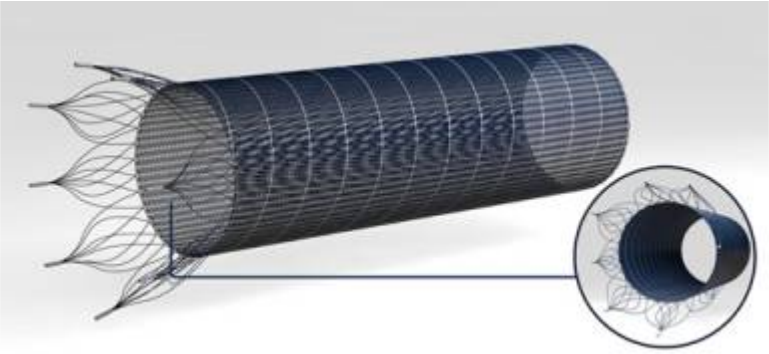
# p64 Flow Modulation Device

(Phenox, Bochum, Germany).

https://phenox.net/products/p64.html



The p64 is the only fully resheathable and mechanically detachable flow diverter available for clinical use.

It allows complete deployment and full recoverability. This provides added safety and security.

• Complete deployment and recoverability ensures optimal placement

• Greater neck coverage due to the 64 Nitinol wire braid maximizes hemodynamic flow effect in the aneurysm

• Visualization is achieved by 2 helical strands along entire length of the implant and eight proximal markers

• p64 is mechanically detached once optimally placed

• Implanted via a 0.027“ ID microcatheter

The p64 is a flow modulation device designed to be used in endovascular treatment of intracranial aneurysms. There is limited data on the long-term effectiveness of the device. A study of Sirakov et al. sought to determine the safety and long-term efficacy of this device.

A retrospective review of aprospectively maintained database was performed to identify all patients treated with a p64 between March 2015 and November 2018 at University Hospital St. Ivan Rilski. Anatomical features, intraprocedural complications, clinical, and angiographic outcomes were also taken into account and reviewed.

A total of 72 patients with 72 aneurysms who met the inclusion criteria were identified. Device placement was successful in all patients. Follow-up angiographic imaging at 6 months showed complete occlusion (O'Kelly-Marotta grading scale [OKM] D) in 55 (76.3%) patients, subtotal aneurysmal filling (OKM B) in 10 (13.8%) patients, and neck remnant (OKM C) in 7 (9.7%) patients. Catheter angiography at 12 months was available for 70 patients (97.2%) and of these patients 91.4% of the aneurysms were completely occluded (OKM D) (64/72). Delayed angiography at 24 months was available for 68 patients (94.4%) and of these 98.5% (67/68) had completely occluded aneurysms. A 36-month angiography was available for 61 patients (84.4%) by which point all aneurysms had been

completely occluded (100%). Permanent morbidity due to delayed aneurysmal rupture occurred in one patient (1.38%). The mortality rate was 0%. Self-limiting mild intimal hyperplasia was seen in 2 patients (2.72%).

Treatment of intracranial aneurysms with a p64 flow modulation device is safe and effective with a high success rate and only infrequent complication [1].

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Girdhar et al., reported the thrombogenic potential of the following flow diversion devices measured experimentally in a novel human blood in-vitro pulsatile flow loop model: Pipeline™ Flex Embolization Device (Pipeline), Pipeline™ Flex Embolization Device with Shield Technology™ (Pipeline Shield), Derivo Embolization Device (Derivo), and P64 Flow Modulation Device (P64). Thrombin generation (Mean ± SD; µg/mL) was measured as: Derivo (28 ± 11), P64 (21 ± 4.5), Pipeline (21 ± 6.2), Pipeline Shield (0.6 ± 0.1) and Negative Control (1.5 ± 1.1). Platelet activation (IU/µL) was measured as: Derivo (4.9 ± 0.7), P64 (5.2 ± 0.7), Pipeline (5.5 ± 0.4), Pipeline Shield (0.3 ± 0.1), and Negative Control (0.9 ± 0.7). They found that Pipeline Shield had significantly lower platelet activation and thrombin generation than the other devices tested ($p < .05$) and this was comparable to the Negative Control (no device, $p > .05$). High resolution scanning electron microscopy performed on the intraluminal and cross-sectional surfaces of each device showed the lowest accumulation of platelets and fibrin on Pipeline Shield relative to Derivo, P64, and Pipeline. Derivo and P64 also had higher thrombus accumulation at the flared ends. Pipeline device with Phosphorylcholine surface treatment (Pipeline Shield) could mitigate device material related thromboembolic complications [2].

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In preliminary in vivo experiments, antithrombogenic hydrophilic coating (HPC) p64 FDSs appeared to be biocompatible, without acute inflammation [3].

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Treatment with p64 is associated with an overall rate of 8.5% moderate in stent stenosis (ISS) (50-75%) and 2.7% severe ISS (>75%), which is comparable with the rate of ISS reported in the literature for other flow diverting stents. There is a tendency for ISS to spontaneously improve over time [4].

## Case series

retrospectively reviewed our prospectively maintained database to identify all patients who underwent treatment for an intracranial saccular (unruptured or beyond the acute hemorrhage phase) aneurysm arising from the anterior circulation with ≥1 p64 between December 2011 and December 2019. Fusiform aneurysms and dissections were excluded. Aneurysms with prior or concomitant saccular treatment (eg, coiling and clipping) were included. Aneurysms with parent vessel implants other than p64 were excluded. Anatomic features, intraprocedural complications, clinical outcome, as well as clinical and angiographic follow-ups were all recorded.

Results: In total, 530 patients (388 females; median age 55.9 yr) with 617 intracranial aneurysms met the inclusion criteria. The average number of devices used per aneurysm was 1.1 (range 1-3). Mean aneurysm dome size was 4.8 mm (range 1-27 mm). Treatment-related morbimortality was 2.4%.

Early, mid-term, and long-term angiographic follow-up showed complete or near-complete aneurysm occlusion in 76.8%, 89.7%, and 94.5%, respectively.

Conclusion: Treatment of intracranial saccular unruptured aneurysms of the anterior circulation using p64 is a safe and effective treatment option with high rate of occlusion at long-term follow-up and low morbimortality [5].

# References


1)
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