ENGINEERING STROKE SOLUTIONS

Summary of Safety and Clinical Performance:

ACCERO® heal Stent
Acandis GmbH

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

Identifier: 2403

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 ACCERO® heal Stent.

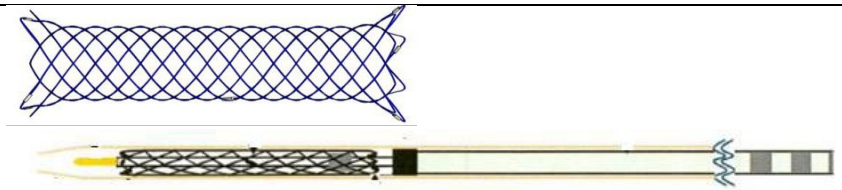
The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9, Rev.1 from March 2022.

The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the ACCERO® heal 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® heal Stent** Article no. 01-001800, 01-001801, 01-001802, 01-001805, 01-001806, 01-001807, 01-001810, 01-001811, 01-001812, 01-001813, 01-001816, 01-001817, 01-001818, 01-001821, 01-001822, 01-001823, 01-001832, 01-001833, 01-001834, 01-001835, 01-001836, 01-001837
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	426065033ACCEROhealR5
Medical device nomenclature	EMDN: P0799 Vascular and Cardiac Prostheses - Other UMDNS: 17-461 (stents, vascular) GMDN: 46352 (stent, bare metal, vascular, intracranial)
Class of device	Class III medical device, as defined in Medical Device Regulation (MDR) EU 2017/745, Annex VIII, rule 8, bullet point 2, and rule 18
Year of first CE certificate	2021
Authorized representative	not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297).

1.2 Intended use of the device

Intended purpose	The ACCERO® heal Stent is used to anchor the embolization materials in the aneurysm when using the stent-assisted coiling method.
Indication(s)	The ACCERO® heal Stent is intended for the treatment of intracranial aneurysms using embolization materials.
Targeted population(s)	*Intended user* The ACCERO® heal 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
	Patient target group No specific patient populations have been defined but patients with contraindications are to be excluded.
Contraindications and/or limitations	- Patients with a life-threatening intracerebral bleeding that requires surgical treatment (and, if possible, clipping). - Patients in whom important side branches emanate from the aneurysm to be treated. - Patients in whom the size of the aneurysm and/or the vessel bearing the aneurysm is not within the indicated range. - Patients who present in the angiography with anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity or stenosis. - Patients with an active bacterial infection. - Patients who were not pretreated with antiplatelet agents prior to the procedure. - Patients in whom anti-platelet and/or anti-coagulation therapy is contraindicated. - Patients who are hypersensitive to nickel-titanium. - Patients who are allergic to heparin.

1.3 Device description

1.3.1 Description of the ACCERO heal Stent

The ACCERO® heal Stent is a self-expanding, fully radiopaque stent, braided from a nitinol (a nickel-titanium alloy) wire with a platinum core (DFT wires). The stent is coated with fibrin-heparin. 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 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. The sizes are specified on the packaging label. The ACCERO® heal Stent is implanted for life.

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, for single-use
Device group	Intracranial neurovascular stent, 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. Transport wire has a preshaped tip (J -shape) to enhance application security. The orange translucent introducer is for optimized visual control for secure transfer of device into the microcatheter hub. The device is a single wire closed loop braided stent for atraumatic stent ends.

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.

1.3.2 Previous generations

The predecessor device is the ACCERO® Stent (1041-4 FDL NG (fourth generation), which has been on the market since April 2021. 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.

The first generation of the ACCERO® heal Stent (1041-7 FDL Matrix) has been on the market since April 2021. The current generation ACCERO® heal Stent (2403 FDL NG Matrix AN) is currently in development.

1.3.3 Accessories

Microcatheters with inner diameters of 0.0165” – 0.017” / 0.021” or 0.027” (recommended Acandis NeuroSlider 17 DLC / 21 DLC or 27 DLC, 27 DLC pro), guide wire and RHV (rotating hemostatic valve).

1.3.4 Combination with other devices

The ACCERO® heal Stent is used in combination with microcatheters and medical devices for neurovascular angiography. Furthermore, coils are applied.

1.4 Complications, warnings and precautions

1.4.1 Complications

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Pseudo)aneurysm, Rupture of or bleeding from aneurysm, (Intracerebral) hemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, Vessel dissection, Vessel perforation, Vessel rupture, Vessel stenosis, Vessel occlusion or thrombosis, Cerebral edema, Infection, (Cerebral) ischemia/infarction, Secondary hemorrhage, Reactions due to radiation exposure, Subarachnoid hemorrhage, Thromboembolic event/stroke, Vasospasm)
- General complications in connection with antiplatelet agents/anticoagulants, anesthetics and contrast agents (e.g. Renal insufficiency)
- Complications in connection with vessel entry (e.g. Hematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during stent delivery/implantation (e.g. No coating function in target area, Transport wire breakage, Stent breakage, Stent folding, Incorrect stent placement, Stent cannot be deployed, Stent cannot be inserted into catheter, Stent cannot be drawn back into catheter, Stent bending, Stent does not detach from transport wire, Stent migration, Insufficient opening, Delayed treatment, Target area inaccessible or cannot be accessed safely, Additional stenting required)
- Other complications in connection with the stent (e.g. Allergic reactions to the stent material, In-stent stenosis, Perforator infarction, Reoperation, Stent occlusion/thrombosis, Incomplete aneurysm occlusion, Occlusion of perforators or branching vessels, Coil migration through the stent mesh)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

The ACCERO® heal Stent and the ACCERO® Stent were demonstrated to be equivalent according to MDR, Annex XIV Part A (3), MDCG 2023-7, Appendix II and MDCG 2020-5. Therefore, a comparable performance as well as safety profile of the ACCERO® heal Stent can be assumed. From the systematic review of the scientific literature and the PMCF measure on the equivalent ACCERO® Stent, only scarce quantitative data on the occurrence of complications could be obtained. No procedure-related morbidity or mortality was observed in the identified studies stating the use of the equivalent ACCERO® Stent. Within the so far identified and evaluated body of literature stating the use of the equivalent ACCERO® Stent in a total of 183 patients and 191 intracranial aneurysms the following complications and respective occurrence rates were reported (chapter 1.5.3.1):

Table 1: Quantification of the occurrence rates of the complications reported for the equivalent ACCERO Stent® after the treatment of 191 intracranial aneurysms in 183 patients.

Reported complications:	**Occurrence rates reported for the equivalent ACCERO® Stent**
Equivalent ACCERO® Stent	
Groin hematoma	Nania A et al., 2020: **1/41 (2.4 %)**
Neurological complications	Beuing O et al., 2020: **2/34 (5.9 %)**
Stent occlusion/thrombosis	Beuing O et al., 2020: **2/30 (6.6 %)** Nania A et al., 2020: **1/41 (2.4 %)** Poncyljusz W et al., 2020: **2/18 (11.1 %)** PMCF study (NCT03957382): **1/25 (4 %)**
Subarachnoid hemorrhage	PMCF study (NCT03957382): **1/25 (4 %)**
Thromboembolic event/stroke	PMCF study (NCT03957382): **1/25 (4 %)**
Vasospasm	Poncyljusz W et al., 2020: **1/18 (5.6 %)**
Stent bending	Poncyljusz W et al., 2020: **1/18 (5.6 %)**
Stent migration	Beuing O et al., 2020: **1/34 (2.9 %)**
Intimal hyperplasia	Kim YH et al., 2025: **1/50 (2 %)**
Stent twisting	Kim & Jung 2024a: **2/26 (7.7 %)**
Hook in problem	Kim & Jung 2024b: **2/26 (7.7 %)**

No new neurological deficits during the hospital stay or a poor procedure- or device-related outcome were reported. Possible reported intra- and post-procedural complications with the device group of (coated) 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. Publications on similar devices of the ACCERO® heal Stent i.e, the LEO+ Stent /Leo+ Baby Stent (BALT Extrusion, Montmorency, France) mentioned the following morbidity and mortality rates:

Table 2: 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® heal 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 device needs to be carefully checked to ensure there is no transportation damage. Under no circumstances, damaged or kinked components should 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 product or perforate a vessel.
- The stent may be shorter after deployment.
- The ACCERO® heal Stent may only be used for the intended purpose. Any use of the ACCERO® heal Stent for other purposes (off-label use) may lead to a deterioration in the patient's state of health or even their death.

Precautions

- The ACCERO® heal Stent is provided sterile and for single use only.
- In case of damage to the sterile barrier, the product must not be used. If any damage is visible, please contact your Acandis representative.
- Do not use the ACCERO® heal Stent after the expiration date printed on the label.
- Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise structural integrity of the ACCERO® heal Stent and/or lead to device failure that, in turn, may result in complications, patient injury or death. Reuse, reprocessing or re-sterilization of the device also increases the risk of contamination of individual components and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of individual components 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 ACCERO® heal Stent.
- In order to minimize potential complications during and after the intervention, attention should be paid to careful medication treatment in accordance with the current guidelines from the medical societies (antiplatelet agents and anticoagulants prior to treatment and anticoagulants du ring the intervention). The administration of unsuitable antiplatelet agents and anticoagulants may lead to a stent thrombosis.

- Medication is an important part of stent treatment. Thus, it is important to instruct the patient to take the prescribed medication after stent implantation and to make them aware of the risks of noncompliance with the medication regimen.

1.4.3 Other relevant aspects of safety

There have been no recalls, FSNs, FSCAs. PMS data covering the period between market launch in April 2021 to October 2024 reveal an overall complaint rate of 2.64 % after 455 sold ACCERO heal® Stents. The incident rate during the current collection period (November 01, 2023 – October 31, 2024) is 1.16%.

Nevertheless, the medical benefit continues to outweigh the residual risk. There were no relevant hits on unduly or unknown risks of the ACCERO heal® Stent or the equivalent 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

Equivalence to the ACCERO® heal Stent is claimed for the ACCERO® Stent according to MDR, Annex XIV Part A (3), MDCG 2023-7, Appendix II and MDCG 2020-5. Clinical data on the equivalent ACCERO® Stent were used for the clinical evaluation to proof conformity with the considered relevant General Safety and Performance Requirements (GSPRs) (see Table 3).

1.5.1.1 Clinical data in the literature on the equivalent ACCERO® Stent

Table 3: Summary of clinical data from publications stating the use of the equivalent ACCERO® Stent. ICA: internal carotid artery, MCA: middle cerebral artery, mRS: Modified Rankin Scale, PICA: Posterior inferior cerebellar artery, PTA: percutaneous transluminal angioplasty, RROG: Raymond Roy Occlusion Grades, SAC: stent-assisted coiling, SAH: subarachnoid hemorrhage.

Reference [Author, title]	Used device	Included patient no. [female / male] average age	Follow-up [months]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Beuing et al., 2020 Stent-assisted coiling of broad-necked intracranial aneurysms with a new braided microstent (ACCERO: procedural results and long-term follow-up	ACCERO® Stent	**32** [27 / 5] 57.1 years	**6 / 18**	- Deployment of the stent was successful in all 34 treatments. - Complete aneurysm occlusion (RROG 1) was achieved in 18 (52.9 %) aneurysms, a neck remnant (RROG 2) was present in 10 (29.4 %) aneurysms. - After an average of 15 months of follow-up, 28/30 aneurysms were completely or near-completely occluded.	- Four (12.5 %) patients had acute SAH with WFNS (World Federation of Neurological Surgeons) grades of 1 (n = 3) and 4 (n = 1), respectively. Approximately half of the patients were retreated after coiling (n = 16) or clipping (n = 2). All aneurysms had a neck width of >4 mm and / or a dome-to-neck ratio of <2. Aneurysm localizations were as follows: anterior communicating artery (n = 13), MCA-bifurcation (n = 7), basilar artery (n = 4), posterior communicating artery (n = 3), peri-callosal artery (n = 2), posterior inferior cerebellar artery (PICA, n = 2) internal carotid artery (ICA, n = 1), carotid-t (ICA-T, n=1) and posterior cerebral artery (n = 1). - Thirty-four aneurysms were treated with stent-assisted coiling using the ACCERO Stent. Sixteen aneurysms were untreated, four of these were ruptured.	The ACCERO stent proved to be safe and effective in the treatment of broad-based intracranial aneurysms. The complication rate and the rate of successful aneurysm occlusions are similar to those of other stents.

Reference [Author, title]	Used device	Included patient no. [female / male] average age	Follow-up [months]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
					- SAC with a single ACCERO Stent was planned in 25 aneurysms, and in 9 cases, primary Y-stenting was considered necessary. - Mild neurological complications occurred in 2/34 (5.9 %) treatments. - In one case (2.9 %), proximal dislocation of the stent occurred by entangling of the pusher wire with the stent struts, which required placement of second stent. No further rescue stents were necessary in this or any other patient. - Two stent occlusions occurred during follow-up. No patient had a poor procedure- or device-related outcome.	
Nania et al., 2020 Early experience treating intracranial aneurysms using ACCERO: a novel, fully visible, low profile braided stent with platinum–nitinol composite wire technology	ACCERO® Stent	**41** [31 / 10] 58 years	**Clinical:** 30 days **Imaging:** **3 / 6** (two patients 9 /12)	- The stent was successfully deployed with good angiographic results and aneurysm occlusion with coils was achieved in 100 % of the patients. - At the early follow-up, available for 37 patients, the complete occlusion rate was 76 %, with only two recurrences needing further treatment. Satisfactory aneurysm occlusion was, therefore, achieved in 95 % of cases.	- 41 aneurysms were treated with stent-assisted coiling. All cases were elective, of which 19 were previously untreated aneurysms and 22 were recurrent aneurysms. - Aneurysm location was anterior communicating artery complex (16), basilar (12 cases), middle cerebral artery bifurcation (9 cases), and internal cerebral artery (4 cases). The average size of the aneurysms was 7.5 mm with range extending from 4 to 22 mm. - In most cases the jailing stent-coiling technique (38 /41) was used; in two cases a Y-stenting technique was adopted. - One case of on table in-stent thrombosis occurred, which resolved after administration of glycoprotein IIB/IIIA inhibitor, with no clinical consequence, and one case of postoperative hematoma at the arteriotomy site, which was managed conservatively.	Stent-assisted coiling with the ACCERO braided stent proved safe and effective.
Poncyljusz et al., 2020 Evaluation of the ACCERO Stent for Stent-Assisted	ACCERO® Stent	**17** [11 / 6] 63 years	**Clinical:** 30 days **Imaging:** **6**	- All stents were deployed successfully. Immediate complete occlusion rate Raymond-Roy occlusion classification (RROC) class I	- Patients were included with unruptured wide necked (neck > 4 mm or dome to neck ratio < 2) brain aneurysms (< 20 mm maximum diameter in any plane).	ACCERO Stent proved excellent support for coil mass with excellent visibility, due to the radiopacity of the

Reference [Author, title]	Used device	Included patient no. [female / male] average age	Follow-up [months]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Coiling of Unruptured Wide-Necked Intracranial Aneurysm Treatment with Short-Term Follow-Up				was achieved in 13 cases and class II in 4 cases. - Ninety days after intervention, the modified Rankin Scale (mRS) value was 0. RROC class I was observed in 88.23 % of cases in follow-up.	- In all cases, the jailing technique was used and after stent implantation, coil embolization was performed. - 17 patients with 18 incidental unruptured aneurysms were electively treated with coiling and the ACCERO Stent. - The aneurysms were located on ICA (58.8 %), MCA (35.3 %) and basilar artery (5.9 %). All aneurysms were wide-necked (dome-to-neck ratio of < 2), 7 (41.2 %) cases were bifurcation aneurysms, and 10 (58.8 %) were sidewall aneurysms. - Complications occurred in 2/17 treatments (11.7 %) and included guidewire stent perforation with SAH and stent deformation. Vascular spasm in the SAH patient subsided before discharge. - No case of stent thrombosis was observed. Perforation occurred due to trauma incited by the long stent's pushing wire of small aneurysm located above the treated aneurysm. Consequently, the patient developed a small SAH and vascular spasm with neurological symptoms. However, the symptoms subsided almost completely until the discharge from the hospital (mRS 1). Stent deformation occurred during the treatment of an aneurysm of the ICA that exhibited complicated anatomy of the syphon. Incomplete opening at the proximal segment of the stent was noticed after implantation. PTA with Eclipse 2L balloon (Balt, Montmorency, France) was performed, which slightly changed the structure of the stent, and eventually it was not hemodynamically relevant. There were no clinical complications or puncture site adverse events.	Platinum-Nitinol composite wire. Also, it demonstrated its effectiveness with good initial occlusion rate for treating wide-necked unruptured intracranial aneurysms

Reference [Author, title]	Used device	Included patient no. [female / male] average age	Follow-up [months]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Kim & Jung 2024a Immediate and short-term results of accero stent-assisted coil embolization: unveiling novel strides in vascular intervention	ACCERO® Stent	**26** [23 / 3 / 65 years]	**Clinical:** n.a. **Imaging: 6**	Technical success: 100 % Clinical Success*: not reported	Stent twisting: 7.7 % Hook in problem: 7.7 %	ACCERO® Stent, with its distinctive structural characteristics and properties, presents challenges like hook-in problems during deployment, underscoring the importance of a comprehensive understanding of its structure. Diverging from other stents, it provides broader metal coverage, suggesting a potential flow diversion effect
Çay & Arat 2024 Appraisal of the Flow Diversion Effect Provided by Braided Intracranial Stents	ACCERO® Stent	**86** [n.a. / n.a. / n.a. years] (Leo baby; n = 69 and ACCERO; n = 17)	**Clinical:** <12 **Imaging: 24.5**	Technical success: not reported Clinical success*: 96.5 % (combined for ACCERO® Stent and Leo baby)	No procedure- or device related complications reported.	Braided stents may be considered to have merely some (partial) flow diversion effect.
Kim YH 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.	ACCERO® Stent	**50** [39 / 11 / 58 years]	**Clinical: 17.1** **Imaging: 6/12**	- Successful stent deployment was achieved in 100% of the cases as well as appropriate wall apposition to the parent artery. - Favorable clinical outcomes were observed in 92% of patients (46/50), including those with subarachnoid hemorrhage. Immediate favorable angiographic outcomes and complete	Intimal hyperplasia: 2 %	ACCERO® Stent is a braided-type stent that requires more attention than stents, such as the Neuroform Atlas or Enterprise stents. However, since the struts of the stent are fully visible, it can be more useful in treating

Reference [Author, title]	Used device	Included patient no. [female / male] average age	Follow-up [months]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
				occlusion were achieved in 90% (45/50) and 74% (37/50) of cases, respectively. - Among the 45 patients who had imaging follow-up, favorable angiographic outcomes and complete occlusion were observed in 93.3% (43/45) and 82.2% (37/45) of cases, respectively.		challenging aneurysms once the user becomes familiar with its use

1.5.1.2 Summary and conclusion on safety and clinical performance

Available references on the equivalent ACCERO® Stent, so far, include clinical data on 90 patients treated with the device (Table 3). The equivalent ACCERO® Stent was tested in three case series and three clinical study by Beuing O et al., Nania A et al., Poncyljusz W et al., Cay and Arat, Kim and Jung and Kim YH, particularly regarding its safety and performance. The articles state that the equivalent ACCERO® Stent provides excellent support for coil mass, constitutes an efficacious device with good initial occlusion rate and is proven effective and safe for treating wide-neck unruptured intracranial aneurysms / broad-based intracranial aneurysms. Furthermore, it was mentioned that the complication rate and the rate of successful aneurysm occlusions are similar to those of other stents on the market.

The ACCERO® heal Stent and the ACCERO® Stent were demonstrated to be equivalent according to MDR, Annex XIV Part A (3), MDCG 2023-7, Appendix II and MDCG 2020-5. Therefore, a comparable performance as well as safety profile of the ACCERO® heal Stent can be assumed.

Clinical performance parameters include:

- **technical success** (i.e., proper stent placement (including adequate stent expansion/opening, complete wall apposition and visibility) as well as
- **clinical success** (i.e., complete/near-complete aneurysm occlusion determined by means of Raymond-Roy occlusion classification (RROC)). An RROC of I and II was considered clinical success.

1.5.1.2.1 Technical success

In literature, **the performance parameter of technical success** i.e., proper stent placement (including adequate stent expansion/opening, complete wall apposition and visibility) is mostly stated as the number of successfully deployed devices. In the following the technical success rates derived from information provided in the literature stating the use of the equivalent ACCERO® Stent are given in Table 4.

Table 4: Technical success rates as derived from the literature (including PMCF data) stating the use of the equivalent ACCERO® Stent after the treatment of 199 intracranial aneurysms in 191 patients

Citation	Patient /aneurysm number	Technical success rate	Comment
Equivalent ACCERO® Stent			
Beuing O et al., 2020	32/34	**34/34 (100 %)**	Deployment of the stent was successful in all 34 treatments. In one case (2.9 %), proximal dislocation of the stent occurred by entangling of the pusher wire with the stent struts, which required placement of a second stent. No further rescue stents were required in this or any other patient."
Nania A et al., 2020	41/41	**41/41 (100 %)**	Stent deployment was successful in all cases with good angiographic results, and satisfactory occlusion of the aneurysm.
Poncyljusz W et al., 2020	17/18	**18/18 (100 %)**	The ACCERO® Stents were deployed successfully in all cases with good wall apposition, which did not require percutaneous transluminal angioplasty (PTA) to be performed inside the stent, except in one case." Furthermore, the paper mentioned that "all stents in various configurations were characterized by excellent visibility, due to radiopacity of the Platinum-Nitinol composite wire, which allowed the visualization of the entire contour of the stent."
Kim and Jung, 2024a	26/31	**26/26 (100 %)**	The Accero stent was deployed successfully in all 26 patients without delivery failure.
Kim YH et al., 2025	50/50	**50/50 (100 %)**	Successful stent deployment was achieved in 50 cases, and appropriate wall apposition to the parent artery.
PMCF study (NCT03957382)	25/25	**23/25 (92 %)**	A high technical success rate of 92.0 % (23/25 patients) was observed

Within the evaluated body of literature (including PMCF data) stating the use of the equivalent ACCERO® Stent in a total of 191 patients with at least 199 intracranial aneurysms the technical success rate achieved by using the equivalent ACCERO® Stent ranges between **92 % – 100 %.**

Similar devices as well as the product group in general show comparable successful results. As revealed by the clinical evaluation, the technical success rates of the similar devices **Leo+ / Leo+(baby**) varied in the range of approx. **19 % – 100 %.** It can thus be concluded that regarding the performance parameter of technical success the equivalent ACCERO® Stent and thus the ACCERO® heal Stent is non-inferior to the state-of-the-art.

1.5.1.2.2 Clinical success

In literature, **the performance parameter of clinical success** i.e., complete/near-complete aneurysm occlusion is assessed using the Raymond-Roy or Modified Raymond-Roy occlusion classification (RROC). An RROC of class I means a complete aneurysm occlusion, class II means a residual neck and class III means a residual aneurysm. An RROC of I and II was considered clinical success. According to the identified literature stating the use of the equivalent ACCERO® Stent, clinical success by means of the RROC was as follows (Table 5).

Table 5: Clinical success rates by means of the Raymond-Roy-Classification (RROC) as given in the literature (including PMCF data) stating the use of the equivalent ACCERO® Stent after the treatment of 216 intracranial aneurysms in 208 patients. Abbreviations: – no data provided

Citation	Patient number	RROC I (complete aneurysm occlusion)	RROC II (residual neck)	RROC III (residual aneurysm)
Equivalent ACCERO® Stent				
Beuing O et al., 2020	30	**21/30 (70.0 %)**	7/30 (23.3 %)	2/30 (6.7 %)
Nania A et al., 2020	37	**28/37 (75.7 %)**	8/37 (21.6 %)	1/37 (2.7 %)
Poncyljusz W et al., 2020	17	**14/17 (82.4 %)**	3/17 (17.7 %)	0/17 (0.0 %)
Cay & Arat 2024	86*	**64/86 (74.4 %)**	**19/86 (22.1 %)**	3/86 (3.5 %)
Kim YH et al., 2025	50	**32/50 (78 %)**	**6/50 (14.6 %)**	3/50 (7.3%)
PMCF study (NCT03957382)	25	**22/25 (88.0 %)**	2/25 (8.0 %)	1/25 (4.0 %)

*Leo baby (n = 69) and Accero (n = 17), no further distinction was made in the analysis. Kim and Jung did not evaluate the clinical success rates

Within the evaluated body of literature stating the use of the equivalent ACCERO® Stent in a total of 208 patients and at least 216 intracranial aneurysms clinical success defined as RROC I/II achieved by using of the equivalent ACCERO® Stent ranges between **93.3 % and 97.3 %**, respectively. As revealed by the clinical evaluation similar devices as well as the product group in general show comparable successful results. The occlusion success rates of the similar devices **Leo+ /Leo+(baby**) varied in the range of approx. **74 % to 85 %**. This also depends on the follow-up time. The combined clinical success rates for ACCERO and Leo baby in (Cay & Arat 2024) is **96.5 %**, thus comparable to the success rates of the other studies. It can thus be concluded that regarding the performance parameter of clinical success the equivalent ACCERO® Stent and thus the ACCERO® heal Stent is non-inferior to the state-of-the-art.

Summary and conclusion: Regarding the clinical outcome parameters for performance the equivalent ACCERO® Stent and thus the ACCERO® heal 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.

1.5.1.3 Clinical outcome parameters for safety

Safety parameters are the frequency of occurrence of complications such as 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.

The scientific literature identified in the clinical evaluation covers such complications in a comprehensible way. Within the limited evaluated body of literature stating the use of the equivalent ACCERO® Stent in a total of 183 patients and 191 intracranial aneurysms the following complications and respective occurrence rates were reported (Table 6).

Table 6: Quantification of the occurrence rates of the complications reported for the equivalent ACCERO® Stent after the treatment of 191 intracranial aneurysms in 183 patients.

Reported complications:	**Occurrence rates reported for the equivalent ACCERO® Stent**	
Equivalent ACCERO® Stent		
Groin hematoma	Nania A et al., 2020:	**1/41 (2.4 %)**
Neurological complications	Beuing O et al., 2020:	**2/34 (5.9 %)**
Stent occlusion/thrombosis	Beuing O et al., 2020: Nania A et al., 2020: Poncyljusz W et al., 2020: PMCF study (NCT03957382):	**2/30 (6.6 %)** **1/41 (2.4 %)** **2/18 (11.1 %)** **1/25 (4 %)**
Subarachnoid hemorrhage	PMCF study (NCT03957382):	**1/25 (4 %)**
Thromboembolic event/stroke	PMCF study (NCT03957382):	**1/25 (4 %)**
Intimal hyperplasia	Kim YH et al., 2025:	**1/50 (2 %)**
Stent twisting	Kim & Jung 2024a:	**2/26 (7.7 %)**
Hook in problem	Kim & Jung 2024b:	**2/26 (7.7 %)**

As revealed by the clinical evaluation, similar devices as well as the device group in general show comparable successful results. When comparing occurrence rates of particular complications related to the use of the equivalent ACCERO® Stent and the similar Leo+ / Leo+(baby), it can be concluded that the risk profiles are quantitatively and qualitatively comparable. It can therefore be concluded that regarding the above safety parameters the equivalent ACCERO® Stent and thus ACCERO® heal Stent is non-inferior to the state-of-the-art.

Summary and conclusion: The ACCERO® heal Stent and the ACCERO® Stent were demonstrated to be equivalent according to MDR, Annex XIV Part A (3), MDCG 2023-7,

Appendix II and MDCG 2020-5. Therefore, a comparable performance as well as safety profile of the ACCERO® heal Stent can be assumed.
Complications occurred with the equivalent ACCERO® Stent were within the known and manageable spectrum of device-and procedure-related complications inherent to this kind of intervention. Hence, the safety profile of the ACCERO® heal Stent seems to be within the expected and known range inherent to the device group of (coated) self-expandable intracranial neurovascular stents serving as anchors for embolization material. This was substantiated by clinical data on the similar Leo+ Baby / Leo+ stents as well as benchmark devices from the same generic device group of (coated) intracranial stents in their regular clinical use.
It can therefore be concluded that 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® heal Stent is non-inferior to the state-of-the-art and can thus be considered a state-of-the-art device regarding safety in its intended purpose.

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

Clinical data could be obtained from a PMCF-study (chapter 1.5.3.1) and medical device databases (chapter 1.5.3.2). Despite a comprehensive and systematic literature search in the relevant databases, no literature could be retrieved stating the use of the ACCERO® heal Stent.

1.5.3.1 Clinical data obtained by clinical trials or PMCF-measures

Acandis is conducting a prospective, multicenter, national PMCF Study with the ACCERO® heal Stent and the equivalent ACCERO® Stent (NCT03957382).
However, as of February 13, 2023, preliminary results on performance and safety after the analysis of data from 25 patients treated with the equivalent ACCERO® Stent and 6 months follow up are available: The study primary endpoint was met with 88 % of treated aneurysms having a complete obliteration (RROC I) at 6 months follow-up (class II RROC was observed in 2 patients (8.0 %) and class IIIa RROC was observed in 1 patient (4.0 %) at 6 months follow-up). Regarding the primary efficacy endpoint the following mRS distribution was observed: mRS 0 (21 patients, 84 %), mRS 1 (1 patient, 4 %), mRS 2 (1 patient, 4 %) and mRS4 (2 patients, 8 %). Compared to baseline 3 patients (12.0 %) had improvement in mRS, in 21 patients (84.0 %) no change was observed and for 1 patient (4.0 %) deterioration was

documented. A high technical success rate of 92.0 % (23/25 patients) was observed. Preliminary results on safety: Low (S)AEs rate was 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 hemorrhage (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)

1.5.3.2 Clinical data from medical device databases

BfArM (German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions): Latest search on April 04, 2025: No entries concerning the ACCERO® heal Stent, the equivalent ACCERO® Stent. One hit concerning the similar Leo+ Stent was identified describing a packaging failure. No entries concerning the benchmark device LVIS but one relevant hit concerning the device group of intracranial neurovascular stents. This hit is a known complication of intracranial neurovascular stents.

MAUDE ("Manufacturer and User Facility Device Experience (MAUDE) Database, maintained by the United States' Food and Drug Administration), latest search on April 04, 2025. As the ACCERO® heal Stent and the equivalent ACCERO® Rex are not marketed in the USA, no searches for the devices were conducted.

- No entries concerning the similar devices Leo Baby and Leo+ Baby
- Some entries concerning the benchmark devices LVIS jr and LVIS Evo regarding deaths, injuries and malfunctions.

The entries deal with risks and complications inherent to the risk profile of the devices and the procedure of stenting of an intracranial aneurysm. Hence, these risks are known to the trained and experienced physician who knows how to handle them. Overall, these entries do not indicate high failure or incident rates of neurovascular stents which are comparable to the ACCERO® heal Stent. Thus, there is no allusion to an unfavorable risk profile of such systems in routine clinical use.

From this point of view, the ACCERO® heal Stent, the equivalent ACCERO® Stent, the similar devices and the benchmark devices appear as safe and eligible 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 treatment of intracranial aneurysms in general and by (coated) self-expanding intracranial neurovascular stents, together with the clinical data from peer-reviewed publications stating the use of the equivalent ACCERO® Stent, the results from the searches in authority-maintained vigilance databases as well as the data collected from PMS and the PMCF study on the ACCERO® heal Stent and the equivalent ACCERO® Stent prove the clinical performance and safety of the ACCERO® heal Stent. The reviewed publications encompassing case series and clinical studies provide sound evidence that by using the equivalent ACCERO® Stent and therefore the ACCERO® heal Stent, a successful and safe occlusion of intracranial aneurysms is feasible. For the equivalent ACCERO® Stent and thus the ACCERO® heal Stent it could be shown that the device achieves a performance by means of technical and clinical success rates as well as has a qualitative and quantitative safety profile comparable to well-established devices from the device group of (coated) self-expandable intracranial neurovascular stents.

Within the evaluated body of literature (including PMCF data) stating the use of the equivalent ACCERO® Stent in a total of 191 patients and 199 intracranial aneurysms the technical success rate achieved by using the device ranges between **92 % – 100 %.** Within the evaluated body of literature stating the use of the equivalent ACCERO® Stent in a total of 208 patients and 216 intracranial aneurysms clinical success defined as RROC I/II achieved by using of the device ranges between **93.3 % and 97.3 %**, respectively. Therefore, the ACCERO® heal Stent and the equivalent ACCERO® Stent are suitable for their intended purpose, namely the occlusion of aneurysms through the technique of stent-assisted coiling. Thus, it can be concluded that the equivalent ACCERO® Stent and therefore also the ACCERO® heal Stent achieves the performances intended by Acandis and meets the requirement for performance.

Complications, ranging from mild to severe, associated with the procedure and the devices themselves as well as the device group in general used in the treatment of intracranial aneurysms by stent-assisted coiling are thoroughly described in the medical scientific literature, thus being known to the professional user. The complications that may occur during and after the treatment with 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 mention morbidity rates from 2.3 % to 4.1 % and mortality rates from 0.6 to 3.5 % (data from 388 patients, follow-up time from 11 months to 5 years) see details in chapter 1.4.1. According to the identified and reviewed literature stating the use of the equivalent ACCERO® Stent (Table 3) as well as the results of the interim analysis of the PMCF study including 25 patients treated with the equivalent ACCERO® Stent and with completed 6 months follow-up , the following complications occurred when the device was used:

- Groin hematoma
- Neurological complications
- Stent bending
- Stent migration
- Stent occlusion/thrombosis
- Subarachnoid hemorrhage
- Thromboembolic event/stroke
- Vasospasm
- Intimal hyperplasia
- Stent twisting as well as a hook in problem

No evidence on unduly or unknown risks of the ACCERO® heal Stent and the equivalent ACCERO® Stent were identified. Further, when comparing occurrence rates of particular complications related to the use of the equivalent ACCERO® Stent and the similar devices Leo+ /Leo+(baby), it can be concluded that the risk profiles are quantitatively and qualitatively comparable. Hence, the safety profile of the equivalent ACCERO® Stent and therefore of the ACCERO® heal Stent seems to be within the expected and known range inherent to the generic device group of self-expandable intracranial neurovascular stents. The basic design, as well as the material used for the devices, have been successfully applied for several years. The ACCERO® heal Stent was subjected to various pre-clinical and laboratory test reports according to (harmonized) standards with successful results. Thus, the ACCERO® heal Stent meets the requirement for safety. It was therefore concluded that complication rates are low, and complications occurred are within the known and manageable spectrum of device-and procedure-related complications inherent to this kind of intervention.

According to the clinical data presented in the scientific literature, the information gained from PMS, PMCF as well as the risk analysis, it can be concluded that risks which may be associated with the intended use of the ACCERO® heal Stent constitute acceptable risks when weighed against the benefits to the patient. Further, it can be concluded that for patients carefully selected for this treatment, undesirable side-effects constitute an acceptable risk

when weighed against the performance intended by the clinician in charge. The main risks are described and documented in detail in scientific literature, thus being known to trained professional user. Therefore, by complying with all warnings and precautions, the ACCERO® heal Stent offers an acceptable benefit-risk profile and meets the requirement for an acceptability of side effects and acceptable benefit-risk profile.

Clinically relevant marketing claims made by Acandis regarding safety and performance are adequately supported by product specifications, performance tests, in vivo tests, a simulated application test, the availability of the 3D Sizing Simulation software ANKYRAS and literature (Poncyljusz W et al., 2020; Nania A et al., 2020; Beuing O et al., 2020 Cay and Arat, Kim and Jung and Kim YH).

In conclusion:

- The ACCERO® heal Stent could be shown to be in compliance with the considered relevant GSPRs.
- The intended clinical benefit associated with the ACCERO® heal Stent is substantiated using relevant and specified clinical outcome parameters.
- Relevant risks are identified, analyzed, mitigated, evaluated, and considered to be acceptable.
- Acceptability of the benefit-risk ratio was assessed under consideration of known hazards and the available clinical data on the ACCERO® heal Stent and the equivalent ACCERO® Stent. As both the intended 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.

1.5.5 Ongoing or planned post-market clinical follow-up

Acandis is conducting a prospective, multicenter, national PMCF Study with the ACCERO® heal Stent and the equivalent ACCERO® Stent (NCT03957382).
The enrollment started on July 23, 2019. In Q2 2022, the ACCERO® heal Stent was included in the PMCF study. Interim results for the ACCERO® heal Stents are not available. As of February 13, 2023, results of an interim analysis including 25 patients with completed 6 months follow-up treated with the equivalent ACCERO® Stent are available. The planned study end is December 31,2026.

1.6 Possible diagnostic of therapeutic alternatives

For intracranial aneurysm treatment by self-expandable intracranial neurovascular stents 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 A et al., 2018).

However, the decision of whether to treat an aneurysm 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 (Arthur AS et al., 2019; Chen JK et al., 2018).

1.7 Suggested profile and training for users

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

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	10993-11	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 products from metals and alloys (ISO 10993-15:2019)	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	10993-18	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 + COR1:2009 + Amd1:2019)	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	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)	2012
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 (ISO 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, Corrected version 2021-12)	2021
EN ISO	22442-1	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22422-1:2020)	2020
EN ISO	22442-2	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2020)	2020
EN ISO	22442-3	Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)	2007
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	2001+AC:2006
EN	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020)	2015+AC:2015+A1:2020
EN	868-2	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods	2017

2 Information for the patient

Document revision: 03

Date issued: May 13th, 2025

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® heal Stent** Article no. 01-001800, 01-001801, 01-001802, 01-001805, 01-001806, 01-001807, 01-001810, 01-001811, 01-001812, 01-001813, 01-001816, 01-001817, 01-001818, 01-001821, 01-001822, 01-001823, 01-001832, 01-001833, 01-001834, 01-001835, 01-001836, 01-001837
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: 426065033ACCEROhealR5
Year of first CE certificate	2021

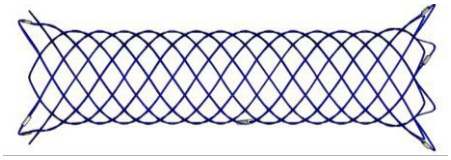
2.2 Intended use of the device

Intended purpose	The ACCERO® heal Stent (a wire mesh) stabilizes the vessel in the brain which has a bulge (intracranial aneurysm). Then, special very small platinum coils (embolization material) are anchored in the aneurysm (stent-assisted coiling method).
Indication(s)	The ACCERO® heal Stent is intended for the treatment of intracranial aneurysms using embolization materials.
Intended patient groups	No specific patient populations have been defined but patients with contraindications are to be excluded.
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 with blood vessels that are very twisted or narrowed (severe vessel tortuosity or stenosis) may not be suitable for a treatment in the vessels (endovascular treatment) when they are examined in a special X-ray test (angiography). - 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. - Patients with allergic reactions to heparin. No limitations are mentioned in the IFU

2.3 Device description

2.3.1 Description of the ACCERO heal Stent



The ACCERO® heal Stent is a self-expanding stent. It is braided of Nitinol wires with a platinum core. 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 surface of the ACCERO® heal is coated with heparin and fibrin, which protects from blood clotting. ACCERO® heal is implanted for a lifetime.

Sizes: Diameters: 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® heal 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 (aneurysm).

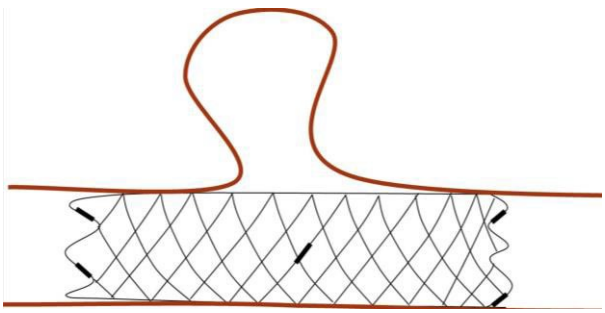


Figure 1: ACCERO® heal (black grid) when placed under the vessel wall bulge (aneurysm).

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® heal.

2.3.3 Accessories

Small, flexible hollow tubes (microcatheters) for insertion.

2.4 Complications, warnings and precautions

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 Complications

Acandis employed a risk management system according to the European Union (EN) adopted ISO (International Organization for Standardization): EN ISO 14971:2019+A11:2021. This is the industry standard. It is written in the risk management report that the ACCERO® heal is safe for treatment. The medical benefits outweigh the residual risk.

Possible complications are known even when the ACCERO® heal Stent is used according to common knowledge. The physicians are aware of these unwanted effects. They can manage them. The most commonly reported complications in a total of 183 patients treated with the equivalent (in terms of technical, biological and clinical characteristics) ACCERO® Stent were:

- Collection of blood outside of blood vessels (hematoma) in the groin
- Complications affecting the nervous system (neurological complications)
- Blockage of the stent (stent occlusion/thrombosis)
- Bleeding in the space that surrounds the brain (subarachnoid hemorrhage)
- Blocking of a blood vessel by a particle that has broken away from a blood clot at its site of formation (thromboembolic event) or a sudden disabling attack or loss of consciousness caused by an interruption in the flow of blood to the brain, especially through thrombosis (stroke)
- Sudden constriction of a blood vessel, reducing its diameter and blood flow. (vasospasm)
- Stent bending

- Stent movement (migration)
- Embolization material movement (migration)
- Thickening of the intima by unspecific reaction (intimal hyperplasia)
- Stent twist

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))
- 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. no coating function in target area, transport wire breakage, stent breakage, stent folding, incorrect stent placement, stent cannot be deployed, stent cannot be inserted into catheter, stent cannot be drawn 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, movement of emolization material)
- Neurological problems (e.g. Speech problems, Weakness on one side of the body, Paralysis on one side of the body, Vision problems, Weakness of the eye muscle)
- 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® heal Stent.
In the following, only the patient-related warnings and precautions are listed:

- 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 have been no relevant aspects of safety.

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

In the literature, physicians reported on 183 patients treated and followed-up with the equivalent ACCERO® Stent (Beuing O et al., 2020; Nania A et al., 2020; Poncyljusz W et al., 2020; Cay and Arat, 2024; Kim YH et al., 2025; Kim and Jung, 2024a) as well as an interim analysis on 25 patients of the PMCF study (NCT03957382)).
The reports mention that the equivalent ACCERO® Stent provides excellent support for the embolization material (small platinum coils) and that the equivalent ACCERO® Stent is an effective device with good occlusion rates (88 % - 95 %). 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 with the equivalent ACCERO® Stent were the known complications with such stents and the surgical procedure. Hence, the safety of the ACCERO® heal Stent seems to be similar to such of other stents on the market.

In general, all authors evaluated the equivalent ACCERO® Stent as safe and efficient self-expandable, intracranial stent for the treatment of intracranial aneurysms by stent-assisted coiling.

A PMCF study with the ACCERO® heal Stent and the equivalent ACCERO® Stent is ongoing. So far, results for the ACCERO® heal Stent have not been available. However, first results are available for patients treated with the equivalent ACCERO® Stent confirming the device's performance and safety.

It can be concluded that the risks which may be associated with the use of the ACCERO® heal Stent constitute acceptable risks when weighed against the benefits to the patient. The ACCERO® heal Stent and the equivalent ACCERO® Stent achieve high technical and clinical success rates. The technical and clinical success rates are comparable to those achieved by the device group of self-expandable intracranial stents.

In conclusion, the ACCERO® heal Stent could be shown to be a state-of-the-art device in accordance with the provisions made by law. The safety and performance of the device can be confirmed.

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

3 Bibliography

No.	Citation
1	Arthur AS, Abecassis IJ, Abi-Aad KR, Albuquerque FC, Almefty RO, Aoun RJN, Barrow DL, Bederson J, Bendok BR, Ducruet AF, Fanous AA, Fennell VS, Flores BC, Griessenauer CJ, Kim LJ, Levitt MR, Mack WJ, Mascitelli J, Min E, Mocco J, Morr S, Nerva JD, Richards AE, Schirmer CM, See AP, Snyder KV, Tian F, Walcott BP, Welz ME. Essential Neurosurgery For Medical Students. Operative Neuro Surgery, 0:0, 2019, 1-43
2	Beuing O, Lenz A, Donitza A, Becker M, Serowy S, Skalej M. Stent-assisted coiling of broad-necked intracranial aneurysms with a new braided microstent (ACCERO®): procedural results and long-term follow-up. Sci Rep. 2020;10(1):412. Published 2020 Jan 15.
3	Çay F & Arat A (2024) Appraisal of the Flow Diversion Effect Provided by Braided Intracranial Stents. Journal of clinical medicine 13:3409.
4	Chen JK, Thyssen JP. Metal Allergy: From Dermatitis to Implant and Device Failure. Springer, 13.04.2018 - 578 Seiten
5	Duan Y, Xu B, Qin X, Mao R, Hu Y, Zhou B, Li J, Chen G. Flow diversion effect of the leo braided stent for aneurysms in the posterior and distal anterior circulations: A multicenter cohort study. Front Neurol. 2022 Sep 27;13:957709.
6	Eker OF, Levrier O, Houdart E, Bonja M, Herbreteau D, Bonafé A, Desal H; LEO+ II Investigators. Endovascular Treatment of Complex Intracranial Aneurysms With LEO+ Stents: The LEO II Cohort Study. Front Neurol. 2022 Jun 28;13:848683.
7	Kim M & Jung Y (2024a) E-269 Immediate and short-term results of accero stent-assisted coil embolization: unveiling novel strides in vascular intervention. Journal of neurointerventional surgery 16:A250.2-A251.
8	Kim M & Jung Y (2024b) E-273 Addressing the ‘hook-in’ problem in accero stent-assisted coil embolization: understanding cases, and solutions. Journal of neurointerventional surgery 16:A252.2-A252.
9	Kim YH, Kim CH, Lee SW, Lee CH, Lee SH, Lee JS, Sung SK, Son DW. Clinical safety and efficacy of stent-assisted coil embolization with ACCERO stent in cerebral aneurysm: Short-term follow-up and precaution for use. J Cerebrovasc Endovasc Neurosurg. 2025 Feb 24.
10	Lindgren A, Vergouwen MD, van der Schaaf I, Algra A, Wermer M, Clarke MJ, Rinkel GJ. Endovascular coiling versus neurosurgical clipping for people with aneurysmal subarachnoid haemorrhage. Cochrane Database Syst Rev. 2018 Aug 15;8:CD003085.
11	Nania A, Dobbs N, DuPlessis J, Keston P, Downer J. Early experience treating intracranial aneurysms using ACCERO®: a novel, fully visible, low profile braided stent with platinum-nitinol composite wire technology [published online ahead of print, 2020 Jun 10]. J Neurointerv Surg. 2020;neurintsurg-2020-015918.
12	Poncyljusz W, Kubiak K, Sagan L, Limanówka B, Kołaczyk K. Evaluation of the ACCERO® Stent for Stent-Assisted Coiling of Unruptured Wide-Necked Intracranial Aneurysm Treatment with Short-Term Follow-Up. J Clin Med. 2020 Aug 31;9(9):E2808.
13	Zhao J, Lin H, Summers R, Yang M, Cousins BG, Tsui J. Current Treatment Strategies for Intracranial Aneurysms. Angiology. 2017 Jan 1:3319717700503.