# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## HealthTech Programme

## GID-IPG10439 Percutaneous insertion of a cerebral protection device during TAVI for preventing stroke

## Final scope

## 1 Introduction

The procedure included in this NICE HealthTech evaluation is percutaneous insertion of a cerebral protection device during transcatheter aortic valve implantation for preventing stroke. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new procedures or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This is a review of existing NICE's guidance on percutaneous insertion of a cerebral protection device to prevent cerebral embolism during transcatheter aortic valve implantation. This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the Interventional procedures programme manual and the NICE HealthTech programme manual.

## 2 Summary of the procedure

In transcatheter aortic valve implantation (TAVI), a new valve is placed inside a faulty valve in the heart. This can cause debris, such as calcium or tissue fragments, to break loose and block arteries supplying blood to the brain, causing a stroke.

In this procedure, before the new heart valve is inserted, a cerebral (brain) protection device is inserted through the skin (percutaneous) and placed inside an artery near the heart. This device filters the debris from the blood or deflects it away from the brain. The device is removed at the end of the TAVI procedure. The aim is to reduce the risk of stroke after TAVI.

# 3 The condition

Stroke can be a potential complication following a transcatheter aortic valve implantation (TAVI; also called transcatheter aortic valve replacement) procedure. This is because debris (such as pieces of calcium, valve and aortic tissue) may be dislodged during TAVI and can enter the cerebral circulation and embolise, which obstructs cerebral blood flow.

TAVI carries a measurable risk typically between 2% and 5% for both major and minor strokes during the first 30 days after the procedure (Nikas 2025). A UK observational study of 8,652 TAVI procedures reported that there were 205 in-hospital strokes, equivalent to an overall in-hospital stroke incidence of 2.4% (Myat 2020).

The risk of stroke after TAVI can vary depending on several factors, including the person's individual risk profile (Nikas 2025). Key risk factors for in-hospital stroke commonly include a history of prior cerebrovascular disease and older age (Myat 2020; Thourani 2019).

Stroke is associated with significant morbidity and mortality. A meta-analysis of 29,043 people undergoing TAVI showed that perioperative strokes were associated with 6 times greater risk of 30-day stroke-related mortality (Muralidharan 2016).

TAVI is used to treat aortic valve disease. It is commonly used for aortic stenosis and may also be considered for aortic regurgitation in some people. In the UK, 10,367 TAVI procedures were performed in 2024 to 2025, representing a 16% increase compared with 2023 to 2024 (NICOR 2025).

This corresponds to a rate of 161 TAVI procedures per million population in 2024 to 2025, an increase from 141 per million population in 2022 to 2023.

In the UK, the prevalence of aortic stenosis among people over 55 years was about 1.5% in 2019 (Strange 2022). The prevalence of aortic stenosis raises with increasing age (Lindman 2016), affecting 2% to 3% of people over 65 years of age and raising to 7% in those aged over 80 years (Hamana 2025). An estimated 291,500 individuals aged 55 years or above were living with symptomatic severe aortic stenosis and 92,000 had asymptomatic severe condition (Strange 2022). Severe aortic stenosis is associated with an increased risk of hospitalisation, valve procedure, morbidity, and mortality.

Hospital Episode Statistics for England reported 21,846 finished consultant episodes for aortic (valve) stenosis (I35.0), 4,481 finished consultant episodes for aortic (valve) stenosis with insufficiency (I35.2) and 2,311 finished consultant episodes for aortic (valve) insufficiency (I35.1) in 2024 to 2025, with most cases in males (NHS England 2025). The mean age was 77 years for people with aortic (valve) stenosis, 73 years for aortic (valve) stenosis with insufficiency, and 62 years for aortic (valve) insufficiency.

# 4 Current practice

TAVI is a minimally invasive procedure. It is primarily indicated to treat severe aortic stenosis in people at high risk for open heart surgery or when surgery is not suitable. Following NHS England's 2023 position statement expanding TAVI eligibility beyond surgical risk, this procedure is increasingly considered for people at low or intermediate surgical risk. However, professional bodies have raised concerns about the clinical appropriateness of the policy (NICE 2025).

TAVI may also be considered for aortic regurgitation in some people (Praz 2025; NICE 2025). NICE's interventional procedure guidance on transcatheter aortic valve implantation (TAVI) for native aortic valve regurgitation recommends its use during the evidence generation period for people who cannot have, or at high risk from, surgical aortic valve replacement.

TAVI-related stroke prevention strategies are currently limited, including avoidance of postprocedural balloon valvuloplasty when possible, pharmacotherapy and cerebral embolic protection in selected people (Khera 2023).

NICE's guideline on stroke and transient ischaemic attack in over 16s describes the diagnosis and initial management of stroke. For acute ischaemic stroke following TAVI, treatment options include conservative treatment (such as antiplatelet therapy and anticoagulation), mechanical thrombectomy and thrombolytic therapy (Hammond-Haley 2024; Khera 2023). However, there is limited data on the optimal management of TAVI-related acute ischaemic stroke.

# 5 Unmet need

While TAVI offers a less invasive alternative to traditional surgical valve replacement, stroke is a serious complication of TAVI and its management remains a major challenge. Data on the optimal management of stroke post TAVI is lacking (Khera 2023). Timely decision-making regarding the suitability for thrombolysis or mechanical thrombectomy in people with stroke following TAVI can be challenging because of the nature and severity of stroke, complex vascular anatomy and comorbidities.

Stroke prevention in TAVI remains limited, because current therapy offers little or only partial protection, leaving an unmet clinical need. Timely interventions to prevent cerebral embolism are essential. Percutaneous insertion of a cerebral protection device during TAVI may help capture debris and reduce stroke risk.

# 6 The procedure

Percutaneous insertion of a cerebral protection device aims to prevent debris dislodged during TAVI from passing into the cerebral circulation. The aim is to reduce the risk of cerebral ischaemic events, particularly stroke.

During the TAVI procedure, before the valve is inserted, a cerebral protection device is inserted percutaneously through the radial or femoral artery. Depending on the type of device used, it is placed into the aortic arch or into the brachiocephalic (also clinically known as 'innominate') and left common carotid arteries (major blood vessels that branches off from the aortic arch which supply the upper part of the body including the brain). It is used to protect the ostia of the brachiocephalic artery and the left common carotid artery, or the left subclavian artery, depending on the type of device used. It works by filtering dislodged debris from the blood, or by deflecting dislodged debris away from the cerebral circulation to the systemic circulation. The device is removed at the end of the TAVI procedure.

There are different types of cerebral protection devices available, such as filter or deflector systems. Different devices can cover different areas, such as all 3 main branches of the aortic arch, or the brachiocephalic trunk and the left common carotid artery.

## 6.1 Innovative aspect of the procedure

Percutaneous insertion of a cerebral protection device can be used during the TAVI procedure. There are no other adjunctive procedures available and there are limited pharmacological options for TAVI-related stroke prevention.

## 6.2 Current known use of the procedure

In the UK, 10,367 TAVI procedures were performed in 2024 to 2025 (NICOR 2025). The proportion of men receiving TAVI was 58%. In England, there were 17,551 procedures recorded as 'plastic repair of aortic valve' (K26) and 60 procedures recorded as 'mechanical embolic protection of artery' (L73.2) during the same period, with most procedures performed in males (NHS England 2025).

Percutaneous insertion of a cerebral protection device during TAVI has been performed in the UK, with 33 TAVI centres being part of the BHF PROTECT TAVI trial (Kharbanda 2025). Use of cerebral protection devices during TAVI increased during the trial but declined from over 8% in August 2024 to under

1% in November 2024 after its completion (NICOR 2025). Outside the trial, this procedure remains around 2% to 3% of TAVI cases.

# 7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

Age is a key risk factor for in-hospital stroke after TAVI. Women have a higher likelihood of experiencing in-hospital stroke, particularly a disabling stroke, following TAVI compared with men (Joshi 2025).

People with stroke after TAVI are likely to be covered by the Equality Act 2010 if their condition has had a substantial adverse impact on normal day to day activities for over 12 months or is likely to do so.

Age, disability and sex are protected characteristics under the Equality Act 2010.

NICE is also committed to reducing health inequalities. TAVI provision varies across England, resulting in geographical disparities in access (Aktaa 2024). This might indicate similar inequalities in the use of percutaneous insertion of a cerebral protection device during TAVI. However, no national or regional data is available for this procedure.

Women, people from ethnic minority backgrounds and those living in the most deprived communities are less likely to receive aortic valve intervention following a diagnosis of aortic stenosis (Aslam 2025; Rice 2023). These observed disparities might indicate similar inequalities in access to percutaneous insertion of a cerebral protection device during TAVI, although no data is available for this procedure.

# 8 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of percutaneous insertion of a cerebral protection device during TAVI to determine whether it works well enough to prevent cerebral ischaemic events, particularly stroke, and is safe enough for use in the NHS.

**Table 1: Decision problem**

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|---|---|
| **Population** | People having a TAVI procedure |
| **Intervention** | Percutaneous insertion of a cerebral protection device |
| **Key efficacy outcomes** (may include but are not limited to) | • Stroke (within 30 days), including severity of stroke<br>• Transient ischemic attack (within 30 days)<br>• Neurocognitive function<br>• New cerebral lesions |
| **Key safety outcomes** (may include but are not limited to) | • Mortality (stroke-related or all-cause mortality)<br>• Major adverse cardiac and cerebrovascular events<br>• Vascular complications, including access site complications<br>• Coronary obstruction<br>• Acute kidney injury<br>• Bleeding |

# 9 NICE team

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March 2026

# Appendix A: Related evidence or guidance

## Relevant registries or emerging key trials

Trial of the F2 Filter and Delivery System for Embolic Protection During TAVR (SHIELD) (NCT06689839). US and Australia; randomised controlled trial (single-blind); estimated enrolment, n=500; estimated study completion date, January 2027. SHIELD assesses the safety and effectiveness of the Encompass F2 Cerebral Protection System versus standard of care (unprotected or Sentinel Cerebral Protection System) during transfemoral transcatheter aortic valve replacement.

Clinical Feasibility and Evaluation Study of POINT-GUARD Embolic Protection Device During TAVR (GUARDIAN) (GUARDIAN) (NCT06962371). Australia; feasibility study (single arm); estimated enrolment, n=30; estimated study completion date, March 2026. This study assesses the clinical performance and safety of the Point-Guard CEPD during a TAVR procedure.

Feasibility Trial of the F2 Filter and Delivery System for Embolic Protection During TAVR (NCT05866640). Georgia; feasibility study (single arm); estimated enrolment, n=10; estimated study completion date, January 2026. This study evaluates the safety and performance of the F2 filter and delivery system used for embolic protection during transcatheter aortic valve replacement.

Cerebral Protection in Transcatheter Aortic Valve Replacement: the PROTEMBO trial (NCT05873816). US, Germany and Poland; randomised controlled trial; estimated enrolment, n=500; estimated study completion date, July 2027. This trial compares the safety and efficacy of the ProtEmbo Cerebral Embolic Protection device to a hybrid control (no embolic protection device ('No Device') and the Sentinel device) in people with severe symptomatic native aortic valve stenosis indicated undergoing a TAVR procedure.

The NICOR UK TAVI registry contains data relevant to percutaneous insertion of a cerebral protection device during TAVI. Also, IPG650 recommends that clinicians wishing to do this procedure should enter the details of all patients into this registry.

## Related NICE guidance, standards or indicators

### NICE interventional procedures guidance

Transcatheter aortic valve implantation for aortic stenosis (2017) NICE Interventional procedures guidance IPG586 (Recommendation: standard arrangements)

Transcatheter aortic valve implantation (TAVI) for native aortic valve regurgitation (2025) NICE Interventional Procedures guidance IPG805 (Recommendation 1: when SAVR is not suitable or is high risk, this procedure can be used in the NHS while more evidence is generated; Recommendation 2: when SAVR is suitable and is not high risk, more research is needed on this procedure)

Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction (2019) NICE International procedures guidance IPG653 (Recommendation: standard arrangements)

### NICE guidelines

Heart valve disease presenting in adults: investigation and management (2021) NICE guideline NG208

Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (2022) NICE clinical guideline NG128

### NICE HealthTech guidance

Transcatheter heart valves for transcatheter aortic valve implantation to treat aortic stenosis: Late-stage assessment (2025) NICE Health technology evaluation HTE31

## Other related documents

### National policy documents

NHS England (2023) Transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) for symptomatic, severe aortic stenosis (adults) to support elective performance

NHS England (2013) Clinical Commissioning Policy: Transcatheter aortic valve implantation (TAVI) for aortic stenosis

GIRFT (2023) Optimising the transcatheter aortic valve implantation pathway