

# The Theoretical Risk of HITS Associated with Heparin Bonded Medical Devices

Certainly the theoretical potential for any heparin-coated or bonded device to cause platelet aggregation and thrombocytopenia in patients with heparin-sensitivity exists, and it is cautioned in the Instructions for Use for the InterGard Heparin vascular graft that surgeons should not implant the heparin-bonded product in patients with known heparin-sensitivity. However, the body of clinical evidence to date does not evidence that a clinical problem of any demonstrated significance is associated with implantation of this product.

InterVascular records indicate that **there are no reported cases of clinical heparin-induced adverse reactions including thrombocytopenia in well over 30,000 implants of the heparin-bonded InterGard vascular prostheses over a 10-year time frame in Europe.** As such, it is concluded that either adverse reactions have not occurred, or that the consequences of any reaction have not been clinically significant.

The vast majority of vascular surgical procedures, as well as coronary and peripheral interventions, involves the use of heparin. In many cases a heparin bolus (frequently 10,000 units or more) is given in the initial stages of the surgery or intervention. Because of the attractive anti-thrombotic and potential anti-hyperplastic effects of heparin, this substance has been incorporated into a wide range of medical devices from cardiopulmonary bypass equipment to pulmonary artery catheters to guidewires and coronary stents.

In light of the tens of thousands of procedures occurring worldwide each year, some incidence of adverse reactions to heparin are inevitable. However, the real and theoretical benefits of using heparin during an intervention, and as a coating or component of devices designed for intravascular use, will continue to outweigh the potential risks for the vast majority of patients.

The relatively small amount of heparin released locally from the InterGard Heparin prosthesis, and the extremely gradual rate at which this heparin is released, may explain why the theoretical risk does not manifest itself clinically.

Although heparin-induced thrombocytopenia has been reported with the use of heparin-coated pulmonary artery catheters, the fact that the InterVascular InterGard Heparin bonded vascular prosthesis is implanted in a peripheral anatomic position may confer additional protection, as these tissues may not be as sensitive as the pulmonary artery.

Finally, InterGard Heparin uses heparin derived from porcine mucosa, which has been found to be less likely to produce a reaction in humans than heparin of bovine origins.

It is therefore believed that thrombocytopenia fortunately appears to be more of a theoretical issue than one of clinical relevance.

## References:

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