

## Coroflex ISAR NEO – Technical Data Sheet

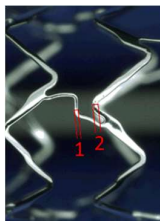
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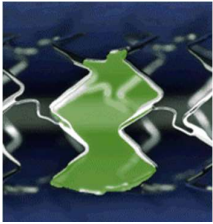
### 1. Administrative Company Information

Name:	B. Braun Melsungen AG Vascular Systems
Manufacturing site:	B. Braun Melsungen AG Vascular Systems Sieversufer 8 12359 Berlin Germany Tel.: +49 30 568 207 300
CE Certificate:	DEKRA <b>EC Design-Examination Certification</b> according to directive 93/42/EEC Certificate registration No.: 51342-23-G0 EC Certificate for the Quality Assurance System No.: 51342-16-02
Regulatory Affairs:	B. Braun Melsungen AG Vascular Systems Regulatory Affairs Dr. Henning Schlicht Sieversufer 8 12359 Berlin, Germany Tel.: +49 30 568 207 230

### 2. Technical Data

#### 2.1 Coroflex ISAR NEO Stent Characteristics:

Stent material:	Cobalt Chromium L-605
Stent design:	Modular Adaptive Open Cell Design
Matrix Coating Technology	50:50 Ratio Sirolimus / Probucol
Coating characteristic	POLYMER-FREE
Coating thickness	4 µm on abluminal stent surface
Drug load stent	1,2 µg/mm <sup>2</sup>
Stent strut thickness w/o coating :	<ul style="list-style-type: none"> <li>0.055 mm (55 µm / 0.0022") for stents from 2.0 – 3.0 mm</li> <li>0.065 mm (65 µm / 0.0026") for stents from 3.5 mm to 4.0 mm</li> </ul>
Stent strut width w/o coating:	 <p>1) 55 µm 2) 80 µm</p>

Cell Diameter of Coroflex ISAR NEO at nominal pressure [NP]:	 <table> <tr><td>2.0 mm:</td><td>2,28 mm<sup>2</sup></td></tr> <tr><td>2.25 mm:</td><td>2,61 mm<sup>2</sup></td></tr> <tr><td>2.5 mm:</td><td>2,96 mm<sup>2</sup></td></tr> <tr><td>2.75 mm:</td><td>3,30 mm<sup>2</sup></td></tr> <tr><td>3.0 mm:</td><td>3,65 mm<sup>2</sup></td></tr> <tr><td>3.5 mm:</td><td>4,02 mm<sup>2</sup></td></tr> <tr><td>4.0 mm:</td><td>4,69 mm<sup>2</sup></td></tr> </table>	2.0 mm:	2,28 mm <sup>2</sup>	2.25 mm:	2,61 mm <sup>2</sup>	2.5 mm:	2,96 mm <sup>2</sup>	2.75 mm:	3,30 mm <sup>2</sup>	3.0 mm:	3,65 mm <sup>2</sup>	3.5 mm:	4,02 mm <sup>2</sup>	4.0 mm:	4,69 mm <sup>2</sup>
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Foreshortening:	-1 %														
Recoil:	approx. 2.8 %														
Approx. Metal Surface Area:	ø 2.00mm = 20 % ø 2.25mm = 18 % ø 2.5mm = 16 % ø 2.75mm = 14 % ø 3.0mm = 13 % ø 3.5mm = 14 % ø 4.0mm = 13 %														
Flexibility crimped stent:	219 mN ( 3.0 x 19 mm)														
Flexibility expanded stent:	58 mN (3.0 x 19 mm)														

## 2.2 Delivery System:

Proximal shaft:	Hypotube, stainless steel, PTFE coated, ø 1.9 F
Distal shaft:	Polyamide with hydrophilic coating, ø 2.5 F
Usable length:	145 cm
Lesion entry profile:	0.016"
Coronary Guide wire:	0.014"
Radiopaque markers:	2 marker bands
Crossing profile, coated Coroflex ISAR NEO:	ø 2.0 mm: 0.031" = 0.79 mm ø 2.25 mm: 0.032" ø 2.5 mm: 0.034" ø 2.75 mm: 0.034" ø 3.0 mm: 0.035" ø 3.5 mm: 0.038" ø 4.0 mm: 0.038" = 0.96 mm
Rated Burst Pressure [RBP]:	18 atm: ø 2.00 – 3.5 mm 15 atm: ø 4.0 mm
Nominal Pressure [NP]:	10 atm: all diameters
Guiding catheter:	5 F standard guiding catheter 6 F for kissing compatibility

### 2.3 USP's: "Coroflex ISAR NEO – Polymer-Free Sirolimus Drug Eluting Stent"

<b>Matrix</b>	<ul style="list-style-type: none"> <li>• „No Plastic“ → 100% Polymer-Free Sirolimus Drug Delivery</li> <li>• Probucol as Excipient (Matrix-Builder), to delay the release of Sirolimus over time (50:50 ratio of sirolimus/probucol)</li> <li>• Abluminal coating for effective drug release (1.2 µg/mm<sup>2</sup> Sirolimus)</li> <li>• Continuous and controlled drug release – complete absorption within 90 days post implantation</li> </ul>
<b>Delivery system</b>	<ul style="list-style-type: none"> <li>• Latest generation catheter platform of B. Braun's SeQuent Neo for improved trackability in comparison to the forerunner product Coroflex ISAR</li> </ul>
<b>Clinical Evidence</b>	<ul style="list-style-type: none"> <li>• Comprehensive clinical evidence from endpoint trials for the Coroflex ISAR coating technology</li> </ul>
<b>Stent Performance</b>	<ul style="list-style-type: none"> <li>• New stent design for less recoil, improved radial stability and better radiopacity in comparison to the forerunner product Coroflex ISAR</li> </ul>

### 3. Packing:

Minimum delivery quantity (product box)	1 unit
Warehouse box:	10 units

### 4. Sterilization:

Sterilization method:	EtO – Ethylene Oxide
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### 5. Further information:

Shelf Life:	24 months <i>please see for revised status at date of importance</i>
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### 6. References:

Stent Length Diameter	9mm	12 mm	16 mm	19 mm	24 mm	28 mm	32 mm	38 mm
2.00 mm	5028910	5028917	5028924	5028931	5028938	5028945	5028952	5028959
2.25 mm	5028911	5028918	5028925	5028932	5028939	5028946	5028953	5028960
2.50 mm	5028912	5028919	5028926	5028933	5028940	5028947	5028954	5028961
2.75 mm	5028913	5028920	5028927	5028934	5028941	5028948	5028955	5028962
3.00 mm	5028914	5028921	5028928	5028935	5028942	5028949	5028956	5028963
3.50 mm	5028915	5028922	5028929	5028936	5028943	5028950	5028957	5028964
4.00 mm	5028916	5028923	5028930	5028937	5028944	5028951	5028958	5028965

## 7. Labeling:

Box and pouch label 1 unit –

<b>DES</b>	<b>Coroflex® ISAR NEO</b>	<b>3.0</b>	<b>16</b>	REF: 5028928 LOT: 20B18809 M: 2022-02-17																														
<b>DES</b>	<b>Coroflex® ISAR NEO</b>	<b>3.0</b>	<b>16</b>	02: Sirolimus-freisetzendes koronares Stentskathetersystem 03: Sirolimus-eluting coronary stent catheter system																														
Radius R 球囊直径	3.0 mm	REF: 5028928	2020-02-18																															
Stent length 支架长度	16 mm	LOT: 20B18809	2022-02-17																															
Delivery 输送系统	0.014" / 0.36 mm	<b>B   BRAUN</b> B. Braun Medical AG, 34109 Melsungen, Germany																																
Min. guiding catheter ID 最小导引导管ID	5 F / 1.65 mm	Uniflex® 5000 R2 3.0 x 16 mm REF: 5028928 LOT: 20B18809																																
Rated burst pressure (RBP) 额定爆破压力	18 atm / 1824 kPa																																	
Normal pressure (NCP) 正常压力	10 atm / 1013 kPa																																	
Balloon length 球囊长度	17 mm																																	
<table border="1"> <thead> <tr> <th>Compliance 顺应性</th> <th>6</th> <th>7</th> <th>8</th> <th>9</th> <th>10</th> <th>11</th> <th>12</th> <th>13</th> <th>14</th> <th>15</th> <th>16</th> <th>17</th> <th>18</th> <th>19</th> </tr> </thead> <tbody> <tr> <td>mmHg</td> <td>2.48</td> <td>2.62</td> <td>2.78</td> <td>2.92</td> <td>3.06</td> <td>3.19</td> <td>3.17</td> <td>3.33</td> <td>3.30</td> <td>3.36</td> <td>3.42</td> <td>3.48</td> <td>3.55</td> <td>3.61</td> </tr> </tbody> </table>					Compliance 顺应性	6	7	8	9	10	11	12	13	14	15	16	17	18	19	mmHg	2.48	2.62	2.78	2.92	3.06	3.19	3.17	3.33	3.30	3.36	3.42	3.48	3.55	3.61
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<p>CE 0124</p> <p>STERILE</p> <p>PK Coroflex® ISAR NEO</p> <p>Reg. No.: 003394</p> <p>Large Manufacturer: B. Braun Medical AG Carl Braun Strasse 1, 34109 Melsungen, Germany Manufactured in: B. Braun Medical AG, Melsungen, Germany Imported by: B. Braun Medical (Pty) Ltd The Pylon, Suite 10, Rayfield Drive, Colton Brook 3, KwaZulu</p> <p>AR</p> <p>REPORTADOR: B. Braun Medical S.A. J.E. Urbino 953 P.2 DISTRIBUIDOR: B. Braun Medical S.A. J.E. Urbino 953 P.2 FABRICANTE: B. Braun Medical AG / Carl Braun Str. 1 - 34109 Melsungen - Alemania Autorizado por la A.N.M.A. T. 869-073 Condiciones de venta: Venta exclusiva y no reembolsable e instituciones sanitarias. C.T. Farm. Mariano Pareda M.N. 13430</p> <p>TR</p> <p>B. Braun Medical (Pty) Ltd, S.S. Marlin Way, Suite 10, Rayfield Drive, Colton Brook 3, KwaZulu</p> <p>MY</p> <p>Reg. No.: 008777/16411 Authorized representative: B. Braun Medical Industries Sdn. Bhd. 11888 Pongsa, Malaysia. www.bbraun.com</p> <p>Version 10_2019-007</p>																																		

Warehouse box 10 units –

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<b>DES</b>	<b>Coroflex® ISAR NEO</b>	<b>3.0</b>	<b>16</b>	02: Sirolimus-freisetzendes koronares Stentskathetersystem 03: Sirolimus-eluting coronary stent catheter system
<b>10 Coroflex® ISAR NEO 3.0 x 16 mm</b>				
DE	Sirolimus-freisetzendes koronares Stentskathetersystem	REF: 5028928	2020-02-18	
GB	Sirolimus-eluting coronary stent catheter system	LOT: 20B18809	2022-02-17	
FR	Système d'endoprothèses coronariennes à élution médicamenteuse	<b>B   BRAUN</b> B. Braun Medical AG, 34109 Melsungen, Germany		
ES	Sistema de stent coronario farmacológico de sirolimus			
IT	Stent coronario a eluzione di sirolimus			
SE	Sirolimus-elutande koronar stentsystem			
FI	Sirolimusia vapauttava sepävaltimon stentijärjestelmä			
NL	Sirolimus-vrijgevend coronaar stentsysteem			
PT	Sistema de stents (endopróteses) coronários com eluição de sirolimus			
CZ	Systém koronárního stentu uvolňující sirolimus			
SK	Systém koronárneho stentu uvoľňujúci sirolimus			
PL	Stent sirolinowy uwalniający sirolimus			
HU	Sirolimust kibocsátó koronáriaesztent-rendszer			
TR	Sirolimus salımlı yapan koroner stent kateter sistemi			
RO	Stent coronarian cu substanta activa Sirolimus			
<p>CE 0124</p> <p>STERILE</p> <p>PK Coroflex® ISAR NEO</p> <p>Reg. No.: 003394</p> <p>Large Manufacturer: B. Braun Medical AG Carl Braun Strasse 1, 34109 Melsungen, Germany Manufactured in: B. Braun Medical AG, Melsungen, Germany Imported by: B. Braun Medical (Pty) Ltd The Pylon, Suite 10, Rayfield Drive, Colton Brook 3, KwaZulu</p> <p>AR</p> <p>REPORTADOR: B. Braun Medical S.A. J.E. Urbino 953 P.2 DISTRIBUIDOR: B. Braun Medical S.A. J.E. Urbino 953 P.2 FABRICANTE: B. Braun Medical AG / Carl Braun Str. 1 - 34109 Melsungen - Alemania Autorizado por la A.N.M.A. T. 869-073 Condiciones de venta: Venta exclusiva y no reembolsable e instituciones sanitarias. C.T. Farm. Mariano Pareda M.N. 13430</p> <p>TR</p> <p>B. Braun Medical (Pty) Ltd, S.S. Marlin Way, Suite 10, Rayfield Drive, Colton Brook 3, KwaZulu</p> <p>MY</p> <p>Reg. No.: 008777/16411 Authorized representative: B. Braun Medical Industries Sdn. Bhd. 11888 Pongsa, Malaysia. www.bbraun.com</p> <p>Version 10_2019-007</p>				