10 p. d. Vainikinių arterijų stentai, padengti -limus klasės vaistu, ūminiams vainikinių arterijų pakenkimams stentuoti

BioMatrix α™ alpha
DRUG ELUTING CORONARY STENT SYSTEM

BIOSENSORS INTERNATIONAL™

TECHNICAL SPECIFICATIONS

DESCRIPTION:

The BioMatrix Alpha™ Drug Eluting Coronary Stent System (BioMatrix Alpha™ DES) is a drug eluting stent (DES) system for coronary use with a drug releasing biodegradable polymer coating. This DES is a combination product comprising two key components: 1. a cobalt chromium stent platform with six and nine crown designs for small vessel (SV) 2.25-3.00 mm and medium vessel (MV) 3.50-4.0 mm diameters, which includes the active BA9™ pharmaceutical ingredient (Biolimus A9™) incorporated into a PLA polymer coating, and 2. the delivery system.

COMPONENT DESCRIPTION:

- A balloon expandable intra-coronary cobalt chromium stent with a drug eluting coating, pre-mounted onto a semi-compliant rapid exchange balloon delivery system.
- A delivery system that has two radiopaque markers, which fluoroscopically mark the ends of the stent to facilitate proper placement.
- A female Luer lock connector hub located at the proximal end of the delivery system. This hub connects to the balloon inflation lumen. The guidewire used in the procedure enters the distal tip of the catheter and exits 27.5 cm proximal to the tip of the delivery system.

COATING COMPONENT DESCRIPTION:

- BA9 drug (USAN/INN: umirolimus) is a semi-synthetic sirolimus derivative with increased lipophilicity.
- BA9 drug on the BioMatrix Alpha DES inhibits smooth muscle cell proliferation within the stent proximity.
- Poly lactic acid (PLA) acts as a carrier for the drug and biodegrades as the drug is eluted from coating.

stentas padengtas biodegraduojančiu (per 90 dienų ištirpstančiu) poli - l - pieno rūgšties arba lygiaverčiu polimeru ir -limus klasės vaistu, turinčiu antiproliferacinį poveikį ir mažinantį restenozių skaičių;

INDICATIONS:

The BioMatrix Alpha stent is indicated for improving coronary luminal diameter for the treatment of *de novo* lesions in native coronary arteries with a reference diameter ranging between 2.25 mm and 4.0 mm. Stents with lengths of 33 and 36 mm are only available for artery diameters ranging between 2.5 mm and 3.5 mm.

STENT DELIVERY SYSTEM:

Catheter design	Rapid exchange	
Usable shaft length	142 cm ± 3 cm	įvedimo sistemos naudojamas ilgis - ne mažesnis kaip 140 cm.
Proximal shaft design	Hypotube	
Proximal shaft coating	PTFE	
Proximal shaft profile	2.0 F / 0.0265''/ 0.67 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	0.016"*	
Balloon material	Polyamide elastomers (Pebax) 72D	
Balloon compliance	Semi-compliant	balionėlis, ant kurio užmautas stentas, yra iš dalies kintamo diametro (semi-compliant - angl.);
Balloon folding	Tri-fold	
Balloon cone	30 degrees	
Radiopaque markers	2 swaged platinum / iridium marker bands	
Length of balloon markers	0.5 / 0.9 mm (distal / proximal)	
Nominal pressure	8 atm / 811 kPa for all models	
Rated Burst Pressure	16 atm / 1621 kPa (2.25-3.00 mm)	14 atm / 1418 kPa (3.50-4.00 mm) — išbandytasis plyšimo slėgis (RBP - angl.) - ne mažesnis nei 16 atm;
Guiding catheter compatibility	5 F	
Guide wire compatibility	0.014'' / 0.36 mm	
Hydrophilic coating	W-II coating - covers the catheter shaft and tip, with the exception of the balloon itself (up to 50 cm to proximal shaft from tip)	
Hub	Luer taper and thread must meet ISO 594-1 gauging test	

STENT PLATFORM:

Stent material	CoCr per ASTM F562		galimybė rinktis kobalto ir chromo lydinio arba 316L plieno (didesnės radialinės jėgos) modelius arba jiems lygiaverčius - "plienas - kitas bukletas"
Stent platform	Chroma™		
Strut design	Corrugated rings		
Link design	“S” connectors and straight connectors		
Strut thickness	MV - 9 crowns: 88 µm	SV - 6 crowns: 84 µm	stento sienelės storis - iki 0.0047" (0,12 mm); "čia yra 0,088 ir 0,084 mm"
Stent crowns	MV - 9 crowns: 3.50-4.00 mm	SV - 6 crowns: 2.25-3.0 mm	
Stent crossing profile	0.041"*		
Flexibility	Very good		
Radiopacity	Good		
Ferromagnetism	Non-ferromagnetic (MRI safe)		
Open cell diameter SV model (3.0 mm)	1.58 mm*		
Foreshortening/Elongation	2.29%*		
Elastic recoil	3.87%*		
Radial strength	> 0.67 bar / 500 mm Hg		

CELL OPENING:	6-crown stent	9-crown stent
Stent over expansion outer diameter[2]	4.76 mm (stent post-dilated with 5.0 mm balloon)	5.95 mm (stent post-dilated with 6.0 mm balloon)
Maximum cell opening[2]	2.08 mm (stent post-dilated with 5.0 mm balloon)	2.34 mm (stent post-dilated with 6.0 mm balloon)
Cell over-expansion perimeter[3]	11.79 mm (stent post-dilated with 3.5 mm balloon)	15.26 mm (stent post-dilated with 4.0 mm balloon)
Cell over-expansion diameter[3]	2.70 mm (stent post-dilated with 3.5 mm balloon)	3.46 mm (stent post-dilated with 4.0 mm balloon)

* Biosensors International internal bench testing performed on 3.0x19 mm stents. Data on file at Biosensors International.
1. BioMatrix Alpha™ stent 3.0x19 mm, N=3 - 2. BioMatrix Alpha™ stent 3.0x19 mm, N=1, BioMatrix Alpha™ stent 4.0x19 mm, N=1
3. Chroma™ stent 3.0 mm, N=1, Chroma™ stent 3.5 mm, N=1 - All balloon used for cell over-expansion were deployed at NP

BIOMATRIX alpha™
DRUG ELUTING CORONARY STENT SYSTEM

BIOSENSORS INTERNATIONAL™

TECHNICAL SPECIFICATIONS

COMPLIANCE TABLE:

Inflation Pressure (ATM)	For stent lengths 9 to 29 mm					
	2.25	**2.50**	**2.75**	**3.00**	**3.50**	**4.00**
8 Nominal	2.25	2.50	2.75	3.00	3.50	4.00
9	2.28	2.54	2.79	3.05	3.56	4.07
10	2.31	2.58	2.83	3.10	3.62	4.14
11	2.34	2.62	2.87	3.15	3.68	4.21
12	2.37	2.66	2.91	3.20	3.74	4.28
13	2.40	2.70	2.95	3.25	3.80	4.35
14 RBP	2.43	2.74	2.99	3.30	**3.86**	**4.42**
15	2.46	2.78	3.03	3.35		
16 RBP	**2.49**	**2.82**	**3.07**	**3.40**		

Inflation Pressure (ATM)	For stent lengths 33 and 36 mm			
	2.50	**2.75**	**3.00**	**3.50**
8 Nominal	2.50	2.75	3.00	3.50
9	2.56	2.83	3.08	3.59
10	2.62	2.91	3.16	3.67
11	2.68	2.98	3.23	3.75
12	2.74	3.04	3.29	3.83
13	2.80	3.09	3.35	3.91
14 RBP	2.85	3.14	3.40	**3.98**
15	2.90	3.19	3.45	
16 RBP	**2.95**	**3.24**	**3.50**	

stentų ilgis - nuo 8 ± 1 mm iki 48 ± 1 mm, diametras - nuo 2,25 ± 0,25 mm iki 4,00 ± 0,25 mm;

Lengths (mm)	Stent diameter					
	Ø 2.25 mm	**Ø 2.50 mm**	**Ø 2.75 mm**	**Ø 3.00 mm**	**Ø 3.50 mm**	**Ø 4.00 mm**
9	BMX6-2209	BMX6-2509	BMX6-2709	BMX6-3009	BMX6-3509	BMX6-4009
14	BMX6-2214	BMX6-2514	BMX6-2714	BMX6-3014	BMX6-3514	BMX6-4014
19	BMX6-2219	BMX6-2519	BMX6-2719	BMX6-3019	BMX6-3519	BMX6-4019
24	BMX6-2224	BMX6-2524	BMX6-2724	BMX6-3024	BMX6-3524	BMX6-4024
29	BMX6-2229	BMX6-2529	BMX6-2729	BMX6-3029	BMX6-3529	BMX6-4029
33		BMX6-2533	BMX6-2733	BMX6-3033	BMX6-3533	
36		BMX6-2536	BMX6-2736	BMX6-3036	BMX6-3536	

42 ir 48 mm - kitas bukletas

Class III device, Rule 8, 13; MDD 93/ 42/ EC

The product is latex and PVC free

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

Storage Conditions:

Store in a cool, dark, dry place. Do not store above 30°C.

Sterilization method: E-Beam

CE certification: 0050

Shelf life: 24 months

For further information or assistance, please contact:

BIOSENSORS INTERNATIONAL™

www.biosensors.com

Legal Manufacturer - Sales and Customer Service:
BIOSENSORS EUROPE SA
Rue de Lausanne 29 - Switzerland
1110 Morges
Tel: + 41 (0)21 804 80 00
Fax: + 41 (0)21 804 80 01

1158000EN - Rev.04