Innovation Fueling Evolution: Two Decades of the GORE® VIABAHN® Endoprosthesis

Through the incorporation of technological advances, the contemporary GORE VIABAHN Device has evolved to offer robust treatment options to a diverse and growing population of patients with peripheral artery disease.

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Beginning with the European introduction of the original GORE® HEMOBAHN® Endoprosthesis in 1996 (Figure 1), the potential of "endovascular bypass" became apparent. Quickly following its United States introduction in 2002, the expanded polytetrafluoroethylene (ePTFE)-lined endoprosthesis was recognized as a potential treatment option for patients with complex superficial femoral artery disease.

BUILDING UPON SUCCESSES OF THE PAST

After incorporating the now-familiar tip-to-hub deployment mechanism in the 6- to 8-mm-diameter devices in 2003, the US Food and Drug Administration (FDA) granted approval for superficial femoral artery implantation in 2005. The proprietary endoluminal CBAS® Heparin Surface—a bioactive, thromboresistant coating—was incorporated in 2007 with the intent to improve thromboresistance (Figure 2). In 2008, the FDA expanded the device's indication to include iliac arteries, compatible with all device sizes.

A manufacturing change in 2009 allowed for laser contouring of the proximal edge, which impacted flow characteristics. That same year, Gore introduced 9- to 13-mm devices compatible with 0.035-inch guidewires. Given the advantages of a reduced crossing profile, 5- to 8-mm heparin-coated devices were offered in a configuration that reduced profile by one French size (0.014- or 0.018-inch guidewire compatible) in 2011, substantially increasing deliverability of the endoprosthesis while minimizing the introducer/sheath size.

The device's proven clinical history in long SFA lesions prompted the development of the longest-length stent or stent-graft at 25 cm (Figure 3), and the FDA approved this device in late 2013. The 25-cm product offering aligns well with the results from the recent VIASTAR trial, where a substantial and statistically significant improvement in primary patency was observed compared to bare-metal stents in lesions ≥ 20 cm (73% vs 33% at 12 months; $P = 0.004$, per-protocol analysis).[1] The 25-cm GORE VIABAHN Device also offers operators cost-savings over using multiple devices, and may reduce procedural and radiation exposure time

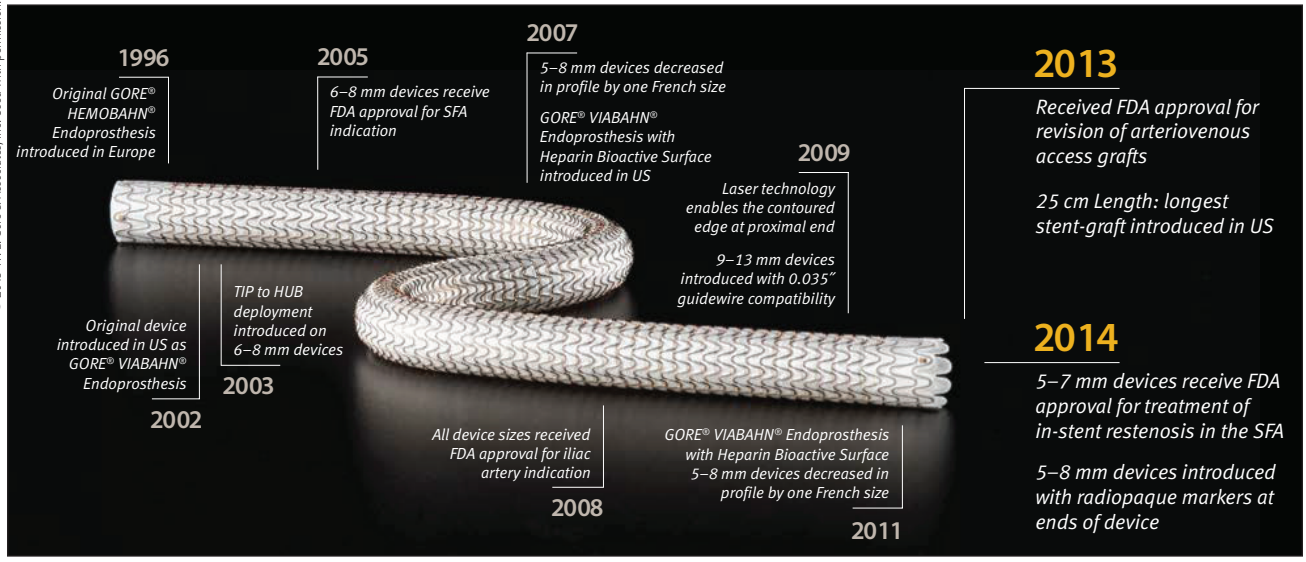

Figure 1. Evolution of the GORE VIABAHN Device over the past 20 years.

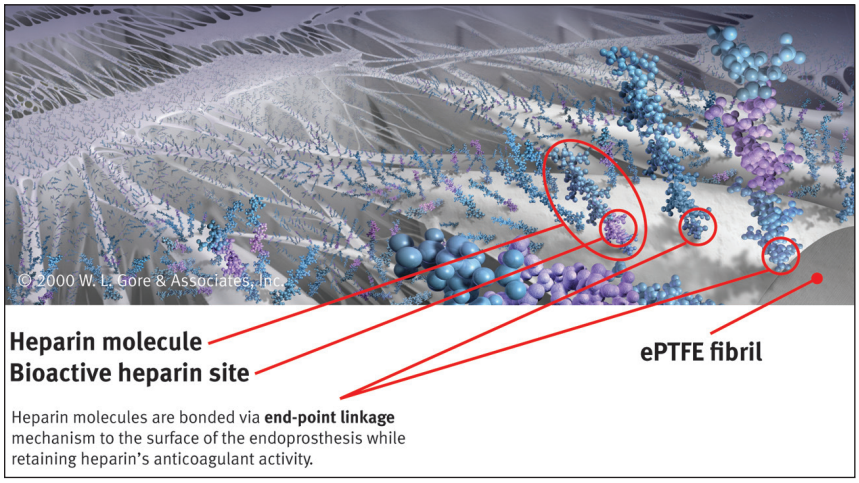

Figure 2. Schematic depicting the mechanism of endpoint covalent bonding (CBAS Heparin Surface) intended to provide thromboresistance via sustained endoluminal heparin bioactivity. Note that the heparin-active site catalytically facilitates antithrombin-thrombin complex formation and then becomes available to repeat the reaction.

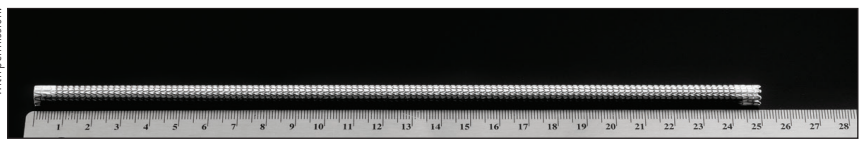

Figure 3. The 25-cm GORE VIABAHN Device was approved in 2013.

Figure 4. Gold radiopaque markers recently added to the ends of 5- to 8-mm devices.

with the benefits of single device deployment as opposed to overlapping shorter devices. That same year saw the FDA approval of the GORE VIABAHN Device for revision of arteriovenous access grafts in dialysis-dependent patients.

With a growing number of previously treated patients returning with in-stent restenosis, welcome data from the RELINE trial[2] supported FDA approval of the 5- to 7-mm GORE VIABAHN Devices for treatment of in-stent restenosis in September 2014. Most recently, all 5- to 8-mm devices have been fitted with radiopaque markers (Figure 4) that allow improved visualization of the device. This recent modification enhances the already high precision of deployment and facilitates visualization of the deployed device, particularly when treating in-stent restenosis.

MEETING FUTURE CHALLENGES WITH TECHNOLOGY OF THE PRESENT

The population of patients with peripheral artery disease continues to grow and become more complex. Simultaneously, the preference for endovascular therapies justifiably rises as well. The maturation rapidity of armamentarium must keep pace with that of our skill-set. Success in this regard can only be achieved through vibrant, synergistic collaboration between physicians and industry leaders so innovation may fuel device evolution to meet the growing needs of our patients. ■

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