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

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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® heal Stent.

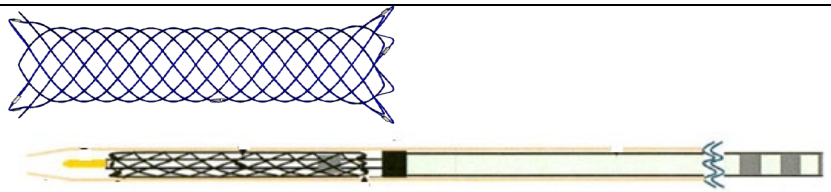
The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9, Rev.1 from March 2022.

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	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 who are allergic to heparin. - Patients with an active bacterial infection. - Patients with life-threatening intracerebral bleeding that requires surgical treatment (e.g. with clipping).

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 on the market since August 2025.

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, Transient ischaemic attack (TIA), 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 twisting, Stent cannot be deployed, Stent cannot be inserted into catheter, 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

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 ACCERO® heal Stent and equivalent ACCERO® Stent, 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 ACCERO® heal Stent and equivalent ACCERO® Stent. Within the so far identified and evaluated body of literature stating the use of the

ACCERO® heal Stent and the equivalent ACCERO® Stent in a total of 184 patients and 192 intracranial aneurysms the following complications and respective occurrence rates were reported (chapter 1.5.3.1):

Table 1: Quantification of the frequency of complications by means of occurrence rates reported for the ACCERO® heal Stent under evaluation and the equivalent ACCERO® Stent in the treatment of at least 192 intracranial aneurysms in 184 patients.

Reported complication	Occurrence rates reported for the **ACCERO® stent /** ACCERO® heal Stent**:**
Stent occlusion/thrombosis	**ACCERO® stent**: 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 %)** ACCERO® heal Stent: PMCF study (NCT03957382): **1/25 (4 %)**
Thromboembolic event/stroke	ACCERO® heal Stent: PMCF study (NCT03957382): **1/25 (4 %)** Capilli F et al., 2025: **1/32 (3.1 %)**
Subarachnoid hemorrhage	ACCERO® heal Stent: PMCF study (NCT03957382): **1/25 (4 %)** Capilli F et al., 2025: **1/32 (3.1 %)**
Aneurysm perforation	ACCERO® heal Stent: Capilli F et al., 2025: **1/32 (3.1 %)**
Groin hematoma	**ACCERO® stent**: Nania A et al., 2020: **1/41 (2.4 %)**
Neurological complications	**ACCERO® stent**: Beuing O et al., 2020: **2/34 (5.9 %)**
Intra-operative in-stent thrombosis	ACCERO® heal Stent: Capilli F et al., 2025: **2/32 (6.2 %)**
In-stent stenosis	ACCERO® heal Stent: Capilli F et al., 2025: **3/32 (9.4 %)**
Coil migration through the stent mesh	ACCERO® heal Stent: Capilli F et al., 2025: **1/32 (3.1 %)**
Incomplete aneurysm occlusion	ACCERO® heal Stent: Capilli F et al., 2025: **6/32 (18.8 %)**
Reoperation	ACCERO® heal Stent: Capilli F et al., 2025: **3/32 (9.4 %)**
Intimal hyperplasia	**ACCERO® stent**: Kim YH et al., 2025: **1/50 (2 %)**
Stent twisting	**ACCERO® stent**: Kim & Jung 2024a **2/26 (7.7 %)**
Hook in problem	**ACCERO® stent**: 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 of the similar devices

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
1.8 % (11/422)	0.6 %(1/422)	256 days	Cortez GM et al., 2026
3.5 % (5/151)	0 % (0/151)	15.7 months	Tang H et al., 2025
n.s.	10 % (2/19)	6 months	Wu Z et al., 2025
5 %(1/20)	0 % (0/20)	18.8 months	Zhang G et al., 2025a

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 expiry date printed on the label.

- Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise structural integrity of the device and/or lead to device failure that, in turn, may result in complications, patient injury or death. Reuse, reprocessing or 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 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 stent 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

There have been no recalls, no FSCAs, CAPAs and trends. PMS data covering the period between market launch in April 2021 to October 2025 reveal an overall complaint rate of 2.75 % after 874 sold ACCERO® heal Stents. The incident rate during the current collection period (November 01, 2024 – October 31, 2025) is 1.43 %.

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).

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. - 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.	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
					- 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 Coiling of Unruptured Wide-Necked Intracranial Aneurysm Treatment with Short-Term Follow-Up	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 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	- 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). - 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**.	**ACCERO® stent** proved excellent support for coil mass with excellent visibility, due to the radiopacity of the Platinum-Nitinol composite wire. Also, it demonstrated its effectiveness with good initial occlusion

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
				observed in 88.23 % of cases in follow-up.	- 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.	rate for treating wide-necked unruptured intracranial aneurysms
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

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
						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 occlusion were achieved in 90% (45/50) and 74% (37/50) of cases, respectively. - Among 45 patients who had imaging follow-up, favorable angiographic outcomes and complete occlusion were observed in 93.3% (43/45) and 82.2%	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 challenging aneurysms once the user becomes familiar with its use

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
				(37/45) of cases, respectively.		

Summary and conclusion: Within the scope of the recent and previous systematic literature searches, a total of 6 publications including clinical data on 184 patients treated with the equivalent ACCERO® Stent were considered eligible according to established in- and exclusion criteria and rated pivotal. The reviewed publications including clinical data on the safety and performance of equivalent ACCERO® Stent encompass three case series (Beuing O et al., 2020, Kim and Jung, 2024a, Nania A et al., 2020) and three clinical studies (Cay and Arat, 2024, Kim YH et al., 2025, Poncyljusz W et al., 2020). Across the above reviewed publications stating the use of the ACCERO® heal Stent, the technical success (i.e., proper stent placement (including adequate stent expansion/opening, complete wall apposition and visibility) was 100 %. The clinical success rate, i.e., complete/near-complete aneurysm occlusion assessed by using the Raymond-Roy or Modified Raymond-Roy occlusion classification (RROC) ranges between 93.3 % and 97.3 %, whereby an RROC of I and II was considered clinical success. Further, the following device-and procedure-related complications and respective occurrence rates were reported:

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 %)**
Groin hematoma	Nania A et al., 2020:	**1/41 (2.4 %)**
Neurological complications	Beuing O et al., 2020:	**2/34 (5.9 %)**
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 %)**

From this, it can be concluded that the equivalent ACCERO® Stent achieves a performance as other devices from the device group. Technical and clinical complication rates were low, and complications occurred 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® Stent Embolisation Device seems to be within the expected and known range inherent to the generic device group of flow diverter devices.

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

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

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data in the literature

In a double-center clinical experience, Capilli and colleagues evaluated the safety, technical performance, and short-term efficacy of the ACCERO® heal Stent in 32 consecutive patients with intracranial aneurysms (Capilli F et al., 2025). A total of 34 ACCERO® heal Stents were implanted in 32 patients (median age 54 years; 87.5% female). Aneurysm locations were distributed as follows: 11 in the middle cerebral artery (MCA), 8 in the anterior communicating artery (ACom), 7 in the basilar artery (BA), 2 in the internal carotid artery (ICA), and 4 in other locations including the posterior communicating artery (PCom) or anterior cerebral artery (ACA). The average aneurysm size was 6.9 ± 3.6 mm (range: 3.2–23.0 mm). Wall apposition of the stent was rated as “optimal” in all cases (100 %). At the end of the procedure, complete aneurysm occlusion (MRRC Class I) was achieved in 28 patients (87.5%). One case resulted in MRRC Class II (3.1%), and another in Class IIIa. One ruptured aneurysm and one case with intraprocedural thrombosis led to MRRC Class IIIb. Periprocedural complications occurred in five patients (15.6%), including one death and one non-fatal stroke in the context of ruptured aneurysms. Intraoperative in-stent thrombosis occurred in two cases (6.3%), both resolving without clinical sequelae. At follow-up, six patients (19.3%) had aneurysm recurrence or residual, and three (9.7%) required retreatment. In-stent stenosis occurred in three patients (9.7%) and resolved with conservative management. The authors concluded that the ACCERO® heal Stent is a reliable and effective option for stent-assisted coiling of intracranial aneurysms. Its low-profile design and HEAL antithrombogenic coating support precise deployment and favorable early clinical outcomes (Capilli F et al., 2025).

Summary and conclusion: Within the scope of the recent and previous systematic literature searches, one publication including clinical data on 32 patients treated with the ACCERO® heal Stent under evaluation was considered eligible according to established in- and exclusion criteria and rated pivotal. The technical success (i.e., proper stent placement (including adequate stent expansion/opening, complete wall apposition and visibility) was 100 %. The clinical success rate, i.e., complete/near-complete aneurysm occlusion assessed by using the Raymond-Roy or Modified Raymond-Roy occlusion classification (RROC) was 93.8 %, whereby an RROC of I and II was considered clinical success. Further, the following device- and procedure-related complications and respective occurrence rates were reported:

Thromboembolic event/stroke	**1/32 (3.1 %)**
Subarachnoid hemorrhage	**1/32 (3.1 %)**
Aneurysm perforation	**1/32 (3.1 %)**
Intra-operative in-stent thrombosis	**2/32 (6.2 %)**
In-stent stenosis	**3/32 (9.4 %)**
Coil migration through the stent mesh	**1/32 (3.1 %)**
Incomplete aneurysm occlusion	**6/32 (18.8 %)**
Reoperation	**3/32 (9.4 %)**

From this, it can be concluded that technical and clinical complication rates were low, and complications occurred 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® Stent Embolisation Device seems to be within the expected and known range inherent to the generic device group of flow diverter devices.

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

Following initial CE certification under the MDD, the ACCERO® heal Stent entered into a limited market release phase. The limited market release phase has been successfully concluded. In the following, results of the limited market release and an interim analysis of the ongoing PMCF-study by Acandis.

1.5.3.2.1 Limited market release

72 ACCERO® heal Stents were implanted within the scope of the limited market release. A total of 16 complications, 4 device-related and 12 procedure-related occurred:

The device-related complications encompass:

- thrombus emboli on both anterior hemispheres; possibly medication errors
- stent did not open completely, solved by manipulation with microwire in J-shape
- thrombus formation at device: periinterventional thrombosis at the end of the stent
- opening problem of the Stent: Non-Opening of the midsection and proximal landing zone, solved with Comaneci 17 stentoplasty

The procedure-related complications encompass:

- during the coil-through procedure, the aneurysm ruptured. Description by physician: “Aneurysm rupture while advancing the coiling catheter through the stent
- High friction during delivery through microcatheter.

- ACCERO® heal Stent 4,0 x 25 mm stuck in microcatheter (Echelon 10), not able to deploy the stent. Catheter was used beforehand and shaped with heat.
- Approximately 12 hours after procedure the patient developed a severe intracerebral hemorrhage in the right basal ganglia, probably because of the intracranial stenosis treatment and underwent neurosurgical evacuation.
- Periprocedural embolic occlusion of the right PICA.
- Intraprocedural severe in stent thrombosis.
- Opening behavior of the stent is limited due to the patient's massive coagulation problems.
- Aneurysm rupture with bleeding
- After WEB detachment dislocation of the WEB in the basilar artery with thrombus formation.
- Stent diameter selected too small by user --> Coil slips upwards out of AN --> fusiform AN
- problems with implanting a coil: minimal thrombus formation at proximal stent end
- device got stuck in NeuroSlider 17 microcatheter. for ACCERO® heal Stent, the NeuroSlider 17 DLC catheter is recommended.

Conclusion: From the results of the limited market release it was concluded that all device-related complications are already known and included in the risk analysis. There are no new findings from the limited market release which must be considered in the technical documentation for ACCERO® heal Stent.
The results provided bases for lifting market release limitation and successfully concluding the limited market release phase.

1.5.3.2.2 PMCF study

Acandis is conducting a prospective, multicenter, national PMCF Study with the ACCERO® heal Stent and the equivalent ACCERO® Stent.
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)

1.5.3.3 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® heal Stent during the preparation of the clinical evaluation report. The search was conducted on April 29, 2026.

BfArM (German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions): Within the recent BfArM database search **from April 29, 2026 no new records**, neither on the ACCERO® heal Stent under evaluation, the equivalent ACCERO the similar Leo+ Baby, Leo+ Baby System and the Leo+ Stent (BALT Extrusion, Montmorency, France) as representative of the device group of intracranial neurovascular stents nor the device group of intracranial neurovascular stents could be retrieved. In the previous search from April 4, 2025, one relevant hit on the device group of intracranial neurovascular stents was yielded dealing with the complication of incomplete wall apposition and braid deformation. These complications are included in the IFU and assessed in the risk management process of the ACCERO® heal Stents. From this point of view, the ACCERO® heal Stent appears to be effective and safe for its intended use.

MAUDE (“Manufacturer and User Facility Device Experience (MAUDE) Database: The MAUDE database was searched for the similar device, another benchmark device, the LVIS and the TPLC Code (QCA). Neither the ACCERO® heal Stent under evaluation nor the

equivalent ACCERO® Stent have been marketed in the U.S.A. Within the recent MAUDE database search from **April 29, 2026, a total of 8 and 13, respectively new records** on the LVIS jr. and LVIS Evo as representative devices of the device group of self-expandable intracranial neurovascular stent, could be retrieved. Fifteen database records deal with injuries and six with malfunctions of the devices. There was no database entry dealing with a death event. The records revealed no device and patient problems that are not already known from the current literature. The TPLC product code report for the product code “QCA” (intracranial Coil-Assist Stent) from 2021 until the date of search i.e., April 29, 2026 revealed “premature activation” for the device and for patients: “no clinical signs, symptoms or conditions” as the most frequent problems. Still, the TPLC product code report further revealed no device and patient problems that are not already known from the current literature.

Conclusion: The entries in the medical device databases 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 devices in routine clinical use. From this point of view, the ACCERO® heal Stent under evaluation, the equivalent ACCERO® Stent as well as the device group of intracranial neurovascular stents, appear to be effective and safe for their intended purpose.

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 ACCERO® heal Stent and 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 ACCERO® heal Stent and the equivalent ACCERO® Stent, a successful and safe occlusion of intracranial aneurysms is feasible. For the ACCERO® heal Stent and the equivalent ACCERO® Stent it could be shown that the devices 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 ACCERO® heal Stent under evaluation and the equivalent ACCERO® Stent in a total of 223 patients and 231 intracranial aneurysms the technical success rate achieved by using the ACCERO® heal Stent under evaluation and the equivalent ACCERO® Stent ranges between **92 % – 100 %.** Within the evaluated body of literature (including PMCF data) stating the use of the ACCERO® heal Stent under evaluation and the equivalent ACCERO® Stent in a total of 252 patients and 252 intracranial aneurysms clinical success defined as RROC I/II achieved by using the ACCERO® heal Stent under evaluation and the equivalent ACCERO® Stent ranges between **93.3 % and 97.3 %**, respectively. Similar devices as well as the product group in general show comparable successful results (CEP chapter 5.9). The occlusion success rates of the similar devices **Leo+ / Leo+(baby**) varied in the range of approx. **74 % to 95.6%**. This also depended on the follow-up time. The combined clinical success rates for ACCERO and Leo baby 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 ACCERO® heal Stent under evaluation and the equivalent ACCERO® Stent are non-inferior to the state-of-the-art. 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 1.8 % to 5 % and mortality rates from 0.0 % to 10 % (data from 1,077 patients, follow-up time from 256 days to 5 years) see details in chapter 1.4.1 - Table 2. According to the identified and reviewed literature stating the use of the ACCERO® Stent heal under evaluation (1.5.3.1) and the equivalent ACCERO® Stent (1.5.1) 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:

- Aneurysm perforation

- Coil migration through the stent mesh
- Groin hematoma
- Incomplete aneurysm occlusion
- In-stent stenosis
- Intimal hyperplasia
- Neurological complications
- Reoperation
- Stent bending
- Stent migration
- Stent occlusion/thrombosis
- Stent twisting as well as a hook in problem
- Subarachnoid hemorrhage
- Thromboembolic event/stroke
- Vasospasm

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 ACCERO® heal Stent and 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. 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 and the equivalent ACCERO® Stent are non-inferior to the state-of-the-art and can thus be considered state-of-the-art devices in their intended clinical purpose. 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. and Capilli F et al., 2025.

In conclusion:

- The ACCERO® heal Stent could be shown to be in compliance with the considered relevant GSPRs specified by the Medical Device Regulation (MDR) EU 2017/745.
- 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. Recruitment was completed in the fourth quarter of 2025. The planned study end is in the second quarter of 2029.

1.6 Possible diagnostic or 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

The 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 standard.

Table 4: Standards adhered to by the 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	10993-2	Biological evaluation of medical devices – Part 2: Animal welfare requirements (ISO 10993-2:2022)	2022
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 + Amd 1:2025)	2017 + A1:2025
EN ISO	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2009/A11:2025

EN ISO	10993-6	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	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 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	10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
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	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	11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	2018+A1:2021
EN ISO	11737-2	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	2020
EN ISO	13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016+AC:2018+A11:2021
EN ISO	14630	Non-active surgical implants - General requirements (ISO 14630:2024)	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 (ISO 14644-4:2022)	2022
EN ISO	14644-5	Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2025)	2025
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	2024
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	868-5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods (EN 868-5:2018)	2019
EN	868-9	Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods (EN 868-9:2018)	2019

2 Information for the patient

Document revision: 04

Date issued: June 24, 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® 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 important vessel branches arising from the aneurysm to be treated. - Patients in whom the size of the aneurysm and/or the diameter of the 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 and/or stenosis) who may not be suitable for treatment in the vessels (endovascular treatment). - Patients who were not pretreated with anti-blood clotting drugs (antiplatelet agents).

	- Patients who cannot be treated with anti-blood clotting drugs (antiplatelet agents and/or anticoagulants). - Patients with allergic reactions to nickel-titanium. - Patients with allergic reactions to heparin. - Patients with an active bacterial infection. - Patients with a life-threatening bleeding in the brain (intracerebral bleeding) that requires surgical treatment (e.g. closure with miniclips (with clipping)). No limitations are mentioned in the IFU

2.3 Device description

2.3.1 Description of the ACCERO® heal Stent

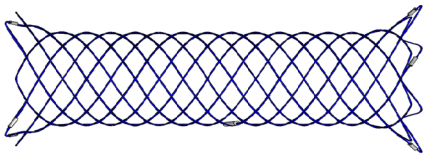


Figure 1: ACCERO® heal Stent

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 Stent is coated with heparin and fibrin, which protects from blood clotting. ACCERO® heal Stent 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 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 (aneurysm).

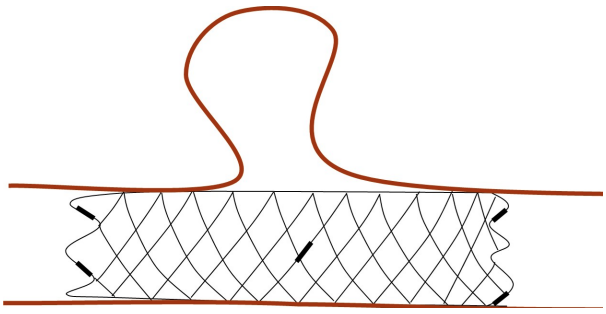


Figure 2: ACCERO® heal Stent (black grid) when placed under the vessel wall bulge (aneurysm).

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® heal Stent.

2.3.3 Accessories

Small, flexible hollow tubes (microcatheters) for insertion.

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 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 reported complications in a total of 32 patients treated with the ACCERO® heal Stent and 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)

- Stent twist
- Thickening of the intima by unspecific reaction (intimal hyperplasia leading to in-stent stenosis
- the aneurysm tears or ruptures, allowing blood to leak out of the artery (Aneurysm perforation)
- The embolization coil, intended to fill the aneurysm, slips through the gaps in the stent and protrudes into the parent artery (Coil migration through the stent mesh)
- The aneurysm is not fully sealed off from th circulation (Incomplete aneurysm occlusion)
- Repeated operation on the same patient, usually in the same area, to fix complications or address issues not resolved by the initial surgery (Reoperation)

In the following, the complete list of possible complications as stated by the manufacturer is described:

General complications in connection with treatments inside the vessel wall (endovascular treatment) or treatments with X-rays and contrast agent (angiographic treatments):

- Ballooning or false ballooning of a blood vessel wall ((Pseudo)aneurysm)
- Bursting of or bleeding from a ballooned blood vessel (Rupture of or bleeding from aneurysm)
- Bleeding (inside the brain) ((Intracerebral) haemorrhage)
- Blockage of a blood vessel by an air bubble, a foreign object, a fatty deposit, or a blood clot (Embolism (air, foreign body, plaque or thrombus))
- Elevated body temperature (Fever)
- Tear within the wall of a blood vessel (Vessel dissection)
- Unintended hole in a blood vessel wall (Vessel perforation)
- Bursting of a blood vessel (Vessel rupture)
- Narrowing of a blood vessel (Vessel stenosis)
- Blockage of a blood vessel or formation of a blood clot inside a vessel (Vessel occlusion or thrombosis)
- Swelling of the brain due to fluid accumulation (Cerebral oedema)
- Invasion and multiplication of harmful micro-organisms in the body (Infection)
- Insufficient blood flow (to the brain) resulting in tissue damage ((Cerebral) ischaemia/infarction)
- Renewed or delayed bleeding (Secondary haemorrhage)

- Side effects caused by exposure to X-ray radiation during the procedure (Reactions due to radiation exposure)
- Bleeding into the space between the brain and its surrounding membranes (Subarachnoid haemorrhage)
- Blood clot blocking a blood vessel, potentially causing a stroke (Thromboembolic event/stroke)
- Temporary disruption of blood flow to the brain causing short-lived stroke-like symptoms (Transient ischaemic attack (TIA))
- Sudden involuntary narrowing of a blood vessel (Vasospasm))

General complications in connection with anti-blood clotting drugs (antiplatelet agents/anticoagulants), anesthetics and contrast agents (e.g. renal failing (insufficiency)):

- Impaired kidney function (Renal insufficiency))

Complications in connection with the insertion point (vascular access):

- Bruising or bleeding at the site where the catheter was inserted (Haematoma or bleeding at puncture site)
- Pain and/or infection at the site where the catheter was inserted (Pain and/or infection at puncture site))

Possible problems when introducing/implanting the stent:

- The stent's protective coating does not work at the intended treatment site (No coating function in target area)
- Breakage of the guidewire used to deliver the stent (Transport wire breakage)
- Fracture or breakage of the stent (Stent breakage)
- The stent folds in on itself (Stent folding)
- The stent is positioned in the wrong location (Incorrect stent placement)
- The stent rotates or twists out of its intended orientation (Stent twisting)
- The stent cannot be loaded into the delivery catheter (Stent cannot be inserted into catheter)
- The stent cannot be released or expanded at the target site (Stent cannot be deployed)
- The stent cannot be pulled back into the delivery catheter (Stent cannot be drawn back into catheter)
- The stent develops a sharp bend or kink (Stent kinking)
- The stent remains attached to the delivery wire and cannot be released (Stent does not detach from the transport wire)

- The stent moves away from its intended position (Stent migration)
- The stent does not fully expand or open as intended (Insufficient opening behaviour)
- The stent does not sit fully against the vessel wall (Insufficient wall apposition)
- The treatment cannot be carried out within the required time frame (Delayed treatment)
- The treatment site cannot be reached or cannot be reached safely (Target area inaccessible or cannot be accessed safely)
- Further stent placement is needed (Additional stenting required))

Other complications in connection with the stent:

- (Local) allergic response to the materials used in the stent ((Local) allergic reactions to the stent material)
- Narrowing of the vessel within the stent (In-stent stenosis)
- Death of brain tissue caused by blockage of small branching vessels (Perforator infarction)
- Need for a repeat surgical or interventional procedure (Reoperation)
- Blockage of the stent by a blood clot (Stent occlusion/thrombosis)
- The aneurysm is not fully sealed off (Incomplete aneurysm occlusion)
- Blockage of small branching blood vessels (Occlusion of perforators or branch vessels)
- Movement of implanted coils through the openings of the stent mesh (Coil migration through the stent mesh)
- Greater mechanical strain placed on the blood vessel wall (Increased stresses to the vessel wall)
- Localized inflammation at or near the stent (Local inflammatory reactions)
- Whole-body allergic or hypersensitivity reaction (Systemic hypersensitivity)
- Inflammation of brain tissue (Cerebritis)

Neurological problems

- Difficulty with speaking or understanding language (Dysphasia)
- Weakness affecting one side of the body (Hemiparesis)
- Complete paralysis of one side of the body (Hemiplegia)
- Reduced or lost vision (Impaired vision)
- Weakness or paralysis of the muscles that control eye movement (Oculomotor paresis)
- Difficulties with speech production or comprehension (Speech disorders))

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 32 patients and 183 patients treated and followed-up with the ACCERO® heal Stent (Capilli F et al., 2025) and the equivalent ACCERO® Stent, respectively (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 of the PMCF study in 25 patients treated with the equivalent ACCERO® Stent (NCT03957382)).
The authors concluded that the ACCERO® heal stent is a reliable and effective option for stent-assisted coiling of intracranial aneurysms. Its low-profile design and HEAL antithrombogenic coating support precise deployment and favorable early clinical outcomes (Capilli F et al., 2025). On the equivalent ACCERO® Stent it was written that it 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 ACCERO® heal stent and 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, the authors evaluated the ACCERO® heal stent and 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).

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