

# pCONUS2 Bifurcation Aneurysm Implant for complex intracranial aneurysms

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is the pCONUS2 Bifurcation Aneurysm Implant. It is used for assisting in the coil occlusion of wide-necked aneurysms that span the division of an artery into 2 branches.
- The **innovative aspects** are that the implant has a less than 5% metal to artery surface ratio and can be used without dual antiplatelet treatment.
- The intended **place in therapy** would be as an alternative to standard care in people with complex intracranial aneurysms.
- The **main points from the evidence** summarised in this briefing are from 1 case series study including a total of 12 adults in secondary care. They show that pCONUS2 is safe and effective at assisting the coil occlusion of an intracranial aneurysm.

- **Key uncertainties** around the evidence or technology are that the evidence is from a case series of only 12 patients. There are no comparative studies evaluating its efficacy against standard care.
- The **cost** of pCONUS2 is £6,760.00 per unit (excluding VAT), or £7,774.00 per unit with the hydrophobic coating (excluding VAT).

## The technology

The pCONUS2 (Phenox) is an implantable intraluminal device for people with complex intracranial aneurysms. It is designed to support the coil occlusion of wide-necked aneurysms that span the division of an artery into 2 branches. The technology consists of a stent-like metal structure. At one end the stent has a crown of metal loops to anchor the implant to the neck of the aneurysm. The device is placed in the artery using a standard microcatheter (with an inner diameter of 0.533 mm). After placement, a microcatheter is used for coil occlusion of the aneurysm. The pCONUS2 is suitable for vessels between 2.50 mm and 3.70 mm in diameter and aneurysms with a neck of over 4 mm. The device has a shaft diameter and length of 4 mm and 15 mm, respectively. The crown diameter is available in sizes ranging from 5 mm to 15 mm.

The pCONUS2 is also available with a hydrophilic polymer coating (HPC). The company claims the coating avoids clots forming by preventing platelets from attaching to the stent and triggering blood to coagulate.

## Innovations

The pCONUS2 has a less than 5% metal to artery surface ratio. The company claims this reduces the risk of thrombogenesis. The device has radiopaque markers along the shaft and in the loops of the crown intended to enhance visibility. The device is retrievable and detachable, which the company claims ensures optimal placement. The company also claims the device can be used without dual antiplatelet drugs, and allows for the coil occlusion of a complex intracranial aneurysm using 1 instead of 2 devices.

## Current care pathway

Radiological imaging of the head, such as computerised tomography or computerised tomography angiography, is used to confirm the presence of an intracranial aneurysm.

Intracranial aneurysms can be treated surgically or using endovascular techniques.

Surgery traditionally involves accessing the aneurysm through an incision in the scalp in front of the ear and permanently clipping the neck of the aneurysm. Supraorbital minicraniotomy for intracranial aneurysm uses a smaller incision just above the eyebrow.

Endovascular techniques for treating intracranial aneurysms work by either blocking the aneurysm with a coil or by diverting the blood flow away from the aneurysm using a stent.

A catheter is used to insert a coil into the aneurysm sac to block the opening. Balloon-assisted treatment involves inflating a balloon temporarily inside the aneurysm sac to keep the coil open.

Alternatively, a stent placed across the neck of the aneurysm can direct blood flow into the parent vessel and away from the aneurysm, while providing a scaffold for endothelial growth to divert blood from the aneurysm sac. Multiple stents can be used to assist with wide-necked or bifurcated aneurysms, for example in Y-stenting or T-stenting. If stents are used, patients are given dual antiplatelet therapy to prevent in-stent thrombosis.

The following publications have been identified as relevant to this care pathway:

- [NICE's interventional procedures guidance on supraorbital minicraniotomy for intracranial aneurysm](#)
- [NICE's medical technologies guidance on the Pipeline Flex embolisation device with Shield Technology for the treatment of complex intracranial aneurysms](#)
- [NICE's interventional procedures guidance on coil embolisation of unruptured intracranial aneurysms](#)

## Population, setting and intended user

This technology is intended for people who need endovascular treatment of a wide-necked intracranial aneurysm. The technology would be used in secondary care by interventional neuroradiologists.

## Costs

### Technology costs

The pCONUS2 costs £6,760.00 (excluding VAT) without the HPC coating and £7,774.00 (excluding VAT) with the HPC coating.

### Costs of standard care

The cost of standard care in neuro-interventional procedures depends on the complexity of the intracranial aneurysm. The approximate costs of the items needed for the different methods of treating an intracranial aneurysm are:

- clips used for surgery approximately £200
- balloon devices approximately £700
- stents for neuro-interventional procedures approximately £3,000
- Pipeline Flex embolisation device £10,450.

## Resource consequences

The technology costs more than standard care. The company claims the technology will reduce complications from thrombogenesis, is easier to use than standard care and is an alternative for patients who cannot have dual antiplatelet treatment.

## Regulatory information

pCONUS2 is a CE marked class III medical device.

## Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified in the development of this briefing.

## 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

1 study is summarised in this briefing.

The study is a case series including 12 patients treated for an intracranial aneurysm using pCONUS2 assisted coil embolism. The study reports that the pCONUS2 was safe and effectively supported coil occlusion.

## Overall assessment of the evidence

The evidence for this technology consists of a case series and case reports. The case series is described in this briefing. There are also 3 case reports of individual patients ([Varrassi et al. 2018](#); [Perez et al. 2018](#); [Viso et al. 2018](#)) that describe the safety and efficacy of pCONUS2 to assist the coil occlusion of an aneurysm, and 1 case report of a procedure using the pCONUS2 with the hydrophilic polymer coating ([Henkes et al. 2019](#)).

The case series summarised in this section is included in a systematic review and meta-analysis ([Sorenson et al. 2019](#)) that reviewed 201 intracranial aneurysm cases treated with coil occlusion using either pCONUS or pCONUS2. The study only included 1 pCONUS2 product but because the versions are similar the results are likely to be generalisable.

There is evidence on the safety of pCONUS2 but none on comparative clinical efficacy or systematic benefit. Comparative evidence assessing how pCONUS2 affects the success rate of coil occlusion, retreatment rate, and treatment without dual antiplatelet therapy would be useful.

## Lylyk et al. (2018)

### Study size, design and location

A retrospective case series of 12 patients treated with pCONUS2 for an intracranial aneurysm.

### Intervention and comparator(s)

Intervention: pCONUS2. No comparator.

### Key outcomes

The device was successfully inserted in all patients. Ten patients had Modified Raymond-Roy Classification (MRRC) grade 1 occlusion, 2 had MRRC grade 2 occlusion. The device successfully prevented coil protrusion in 10 of the 12 patients. Small non-occlusive thrombi were seen in 3 patients. Six patients had post-treatment angiography (mean follow-up time 4.6 months): 4 showed stable occlusion, 1 showed a small stable neck remnant and 1 showed deterioration with recanalisation of the aneurysm.

### Strengths and limitations

This small case series is low-quality evidence. Because it is retrospective the likelihood of selection bias is increased. Ten of the 12 patients were women, limiting the generalisability of the results to men. Two of the patients were also treated with an embolisation device. Uncontrolled variables in the study may confound the results. All patients had dual antiplatelet therapy.

## Sustainability

The company has not submitted any sustainability claims.

## Recent and ongoing studies

pCONUS2 Treatment of Wide Neck Intracranial Aneurysms 2 (pToWin2). ClinicalTrials.gov identifier: NCT03273478. Status: ongoing but not recruiting. Indication: intracranial aneurysm. Devices: pCONUS2, Phenox GmbH. Date: expected completion Dec 2021.

Location: US.

## Expert 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.

Six experts were familiar with the technology and 4 had used it before.

## Level of innovation

Two experts said the technology was innovative. Three said it was better than current alternatives and previous versions of the device. All said the pCONUS2 is a specialist device and is not widely used. All said the technology has not been superseded but all acknowledged there are comparator devices available.

## Potential patient impact

Five experts said the technology would benefit people with wide-necked aneurysms for whom treatment options are limited, such as middle cerebral bifurcation aneurysms and basilar or carotid termination aneurysms. Three said the use of single antiplatelet therapy has fewer associated complications than dual antiplatelet therapy. One said using pCONUS2 may reduce thromboembolic complications.

## Potential system impact

All experts said the technology would reduce the number of neurosurgical procedures by increasing the range of aneurysms that can be treated endovascularly. Two experts said using endovascular treatment instead of surgical treatment would reduce intensive care bed days. All experts said adopting pCONUS2 would have no impact on resources. Two experts believed the technology would cost more than standard care, 1 believed the technology would be cost saving and 3 said it would be cost neutral.

## General comments

Two experts said more evidence is needed to prove the safety of using the device with single antiplatelet therapy. Five said the technology should be available as an addition to standard care and used when standard care is not appropriate. One said the technology would replace Y-stenting. Two experts said there would be a learning curve for inexperienced interventional neuroradiologists.

## Expert commentators

The following clinicians contributed to this briefing:

- Dr Pervinder Bhogal, consultant interventional neuroradiologist, Royal London Hospital, Barts NHS Trust. Dr Bhogal is a consultant and proctor for Phenox but has not been involved in the development of pCONUS2.
- Dr Joe Leyon, consultant interventional neuroradiologist, St George's NHS University Foundation Trust. Dr Leyon has been a consultant for the aneurysm treatment device manufacturers Stryker UK Ltd, Medtronic Ltd and Microvention.
- Dr Robert Crossley, consultant interventional neuroradiologist, North Bristol Hospitals NHS Trust. Dr Crossley has been a consultant for the aneurysm treatment device manufacturers Stryker UK Ltd and Microvention.
- Dr Tony Goddard, consultant interventional neuroradiologist, Leeds General Infirmary. Dr Goddard has been a paid proctor for pCONUS2 as well as other devices manufactured by Phenox.
- Dr Shelley Renowden, consultant neuroradiologist, Southmead Hospital. No interests declared.
- Dr David Minks, consultant interventional neuroradiologist, Newcastle Upon Tyne Hospitals NHS Foundation Trust. Dr Minks facilitates the administration of the British Society of Neuroradiologists and the UK Neurointerventional Group.

## Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out



the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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