ENGINEERING STROKE SOLUTIONS

Summary of Safety and Clinical Performance:

NeuroSlider® DLC

Acandis GmbH

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

Identifier: 2200

Table of contents

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 DLC.

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 DLC, 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 17 DLC (DLC 1.9F)** # 01-000282 (155 cm) / # 01-000283 (160 cm) / # 01-000284 (167 cm) – **NeuroSlider 21 DLC (DLC 2.5 F)** # 01-000292 (155 cm) / # 01-000293 (160 cm) / # 01-000294 (167 cm) – **NeuroSlider 27 DLC pro (DLC pro 3F)** # 01-000277 (155 cm) – **NeuroSlider 27 DLC (DLC 3F)** # 01-000276 (155 cm) – **NeuroSlider 39 DLC (DLC 4F)** # 01-000262 (125 cm) / # 01-000263 (135 cm) / # 01-000264 (145 cm) – **NeuroSlider 52 DLC pro (DLC pro 5F)** # 01-000261 (145 cm) / #01-000260 (135 cm) / # 01-000259 (125 cm) / # 01-000258 (115 cm) / # 01-000257 (105 cm) – **NeuroSlider 52 DLC (DLC 5F)** # 01-000256 (145 cm) / # 01-000255 (135 cm) / # 01-000254 (125 cm) / # 01-000253 (115 cm) / # 01-000252 (105 cm)
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	426065033NeuroSliderDLC7Z
Medical device nomenclature	UMDNS: 17-846 (catheters, Intravascular, guiding) GMDN: 10691 (Catheters, vascular, microflow) EMDN: C010402020380 (embolisation devices - accessories
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 DLC was first CE-marked according to MDD in 2019
Authorized representative	not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297).

1.2 Intended use of the device

Intended purpose	The NeuroSlider DLC 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 DLC is intended for the diagnostics or treatment of peripheral and cerebrovascular diseases that can be treated endovascularly.
Targeted population(s)	Intended user The NeuroSlider DLC may only be used by 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.
Contra-indications and/or limitations	The NeuroSlider DLC is contraindicated for patients who present in the angiography with anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity. The NeuroSlider 52 DLC and the NeuroSlider 52 DLC pro are contraindicated for patients whose vessels have a degree of stenosis higher than 80 %. General contraindications in connection with endovascular and/or angiography treatments must be taken into consideration No limitations are mentioned in the IFU

1.3 Device description

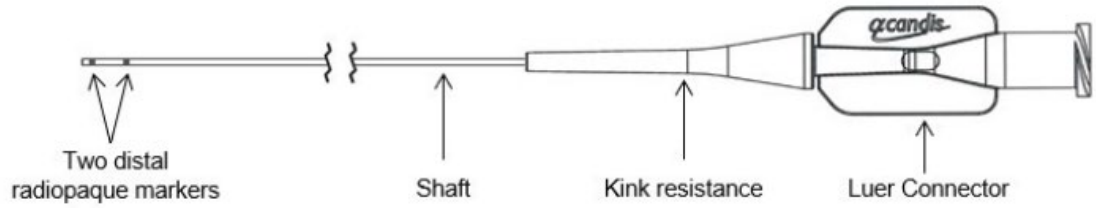
1.3.1 Description of the NeuroSlider

The NeuroSlider DLC is an endhole, single lumen catheter, which is introduced into the blood vessel via a steerable delivery system. At its proximal end, the NeuroSlider DLC is equipped with a standard Luer connector for the attachment of accessories. The rigidity of the catheter shaft decreases distally, enabling easy access of distal and tortuous vessel segments. One or two radiopaque markers on the distal end facilitate visibility under fluoroscopy. The outer surface of the catheter has a hydrophilic coating for improved lubricity. The catheter tip is shapeable. The sizes are specified on the label.
The catheters are provided sterile for single use only. The Acandis NeuroSlider DLC is compatible with standard guiding catheters/sheaths and guide wires.

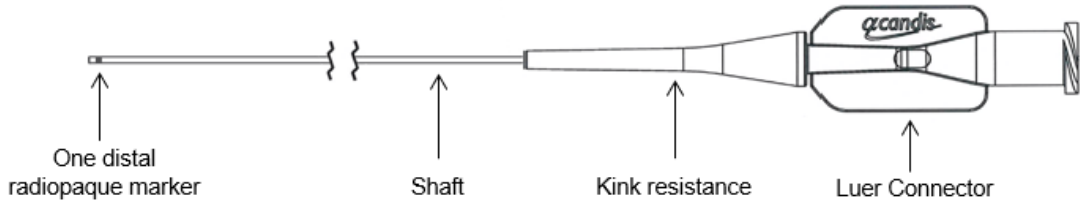
Application principle: Insertion of the catheter using a suitable guide wire and appropriate accessories (such as guide catheter, sheath, hemostatic valves, infusion bags, etc.) to safely reach the target zone for controlled selective infusion of medically prescribed therapeutic or diagnostic agents and for the delivery of devices (e.g. stents)

Table 1: Characteristics of the NeuroSlider DLC, ID: inner diameter, OD: outer diameter

NeuroSlider® 17 / 21 DLC



NeuroSlider® 27 / 39 / 52 DLC,
NeuroSlider® 27 / 52 DLC pro



	ID (inch)	OD dist. / prox. (French)	Usable length (cm)	Tip shape	Tip marker
NeuroSlider 17 DLC	0.0165	1.9 / 2.3	167, 160, 155	Straight (shapeable)	2
NeuroSlider 21 DLC	0.021	2.3 / 2.6	167, 160, 155		
NeuroSlider 27 DLC	0.027	3.0 / 3.1	155		1
NeuroSlider 27 DLC pro	0.027	3.0 / 3.1	155		
NeuroSlider 39 DLC	0.039	4.0 / 4.1	145, 135, 125		
NeuroSlider 52 DLC	0.052	5.0 / 5.1	145, 135, 125, 115, 105		
NeuroSlider 52 DLC pro	0.052	5.0 / 5.1	145, 135, 125, 115, 105		

1.3.2 Previous generations

The previous generation of the NeuroSlider DLC was the NeuroSlider 2F/2.5F/3F, first CE approval according to MDD in July 2013.

1.3.3 Accessories

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 DLC:
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, Thromboembolic event/stroke, Subarachnoid haemorrhage, Vasospasm, Intoxication)
- General complications in connection with thrombocyte aggregation inhibitors/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. Catheter breakage, Incorrect catheter placement, Catheter cannot be withdrawn, Catheter bending, Catheter collapses near tip, Catheter compression, Catheter damage, Therapeutic or diagnostic aids cannot be used, Delayed treatment, Target area inaccessible or cannot be accessed safely)
- Other complications in connection with the catheter (e.g. Allergic reactions to the catheter material, Aneurysm perforation, (Distal) embolisation including previously unaffected areas)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

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

1.4.2 Warnings and precautions

Warnings

- The NeuroSlider DLC may only be used by physicians who have the required background knowledge and experience in the field of interventional radiology.
- No special patient populations defined but patients with contraindications are to be excluded.
- Before use, the NeuroSlider DLC must be carefully checked to ensure there is no transportation damage. Under no circumstances should damaged or kinked catheters be used.
- The infusion pressure must not exceed the values given in the flow rate table. Exceeding these values may cause cracks/ruptures in the catheter. After using contrast agents, ensure that the catheter 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 catheter must be removed in order to determine what caused the blockage, or it must be replaced with a new catheter.
- 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 or injury of the vessel wall.
- Compatibility of the NeuroSlider DLC with liquid embolisates cannot be guaranteed. It is not suitable for liquid embolisates based on cyanoacrylate and dimethyl sulfoxide (DMSO). The catheter may adhere to the embolization 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 NeuroSlider DLC is provided sterile and for single use only.
- In case of damage to the sterile barrier, the system must not be used. If any damage is visible, please contact your Acandis representative.
- Do not use the NeuroSlider DLC after the expiration date printed on the label.
- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise structural integrity of the device and/or lead to device 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 NeuroSlider DLC must be kept hydrated to maintain its lubricious properties.

- Once the NeuroSlider DLC is inside in 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 devices and substances used together with the NeuroSlider DLC.

1.4.3 Other relevant aspects of safety

Since market entry in May 2019, the total complaint rate is 0.28 %, and the total incident rate is 0.02 %. The NeuroSlider DLC has demonstrated that compliance remains. The medical benefit continues to outweigh the residual risk.

There were also no hits on unduly or unknown risks of the NeuroSlider DLC 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 of equivalent devices from other manufacturers were used for the clinical evaluation. As the variants of the NeuroSlider/NeuroSlider DLC 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

It has to be noted that publications stating the use of NeuroSlider family devices are also reviewed as it is expected that for the NeuroSlider DLC no or only very few publications will be identified within the scope of literature search. This is justified as the technical differences between NeuroSlider and NeuroSlider DLC devices are negligible and do not have an impact on their clinical application. Hence, clinical data are interchangeable i.e., clinical data on the NeuroSlider device family gained from literature were also used for the evaluation of safety and performance of the NeuroSlider DLC. The NeuroSlider DLC is optimized for the delivery of braided stents.

Relevant clinical data on the NeuroSlider family devices and thus, the NeuroSlider DLC 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 09, a total of 25 publications encompassing 11 clinical studies and 14 case series gathering real-world data on the application of the NeuroSlider (DLC) in its intended use and regular clinical practice from which the safety and performance of the NeuroSlider (DLC) device family can be deduced were evaluated. In the reviewed clinical literature, a total of roughly 2,091 NeuroSlider microcatheters with different inner diameters (0.017", 0.021", 0.027" – all available device variants are covered) were used in just as many patients for the delivery of different neurovascular stents as well as other catheters.

The authors did not report any performance or safety issues 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 family devices are summarized in the following table.

Table 2: Summary of clinical data from publications stating the use of NeuroSlider family devices. References in alphabetical order.

Author (et al.), Year	Patient/Device №	Inner diameter [inches]	Safety/ performance statements/issues
Beuing O 2020	32/34	17	none
Brassel F 2016	16/16	17	none
Daglioglu E 2020	146/146	27	none
Dange NN and Roy JM 2022	13/13	21/27	none
Dietrich P 2020	85/48	17	none
Feick J 2023	366/366	17	none
Fujimura S 2022	23/23	27	none
Goertz L 2019	59/59	27	none
Goertz L 2020a	131/131	17	none
Goertz L 2020b	12/12	27	none
Goert L 2023	1/1	27	none
Kabbasch C 2015	14/14	17	none
Kallenberg K 2016	119/119	27	none
Karhi S 2018	199/199	21	none
Kaschner M 2020	33/33	21	none
Kaschner MG 2019	40/40	21	none
Kollikowski AM 2020	151/151	21/27	none
Kraus B 2018	42/42	27	none
Pflaeging M 2021	19/19	17	none
Strinitz M 2021	58/58	17/21	none
Topcuoglu OM 2018	7/7	27	none
Tureli D 2016	47/47	17	none
Vogt ML 2022	298/298	17/21	none

Author (et al.), Year	Patient/Device №	Inner diameter [inches]	Safety/ performance statements/issues
Weiss D 2022	174/174	17/21	none
Zaeske C 2020	49/49	27	none
Total	**2,091 / 2,091**		

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

a) Clinical data on the NeuroSlider DLC will be collected from completed studies REVISAR and HYBRID of other Acandis products - the APERIO Hybrid and APERIO Hybrid 17/21- used together with the NeuroSlider DLC. In the REVISAR and HYBRID thrombectomy studies all adverse events related to the intervention are recorded. As the APERIO and APERIO hybrid are normally used together with a NeuroSlider DLC catheter, clinical data on the safety and performance of the NeuroSlider DLC is also collected in these studies.

b) In addition, clinical data on the NeuroSlider DLC will be collected in the ongoing DERIVO 2 heal Study ("REheal") (compatibility of DERIVO 2 heal and NeuroSlider DLC as per IFU).

No results from the HYBRID and REVISAR PMCF studies are available yet.

The "REheal" PMCF study (NCT05543447) has started in December 2022. Estimated study completion is January 2027.

First results regarding the NeuroSlider DLC are expected in the middle of 2025 (personal information Acandis, February 2024).

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 DLC,
- the NeuroSlider family devices,
- 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 January 16, 2024 and the searched period in the MAUDE database encompassed December 11, 2022 to January 16, 2024.

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 DLC, the similar Rebar 14 / 18 / 27 microcatheter or the device group of microcatheters.

It has to be noticed that the vast majority of the records in the MAUDE database from Nov 2020 to January 2024 were no device- or procedure-related complications.

Acandis has included the potential complications/patient problems in the instructions for use of the NeuroSlider DLC. Thus, there is no allusion to an unfavorable risk profile in routine clinical use. Also, from this point of view, the Acandis NeuroSlider (DLC) family devices, the similar device as well as the whole device group of microcatheters appear to be effective and safe for their intended use.

1.5.4 An overall summary of the clinical performance and safety

The clinical literature reflecting the state-of-the-art in the 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 (DLC) family devices and the similar Rebar microcatheter, together with the results from the searches in authority-maintained vigilance databases as well as the data collected from PMS and PMCF on the NeuroSlider DLC prove the clinical performance and safety of the NeuroSlider DLC 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 methods. There are a 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 and specific clinical features of the evaluated devices are 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 family devices provide sound evidence that by using intravascular microflow catheters in general and the NeuroSlider family devices, in particular, successful and safe infusion of therapeutic or diagnostic agents or devices (e.g., different stents and coils) is feasible.

Hence, the Acandis NeuroSlider family devices and thus, the NeuroSlider DLC are suitable for their intended use 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 DLC achieves the performances intended by Acandis and meets the requirement for performance.

Microcatheters are applied minimally invasive 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 method that does not pose an unduly high risk for the patient. 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 device's use and microcatheters in general are described in detail in the medical scientific 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), thus being known to the professional user.

The potential complications identified from the clinical literature that can occur using intravascular microflow catheter encompass the general complications of cerebral embolization including hemorrhage and ischemia as well as neurological deficits including stroke and death, trapping of microcatheter, microcatheter rupture / breakage, arterial perforation/dissection/rupture, aneurysm perforation/rupture, minor complications including ematoma, 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 family devices, there were no reports on technical and clinical complications related to the NeuroSlider family devices. No evidence on unduly or unknown risks emanating from the NeuroSlider DLC was identified. 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. The risk of bacterial colonization will be added in the next revision of the IFU and the risk analysis. Warnings and contraindications, as well as complications, are addressed in the instructions for use.

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 DLC was subjected to various pre-clinical and laboratory test reports e.g.,

biocompatibility according to (harmonized) standards with successful results. Thus, the NeuroSlider DLC 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 DLC 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 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 NeuroSlider DLC offers an acceptable benefit-risk profile and meets the requirement for an 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 DLC:

- Significant delayed treatment: 0.13 %
- Delayed treatment: 0.03 %

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

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

1.5.5 Ongoing or planned post-market clinical follow-up

Clinical data from PMCF measures on the NeuroSlider DLC will be collected from the completed studies REVISAR, HYBRID and the ongoing study REheal of other Acandis products (see 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 DLC 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	2001+AC:2006
EN	868-2	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods	2017
EN ISO	10555-1	Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2013 + Amd 1:2017), cited as 2018	2013+A1:2017
EN ISO	10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	2020
EN ISO	10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2009
EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	2021

Mnemonic	Number	Title	Revision
EN ISO	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	2018
EN ISO	10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008 + Cor 1:2009 + Amd 1:2019)	2008+AC:2009+ A1:2022
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 10993-2:2006)	2006
EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)	2020
EN ISO	11135	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014+Amd.1:2018)	2014+A1:2019
EN ISO	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	2017
EN ISO	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)	2017
EN ISO	11139	Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards+ ISO 11139:2018	2018
EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	2020/A11:2022
EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	2020/A11:2022
EN ISO	11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	2018+A1:2021
EN ISO	13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016+AC:2018+ A11:2021
EN ISO	14644-5	Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)	2004
EN ISO	14644-4	Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (SO 14644-4:2001)	2001
EN ISO	14644-3	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)	2019
EN ISO	14644-2	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	2015

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
ISO	14698-2	Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data TECHNICAL CORRIGENDUM 1	2003/Cor. 1:2004
ISO	14698-1	Cleanroom and associated controlled environments - Biocontamination control - Part 1: General principles and methods	2003
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+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

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

2 Information for the patient

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

3 Bibliography

1 Beuing O, Lenz A, Donitza A, Becker M, Serowy S, Skalej M (2020) Stent-assisted coiling of broad-necked intracranial aneurysms with a new braided microstent (Accero): procedural results and long-term follow-up. Scientific reports 10:412.

2 Brassel F, Grieb D, Meila D, Schlunz-Hendann M, Greling B, Melber K (2017) Endovascular treatment of complex intracranial aneurysms using Acandis Acclino stents. Journal of neurointerventional surgery 9:854–859.

3 Daglioglu E, Akmangit I, Acik V, Alagoz F, Sayin B, Uckun OM, Belen AD, Arat A (2020) The Experience of the DerivoÂ® Embolisation Device in Intracranial Aneurysms. Turkish neurosurgery 30:30–37.

4 Dange NN & Roy JM (2022) Initial Experience with the Contour Device in the Treatment of Ruptured Intracranial Wide-necked Bifurcation Aneurysms: A Single-operator, Multicenter Study. Neurology India 70:2059–2064.

5 Dietrich P, Gravius A, Mühl-Benninghaus R, Yilmaz U, Kettner M, Bomberg H, Reith W, Simgen A (2021) Single Center Experience in Stent-Assisted Coiling of Complex Intracranial Aneurysms Using Low-Profile Stents The ACCLINO® Stent Versus the ACCLINO® Flex Stent. Clinical neuroradiology 31:99–106.

6 Feick J, Pham M, März AG, Vogt ML, Strinitz M, Stoll G, Schuhmann MK, Kollikowski AM (2023) Distinct Alterations in Oxygenation, Ion Composition and Acid-Base Balance in Cerebral Collaterals During Large-Vessel Occlusion Stroke. Clinical neuroradiology 33:973–984.

7 Fujimura S, Brehm A, Takao H, Uchiyama Y, Karagiozov K, Fukudome K, Yamamoto M, Murayama Y, Psychogios M-N (2022) Hemodynamic Characteristics and Clinical Outcome for Intracranial Aneurysms Treated with the Derivo Embolization Device, a Novel Second-Generation Flow Diverter. World neurosurgery 159:e252-e259.

8 Goertz L, Dorn F, Kraus B, Borggrefe J, Forbrig R, Schlamann M, Liebig T, Turowski B, Kabbasch C (2019) Improved Occlusion Rate of Intracranial Aneurysms Treated with the Derivo Embolization Device: One-Year Clinical and Angiographic Follow-Up in a Multicenter Study. World neurosurgery 126:e1503-e1509.

9 Goertz L, Hesse N, Liebig T, Ahmad W, Abdullayev N, Krischek B, Kabbasch C, Dorn F (2020) Retreatment strategies for recurrent and residual aneurysms after treatment with flow-diverter devices. Neuroradiology 62:1019–1028.

10 Goertz L, Smyk MA, Siebert E, Turowski B, Borggrefe J, Mpotsaris A, Bohner G, Schlamann M, Dorn F, Liebig T, Kabbasch C (2021) Low-Profile Laser-Cut Stents for Endovascular Treatment of Intracranial Aneurysms Incidence, Clinical Presentation and Risk Factors of Thromboembolic Events. Clinical neuroradiology 31:107–115.

11 Goertz L, Zopfs D, Schönfeld M, Zaeske C, Pennig L, Brinker G, Schlamann M, Kabbasch C (2023) First clinical experience with the Derivo 2heal embolization device for the treatment of intracranial aneurysms. Interventional neuroradiology journal of peritherapeutic neuroradiology, surgical procedures and related neurosciences:15910199231193577.

12 Gross BA, Albuquerque FC, Moon K, Ducruet AF, McDougall CG (2017) Endovascular treatment of previously clipped aneurysms: continued evolution of hybrid neurosurgery. J NeuroIntervent Surg 9:169–172.

13 Kabbasch C, Liebig T, Faymonville A, Dorn F, Mpotsaris A (2015) Initial Clinical Experience with a New Self-Expanding Nitinol Microstent for the Treatment of Wide-Neck Intracranial Cerebral Aneurysms: The Acandis Acclino Stent. Journal of Vascular and Interventional Neurology 8:1–6.

14 Kallenberg K, Solymosi L, Taschner CA, Berkefeld J, Schlamann M, Jansen O, Arnold S, Tomandl B, Knauth M, Turowski B (2016) Endovascular stroke therapy with the Aperio thrombectomy device. J NeuroIntervent Surg 8:834–839.

15 Karadeli HH & Kuram E (2023) Single Component Polymers, Polymer Blends, and Polymer Composites for Interventional Endovascular Embolization of Intracranial Aneurysms. Macromolecular bioscience:e2300432.

16 Karhi S, Nerg O, Miettinen T, Mäkipaakkanen E, Taina M, Manninen H, Vanninen R, Jäkälä P (2018) Mechanical Thrombectomy of Large Artery Occlusion Is Beneficial in Octogenarians. In vivo (Athens, Greece) 32:1223–1230.

17 Kaschner M, Lichtenstein T, Weiss D, Turowski B, Goertz L, Kluner C, Schlamann M, Mathys C, Kabbasch C (2020) The New Fully Radiopaque Aperio Hybrid Stent Retriever: Efficient and Safe? An Early Multicenter Experience. World neurosurgery 141:e278-e288.
18 Kaschner MG, Rubbert C, Caspers J, Karsten J, Kraus B, Lee J-I, Gliem M, Jander S, Turowski B (2018) A Retrospective Single-Center Case Series of Direct Aspiration Thrombectomy as First-Line Approach in Ischemic Stroke and Review of the Literature. Journal of stroke and cerebrovascular diseases the official journal of National Stroke Association 28:640–648.
19 Kollikowski AM, Schuhmann MK, Nieswandt B, Müllges W, Stoll G, Pham M (2020) Local Leukocyte Invasion during Hyperacute Human Ischemic Stroke. Annals of neurology 87:466–479.
20 Kraus B, Goertz L, Turowski B, Borggrefe J, Schlamann M, Dorn F, Kabbasch C (2019) Safety and efficacy of the Derivo Embolization Device for the treatment of unruptured intracranial aneurysms: a multicentric study. Journal of neurointerventional surgery 11:68–73.
21 Liu C, Wu X, Hu X, Wu L, Guo K, Zhou S, Fang B (2023) Navigating complexity: a comprehensive review of microcatheter shaping techniques in endovascular aneurysm embolization. Frontiers in neurology 14:1245817.
22 Pflaeging M, Goertz L, Smyk MA, Turowski B, Mpotsaris A, Pennig L, Borggrefe J, Krischek B, Kabbasch C (2021) Treatment of recurrent and residual aneurysms with the low-profile Acandis Acclino stent: Multi-center review of 19 patients. Journal of clinical neuroscience official journal of the Neurosurgical Society of Australasia 90:199–205.
23 Strinitz M, Pham M, März AG, Feick J, Weidner F, Vogt ML, Essig F, Neugebauer H, Stoll G, Schuhmann MK, Kollikowski AM (2021) Immune Cells Invade the Collateral Circulation during Human Stroke: Prospective Replication and Extension. International journal of molecular sciences 22.
24 Topcuoglu OM, Arat A, Peker A, Sarikaya B (2018) Intermediate catheter placement distal to the cerebral aneurysm during flow diversion embolization with the Surpass device. Journal of neurointerventional surgery 10:e35.
25 Tureli D, Sabet S, Senol S, Andac N, Donmez H, Geyik S, Baltacioglu F, Cekirge S (2016) Stent-assisted coil embolization of challenging intracranial aneurysms: initial and mid-term results with low-profile ACCLINO devices. Acta neurochirurgica 158:1545–1553.
26 Vogt ML, Kollikowski AM, Weidner F, Strinitz M, Feick J, Essig F, Neugebauer H, Haeusler KG, Pham M, Maerz A (2022) Safety and Effectiveness of the New Generation APERIO® Hybrid Stent-retriever Device in Large Vessel Occlusion Stroke. Clinical neuroradiology 32:141–151.
27 Weiss D, Rubbert C, Ivan VL, Lee J-I, Gliem M, Jander S, Caspers J, Turowski B, G Kaschner M (2022) Mechanical thrombectomy in stroke patients with acute occlusion of the M1- compared to the M2-segment: Safety, efficacy, and clinical outcome. The neuroradiology journal 35:600–606.
28 Zaeske C, Goertz L, Dorn F, Turowski B, Abdullayev N, Schlamann M, Liebig T, Kabbasch C (2021) Comparative Analysis of the Pipeline and the Derivo Flow Diverters for the Treatment of Unruptured Intracranial Aneurysms-A Multicentric Study. World neurosurgery 145:e326-e331.