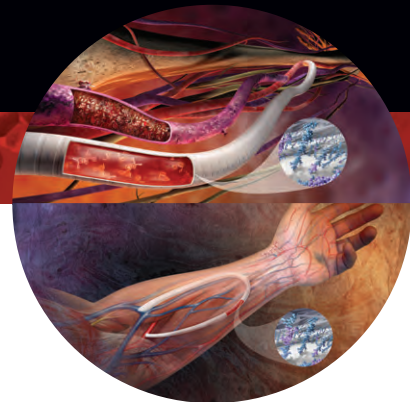


In controlled multi-patient studies, there is no evidence of a link between Heparin-Induced Thrombocytopenia (HIT) and the presence of Devices with the CARMEDA® BioActive Surface (CBAS® Surface)

PERFORMANCE by design

Available data on HIT and CBAS® Surface devices suggest that the risk of developing HIT due to the covalently immobilized heparin present in the CBAS® Surface on Gore Vascular Devices is very low.



There are no reported cases of HIT in multi-patient clinical studies of Gore Vascular Devices with the CBAS® Surface.

- There are no reported incidents of HIT in known published, clinical studies¹⁻¹¹ (n_{total devices} = 1236) which report adverse events of Gore Vascular Devices with the CBAS® Surface.
- In a study by Heyligers, *et al*¹¹ 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*¹² a series of 45 patients who received a GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface were monitored for reductions in platelets. None of the 45 patients experienced HIT.

The presence of a device with the CBAS® Surface does not contribute to an increased rate of HIT antibody formation or persistence of antibodies over time.

- In HIT studies conducted on patients who received non-Gore CBAS® Surface devices (n = 30 and n = 57), the presence of the CBAS® Surface was not found to contribute to an increased rate of HIT antibody formation or persistence of the antibodies over time.^{13,14} Patients with the CBAS® Surface devices lost expression of HIT antibodies when systemic heparin was discontinued, suggesting that the presence of the covalently immobilized heparin in devices with the CBAS® Surface does not contribute to the persistence of HIT antibodies.^{13,14}

In some patients with suspected HIT, GORE® PROPATEN® Vascular Grafts have remained implanted without HIT-related sequelae.

- The incidence of HIT in patients receiving systemic heparin is low, < 1-5%, depending upon the patient population and the type of heparin used.¹⁵ While physicians have reported suspected cases of HIT in patients who have also received a Gore Vascular Device with the CBAS® Surface, the incidence is less than 0.1%. In the majority of these cases, the devices remained implanted in the patient with no HIT-related sequelae.¹⁶

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

- There are three published single-patient case reports describing HIT in patients having a GORE® PROPATEN® Vascular Graft.^{17,18,19} Each patient was given several thousand IU of unfractionated heparin systemically during the surgical implantation of the vascular graft. As with most interventions in the vascular system, the administration of systemic heparin in these procedures makes it impossible to judge whether or not the device with the CBAS® Surface contributed to the development of HIT.

There is a risk of developing HIT in any vascular procedure involving heparin. The risk to certain patient populations from systemically administered intra-operative heparin is well understood. In contrast, the possibility of developing HIT due to the covalently immobilized heparin in the CBAS® Surface has been difficult to assess because of the near-ubiquitous use of systemic heparin in conjunction with implantation of vascular devices.

However, based on the lack of empirical evidence for a causal link between the CBAS® Surface and HIT, it can be reasonably concluded that the risk of HIT involving Gore Vascular Devices having the CBAS® Surface is very low.



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For information regarding the indications and contraindications of individual Gore Vascular Devices, consult the appropriate Instructions for Use.



W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific) 800.437.8181 (United States)
00800.6334.4673 (Europe) 928.779.2771 (United States)

goremedical.com

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