

TECHNICAL DATA SHEET

luminor 14

DESCRIPTION

Paclitaxel eluting balloon with coaxial design (OTW), intended for dilatation of lesions located at the femoral, popliteal and infrapopliteal arteries.

The catheter features two coaxial tubes throughout its length; it has a dual lumen from the proximal connection to the balloon. The inner lumen is for guide wire insertion and leading to the lesion; while the outer lumen allows contrast liquid passage for balloon in-deflation and this it comprises the indeflation channel.

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

On the proximal part of the catheter, there is a hub comprising two ports; one for balloon in-deflation and another one for guide wire passage.

The balloon is supplied in different lengths (from 40 to 200 mm) and diameters (from 1.5 to 4 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

(10-15% of compliance from nominal pressure to RBP)

| NOMINAL PRESSURE | 7 atm |
|------------------------------|--------|
| RATED BURST PRESSURE (RBP) | 16 atm |
| AVERAGE BURST PRESSURE (ABP) | 22 atm |



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| BALLOON PROFILE (crossing profile at maximum balloon length) | |
|--|---|
| Diameter (mm) | INCHES =mm=FRENCH |
| 1.5 | 0.026= 0.67= 2.0F |
| 2 | 0.029= 0.75= 2.2F |
| 2.5 | 0.032= 0.83= 2.5F |
| 3 | 0.035= 0.91= 2.7F |
| 3.5 | 0.038= 0.99= 3.0F |
| 4 | 0.042= 1.08= 3.2F |
| RADIOPAQUE MARKERS | |
| 2 polymeric markers based on tungsten with high flexibility | |
| DIMENSIONS | |
| Catheter shaft | 3.9F Proximal |
| | 2.6F Distal |
| Entry profile | 0.017 inches |
| Recommended guide wire | 0.014 inches |
| INTRODUCER COMPATIBILITY | |
| | 4F for all diameters |
| DEFLATION TIMES | |
| | Maximum 10s for all diameters and lengths |
| AVAILABLE DIAMETERS | 1.5 to 4 mm |
| AVAILABLE LENGTHS | 40 to 200 mm |
| Assays conducted according to the standards ISO 10555 and UNE EN 10993 | |