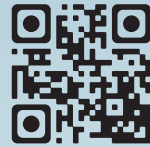




BIOFREEDOM™
POLYMER- & CARRIER-FREE DRUG-COATED CORONARY STENT SYSTEM



Freedom to treat
High Bleeding Risk (HBR) patients

Ordering Information

| Stent Diameter (mm) | Stent Length (mm) | | | | | | | |
|---------------------|-------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| | 8 | 11 | 14 | 18 | 24 | 28 | 33 | 36 |
| 2.25 | BFR1-2208 | BFR1-2211 | BFR1-2214 | BFR1-2218 | BFR1-2224 | BFR1-2228 | NA | NA |
| 2.50 | BFR1-2508 | BFR1-2511 | BFR1-2514 | BFR1-2518 | BFR1-2524 | BFR1-2528 | BFR1-2533 | BFR1-2536 |
| 2.75 | BFR1-2708 | BFR1-2711 | BFR1-2714 | BFR1-2718 | BFR1-2724 | BFR1-2728 | BFR1-2733 | BFR1-2736 |
| 3.00 | BFR1-3008 | BFR1-3011 | BFR1-3014 | BFR1-3018 | BFR1-3024 | BFR1-3028 | BFR1-3033 | BFR1-3036 |
| 3.50 | BFR1-3508 | BFR1-3511 | BFR1-3514 | BFR1-3518 | BFR1-3524 | BFR1-3528 | BFR1-3533 | BFR1-3536 |
| 4.00 | BFR1-4008 | BFR1-4011 | BFR1-4014 | BFR1-4018 | BFR1-4024 | BFR1-4028 | NA | NA |

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* Bleedings were defined as: 1) TIMI major or minor 2) type 3 or 5 BARC; 3) STEEPLE major bleeding; or 4) GUSTO moderate or severe bleeding. 1st and 2nd generation DES. Mean DAPT duration was 8.5 months (short DAPT) and 23.2 months (long DAPT).

BioFreedom™ Drug-Coated Stent is CE Mark approved. Data on file at Biosensors International for any sustained claims in this brochure.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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Freedom to treat
High Bleeding Risk (HBR) patients



Freedom to treat

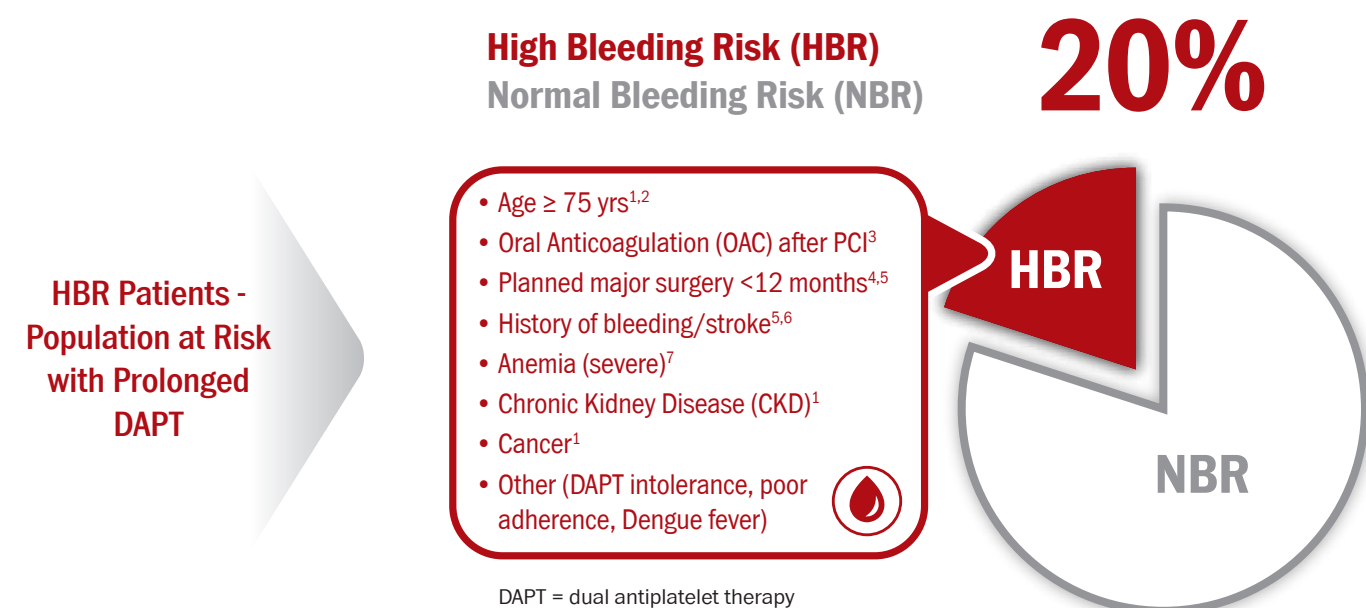


PCI in High Bleeding Risk (HBR) patients

Balancing ischemic & bleeding risk with DAPT.

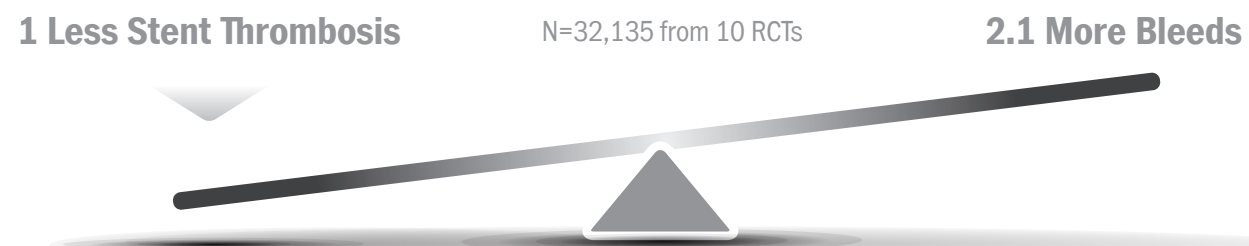
Drug-Eluting Stents (DES) require dual antiplatelet therapy (DAPT), a combination of aspirin and a P2Y₁₂ inhibitor, for a prolonged period after stent implantation in order to avoid stent thrombosis (ST). However, prolonged DAPT has been shown to increase the risk of bleeding in the general PCI population, High Bleeding Risk (HBR) patients are at even greater risk.

At Least 20% of PCI patients are High Bleeding Risk¹⁻⁹



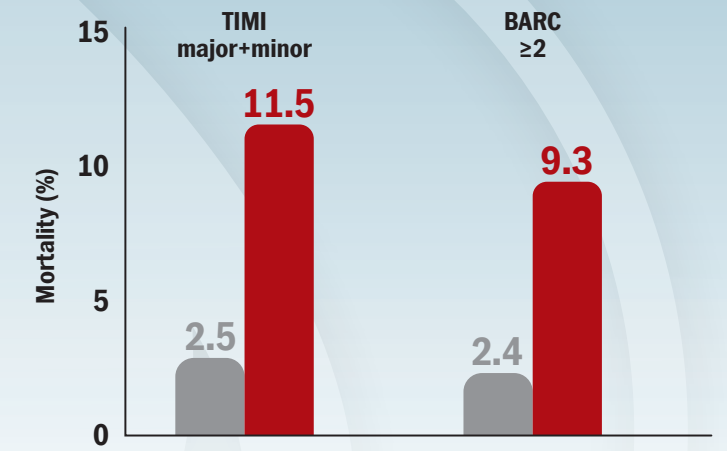
The Challenge is to Balance the Ischemic Risk vs. the Bleeding Risk Associated with Long-term DAPT which is more Critical in HBR Patients

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



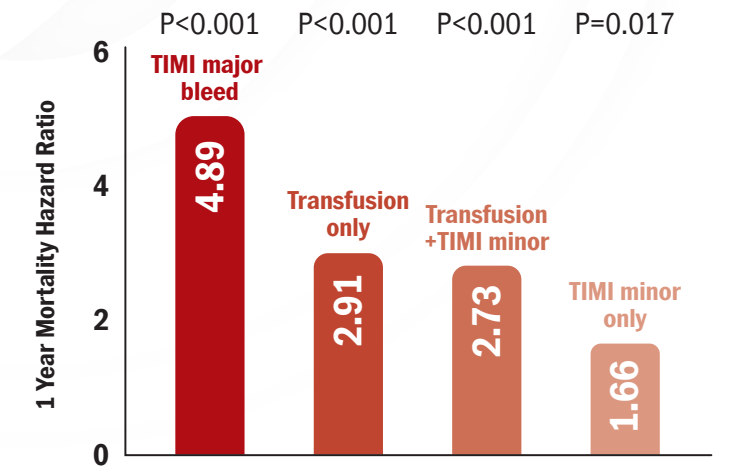
Bleeding is Associated with a 4-fold Increase in the Risk of Mortality¹¹

● No Bleeding ● Bleeding



N=12,459 PCI patients
(ISAR REACT, REACT-2, REACT-3, REACT-3A, SWEET, SMART)
5.4% in-hospital BARC ≥ 2 bleeding, HR (95% CI) 4.2 (3.2-5.5)
3.0% TIMI major+minor bleeding, HR (95% CI) 5.0 (3.7-6.9)

TIMI Major Bleeding and Transfusion within 30 days Have the Highest Mortality Risk at 1 Year¹²



N=17,034 PCI patients
(REPLACE-2, ACUITY, HORIZONS), 1.6% non-CABG TIMI major bleeding

HBR Patients Require an Individualized Approach, BioFreedom Provides a More Appropriate Treatment Strategy

