

# VEST external stent for coronary artery bypass grafts

Medtech innovation briefing

Published: 2 August 2017

[www.nice.org.uk/guidance/mib115](http://www.nice.org.uk/guidance/mib115)

## Summary

- The **technology** described in this briefing is the venous external support, or VEST, a kink-resistant external stent for saphenous vein grafts used during coronary artery bypass graft (CABG) surgery.
- The **innovative aspects** are that it is the only available device which externally supports vein grafts. This aims to preserve graft patency and reduce the need for reintervention.
- The intended **place in therapy** would be as an adjunct to standard CABG surgery, during which vein graft support devices are not currently used.
- The **main points from the evidence** summarised in this briefing are from 2 published studies and 2 published sub-analyses involving a total of 60 people having CABG. These show some improvements in proxy outcomes but no differences in graft failure rate when compared with unstented grafts.

- **Key uncertainties** are that the evidence base is still developing, with no direct comparison of patients having CABG with or without VEST for more than 12 months.
- The **cost** of VEST is £700 per unit (exclusive of VAT). The **resource impact** is that VEST may increase costs compared with standard care because of the additional cost of the stent, depending on the number of vein grafts used. This could be offset if further evidence confirms a reduced reintervention rate.

## The technology

VEST (venous external support; Vascular Graft Solutions [VGS]) is an external stent for use in coronary artery bypass graft (CABG) surgery in which at least 1 saphenous vein is used as the bypass conduit. It is designed to improve conduit haemodynamics and reduce lumen irregularities, wall tension and intimal hyperplasia, with the ultimate aim of reducing the progression of vein graft disease and therefore the need for reintervention.

VEST is made of a cobalt chromium alloy mesh, which is designed to be kink and crush resistant. It is available in various lengths and diameters, and its implantation is done in a similar way to standard grafting techniques. Before being implanted, the correct size is chosen using the VGS selection tool (provided with the device). During CABG, VEST is threaded over the nonpressurised vein graft towards the distal anastomosis, then manipulated to cover the distal end of the graft (for sequential segments, an additional VEST device may be needed). VEST is then expanded by gently squeezing until it covers the entire vessel length. In doing so, VEST elongates and simultaneously reduces in diameter (for sequential grafts, this step is repeated for each VEST threaded onto each segment). Expansion can be done either before or after stitching the proximal anastomosis.

VEST cannot be used:

- for vein graft segments less than 4 cm
- for vein graft segments with an external pressurised diameter less than 3 mm
- in people with a known allergy to cobalt chrome alloy or its components. VEST was previously marketed as VGS Fluent.

## Innovations

VEST is the only external stent designed to be used with vein grafts during CABG. It is designed to reduce the incidence of future cardiac events and the need for further interventions in people who have had CABG.

## Current NHS pathway

There are 2 main revascularisation procedures used to treat coronary heart disease: CABG, and percutaneous coronary intervention (PCI).

The NICE guideline on [stable angina](#) recommends that both CABG and PCI should be considered for people with stable angina whose symptoms are not satisfactorily controlled with optimal medical treatment. It recommends that CABG should be used as standard revascularisation care in people with complex coronary lesions or left main coronary diseases. The choice of revascularisation strategy will depend on many factors including angiographic suitability, patient choice, age, and the presence of diabetes and other comorbidities. If both CABG and PCI are options, the guideline states that PCI is preferable because it is more cost effective (but patient preference should be taken into account once the risks, benefits and limitations of each procedure have been explained). The NICE guideline on [unstable angina and NSTEMI](#) makes similar recommendations. The use of vein grafts during CABG is not covered by NICE guidance.

NICE is not aware of similar CE-marked technologies which fulfil a similar function to VEST.

## Population, setting and intended user

VEST is intended to be implanted by cardiac surgeons in hospital operating theatres, which may be in secondary or specialist tertiary care centres. VEST will be used during CABG. It may be of particular use in younger patients or in those at higher risk of complications.

The company states that no changes are needed to current surgical techniques to incorporate VEST. Surgeons must be trained in implanting the device, but clinical experts advised that any training would be minimal.

## Costs

### Technology costs

A single VEST costs £700 (excluding VAT); 1 or 2 devices may be needed per procedure. No other consumables are needed, but this would be in addition to the cost of a standard CABG (see below).

It takes about 1 minute to implant VEST and no stitches or adhesives are needed to keep the device in place. The cost of VEST includes training provided by the company, consisting of in-theatre training with company representatives, local proctors and a dedicated implantation model.

### Costs of standard care

The [2017/18 national tariff](#) for a CABG ranges from £6,594 (HRG code ED28C, standard CABG with CC score 0 to 4) to £13,547 (HRG code ED26A, complex CABG with CC score of 10 and above).

## Resource consequences

No published economic evidence was identified.

Using VEST would increase the costs of CABG by 10% to 20%. These costs could be offset if the device reduced the incidence of vein graft failure, and if this meant that fewer reinterventions were needed.

It is unlikely that any changes will be needed in the way services are organised and provided in order to adopt VEST.

VEST has been available since 2014 and is currently used in 5 NHS trusts.

## Regulatory information

VEST was CE marked as a class III device in January 2014. The device was rebranded as VEST in December 2013; it was previously known as VGS Fluent.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

## Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

No equality issues were identified.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

## Published evidence

The published evidence on VEST comprises 1 prospective randomised trial ([Taggart et al. 2015 \[VEST-I\]](#)), 1 non-comparative study ([Taggart et al. 2017 \[VEST-II\]](#)) and 2 sub-studies ([Meirson et al. 2015](#), [Webb et al. 2015](#)), including a total of 60 people who had a procedure that used VEST.

VEST-I showed improvements in proxy outcomes at 12 months with VEST (such as uniformity of lumen diameter, thrombus formation and occlusion, which may indicate future risk of graft failure), but no difference in graft failure rate. There was also a high degree of graft failure in VEST-supported saphenous vein grafts to the right territory; this was

possibly because of the use of metal clips with VEST, which is against the company's recommendations. The VEST-II study showed an improved degree of technical success compared with VEST-I. Table 1 summarises the published clinical evidence, as well as its strengths and limitations.

## Overall assessment of the evidence

The evidence base on VEST is still developing and is currently limited in terms of both quantity and follow-up. Nevertheless, the published studies were done in a UK NHS setting. Large-scale randomised controlled trials are ongoing that compare long-term clinical outcomes in separate study groups with and without VEST.

A publically available video, uploaded to YouTube by the company, suggests the availability of 5-year case series data on VEST-supported saphenous vein grafts. However, no published report on these data was identified (Vascular Graft Solutions 2016, [available online](#)).

**Table 1 Published evidence**

Taggart et al. 2015 (VEST-I)	
Study size and design	Prospective randomised study in 30 people having on-pump multivessel SVG including a left internal mammary artery graft to the left anterior descending coronary artery and SVGs to right and circumflex territories.
Intervention and comparator(s)	Each patient had the intervention (VEST-stented SVG) and control (non-stented SVG); 1 VEST device was randomly assigned intraoperatively to a single SVG, with 1 or more SVG remaining non-stented.  Randomisation of which SVG had VEST (either circumflex or right coronary artery) was done intraoperatively by sealed envelope after the distal anastomosis.

<p>Key outcomes</p>	<p>The SVG mean intimal hyperplasia area, assessed by IVUS at 12 months in 43 SVGs, was significantly reduced with VEST (<math>4.37 \pm 1.40 \text{ mm}^2</math>) versus non-stented SVG (<math>5.12 \pm 1.35 \text{ mm}^2</math>, <math>p=0.04</math>). Overall SVG failure rates did not differ significantly between the 2 groups (30% stented vs 28.2% non-stented SVG; <math>p=0.55</math>). The stented versus non-stented SVG failure rates were significantly lower in the circumflex territory (17.6% vs 27.5%; <math>p=0.02</math>) and significantly higher in the right territory (46.2% vs 13.4%; <math>p=0.01</math>).</p> <p>Lumen regularity, using the Fitzgibbon classification, showed a higher proportion of stented SVGs were in class I (62% vs 39%; <math>p=0.08</math>) and with a lower incidence of SVG ectasia (6.7% vs 28.2%; <math>p=0.05</math>).</p> <p>It was hypothesised that the high failure rate of VEST-stented SVG to the right territory was a result of using metal clips to ligate SVG side branches and fix VEST to the anastomoses, which was not part of the company's instructions. In the left territory, the patency rates were higher than the control. This was the rationale for initiating the VEST-II study.</p>
<p>Strengths and limitations</p>	<p>VEST-I was a first-in-man randomised study comparing vein grafts in the same patients with and without VEST.</p> <p>It had only 1-year follow-up measuring intimal hyperplasia, which is a surrogate outcome for vein graft disease. It included a small number of patients and there was no separate control group (all patients had both VEST and control), so no differences in clinical outcomes could be reported. It was also a company-funded study; the first author is a company shareholder and has received honoraria from the company.</p>
<p><u>Taggart et al. 2017 (VEST-II)</u></p>	

<p>Study size and design</p>	<p>Prospective single-arm study in 30 people having on-pump multivessel SVG, with at least 1 vein graft bypass indicated for the right coronary artery. Single centre in UK.</p> <p>Researchers investigated whether avoidance of both fixation of the external stent to the anastomoses and the use of metal clips to ligate SVG side branches would improve the early patency of externally stented SVG to the right coronary artery. This was because of high failure rate in the right territory observed in VEST-I (see above). Because the right and left territories are different in anatomical structure and haemodynamics and cannot be compared (unless properly randomised), the results were compared with published historical VEST-I data on SVG to the right territory.</p>
<p>Intervention and comparator(s)</p>	<p>In each patient, an SVG to the right territory had VEST, and all other venous grafts to the left side were unsupported. SVG patency was assessed by CT angiography at 3 to 6 months (graft failure defined as occlusion or &gt;50% stenosis). No control arm was used for this study: instead, results were compared with the historical VEST-I data of SVG failure rate to the right territory.</p>
<p>Key outcomes</p>	<p>29 patients (96.6%) completed follow-up and CT angiography data were available for a total of 43 SVGs, (29 stented and 14 non-stented SVGs) and 47 arterial grafts. Patency of stented SVGs was 86.2% (25/29 on CTA). Avoidance of both metallic clips to ligate side branches and of fixation of VEST stents to 42 of the anastomoses improved patency of stented SVG to the right coronary territory.</p> <p>The patency rates were comparable to those generally described in literature on early patency rates of SVGs to the right coronary territory (in the range of 71% to 86% at 6 to 12 months). This study showed that when specific recommendations for use are followed, the VEST external stent for SVGs to the right territory is safe.</p>
<p>Strengths and limitations</p>	<p>This was a non-randomised study with no control group, using historical control data. It was done at a single centre and had a short follow-up. It was also another company-funded study; the first author is a company shareholder and has received honoraria from the company.</p>
<p><u>Meirson et al. 2015</u></p>	



Study size and design	Post-hoc computational fluid dynamics analysis of data from 29 patients in the VEST-I trial. Diffuse flow patterns were assessed using mean values of various hemodynamic parameters, including time-averaged wall shear stress and OSI. Focal flow disturbances were characterised using percentile analysis of each parameter.
Intervention and comparator(s)	See VEST-I.
Key outcomes	In both diffuse and focal flow-pattern analyses, OSI was significantly lower in the stented vs non-stented SVG group ( $p=0.009$ and $p<0.003$ respectively). No statistically significant differences were observed in time-averaged wall shear stress values. High OSI values were correlated with the development of intimal hyperplasia ( $p=0.01$ ).
Strengths and limitations	This study has the same limitations as VEST-I, as well as being a post-hoc study (the original study did not specify these outcomes in the original protocol).
<u>Webb et al. 2015</u>	
Study size and design	This VEST-I sub-study assessed SVGs with and without OCT in the 24 patients in VEST-I that had coronary angiography with OCT imaging using a non-occlusive technique.
Intervention and comparator(s)	See VEST-I (1-year follow-up).
Key outcomes	Mean cross-sectional area was greater in unstented vs stented grafts ( $8.4\pm 3$ vs $7.6\pm 2.7$ mm; $p=0.005$ ). The lumen of the stented grafts was more homogeneous (difference between maximum and minimum lumen diameter was significantly smaller in stented compared with unstented grafts, $0.28\pm 0.19$ vs $0.33\pm 0.23$ mm respectively; $p=0.006$ ), and more circular (mean eccentricity index $0.08\pm 0.06$ vs $0.10\pm 0.06$ , stented vs unstented respectively; $p=0.019$ ). Adherent thrombus was identified in 3 grafts (all unstented).

Strengths and limitations	This study has the same limitations as VEST-I. The main VEST results did not report the OCT results because many of the conduits were too large to image the entire circumferential depth of the vessel wall. OCT findings may also highlight the early changes occurring in SVGs after implantation of aorto-coronary bypass conduits, changes that may accelerate vein graft failure.
Abbreviations: IVUS, intravascular ultrasonography; OCT, optical coherence tomography; OSI, oscillatory shear index; SVG, saphenous vein graft.	

## Recent and ongoing studies

- [VEST-III](#). ClinicalTrials.gov: NCT02511834. Status: Enrolment completed. Indication: coronary artery disease. Estimated primary completion date: October 2018. Expected enrolment: 200. Comparing CABG with and without VEST.
- [VEST-IV](#). IRAS ID: 188108. 5-year follow-up study of VEST-I in 27 patients who had at least 1 patent vein graft at 12 months after CABG. The results are expected to be published in late 2017.

## Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Four specialist commentator responses were received. One specialist commentator uses VEST regularly, and is involved in an ongoing randomised study. Another had used VEST in 8 patients as part of a trial. The remaining 2 specialist commentators were familiar with the device but had not used it before.

## Level of innovation

All 4 specialist commentator noted that VEST was novel and innovative compared with current practice. None was aware of any CE-marked alternatives available on the market.

One specialist commentator noted the disparity between the size of the potential

benefitting population (that is, 17,000 CABG procedures are done each year in the UK) and the low uptake and small number of reported cases in the literature (n=60).

## Potential patient impact

The specialist commentators agreed that VEST could improve patient outcomes if it were proven to be effective, specifically by reducing repeat revascularisations and reducing myocardial infarction, ischaemic heart damage and angina. One commentator agreed that VEST could improve patients' post-operative experience by reducing 'demand management', with fewer admissions for recurring angina and fewer catheter lab interventions and repeat CABGs needed. Another thought that VEST may allow for longer symptomatic and prognostic benefit after CABG. One highlighted evidence to show that people with vein graft occlusion have lower quality and quantity of life.

Two specialist commentators thought that the external wall support provided by VEST may avoid graft kinking and abnormal dilatation and reduce intimal hyperplasia, thereby increasing potentially improving graft patency. One commentator highlighted that the benefit of revascularisation depends on graft patency, and despite secondary prophylaxis, vein graft patency may be limited: older studies show that up to 50% of grafts become compromised by 10 years (although more widespread use of higher-dose statins may make these data less relevant to current practice). Another agreed that VEST may increase the lifespan of vein grafts used as conduits in CABG surgery.

Two specialist commentators stated that VEST may be of particular benefit to people with diabetes, because they are greater risk of coronary artery disease and vein graft disease so are more likely to have an earlier than expected vein graft occlusion. People with severe disease or those presenting at a young age for CABG (less than 40 years) are also likely to benefit from VEST, because these people are most affected by graft longevity.

One specialist commentator said they would like to offer VEST to all their patients with an expected lifespan of more than 5 years.

## Potential system impact

One specialist commentator raised concerns that VEST may have no use to the NHS unless a prospective randomised trial on its use could demonstrate its clinical benefits. They noted there is a substantial cost associated with each VEST device.

Another specialist commentator did not think that VEST would reduce length of stay or affect the length of CABG itself, but that it would increase costs if it were used routinely for all CABG patients having venous conduits as part of their operation. This commentator stated that VEST may lead to overall cost savings by reducing demand for drug therapy, as well as catheter-based and surgical procedures for recurring angina.

Two specialist commentators observed that if better graft patency with VEST can be proven, adopting the device could lead to cost savings for the NHS both in economic terms and in increased patient life years. One of these specialist commentators highlighted that VEST has the potential to become standard care for all CABG procedures using saphenous vein grafts, which would increase upfront procedure costs.

All 4 felt that special training would be needed but most thought it would be minimal, because VEST is easily adapted to current surgical techniques. None of the specialist commentators thought any changes in facilities or infrastructure would be needed to use VEST.

## General comments

All 4 specialist commentators highlighted the need for evidence from larger, well-powered studies to show improved vein graft patency and cost savings for the NHS. One stated that this could be done by following-up a significant cohort of patients for at least 5 years and comparing costs with non-VEST matched controls. Another stated this should be done in young patients over a 10-year period. One specialist commentator felt that the current evidence, comprising small single-centre studies and short follow-ups, is not strong enough to recommend a change to current practice.

None of the specialist commentators was aware of any safety alerts, but 1 quoted a published report showing that a VEST-supported saphenous vein graft with an additional coating of bioglue resulted in worse outcomes than a standard saphenous vein graft.

## Specialist commentators

The following clinicians contributed to this briefing:

- Mr Stephen Large, cardiothoracic surgeon, Papworth Hospital NHS Foundation Trust.  
No conflicts of interest declared.

- Mr Sunil Ohri, consultant cardiac surgeon, University Hospital Southampton. No conflicts of interest declared.
- Mr Joseph Zacharias, consultant cardiothoracic surgeon, Lancashire Cardiac Centre, Blackpool Teaching Hospitals NHS Foundation Trust. Mr Zacharias has a proctoring agreement with Edwards Life Science and Abbott.
- Mr David Jenkins, consultant cardiothoracic surgeon, Papworth Hospital NHS Foundation Trust. No conflicts of interest declared.

## Development of this briefing

This briefing was developed by NICE in accordance with published process and methods.

ISBN: 978-1-4731-2618-3