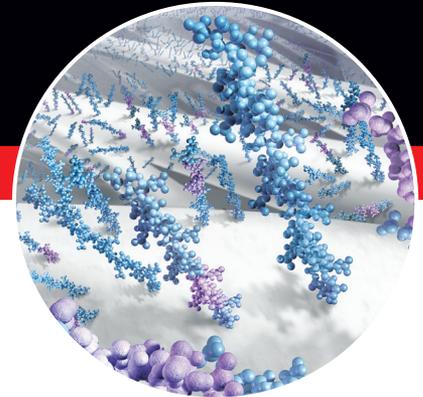


Heparin Induced Thrombocytopenia Type II (HIT) and the CBAS Heparin Surface



There is no evidence to support a causative or contributory association of the CBAS Heparin Surface and the condition of HIT*

The risk of HIT for patients receiving systemic heparin is low.

- The incidence of HIT in patients receiving systemic heparin is low, < 1–5%, depending upon the patient population and the type of heparin used¹
- The incidence of HIT in the pediatric patient population is extremely low. According to the Kids' Inpatient Database (KID),² in all patients less than 1 year of age (n = 4,252,702), there were only 20 HIT diagnoses. Additionally, only 3 out of 1,852 patients who were implanted with any type of pediatric shunt were diagnosed with HIT (0.16%).
- Analysis of reports received by Gore related to vascular devices with the CBAS Heparin Surface yield an incidence of suspected HIT events of less than 0.006%. In some patients with suspected HIT, devices with the CBAS Heparin Surface have remained implanted without HIT-related clinical sequelae.³

In patients enrolled in various studies of Gore products having the CBAS Heparin Surface that tracked adverse events, there have been no reports of contribution of the CBAS Heparin Surface to HIT or the formation or persistence of HIT antibodies.⁴⁻¹⁴

- In a study by Heyligers *et al*,¹⁵ HIT-inducing antibodies were not detected in any of the patients (n = 10) that received a GORE® PROPATEN® Vascular Graft, even six weeks post-implantation
- In a study by Chadda *et al*,¹⁶ a series of 45 patients who received a GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface[†] were monitored for HIT (defined as a platelet count fall of greater than 50%). None of the patients experienced HIT.[‡]
- In HIT studies conducted on patients who received non-Gore devices with the CARMEDA® BioActive Surface[§] (n = 30 and n = 57), the presence of the CARMEDA® BioActive Surface was not found to contribute to an increased rate of HIT antibody formation or persistence of the antibodies over time^{17,18}

Administration of systemic heparin confounds interpretation of the cause of HIT events.³

- As with most interventions in the vascular system, the administration of systemic heparin in these procedures makes it impossible to conclude whether or not the device with the CBAS Heparin Surface contributed to the development of HIT
- The total amount of heparin on a device with the CBAS Heparin Surface is extremely small in comparison to a therapeutic dose of heparin (data on file 2017, 2018; W. L. Gore & Associates, Inc.; Flagstaff, AZ.)
- There are four published single-patient case reports describing HIT in patients having a Gore device with the CBAS Heparin Surface.¹⁹⁻²² Each patient was given several thousand IU of unfractionated heparin systemically during the surgical implantation of the device.

Based on the lack of empirical evidence for a causal link between the CBAS Heparin Surface and HIT, it can be reasonably concluded that the risk of HIT involving Gore devices having the CBAS Heparin Surface is very low.

- Nonetheless, the IFUs for Gore devices with the CBAS Heparin Surface acknowledge the potential for HIT in association with any vascular procedure and Gore devices with the CBAS Heparin Surface are contraindicated for use in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of HIT Type II

* Clinical experience of published literature, product surveillance reviews and analysis of clinical data for devices with the CBAS Heparin Surface.

† As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS Heparin Surface.

‡ Also referred to as the GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in some regions.

§ The heparin technology of the CARMEDA® BioActive Surface is marketed as the CBAS Heparin Surface for Gore vascular devices.



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GORE® PROPATEN® Vascular Graft

INDICATIONS FOR USE: GORE® PROPATEN® Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access or for other vascular procedures. **CONTRAINDICATIONS:** A. DO NOT use the GORE® PROPATEN® Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. B. DO NOT use any configuration of GORE® PROPATEN® Vascular Grafts with Removable Rings, Non-Removable Rings or Integrated Rings for coronary artery bypass or cerebral reconstruction procedures. C. DO NOT use GORE® PROPATEN® Vascular Grafts as a patch. If cut and used as a patch, GORE® PROPATEN® Vascular Grafts may lack adequate transverse strength. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

GORE® VIABAHN® Endoprosthesis

INDICATIONS FOR USE IN THE U.S.: The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–7.5 mm, in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0–6.5 mm and in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0–12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. **CONTRAINDICATIONS:** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is contraindicated for noncompliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

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