

## The Zenith® AAA – Endovascular Graft

a report by

**Cook**

### History and Development

The Zenith® AAA Endovascular Graft with the H & L-B One-Shot™ Introducer System was created through the collaborative efforts between the Australian physician Michael Lawrence-Brown and the Australian developer David Hartley as well as physicians Timothy A M Chuter (USA), Professor Krassi Ivancev (Sweden) and Professor Brian Hopkinson (UK).

Since 1994, continuous research and development has led to modifications in the design, features and protocols of the Zenith®.

The current endovascular stent graft design, consisting of Z-stents covered with polyester graft material, was first used to treat abdominal aortic aneurysms (AAAs) on 23 March 1993 at the Royal Perth Hospital in Perth, Australia.

Bench and animal testing were also conducted using the one-piece and the two-piece bifurcated modular system from December 1993 to July 1994.

In July 1994, the first modular bifurcated graft was implanted. Today, more than 10,000 Zenith® AAA and also several hundreds of Zenith® TAA Endovascular Stent Grafts have been implanted with promising results.

The European launch of the custom-made one-piece and two-piece bifurcated design took place in December 1998. This system, from the very start, had the advantage of being tailored to fit the anatomy of the patient, having a long main body with a low bifurcation very close to the native bifurcation and legs that could be designed to end close to the iliac bifurcation or even land in the external iliac if needed. The contralateral leg was designed to have an extension added on, which made this system modular.

Diameters of the top part ranged from 20mm up to 32mm loaded in 18 Fr. or 20 Fr. H & L-B one-shot™ introducer systems, and the leg diameters from 8mm to 24mm loaded in 14 Fr. or 16 Fr. introducers. Different kinds of conical constructions

in the iliac portion could be manufactured to seal a wide range of iliac anatomies.

The suprarenal stent with barbs on every strut was a part of the original design and was soon recognised to achieve optimal fixation of the stent graft. The barbs are placed on different levels on each of the 10/12 struts. Pull-strength tests have demonstrated that, when imbedded into the vessel wall, the proximal end of this graft remains more stable than any other stent graft available on the market. This construction means that the Zenith® system has been constructed in such a way that it must be placed in a juxtarenal and sometimes juxtamesenteric position. This is beneficial since it is known that this placement is relatively safe and offers the potential benefit of being associated with reduced incidences of proximal, direct endoleaks. Furthermore, this region of the abdominal aorta represents the strongest site for implantation associated with the orientation of the elastic fibres and with the shear forces due to the local blood flow.

The introducer system had a long COON's taper and a low friction sheath with a large haemostatic valve. This design made it possible for the system to pass even tortuous iliac vessels. The stent graft was preloaded in the introducer system and, by pulling back the sheath, the graft body was opened. To achieve safety and accuracy, the system had two safety wires, one to fixate the uncovered stent that was captured in a cartridge in the proximal dilator end and a second wire that locked the ipsilateral leg to the pusher rod.

With these features, the stent graft can be partly deployed and repositioned and reoriented in relation to the renal arteries and the location of the native bifurcation.

The chosen materials used for the Zenith® system have been used for comparable applications and have shown excellent durability.

The Gianturco Stainless Steel Stent was patented in 1984 and has, since that date, been used for several vascular applications.



A very strong and heavy graft material of twill weave construction also used for open surgery has been used to obtain a good seal and fixation for the sutures holding the Z-Stent attached to the graft. The porosity of the graft is 350ml/min/cm<sup>2</sup> and the thickness 0.35mm.

The sheath material is PTFE to obtain a thin but strong wall with low friction.

Both monofilament and multifilament sutures have been used to create a safe construction of the stent graft. The Z-stents are independent from each other to obtain the flexibility needed but, at the same time, creating columnar strength.

The stents are placed inside the graft at the landing areas proximal and distally to obtain a good seal, and outside in the remaining part of stent body and leg segments. This construction reduces the risk of wire guide and catheter entanglement.

The long body design ensures good blood flow within the graft and the low stent graft bifurcation reduces the pull-down forces on the device from 10N down to approximately 2N.

The design of the graft also deals with the vector forces created by the blood flow passing through the graft as described in an article by Dr Michael Lawrence-Brown, Perth, Australia.

In December 1999, the Zenith® Tri-Fab system was launched. It has a complete modular design based on three individual components that can be ordered easily from stock, shortening delivery time considerably, but still having approximately 50,000 possible combinations to treat a wide variety of patients.

The materials and the introducer were unchanged. The stent graft construction was changed slightly, adding more flexibility to the legs and also changing the stent height in the mid portion of the stent graft. By learned experience, the body lengths were reduced to five, still allowing the graft bifurcation to

be near the native bifurcation. The extra joint on the ipsilateral side, if planned right, would be well supported by the common iliac artery, giving the desired stability.

Stent graft diameters of 34mm and 36mm can now be ordered as custom-made devices loaded in 20 Fr. introducer systems.

In Europe, the Zenith® AAA System has been recognised to be the market leader in data published by BIBA in February 2003.

A system for thoracic aortic aneurysms has been in clinical evaluation worldwide and will be launched in Europe at the end of 2003.

A special set for emergency use has been launched in 2003. The high mortality rate for this type of patient in open surgery, which is more than 50%, has already been reduced by using endovascular techniques demonstrated by the Nottingham and Groningen teams.

The unique deployment system of the Zenith AAA Stent Graft has also led to the development of the technique of fenestrated stent, allowing the blood to pass into side branches even for patients with limited sealing areas for the stent graft. Even though this is very new, the short-term results look promising.

In May 2003, the US Food and Drug Administration (FDA) approved the Zenith® Endovascular Graft and the third generation is now supplied to the US market.

The approval was based on a 15-centre clinical trial of 352 patients between January 2000 and July 2001 with one, six and 12-month follow-ups.

The study met all clinical endpoints, in addition to achieving 0% migration equal to or greater than 10mm, a 99.7% deployment success rate, a 98.7% rate of aneurysm diameter decreasing or staying unchanged, and a 7.4% rate for all types of endoleaks. ■