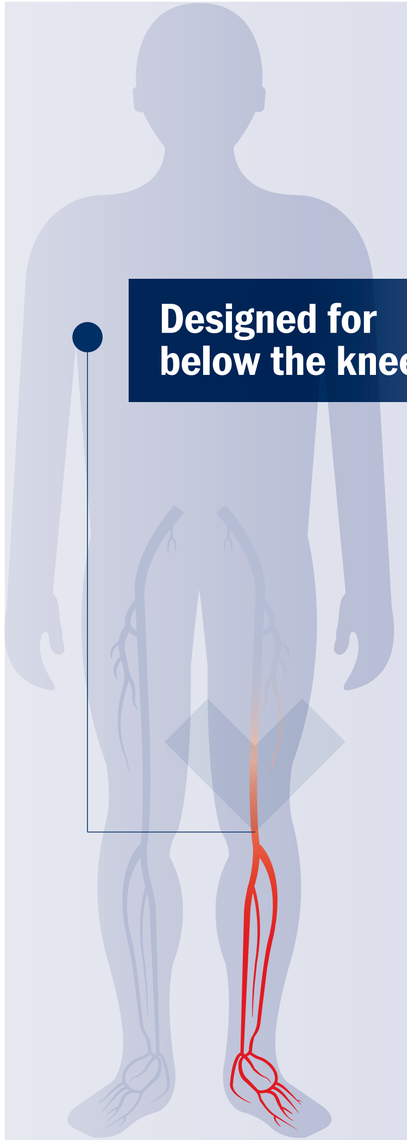

Designed for below the knee interventions

BioPath™ 014 offers excellent pushability, trackability and crossability due to a low balloon profile, low tip entry profile and a hydrophilic coating on the distal shaft of the catheter.

BioPath 014, with its unique shellac coating, delivers the designated paclitaxel dosage where it matters most – across the target lesion.

BioPath 014 is indicated for:

> De-novo lesions

> Restenosis after realisation of balloon and /or stent PTA

> Pre- and post-dilatation in case of peripheral stent implantation

Digitally signed by Ostapciuc Alexandr
Date: 2022.01.06 15:11:37 EET
Reason: MoldSign Signature
Location: Moldova

BIOPATH™ 014
PACLITAXEL ELUTING PTA BALLOON CATHETER (OTW)

Latest generation paclitaxel-eluting balloon for peripheral interventions

Ordering Information

Balloon diameter (mm)	Balloon length (mm)			
	40	80	120	150
2.0	BPTH-14-2040 L	BPTH-14-2080 L	BPTH-14-20120 L	BPTH-14-20150 L
	BPTH-14- 2040 XL	BPTH-14-2080 XL	BPTH-14-20120 XL	BPTH-14-20150 XL
2.5	BPTH-14-2540 L	BPTH-14-2580 L	BPTH-14-25120 L	BPTH-14-25150 L
	BPTH-14-2540 XL	BPTH-14-2580 XL	BPTH-14-25120 XL	BPTH-14-25150 XL
3.0	BPTH-14-3040 L	BPTH-14-3080 L	BPTH-14-30120 L	BPTH-14-30150 L
	BPTH-14-3040 XL	BPTH-14-3080 XL	BPTH-14-30120 XL	BPTH-14-30150 XL
3.5	BPTH-14-3540 L	BPTH-14-3580 L	BPTH-14-35120 L	BPTH-14-35150 L
	BPTH-14-3540 XL	BPTH-14-3580 XL	BPTH-14-35120 XL	BPTH-14-35150 XL
4.0	BPTH-14-4040 L	BPTH-14-4080 L		
	BPTH-14-4040 XL	BPTH-14-4080 XL		

L: 120 cm usable catheter length
XL: 150 cm usable catheter length

1. Axel D.L. et al. Circulation 1997; 96:636-45
2. A. Posa et al. Catheterization and Cardiovascular Interventions 76:395–403 (2010)
3. Data on file

BioPath™ 014 paclitaxel-eluting balloon catheter is CE Mark approved.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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BIOPATH™ 014
PACLITAXEL ELUTING PTA BALLOON CATHETER (OTW)

Latest generation paclitaxel-eluting balloon for peripheral interventions

the right reach

BIOSENSORS INTERNATIONAL™

The right choice

The treatment process

With balloon dilatation, the injuries to the arterial wall initiate an inflammatory reaction with an excretion of growth factors which trigger the onset of cell division and smooth muscle cell migration.

Paclitaxel prevents restenosis by stabilizing microtubal formation and thus prevents the cells going through the phases of replication, resulting in the inhibition of cell division.

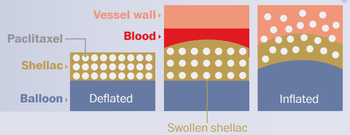
Paclitaxel reduces the excretion of the platelet derived growth factor (PDGF) that mediates vascular smooth muscle cell migration to the intima[1].

The BioPath™ 014 balloon coating

- The BioPath 014 balloon coating consists of a 1:1 mixture of paclitaxel (3 µg/mm^2) and shellac, a natural resin approved by the FDA (GRAS), and by Europe (E904) as a food additive.
- BioPath 014 delivers the designated concentration of paclitaxel locally to the arterial tissue.
- The properties of shellac protect the paclitaxel during transition and placement.

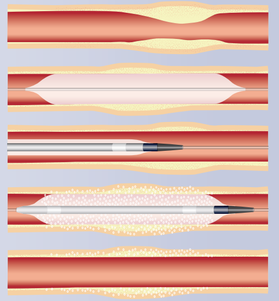
Delivering the drug

Once in contact with blood, the shellac and paclitaxel coating swells and begins to open, facilitating the pressure-induced transfer of the paclitaxel.



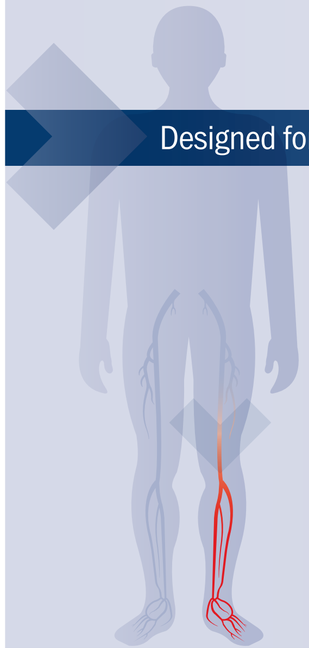
Delivering the paclitaxel drug

Immediately after the controlled PTA, injury to the vessel wall key pathways contribute to the formation of neointimal hyperplasia.
Injury from cracking plaque can lead to narrowing of the lumen.
The paclitaxel dose will act over the short term to inhibit cell re-growth.



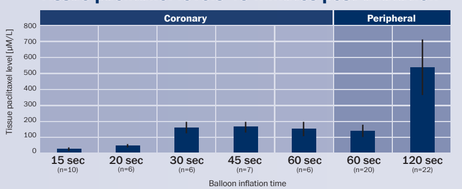
1. Pre-dilatation prepares the way for the delivery of paclitaxel from the BioPath 014 balloon surface.
2. BioPath 014 is advanced to the lesion site.
3. Once the operator is satisfied with the position of BioPath 014 across the lesion, an inflation at 6 bar for at least 60 seconds will deliver the paclitaxel through the cracked plaque and onto the vessel wall.
4. BioPath 014 is then withdrawn. The shellac carrier remains on the balloon surface.

Designed for below the knee interventions



For illustration purpose only - not to scale.

Coronary[2] and Peripheral[3] – Tissue paclitaxel levels 45 minutes post-dilatation



A choice of balloon length and diameter, on two catheter shaft lengths

Available balloon diameters	2.0, 2.5, 3.0, 3.5 and 4.0 mm
Balloon lengths	40, 80, 120 and 150 mm
Usable catheter lengths	L: 120 cm or XL: 150 cm
Recommended guide wire	0.014”

BioPath™ 014