

**Coroflex ISAR NEO – Technical Data Sheet**

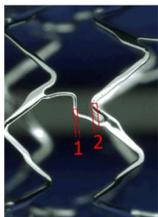
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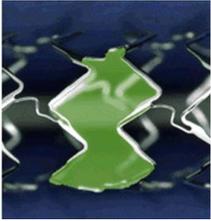
**1. Administrative Company Information**

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:	 <ul style="list-style-type: none"> <li>1) 55 µm</li> <li>2) 80 µm</li> </ul>

Cell Diameter of Coroflex ISAR NEO at nominal pressure [NP]:	 <table border="0"> <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>	SEP 062928 1007 20B18809 01 2022-02-17 013040495470003217322011051002018908																														
<b>DES</b>	<b>Coroflex® ISAR NEO</b>	<b>3.0</b>	<b>16</b>	DE Sirolimus-freisetzendes koronares Stentskathetersystem DE Sirolimus-eluting coronary stent catheter system																														
Radius R 球囊直径	3.0 mm	REF 5028928	LOT 20B18809	2020-02-18																														
Stent length 支架长度	16 mm	REF 5028928	LOT 20B18809	2022-02-17																														
Distances 球囊长度	0.014" / 0.36 mm	<b>B BRAUN</b> B. Braun Medical AG, D-34285 Melsungen, Germany																																
Min. opening catheter ID 球囊最小内径	5 F / 1.65 mm	Coroflex® ISAR NEO 3.0 x 16 mm REF 5028928 LOT 20B18809																																
Rated burst pressure (RBP) 球囊额定爆破压力	18 atm / 1824 kPa	B. Braun Medical AG, D-34285 Melsungen, Germany																																
Nominal pressure (NOM) 球囊额定压力	10 atm / 1013 kPa	REF 5028928 LOT 20B18809																																
Radius length 球囊长度	17 mm	REF 5028928 LOT 20B18809																																
<table border="1"> <thead> <tr> <th>Compliance</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>球囊顺应性</td> <td>2.48</td> <td>2.62</td> <td>2.78</td> <td>2.92</td> <td>3.06</td> <td>3.10</td> <td>3.17</td> <td>3.23</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	6	7	8	9	10	11	12	13	14	15	16	17	18	19	球囊顺应性	2.48	2.62	2.78	2.92	3.06	3.10	3.17	3.23	3.30	3.36	3.42	3.48	3.55	3.61
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<p>PK Coroflex® ISAR NEO Reg. No.: DE3334 Legal Manufacturer: B. Braun Medical AG Cart Brau-Strasse 1, 34212 Melsungen, Germany Manufacturing site: B. Braun Medical AG Vascular Systems, Industriepark 8, 32339 Berlin, Germany Imported by: B. Braun Medical (Pty) Ltd The Pylon, Suite 116, Regency Court, Clifton Block 3, Kaitiaki</p>																																		
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Warehouse box 10 units –

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<b>10 Coroflex® ISAR NEO 3.0 x 16 mm</b>				
DE	Sirolimus-freisetzendes koronares Stentskathetersystem DE Sirolimus-eluting coronary stent catheter system DE Sirolimus-freisetzendes koronares Stentskathetersystem DE Sirolimus-eluting coronary stent catheter system	REF 5028928	LOT 20B18809	2020-02-18
ES	Sistema de stent coronario farmacológico de sirolimus ES Sistema de stent coronario farmacológico de sirolimus	REF 5028928	LOT 20B18809	2022-02-17
IT	Stent coronarico a eluzione di Sirolimus IT Stent coronarico a eluzione di Sirolimus	REF 5028928	LOT 20B18809	2022-02-17
SE	Sirolimus-elutande koronart stentsystem SE Sirolimus-elutande koronart stentsystem	REF 5028928	LOT 20B18809	2022-02-17
FI	Sirolimusia vapauttava sepelvaltimon stentijärjestelmä FI Sirolimusia vapauttava sepelvaltimon stentijärjestelmä	REF 5028928	LOT 20B18809	2022-02-17
NL	Sirolimus-vrijgevend coronair stentsysteem NL Sirolimus-vrijgevend coronair stentsysteem	REF 5028928	LOT 20B18809	2022-02-17
PT	Sistema de stents (endopróteses) coronários com eluição de sirolimus PT Sistema de stents (endopróteses) coronários com eluição de sirolimus	REF 5028928	LOT 20B18809	2022-02-17
CZ	Systém koronárního stentu uvolňující sirolimus CZ Systém koronárního stentu uvolňující sirolimus	REF 5028928	LOT 20B18809	2022-02-17
SK	Systém koronárneho stentu uvoľňujúci sirolimus SK Systém koronárneho stentu uvoľňujúci sirolimus	REF 5028928	LOT 20B18809	2022-02-17
PL	Stent sirolimowy uwalniający sirolimus PL Stent sirolimowy uwalniający sirolimus	REF 5028928	LOT 20B18809	2022-02-17
HU	Sirolimusz kibocsátó koronáriaesztent-rendszer HU Sirolimusz kibocsátó koronáriaesztent-rendszer	REF 5028928	LOT 20B18809	2022-02-17
TR	Sirolimus salımlı yapılı koronar stent kateter sistemi TR Sirolimus salımlı yapılı koronar stent kateter sistemi	REF 5028928	LOT 20B18809	2022-02-17
RO	Stent coronarian cu substanta activa Sirolimus RO Stent coronarian cu substanta activa Sirolimus	REF 5028928	LOT 20B18809	2022-02-17
<p>CE 0124</p> <p>STERILEEO</p> <p>PK Coroflex® ISAR NEO Reg. No.: DE3334 Legal Manufacturer: B. Braun Medical AG Cart Brau-Strasse 1, 34212 Melsungen, Germany Manufacturing site: B. Braun Medical AG Vascular Systems, Industriepark 8, 32339 Berlin, Germany Imported by: B. Braun Medical (Pty) Ltd The Pylon, Suite 116, Regency Court, Clifton Block 3, Kaitiaki</p>				
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