



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 <i>Article no. long tip (LT) variation:</i> 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 | <ul style="list-style-type: none"> - UMDNS: 17-184 Catheters, angioplasty, balloon dilatation - GMDN 17184 Peripheral angioplasty balloon catheter, basic - EMDN: C010499 Angiography 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) | <p>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).</p> <p>Intended target group: No specific patient populations defined but patients with contraindications are to be excluded.</p> |
| Contraindications and/or limitations | <p>Usage is contraindicated for the following patients:</p> <ul style="list-style-type: none"> - 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. <p>General contraindications in connection with endovascular and / or angiographic treatments must be taken into consideration.</p> <p>No limitations are mentioned in the IFU.</p> |

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 | <p><i>Long tip variation</i> <i>Tip length: 10 mm</i> 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</p> <p><i>Short tip variation</i> <i>Tip length: 4 mm</i> Balloon diameters: 2.0 / 2.5 / 3.0 / 3.5 / 4.0 mm Balloon length: 8 mm / 15 mm</p> |
|--------------|---|

| | |
|------------------|--|
| | Usable length: 155 cm Outer diameter: 2.7 French distal / 3.7 French proximal |
| Sterility | Sterile, EO-Sterilization, 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 NeuroSpeed PTA Balloon Catheter 2000-1, which has been on the market since September 2023, has an additional balloon length of 15 mm. This is now being replaced by the NeuroSpeed PTA Balloon Catheter 2000-2 which is produced by Bavaria Medizin Technologie GmbH (BMT) and Acandis. The NeuroSpeed PTA Balloon Catheter 2000-2 is available in short tip and long tip variant.

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) haemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, Vessel dissection, Vessel perforation, Vessel rupture, Hyperperfusion syndrome, Infection, (Cerebral) ischaemia / infarction, Secondary haemorrhage, Reactions due to radiation exposure, Subarachnoid haemorrhage, 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, Guide wire lumen cannot be flushed, Delamination or degradation of the hydrophilic coating, Particles are introduced in the bloodstream during an angioplasty procedure, Stent delivery and / or withdrawal is not possible)
- 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; Camurcuoglu et al. 2024), 0 – 16 % (Meyer et al. 2020; Stracke et al. 2020a; Stracke et al. 2020b; Naftali et al. 2023; Lin et al. 2024; Dorn et al. 2025), 0 – 40 % (Meyer et al. 2020; Stracke et al. 2020b; Naftali et al. 2023; Camurcuoglu et al. 2024; Lin et al. 2024; Sarshayev et al. 2024; Dorn et al. 2025) respectively. In 13 publications, no complications were observed. There were three device-related complications observed in the ASSISTENT study. 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.
- As there is a risk of subacute thrombosis, vascular complications and / or bleeding when using the PTA balloon catheter, careful patient selection is required.
- 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 or if the packaging has been opened accidentally, 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 resterilize. Reuse, reprocessing or reserialization 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 resterilizing 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 0.37 % since first CE approval and 0,44 % in the current evaluation period (2023-11-01 – 2024-10-31). There are two preventive and / or corrective actions (CAPAs) ongoing from the previous evaluation period that only affected the supplier and there are three CAPAs ongoing from the current evaluation period which also only affected the supplier. The serious incident rate is 0.01 % in the last four years and 0.1 % 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 is available.

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data in 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 x 15 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 x 8 mm with Credo 5 x 20 mm | Critical stenosis Vertebra-basilar transient ischemic attacks | Basilar artery |

| Author | Study design | # of patients | Used devices | Indications | Location of stenosis |
|-------------------------|--|---------------|--|---|---|
| Camurcuoglu et al. 2024 | Clinical study, retrospective analysis | 32 | <ul style="list-style-type: none"> - NeuroSpeed Balloon Catheter with CREDO stents (n = 8) in stenoses 30 – 50 % - Neuroform Atlas stent system (n = 18) in stenoses < 30 % - Coronary balloon-expandable stents (n = 4) in presence of distal ICA or isolated VA V4 stenosis - LVIS stent system (n = 2) - Gateway balloon catheter | Symptomatic intracranial atherosclerotic stenosis | <p>ICA (n = 14), VA (n = 12), MCA (n = 4), BA (n = 2)</p> <p>The CREDO Stent was used in 4 ICA and 4 VA cases.</p> |
| Dorn et al. 2025 | Case series, retrospective analysis | 81 | NeuroSpeed Balloon Catheter with CREDO heal Stent | Rescue stenting of intracranial stenosis | ACA (2.5 %), MCA (50.6 %, M1-, M2- and M3-segment), PCA (6.2 %, P1-, P2-segment), intracranial ICA (14.8 %), BA (18.5 %) and V4-segment (7.4 %) |
| Lin et al. 2024 | Clinical study, retrospective analysis | 29 | <ul style="list-style-type: none"> - NeuroSpeed Balloon Catheter with CREDO Stent (n = 12) - Gateway PTA Balloon Catheter with Wingspan Stent (n = 17) | Rescue stenting or balloon angioplasty of Medium/distal vessel occlusions | M2 segment |
| Ramazanoğlu et al. 2025 | Case series, retrospective analysis | 20 | NeuroSpeed Balloon Catheter with CREDO Stent | Intracranial atherosclerotic disease | MCA (55 %), BA (35 %), ICA (5 %), Vertebral (5 %) |

| | | | | | |
|--------------------------|---|-----|---|--|---|
| Sarshayev et al. 2024 | Case series, retrospective analysis | 216 | <ul style="list-style-type: none"> - NeuroSpeed Balloon Catheter with CREDO (n = 8) - Ultimaster (Terumo Corporation, Tokyo, Japan; n = 135) - Resolute Integrity, Onyx (Medtronic Inc., Santa Rosa, CA, USA; n = 19) - Promus PREMIER (Boston Scientific Corporation, Marlborough, MA, USA; n = 11) - BioMime (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India; n = 1) - Supraflex (Sahajanand Medical Technologies Ltd., Surat, India; n = 1) - Acclino flex (Acandis GmbH, Pforzheim, Germany; n = 67) - Neuroform Atlas (Stryker Corporation, Fremont, CA, USA; n = 12) - Xience Xpedition (Abbott Vascular, Santa Clara, CA, USA; n = 11) - Orsiro (BIOTRONIK SE & Co., Berlin, Germany; n = 11) - Solitaire (Medtronic Inc., Santa Rosa, CA, USA; n = 2) | <p>Stenting of intracranial atherosclerosis with $\geq 70\%$ intracranial artery stenosis</p> | <p>ICA, (54.5 %), MCA (12.3 %), VA (21.2 %), BA (10.4 %), PCA (1.1 %)</p> |
|--------------------------|---|-----|---|--|---|

| Author | Study design | # of patients | Used devices | Indications | Location of stenosis |
|--------|--------------|---------------|--|-------------|----------------------|
| | | | - LEO (Balt Extrusion, Montmorency, France; n = 1) | | |

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 is mandatory to confirm the clinical benefit of endovascular treatment of intracranial stenosis. |
| Nordmeyer et al. 2019 | TICI \geq 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 score 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. |

| Author | Technical success | Pre-procedural stenosis | Post-procedural stenosis | Neurological outcome | Complications | Conclusion on safety and performance |
|-------------------------|-------------------|--|------------------------------|---|--|--|
| 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 remains the optimal choice in medical failure with minimal procedure risk. |
| Camurcuoglu et al. 2024 | 100 % | < 30 – > 50 % (mean 91.7 ± 6.3 %) | Mean 22.1 ± 4.7 % | Clinical success (absence of stroke, TIA or death within 30 days) = 87.5 %. | Ischemic stroke occurred in 6.2 %, hemorrhagic stroke in 3.1 % and death due to widespread cerebellar infarction in 3.1 % of patients. | Endovascular treatment in carefully selected patients provides safe and effective treatment for patients with symptomatic ICAS. No conclusions on the safety or performance of the NeuroSpeed PTA Balloon Catheter itself were drawn. |
| Dorn et al. 2025 | 95.1 % | ASPECTS = 9 (range 5 – 10) 89 ± 9.7 % | 72.8 ± 26 % | Median NIHSS at discharge was 5.7 mRS 0 – 2 after 30 – 280 days was 42 % | Intracranial hemorrhage occurred in 1.2 %, extracranial ICA dissection in 1.2 %, fatal ICH in 1.2 %, minor SAH in 5 %, in-stent thrombosis in 6.1 %, dissection of the target vessel in 2.5 % and vessel perforation in 1.2 % patients Death was observed in 12.3 % | Proofs safety and efficacy of the novel CREDO heal stent system for rescue stenting of patients with LVOs and an underlying ICAD. No direct conclusions on the safety or performance of the NeuroSpeed PTA Balloon Catheter itself were drawn. |
| Lin et al. 2024 | 91.7 % | > 70 % | 81.3 % ± 8.3 % (70 % – 90 %) | Not described | Periprocedural hemorrhage: 12 % with Wingspan and 0 % with CREDO ($p = 1.00$) Silent embolic ischemic lesions on periprocedural on MRI: 76 % with Wingspan and 58 % with CREDO ($p = 0.42$) In-stent restenosis > 50 % after 1 year: 24 % with Wingspan and 17 % with CREDO ($p = 1.0$). | The technical success, safety, and outcomes of the Credo stent system were comparable to those of the Wingspan stent system in the management of severe medically refractory intracranial artery stenosis patients. |

| Author | Technical success | Pre-procedural stenosis | Post-procedural stenosis | Neurological outcome | Complications | Conclusion on safety and performance |
|-------------------------|--|-------------------------|--------------------------|--|--|--|
| Ramazanoğlu et al. 2025 | Not described | Not described | Not described | 90-day-mRS: 0.80 ± 1.06 | None described | Stenting may have a greater role in the secondary prevention of ICAD than the best medical treatment. No direct conclusions on the safety or performance of the NeuroSpeed PTA Balloon Catheter itself were drawn. |
| Sarshayev et al. 2024 | Only described that one stent could not be deployed. | ≥ 70 % | Not described | Worsening of mRS > 2 occurred in four patients | The peri-procedural complication rate including two ischemic stroke-related deaths was 0.7 %. Three patients had immediate thrombosis, one in-stent thrombosis on day 7 and one case of aphasia, another one had a sigmoid and transverse sinus thrombosis. Technical issues comprised one failure of stent deployment due to vessel tortuosity. | The low complication rates observed highlight the potential safety and efficacy of modern endovascular techniques for ICAS treatment. |

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 balloon 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 Neuro-Speed) 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 $\geq 70\%$ 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 siphon stenosis; one month earlier there was a minor stroke with left hemiparesis. | Right carotid siphon |
| 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 \geq 2b: 29.6 % | - | mENR: n = 19 mRS \leq 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 \geq 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-procedural 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) Intragenic 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 et al. 2023 | 100 % | Sub-occlusion | Restoration to normal flow time | mRS 0 after 3 months | None | The prompt neuro-sonographical 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 | 41 | 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 %). |

| Author | Study design | # of patients | Used devices | Indications | Location of stenosis |
|-----------------------|--------------|---------------|--|--------------------|----------------------|
| Gasparini et al. 2024 | Case report | 1 | NeuroSpeed Balloon Catheter 3 mm with Atlas 4.5 mm (Stryker) pITA (Phenox) | Calcified stenosis | Basilar artery |

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. |
|------------------------|----------------------------------|---|--|--|--|---|

| Author | Technical success | Pre-procedural stenosis | Post-procedural stenosis | Neurological outcome | Complications | Conclusion on safety and performance |
|-----------------------|-------------------|-------------------------|--------------------------|----------------------|--|---|
| Gasparini et al. 2024 | Not described | Not described | Resistant stenosis | Not described | Possibility of dissection and vessel rupture mentioned | Shockwave intra-vascular lithotripsy of calcified stenoses needs further investigation. No conclusions on the safety or performance of the NeuroSpeed PTA Balloon Catheter itself were drawn. |

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 15 included clinical studies and case series, in which the NeuroSpeed PTA Balloon Catheter was used have quite similar retrospective study designs. All trials included 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 = 13). 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. Nine articles gave the stenosis grade before and after the procedure (Möhlenbruch et al. 2016; Buonomo et al. 2021; Kuršumović et al. 2021; AIMatter et al. 2023; Cohen & Henkes 2023; Camurcuoglu et al. 2024; Lin et al. 2024; Pielenz et al. 2024; Dorn et al. 2025), 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 at least 2026. According to the PSUR, 128 patients have been enrolled meanwhile. A total of 21 AEs were reported in the interim analysis of 50 enrolled patients. 16 of the reported AEs met the criteria for SAE. Of those 16 SAEs, three were related to the medical device. No new risks were identified.

So far, 65 patients have been enrolled in the RECHRUT PMCF study. There were twelve SAEs and two AEs reported. One SAE was defined as procedure and product related. 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 July 08, 2025.

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

MAUDE: In the latest search nineteen entries concerning the similar device Gateway PTA balloon catheter: The hit did not yield any unknown complications for intracranial PTA balloon catheters.

1.5.4 An overall summary of 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, 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 end in 2026 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 | 2024 |
| 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 10555-4:2023) | 2023 |
| EN ISO 10555-1 | Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2023) | 2023 |
| EN ISO 10993-10 | Biological evaluation of medical devices – 2023 Part 10: Tests for skin sensitisation. (ISO 10993-10:2021) | 2023 |
| 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 + Amd 1:2022) | 2020 + A1:2023 |
| EN ISO 10993-17 | Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2023) | 2023 |

| Standard | Title | Revision |
|-----------------|---|-------------------------------|
| 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 + Amd1:2019) | 2008 + AC:2009 +A1:2022 |
| 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+Amd1:2018) | 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 + Amd1:2024) | 2018 + A1:2024 |
| EN ISO 11607-2 | Packaging for terminally sterilised medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607- 2:2019 + Amd1:2023) | 2020 +A1:2023 |
| 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 + Amd 1:2023) | 2020 +A1:2023 |
| 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 + Amd1:2021) | 2018 + A1:2021 |
| EN ISO 11737-2 | Sterilization of health care products – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019) | 2020 |
| 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 14644-4:2022) | 2022 |
| EN ISO 14644-3 | Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019) | 2019 |

| Standard | Title | Revision |
|-----------------|---|---------------------------|
| 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 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 |
| EN ISO 80369-1 | Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1 :2018) | 2018 |
| EN ISO 80369-20 | Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2024) | 2024 |

2 Information for the patient

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

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