ENGINEERING STROKE SOLUTIONS

Summary of Safety and Clinical Performance:

ACCERO® Stent

Acandis GmbH

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

Identifier: 2400

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1 Information for the professional user

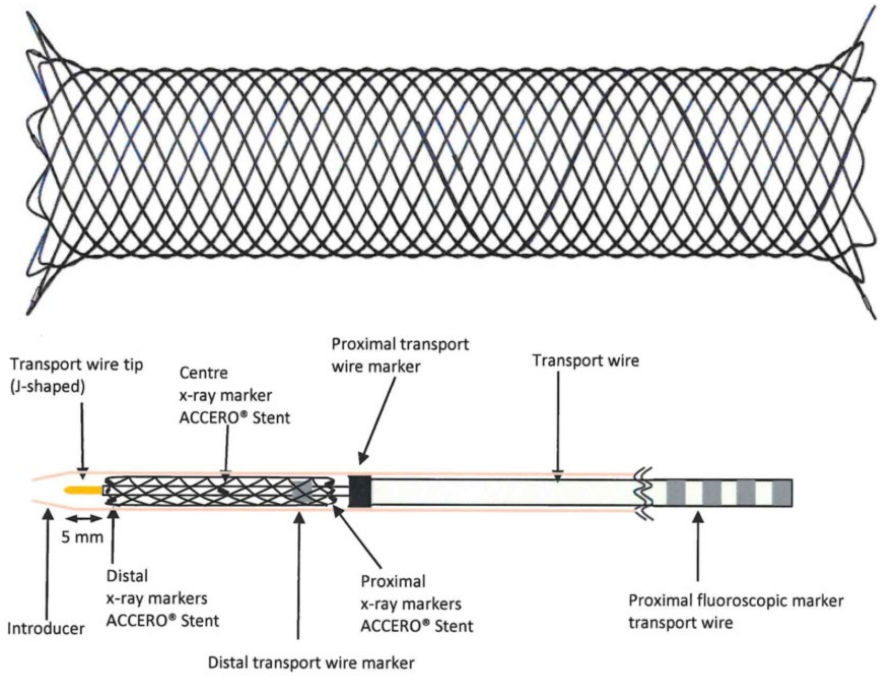
This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the ACCERO® Stent.

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 ACCERO® Stent, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.
In addition to this information, there is a summary intended for patients (chapter 2).

1.1 Device identification and general information

Device trade name(s)	ACCERO® Stent (Article no. 01-000800 – 01-000808, 01-000810, 01-000811, 01-000813, 01-000814, 01-000841, 01-000842, 01-000845, 01-000881 – 01-000886)
Picture	
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	426065033ACCEROWF
Medical device nomenclature	UMDNS: 17-461 (vascular stent) GMDN: 46352 (bare-metal intracranial vascular stent) EMDN: P0799 (vascular and cardiac prostheses – other)
Class of device	Class III medical devices, as defined in Medical Device Regulation (MDR) EU 2017/745, Annex VIII, rule 08, bullet point 02
Year of first CE certificate	2015
Authorized representative	not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297)

1.2 Intended use of the device

Intended purpose	The ACCERO® Stent is used to anchor the embolization materials in the aneurysm when using the stent-assisted coiling method.
Indication(s)	The ACCERO® Stent is intended for the treatment of intracranial aneurysms using embolisation materials.
Targeted population(s)	No special patient populations defined but patients with contraindications are to be excluded. The ACCERO® Stent should be applied only by physicians who have the required background knowledge and experience in the field of interventional neuroradiology and the treatment of intracranial aneurysms.
Contraindications and/or limitations	Implantation is contraindicated for the following patients: - Patients in whom important side branches emanate from the aneurysm to be treated. - Patients in whom the size of the aneurysm and/or the size of the vessel carrying the aneurysm is not within the indicated range. - Patients in whom angiography reveals anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity and/or stenosis. - Patients who were not pre-treated with antiplatelet agents prior to the procedure. - Patients in whom treatment with antiplatelet agents and/or anticoagulants is contraindicated. - Patients who are hypersensitive to nickel-titanium. - Patients with an active bacterial infection. - Patients with life-threatening intracerebral bleeding that requires surgical treatment (e.g. with clipping). No limitations are mentioned in the IFU.

1.3 Device description

1.3.1 Description of the ACCERO® Stent

The ACCERO® Stent is a self-expanding, fully radiopaque stent, braided from a nitinol (a nickel-titanium alloy) wire with a platinum core. The stent has three radiopaque platinum/iridium markers each at the distal and proximal ends, and an additional radiopaque platinum/iridium

marker at the center of the stent. The stent is preloaded on a transport wire in an introducer. The transport wire is also made from nitinol for enhanced flexibility while being king resistant. The atraumatic J-shaped tip of the transport wire as well as one distal and one proximal transport wire marker are likewise radiopaque. The distal transport wire marker identifies the point up to which the stent can be repositioned. A crown sleeve mechanically interlocks with the stent. The sizes are specified on the packaging label.

Sizes	Ø 2.5 / 3.0 / 3.5 / 4.0 / 4.5 / 5.5 mm lengths: 10 / 15 / 20 / 25 / 30 / 40 / 50 / 60 mm
Sterility	Yes, ETO sterilization, for single-use.
Generic device group	Intracranial neurovascular stents, self-expandable
MR conditional	up to 3 Tesla
Foreshortening	≤ 65 %
Stent surface area	< 20 %

The transport wire has improved grip and wire stability to ensure easy and smooth stent delivery. The orange translucent introducer is for optimized visual control for secure transfer of device into the microcatheter hub.
The folded stent is introduced with the delivery system up to the intracranial target zone. When placed under the neck of the aneurysm, the folded stent is advanced out of the tube of the delivery system. The stent expands to its original shape. The stent length should cover the neck of the aneurysm adequately. Secure repositioning of the stent is possible up to more than 90 % of stent deployment. Then, coiling embolisation material is applied. The ACCERO® Stent is implanted for a lifetime.

1.3.2 Previous generations

The first generation of the ACCERO® Stent has been on the market since May 2015, the second generation since July 2018, the third generation since January 2020 and the fourth generation since April 2021. The current ACCERO® Stent generation (2400-1 FDL) is currently under submission.

The changes for the generations include e.g. range extensions and design optimization as improved visibility and positioning of the stent by adding additional markers with optimization of x-ray visibility.

1.3.3 Accessories

Guide wire, RHV (rotating haemostatic valve).

1.3.4 Combination with other devices

A microcatheter with a matching inner diameter is required to introduce the ACCERO® Stent. The ACCERO® Stent is intended for use in combination with the NeuroSlider DLC. The required microcatheter size is specified on the label. The NeuroSlider DLC is the only microcatheter which was tested for compatibility with the ACCERO® Stent.

1.4 Complications, warnings and precautions

1.4.1 Complications

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, Vessel dissection, Vessel perforation, Vessel rupture, Vessel stenosis, Vessel occlusion or thrombosis, Cerebral oedema, Infection, (Cerebral) ischaemia/infarction, Secondary haemorrhage, Reactions due to radiation exposure, Subarachnoid haemorrhage, Thromboembolic event/stroke, Transient ischaemic attack (TIA), 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 stent delivery/implantation (e.g. Transport wire breakage, Stent breakage, Stent folding, Incorrect stent placement, Stent twisting, Stent cannot be inserted into catheter, Stent cannot be deployed, Stent cannot be drawn back into catheter, Stent kinking, Stent does not detach from the transport wire, Stent migration, Insufficient opening behaviour, Insufficient wall apposition, Delayed treatment, Target area inaccessible or cannot be accessed safely, Additional stenting required)
- Other complications in connection with the stent (e.g. (Local) Allergic reactions to the stent material, In-stent stenosis, Perforator infarction, Reoperation, Stent occlusion/thrombosis, Incomplete aneurysm occlusion, Occlusion of perforators or branch vessels, Coil migration through the stent mesh, Increased stresses to the vessel wall, Local inflammatory reactions, Systemic hypersensitivity, Cerebritis)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)

- Death

Since market launch the following complications were recorded for the ACCERO® Stent:
Significant delayed treatment: 1.36 %
Neurological deficits: 0.16 %
Vascular trauma: 0.04 %

From the systematic review of the scientific literature and PMCF measures, only scarce quantitative data on the occurrence of complications with the ACCERO® Stent could be obtained. No procedure-related morbidity or mortality was observed in the identified studies with the ACCERO® Stent. According to the identified literature on the ACCERO® Stent, the following complications only occasionally occurred:

Stent occlusion/thrombosis:	(Beuing et al. 2020) :	2/30 (6.6 %)
	(Nania et al. 2020):	1/41 (2.4 %)
	(Poncyljusz et al. 2020):	2/18 (11.1 %)
	PMCF study (NCT03957382):	1/25 (4 %)
Thromboembolic event/stroke:	PMCF study (NCT03957382):	1/25 (4 %)
Subarachnoid hemorrhage:	PMCF study (NCT03957382):	1/25 (4 %)
Groin hematoma:	(Nania et al. 2020):	1/41 (2.4 %)
Neurological complications:	(Beuing et al. 2020):	2/34 (5.9 %)
Stent twisting	(Kim & Jung 2024a)	2/26 (7.7 %)
Hook in problem	(Kim & Jung 2024a)	2/26 (7.7 %)
Intimal hyperplasia	(Kim et al. 2025)	1/50 (2 %)

No new neurological deficits during the hospital stay or a poor procedure- or device-related outcome were reported. According to the literature, the described complication rates are similar to those of other intracranial stents.
Possible reported complications during and after the treatment with the product group of intracranial stents are aneurysm perforation or rupture, recurrence of aneurysm or insufficient intracranial aneurysm treatment (e.g., through incomplete occlusion of aneurysm), neurological complications, thromboembolic complications and ischemia, stroke, re-bleeding, vasospasm, angiography related risks or stent-related complications. Clinical data on similar devices (LEO+ Stent /LEO+ Baby Stent, BALT Extrusion) mentioned the following morbidity and mortality rates:

Morbidity	Mortality	Follow-up time	Author
2.3 % (2/85)	3.5 % (3/85)	5 years	Pumar JM et al.,2021
4.1 % (7/170)	0.6 % (1/170)	18 months	Eker et al., 2022
2.8 % (3/133)	0.8 % (1/133)	11.4 months	Eker et al., 2022 Duan et al., 2022

1.4.2 Warnings and precautions

Warnings

- The ACCERO® Stent should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional neuroradiology and have the required expertise in the treatment of intracranial aneurysms.
- 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 components be used.
- On no account whatsoever should you continue advancing the stent if you encounter resistance without first finding out the cause as otherwise you could damage the stent or perforate a vessel.
- The stent may be shorter after deployment.
- 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 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 performance of a responder test is recommended to reduce the risk of complications. For this purpose, the efficacy of the antiplatelet agent is tested prior to application of the product.
- In order to minimise potential complications during and after the intervention, attention should be paid to careful medication treatment in accordance with the current medical association guidelines (antiplatelet agents and anticoagulants prior to treatment and anticoagulants during the intervention). The administration of unsuitable antiplatelet agents and anticoagulants may lead to a stent thrombosis.
- The medication is an important part of the treatment. Patients must be advised to take medication regularly and informed of the potential risks of non-compliance.

1.4.3 Other relevant aspects of safety

The ACCERO® Stent has been on the market since 2015.

From CE-approval to September 30, 2025 a total of 5,387 ACCERO® Stents were sold. Acandis PMS data on the ACCERO® Stent since CE-approval show 60 complaints equal to a low complaint rate of 1.11 %.

In the recent PMS data collection period (October 2024 to September 2025) a total of 3 complaints equal to a low complaint rate of 0.34 % was recorded. The present complaints did not lead to the initiation of preventive and / or corrective actions (CAPA).

In the recent PMS data collection period (October 2024 to September 2025) serious incidents were reported. These incidents lead to insufficient device opening and to significant delay in treatment. All of these incidents were most likely caused by a wrong handling of the user. None of these incidents could be traced back to a product or process defect.

The medical benefit continues to outweigh the residual risk.

There were also no relevant hits on unduly or unknown risks of the ACCERO® Stent in the databases of competent authorities.

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

1.5.1 Summary of clinical data related to equivalent devices

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

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

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

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data in literature

Table 1: Summary of clinical data on publications stating the use of the ACCERO® Stent

Author, year	Title	Patient / aneurysms	Follow-up time	Safety	Performance
(Beuing et al. 2020)	Stent-assisted coiling of broad-necked intracranial aneurysms with a new braided microstent (ACCERO® Stent): procedural results and long-term follow-up	32/34	15 months	Neurological complications: 5.9 % Stent occlusions: 6.6 %	Technical success: 100 % Clinical success*: 93.3 %
(Nania et al. 2020)	Early experience treating intracranial aneurysms using ACCERO® Stent: a novel, fully visible, low profile braided stent with platinum-nitinol composite wire technology	41/41	6 months	Stent occlusion/thrombosis: 2.4 % Groin hematoma: 2.4 %	Technical success: 100 % Clinical success*: 97.3 %
(Poncyljusz et al. 2020)	Evaluation of the ACCERO® Stent Stent for Stent-Assisted Coiling of Unruptured Wide-Necked Intracranial Aneurysm Treatment with Short-Term Follow-Up	17/18	6 months	Stent occlusion/thrombosis: 11.1 % %	Technical success: 100 % Clinical success*: 100 %
(Kim & Jung 2024a)	Immediate and short-term results of ACCERO® Stent stent-assisted coil embolization: unveiling novel strides in vascular intervention	26/31	6 months	Stent twisting: 7.7 % Hook in problem: 7.7 %	Technical success: 100 % Clinical Success*: not reported
(Çay & Arat 2024)	Appraisal of the Flow Diversion Effect Provided by Braided Intracranial Stents	86 (Leo baby; n = 69 and ACCERO®	24.5 months	No procedure- or device related complications reported.	Technical success: not reported Clinical success*: 96.5 % (combined for ACCERO® Stent and Leo baby)

Author, year	Title	Patient / aneurysms	Follow-up time	Safety	Performance
		Stent; n = 17)			
PMCF study (NCT03957382)	Evaluation of safety and efficacy of the ACCERO® Stent for intracranial aneurysm treatment	25/25	6 months	Stent occlusion/thrombosis: 4 % Thromboembolic event/stroke: 4 % Subarachnoid hemorrhage: 4 % Insufficient stent opening: 4 %	Technical success: 92 % Clinical success*: 96 %
(Kim et al. 2025)	Clinical safety and efficacy of stent-assisted coil embolization with ACCERO® Stent in cerebral aneurysm: Short-term follow-up and precaution for use	50/51	12 months	Intimal hyperplasia: 2 %	Technical success: 98 % Clinical success*: 90 %
(Yeomans et al. 2025)	pCONUS 2 and pCONUS 2-HPC in the treatment of wide-necked intracranial aneurysms: Multicentre UK experience	1/1	6 months	No procedure- or device related complications reported.	Technical success: 100 % Clinical Success*: not reported
(Zur et al. 2026)	Endovascular stenting of bilateral hypoplastic jugular bulb in a toddler with elevated intracranial pressure: a case report	1/1	9 months	No procedure- or device related complications reported.	Technical success: 100 % Clinical Success*: not reported

*RROC1 + RROC2

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

Acandis is currently conducting a clinical trial. The interim results are described in chapter 1.5.5.

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 ACCERO® Stent during the preparation of the clinical evaluation report. The search was conducted on March 19, 2026 and the time frame comprised no limits.

BfArM (German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions): Latest search in March 2026: No entries concerning ACCERO® Stent, the similar devices Leo Baby and Leo+ Baby and the benchmark devices LVIS, LVIS jr and LVIS Evo.
The search term „Leo Balt“ resulted in one hit on a lot recall for the stent Leo+ in 2017. The packages contained a microcatheter with the wrong size (21 MP instead of 25MP). There was no clinical risk as the slider of the stent did not fit into the lumen of the catheter and therefore the wrong size was noticed at the beginning of the procedure.

MAUDE (“Manufacturer and User Facility Device Experience (MAUDE) Database, maintained by the United States’ Food and Drug Administration), latest search on March 19, 2026.
No entries concerning ACCERO® Stent. The ACCERO® Stent is not marketed in the USA.
No entries concerning the similar devices Leo Baby and Leo+ Baby. The devices Leo and Leo Baby are not marketed in the USA.
For the similar device LVIS jr. and LVIS Evo the MMAUDE database search revealed a total of 15 entries for injuries and 5 entries for malfunctions. The causes of injury include the following device problems:
Adverse event without identified device or use problem (8); Retraction Problem, Detachment of device or device component, Migration (1); Device stenosis (2); Adverse event without identified device or use problem, Physical resistance/sticking (1); Obstruction of flow, Adverse event without identified device or use problem (1); Activation failure (1); Difficult to open or close (1).

The following patient problems were reported:
Stroke/CVA, Thrombosis/Thrombus (1); Ischemia Stroke (1); Thrombosis/Thrombus (2); No clinical signs, Symptoms or Conditions (1); No clinical signs, symptoms or conditions (3); Intracranial hemorrhage, Paresis, Hydrocephalus, Ruptured aneurysm (1); Dysphasia, Obstruction/Occlusion (1); Obstruction/Occlusion (1); Stenosis (1); Stroke/CVA, Speech disorder (1); Inflammation, Ischemia stroke, Thrombosis/Thrombus (1); Obstruction/Occlusion, Thrombosis/Thrombus (1); Hemorrhagic stroke, Ischemia stroke (1).

1.5.4 An overall summary of clinical performance and safety

The clinical evaluation of the ACCERO® Stent is based upon several product-specific documents, including a risk analysis and the comprehensive Instructions for Use, as well as test reports on biological testing, demonstrating fulfillment of the biological requirements.
Based on these documents, it can be summarized that the procedural and product-specific risks, corresponding warnings and precautions are adequately provided for the user and offer information on risks associated with the ACCERO® Stent and its clinical application. Thus, the ACCERO® Stent meets the requirement for safety. Potential risks of the ACCERO® Stent are acceptable residual risks for the patient and the user. The main risks are described and documented in detail in scientific literature, thus being known to the trained interventional neuroradiologists. Therefore, by complying with all warnings and precautions, the ACCERO® Stent offers an acceptable benefit/risk profile, which was also confirmed by several clinical studies conducted by Acandis.
Regarding the **clinical outcome parameters for safety** that could be compared to the state-of-the-art by means of the similar Leo+ / Leo+(baby), the ACCERO® Stent is non-inferior to the state-of-the-art and can thus be considered a state-of-the-art device in its intended clinical purpose.

Within the evaluated body of literature stating the use of the ACCERO® Stent, the **technical success rate** (i.e., proper stent placement (including adequate stent expansion/opening, complete wall apposition and visibility) achieved by using the ACCERO® Stent ranges between **92 % – 100 %.**
Within the evaluated body of literature stating the use of the ACCERO® Stent, **clinical success** defined as RROC I/II achieved by using of the ACCERO® Stent ranges between **90 % and 97.3 %**, respectively.
In conclusion, regarding the clinical outcome parameters for performance the ACCERO® Stent is non-inferior to the state-of-the-art and can thus be considered a state-of-the-art device in its intended purpose.

The regular Post-Market Surveillance (PMS) data show a low complaint rate, with reported incidents only concerning already known complications. Data of a post-approval (equivalent to a Post-Market Clinical Follow-Up (PMCF)) study demonstrated a positive safety profile and continued effectiveness through five years postoperatively.
Acandis plans and will conduct further dedicated scientific PMCF measures beyond regular complaint and incident statistics.

The claims made by the manufacturer for the ACCERO® Stent such as

- Brilliant full-length visibility due to nitinol composite wires with platinum core
- Easy and accurate placement due to additional radiopaque stent markers
- Excellent flexibility and wall apposition
- Optimized flaring of the stent ends
- Repositionable up to 90 % of its length
- BlueXide® surface finishing for optimized haemocompatibility
- CE mark approved for vessel diameters from 1.5 – 4.0 mm
- Compatible with 0.0165'' – 0.017'' ID microcatheters

The claims made by Acandis on the ACCERO® Stent are supported by pre-clinical tests and published literature and are therefore acceptable from the clinical evaluation's point of view.

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

The clinical effectiveness and safety of self-expandable intracranial neurovascular stents in the treatment of diverse forms and different states of intracranial aneurysms at diverse locations has been supported by systematic reviews and meta-analyses, clinical studies and case series on benchmark devices and the device group of self-expandable intracranial neurovascular stents.
Therefore, the treatment of intracranial aneurysms by self-expandable intracranial neurovascular stents such as the ACCERO® Stent is a commonly used and widely accepted endovascular treatment method. It is minimally invasive and nowadays used to treat a variety of intracranial aneurysms. Since a clinical benefit is achieved and the device-specific risks correspond to the state-of-the-art, the benefit-risk ratio is considered to be acceptable.

In conclusion, the ACCERO® Stent 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

Acandis is conducting a prospective, multicenter, national PMCF Study with the optimized ACCERO® Stent.

The results of interim analysis (2023-02-13) of 25 patients show that the study primary endpoint was met with 88 % of treated aneurysms having a complete obliteration (Raymond Roy Classification I) at 6 months follow-up (class II RRC was observed in 2 patients (8.0 %) and class IIIa RRC was observed in 1 patient (4.0 %) at 6 months follow-up).

A high technical success rate of 92.0 % (23/25 patients) and low (S)AEs rate were observed (5 adverse events, two of which met the criteria of a serious event):

SAEs:

- Stent does not detach from transport wire resulting in thromboembolic event/stroke and subsequent subarachnoid haemorrhage (device and procedure related event)
- Percutaneous coronary intervention (PCI) (not device nor procedure related event)

AEs:

- Target area inaccessible or cannot be accessed safely (device and procedure related event)
- Insufficient stent opening (device and procedure related event)
- Stent occlusion/ thrombosis (device and procedure related event)

1.6 Possible diagnostic or therapeutic alternatives

The treatment of intracranial aneurysms by self-expandable intracranial neurovascular stents such as the ACCERO® Stent is a commonly used and widely accepted endovascular treatment method. It is minimally invasive and nowadays used to treat a variety of intracranial aneurysms. Since a clinical benefit is achieved and the device-specific risks correspond to the state-of-the-art, the benefit-risk ratio is considered to be acceptable.

However, the decision of whether to treat an aneurysm, in general, or not can be clinically complex. Several factors must be considered, including age, the health of the patient, an assessment of the natural history of the aneurysm, size and location of the aneurysm, and the technical capabilities of the treating surgeon (Chen & Thyssen 2018; Arthur et al. 2019).

Considering the possible severity of the complications related to the use of self-expandable intracranial neurovascular stents, the decision-making for using the devices should be well-conceived and it is necessary for the clinician in charge to thoroughly consider the alternatives

before treatment by self-expandable intracranial neurovascular stents. All indications and contraindications must be taken into account, as well. Nevertheless, clinical literature on the ACCERO® Stent, the similar and the device group of self-expandable intracranial neurovascular stents, in general, showed that treatment of intracranial stents with self-expandable intracranial neurovascular stents was beneficial and safe in different kinds of intracranial aneurysms.

For intracranial aneurysm treatment by self-expandable intracranial neurovascular stents serving as anchors for embolization material there are available alternative treatment methods including:

Surgical approaches including microsurgical clipping, temporary artery occlusion, microscope-integrated near-infrared indocyanine green video angiography, aneurysm wrapping, bypass surgery and bipolar coagulation for micro-aneurysms as well as intra-operative Doppler sonography are mentioned as alternative treatments for aneurysms to stent-assisted coiling (Zhao J et. al 2017). According to the literature, endovascular coiling is associated with a better outcome compared to neurosurgical clipping (Lindgren et al. 2018).

1.7 Suggested profile and training for users

The device ACCERO® Stent should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional neuroradiology and have the required expertise in the treatment of intracranial aneurysms.

1.8 Reference to harmonized standards and common specifications applied

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

Table 2: Standards adhered to by Acandis GmbH

Mnemonic	Number	Title	Revision
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	10993-10	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)	2023
EN ISO	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	2018
EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	2021
EN ISO	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation	2023

Mnemonic	Number	Title	Revision
		products from metals and alloys (ISO 10993-15:2019)	
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	10993-18	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	10993-2	Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2022)	2022
EN ISO	10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
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	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)	2017
EN ISO	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2009
EN ISO	10993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)	2016
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	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	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)	2017
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	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	11607-1	Packaging for terminally sterilized 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	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	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	2020

Mnemonic	Number	Title	Revision
		performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	
EN ISO	13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016+AC:2018+ A11:2021
EN ISO	14630	Non-active surgical implants - General requirements (ISO 14630:2012)	2024
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	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	14644-3	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)	2019
EN ISO	14644-4	Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (SO 14644-4:2022)	2022
EN ISO	14644-5	Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)	2004
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)	2021
EN ISO	25539-1	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)	2017
EN ISO	25539-2	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020)	2020
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	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)	2015+COR1:2016+A1:2020
EN	868-2	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods	2017

2 Information for the patient

Document revision: 04

Date issued: March 19, 2026

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 device. The information presented below is intended for patients or lay persons. An extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an implant card or the instructions for use to provide information on the safe use of the device.

2.1 Device identification and general information

Device trade name(s)	**ACCERO® Stent** (Article no. 01-000800 – 01-000808, 01-000810, 01-000811, 01-000813, 01-000814, 01-000841, 01-000842, 01-000845, 01-000881 – 01-000886)
Manufacturer's name and address	Acandis GmbH, Theodor-Fahrner-Straße 6, 75177 Pforzheim, Germany
Basic UDI-DI	The Unique Device Identification System is a system for the unambiguous identification of medical devices. The basic UDI for the ACCERO® Stent is 426065033ACCEROWF
Year of first CE certificate	2015

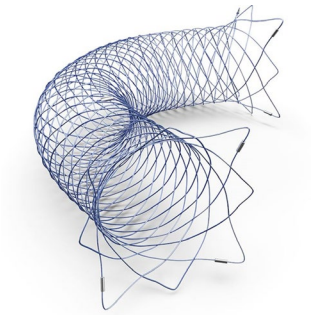
2.2 Intended use of the device

Intended purpose	The ACCERO® Stent (a wire mesh) is used to anchor the embolization materials in the aneurysm (vessel bulge) when using the stent-assisted coiling method.
Indication(s)	The ACCERO® Stent is intended for the treatment of intracranial aneurysms (bulged brain vessels) using embolization materials.
Intended patient groups	There are no specific restrictions based on age, weight, health status or ethnic or cultural group (ethnicity).
Contraindications	- Patients with a life-threatening bleeding in the brain (intracerebral hemorrhage) which must be treated by surgery. Closure with miniclips (clipping) should be possible - Patients with important vessel branches (branch arteries) arising from the aneurysm to be treated. - Patients in whom the size of the aneurysm and/or the diameter of the brain vessel in which the aneurysm is located do not match the size of the stent

	- Patients who present in the angiography with anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity or stenosis (vessel tortuosity or stenosis). - Patients with a bacterial infection. - Patients who were not pretreated with anti-blood clotting drugs. - Patients who cannot be pretreated with anti-blood clotting drugs. - Patients with allergic reactions to nickel-titanium. No limitations are mentioned in the IFU

2.3 Device description

2.3.1 Description of the ACCERO® Stent



The ACCERO® Stent is a self-expanding stent. It is braided of Nitinol wires. The stent is sterile and biocompatible. It is free of latex and salts or ester of phthalic acid (phthalate). The stent can be seen under X-rays. The ACCERO® Stent is implanted for a lifetime.

Sizes	Ø 2.5 / 3.0 / 3.5 / 4.0 / 4.5 / 5.5 mm lengths: 10 / 15 / 20 / 25 / 30 / 40 / 50 / 60 mm

2.3.2 Mode of action

The ACCERO® Stent is inserted through a small, flexible hollow tube (microcatheter). The insertion point is usually in the groin. The folded device is advanced with a transport wire up to the place of the vessel wall bulge.

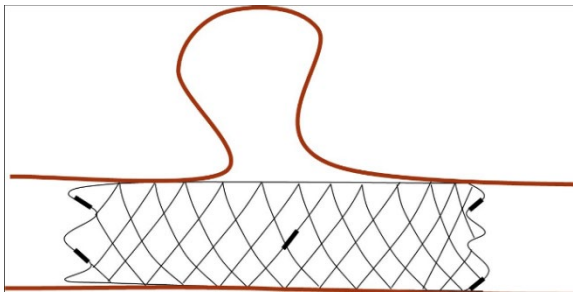


Figure 1: ACCERO® Stent (black grid) when placed under the vessel wall bulge (aneurysm).

When correctly placed, the folded device expands itself. Then, it is fixed firmly (implanted).

The transport wire and the microcatheter are removed. Afterwards, the physician fills the aneurysm with special very small platinum coils. The coils are not part of the ACCERO® Stent.

2.3.3 Accessories

Guide wire, RHV (rotating haemostatic valve).

2.4 Risks and warnings

Contact your healthcare professional, if you believe that you are experiencing side effects related to the device, its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional, if needed.

2.4.1 Residual risks and undesirable effects

Acandis employed a risk management system according to the ISO (International Organization for Standardization): ISO 14971:2019. This is the industry standard. It is written in the risk management report that the ACCERO® Stent is safe for treatment. The medical benefits outweigh the residual risk.

Possible complications are known even when the ACCERO® Stent is used according to common knowledge. The physicians are aware of these unwanted effects. They can manage them. The most commonly reported complications with 90 patients were

- Blood vessel perforation with bleeding in the brain
- Contraction of the blood vessel
- Closure of the stent
- Mild abnormal functions of the body
- Further treatment needed

Since market launch the following complications were recorded for the ACCERO® Stent:
Significant delayed treatment: 1.36 %
Neurological deficits: 0.16 %
Vascular trauma: 0.04 %

In the following, the complete list of possible complications is described:

- General complications in connection with treatments inside the vessel wall (endovascular treatment) or treatments with X-rays and contrast agent (angiographic treatments: (e.g. false aneurysm (pseudoaneurysm), rupture of or bleeding from aneurysm, bleeding, bleeding in the brain (intracerebral hemorrhage, subarachnoid

hemorrhage), blood clotting (embolism), fever, tears or holes in the wall of a blood vessel (vessel dissection, vessel perforation), vessel rupture, narrowing of the vessel (vessel stenosis), vessel injury (vessel trauma), swelling in the brain due to stored fluid (cerebral edema), infection, limited blood supply, limited blood supply in the brain ((cerebral) ischemia/infarction), bleeding after the intervention (secondary hemorrhage) reactions due to radiation exposure, stroke (thromboembolic event/stroke), contraction of the blood vessel (vasospasm), poisoning)

- General complications in connection with anti-blood clotting drugs (antiplatelet agents/anticoagulants), anesthetics and contrast agents (e.g. renal failing (insufficiency))
- Complications in connection with the insertion point (vascular access) (e.g. bruise (hematoma), bleeding, paint or infections at the insertion point of the catheter (puncture site)
- Possible problems when introducing/implanting the stent (e.g. stent breakage, stent folding, incorrect stent placement, stent cannot be deployed, stent cannot be pulled back into catheter, stent kinking, stent does not detach from transport wire, stent movement (migration), insufficient opening, delayed treatment, area of the aneurysm (target area) inaccessible or cannot be accessed safely, additional stenting required)
- Other complications in connection with the stent (e.g. allergic reactions to the device material, closure of the stent, blood clotting within the blood vessel (thrombosis), narrowing of the stent (in-stent stenosis, reoperation, incomplete closure (occlusion) of the aneurysm, closure of a branch of a blood vessel)
- Deficits of the brain (neurological deficits), e.g. speech impediment (dysphasia), speech disorders, impaired vision, weakening of the eye muscles (oculomotor paresis), weakening or paralysis of one side of the body (hemiparesis or hemiplegia).
- Death (was not observed yet during the surgery).

2.4.2 Warnings and precautions

Acandis gives comprehensive information on warnings, cautions and precautions for the user to ensure a safe and successful implantation of the ACCERO® Stent.
In the following, only the patient-related warnings and precautions are listed:

- The ACCERO® Stent should only be used by medical doctors who have the required background knowledge and experience in the minimally invasive treatment of the brain using imaging techniques (interventional neuroradiology) and experience in treating vessel wall bulges in the brain (intracranial aneurysm).

- The ACCERO® Stent is delivered sterile and for single use only. It must not be reused, reprocessed or re-sterilized.
- The effect of the pretreatment with anti-blood clotting drugs should be checked before the intervention to minimize potential complications.
- Anti-blood clotting drugs (antiplatelet agent and anticoagulant therapy prior to treatment and anticoagulants during the surgery). should be given accordance with the current guidelines from the medical societies. If unsuitable drugs are given, this can lead to blood clotting.
- Drugs (the medication) are an important part of stent treatment to avoid potential complications. For this reason, patients should carefully take the prescribed medication

2.4.3 Other relevant aspects of safety

Since market launch, there were no relevant aspects of safety.

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

Physicians reported on 2100 patients who were treated and followed-up with the ACCERO® Stent (Beuing et al. 2020; Nania et al. 2020; Poncyljusz et al. 2020; Kim et al. 2025; Yeomans et al. 2025; Zur et al. 2026). The reports mentions that the ACCERO® Stent provides excellent support for the small platinum coils (embolization material) and that the ACCERO® Stent is an effective device with good occlusion rates (90 %– 97.3 %). Furthermore, it is mentioned that successful aneurysm occlusions are similar to those of other stents on the market.
That is also valid for the numbers of the complications. The observed complications were the known complications with such stents and the surgical procedure. Hence, the safety of the ACCERO® Stent seems to be similar to such other stents on the market.
In general, all authors evaluated the ACCERO® Stent as a safe and efficient self-expandable, intracranial neurovascular stent for aneurysm occlusions in the treatment of intracranial aneurysms by stent-assisted coiling.

2.6 Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation. Several factors must be considered for the treatment of an aneurysm, e.g. age, general health status, history of the aneurysm, size and location of the aneurysm, and the technical capabilities of the surgeon.

Therapeutical alternatives are open surgeries, e.g. microsurgical clipping, temporary vessel closure, external wrapping to prevent enlargement of the aneurysm (aneurysm wrapping), bypass surgery and electrosurgical coagulation in case of micro-aneurysms.
In most cases, endovascular coiling has better results than neurosurgical clipping.

2.7 Suggested profile and training for users

The ACCERO® Stent should only be used by medical doctors who have the required background knowledge and experience in the minimally invasive treatment of the brain using imaging techniques (interventional neuroradiology) and experience in treating vessel wall bulges in the brain (intracranial aneurysm).

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