SmartReactors

PRELIMINARY HEMOCOMPATIBILITY TESTING OF **CAMOUFLAGE™ COATING TECHNOLOGY** ON COMMERCIALLY AVAILABLE VENOUS STENTS

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1 Executive Summary

Venous stents are blood-contacting medical devices used to restore and maintain venous patency in patients with venous obstruction. Following implantation, the stent surface is exposed directly to circulating blood, making the interaction between the device surface and blood components an important consideration in device performance. Protein adsorption, platelet adhesion and activation, fibrin formation and accumulation of other blood-derived components can contribute to the deposition of material on blood-contacting surfaces.

This preliminary study evaluated Smart Reactors Camouflage™ Coating Technology on two commercially available venous stent platforms: the Medtronic Abre and Boston Scientific Wallstent. A total of eight stent samples were evaluated, with Camouflage™ coated and uncoated samples exposed to fresh heparinized ovine blood for 1 hour or 1.5 hours at 37 °C. Following exposure, the samples were rinsed, visually assessed and dried before weighing to determine the relative increase in dry mass associated with retained blood-derived material.

Across both stent platforms and both exposure periods, the Camouflage™ coated samples demonstrated visibly less blood-derived material on the stent surfaces than the corresponding uncoated samples. The dry mass measurements supported these observations, with the coated samples demonstrating lower relative increases in dry mass under all four test conditions.

For the Medtronic Abre, the relative dry mass increase was 4.65% for the coated sample compared with 8.51% for the uncoated sample following 1 hour of exposure, and 3.20% compared with 8.08% following 1.5 hours. For the Boston Scientific Wallstent, the corresponding values were 4.12% and 37.65% following 1 hour, and 6.20% and 75.64% following 1.5 hours for the coated and uncoated samples, respectively.

The results demonstrate a consistent reduction in retained blood-derived material on Camouflage™ coated venous stent surfaces under the conditions tested. The findings provide preliminary evidence that Camouflage™ can modify blood-material interactions on commercially available venous stent platforms and support further evaluation of the technology as a potential surface modification for established blood-contacting vascular devices.

2 Background & Rationale

Venous stents are used to restore and maintain vessel patency in patients with venous obstruction. The stent provides a mechanical scaffold that maintains the lumen of the vessel following treatment. As with other vascular implants, the stent surface is directly exposed to circulating blood following implantation. The interaction between the blood-contacting surface and circulating blood components is therefore an important consideration in the biological response to the device.

When blood contacts an implanted material, proteins rapidly adsorb to the device surface and form an interfacial layer that influences subsequent cellular and blood-component interactions. These interactions can include platelet adhesion and activation, fibrin formation and accumulation of other blood-derived components. Excessive accumulation of thrombotic material on a vascular implant can contribute to impaired device patency and may affect long-term device performance.

The design and surface characteristics of a venous stent can influence blood-material interactions. Commercially available venous stents incorporate different materials, surface finishes and structural geometries, resulting in variations in the blood-contacting surface presented to circulating blood. Modifying this surface provides an opportunity to influence the biological response while retaining the underlying mechanical design and functional characteristics of an established stent platform.

Camouflage™ is a proprietary, drug-free coating technology developed by Smart Reactors for blood-contacting medical devices. The technology incorporates recombinant protein and synthetic polymer layers designed to modify the interface between the device, and the blood and surrounding vasculature. The nanoscale coating is intended to reduce thrombogenic interactions at the device surface while providing a surface that supports endothelial cell attachment and vascular healing.

The present study was undertaken as a preliminary evaluation of Camouflage™ to investigate whether the coating can have a positive effect on the hemocompatibility of commercially available venous stents already approved for clinical use. Medtronic Abre and Boston Scientific Wallstent samples were evaluated using coated samples and uncoated controls following exposure to fresh heparinized ovine blood. The study assessed the visible accumulation and retained mass of blood-derived material on the stent surfaces following controlled exposure periods. The findings provide an initial assessment of the effect of Camouflage™ surface modification on blood-material interactions and support further hemocompatibility evaluation.

3 Camouflage™ Coating Technology

Camouflage™ is a proprietary coating technology developed by Smart Reactors for blood-contacting medical devices. The coating's incorporation of recombinant protein and synthetic polymer layers is designed to regulate protein adsorption at the device-blood interface, reducing thrombogenic interactions while providing a surface that supports endothelial cell attachment and vascular healing.

Camouflage™ is a drug-free coating with nanoscale thickness, allowing the biological interface of the device to be modified without substantially altering its underlying structure or mechanical properties. The technology is intended to reduce thrombogenicity and

support controlled endothelialization following implantation.

Key attributes of Camouflage™ include:

- Drug-free
- Nanoscale coating thickness
- Reduced thrombogenicity
- Supports controlled endothelialization and vascular healing

4 Study Design & Methods

4.1 Study Objective

The aim of this preliminary study was to evaluate the effect of Smart Reactors Camouflage™ Coating Technology on blood-component accumulation on commercially available venous stents. Two commercially available venous stent platforms were evaluated using coated and uncoated samples following exposure to fresh heparinized ovine blood.

4.2 Venous Stent Samples

A total of eight venous stent samples were evaluated across two commercially available stent platforms. The sample distribution is shown in Table 1.

Table 1: Venous stent sample allocation by device platform and coating condition.

Stent platform	Camouflage™ Coated	Uncoated
Medtronic Abre	2	2
Boston Scientific Wallstent	2	2
Total	4	4

Stent samples were cut to an approximate length of 20 mm prior to testing. Each sample was weighed before blood exposure to establish its initial dry mass.

4.3 Blood Exposure

Fresh heparinized ovine blood was used for the study at a heparin concentration of 0.8 IU/mL. Testing was initiated within one hour of blood collection to minimize changes in blood condition prior to testing.

For each test condition, 20 mL of blood was transferred into a Falcon tube. The stent sample was then fully submerged. Samples were incubated at 37 °C for either 1 hour or 1.5 hours. For each stent platform, one coated sample and one uncoated sample were evaluated at each exposure time.

4.4 Sample Processing and Assessment

Following incubation, the stent samples were removed from the blood and rinsed with saline solution to remove blood components that were not attached or adhered to the stent surface. The samples were then visually examined and imaged to assess the extent and distribution of material deposited on the stent surface.

Following imaging, the samples were fully dried and weighed again. The increase in mass following blood exposure was calculated by subtracting the initial dry mass from the final dry mass:

$$\textbf{\textit{Mass increase}} = \textit{Final dry mass} - \textit{Initial dry mass}$$

The resulting mass increase was used as an indication of the amount of dry blood-derived material retained on the stent surface following exposure to blood.

Macroscopic images of the complete stent samples and representative microscopic images at 20× magnification were obtained for comparison of coated and uncoated samples.

5 Results

Macroscopic examination of the stent samples showed a visible difference in blood-derived material accumulation between Camouflage™ coated and uncoated surfaces.

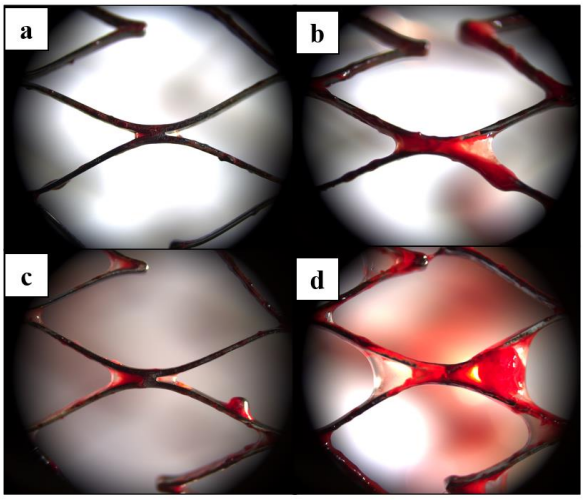


Figure 1: Representative 20× microscopic images of Medtronic Abre venous stent samples following blood exposure. (A) Camouflage™ coated, 1 hour; (B) uncoated, 1 hour; (C) Camouflage™ coated, 1.5 hours; (D) uncoated, 1.5 hours.

For both the Medtronic Abre and Boston Scientific Wallstent platforms, the coated samples showed less surface coverage and visible material deposition than the

corresponding uncoated samples following 1 hour and 1.5 hours of blood exposure. This difference was observed in both the macroscopic images of the complete stent samples (Figures 2 and 4) and the representative 20× microscopic images (Figures 1 and 3).

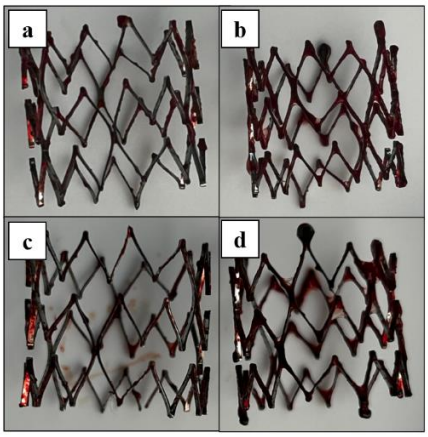


Figure 2: Macroscopic images of Medtronic Abre venous stent samples following blood exposure. (A) Camouflage™ coated, 1 hour; (B) uncoated, 1 hour; (C) Camouflage™ coated, 1.5 hours; (D) uncoated, 1.5 hours.

For the Medtronic Abre stents, the coated samples showed less visible material deposition than the corresponding uncoated samples at both exposure periods, as shown in the microscopic and macroscopic images (Figures 1 and 2). A similar result was observed for the Boston Scientific Wallstent samples, with the Camouflage™ coated samples showing visibly less material accumulation than the uncoated samples at both exposure periods (Figures 3 and 4).

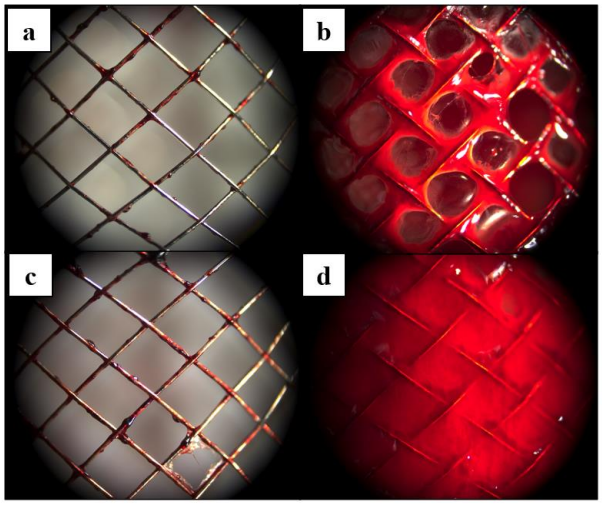


Figure 3: Representative 20× microscopic images of Boston Scientific Wallstent venous stent samples following blood exposure. (A) Camouflage™ coated, 1 hour; (B) uncoated, 1 hour; (C) Camouflage™ coated, 1.5 hours; (D) uncoated, 1.5 hours.

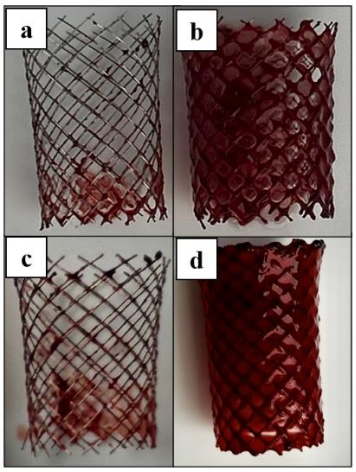


Figure 4: Macroscopic images of Boston Scientific Wallstent venous stent samples following blood exposure. (A) Camouflage™ coated, 1 hour; (B) uncoated, 1 hour; (C) Camouflage™ coated, 1.5 hours; (D) uncoated, 1.5 hours.

The dry mass measurements provided a quantitative comparison of the material retained on the stent samples following blood exposure. The change in dry mass was expressed as a fraction of the original dry mass of each stent sample. Across both stent platforms and both incubation periods, the Camouflage™ coated samples demonstrated a lower relative increase in dry mass compared with the uncoated samples.

For the Medtronic Abre stent (Figure 5), the Camouflage™ coated sample demonstrated a relative dry mass increase of 4.65% following 1 hour of blood exposure, compared with 8.51% for the uncoated sample. Following 1.5 hours of incubation, the Camouflage™ coated sample demonstrated a relative dry mass increase of 3.20%, compared with 8.08% for the uncoated sample.

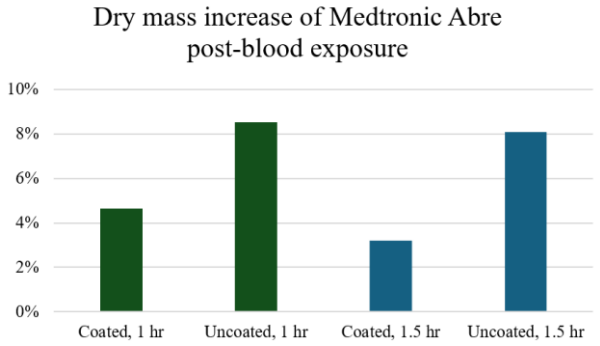


Figure 5: Relative dry mass increase of Camouflage™ coated and uncoated Medtronic Abre stents following blood exposure at 1 and 1.5 hours.

A greater difference was observed for the Boston Scientific Wallstent (Figure 6). Following 1 hour of blood exposure, the Camouflage™ coated sample demonstrated a relative dry mass increase of 4.12%, compared with 37.65% for the uncoated sample. Following 1.5 hours of incubation, the Camouflage™ coated sample demonstrated a relative dry mass increase

of 6.20%, compared with 75.64% for the uncoated sample.

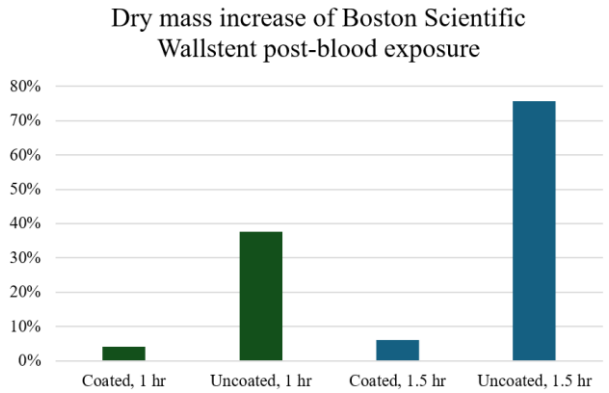


Figure 6: Relative dry mass increase of Camouflage™ coated and uncoated Boston Scientific Wallstent samples following blood exposure at 1 and 1.5 hours.

Overall, the uncoated samples demonstrated greater relative mass accumulation than the Camouflage™ coated samples across both stent platforms and both incubation periods. The greatest difference was observed for the Wallstent following 1.5 hours of blood exposure, where the uncoated sample exhibited a 75.64% increase in dry mass, compared with a 6.20% increase for the Camouflage™ coated sample.

These preliminary findings demonstrate a consistent reduction in retained blood-derived material on Camouflage™ coated stent surfaces compared with uncoated controls under the conditions tested.

6 Discussion

The results of this preliminary study demonstrate a consistent difference in blood-derived material accumulation between Camouflage™ coated and uncoated venous stent samples. Across both commercially available stent platforms and both blood exposure periods, the coated samples showed visibly less material deposited on the stent surface. This observation was supported by the dry mass measurements, with the uncoated samples demonstrating greater relative increases in dry mass than the corresponding coated samples in all four test conditions.

For the Medtronic Abre stent, the Camouflage™ coated sample demonstrated a relative dry mass increase of 4.65% following 1 hour of blood exposure, compared with 8.51% for the uncoated sample. Following 1.5 hours of incubation, the relative dry mass increase was 3.20% for the coated sample compared with 8.08% for the uncoated sample. For the Boston Scientific Wallstent, the difference was more pronounced. Following 1 hour of blood exposure, the coated sample demonstrated a relative dry mass increase of 4.12%, compared with 37.65% for the uncoated sample. Following 1.5 hours, the coated sample demonstrated a relative increase of 6.20%, compared with 75.64% for the uncoated sample.

The magnitude of the difference between coated and uncoated samples varied between the two stent platforms. The Wallstent demonstrated substantially greater relative mass accumulation on the uncoated samples than the Abre stent under both exposure conditions. Differences between stent platforms may be influenced by factors including stent design, surface characteristics, geometry and the amount of blood-contacting surface area. Despite these differences, the consistent direction of the results across both platforms indicates that the Camouflage™ coated surfaces retained less blood-derived material under the conditions tested.

Blood-material interactions begin immediately following exposure of a device surface to circulating blood. Protein adsorption and subsequent interactions with platelets, fibrin and other blood components can contribute to the formation and accumulation of thrombotic material on the device surface. The extent of this response can be influenced by the surface characteristics of the device.

Camouflage™ is designed to modify the blood-contacting interface. The reduced accumulation of blood-derived material observed on the coated samples is consistent with the intended function of the coating, modifying the interaction between the device surface and the blood. These findings therefore provide preliminary evidence that Camouflage™ can modify the interaction of commercially available venous stent surfaces with blood.

The difference between coated and uncoated samples was particularly pronounced for the Wallstent and became greater at the longer exposure period. The relative dry mass increase of the uncoated Wallstent reached 75.64% following 1.5 hours of blood exposure, compared with 6.20% for the Camouflage™ coated sample. This represents approximately a 12-fold greater relative mass increase for the uncoated sample. In comparison, the difference for the Abre stent was smaller, with the uncoated sample demonstrating approximately 1.8-fold and 2.5-fold greater relative mass increases than the coated sample following 1 hour and 1.5 hours of exposure, respectively.

These findings highlight the potential of Camouflage™ to improve the blood-contacting performance of venous stents that are already approved and commercially available. The drug-free composition and nanoscale thickness of the coating will have minimal impact on the underlying stent geometry and mechanical properties, providing a potential approach to improving established stent platforms without altering their fundamental design.

Overall, the findings demonstrate a consistent reduction in retained blood-derived material on Camouflage™ coated venous stents compared with uncoated controls. The results support further evaluation of Camouflage™ as a surface modification for commercially available venous stents and other blood-contacting vascular devices.

7 Clinical Industrial Benefits of Camouflage™

For Device Manufacturers: As a non-pharmaceutical solution, Camouflage™ offers a more straightforward regulatory pathway, making it easier to integrate into existing medical device approvals.

For Clinicians: The coating minimizes thrombosis and inflammatory responses, leading to improved patient safety and better procedural outcomes with reduced dependency on long-term antiplatelet therapy.

For Patients: Camouflage™ promotes faster healing, reduces complications, and enhances long-term vascular integration, leading to quicker recovery times and improved quality of life.

8 Conclusion

This preliminary study evaluated the effect of Camouflage™ Coating Technology on blood-derived material accumulation on two commercially available venous stent platforms. Across both the Medtronic Abre and Boston Scientific Wallstent samples, the Camouflage™ coated stents demonstrated visibly less material deposition than the corresponding uncoated controls following 1 hour and 1.5 hours of exposure to fresh heparinized ovine blood.

The mass measurements supported these observations, with the uncoated samples demonstrating greater relative increases in dry mass than the coated samples across all test conditions. For the Medtronic Abre, the relative dry mass increase was 4.65% for the coated sample compared with 8.51% for the uncoated sample following 1 hour of exposure, and 3.20% compared with 8.08% following 1.5 hours. For the Boston Scientific Wallstent, the relative dry mass increase was 4.12% for the coated sample compared with 37.65% for the uncoated sample following 1 hour, increasing to 6.20% compared with 75.64% following 1.5 hours.

These findings provide preliminary evidence that Camouflage™ can reduce the accumulation of blood-derived material on venous stent surfaces under the conditions tested. The consistent reduction observed across both stent platforms supports further investigation of Camouflage™ as a potential surface modification for commercially available venous stents and other blood-contacting vascular devices.

9 About Us

Smart Reactors delivers cutting-edge hemocompatible coating technologies for medical devices. Services include coating selection, regulatory support, and commercialization. Founded in 2019 by industry experts with over 50 years of combined experience, Smart Reactors excel in creating advanced biomaterial solutions and providing superb customer service.