Coating makes the difference

DIOR®
2nd Generation
PACLITAXEL-ELUTING CORONARY BALLOON DILATATION CATHETER

Eurocor
The DIOR® bioshell coating matrix consists of a natural resin, which is EMEA and FDA approved (GRAS) as food additive under E 904. Shellac is a natural resin composed of shellolic and aleuritic acid. The excellent film forming properties of shellac are used to coat gastric resistant tablets.

The coating consists of a 1:1 mixture of paclitaxel with shellac applied to the balloon. In contact with body liquid the hydrophilic shellac-network of the composite swells and opens the structure for the pressure-induced fast release of paclitaxel on the inflated balloon.

Exclusive bioshell coating
Compared to competitive products shellac gives the balloon a shiny appearance

Paclitaxel eluting PTCA balloon catheter with a bioshell coating matrix with excellent paclitaxel concentration in the arterial tissue

- Low-dose drug application of paclitaxel, reduces smooth muscle cell proliferation for the successful treatment of coronary in-stent restenosis
- Significant reduction of the incidence of recurrent in-stent restenosis
- High effective drug with a short term dilatation of 45 seconds
- Ease of reinvention

The bifurcation strategy
Successful treatment of coronary bifurcation lesions with DIOR®
Provisional stenting of the main branch only and drug eluting balloon dilatation of the side branch enhance a favorable outcome by fewer adverse events and repeat interventions.

*Very smooth surface
Bioshell coating for excellent arterial tissue paclitaxel concentration

The DIOR® bioshell coating is a 1:1 mixture of shellac and paclitaxel. This mixture allows a short and save application of paclitaxel into the arterial tissue. Paclitaxel dosage: $3 \mu g/mm^2$ balloon surface area.

Compared to the first DIOR®, the tissue concentration of paclitaxel in the DIOR® Second Generation is 20 times higher.

Advantages of exclusive bioshell coating

The DIOR® coating shows no signs of cytotoxicity after direct or indirect contact with endothelial cells. The DIOR® shellac coating allows the adhesion of new endothelial cells. The DIOR® shellac coating shows no signs of pro-inflammatory activation.

Investigation of cytotoxicity

Shellac extraction product
(24 h extraction in cell culture medium)

Quantification of cell quantity
Metabolic cell activity (MTS-assay)

No signs of pro-inflammatory activation

IL-8-release

Shellac extraction products (24 h). Exposition of confluent HDMEC with extraction products (24h). Tumour necrosis factor (TNF) as a positive control group.

DIOR® 2nd Generation
Paclitaxel-eluting PTCA balloon catheter

- DIOR® is not an implant. After the treatment you have no material behind.
- DIOR® can eliminate the stent-in-stent reintervention.
- DIOR® prevents additional stiffening of the stented artery.
- DIOR® shortens the antiplatelet therapy up to 3 months.
- DIOR® offers an alternate treatment in bifurcations, by using it in side branches.
- DIOR® has shown excellent clinical outcomes in small vessel without stenting (Spanish Registry with >220 patients).

20 porcine arteries were treated with the DIOR® Second Generation balloon in a time-dependent matter. Arteries were dissected and sent to a blinded laboratory for paclitaxel determination.
Excellent clinical efficacy and safety

Histological Evaluation in preclinical setting

Porcine coronary arteries were dilated (1.3:1 balloon/artery ratio) with either DIOR® balloon (3μg/mm² Paclitaxel balloon surface) or non coated balloon. Follow up angiography and obduction: 14 days post balloon dilatation.

Excellent late lumen loss results with 0.13 mm neointima thickness

Paclitaxel selectively reduces the proliferation of smooth muscle cells. The endothelial cells show a better resistance to paclitaxel than the smooth muscle cells due to the different affinity of the connective structure on the cell surface. Paclitaxel does not influence non-proliferating cells as a result of cytokine and growth factor stimulation. The DIOR® paclitaxel-releasing balloon dilatation catheter enhances a smooth re-endothelialization process.

What is most important

Paclitaxel prevents restenosis by blocking proper microtubal formation, thus it reduces cell division and migration. It inhibits inflammatory processes. After balloon dilatation, injuries to the arterial wall stimulate inflammatory reaction, and the excretion of growth factors occurs as an important process along with the onset of cell division and the migration of smooth muscle cells. Paclitaxel reduces platelet derived growth factor (PDGF) that mediates vascular smooth muscle cell migration to the intima.


### Technical Data

<table>
<thead>
<tr>
<th>DIOR® Second Generation</th>
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<tbody>
<tr>
<td>Catheter design</td>
<td>RX</td>
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<tr>
<td>Catheter shaft</td>
<td>HypoTube shaft</td>
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<tr>
<td>Balloon material</td>
<td>Polyamide blend</td>
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<tr>
<td>Usable catheter length</td>
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<tr>
<td>Recommended guide wire</td>
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<td>Guide wire lumen length</td>
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<td>Distal tip length</td>
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<td>Tip profile</td>
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<td>Proximal shaft diameter</td>
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<td>Distal shaft diameter</td>
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<td>Average burst pressure (ABP)</td>
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### Compliance chart

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<th>Bar</th>
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<td>Rated burst pressure (RBP)</td>
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Nominal pressure 6 bar/Rated burst pressure 16 bar (at 37 °C)
Exception: Balloons at 4 mm and > 20 mm length, rated burst pressure = 14 bar.

### DIOR® Product order information

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Balloon diameter (mm)</th>
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<tr>
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<tr>
<td>20</td>
<td>Dior 2.00-20</td>
<td>Dior 2.25-20</td>
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<tr>
<td>30</td>
<td>Dior 2.00-30</td>
<td>Dior 2.25-30</td>
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Current DIOR® trials
I. DIOR® dilatation randomized trial (A. Colombo, Multi-Center)
II. DEB-AMI randomized trial (P. Stella, Acute myocardial infarct, Multi-Center)
III. DES-ISR Registry (F. Mauri, Multi-Center)
IV. DIOR®-Registry (Internationales Register)
V. Valentines Trial, weltweites Register (Dres. Silber, Stella, Sangiorgi)
VI. DIOR vs. DES, Multicenter Spain (Dr. Serra)

International Publications
I. Pieter Stella et al., Catheterization and Cardiovascular Interventions, 71:629-635 (2008)
II. Aniko Posa et al., Coronary Artery Disease, 19:243-247 (2008)
III. Ron Waksman et al., Catheterization and Cardiovascular Interventions, 73:643-652 (2009)
IV. Dorothea I. Axel et al., Circulation 1997, Paclitaxel Inhibits Arterial Smooth Muscle Cell Proliferation and Migration In Vitro and In Vivo Using Local Drug Delivery, 96:636-645
V. DEBUIT randomized trial (P. Stella, Bifurcation Study, Multi-Center)
VI. Rembert Pogge v. Strandmann et al., Euro Intervention PCR Supplement (2009)
VII. Kostas Spargias et al., JoIC (2009)

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