GERMAN EXCELLENCE

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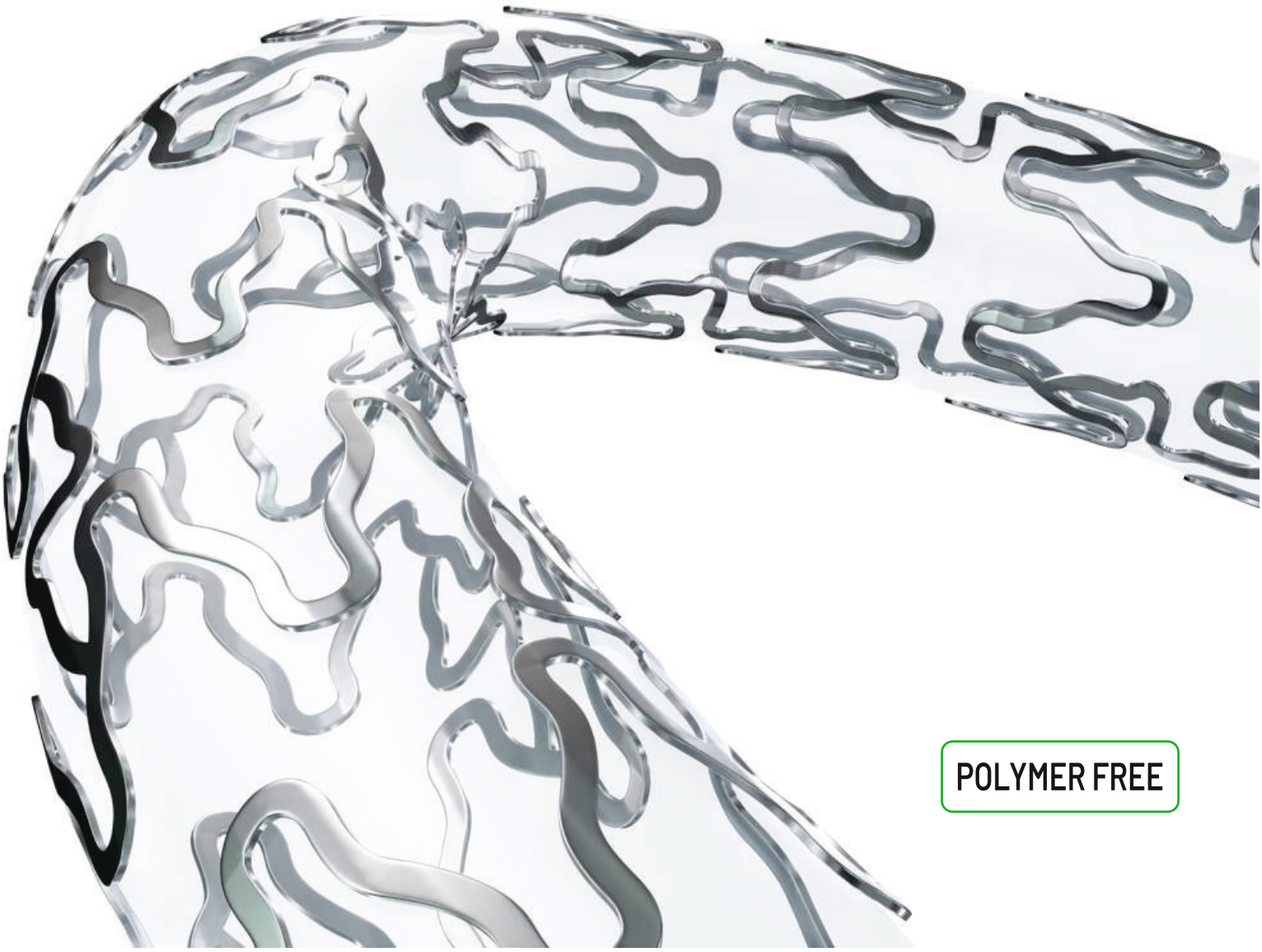
LIMITLESS POSSIBILITIES

PAVING THE PATH TOWARDS
A HEALTHIER TOMORROW

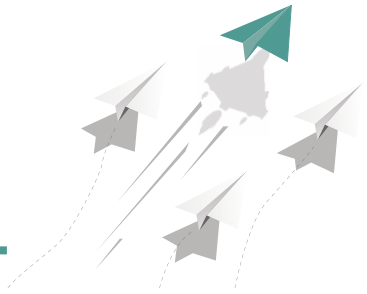
vivo ISAR

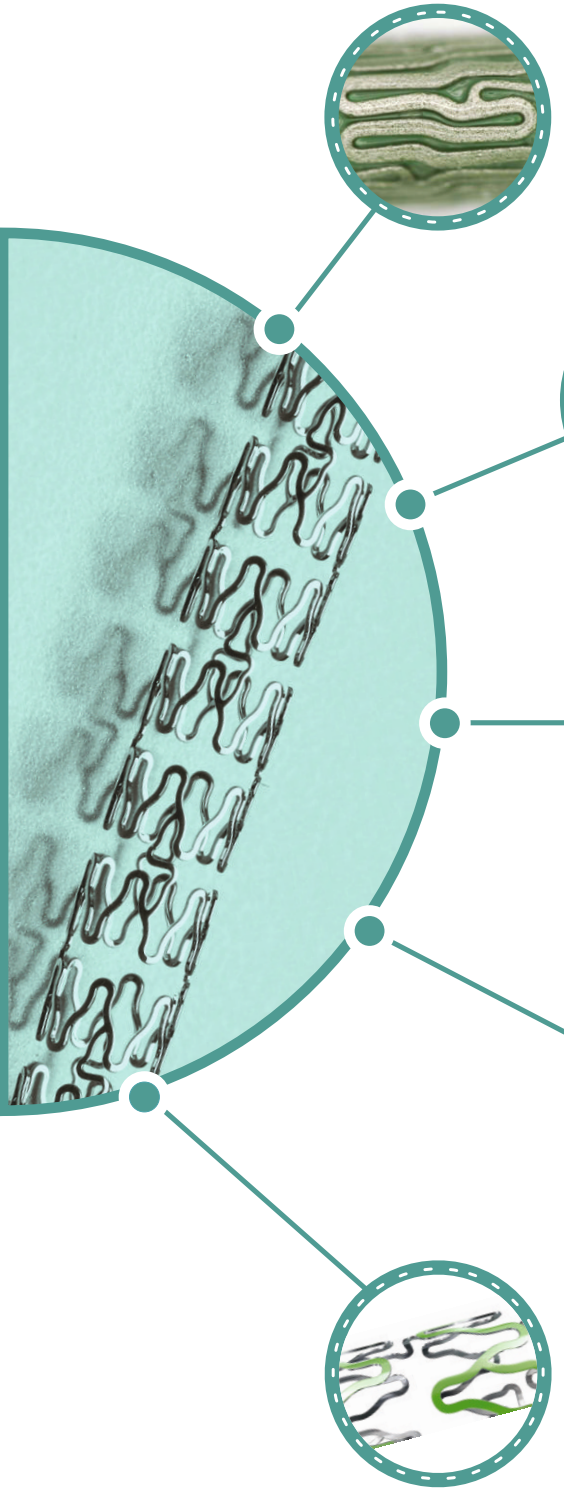
Polymer Free Sirolimus Eluting Coronary Stent System



POLYMER FREE

Definitely different





MICROPOROUS SURFACE

Micropores are created by sandblasting technique – A unique method used to enhance continuous drug delivery where pores are created to ensure optimum drug release kinetics which prevents neointimal proliferation leading to restenosis and stent thrombosis.

PROBUCOL

Mimics the function of polymer by slowing down the release of sirolimus drug.

SHELLAC RESIN (WAX FREE)

Prevents flaking and webbing of drug co-mix.

SIROLIMUS (trusted & time tested)

An anti-inflammatory and anti-proliferative agent.

ABLUMINAL COATING

Facilitates uni directional drug release and less systemic exposure, ensuring improved healing and faster endothelialization.

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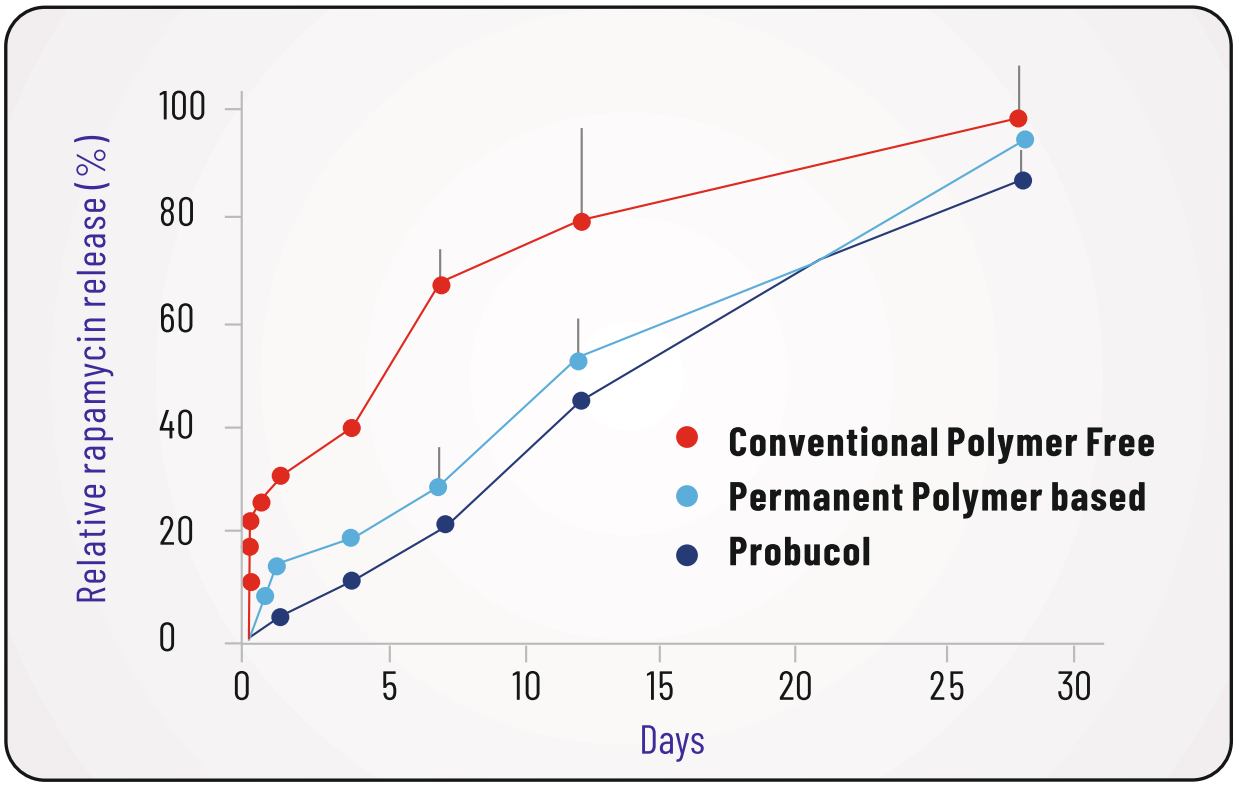
PROBUCOL

A safer solution replacing the need for polymers

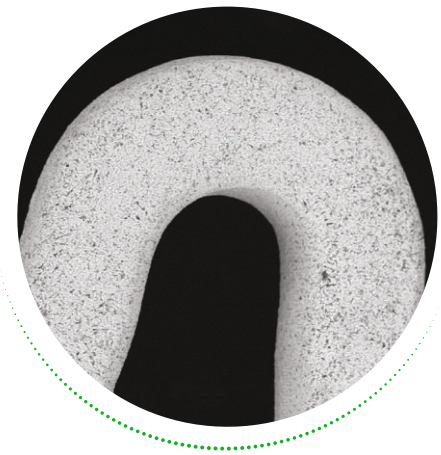
Probucol mimics the function of polymer by optimizing the drug release kinetics

80% OF DRUG IS RELEASED IN **28 DAYS***

Drug Release Kinetics



*Biomaterials 2009 Feb;30(4):632-7



SEM Picture of the unique Microporous Surface[1]

100% pore coverage of the surface

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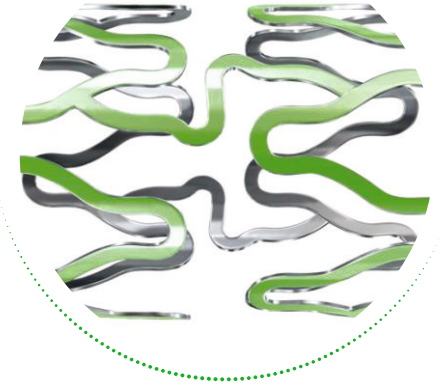
For optimal drug release kinetics



Abluminal coating of Sirolimus-Probucol matrix with Shellac resin (wax free)[2]

For faster endothelialization

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Preventing drug co-mix breakups during expansion

VIVO ISAR Technical Specifications

Stent Material	Cobalt Chromium (L605)
Strut Thickness	Small Vessel 0.068 mm Medium Vessel 0.079 mm
Drug	Sirolimus Drug
Drug Dose	2.6 µg/mm ^{2}
Polymer	Polymer Free
Coating Technology	Spray Coating
Coating	Polymer Free Sirolimus Eluting Coronary Stent System
Proximal Shaft	>0.65 mm (1.9F)
Distal Shaft	>0.90 mm (2.70F)
Usable Length	143±5cm
Guiding Catheter Compatibility	5F
Guide Wire Compatibility	0.014 "
Nominal Pressure (NP)	11 Bar
Rated Burst Pressure (RBP)	16 Bar
Crossing Profle	0.85~1.10 mm
Tip Entry Profle	0.41 mm

1. Catheter Cardiovasc Interv. 2005 Jul; 65 (3) : 374-380
2. Circulation : Cardiovascular Interventions., 2010 Aug;3(4):384-93.

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LIMITLESS POSSIBILITIES

POLYMER
AN UNAVOIDABLE RISK

Polymer Based Conventional DES	New Generation Polymer Free Stent ViVO ISAR
Chronic Inflammation and Delayed Endothelialization[1]	No Polymer Related Side Effects
Persistent Platelet Activation and Fibrin Deposition[2]	Optimum Drug Release Kinetics with Probucol
Flaking and Webbing of Drug Polymer Matrix[3]	10 Years of Proven Safety & Efficacy in Diabetic, STEMI and CAC patient

1. Int J Cardiovasc Imaging. 2021; 37 (3) : 791–801

2. Therapeutic Advance in Cardiovascular Disease

3. J Biomed Mater Res B Appl Biomater. 2009 Oct;91(1):441-51

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LIMITLESS POSSIBILITIES

VIVO ISAR

Polymer Free Sirolimus Eluting Coronary Stent System

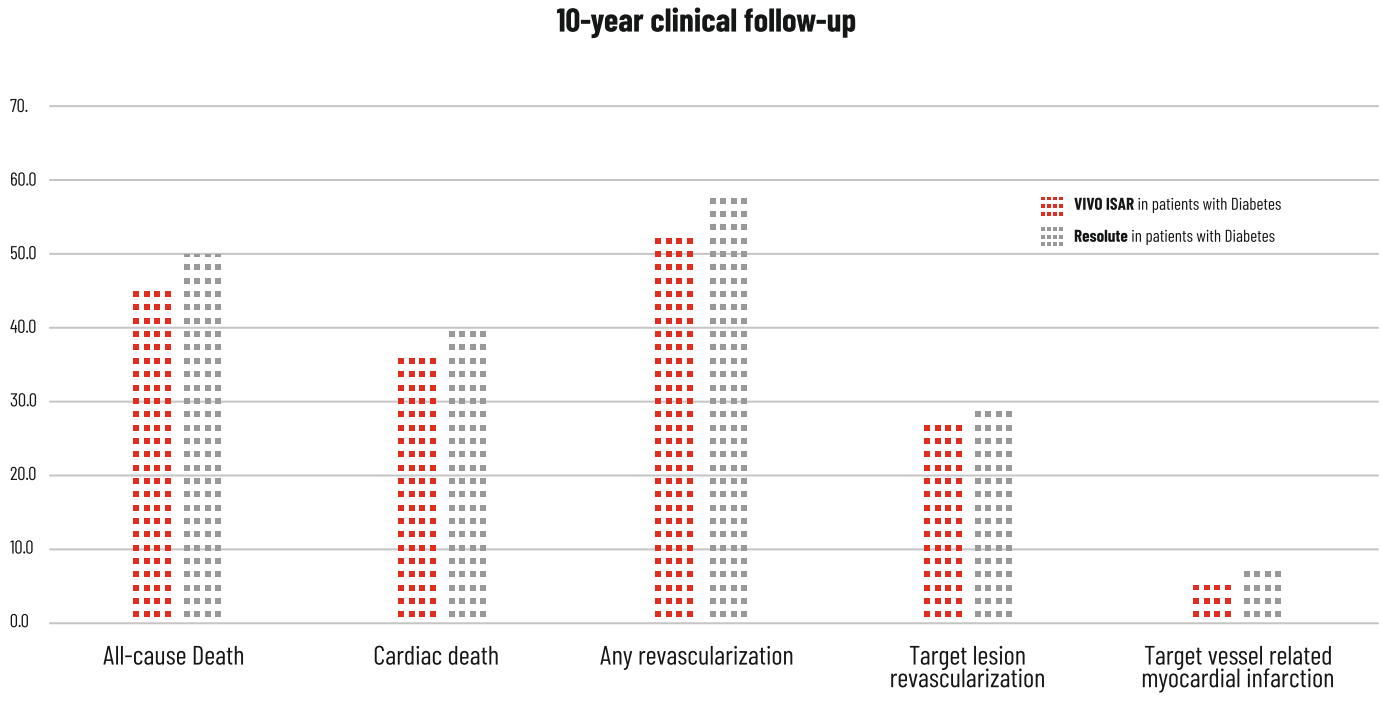
10 Year Follow up Data in Diabetic Patients*

STUDY BACKGROUND

- DES with 10 years data of safety & efficacy in Diabetic patient subset.

EFFICACY & SAFETY OUTCOMES

- Numerically low rates of All cause mortality.
- Notably low rates of Target vessel related myocardial infarction (33%).
- Significantly low rates of stent thrombosis (1.2%).



*Clinical Research in Cardiology (2021) 110:1586–1598

Clinical Studies

All Comers | JACC [1] | 2020

In this long-term analysis at 10 years, polymer-free **VIVO ISAR** showed similar efficacy & safety profiles as durable polymer-based ZES. Studied in 3002 patients

Diabetes | Clinical Research in Cardiology [2] | 2021

At 10 years, the outcomes of patients treated with **VIVO ISAR** compared with durable polymer-based ZES were similar in the subgroup of **Diabetic** patients. Studied in 3002 patients

Numerically low rates of all-cause mortality

Notably low rates of TVMI i.e. 33%

Low rates of stent Thrombosis i.e. 1.2% at 10 years follow up

EuroIntervention [3] | 2022

New-generation DES have been shown to improve both safety and efficacy outcomes as compared to early generation DES, including for patients with **Coronary Artery Calcification** At 10 years Clinical outcomes in patients with moderate-severe coronary calcification according to polymer coating strategies PF DES (n =755) TLR 26.1%, MI 6.5%, Definite or probable stent thrombosis 1.8% are lower as compared to Biodegradable Polymer or Permanent Polymer

EDIZIONI MINERVA MEDICA [4] | 2023

10 Years Follow-up with 3002 Patients, Polymer-Free DES Showed Similar Results With Regards To Safety & Efficacy When Compared With DES With Permanent Polymer in **ACS Subset**

1. Journal of the American College of Cardiology. 2020 Jul 14;76(2):146-58.

2. Clinical Research in Cardiology (2021) 110:1586–1598

3. Eurointervention: Journal of Europe in Collaboration with the Working Group on Interventional Cardiology of the European Society of Cardiology. 2022 Dec 1:EIJ-D.

4. Versaci F, et.al., Very long-term outlook of acute coronary syndromes after percutaneous coronary intervention with implantation of polymer-free versus durable-polymer new-generation drug-eluting stents. Minerva medica.

Ordering Information

Length (mm)	VIVO ISAR Reference No.						
	Diameter (mm)						
	2.00 mm	2.25 mm	2.50 mm	2.75 mm	3.00 mm	3.50 mm	4.00 mm
8.00	VISR2008	VISR2208	VISR2508	VISR2708	VISR3008	VISR3508	VISR4008
12.00	VISR2012	VISR2212	VISR2512	VISR2712	VISR3012	VISR3512	VISR4012
16.00	VISR2016	VISR2216	VISR2516	VISR2716	VISR3016	VISR3516	VISR4016
18.00	VISR2018	VISR2218	VISR2518	VISR2718	VISR3018	VISR3518	VISR4018
21.00	VISR2021	VISR2221	VISR2521	VISR2721	VISR3021	VISR3521	VISR4021
24.00	VISR2024	VISR2224	VISR2524	VISR2724	VISR3024	VISR3524	VISR4024
28.00	VISR2028	VISR2228	VISR2528	VISR2728	VISR3028	VISR3528	VISR4028
32.00	VISR2032	VISR2232	VISR2532	VISR2732	VISR3032	VISR3532	VISR4032
36.00				VISR2736	VISR3036	VISR3536	VISR4036
40.00				VISR2740	VISR3040	VISR3540	VISR4040
44.00				VISR2744	VISR3044	VISR3544	VISR4044
48.00				VISR2748	VISR3048	VISR3548	VISR4048

*Please contact our Customer Care for available sizes

Compliance Chart

Balloon ⌀ (mm)	Inflation Pressure (atm/bar/10^5 Pa)														
						NP*					RBP**				
	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
⌀ 2.00	1.83	1.87	1.90	1.93	1.96	2.00	2.03	2.06	2.10	2.13	2.16	2.20	2.23	2.26	2.29
⌀ 2.25	2.08	2.11	2.14	2.18	2.21	2.25	2.28	2.31	2.35	2.38	2.42	2.45	2.48	2.52	2.55
⌀ 2.50	2.33	2.36	2.40	2.43	2.47	2.50	2.53	2.57	2.60	2.64	2.67	2.70	2.74	2.77	2.81
⌀ 2.75	2.58	2.61	2.65	2.68	2.71	2.75	2.78	2.81	2.85	2.88	2.91	2.94	2.98	3.01	3.04
⌀ 3.00	2.81	2.85	2.89	2.92	2.96	3.00	3.04	3.07	3.11	3.15	3.18	3.22	3.26	3.29	3.33
⌀ 3.50	3.29	3.34	3.38	3.42	3.46	3.50	3.55	3.59	3.63	3.67	3.71	3.76	3.80	3.84	3.88
⌀ 4.00	3.75	3.80	3.85	3.90	3.95	4.00	4.06	4.11	4.16	4.21	4.26	4.31	4.36	4.41	4.46

*Nominal Pressure **Rated Burst Pressure

CE 1434

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Please refer to the Instructions for Use supplied with these devices for indications, contraindications, Adverse Events, suggested procedures, warnings and precautions.

Ref. No. VISR.BC.01-25.Rev.01