ENGINEERING STROKE SOLUTIONS

Summary of safety and clinical performance:

NeuroSlider®

Acandis GmbH

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

Identifier: 2201

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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 NeuroSlider®.

The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9 of the Medical Device Coordination Group.

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

1.1 Device identification and general information

Device trade name(s)	**NeuroSlider®**	
	Model	Article number
	NeuroSlider® 17	01-000272
	NeuroSlider® 21	01-000273
	NeuroSlider® 27	01-000274
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	426065033NeuroSlider93	
Medical device nomenclature	– EMDN: C010499 (angiography and hemodynamics devices – other) – UMDNS: 17-846 (catheters, intravascular, guiding) – GMDN: 10691 (Intravascular microflow catheter)	
Class of device	Class III medical device, as defined in Medical Device Regulation (MDR) EU 2017/745, Annex VIII, rule 7, bullet point 2	
Year of first CE certificate	NeuroSlider® was first CE-marked according to MDD in July of 2013	
Authorized representative	Not applicable	
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297)	

1.2 Intended use of the device

Intended purpose	The NeuroSlider® is intended for the controlled selective infusion of medically prescribed therapeutic or diagnostic agents and the delivery of devices (e.g. stents).
Indication(s)	The NeuroSlider® is intended for the diagnosis or endovascular treatment of peripheral and cerebrovascular disease.
Targeted population(s)	Intended user: Physicians who have the required background knowledge and experience in the field of interventional radiology.

	Patient target group: No special patient populations defined but patients with contraindications are to be excluded.
Contraindications and/or limitations	The NeuroSlider® is contraindicated for patients in whom angiography reveals 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.

1.3 Device description

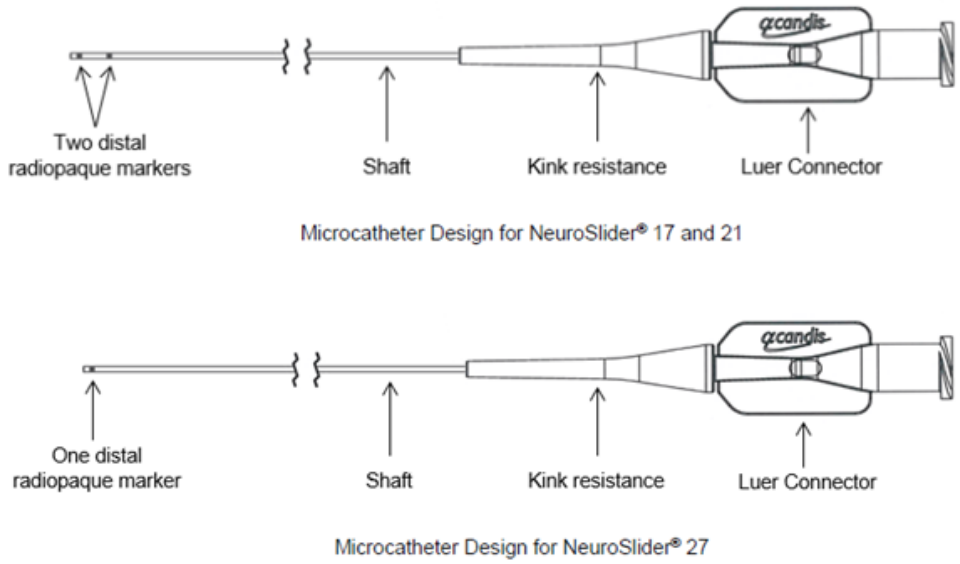
1.3.1 Description of the NeuroSlider®

The NeuroSlider® is a single-lumen, distally open microcatheter, which is inserted into the blood vessels using a controllable delivery system. At its proximal end, the NeuroSlider® is equipped with a standard Luer connection for attaching accessories. The rigidity of the microcatheter shaft decreases in a distal direction, thus making it possible to easily reach distal and tortuous vessel sections. One or two x-ray markers at the distal end increase visibility during fluoroscopy. The outer surface of the microcatheter has a hydrophilic coating for improved lubricity. The microcatheter tip can be shaped. The sizes are specified on the label, see Table 1.

There is no hydrophilic coating at the very proximal end to facilitate handling.
The microcatheter is provided sterile for single use only. The Acandis NeuroSlider® is compatible with standard guiding catheters/sheaths and guide wires.

Application principle
Insertion of the microcatheter 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 controlled selective infusion of medically prescribed therapeutic or diagnostic agents and for the delivery of devices (e.g. stents).

Table 1: Characteristics of the Acandis NeuroSlider®



	ID (inch)	OD dist. / prox. (French)	Usable length (cm)	Tip shape	Tip marker
NeuroSlider 17 # 01-000272	0.0165	1.9 / 2.1	155	Straight (shapeable)	2
NeuroSlider 21 # 01-000273	0.021	2.4 / 2.5	155	Straight (shapeable)	2
NeuroSlider 27 # 01-000274	0.027	3.0 / 3.1	155	Straight (shapeable)	1

1.3.2 Previous generations

The first generation of NeuroSlider® has been on the market since July 2013 and the second generation since March 2018. This second generation received CE mark on December 17, 2023 under the provisions of the MDR.

1.3.3 Accessories

Guide wire, RHV (rotating hemostatic valve), syringe, tip shaping mandrel, guiding catheter/sheath.

If shaping of the catheter tip desired, shaping is possible by the use of steam and tip shaping mandrel.

1.3.4 Combination with other devices

Laser-cut and braided devices, e.g appropriate Acandis stents, compatibility is defined on device label.

1.4 Risks and warnings

1.4.1 Residual risks and undesirable effects

According to the risk management, after risk-mitigating measures, there are no unacceptable residual risks. As adverse effects or injuries may occur peri-interventionally, Acandis specifies the following possible complications and undesirable side effects for their NeuroSlider®:

Possible complications, among others, include the following:

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Pseudo)aneurysm, Rupture of or bleeding from aneurysm, (Intracerebral) haemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, (Arteriovenous) fistula, Vessel dissection, Vessel perforation, Vessel rupture, (Abrupt) vessel occlusion or thrombosis, Infection, (Cerebral) ischaemia/infarction, Secondary haemorrhage, Reactions due to radiation exposure, Subarachnoid haemorrhage, Thromboembolic event/stroke, Vasospasm)
- General complications in connection with antiplatelet agents/anticoagulants, anaesthetics and contrast agents (e.g. Renal insufficiency)
- Complications in connection with vessel entry (e.g. Haematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during catheter delivery (e.g. Delamination or degradation of the hydrophilic coating, Catheter lumen cannot be flushed, Catheter breakage, Incorrect catheter placement, Catheter cannot be withdrawn, Catheter bending, Catheter compression, Catheter damage, Particles enter the bloodstream during the intervention, 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, Aneurysm perforation, (Distal) embolization including previously unaffected areas, Local inflammatory reaction, Systemic immune response)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

As no complications related to the use of the NeuroSlider® were reported by the identified and reviewed publications stating the devices' use, no quantitative data on the occurrence rate of complications with the NeuroSlider® could be drawn (chapter 1.5.3.1). Concerning PMCF measures, clinical data on the NeuroSlider® were collected by two finished studies (see chapter 1.5.3.2).

1.4.2 Warnings and precautions

Warnings

- The NeuroSlider® should be applied only by physicians who have the necessary background knowledge and the required experience in the field of interventional radiology.
- No specific patient populations have been defined but patients with contraindications are to be excluded.
- Before use, the product needs to be carefully checked to ensure there is no transportation damage. Under no circumstances should damaged or kinked microcatheters be used.
- The microcatheter is intended for short-term use in a surgical environment for no longer than 24 hours. To prevent infections, it must be ensured that the hygiene standards are complied with and monitored throughout the entire period of use. If used for longer periods, bacterial colonisation of the microcatheter may occur.
- The infusion pressure must not exceed the values specified in the flow table. Exceeding these values may cause cracks/ruptures in the microcatheter. After using contrast agents, ensure that the microcatheter is adequately flushed.
- If the infusion flow is interrupted, no attempt must be made to correct this by applying a high pressure infusion. Instead, the microcatheter must be removed in order to determine what caused the blockage or it must be replaced by a new microcatheter.
- On no account whatsoever should you continue advancing the microcatheter if you encounter resistance without first finding out the cause as otherwise you could damage the microcatheter or perforate a vessel.
- intraluminal instruments must never be moved against resistance within the microcatheter. The application of too much force against resistance may lead to damage (e.g. cracks/ruptures) to the instrument or injury to the vessel wall.
- Compatibility of the NeuroSlider® with liquid embolisates cannot be guaranteed. It is not suitable for liquid embolisates based on cyanoacrylate and dimethyl sulfoxide (DMSO). The microcatheter may adhere to the embolisation material.
- 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 product 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 expiry date printed (see 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 NeuroSlider® must be kept hydrated to maintain its lubricious properties.
- Once the NeuroSlider® is inside the body, it should only be moved under fluoroscopy. Do not remove the microcatheter without checking how the tip reacts.
- The manufacturers' instructions for use should be observed for all devices and substances used together with the NeuroSlider®.

1.4.3 Other relevant aspects of safety

The total complaint rate and the total incident rate since market release are low with 0.15 % and 0.019 %, respectively.
The medical benefit continues to outweigh the residual risk.
There were also no relevant hits on unduly or unknown risks of the NeuroSlider® in the databases of competent authorities.

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

1.5.1 Summary of clinical data related to equivalent devices

No clinical data from equivalent devices from other manufacturers were used for the clinical evaluation. As the variants of the NeuroSlider® have an identical clinical application, principle of operation and material, the clinical evaluation was conducted by pooling the clinical data of the different variants and evaluating them together.

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

Relevant clinical data on the NeuroSlider® are sourced from published clinical references (identified by a systematic literature search in relevant electronic databases). The references for these articles can be found in the bibliography at the end of the document. For the recent CER revision 12, a total of 32 publications encompassing 17 clinical studies and 15 case series gathering real-world data on the application of the NeuroSlider® in its intended use and regular clinical practice from which the safety and performance of the NeuroSlider® can be deduced were evaluated. In the identified and reviewed clinical literature, a total of roughly 2,659 NeuroSlider® microcatheters with different inner diameters (0.017”, 0.021”, 0.027”) were used in just as many patients for the delivery of different neurovascular stents as well as other catheters or the aspiration of blood samples.

The authors did not report any performance or safety issues directly related to the use of the NeuroSlider® microcatheters. It can thus, be stated that all NeuroSlider® microcatheters demonstrated proper safety and performance as intended by the Acandis.

The identified and reviewed publications stating the use of NeuroSlider® are summarized in the following table.

Table 2: Summary of clinical data from publications stating the use of NeuroSlider®. References in alphabetical order. ID, inner diameter of the used NeuroSlider® variant; n.s., not specified

Author (et al.), Year	Patient/Device №	ID [inch]	Device-related safety/ performance statements/ issues
Beuing O, 2020	32/34	0.0165	none
Brassel F, 2016	16/16	0.0165	none
Daglioglu E, 2020	146/146	0.027	none
Dange NN and Roy JM, 2022	13/13	0.021/0.027	none
Dietrich P, 2020	85/48	0.0165	none
Feick J, 2023	366/366	0.0165	none
Fujimura S, 2022	23/23	0.027	none
Goertz L, 2019	59/59	0.027	none
Goertz L, 2020a	131/131	0.0165	none
Goertz L, 2020b	12/12	0.027	none
Goertz L, 2023	1/1	0.027	none
Goertz L, 2024a	26/26	0.027	none
Goertz L, 2025	<60/<60	0.027	none
Ivan VL, 2025	118/118	0.021	none

Author (et al.), Year	Patient/Device №	ID [inch]	Device-related safety/ performance statements/ issues
Kabbasch C, 2015	14/14	0.0165	none
Kallenberg K, 2016	119/119	0.027	none
Karhi S, 2018	199/199	0.021	none
Kaschner M, 2020	33/33	0.021	none
Kaschner MG, 2019	40/40	0.021	none
Kollikowski AM, 2020	151/151	0.021/0.027	none
Kollikowski AM, 2024	132/132	0.021/0.027	none
Kraus B, 2018	42/42	0.027	none
Ozdemir G, 2026	48/48	0.0165/0.021/0.027	none
Pflaeging M, 2021	19/19	0.0165	none
Schob S, 2026	<36/<36	0.027	none
Starke A, 2024	105/105	0.0165/0.021	none
Strinitz M, 2021	58/58	0.0165/0.021	none
Topcuoglu OM, 2018	7/7	0.027	none
Tureli D, 2016	47/47	0.0165	none
Vogt ML, 2022	298/298	0.0165/0.021	none
Weiss D, 2022	174/174	0.0165/0.021	none
Zaeske C, 2020	49/49	0.027	none
Total	**~ 2,659 / ~ 2,659**		

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

Conclusions on the NeuroSlider®'s safety and performance have been drawn from completed studies i.e., "REVISAR" (NCT04479020) and "HYBRID" (NCT04457479). These PMCF studies deal with the APERIO Hybrid (17/21) Thrombectomy Device used together with the NeuroSlider®. The APERIO Hybrid (17/21) Thrombectomy Device is intended for use in combination with the NeuroSlider®, the only microcatheter tested for compatibility with these devices (as per IFU).

In the course of the REVISAR PMCF study a NeuroSlider® was used in 31 cases (26.0 %). For 22 patients of those no sizes were documented, the NeuroSilder 17 and NeuroSlider® 21 were used in 7 and 2 patients, respectively. No adverse events or serious adverse events related to the study device and/or the NeuroSlider® occurred.

During the HYBRID PMCF study a NeuroSlider® was applied in 64 patients (37 %). The NeuroSlider® 17 was used in 5 of those cases (7.8 %), the NeuroSlider® 21 in 59 cases (92.2 %). No adverse events or serious adverse events related to the study device and/or the NeuroSlider® occurred.

Clinical data from the PMCF studies REVISAR and HYBRID confirm that the NeuroSlider® demonstrates a favorable clinical performance and safety profile when used in combination with devices of the APERIO stent retriever family in the treatment of acute ischemic stroke. Across both studies, the NeuroSlider® was applied in a total of 95 patients (n = 31 in REVISAR and n = 64 in HYBRID), representing between 26 % and 37 % of the respective study

populations. The use of the NeuroSlider® facilitated successful thrombectomy procedures in both distal and medium vessel occlusions without any device-related adverse events or serious adverse events. These results are consistent across different NeuroSlider® sizes (17 and 21), and no safety concerns or device malfunctions were reported. The overall clinical and technical outcomes of the studies-characterized by high rates of successful recanalization (mTICI ≥ 2b in > 84 % of patients), favorable functional outcomes at 90 days (mRS ≤ 2 in 68 - 79 % of patients), and absence of symptomatic intracranial hemorrhage - support the safe and effective clinical performance of the combined use of the APERIO device family with the NeuroSlider®. In summary, the available PMCF data provide sufficient clinical evidence that the NeuroSlider® performs as intended under routine clinical conditions and does not pose any additional or unforeseen risks to patients. The results confirm that the clinical benefits of the device continue to outweigh the residual risks, and no corrective or preventive actions are required at this time.

1.5.3.3 Clinical data in medical device databases

The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions and the medical device registries “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States’ Food and Drug Administration were searched for clinical data on

- the NeuroSlider®,
- the similar Rebar 14 / 18 / 27 (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA) as well as
- the device group of intravascular microflow catheters (microcatheters)

The most recent search was conducted on April 1, 2026 in the BfArM and the MAUDE database. The period searched in the MAUDE database encompassed January 16, 2024 to April 7, 2025.

BfArM: No records dealing with the NeuroSlider® under evaluation and the Rebar Reinforced Micro Catheter (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA) as representative of the device group of Intravascular microflow catheter (microcatheter) could be retrieved from recent BfArM database research. For the device group of microcatheters no new database records could be identified in the current database search. Previous relevant hits deal with device incompatibilities, device coating damage, adhesive remains in the working channel, failed endotoxin testing and labeling issues

MAUDE: Since the previous search in April 2025 various new database entries dealing with the Rebar were added to the MAUDE database. The records on death events report that the

adverse event was without identified device or use problem. Similarly, also the majority of database records reporting injuries state that adverse events were without identified device or use problem. Reported patient problems for death and injury events report already known and no undue complications.

TPLC report: The TPLC product code report for the product code KRA *(i.e., catheter, continuous flush)* from 2021 until the date of search i.e., April 1, 2026 revealed mostly "physical resistance / sticking" and "no clinical signs, symptoms or conditions as the most prominent device and patient problems, respectively. The TPLC product code report further revealed no device and patient problems that are not already known from the current literature. The increase in the number of reports and events over the years indicates that the device group is becoming more widely used in everyday clinical practice what is associated with a corresponding increase in the number of complications.

Conclusion: In general, the survey of the databases did not reveal any undue or so far unknown emerging device- or procedure-related risks associated with the use of the NeuroSlider®, the similar Rebar 14 / 18 / 27 microcatheter or the device group of microcatheters. There is no allusion to an unfavorable risk profile of microcatheters in routine clinical use.
The NeuroSlider® under evaluation and the similar Rebar 14 / 18 / 27 microcatheter (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA) as representative of the device group of Intravascular microflow catheter (microcatheter) as well as the whole device group of microcatheters appear to be effective and safe for their intended purpose. Acandis has included the potential device- and procedure-related complications in the instructions for use of the NeuroSlider®.

1.5.4 An overall summary of the clinical performance and safety

The clinical literature reflecting and summarizing the state-of-the-art in selective infusion as well as device deployment (e.g., stents, coils) into peripheral and cerebral vessels using intravascular radiological microflow catheters, publications stating the use of the NeuroSlider® and the similar Rebar microcatheter, together with the results from the searches in authority-maintained medical device vigilance databases as well as the data collected from PMS and PMCF on the NeuroSlider® devices prove the clinical performance and safety of the NeuroSlider® and the generic device group of intravascular microflow catheters in general. The diagnostics or treatment of peripheral and cerebrovascular diseases that can be treated endovascularly e.g., intracranial aneurysms and ischemic stroke, by the selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by

intravascular microflow catheters (microcatheters) are commonly used and widely accepted clinical methods as evidenced by e.g., several international guidelines. There are studies describing different techniques for the use of microcatheters. E.g. their performance is evaluated in y-stenting as well as the rendezvous wire or kissing wire technique. They all deemed the use of microcatheters as safe and effective in various indications. Therefore, the indications, contraindications, specific clinical features as well as possible complications related to the use of the evaluated devices can assumed to be known to trained medical staff performing endovascular interventions. The reviewed clinical literature on the state-of-the-art in selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters) and the literature including clinical data on the use of the NeuroSlider® provide sound evidence that by using intravascular microflow catheters in general and the NeuroSlider®, in particular, successful and safe infusion of therapeutic or diagnostic agents or devices (e.g., different stents and coils) is feasible. It could be shown that the NeuroSlider® meets the acceptance criteria for the established performance parameter of technical success and is, regarding performance, a state-of-the-art device. Hence, the Acandis NeuroSlider® is suitable for its intended purpose of controlled selective infusion of medically prescribed therapeutic or diagnostic agents and the delivery of devices (e.g. stents) into peripheral and cerebral vessels. Thus, it can be concluded that the NeuroSlider® achieves the performances intended by Acandis and meets the requirement for performance.

Microcatheters are applied minimally invasively, circumventing the risks of open surgery. Data from clinical literature show that the use of microcatheters in the selective infusion, as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels, is a safe and the method that does not pose an unduly high risk for the patient and the risk profile of intravascular microflow catheters has been thoroughly characterized. However, complications associated with the selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters) cannot be ruled out completely. The main risks associated with the NeuroSlider®'s use and microcatheters in general are described in detail in the medical scientific literature summarizing and reflecting the state-of-the-art in selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters), thus being known to the professional user.

These potential complications, identified from the clinical literature, that can occur using intravascular microflow catheter encompass the general complications of cerebral embolization (hemorrhage and ischemia, neurological deficits, stroke and death), trapping of microcatheter, microcatheter rupture / breakage, arterial perforation/dissection/rupture,

aneurysm perforation/rupture, minor complications (hematoma, pain lasting a day due to puncture site oppression) and angiography-related complications (sedation/anesthesia-related risks and arterial spasm). In the evaluated literature stating the use of the NeuroSlider®, there were no reports on technical and clinical complications related to the NeuroSlider®. It could be shown that the NeuroSlider® meets the acceptance criteria for the established safety parameters and is, regarding safety, a state-of-the-art device.

No evidence on unduly or unknown risks emanating from the NeuroSlider® was identified. Warnings and contraindications, as well as complications, are addressed in the instructions for use. The risks identified within the scope of the risk management process are consistent with the risks addressed in the instructions for use and identified in the clinical literature. Moreover, the active risk management implemented by Acandis for the NeuroSlider® reduced all unacceptable risks to acceptable risks and the residual risks are reduced as far as possible. In the risk management, Acandis summarized that the residual risks are reduced as far as possible. Based on this result, the product is safe for treatment. The clinical experiences, market surveillance data, literatures of the show that the considerable benefits provided to the patient outweigh the residual risk. Therefore, currently, no open questions on the safety of the device arise from the risk management.

Overall, it can be stated that procedural and product-specific risks, corresponding warnings and precautions are adequately provided to the professional user in order to reduce the frequency of the aforementioned potential complications. The basic design, as well as the material used for the devices, have been successfully applied for several years. The NeuroSlider® was subjected to various pre-clinical and laboratory test reports e.g., biocompatibility according to (harmonized) standards with successful results. Thus, the NeuroSlider® meets the requirement for safety.

According to the clinical data presented in the scientific literature, the information gained from PMS including PMCF measures as well as the risk analysis, it can be concluded that risks which may be associated with the intended use of the NeuroSlider® 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 professional user in charge. The main risks are described and documented in detail in the scientific literature, thus being known to the trained professional user. The clinical benefit is achieved and the device-specific risks correspond to the state-of-the-art. Therefore, by complying with all warnings and precautions, the clinical benefit continues to outweigh the residual risks and the NeuroSlider® offers an acceptable benefit-risk profile and meets the requirement for the acceptability of side effects and acceptable benefit-risk profile.

The regular PMS data show very low complaint and incident rates. Since market launch, the following complications were recorded for the NeuroSlider®:

- (Significant) delayed treatment: 0.098 %
- Impaired blood flow and/or neurological deficits 0.005 %
- Infection: 0.009 %
- N/A (not product related): 0.094 %
- Vascular Trauma: 0.005 %

Acandis' performance and safety-related claims concerning the NeuroSlider® can be adequately justified by usability tests and PMS data.

In conclusion, the Acandis NeuroSlider® could be shown to be in compliance with the considered relevant General Safety and Performance Requirements (GSPRs) as specified by the Medical Device Regulation (MDR) EU 2017/745. The safety and performance of the NeuroSlider® can be confirmed.

1.5.5 Ongoing or planned post-market clinical follow-up

Conclusions on the NeuroSlider® (DLC)'s performance and safety have been drawn from completed studies i.e., the "REVISAR" (NCT04479020) and "HYBRID" (NCT04457479) as well as the ongoing "REheal" study (NCT05543447), all dealing with the APERIO® Hybrid (17/21) Thrombectomy Device or the DERIVO® 2heal Embolisation Device. The latter are intended for use in combination with the NeuroSlider® (DLC), the only microcatheter tested for compatibility with these devices (as per IFU; see also chapter 1.5.3.2).

1.6 Possible diagnostic of therapeutic alternatives

The **conventional open surgical approach** was identified as alternative to the **endovascular diagnostics or treatment** of peripheral and cerebrovascular diseases by the infusion and delivery of therapeutic agents and devices using microcatheters.

The endovascular intervention technique has gained prominence in the treatment of intracranial aneurysms due to its minimal invasiveness and shorter recovery time (Liu C et al., 2023). In case of intracranial aneurysms, for instance, this alternative is clipping that requires craniotomy, an invasive surgery of the brain, after which a neurosurgeon embeds a clip along the aneurysm neck to block it from normal circulation. Clipping involves serious inherent risks to the patient. Also, clipping is not always feasible because of the inaccessible region of the aneurysm in the brain or patients with high risk for surgery because of age or related medical cases. Due to these limitations of clipping, endovascular treatment without open surgery has

become an attractive option (Karadeli HH and Kuram E, 2023). Hybrid approaches of surgical and endovascular treatment techniques are also described (Gross BA et al., 2017).

1.7 Suggested profile and training for users

The NeuroSlider® may only be used by physicians who have the required background knowledge and experience in the field of interventional radiology.

1.8 Reference to harmonized standards and common specifications

Mnemonic	Number	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	868-5	Packaging for terminally sterilized medical devices Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	2018
EN	868-9	Packaging for terminally sterilized medical devices Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods	2018
EN ISO	10555-1	Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2023)	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
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	10993-10	Biological evaluation of medical devices - Part 10: Tests for skin sensitisation (ISO 10993-10:2021)	2023
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
EN ISO	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2009/A11:2025
EN ISO	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017+Amd 1:2025)	2017+A1:2025

Mnemonic	Number	Title	Revision
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+Amd 1:2024)	2018+A1:2024
EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019+Amd 1:2023)	2020+A1:2023
EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019+Amd1:2023)	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 + Amd 1:2021)	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 14644-5:2025)	2025
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
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

Mnemonic	Number	Title	Revision
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 information to be supplied by the manufacturer - 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+COR1:2016+A1:2020)	2015+AC:2015+ A1:2020
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	80369-7	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	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (ISO 80369-20:2024)	2024

Acandis also adhered to several ISO standards and internal standards during the pre-clinical and laboratory testing of the NeuroSlider®.

2 Information for the patient

This part of the SSCP is not deemed necessary for the NeuroSlider®.

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