

TECHNICAL DATA SHEET

luminor 35

DESCRIPTION

Paclitaxel eluting balloon catheter with dual lumen design (OTW), intended for dilatation of lesions located at the iliac, femoral, iliofemoral, popliteal, infrapopliteal and renal arteries.

The catheter features a dual lumen tube from the proximal connection to the balloon. One lumen is for guide wire insertion and catheter leading to the lesion; while the other one allows contrast liquid passage for balloon indeflation and this it comprises the in-deflation channel.

The balloon is coated with the drug Paclitaxel; which is included in a physiologically innocuous matrix.

At the proximal end, there is a hub comprising two ports; one for balloon indeflation and another one for guide wire passage.

The balloon is supplied in different lengths (from 20 to 150 mm) and diameters (from 5 to 7 mm).

The catheter is coated for minimize friction.

MATERIAL

Nylon/Pebax. The product does not contain latex components.

BALLOON COATING

Paclitaxel eluting formulation, 3 μg/mm²

BALLOON

Semi-compliant

(10% of compliance from nominal pressure to RBP)

| NOMINAL PRESSURE | 7 atm |
|------------------------------|--------|
| RATED BURST PRESSURE (RBP) | 16 atm |
| AVERAGE BURST PRESSURE (AVP) | 23 atm |



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| BALLOON PROFILE (crossing profile) | |
|--|------------------------|
| Diameter | INCHES =MM=FRENCH |
| 5.0 | 0.065" = 1.65mm = 4.9F |
| 6.0 | 0.071" = 1.81mm = 5.4F |
| 7.0 | 0.077" = 1.97mm = 5.9F |
| RADIOPAQUE MARKERS | |
| 2 Platinum/Iridium markers embedded on the guiding lumen | |
| DIMENSIONS | |
| Catheter shaft | 4F |
| Entry profile | 0.037 inches |
| Recommended guide wire | 0.035 inches |
| INTRODUCER COMPATIBILITY | |
| Ø [mm]: 5.0 | 5F |
| Ø [mm]: 6.0 - 7.0 | 6F |
| DEFLATION TIMES | |
| Ø [mm]: 5 to 7 | 8s maximum |
| AVAILABLE DIAMETERS | 5mm to 7mm |
| AVAILABLE LENGHTS | 20mm to 150mm |
| Assays conducted according to the standards ISO 10555 and UNE EN 10993 | |