LEADERS FREE

BIOSENSORS INTERNATIONAL™

LEADERS FREE: Complex PCI for patients at high bleeding risk
Two years outcome of a sub-study

Roxana Mehran MD, Jaya Chandrasekhar MBBS, Philip Urban MD, Robaayah Zambahari MD , Irene Lang MD, Ute Windhoevel, Christian Spaulding MD, Samuel Copt PhD, Hans-Peter Stoll MD, and Marie-Claude Morice MD for the *LEADERS FREE* Investigators

Presented by P. Urban EuroPCR 2018

Potential conflicts of interest

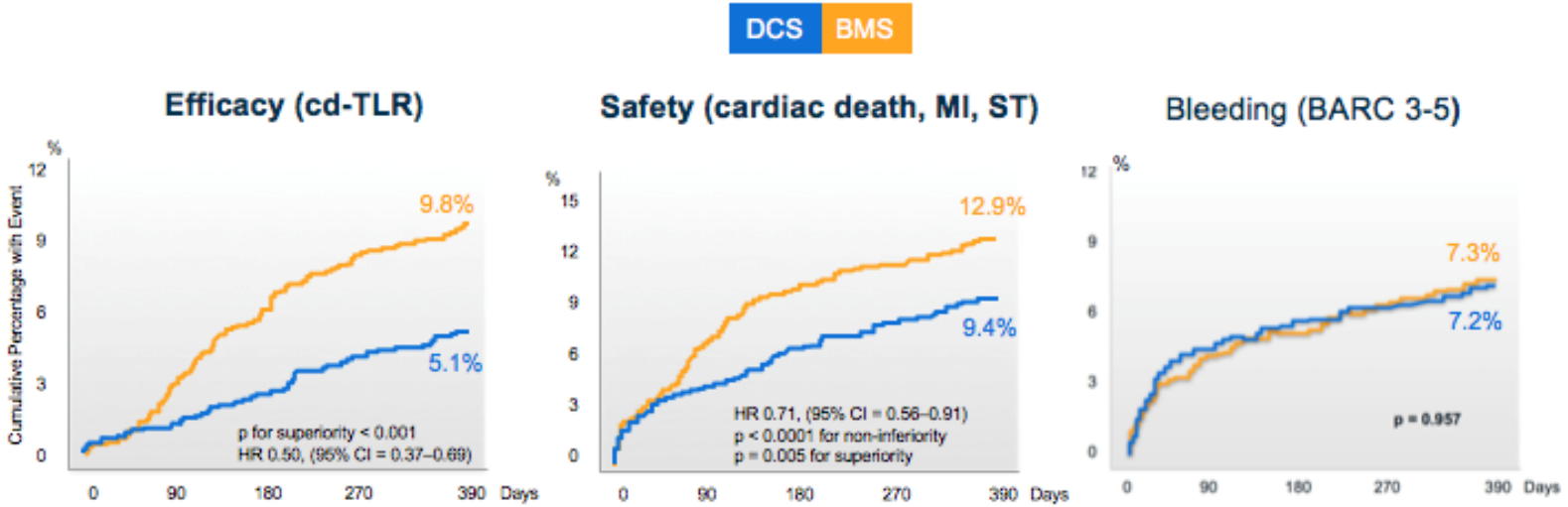
Speaker's name : Philip Urban, Meyrin-Genève

☑ I have the following potential conflicts of interest to report:

Receipt of honoraria or consultation fees:

Abbott Vascular, Biosensors International Group Ltd,
Edwards Lifesciences Corp., Terumo Europe NV

Primary Endpoints and Major Bleeding at 1 Year



BioFreedom™ DCS vs. **Gazelle™ BMS**

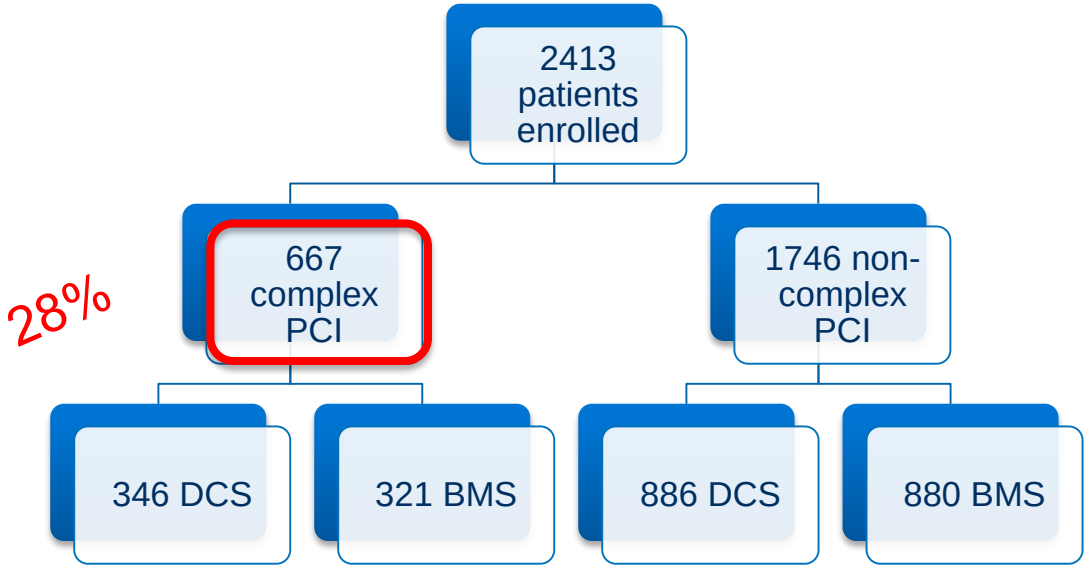
DAPT mandated for 1 month only, followed by long-term SAPT

Urban P et al. N Engl J Med 2015;373:2038-47

LEADERS FREE & COMPLEX PCI

What did we study?

Determine the incidence and two-year outcome of complex PCI in HBR patients enrolled in the *Leaders Free* trial

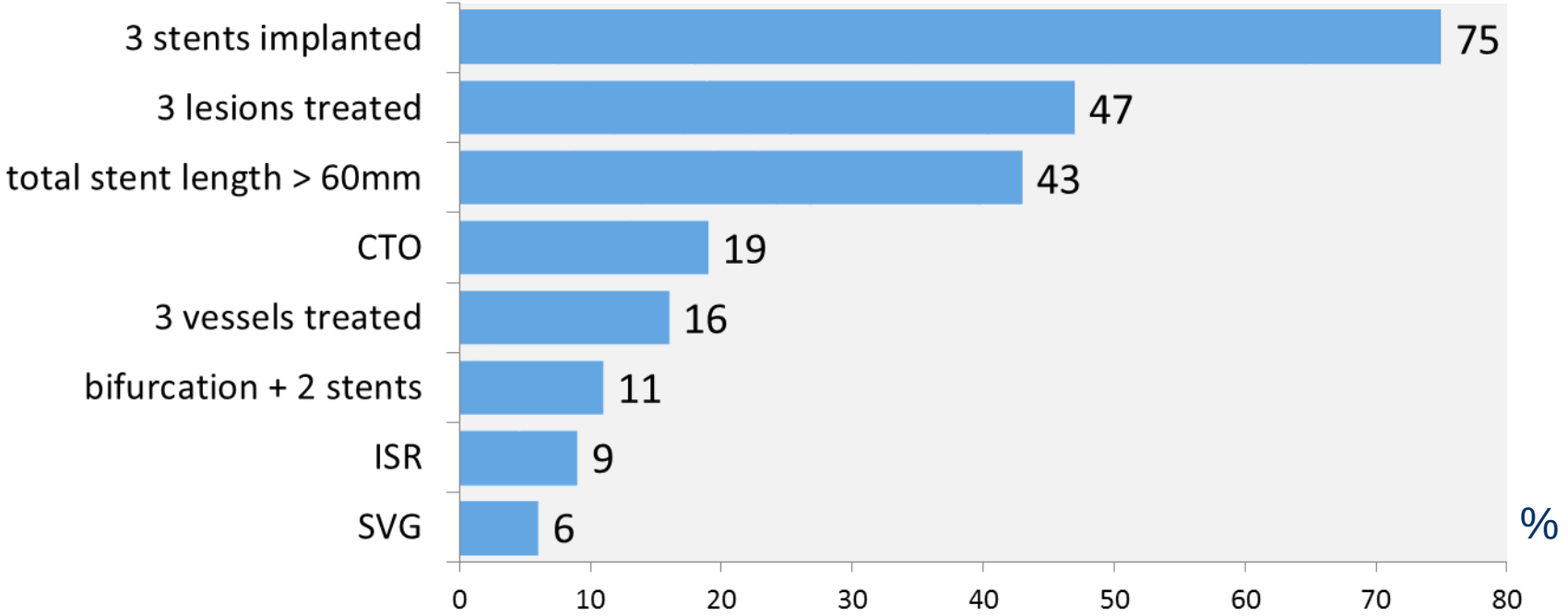


11929-000-EN_Rev.01

LEADERS FREE & COMPLEX PCI

How was the study executed?

Diagnostic criteria for 667 complex PCI (one or more)



11929-000-EN Rev.01

If none of the above, PCI was considered «non-complex»

LEADERS FREE & COMPLEX PCI

What are the essential results?

Baseline characteristics

	Complex PCI	Non-complex PCI	p value
Mean age (years)	76.5 ± 8.8	75.3 ± 9.5	0.006
Female gender	176 (26.4%)	559 (32.0%)	0.007
ACS presentation	200 (30.0%)	452 (25.9%)	0.043
Diabetes	241 (36.3%)	557 (31.9%)	0.042
Renal insufficiency	172 (25.9%)	349 (20.1%)	0.002
Prior coronary revascularisation	195 (29.5%)	417 (24.3%)	0.006
Anaemia or recent transfusion	119 (17.8%)	255 (14.6%)	0.0495
Mean number of trial inclusion criteria	1.83 ± 0.95	1.73 ± 0.86	0.03
Multivessel disease	550 (84.1%)	797 (46.1%)	<0.0001

Other major baseline characteristics were not significantly different between the 2 groups

11929-000-EN Rev.01

LEADERS FREE & COMPLEX PCI

What are the essential results?

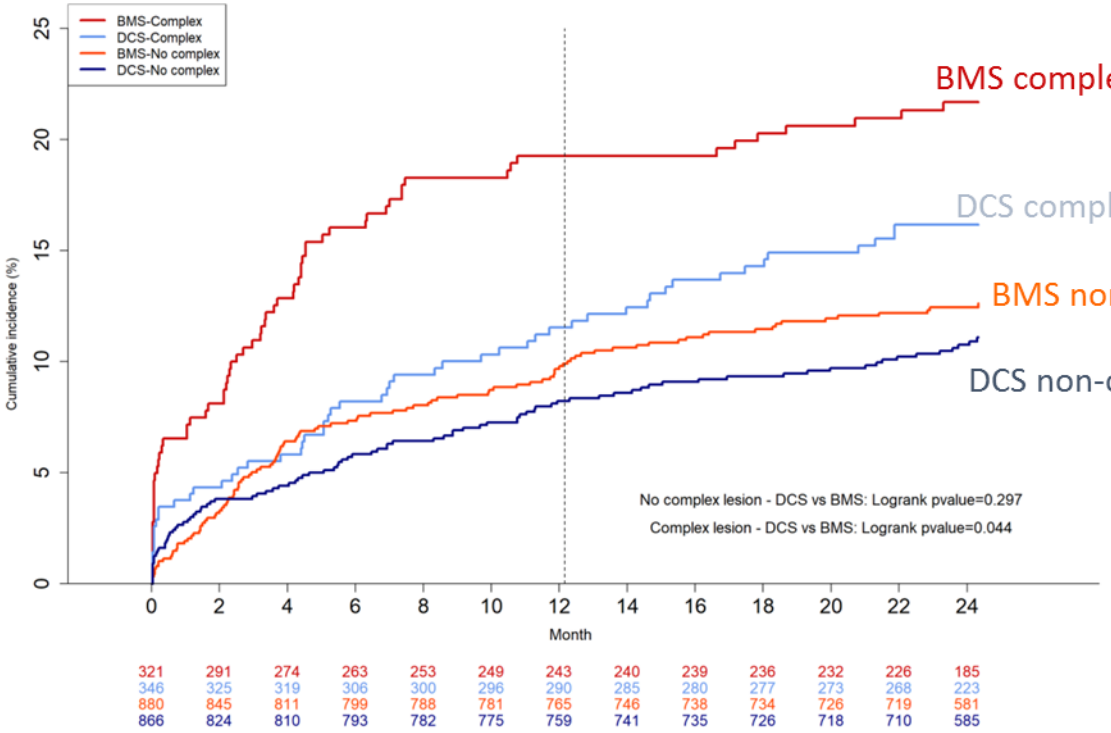
Procedure characteristics

	Complex PCI	Non-complex PCI	p value
Radial access	412 (53.2%)	1110 (62.7%)	<0.0001
Staged procedure	108 (13.9%)	25 (1.4%)	<0.0001
Multi-lesion procedure	500 (64.5%)	432 (24.4%)	<0.0001
Multi-vessel procedure	335 (43.2%)	218 (12.3%)	<0.0001
Mean number of implanted stents / patient	2.7 ± 1.3	1.3 ± 0.5	<0.0001
Total length of implanted stents / patient	51.0 ± 26.6	24.2 ± 11.0	<0.0001
Mean minimal nominal stent diameter	2.7 ± 0.4	3.0 ± 0.5	<0.0001

11929-000-EN_Rev.01

LEADERS FREE & COMPLEX PCI

Primary safety endpoint (cardiac death/MI/ST)



BMS complex, 21.7%

HR 0.70 (95% CI 0.49-0.99) P < 0.05

DCS complex, 16.2%

BMS non-complex, 12.6%

NS

DCS non-complex, 11.1%

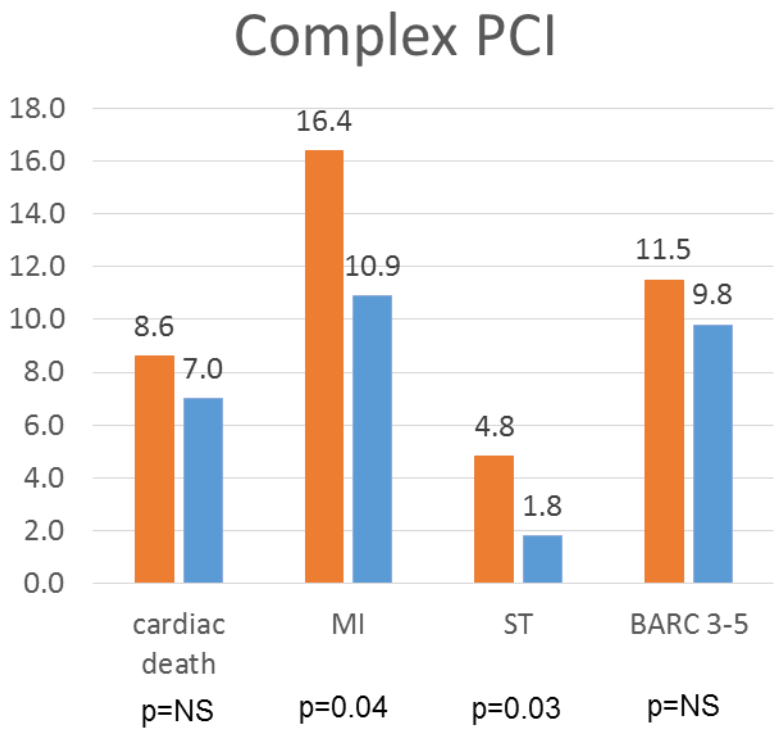
NNT
Complex 18
Non-complex 67

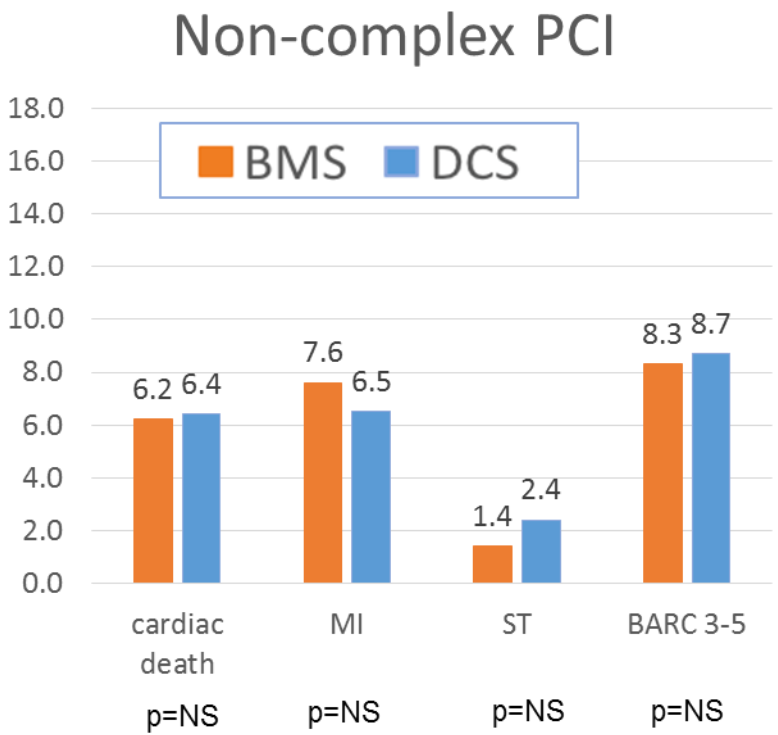
P for interaction = NS

11929-000-EN Rev.01

LEADERS FREE & COMPLEX PCI

What are the essential results?

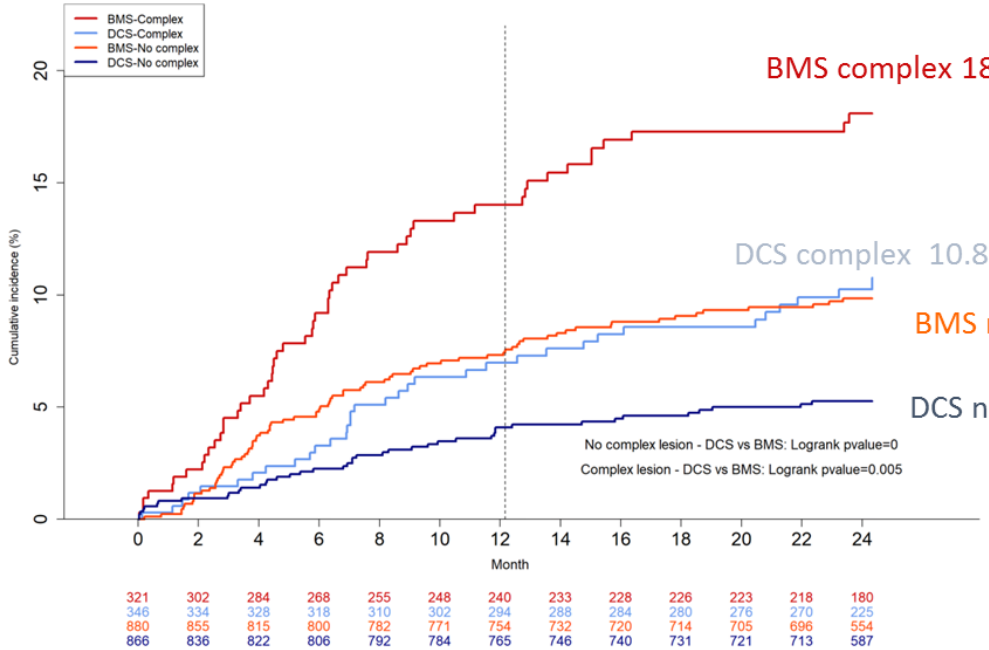




LEADERS FREE & COMPLEX PCI

What are the essential results?

Primary efficacy endpoint (clinically indicated TLR)



BMS complex 18.1%

DCS complex 10.8%

HR 0.54 (95% CI 0.35-0.83) P < 0.005

BMS non-complex 9.9%

DCS non-complex 5.3%

HR 0.52 (95% CI 0.36-0.75), p<0.001

NNT
Complex 14
Non-complex 22

P for interaction = NS

LEADERS FREE & COMPLEX PCI

The essentials to remember

- **Why**: DCS have never been specifically tested for complex PCI
- **Who**: 667 HBR patients with complex PCI enrolled in *Leaders Free* (28%)
- **How**: One month DAPT for all after randomisation to DCS or BMS and 2 years follow-up
- **Results**: The safety and efficacy benefits of a BA9-DCS over a BMS were maintained independently of PCI complexity
- **Why is this important**:
- The absolute benefits of BA-9 DCS over BMS were greater for patients undergoing complex PCI
- There is no subset of patients for whom BMS is a better option that DCS

11929-000-EN_Rev.01

LEADERS FREE & COMPLEX PCI

CLINICAL RESEARCH
CORONARY INTERVENTIONS

EuroIntervention 2018;14-online publish-ahead-of-print May 2018

euro PCR 2018 LATE BREAKING TRIALS

Biolimus A9 polymer-free coated stents in high bleeding risk patients undergoing complex PCI: evidence from the LEADERS FREE randomised clinical trial

Janusz Lipiecki[1], MD; Philippe Brunel[2], MD; Marie-Claude Morice[3], MD; Christan Roguelov[4], MD; Simon Walsh[5], MD; Gert Richardt[6], MD; Pedro Eerdmans[7], MD; Robaayah Zambahari[8], MD; Jacques Berland[9], MD; Samuel Copt[10], PhD; Hans-Peter Stoll[10], MD; Philip Urban[11]*, MD

1. ELSAN, Pôle Santé République Centre de Cardiologie Interventionnelle, Clermont-Ferrand, France; 2. Hôpital Privé Dijon-Bourgogne, Dijon, France; 3. Ramsay Générale de Santé, ICPS, Massy, France; 4. CHUV, Lausanne, Switzerland; 5. Belfast Health & Social Care Trust, Belfast, Northern Ireland, United Kingdom; 6. Segeberger Kliniken, Herzzentrum, Bad Segeberg, Germany; 7. DEKRA, Arnhem, the Netherlands; 8. National Heart Institute, Kuala Lumpur, Malaysia; 9. Clinique Saint-Hilaire, Rouen, France; 10. Biosensors, Morges, Switzerland; 11. Hôpital de la Tour, Geneva, Switzerland

KEYWORDS

- adjunctive pharmacotherapy
- bifurcation
- bleeding
- chronic coronary total occlusion
- in-stent restenosis
- saphenous vein graft

Abstract

Aims: The LEADERS FREE trial has demonstrated that a polymer-free Biolimus A9-coated stent (BA9-DCS) is superior to a bare metal stent (BMS) for high bleeding risk (HBR) patients when treated with one month of dual antiplatelet therapy (DAPT). This analysis aimed to determine the impact of PCI procedure complexity on the two-year results.

Methods and results: Six hundred and sixty-seven (667) patients enrolled in the LEADERS FREE (BA9-DCS 346, BMS 321) underwent a complex PCI, defined by one or more of eight characteristics: total stent length ≥60 mm, ≥3 vessels or lesions treated, ≥3 stents implanted, bifurcation lesion treated with ≥2 stents, chronically occluded, restenotic or saphenous vein graft lesion. Patients undergoing complex PCI were older, more often male, and presented with more ACS, diabetes, renal insufficiency, anaemia and multivessel disease. They derived major benefit from DCS over BMS for safety (16.2% vs. 21.7%, HR 0.70 [0.49-0.99], p<0.05) and for efficacy (10.8% vs. 18.1%, HR 0.54 [0.35-0.83], p<0.005). For the 1,746 patients with non-complex PCI, DCS demonstrated superior efficacy (5.3% vs. 9.9%, HR 0.52 [0.36-0.75], p<0.001, p for interaction NS) and similar safety to BMS (11.1% vs. 12.6%, NS, p for interaction NS).

Conclusions: Compared to BMS, the BA9-DCS maintained both efficacy and safety benefits when used in complex PCI procedures.

DOI: 10.4244/EIJ-

DISCLAIMER

BioFreedom, Gazelle and BA9 are trademarks or registered trademarks of Biosensors International Group, Ltd.
BioFreedom is CE Mark approved.
All other cited trademarks are the property of their respective owners.
Data on file at Biosensors International for any sustained claims in this document.
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, except EuroPCR 2018.**

11929-000-EN_Rev.01

11929-000-EN Rev.01

BIOSENSORS
INTERNATIONAL™

11929-000-EN Rev.01