FREEWAY™ Product Backgrounder

FREEWAY™ is the latest second-generation drug-eluting percutaneous transluminal angioplasty (PTA) technology specifically designed for infrapopliteal and superficial femoral artery (SFA) interventions. The development of drug-eluting balloons (DEBs) has provided the opportunity to deliver a drug locally over a short period of time, which avoids chronic inflammation, respects the original vessel anatomy and treats lesions when stents are not a viable option [Zimarino, De Caterina, 2009].

The introduction of DIOR®, the paclitaxel coated coronary balloon dilatation catheter, has provided cardiologists with the opportunity to treat both high-risk and low-risk percutaneous coronary intervention (PCI) patients effectively while reducing adverse events and restenosis rates [Fanggiday, 2008].

Using the same technology as DIOR®, FREEWAY™ is a paclitaxel-eluting over-the-wire (OTW) balloon catheter designed specifically for infrapopliteal and SFA interventions. It is coated with a 1:1 shellac:paclitaxel resin, which releases paclitaxel as the balloon is inflated within the vessel. Shellac does not trigger an inflammatory response and its smooth surface makes it less likely to aggravate the vessel wall [Peters, 2009]. Paclitaxel inhibits smooth muscle cell migration triggered by platelet-derived growth factor (PDGF) and selectively inhibits the proliferation of smooth muscle cells to help prevent restenosis [Axel, 1997].

Insertion of a balloon or stent to a vessel will result in hyperplasia of the inner vessel wall. This may eventually lead to massive neointimal proliferation in the treated lesion area. The addition of paclitaxel to the balloon catheter offers the opportunity to deliver an anti-proliferative agent directly to the potential site of injury. After inflation of the FREEWAY™ balloon catheter, paclitaxel is released into the artery wall. This acts immediately to inhibit cell growth, by inhibiting the proliferation of smooth muscle cells and leading to smoother arteries.

There are two FREEWAY™ PTA catheters:

- FREEWAY™ 014 – This is indicated for below-the knee (BTK) and lower limb procedures. It has an enhanced 0.014” guide wire diameter.
- FREEWAY™ 035 – This is indicated for SFA procedures. It has an enhanced 0.035” guide wire diameter.

Technical information

- Loaded with 3.0 µg paclitaxel/mm^2 into the microporous balloon surface.
- Low-primary crossing profile with good trackability and flexibility.
- Tapered tip for easier lesion crossing.
- During insertion, the three-folded structure of the balloon protects the drug from early wash-off.
- Inflation of the balloon for 45–60 seconds distributes the full, clinically effective dose of paclitaxel equally over the lesion.
- Greatly reduced deflation time compared to competitor products.

References

Axel DI, Kunert W, Göggelman C et al. Paclitaxel inhibits arterial smooth muscle cell proliferation and migration *in vitro* and *in vivo* using local drug delivery. *Circulation* 1997; 96: 636–645.

Fanggiday JC, Stella PR, Guyomi SH, Doevendans PA. Safety and efficacy of drug-eluting balloons in percutaneous treatment of bifurcation lesions: the DEBIUT (drug-eluting balloon in bifurcation Utrecht) registry. *Catheter Cardiovasc Interv* 2008; 71: 629–635.

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Peters K, Prinz C, Salamon A et al. Evaluation of shellac as coating for intravascular devices. Testing of *in vitro* compatibility by endothelial and smooth muscle cells. Presented at the Jahrestagung der Deutschen Gesellschaft fu□r Biomaterialien, 8–10 October, 2009, Tu□bingen, Germany.
Zimarino M, De Caterina R. Drug-eluting balloons for percutaneous coronary interventions. *Thromb Haemost* 2009; 101: 9–11.