

TECHNICAL SPECIFICATIONS

DESCRIPTION:

Gazelle™ Coronary Stent System includes: a balloon expandable intracoronary 316 L stainless steel stent mounted onto a semi-compliant balloon delivery catheter. The balloon delivery catheter has two radiopaque markers which fluoroscopically mark the ends of the stent. The active balloon length is closely sized to the length of the stent to prevent over expansion of tissue proximal or distal to the stent. At the proximal end of the system is a female Luer Lock connector hub. This hub connects to the balloon inflation lumen. The guide wire enters the distal tip of the catheter and exits 23 cm proximal to the tip.

INDICATIONS:

Gazelle™ is indicated for use in patients eligible for balloon angioplasty with symptomatic ischemic heart disease due to de novo native coronary artery lesions with reference vessel diameter in the range of 2.25 mm to 4.00 mm (see "Instruction For Use" for more details).

STENT DELIVERY SYSTEM:

Catheter design	Rapid Exchange
Usable shaft length	142 cm
Proximal shaft design	Hypotube
Proximal shaft coating	PTFE
Proximal shaft profile	2.0 F / 0.0265" / 0.67 mm
Shaft markers placement	90 and 100 cm from tip
Distal shaft profile (3.0 mm)	2.6 F / 0.034" / 0.86 mm
Lesion entry profile	0.018" / 0.46 mm
Balloon material	Polyamide Elastomer
Balloon compliance	Semi-compliant
Balloon folding	Tri-Fold
Balloon cone	30 degrees
Radiopaque markers	2 swaged platinum/iridium marker bands
Length of balloon markers	1 mm
Nominal pressure	6 atm (608 kPa)
Rated Burst Pressure	16 atm (1621 kPa) 2.25-3.25 mm
	14 atm (1418 kPa) 3.50-4.00 mm
Guiding catheter compatibility	5 F (min I.D. 0.055") / 1.40 mm
Guide wire compatibility	0.014" / 0.36 mm
Hydrophilic coating	W-II coating



STENT PLATFORM:

Stent material	Stainless steel 316 L
Stent platform	S-Stent™
Strut design	Corrugated rings
Link design	Quadrature Link™
Strut thickness	0.0047" / 0.12 mm
Strut length	1.2 mm (6-crown model) & 1.0 mm (9-crown model)
Stent crowns	6 crowns (2.25 mm-3.25 mm); 9 crowns (3.5 mm-4.00 mm)
Crossing profile (3.0 mm)	0.042" / 1.07 mm
Flexibility	Very good
Radiopacity	Good*
Ferromagnetism	Non ferromagnetic (MRI safe)
Open cell diameter (3.0 mm)	1.47 mm*
Foreshortening	-0.7%*
Elastic recoil	367%*
Radial strength	> 1.50 bar*

* Schmidt W. et al., A comparison of the mechanical performance characteristics of seven drug-eluting stent systems; CCI 2009 73:350-360

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COMPLIANCE TABLE:

Pressure (atm)	Stent Internal Diameter (mm)						
	2.25	2.50	2.75	3.00	3.25	3.50	4.00
4	2.19	2.44	2.69	2.94	3.19	3.44	3.94
5	2.22	2.47	2.72	2.97	3.22	3.47	3.97
6 Nominal Pressure (NP)	2.25	2.50	2.75	3.00	3.25	3.50	4.00
7	2.28	2.53	2.78	3.03	3.28	3.53	4.03
8	2.31	2.56	2.81	3.06	3.31	3.56	4.06
9	2.34	2.59	2.84	3.09	3.34	3.59	4.09
10	2.37	2.62	2.87	3.12	3.37	3.62	4.12
11	2.40	2.65	2.90	3.15	3.40	3.65	4.15
12	2.43	2.68	2.93	3.18	3.43	3.68	4.18
13	2.47	2.71	2.96	3.21	3.47	3.71	4.21
14	2.50	2.74	2.99	3.24	3.50	3.74	4.24
15	2.52	2.77	3.02	3.27	3.52		
16 Rated Burst Pressure (RBP)	2.55	2.80	3.05	3.30	3.55		

ORDERING INFORMATION:

Stent Diameter (mm)	Stent Length (mm)					
	8	11	14	18	23 / 24	28
2.25	GAZ-2208	GAZ-2211	GAZ-2214	GAZ-2218	GAZ-2224	GAZ-2228
2.50	GAZ-2508	GAZ-2511	GAZ-2514	GAZ-2518	GAZ-2524	GAZ-2528
2.75	GAZ-2708	GAZ-2711	GAZ-2714	GAZ-2718	GAZ-2724	GAZ-2728
3.00	GAZ-3008	GAZ-3011	GAZ-3014	GAZ-3018	GAZ-3024	GAZ-3028
3.25	GAZ-3208	GAZ-3211	GAZ-3214	GAZ-3218	GAZ-3224	GAZ-3228
3.50	GAZ-3508	GAZ-3511	GAZ-3514	GAZ-3518	GAZ-3523	GAZ-3528
4.00	GAZ-4008	GAZ-4011	GAZ-4014	GAZ-4018	GAZ-4023	GAZ-4028

Class III device, Rule 8; MDD 93/42/EC

The product is LATEX & PVC FREE

Single Use Product
Sterile unless package is open or damaged
Do not reuse or resterilize

Storage Conditions:

Store in a cool, dark, dry place

Sterilization method: Ethylene Oxide

CE certification: TUV Nord 0044

Shelf life: 24 months

For further information or assistance, please contact:



Legal Manufacturer:

BIOSENSORS INTERNATIONAL Pte Ltd
21 Kallang Avenue - #07-165/171
Singapore 339412
Tel: +65 6293 8066
Fax: +65 6298 6242

European Representative:

BIOSENSORS EUROPE SA
Rue de Lausanne 29
1110 Morges - Switzerland
Tel: +41 (0)21 804 80 00
Fax: +41 (0)21 804 80 02

www.biosensors.com