

## TECHNICAL SPECIFICATIONS

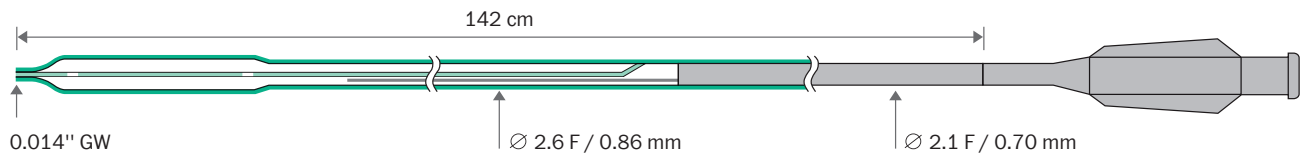
### DESCRIPTION:

Biosensors International RISE™ NC, rapid exchange (RX) Non-Compliant (NC) Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Catheter, has an integrated shaft system and a balloon near the distal tip. The shaft has one lumen to inflate/deflate the balloon and a second lumen for the advancement on a guidewire.

### INDICATIONS:

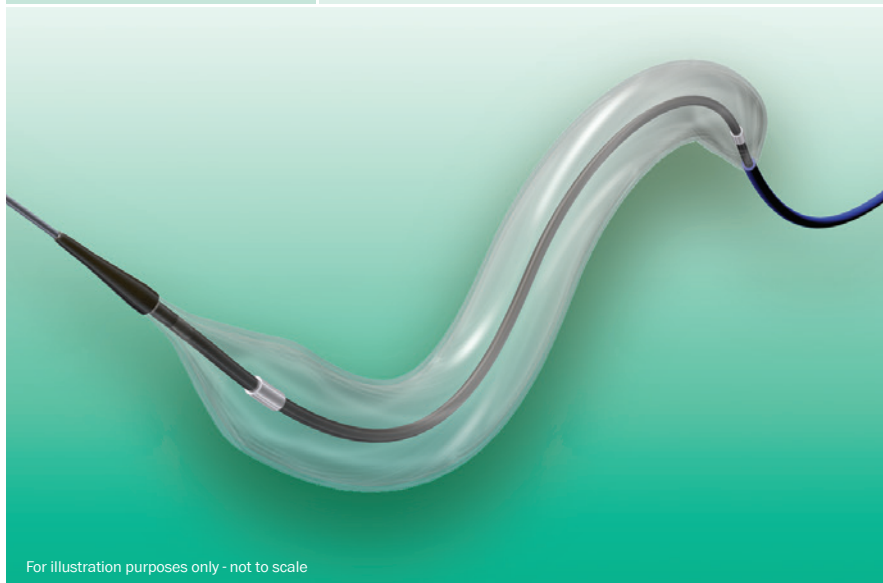
The Biosensors International RISE NC PTCA Balloon Catheter is indicated for:

- > Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
- > Post-delivery expansion of balloon expandable coronary stents.



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Catheter design	Rapid Exchange
Usable shaft length	142 cm ± 3 cm
Proximal shaft design	Hypotube
Proximal shaft coating	PTFE
Proximal shaft profile	2.1 F / 0.0274" / 0.70 mm
Shaft markers placement	90 cm ± 2 cm and 100 cm ± 2 cm from tip
Distal shaft profile	2.6 F / 0.034" / 0.86 mm
Lesion entry profile	0.018" / 0.46 mm
Crossing profile	≤0.051"
Balloon material	Nylon 12
Balloon compliance	Non-compliant
Balloon folding	Tri-Fold
Balloon cone	30 degrees
Radiopaque markers	2 swaged platinum/iridium marker bands
Length of balloon markers	1mm
Nominal pressure	14 atm / 1419 kPa for all models
Rated Burst Pressure	20 atm / 2027 kPa (for 2.00 - 4.00 mm balloon diameter)
	18 atm / 1824 kPa (for 4.50 mm balloon diameter)
Guiding catheter compatibility	5 F for all models (min. guiding catheter ID of 0.056" / 1.42mm)
Guide wire compatibility	0.014" / 0.36 mm
Hydrophilic coating	W-II coating - covers the catheter shaft, with the exception of the balloon and the tip (up to 50cm to proximal shaft from tip)



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### COMPLIANCE TABLE:

Pressure (atm)	Balloon Size (mm)									
	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50
14 Nominal Pressure (NP)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50
15	2.02	2.27	2.52	2.77	3.02	3.28	3.53	3.78	4.03	4.54
16	2.03	2.28	2.53	2.78	3.03	3.30	3.55	3.80	4.05	4.58
17	2.05	2.30	2.55	2.80	3.05	3.33	3.58	3.83	4.08	4.61
18 Rated Burst Pressure (RBP)	2.07	2.32	2.57	2.82	3.07	3.35	3.60	3.85	4.10	4.65
19	2.08	2.33	2.58	2.83	3.08	3.38	3.63	3.88	4.13	-
20 Rated Burst Pressure (RBP)	2.10	2.35	2.60	2.85	3.10	3.40	3.65	3.90	4.15	-

### ORDERING INFORMATION:

Balloon Size (mm)	Balloon Length (mm)					
	8	10	12	15	20	25
2.00	NCB-20008	NCB-20010	NCB-20012	NCB-20015	NCB-20020	NCB-20025
2.25	NCB-22508	NCB-22510	NCB-22512	NCB-22515	NCB-22520	NCB-22525
2.50	NCB-25008	NCB-25010	NCB-25012	NCB-25015	NCB-25020	NCB-25025
2.75	NCB-27508	NCB-27510	NCB-27512	NCB-27515	NCB-27520	NCB-27525
3.00	NCB-30008	NCB-30010	NCB-30012	NCB-30015	NCB-30020	NCB-30025
3.25	NCB-32508	NCB-32510	NCB-32512	NCB-32515	NCB-32520	NCB-32525
3.50	NCB-35008	NCB-35010	NCB-35012	NCB-35015	NCB-35020	NCB-35025
3.75	NCB-37508	NCB-37510	NCB-37512	NCB-37515	NCB-37520	NCB-37525
4.00	NCB-40008	NCB-40010	NCB-40012	NCB-40015	NCB-40020	NCB-40025
4.50	NCB-45008	NCB-45010	NCB-45012	-	-	-

#### Class III device, Rule 6; MDD 93/42/EC

Single use product  
Sterile unless package is open or damaged  
Do not reuse or resterilize  
The product is LATEX & PVC FREE

#### Sterilization method:

Ethylene Oxide

#### CE certification:

CE 0344

#### Shelf life:

24 months

#### Storage conditions:

Store in a cool, dark, dry place

Rise NC is a trademark or registered trademark of Biosensors International Group, Ltd. Rise is CE Mark approved. CAUTION: The law restricts these devices to sale by or on the order of a physician and these products are intended for the use by or under the direction of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Not available in the United States and any other country where applicable health authority product registration has not been obtained. Information contained herein only for presentation outside the US and France. © 2019 Biosensors International Group, Ltd. All rights reserved.

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