



HBR



SMS



BA9

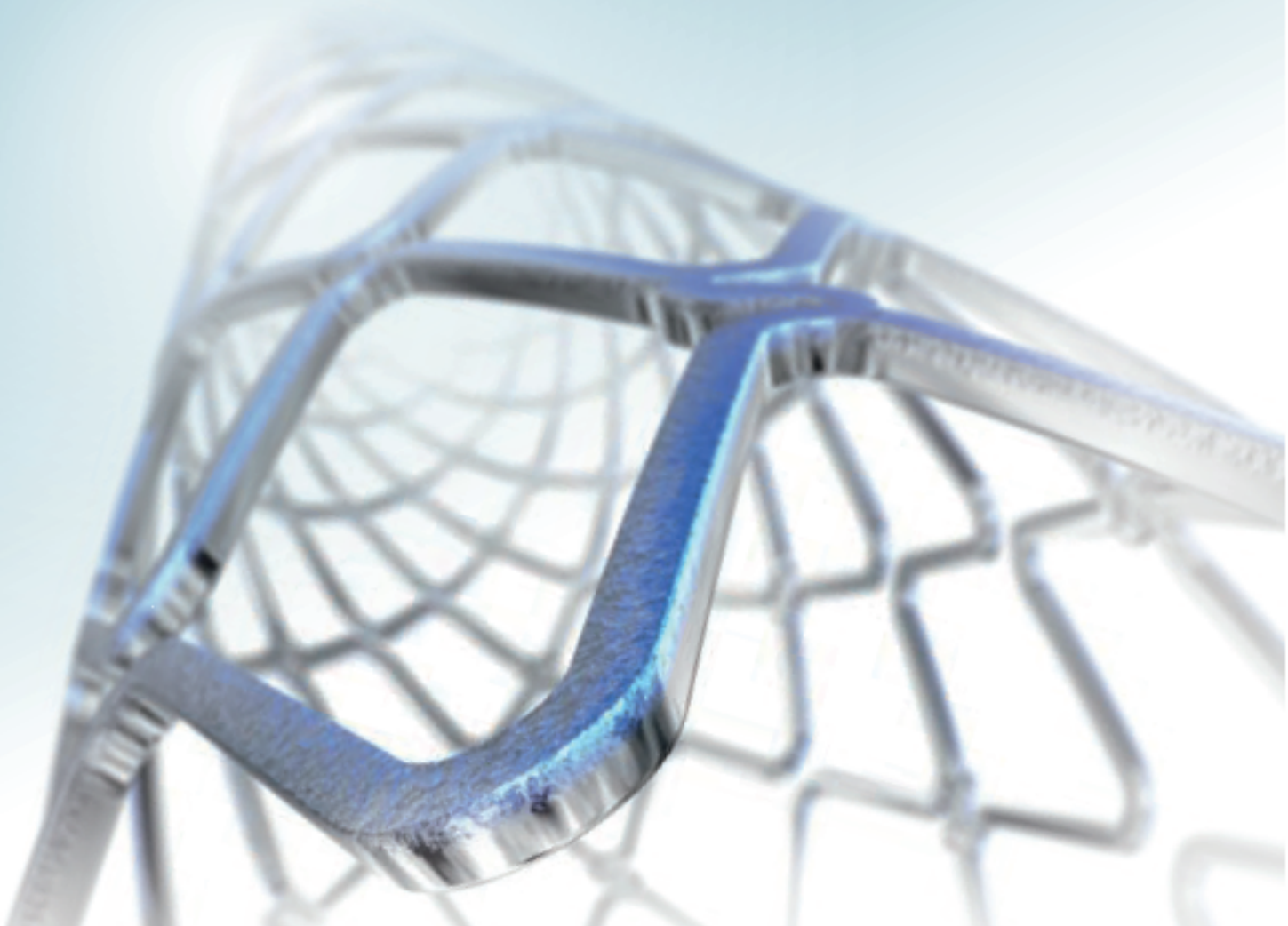
BIOFREEDOM™

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

Powered by



Freedom to treat





Meeting the Need of High Bleeding Risk (HBR) Patients

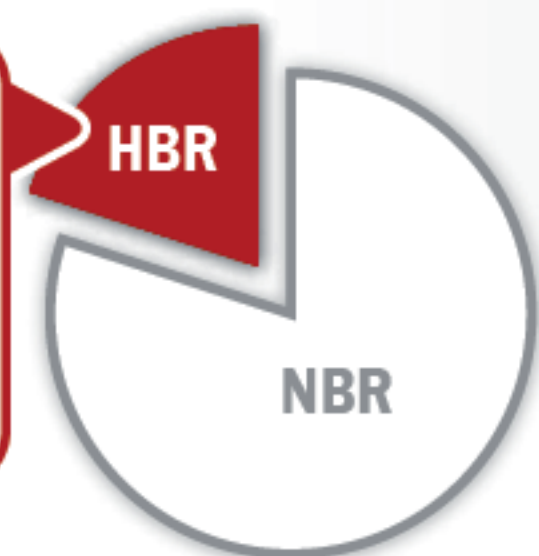
At least 20% of PCI patients are High Bleeding Risk (HBR) where there is a need to avoid prolonged dual antiplatelet therapy (DAPT).^{1,9} BioFreedom, as a Drug-Coated Stent (DCS), is safer and more efficacious than BMS in High Bleeding Risk patients.

By directly delivering BA9 - an effective anti-restenotic therapy - without polymer or carrier and becoming a BMS at 28 days, the DAPT regime can be shortened when treating patients with the BioFreedom stent.

High Bleeding Risk (HBR)
Normal Bleeding Risk (NBR)

20%

- Age ≥ 75 yrs^{1,2}
- Oral Anticoagulation (OAC) after PCI³
- Planned major surgery <12 months^{4,5}
- History of bleeding/stroke^{5,6}
- Anemia (severe)⁷
- Chronic Kidney Disease (CKD)¹
- Cancer¹
- Other (DAPT intolerance, poor adherence, Dengue fever)



DAPT = dual antiplatelet therapy

Balancing the Ischemic & Bleeding Risk for HBR Patients with 1 Month DAPT

1 Less Stent Thrombosis

N=32,135 from 10 RCTs

2.1 More Bleeds



Recent meta-analysis¹⁰ indicates that long-term DAPT prevents 1 Stent Thrombosis but increases bleeding by 2.1 events.*

LEADERS FREE

The landmark trial (Prospective, Double Blind Randomised (1:1)) evaluating BioFreedom (DCS) in High Bleeding Risk (HBR) patients with 1 month DAPT



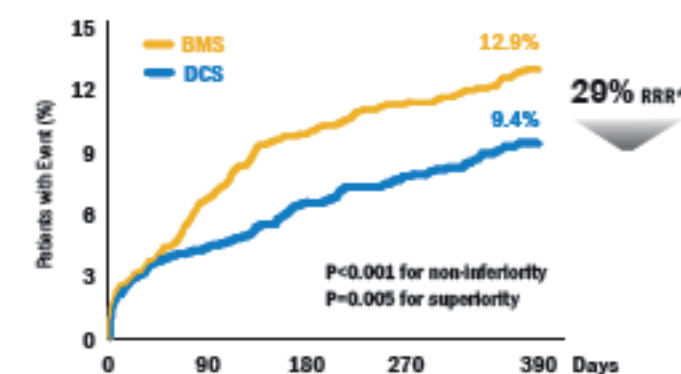
BioFreedom is the only active stent with 1 month DAPT that has demonstrated superior outcomes to BMS¹¹

With LEADERS FREE, BioFreedom becomes the standard of care for High Bleeding Risk (HBR) patients¹¹

Significantly Safer than BMS¹¹

29% Reduction in the Rate of the Composite of Cardiac Death, MI, ST

Primary Safety Endpoint (Composite of Cardiac Death, MI, ST)



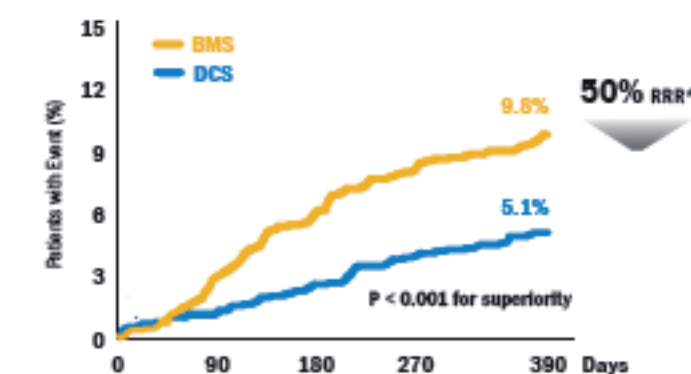
Number at Risk	DCS	1221	1146	1105	1081	1045
BMS	1211	1115	1066	1037	1000	

390 days chosen for assessing primary endpoint to capture potential events driven by the 360 day follow up contact
Hazard Ratio (HR) 0.71; 95% CI: 0.50 to 0.91; P = 0.005 for superiority
* Relative Risk Reduction

Significantly more Effective than BMS¹¹

50% Reduction in the Rate of Restenosis

Primary Efficacy Endpoint (Clinically-Driven TLR)

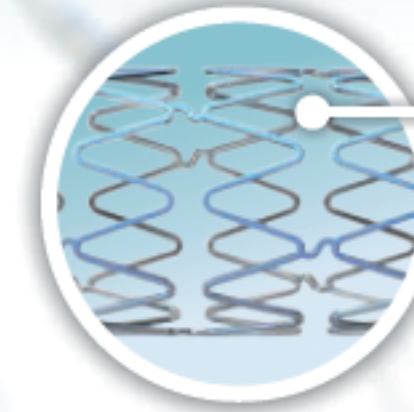


Number at Risk	DCS	1221	1167	1130	1098	1063
BMS	1211 <td>1131 <td>1072 <td>1034 <td>984 </td></td></td></td>	1131 <td>1072 <td>1034 <td>984 </td></td></td>	1072 <td>1034 <td>984 </td></td>	1034 <td>984 </td>	984	

390 days chosen for assessing primary endpoint to capture potential events driven by the 360 day follow up contact
Hazard Ratio (HR) 0.52; 95% CI: 0.37 to 0.69; P < 0.001 for superiority
* Relative Risk Reduction

Juno Stent Platform

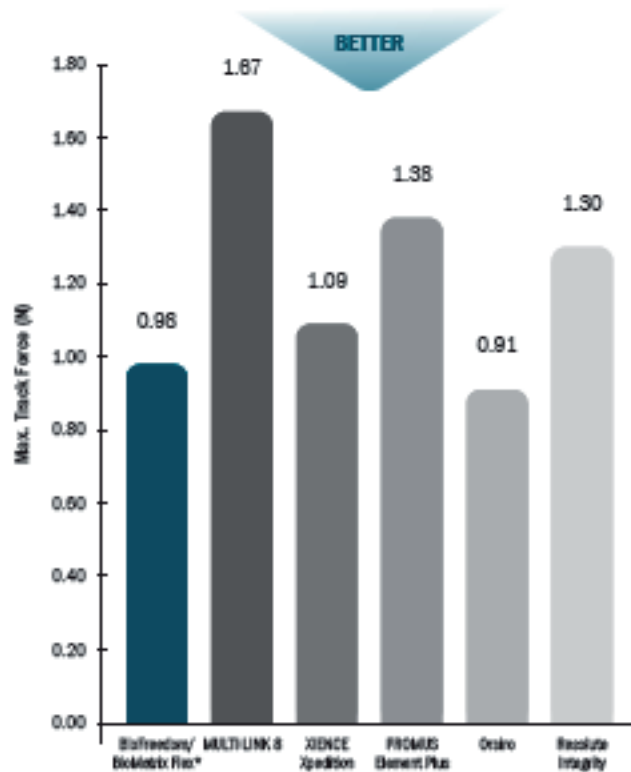
Stent Platform Optimised for Delivery to the Coronary Lesion



Largest Cell Openings & Lowest Longitudinal Stent Deformation of 2nd Generation DES

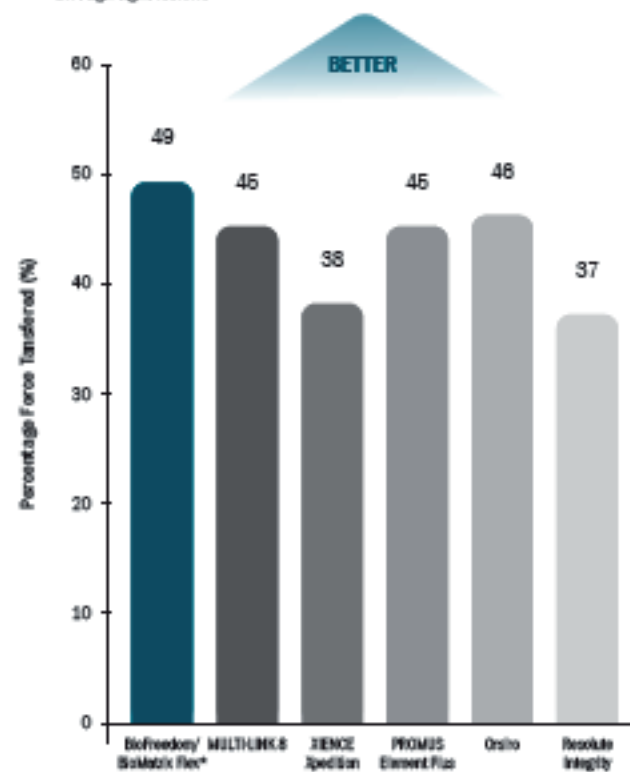
Trackability

Lower peak force represents better trackability, which allows better navigation of the delivery system through the blood vessels



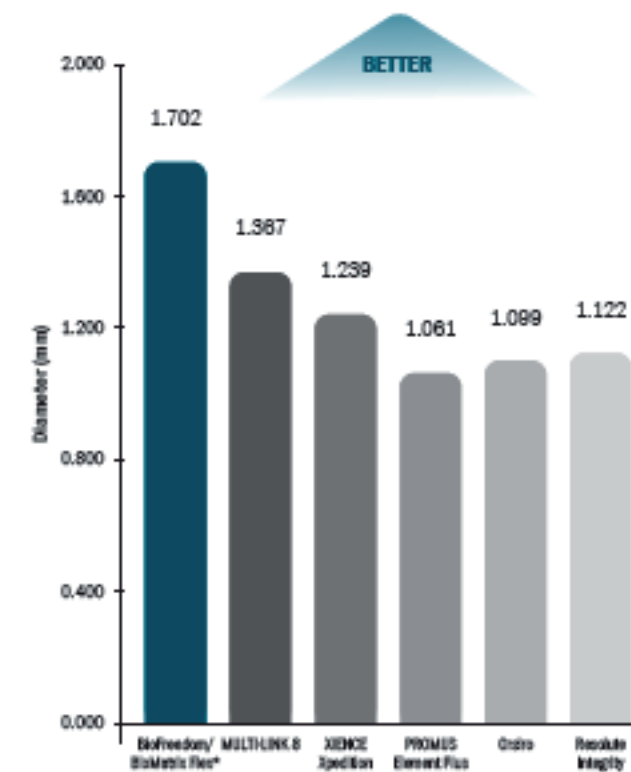
Pushability

Higher pushability is desired to increase the efficiency of the force exerted by the clinician to move the catheter through blood vessels and advance through tight lesions

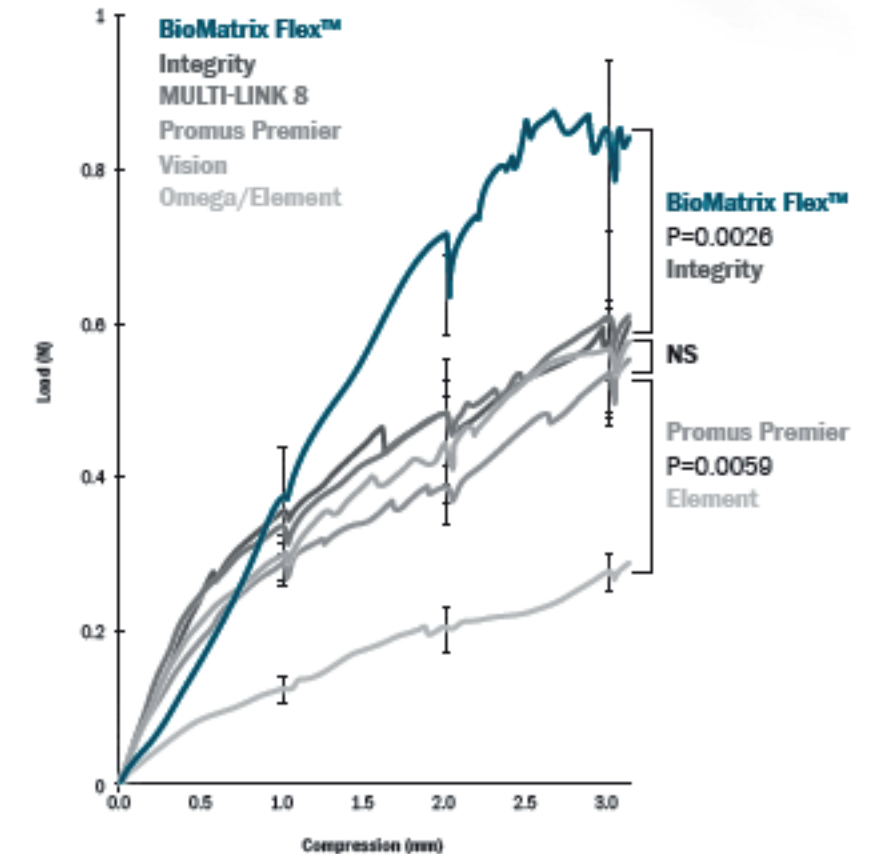


Cell Opening Diameter

Large cell opening diameter is desirable, as it provides better access to side branch for subsequent stents



Longitudinal Compression Lowest Longitudinal Stent Deformation of 2nd GEN¹⁴



* Shares same metal platform and delivery system.