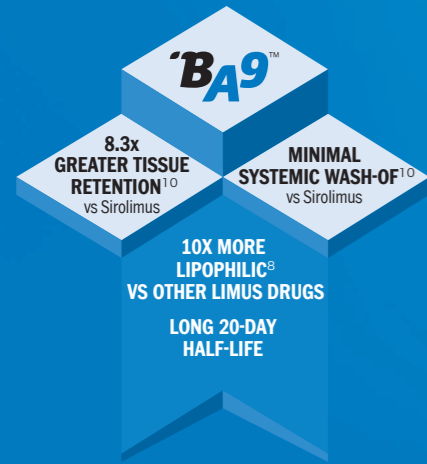


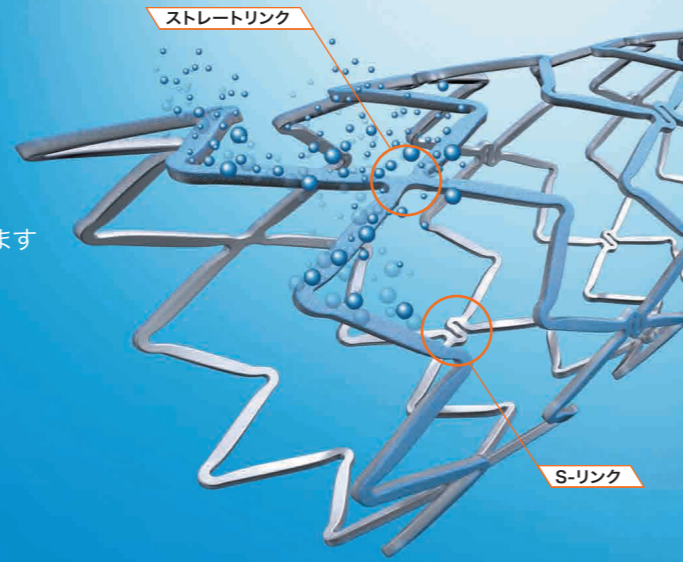
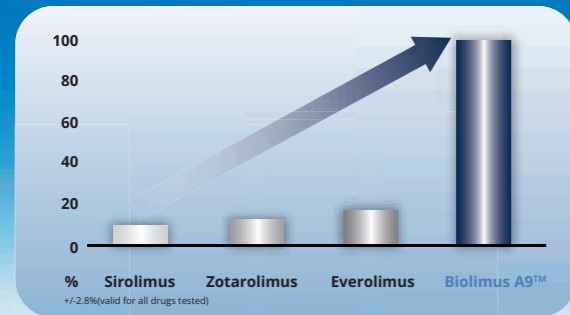
BIOFREEDOM[™] ultra



- 細胞増殖抑制性能を示すリムス系薬剤BA9
- 高い親油性により、素早く組織に浸透し、細胞に取り込まれます
- 高い局所的バイオアベイラビリティ:
 - 標的病変への持続的な薬剤のリリースが可能⁸
 - 一般的なリムス系薬剤より半減期が長い⁹



BA9[™] drug 10 times more lipophilic than Sirolimus



STENT PLATFORM

SMS TREATMENT (ABLUMINAL SURFACE)

Powered by



DCS BA9 APPLICATION DIRECTLY ON THE STENT



1. Ueki et al. Validation of Bleeding Risk Criteria (ARC-HBR) in Patients Undergoing Percutaneous Coronary Intervention and Comparison with Contemporary Bleeding Risk Scores. EuroIntervention. 2020 Feb 18. doi: 10.4244/EIJ-D-20-00052
 2. Data from BioFreedom Ultra. Biolimus-A9 coated thin Strut Stents in High Bleeding Risk Patients Evidence from the LEADERS FREE III Study. F.R.Eberli et al., Presented at PCR eCourse June 2020
 3. Data from BioFreedom in LEADERS FREE: Urban P. et al. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk New England Journal of Medicine 2015, October 14, DOI: 10.1056/NEJMoa1503943
 4. Data from Gazelle. Urban P. et al. Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk. New England Journal of Medicine 2015, October 14, DOI: 10.1056/NEJMoa1503943
 5. Data from BioFreedom. Garot P et al. 2-Year Outcomes of High Bleeding Risk Patients After Polymer-Free Drug-Coated Stents. JACC VOL.6 9, No.2, 2017
 6. M. W. Krucoff. Global Approach to High Bleeding Risk Patients With Polymer-Free Drug-Coated Coronary Stents: The LF II Study. Circ Cardiovasc Interv. 2020 Apr;13
 7. S. Saito. LEADERS FREE Japan study (single BioFreedom DCS arm with 1-month DAPT, compared to BMS arm of LEADERS FREE). ePoster EuroPCR 2017
 8. Biosensors International data on file
 9. With BioFreedom compared to BMS. BioFreedom is the predicate device of BioFreedom Ultra
 10. Sirolimus analog lipophilicity dictates release kinetics and tissue retention after implantation of polymer free drug eluting stents. R. Tzafirri, Poster Presentation EuroPCR 2017
- s. Struts for specific stent diameter (small vessel).

BioFreedom[™] Ultraは、Biosensors International Group, Ltd.の登録商標です。
BioFreedom[™] Ultraは、CEマークの承認を受けています。

■ 販売名: BioFreedom Ultra 薬剤コーテッドステント
■ 医療機器承認番号: 30400BZX00081000

【製造販売元】



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BSJ20200312-500

BIOFREEDOM[™] ultra

POLYMER- & CARRIER-FREE
DRUG-COATED CORONARY STENT SYSTEM



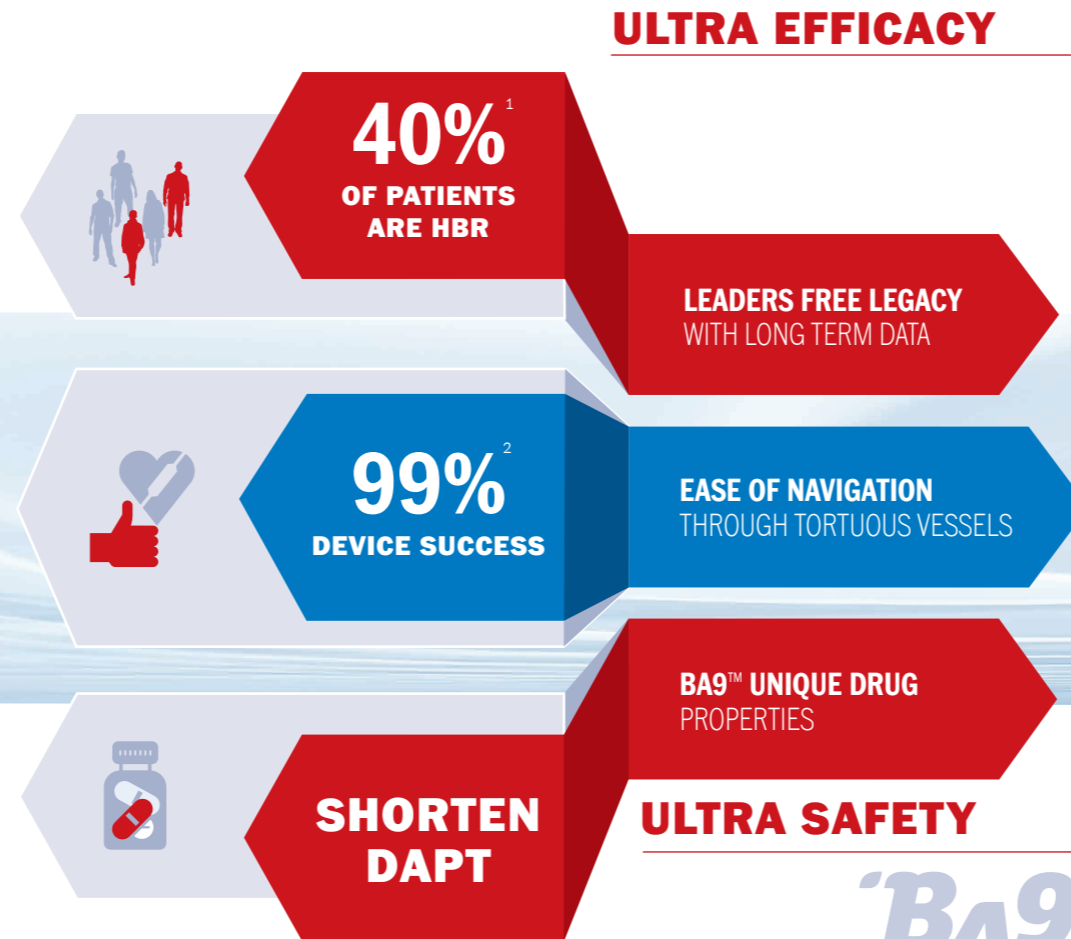
ULTRA RESPONSIVE
FOR ALL STEPS
OF THE PATIENT JOURNEY



BIOSENSORS
INTERNATIONAL[™]

LEADING THE WAY AT DECISIVE MOMENTS

What if the choices you make today, could allow you to focus on what matters most to you?



Clinical outcomes at 1 year	DCS CoCr LF III ² (n=401)	DCS StS LF I ³ (n=1221)	BMS LF I ⁴ (n=1211)
Primary Safety Endpoint*	8.0%	9.2%	12.7%
Cardiac Death	3.7%	4.1%	5.1%
Myocardial Infarction	4.4%	5.9%	8.7%
Def/Prob. Stent Thrombosis	1.0%	2.0%	2.2%
Clinically-Driven TLR**	4.2%	4.9%	9.3%
BARC 3-5	5.4%	7.2%	7.2%
All Death	6.4%	7.5%	8.7%

Procedural characteristics	DCS CoCr LF III ² (n=401)	DCS StS LF I ³ (n=1221)	BMS LF I ⁴ (n=1211)
Lesion Success	99%	98%	98%
Device Success	99%	98%	98%
Procedure Success	97%	94%	94%

* p-value for non-inferiority vs DCS LF I: 0.0006 (non-inferiority margin: 3.9%)
** p-value for superiority vs BMS LF I: < 0.0001

ALL-COMER HBR: HBR, HBR-ACS, UNCERTAIN

薄いコバルトクロム製ストラット (84μm)⁸とステントデザイン、改良されたデリバリーシステムの組み合わせにより、優れたトラッカビリティとプッシュビリティを發揮し、クロッサビリティを向上しました。

Ease of delivery

BA9™ UNIQUE DRUG PROPERTIES

約28日間で、およそ98%のBA9がステントから放出されます⁸

LEADERS FREE III² ST at 1 year >>1%

LEADERS FREE⁵ very late ST at 2 years >>0.1%

ULTRA REPRODUCIBLE

Positive outcomes reproducible to all patients

3,000人のHBR患者⁹を対象とした無作為化臨床試験 LEADERS FREE global clinical trial (I, II, III, Japan)^{2,6,7}では、HBR患者の幅広い領域で治療効果の有意な改善が証明されています。

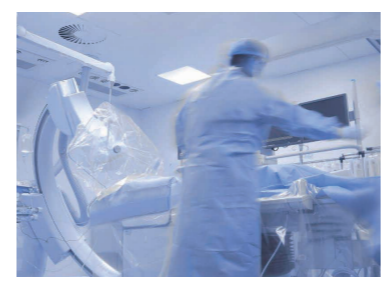
BEFORE IMPLANTATION

DURING IMPLANTATION

ULTRA DELIVERABLE

Efficient procedure

BioFreedom™ Ultraは、手技時間を短縮することに貢献し、患者様の負担を軽減することが可能です。

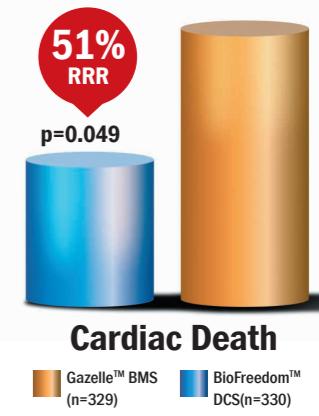


AFTER IMPLANTATION

QUALITY OF LIFE

51% Cardiac Death reduction in ACS Patients with BioFreedom™^{3,7}

1% ST at 1 year in HBR patients with BioFreedom™ Ultra²



350,000 patients⁸ treated