTH-35-40100 L	BPTH-35-40120 L	BPTH-35-40150 L
5.0	BPTH-35-5020 S	BPTH-35-5040 S	BPTH-35-5060 S	BPTH-35-5080 S	BPTH-35-50100 S	BPTH-35-50120 S	BPTH-35-50150 S
	BPTH-35-5020 L	BPTH-35-5040 L	BPTH-35-5060 L	BPTH-35-5080 L	BPTH-35-50100 L	BPTH-35-50120 L	BPTH-35-50150 L
6.0	BPTH-35-6020 S	BPTH-35-6040 S	BPTH-35-6060 S	BPTH-35-6080 S	BPTH-35-60100 S	BPTH-35-60120 S	BPTH-35-60150 S
	BPTH-35-6020 L	BPTH-35-6040 L	BPTH-35-6060 L	BPTH-35-6080 L	BPTH-35-60100 L	BPTH-35-60120 L	BPTH-35-60150 L
7.0	BPTH-35-7020 S	BPTH-35-7040 S	BPTH-35-7060 S	BPTH-35-7080 S	BPTH-35-70100 S	BPTH-35-70120 S	BPTH-35-70150 S
	BPTH-35-7020 L	BPTH-35-7040 L	BPTH-35-7060 L	BPTH-35-7080 L	BPTH-35-70100 L	BPTH-35-70120 L	BPTH-35-70150 L
8.0	BPTH-35-8020 S	BPTH-35-8040 S	BPTH-35-8060 S	BPTH-35-8080 S	BPTH-35-80100 S		
	BPTH-35-8020 L	BPTH-35-8040 L	BPTH-35-8060 L	BPTH-35-8080 L	BPTH-35-80100 L		

S: 80 cm Usable catheter length
L: 135 cm Usable catheter length

For further information or assistance, please contact: