ENGINEERING STROKE SOLUTIONS

Summary of Safety and Clinical Performance:

NeuroSpeed® PTA Balloon Catheter

Acandis GmbH

Summary of Safety and Clinical Performance according to Medical Device Regulation (MDR) EU 2017/745

Identifier: 2000

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1 Information for the professional user

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the NeuroSpeed® PTA Balloon Catheter.

The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9, Rev.1 from March 2022.

The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the NeuroSpeed® PTA Balloon Catheter, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1.1 Device identification and general information

Device trade name(s)	**NeuroSpeed® PTA Balloon Catheter** Article no. 01-000600, 01-000601, 01-000602, 01-000603, 01-000604, 01-000605 01-000610, 01-000611, 01-000612, 01-000613, 01-000614, 01-000615
Manufacturer's name and address	Acandis GmbH, Theodor-Fahrner-Straße 6, 75177 Pforzheim, Germany
Manufacturer's single registration number (SRN)	DE-MF-000006259
Basic UDI-DI	426065033NeuroSpeedNR
Medical device nomenclature	- UMDNS: 17-184 Catheters, angioplasty, balloon dilatation - GMDN 17184 Peripheral angioplasty balloon catheter, basic - EMDN: C010499 Anqiography and Hemodynamics Devices - Other
Class of device	Class III medical product, as defined in Medical Device Regulation (MDR) EU 2017/745 Annex VIII, classification rule 7, bullet point 2
Year of first CE certificate	2014
Authorized representative	Not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297).

1.2 Intended use of the device

Intended purpose	The NeuroSpeed® PTA Balloon Catheter is intended for the dilation of intracranial arteries for improving perfusion. The NeuroSpeed® PTA Balloon Catheter is intended for the delivery of the self-expanding CREDO® Stent/CREDO® heal Stent. Please observe the instructions for use of the CREDO® Stent/CREDO® heal Stent.
Indication(s)	The NeuroSpeed® PTA Balloon Catheter is indicated for the treatment of intracranial stenosis.

Targeted population(s)	*Intended user:* The NeuroSpeed® PTA Balloon Catheter should be applied only by physicians who have the necessary background knowledge and experience in the field of percutaneous transluminal angioplasty (PTA). *Intended target group:* No special patient populations defined but patients with contraindications are to be excluded.
Contraindications and/or limitations	Usage is contraindicated for the following patients: – Patients in whom it is assumed that effective angioplasty of the lesion cannot be performed. – Patients in whom treatment with antiplatelet agents and/or anticoagulants is contraindicated. – Patients who present in the angiography with anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity. General contraindications in connection with endovascular and/or angiographic treatments must be taken into consideration. No limitations are mentioned in the IFU.

1.3 Device description

1.3.1 Description of the NeuroSpeed® PTA Balloon Catheter

The NeuroSpeed® PTA Balloon Catheter is an over-the-wire coaxial catheter with a balloon near the distal tip for percutaneous transluminal angioplasty (PTA). The catheter dimensions and balloon sizes are specified on the packaging label. The balloon diameters at the corresponding pressure values can be seen in the compliance chart. The PTA balloon catheter has X-ray markers that simplify placement under fluoroscopy. One X-ray marker identifies the catheter tip, while two further X-ray markers identify the nominal length of the balloon. There are two Luer connections at the proximal end of the catheter: the central lumen for guiding the guide wire and a lateral lumen for inflating and deflating the balloon. The outer surface of the catheter has a hydrophilic coating for improved lubricity. Stent placement after Balloon PTA is possible without changing the catheter.

Sizes	Balloon diameters: 1.5 / 2.0 / 2.5 / 3.0 / 3.5 / 4.0 mm Balloon length: 8 mm / 15 mm Usable length: 150 cm Outer diameter: 2.7 French distal / 3.7 French proximal
Sterility	Yes, for single-use

Insertion of the catheter using a suitable guide wire and appropriate accessories (such as guide catheter, sheath, hemostatic valves, infusion bags, etc.) to safely reach the target zone for a controlled placement in the middle of the stenosis, inflation of the balloon with a manometer and for delivery of the CREDO® (heal) Stent.

1.3.2 Previous generations

The first generation of the NeuroSpeed PTA Balloon Catheter (1019-1) has been on the market since May 2014, the second generation (1019-1, range extension) since December 2015, the third generation (1019-1, optimization components and process) since October 2018.
The current generation of the NeuroSpeed PTA Balloon Catheter has an additional balloon length of 15 mm (2000-1) since September 2023 (document B02).

1.3.3 Accessories

No accessories.

1.3.4 Combination with other devices

Compatible with inflation pump, standard guide wire, RHV (rotating hemostatic valve), lockable vacuum syringe, guiding catheter/sheath and compatible with CREDO® (heal) Stent.

1.4 Risks and warnings

1.4.1 Residual risks and undesirable effects

Possible complications, among others, include the following:

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Intracerebral) hemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, Vessel dissection, Vessel perforation, Vessel rupture, Hyperperfusion syndrome, Infection, (Cerebral) ischemia/infarction, Secondary hemorrhage, Reactions due to radiation exposure, Subarachnoid hemorrhage, Thromboembolic event/stroke, Vasospasm)
- General complications in connection with thrombocyte aggregation inhibitors/ anticoagulants, anesthetics and contrast agents (e.g. Renal insufficiency)
- Complications in connection with vessel entry (e.g. Hematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during catheter delivery (e.g. Balloon failure, Catheter breakage, Incorrect catheter placement, Catheter cannot be withdrawn, Catheter bending, Catheter compression, Catheter damage, Therapeutic or diagnostic aids cannot be used, Delayed treatment, Target area inaccessible or cannot be accessed safely)
- Other complications in connection with the catheter (e.g. Allergic reactions to the catheter material, (Distal) embolization including previously unaffected areas, (Re)stenosis)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

In the scientific literature, the most common complications are stroke recurrence, intracranial hemorrhage and death. The range of stroke recurrence, intracranial hemorrhage and death in the literature on the NeuroSpeed PTA Balloon Catheter were 1.7 – 7.7 % ((Meyer et al. 2020) ASSISTANT), 4 – 16 % (Meyer et al. 2020; Stracke et al. 2020a; Stracke et al. 2020b; Naftali et al. 2023), 2.7 – 40 % (Meyer et al. 2020; Stracke et al. 2020b; Naftali et al. 2023) respectively. In eleven publications, no complications were observed (Möhlenbruch et al. 2016). Only one device-related complication was observed in the ASSISTENT PMCF study (long distance dissection). In total, 7.7 % of the patients experienced a symptomatic and 7.7 % an asymptomatic intracranial hemorrhage. There were two deaths (7.7 %). Stroke rates were divided into non-disabling in the region of the target vessel (3.9 %), non-disabling outside the region of the target vessel (0 %), disabling in the region of the target vessel (7.7 %) and disabling outside the region of the target vessel (3.9 %).

1.4.2 Warnings and precautions

Warnings:

- The NeuroSpeed PTA Balloon Catheter should be applied only by physicians who have the necessary background knowledge and experience in the field of percutaneous transluminal angioplasty (PTA).
- No specific patient populations have been defined but patients with contraindications are to be excluded.
- Because application of the PTA balloon catheter involves the risk of subacute thrombosis, vascular complications and/or hemorrhages, it is necessary to select patients with care.
- Before use, the product needs to be carefully checked to ensure there is no transportation damage. Under no circumstances should damaged or kinked catheters be used.
- On no account whatsoever should you continue advancing the catheter if you encounter resistance without first finding out the cause, as otherwise you could damage the catheter or perforate the vessel.
- Intraluminal instruments must never be moved against resistance within the catheter. The application of too much force against resistance may lead to damage (e.g. cracks/ruptures) to the instrument and/or the catheter or injury to the vessel wall.
- Compatibility of the NeuroSpeed PTA Balloon Catheter with liquid embolizates cannot be guaranteed. It is not suitable for liquid embolizates based on cyanoacrylate and dimethylsulphoxide (DMSO).
- A corresponding treatment with anticoagulant and antiplatelet agents must be performed in accordance with well-established medical standards.

- The product may only be used for the intended purpose. Any use of the product for other purposes (off-label use) may lead to a deterioration in the patient's state of health or even their death.

Precautions:

- The product is provided sterile and for single use only.
- In case of damage to the sterile barrier, the product must not be used. If any damage is visible, please contact your Acandis representative.
- Do not use the product after the expiration date printed on the label.
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise structural integrity of the components and/or lead to failure that, in turn, may result in complications, patient injury or death. Reuse, reprocessing or resterilising the device also increases the risk of contamination of the device and/or causes patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The hydrophilic coating of the outer surface of the catheter must be kept hydrated to maintain its lubricious properties.
- Once the catheter is inside the body, it should only be moved under fluoroscopy. Do not remove the catheter without checking how the tip reacts.
- The manufacturers' instructions for use should be observed for all materials used together with the PTA balloon catheter.

1.4.3 Other relevant aspects of safety

The complaint rate is 0.40 % since first CE approval and 0,22 % in the current evaluation period (2022-11-01 – 2023-10-31). There were two preventive and/or corrective actions (CAPA) in the current evaluation period that only affected the supplier. The serious incident rate is 0.01 % since first CE approval. There were no FSNs or FSCAs in the last four years.
The medical benefit continues to outweigh the residual risk.
In April 2017, there was a voluntary medical device recall of the affected batch due to a leakage at the Luer hub.

1.5 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

1.5.1 Summary of clinical data related to equivalent devices

No clinical data of an equivalent devices from other manufacturers were used for the clinical evaluation.

1.5.2 Summary of clinical data from conducted investigations of the device before CE-marking

No clinical data from proprietary investigations before CE-marking are available.

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data in the literature

1.5.3.1.1 Clinical data in the literature on the NeuroSpeed® PTA Balloon Catheter in combination with CREDO® / CREDO® heal Stent

Table 1: Study details. ICA = intracranial artery, TIA = transient ischemic stroke, PTA = percutaneous transluminal angioplasty, ICAD = intracranial atherosclerotic disease, MCA = middle cerebral artery

Author	Study design	# of patients	Used devices	Indications	Location of stenosis
Diana et al. 2021	Case report	1	NeuroSpeed 2.5 x 8 mm with CREDO 4 x 15 mm	Intracranial angioplasty and stenting in patients with high ischemic stroke risk.	ICA siphon
Papa et al. 2020	Case report (Conference abstract)	3	NeuroSpeed PTA Balloon Catheter with Neuroform (n = 1) CREDO Stent (n = 2)	Recurrent TIA or stroke after failure of best medical treatment	Not mentioned.
Nordmeyer et al. 2019	Case series (Poster abstract)	17	NeuroSpeed PTA Balloon Catheter with CREDO heal	Initial large vessel occlusion and suspected underlying stenosis < 24 h after symptom onset. Rescue stenting was indicated in seven cases, in eight cases, symptomatic ICAD were treated.	Not further specified.
Falcon et al. 2024	Case report	1	NeuroSpeed 3 x 18 mm with Credo Stent 4.5 x15 mm	Intracranial atherosclerotic stenosis	Basilar artery
AlMatter et al. 2023	Case report	1	NeuroSpeed 2 x 8 mm with Credo Stent 3 x 20 mm	High-grade, symptomatic atherosclerotic stenosis	Left internal carotid artery
Kuršumović et al. 2021	Case report	1	NeuroSpeed 2 x 8 mm with Credo Stent 3 x 15 mm	Transient ischemic attack due to severe stenosis	Left MCA
Ranxha et al. 2023	Case report	2	NeuroSpeed 2.5 x8 mm with Credo 5 x 20 mm	Critical stenosis Vertebra-basilar transient ischemic attacks	Basilar artery

Table 2: Outcome parameters of pivotal clinical data. mRS = modified Rankin Scale, TICI = thrombolysis in cerebral ischemia, ICAD = intracranial atherosclerotic disease, NIHSS = National Institutes of Health Stroke Scale, ASPECTS = Alberta stroke program early CT score

Author	Technical success	Pre-procedural stenosis	Post-procedural stenosis	Neurological outcome	Complications	Conclusion on safety and performance
Diana et al. 2021	significant	-	-	mRS 1	Seizures, respiratory failure, cerebral hyperperfusion syndrome, no procedural complications	Cerebral hyperperfusion syndrome is a severe and underestimated complication of intracranial artery stenosis.
Papa et al. 2020	100 %	> 75 %	-	Not assessed	No complications	Clinical and angiographic results were encouraging. More data are mandatory to confirm the clinical benefit of endovascular treatment of intracranial stenosis.
Nordmeyer et al. 2019	TICI ≥ 2b = 82.3 %	Not assessed	Not assessed	Not assessed	One device-related complication (not further specified)	The CREDO heal Stent is a promising treatment option for patients with symptomatic ICAD or with persistent vascular occlusion. The final TICI sore is in accordance with uncoated devices. Its effectiveness regarding long-term ischemic complication has to be further evaluated.
Falcon et al. 2024	100 %	Near-occlusive	No evidence of stenosis	mRS = 3 after 3 months	None	The combination of the Neurospeed over-the wire balloon catheter with the Credo stent allows balloon dilatation and stent deployment in a single procedure.
AlMatter et al. 2023	100 %	90 %	50 %	Death	No intra-procedural complications, peri-procedural hemodynamic compromise	Periprocedural hemodynamic compromise is a rare or at least underreported complication of the endovascular management of severe ICAD.
Kuršumović et al. 2021	100 %	ASPECTS = 10, > 70 %	< 50 %	NIHSS = 1	None	Undersized balloon dilatation followed by the deployment of a self-expanding stent is a viable treatment option also during the acute phase of these patients
Ranxha et al. 2023	100 %	Severe stenosis	Good reopening	Not described	None	Angioplasty of basilar artery remain the optimal choice in medical failure with minimal procedure risk.

Most of the trials evaluated the safety and performance of the procedure in general or the additionally used stents, Therefore, only limited information on NeuroSpeed® PTA Balloon Catheter-related endpoints alone could be extracted from these publications.

1.5.3.1.2 Clinical data in the literature on the NeuroSpeed® PTA Balloon Catheter alone

Remark: According to the instructions for use, the NeuroSpeed® PTA Balloon Catheter is intended for the delivery of the CREDO® Stent/CREDO® heal Stent. Hence, the use without one of these stents is off-label.

Table 3: Study details. PTA = percutaneous transluminal angioplasty

Author	Study design	# of patients	Used devices	Indications	Location of stenosis
Bhogal et al. 2022	Case series: retrospective review of prospectively maintained database	24	NeuroSpeed: n = 1 2 x 15 mm	Angioplasty after fish-mouthing of the p64 HPC flow diverter	M1 (n = 1)
Guenego et al. 2024	Case series	8	NeuroSpeed ballon 1.5 x 8 mm, 2 x 8 mm	Cerebral vasospasm following aneurysmal subarachnoid hemorrhage	Supraclinoid internal carotid artery, A1 and A2 segments of the anterior cerebral artery, M1 and M2 segments of the middle cerebral artery
Giang et al. 2022	Case report	1	NeuroSpeed PTA Balloon Catheter 2.0 x 8 mm Jade balloon (OrbusNeich) 3.5 x 80 mm	Minor ischemic stroke resulting in right hemiparesis	Ipsilateral internal carotid artery stenosis

Table 4: Outcome parameters of pivotal clinical data. mRS = modified Rankin Scale, n.a. = not applicable, aSAH = aneurysmal subarachnoid hemorrhage, CCA = common carotid artery

Author	Technical success	Pre-procedural stenosis	Post-procedural stenosis	Neurological outcome	Complications	Conclusion on safety and performance
Bhogal et al. 2022	100 %	n.a.	n.a.	mRS ≤ 1 n = 24	None	Fish-mouthing appearance was significantly improved with the NeuroSpeed, with good flow through the device and no complications
Guenego et al. 2024	92 %	-- (aneurysm)	-- (aneurysm)	mRS after 3 months: 2 (n = 2) 3 (n = 2) 4 (n = 2) 5 (n = 1) 6 (n = 1)	Post-procedural cervical dissection caused by the main catheter (2 %) Post-procedural distal clots while retrieving the balloon (2 %)	The Neurospeed balloon is effective in the treatment of cerebral vasospasm following aSAH
Giang et al. 2022	No (first attempt with NeuroSpeed) 100 % with second intervention	Not assessed	Not assessed	After second intervention: mRS 1 3 months after discharge	After first intervention: Hemiplegia, increase in hypertense lesions in the left hemisphere, near occlusion in the left internal carotid artery Second intervention: none	With the first intervention using the NeuroSpeed PTA Balloon Catheter, the stent could not reach the stenosis site due to the presence of a tortuous type III aortic arch in the left CCA. In a second approach, a transcervical approach instead of the transfemoral was used and succeeded. No conclusions on the safety and performance of the NeuroSpeed PTA Balloon Catheter were drawn.

1.5.3.1.3 Clinical data in the literature on the NeuroSpeed® PTA Balloon Catheter in combination with the ACCLINO (flex) Stent

Remark: According to the instructions for use, the NeuroSpeed® PTA Balloon Catheter is intended for the delivery of the CREDO® Stent/CREDO® heal Stent. Hence, the use together with the ACCLINO (flex) Stent is off-label.

Table 5: Study details. ICS = intracranial atherosclerotic stenosis, ICA = intracranial artery, TIA = transient ischemic stroke, VA = vertebral artery, BA = basilar artery, ICAD = intracranial atherosclerotic disease, MCA = middle cerebral artery, PTA = percutaneous transluminal angioplasty

Author	Study design	# of patients	Used devices	Indications	Location of stenosis
Möhlenbruch et al. 2016	Case series: Retrospective review of prospectively collected database	6	NeuroSpeed: 4 x 2 x 8 mm 1 x 3.5 x 8 mm 1 x 4 x 8 mm with ACCLINO Flex Stent	1) failure of dual antiplatelet therapy defined as recurrent TIA or ischemic stroke 2) presence of ICS of ≥ 70 % 3) endovascular accessibility of the target lesion as judged by CT angiography or MRI angiography	V4 (n = 3) M1 (n = 2) supraclinoid portion of the ICA (n = 1)
Stracke et al. 2020b	Case series: retrospective review	50	NeuroSpeed with ACCLINO (flex)	Bailout stenting for acute ischemic stroke after failed thrombectomy	M1 (n = 17) M2 (n = 1) VA (n = 10) BA (n = 14)
Meyer et al. 2020	Case series: multi-center cohort study	76	NeuroSpeed: n = 58 Microcatheters n = 18 with ACCLINO (flex) Stent	Secondary stroke prevention in patients with symptomatic intracranial stenosis due to 1) Recurrent stroke 2) TIA	Terminal internal carotid artery (n = 21) M1 (n = 17) M2 (n = 2) Anterior cerebral artery (n = 2) V4 (n = 23) BA (n = 11)
Stracke et al. 2020a	Clinical study: retrospective analysis	61	NeuroSpeed Microcatheters with ACCLINO (flex) Stent	Bailout stenting for acute ischemic stroke after failed thrombectomy	ICA M1 M2 VA BA (Numbers not separated for different stent types used)

Author	Study design	# of patients	Used devices	Indications	Location of stenosis
Capirossi et al. 2022	Case report	1	NeuroSpeed 4.0 x 8 mm with ACCLINO flex HRF 5.0 x 25 mm	Symptomatic right carotid syphon stenosis; one month earlier there was a minor stroke with left hemiparesis.	Right carotid syphon
Borota et al. 2022	Case report	1	NeuroSpeed PTA Balloon Catheter with ACCLINO HRF 3 x 20 mm	Wake-up stroke with basilar artery occlusion caused by spontaneous dissection in a 15-year-old	Basilar artery at the level of the anterior inferior cerebellar arteries
Naftali et al. 2023	Clinical study	33	NeuroSpeed balloon catheter 1.5 – 4.5 mm with Acclino flex (or Onyx or Baby Leo)	Acute or elective treatment of intracranial atherosclerotic disease	Vertebral, basilar, internal carotid artery, middle cerebral artery
Parodi et al. 2023	Case report	1	NeuroSpeed With Acclino flex	Aneurysmal subarachnoid hemorrhage, ICA sub-occlusion	Right ICA

Table 6: Outcome parameters of pivotal clinical data (mRS = modified Rankin Scale, NIHSS = National Institutes of Health Stroke Scale, TICI = thrombolysis in cerebral ischemia, mENR = major early neurological recovery, (s)ICH = (symptomatic) intracranial hemorrhage, ICS = intracranial atherosclerotic stenosis, (e)ICS = (elective) intracranial stenting, FBTS = first balloon then stent, SAE = serious adverse event, n.a. = not applicable), PTA = percutaneous transluminal angioplasty, ICAD = intracranial atherosclerotic disease, aSAH = aneurysmal subarachnoid hemorrhage, BMT = best medical treatment, TIA = transient ischemic stroke

Author	Technical success	Pre-procedural stenosis	Post-procedural stenosis	Neurological outcome	Complications	Conclusion on safety and performance
Möhlenbruch et al. 2016	100 %	82.5 % (median)	10 %	mRS: Unchanged: n = 4 (2 x 1, 1 x 4, 1 x 3) significantly improved: n = 2 (2 to 1; 1 to 0)	None	FBTS bears the specific potential to reduce wire perforations, which so far have been linked to major procedure-related adverse events of endovascular ICS treatment.
Stracke et al. 2020b	--- mTICI ≥ 2b: 29.6 %	-	-	mENR: n = 19 mRS ≤ 2: n = 13 (of 32 as 18 are missing) NIHSS: Improved non-significantly from 12 to 8 (median)	No intervention-related SAEs sICH: 4 % 90-day mortality: 17.1 %	Intracranial bailout stenting with the ACCLINO (Flex) Stent and the NeuroSpeed Balloon Catheter after failed MT is a feasible and effective recanalization method for atherosclerotic stenosis-based Stroke that is especially associated with low rates of sICH.
Meyer et al. 2020b	100 %	-	-	mRS all unchanged (median mRS = 1)	No intervention-related SAEs Peri-procedural stroke: 6.5% Asymptomatic ICH: 5.2 % In-stent restenosis: 25 % Stroke recurrence: 1.3 % Stroke-related deaths: 2.6 %	Stenting for symptomatic intracranial stenosis with the ACCLINO (flex) / NeuroSpeed balloon catheter was safe and reinforced eICS as an endovascular therapy option for secondary stroke prevention.
Stracke et al. 2020a	--- mTICI ≥ 2b: 82.9 %	-	-	mRS 1 – 2: n = 15 mRS 3: n = 20 NIHSS improved from 13 to 6 (median)	sICH: 9.1 %	The use of the ACCLINO/ACCLINO flex stent (Acandis GmbH) was associated with a significantly lower rate of sICH. Use of rescue stent angioplasty can be considered for acute intracranial large vessel occlusion in cases after unsuccessful stent-retriever thrombectomy.

Author	Technical success	Pre-procedural stenosis	Post-procedural stenosis	Neurological outcome	Complications	Conclusion on safety and performance
Capirossi et al. 2022	Disappearance of stenotic diaphragm with a minimal residual stenosis	High-grade	Minimal	Not assessed	No complications	Endovascular treatment is an effective and safe method for eliminating pulsatile tinnitus in patients with severe intracranial carotid artery stenosis.
Borota et al. 2022	100 %	Not assessed	Reconstructed lumen of the but narrowed origins of superior cerebellar arteries	mRS 1 at discharge, NIHSS and mRS 0 after 11 months	Pneumonia, swallowing problems, tetraplegia	Despite a huge pons infarction and the two different interventions a few hours apart, the neurological outcome was surprisingly favorable in this patient.

Author	Technical success	Pre-proce-dural stenosis	Post-procedural stenosis	Neurological outcome	Complications	Conclusion on safety and performance
Naftali et al. 2023	Not described	Not described	Not described	mRS after 90 days: Bail-out group: mRS 0 – 2 in n = 6 elective stenting group: mRS 0 – 2 in n = 10	Bail-out stenting group: Peri-procedural: ICH (n = 1) Iatrogenic dissections (n = 3) Pneumonia (n = 3) Death (n = 8) During follow-up (8 ± 5 months): Ipsilateral stroke after 2 months (n = 1) TIA (n = 1) Elective stenting group: Peri-procedural: Small and asymptomatic SAH (n = 2) Peri-procedural symptomatic stroke in a non-related territory (n = 1) During follow-up (12 ± 6 months): TIA (n = 2)	Treatment of intracranial stenosis may be feasible in elective procedures (after BMT failure). Stenting is still an important tool in the treatment of this challenging disease, which carries a high burden of severe disability and mortality.
Parodi	100 %	Sub-occlusion	Restoration to normal flow time	mRS 0 after 3 months	None	The prompt neurosonological diagnosis led to patient's good outcome.

The ACCLINO (flex) Stent obtained CE marking in May 2014 and was originally developed for stent-assisted coil embolization of intracranial aneurysms. It is technically identical to the CREDO Stent and can thus be used together with the NeuroSpeed PTA Balloon Catheter as well.

1.5.3.1.4 Clinical data in the literature on the NeuroSpeed® PTA Balloon Catheter in combination with other stents

Remark: According to the instructions for use, the NeuroSpeed® PTA Balloon Catheter is intended for the delivery of the CREDO® Stent/CREDO® heal Stent. Hence, the use together with other stents is off-label.

Table 7: Study details. BA = basilar artery, ICA = intracranial artery, VA = vertebral artery, PTA = percutaneous transluminal angioplasty

Author	Study design	# of patients	Used devices	Indications	Location of stenosis
Buonomo et al. 2021	Case series	10	NeuroSpeed: n = 7 with Neuroform Atlas stent	Acute ischemic stroke or TIA	BA (n = 4) ICA (n = 2) VA (n = 1) (PTA patients)
Krug et al. 2023	Case report (poster abstract)	1	NeuroSpeed 2 x 8 mm and pEGASUS HPC stent 3.5 x 15 mm	Persisting stenosis after the first and re-occlusion after the second thrombectomy	Right posterior communicating artery
Cohen & Henkes 2023	Case report	1	NeuroSpeed PTA balloon catheter 2.5 x 8 mm, Gateway 2.5 x 15 mm (Boston Scientific) with Coroflex ISAR NEO 2.75/9 mm (B. Braun)	Progressive right hemispheric ischemic stroke after intracranial atherothrombotic occlusion	Right ICA
Pielenz et al. 2024	Clinical study	43	Balloon angioplasty: NeuroSpeed in 55.8 % of cases Stent deployment: NeuroSpeed in 51.2 % of cases (1.5 – 4 x 8 – 20 mm), Excelsior SL10 (Stryker) in 34.9 % With pEGASUS-HPC	Acute ischemic stroke (86.1 %)	Middle cerebral artery (M1: 46.5 %; M2: 9.3 %), internal carotid artery (ICA, C2: 7.0 %; C4 and C6 each 4.7 %, C7: 16.3 %), vertebral artery (14.0 %) and basilar artery (9.3 %).

Table 8: Outcome parameters of pivotal clinical data. mRS = modified Rankin Scale, PTA = percutaneous transluminal angioplasty, NIHSS = National Institutes of Health Stroke Scale, SICH = symptomatic intracranial hemorrhage

Author	Technical success	Pre-procedural stenosis	Post-procedural stenosis	Neurological outcome	Complications	Conclusion on safety and performance
Buonomo et al. 2021	100 %	85.4 % (PTA patients)	54.4 % (PTA patients)	mRS ≤ 2: n = 7 (PTA patients) NIHSS improved from 8.7 ± 12.4 to 5 ± 9.79 (mean)	None	Intracranial stenosis endovascular treatment with Neuroform Atlas stent provides encouraging results, with or without the use of NeuroSpeed.
Krug et al. 2023	100 %	Persisting stenosis after the first and re-occlusion after the second thrombectomy	Complete reperfusion	NIHSS = 2	None described	No conclusion given
Cohen & Henkes 2023	Navigation with NeuroSpeed impossible, 100 % with Gateway	75 – 80 %	No residual stenosis	Death	Parenchymal hemorrhage resulting in death	In the future, repeating pre-angioplasty maneuvers will be considered, and the need for intracranial stenting be reconsidered, and (most importantly) an even more stringent control of postprocedural arterial pressure shall be maintained.

Pielenz et al. 2024	83.7 % with the NeuroSpeed	86 % in the emergency and 87 % in the elective groups respectively	34 % in the emergency group and 29 % in the elective group	NIHSS = 10 in the emergency and 4 in the elective groups respectively mRS 0 – 2 in n = 7 in the emergency group and n = 2 in the elective group. The mean mRS score of 2.7 showed no change.	Technical difficulties (16.3 %): 4 stents had to be discarded when used with the NeuroSpeed (dislocation caused by friction n = 3, prevention of delivery n = 1) No intra-procedural hemorrhagic complications occurred in elective cases. One dilation distal to the stenosis occurred after pre-dilation. In the emergency group, 2 emboli occurred distally to the stent. Another patient had an in-stent thrombosis. 3 iatrogenic dissections occurred, 1 caused by pre-dilation and 2 by failed positioning of balloon-mounted stents. 3 post-procedural complications related to the stent occurred, 1 hemorrhagic and 2 ischemic events In total, 11 patients died in the emergency group. SICH occurred in 17 % in the elective group and 0 % in the emergency group.	Feasibility of using the pEGASUS-HPC stent system was shown, especially in emergency situations when thrombectomy fails.

Most of the trials evaluated the safety and performance of the procedure in general or the additionally used stents, Therefore, only limited information on NeuroSpeed® PTA Balloon Catheter-related endpoints alone could be extracted from these publications.

The ten included clinical studies and case series, in which the NeuroSpeed PTA Balloon Catheter was used have quite similar retrospective study designs. All included trials were uncontrolled and had varying numbers of enrolled patients. Indications and location of stenoses are in line with the intended use and indication given by Acandis. Most other literature were case reports (n = 12). Two case series (Bhogal et al. 2022; Guenego et al. 2024) and a case report (Giang et al. 2022) described the use of the NeuroSpeed PTA Balloon Catheter alone, in all other cases it was used together with a stent.

1.5.3.1.5 Summary and conclusion on safety and performance from literature

The purpose of PTA for atherosclerotic occlusion is to achieve long-term patency by mechanical dilatation. The studies applied recognized radiological endpoints (improved patency and perfusion) as well as patient-centered endpoints providing evidence on the clinical results (improved symptoms, recurrent symptoms, adverse neurological events). However, as the NeuroSpeed® PTA Balloon Catheter was mostly described together with the use of a stent, only indirect conclusions on its contribution to the technical and clinical success can be drawn. As the success rates in general were high, it can be concluded that the NeuroSpeed® PTA Balloon Catheter fulfilled its intended use. Additionally, complications related to the NeuroSpeed® PTA Balloon Catheter or the procedure of PTA were low, thus, it can be deemed safe in its intended use.

Chosen endpoints

The most important clinical endpoint to determine the performance of the NeuroSpeed PTA Balloon Catheter with or without the CREDO / CREDO heal / ACCLINO (flex) stent is the rate of vessel lumen patency as well as neurological outcome. Six articles gave the stenosis grade before and after the procedure (Möhlenbruch et al. 2016; Buonomo et al. 2021; Kuršumović et al. 2021; AlMatter et al. 2023; Cohen & Henkes 2023; Pielenz et al. 2024), a further six described it in words (Papa et al. 2020; Capirossi et al. 2022; Krug et al. 2023; Parodi et al. 2023; Ranxha et al. 2023; Falcon et al. 2024). In all cases, patency improved. Two publications described the use of NeuroSpeed PTA Balloon Catheter alone. In one case, the NeuroSpeed was applied for angioplasty of fish-mouthing of the p64MW HPC flow diverter (phenox GmbH, Bochum, Germany) after aneurysm occlusion (Bhogal et al. 2022). In the other case, the NeuroSpeed PTA Balloon Catheter was used to treat a cerebral vasospasm after aneurysmal subarachnoid hemorrhage (Guenego et al. 2024).

Neurological outcome assessed by mRS was unchanged or even improved in 12 of the 22 publications. Favorable functional outcome is defined as mRS ≤ 2.

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

Acandis has been conducting the registry ASSISTENT (AcandiS Stenting of Intracranial STENosis – RegisTry) since May 2016. The study was interrupted and restarted. Recruitment is ongoing until 2025. According to the PSUR, 110 patients have been enrolled meanwhile. A total of 21 AEs were reported of which 16 met the criteria for a SAE. Of those 16 SAEs, three were related to the medical device. No new risks were identified.

So far, 25 patients have been enrolled in the RECHRUT PMCF study. There were nine SAEs and one AE reported until December 2023. No new risks were identified because the study is ongoing.

1.5.3.3 Clinical data from medical device databases

The medical device databases “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States’ Food and Drug Administration as well as the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions were searched for clinical data on the NeuroSpeed® PTA Balloon Catheter (BfArM) and Gateway PTA balloon catheter (MAUDE) during the preparation of the clinical evaluation report. The searches were conducted on August 06, 2024.

BfArM: In the latest search no entries concerning the NeuroSpeed® PTA Balloon Catheter.

MAUDE: In the latest search one entry concerning the similar device Gateway PTA balloon catheter: There was a device problem (leak/splash) which did not affect the patient.

1.5.4 An overall summary of the clinical performance and safety

The clinical literature reflecting the state-of-the-art in treatment of intracranial stenoses with intracranial neurovascular stents combined with intracranial PTA balloon catheters, including the use of the NeuroSpeed® PTA Balloon Catheter, together with the results from the searches in authority-maintained vigilance databases as well as the data collected from the PMCF study on the NeuroSpeed® PTA Balloon Catheter prove the clinical performance and safety of the NeuroSpeed® PTA Balloon Catheter. The reviewed studies provide sound evidence that by using these devices, a successful and safe treatment of intracranial stenoses is feasible. It

could be shown that the combination of NeuroSpeed® PTA Balloon Catheter and CREDO® Stent/ CREDO® heal Stent /ACCLINO® (flex) Stent achieves technical and clinical success rates that are comparable to the state-of-the-art. Technical success could be reached in 92.3 % (ASSISTENT study) and 83.7 – 100 % (literature) of the patients respectively. Clinical success in terms of mRS 0 – 2 was reached in 58 % (ASSISTENT study) and 21 – 100 % (literature) of patients. The overall complication rate was 26.9 % (ASSISTENT study) of patients. From scientific literature this number cannot be directly derived as the complications are described not as depicted as in the study reports.

According to the clinical data presented in the scientific literature, the information gained from the ASSISTENT and RECHRUT studies and PMS as well as the risk analysis, it can be concluded that risks which may be associated with the intended use of the NeuroSpeed® PTA Balloon Catheter constitute acceptable risks when weighed against the benefits to the patient. Further, it can be concluded that for patients carefully selected for this treatment, undesirable side-effects constitute an acceptable risk when weighed against the performance intended by the clinician in charge. The main risks are described and documented in detail in the scientific literature, thus being known to trained professional user. Therefore, by complying with all warnings and precautions, the NeuroSpeed® PTA Balloon Catheter offers an acceptable benefit-risk profile and meets the requirement for an acceptability of side effects and acceptable benefit-risk profile.

Clinically relevant marketing claims in Acandis' brochure and on the website are acceptable claims as they are adequately justified by Acandis.

In conclusion, the NeuroSpeed® PTA Balloon Catheter could be shown to be in compliance with the General Safety and Performance Requirements specified by the Medical Device Regulation (MDR) EU 2017/745.

1.5.5 Ongoing or planned post-market clinical follow-up

Both the ASSISTENT and the RECHRUT studies are still ongoing with planned recruitment until October 2025 and January 2027 respectively.

1.6 Possible diagnostic or therapeutic alternatives

There are treatment alternatives to intracranial stenting. These include medical management, surgery, mechanical thrombectomy and percutaneous intraluminal angioplasty without stenting. For each patient it should be evaluated individually, which treatment option is the

most promising for good neurological outcome. Concluding from the scientific literature, surgery is associated with the least favorable neurologic outcome, whereas mechanical thrombectomy is a standard treatment of acute ischemic stroke caused by large vessel occlusion. PTA is widely applied in arterial stenosis treatment. Balloon angioplasty and/or stenting was feasible in acute large vessel occlusions, resulting in favorable angiographic and clinical outcomes with an acceptable safety profile. However, the outcomes in terms of stroke and death rates vary widely (4 – 40 %) within 30 days of treatment. Restenosis is seen in 24 – 50 % of these patients.

1.7 Suggested profile and training for users

Physicians who have the necessary background knowledge and experience in interventional neuroradiology and stent-assisted percutaneous transluminal angioplasty (PTA).

1.8 Reference to harmonized standards and common specifications applied

Acandis adhered to the following standards, which are listed as harmonized by the European Union, or are the most recent version of the respective standard.

Table 9: Standards adhered to by Acandis

Standard	Title	Revision
EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2001 +AC:2006
EN 868-2	Packaging for terminally sterilised medical devices - Part 2: Sterilization wrap – Requirements and test methods	2017
EN ISO 10555-4	Sterile, single-use intravascular catheters. Balloon dilatation catheters (ISO 10555-4:2013)	2013
EN ISO 10555-1	Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2013 + Amd 1:2017)	2013+ A1:2017
EN ISO 10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
EN ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	2020
EN ISO 10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2009
EN ISO 10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	2021
EN ISO 10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	2018
EN ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008 + Cor 1:2009 + Amd 1:2019)	2008 + AC:2009 +A1:2022

Standard	Title	Revision
EN ISO 10993-5	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2009
EN ISO 10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)	2017
EN ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	2014
EN ISO 10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2022)	2022
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)	2020
EN ISO 11135	Sterilization of health care products – Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014+Amd.1:2018)	2014 +A1:2019
EN ISO 11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	2017
EN ISO 11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)	2017
EN ISO 11139	Sterilization of health care products – Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)	2018
EN ISO 11607-2	Packaging for terminally sterilised medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607- 2:2019)	2020 +A11:2022
EN ISO 11607-1	Packaging for terminally sterilised medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	2020 +A11:2022
EN ISO 11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	2018 + A1:2021
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016 +AC:2018 +A11:2021
EN ISO 14644-5	Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)	2004
EN ISO 14644-4	Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2001)	2001
EN ISO 14644-3	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)	2019
EN ISO 14644-2	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	2015
EN ISO 14644-1	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)	2015
EN ISO 14698-2	Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data TECHNICAL CORRIGENDUM 1	2003/ Cor. 1:2004
EN ISO 14698-1	Cleanroom and associated controlled environments – Biocontamination control - Part 1: General principles and methods	2003

Standard	Title	Revision
EN ISO 14971	Medical devices. Application of risk management to medical devices (ISO 14971:2019)	2019+ A11:2021
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)	2021
EN 17141	Cleanrooms and associated controlled environments - Biocontamination control	2020
EN ISO 20417	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12))	2021
EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)	2015+AC:2015 + A1:2020
EN ISO 80369-7	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)	2021

2 Information for the patient

This part of the SSCP is not deemed necessary for the NeuroSpeed® PTA Balloon Catheter.

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