ENGINEERING STROKE SOLUTIONS

Summary of safety and clinical performance:

ACCLINO® flex plus Stent

ACANDIS GmbH

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

Identifier: 2600

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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 ACCLINO® flex plus Stent manufactured by Acandis GmbH (in the following 'Acandis').
The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the Medical Device Coordination Group Document MDCG 2019-9.

The SSCP has no validity per se but shall be reviewed and updated if needed to ensure that any clinical and/or safety information in the SSCP remains correct and complete (therefore when relevant parts of the technical documentation are updated).

The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the ACCLINO® flex plus 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.

1.1 Device identification and general information

Device trade name(s)	**ACCLINO® flex plus Stent**	
	Model	Article number
	ACCLINO® flex plus Stent	01-001122 – 01-001126 01-001132 – 01-001136 01-001142 – 01-001146 01-001152 – 01-001156 01-001162 – 01-001166 01-001173 – 01-001176 01-001193 – 01-001197, 01-001199, 01-001201 01-001213, 01-001215, 01-001217, 01-001219, 01-001221 01-001183 – 01-001187, 01-001189, 01-001191 01-001203 – 01-001207, 01-001209, 01-001211 01-002223, 01-002225 01-002255, 01-002257, 01-002259, 01-002261, 01-002263, 01-002265
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	426065033ACCLINOfpVV	
Medical device nomenclature	UMDNS; 17-461 Stents, vascular GMDN: 46352 Stent, bare metal, vascular, intracranial EMDN: P0799 (Vascular and Cardiac Prostheses – Other)	
Class of device	Class III, Medical Device Regulation (MDR) EU 2017/745, Annex VIII, rule 8 point 2	
Year of first CE certificate	On the European Market since July 2016	
Authorized representative	Not applicable	
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297)	

1.2 Intended use of the ACCLINO® flex plus Stent

1.2.1 Intended purpose

The ACCLINO® flex plus Stent is used to anchor the embolisation materials in the aneurysm when using the stent-assisted coiling method.

1.2.2 Indication and target population

The ACCLINO® flex plus Stent is intended for the treatment of intracranial aneurysms using embolisation materials.

No specific patient populations have been defined but patients with contraindications are to be excluded.

1.2.3 Contraindications and limitations

Implantation is contraindicated in the following patients:

- Patients in whom the size of the aneurysm and/or the size of the vessel carrying the aneurysm is not within the indicated range.
- Patients in whom angiography reveals anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity and/or stenosis.
- Patients who were not pre-treated with antiplatelet agents prior to the procedure.
- Patients in whom treatment with antiplatelet agents and/or anticoagulants is contraindicated.
- Patients who are hypersensitive to nickel-titanium.
- Patients with an active bacterial infection.
- Patients with an acute ruptured aneurysm should not be treated with the ACCLINO flex plus Stent alone.
- Patients in the acute phase after subarachnoid haemorrhage.

1.3 Description of the device

1.3.1 Description of the devices

The ACCLINO® flex plus Stent is a stent for the treatment of intracranial aneurysms, using the stent-assisted coiling method. The stent is intended to be used with embolization material like a metal coil. The stent is deployed before the embolization coil is implanted.

The stents are self-expanding stents – made of laser-cut Nitinol – with closed-cell design and three radiopaque markers on each end and are intended for the treatment of intracranial

aneurysms. Each stent is preloaded on a transport wire in an introducer. The tip of the transport wire is designed a J-shape.

Sizes	Diameter: 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 8.0, 10.0 mm Length: 15, 20, 25, 30, 35, 40, 50, 60, 70, 80 mm
Sterility	Yes, ETO sterilized, for single-use
Generic device group	Intracranial neurovascular stent, self-expandable
MR conditional	up to 3 Tesla acc. ASTM F2052, F2213, F2119, F2182
Foreshortening	< 30 %
Stent surface area	≤ 6.5 %

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. Further embolization materials may be applied.

1.3.2 Previous generations of the device

The ACCLINO® flex plus Stent is a device of the Acandis ACCLINO family. The first generation of ACCLINO (1.9F) was CE marked in 2012 and the first ACCLINO flex Stent was CE-marked in February 2014. Furthermore, the ACCLINO® flex plus Stent was CE-marked in July 2016.

1.3.3 Description of the accessories

The ACCLINO® flex plus Stent is compatible with Acandis NeuroSlider (DLC) microcatheters with an inner diameter of

- 0.0165” / 0.0170” (stent Ø diameters 3.0 – 5.5 mm)
- 0.021” (stent Ø diameter 6.5 mm)
- 0.027” (stent Ø diameter 6.0, 7.0, 8.0 and 10 mm)

1.3.4 Description of other devices and products used in combination

The ACCLINO® flex plus Stent is used in combination with the Acandis NeuroSlider® (DLC) 0.0165 – 0.017 / 0.021 / 0.027”.

1.4 Risks, warnings and precautions

1.4.1 Residual risks and undesirable effects

According to the IFU potential complications, among others, include the following:

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Pseudo)aneurysm, Rupture of or bleeding from aneurysm, (Intracerebral) haemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, Vessel dissection, Vessel perforation, Vessel rupture, Vessel stenosis, Vessel occlusion or thrombosis, Cerebral oedema, Infection, (Cerebral) ischaemia/infarction, Secondary haemorrhage, Reactions due to radiation exposure, Subarachnoid haemorrhage, Thromboembolic event/stroke, Transient ischaemic attack (TIA), Vasospasm).
- General complications in connection with antiplatelet agents/anticoagulants, anaesthetics and contrast agents (e.g. Renal insufficiency).
- Complications in connection with vessel entry (e.g. Haematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during stent delivery/implantation (e.g. Transport wire breakage, Stent breakage, Stent folding, Incorrect stent placement, Stent cannot be inserted into catheter, Stent cannot be deployed, Stent cannot be drawn back into catheter, Stent bending, 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 stress to the vessel wall, Local inflammatory reactions, Systemic hypersensitivity, Cerebritis).
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders).
- Death.

1.4.2 Warnings, precautions and cautions

Warnings

- The ACCLINO flex plus Stent should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional neuroradiology and have the required expertise in the treatment of intracranial aneurysms.
- No specific patient populations have been defined but patients with contraindications are to be excluded.
- Before use, the product needs to be carefully checked to ensure there is no transportation damage. Under no circumstances should damaged or kinked components be used.
- On no account whatsoever should you continue advancing the stent if you encounter resistance without first finding out the cause as otherwise you could damage the stent or perforate a vessel.
- The stent may be shorter after deployment.
- The product may only be used for the intended purpose. Any use of the product for other purposes (off-label use) may lead to a deterioration in the patient's state of health or even their death.

Precautions

- The product is provided sterile and for single use only.
- In case of damage to the sterile barrier or if the packaging has been opened accidentally, the product must not be used. If any damage is visible, please contact your Acandis® representative.
- Do not use the product after the expiry date printed on the label.
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise structural integrity of the components and/or lead to failure that, in turn, may result in complications, patient injury or death. Reuse, reprocessing or resterilising the device also increases the risk of contamination of the device and/or causes patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The performance of a responder test is recommended to reduce the risk of complications. For this purpose, the efficacy of the antiplatelet agent is tested prior to application of the product.
- In order to minimise potential complications during and after the intervention, attention should be paid to careful medication treatment in accordance with the current medical association guidelines (antiplatelet agents and anticoagulants prior to treatment and

anticoagulants during the intervention). The administration of unsuitable antiplatelet agents and anticoagulants may lead to a stent thrombosis.

- The medication is an important part of the treatment. Patients must be advised to take medication regularly and informed of the potential risks of non-compliance.

Cautions during implantation procedure

Selection

- If the stent is the wrong size, this could damage the vessel or lead to migration of the stent!

Preparation

- In the case of bifurcations or severe vessel tortuosity distally to the aneurysm neck, the tip of the microcatheter should be positioned further distally!
- The tip of the transport wire must be located in the introducer!
- The tip of the transport wire must not be shaped!
- The stent must not be partially unfolded!
- The stent must not be pushed out of the introducer!

Insertion

- Ensure that the system is free from air!
- Do not apply excessive force!
- On no account whatsoever should you continue advancing the stent if you encounter resistance!
- Once the stent has been fully inserted into the microcatheter, it cannot be drawn back into the introducer!

Deployment

- Use of the ACCLINO flex plus Stent has not been tested in combination with any other medicinal auxiliary products. Special care is required when using auxiliary products and the manufacturer's instructions for use must be observed in each case!
- If you encounter considerable resistance when drawing the microcatheter forwards, initially pull the microcatheter carefully back, without exceeding the repositioning limit of the stent. Then push the microcatheter once again over the partially expanded stent!

1.4.3 Other relevant aspects of safety

No field safety corrective action or field safety notice related to the ACCLINO® flex plus Stent are published.

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

1.5.1 Summary of clinical data related to equivalent device

No clinical data of equivalent-, similar- or comparable devices from other manufacturers were used for the clinical evaluation.

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

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

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data from investigations before CE-marking

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

1.5.3.2 Clinical data in the literature

Clinical data sourced from clinical studies on the ACCLINO® flex plus Stent, which are the basis of the clinical evaluation report.
The references for these articles can be found in the bibliography at the end of the document.

Clinical data were identified for the ACCLINO® flex plus Stent, as well as for the Acandis ACCLINO® flex (plus) Stent family, which covers several stents with different dimensions, to allow the treatment of varying individual anatomies. Also, the current stent line evolved since the first ACCLINO®, the ACCLINO® 1.9F. Since the ACCLINO® 1.9F, the material and general design of the ACCLINO® Stents was similar throughout: laser-cut Nitinol with a closed-cell design. However, with the introduction of the ACCLINO® flex Stent the ends of the stent received a flare, which was maintained with the subsequent member of the family, the ACCLINO® flex plus Stent. With the ACCLINO® flex plus Stent new Ptlr x-ray markers were introduced.
As all the stents of the ACCLINO® flex (plus) Stent family feature a near-identical general design with comparable physical properties, it was judged to be feasible to pool all stents for

the data analysis of the ACCLINO® flex plus Stent, as the achieved clinical safety and performance is considered identical.

To demonstrate the performance of the ACCLINO® flex plus Stent, a pooled proportion analysis using the random effects model was conducted on basis of the clinical data sets identified and selected in the clinical evaluation. The chosen performance endpoints were:

- Technical success
- Immediate complete occlusion (RROC1)
- Immediate complete/near-complete occlusion (RROC 1/2)
- Complete occlusion at follow-up (RROC1)
- Complete/near-complete occlusion at follow-up (RROC 1/2)

All occlusion rates were based on the (modified) Raymond Roy Occlusion Classification score. The analysis included 13 studies with 677 treated patients (Kabbasch C et al., 2015; Brassel IF et al., 2016A; Brassel IF et al., 2016B; Tureli D et al., 2016; Goertz L et al., 2019; Martínez-Galdámez M et al, 2019; Behme D et al., 2019; Dietrich P et al., 2020; Goertz L et al., 2020; Pflaeging M et al., 2021; Melber K et al., 2022; Goertz L et al., 2023A; Goertz L et al., 2023B).

Technical success

The calculation showed a pooled proportion of technical success of 99.88 % (random effects model, 95 % CI: 98.54 to 100 %).

Immediate complete occlusion

The calculation showed a pooled proportion of immediate complete occlusion of 85.57 % (random effects model, 95 % CI: 74.30 to 94.25 %).

Immediate complete/near-complete occlusion

The calculation showed a pooled proportion for immediate complete/near occlusion of 96.43 % (random effects model, 95 % CL: 93.35 to 98.73 %).

Complete occlusion at follow-up

The calculation showed a pooled proportion of immediate complete occlusion of 83.18 % (random effects model, 95 % CL: 72.80 to 91.71 %). The follow-up ranged from 137 ± 50 days to 36 months (range 9 – 80 months).

Complete/near-complete occlusion at follow-up

The calculation showed a pooled proportion of immediate complete occlusion of 91.73 % (random effects model, 95 % CL: 82.85 to 97.97 %). The follow-up ranged from 137 ± 50 days to 36 months (range 9 – 80 months).

These results were compared to up-to-date systematic reviews and meta-analyses on the topic of intracranial aneurysm treatment, including data on over 5,700 patients (Goyal RK et al., 2020; Pranata R et al., 2020; Toccaceli G et al., 2020; Akram U et al., 2024).

The pooled-proportion analysis of the ACCLINO® flex plus Stent gives good overall representation of the efficacy of the stents in terms of technical success and occlusion rates in comparison to the above-mentioned systematic reviews and meta-analyses: on par or above other established stents and better than the summarized results of endovascular intracranial aneurysm treatment with several devices in general.

The ACCLINO flex (plus) Stent family's technical success rate is comparable to technical success rates identified by Pranata and colleagues in two publications: 100 % and 98 %.
Concerning the immediate occlusion rate, compared to the results of the other publications, the immediate occlusion rate of the ACCLINO flex (plus) Stent family is higher than the immediate occlusion rates of other stents (reported by Goyal RK et al., 2020 and Akram U et al., 2024), as well as the calculated average occlusion rate of SAC, endovascular intracranial aneurysm treatment in general and surgical treatment of ICAS (reported by Toccaceli G et al., 2020), with 96.4 % compared to 88.0 %, 81.2 %, 81.9 %, 65.1 %, 88.5 % and 93.0 %, respectively.

Considering the complete/near-complete occlusion rates after follow-up, the results are similar to the immediate occlusion rates, with the ACCLINO flex (plus) Stent family achieving a better occlusion rate than other devices or the general field of endovascular aneurysm treatment.
During follow-up, stents and additional embolization material may achieve further improvement of the state of the aneuryms due to better embolization of the aneurysm over time. Therefore, occlusion rates are often different than immediately after treatment, without further interventions. This is also reflected in the investigated data sets, with the ACCLINO flex (plus) Stent family achieving 91.73 %, the Neuroform Atlas achieving 95.0 % as well as the Enterprise and the Neuroform achieving 84.81 % (both stents investigated in a single publication) (Goyal RK et al., 2020; Akram U et al., 2024). Also, the calculated average occlusion rates of SAC, endovascular intracranial aneurysm treatment in general, as well as

surgical treatment, were higher than immediately after treatment with 81.9 %, 78.10 % and 95.70 %, respectively.

1.5.3.3 Clinical data obtained by clinical trials or PMCF measures

No clinical data from PMCF measures are available.

1.5.3.4 Clinical data in medical device registries

The medical device registry of Germany, the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions) was searched for clinical data on the Acandis ACCLINO® flex plus Stent during the preparation of the clinical evaluation report. The search was conducted on November 18th, 2025. No time period restriction was applied.
The BfArM database search revealed no entries associated with the Acandis ACCLINO® flex plus Stent. There was no medical risk for patients or increased risk of injury to users.

1.5.4 An overall summary of the clinical performance and safety

The clinical literature identified in the clinical evaluation report shows the clinical performance of the device. As the devices have an identical clinical application, principle of operation and material, the results of the clinical evaluation were deemed valid for all variants of the device. The results of the aggregated studies show that the ACCLINO® flex plus Stent is a suitable treatment option for the treatment of intracranial aneurysms, as it shows comparable, or better, results of technical success and aneurysm occlusion as alternative treatments and/or devices. The clinical evaluation of the ACCLINO® flex plus Stent is based upon several product-specific documents, including a risk analysis and comprehensive instructions for use, as well as test reports on biological testing, demonstrating fulfillment of the biological requirements.
Based on these documents, it was summarized that the procedural and product-specific risks, corresponding warnings and precautions are adequately provided for the user and offer information on risks associated with the ACCLINO® flex plus Stent and its clinical application. Complications directly associated with the implants cannot be ruled out completely, but the basic design as well as the material used for the device (and its nearly identical predecessors) have been successfully applied for several years. The risks described in the literature and the IFUs are consistent. Thus, the ACCLINO® flex plus Stent meets the requirement for safety. Also, no evidence on unduly or unknown risks of the ACCLINO® flex plus Stent was identified in the clinical evaluation report.

According to the risk management, the benefits of the devices overweigh the identified risks. It can be concluded that risks which may be associated with the intended use of the ACCLINO®

flex plus Stent constitute acceptable risks when weighed against the benefits to the patient according to the clinical data presented in the scientific literature, the Post-Market Surveillance (PMS) as well as the risk analysis. The main risks are described and documented in detail in the scientific literature, thus being known to the medical expert. Therefore, by complying with all warnings and precautions, the ACCLINO® flex plus Stent offers an acceptable benefit/risk profile.

The regular PMS data show a low complaint rate, with reported incidents only concerning already known complications.

The marketing claims are justified by the technical characteristics, performed preclinical tests and the clinical literature.

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

1.5.5 Ongoing or planned post-market clinical follow-up

In their PMCF plan, Acandis states that no PMCF studies will be conducted for ACCLINO® flex plus Stent, because it is a state-of-the-art product that has been established in the market for many years and its safety and performance has already been confirmed by the collection of many previous PMS data and clinical evaluations. For this reason, no further PMCF activities are needed. This is deemed sufficient, as Acandis describes in detail the current level of evidence of the device and the absence of open questions on the safety and performance of the device, which would necessitate specific PMCF activities.

1.6 Therapeutic alternatives for treatment of intracranial aneurysms

Alternative therapeutic treatments are the simple coiling (only coiling), the balloon-assisted coiling, surgical clipping and the use of flow diverter stents.

1.7 Suggested profile and training for users

According to the Instruction for Use (IFU) the ACCLINO® flex plus Stent should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional neuroradiology and have the required expertise in the treatment of intracranial aneurysms.

1.8 Reference to harmonized standards and common specifications

Reference and title of standard	Version
EN ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)	2020
EN ISO 10993-10 Biological evaluation of medical devices - Part 1O: 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: Toxicological risk assessment of medical device constituents (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 + Amd 1:2025, Corrected version 2025-04)	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 + Cor 1:2009 + Amd 1:2019)	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 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

Reference and title of standard	Version
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 14630:2024)	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 controller environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	2015
EN ISO 14644-3 Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)	2019
EN ISO 14644-4 Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (SO 14644-4:2022)	2022
EN ISO 14644-5 Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)	2004
EN ISO 14971 Medical devices. Application of risk management to medical devices (ISO 14971:2019)	2019 + A11:2021
EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)	2021
EN 17141 Cleanrooms and associated controlled environments - Biocontamination control	2020
EN ISO 20417 Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021)	2021
EN ISO 25539-1 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539- 1:2017)	2017
EN ISO 25539-2 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020)	2020

Reference and title of standard	Version
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

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 ACCLINO® flex plus Stent. The information presented below is intended for patients or lay persons. A more 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 ACCLINO® flex plus Stent.

2.1 Device identification and general information

2.1.1 Device trade name

Acandis GmbH (in the following ‘Acandis’) manufactures catheter based medical devices for interventional radiology. Among its products is the ACCLINO® flex plus Stent.

2.1.2 Manufacturer’s name and address

Acandis GmbH,
Theodor-Fahrner-Straße 6,
75177 Pforzheim
Germany

2.1.3 Basic UDI-DI

The Unique Device Identification System is a system for the unambiguous identification of medical devices. The Basic UDI-DI for the ACCLINO® flex plus Stent is 426065033ACCLINOfpVV

2.1.4 Year when the first certificate was issued covering the device

The first model of the ACCLINO® flex plus Stent was CE-marked in 2016.

2.2 Intended use of the ACCLINO® flex plus Stent

2.2.1 Intended purpose of the ACCLINO® flex plus Stent

The product is used to secure (anchor) the material (embolisation materials), that is used to fill the vessel wall bulge in your brain (aneurysm). The method is called stent-assisted coiling method.

2.2.2 Indications and intended patient group

The product is used in the treatment of vessel wall bulges in the brain (intracranial aneurysms) using materials to clot the blood in these bulges (embolisation materials).

There is no specific patient group. Your doctor decides if the product can be used on you or not, considering indications and contraindications.

2.2.3 Contraindications

This device shall not be used if:

- The vessel wall bulge (aneurysm) or the vessel bevor the bulge is too small or too big.
- You cannot be treated with anti-blood clotting (anti-coagulation) therapy.
- The X-rays of blood vessels (angiography) show that your anatomy is not suited for treatment inside the blood vessel (endovascular treatment). Also, the vessel can be bent heavily or narrowed (severe vessel tortuosity and / or stenosis).
- You are right after a bleeding in the brain (subarachnoid hemorrhage).
- You have a bacterial infection.
- You have a broken vessel wall bulge, your doctor should use other devices as well.
- You were not treated with anti-blood clotting therapy.
- You are sensitive to certain materials (hypersensitive to nickel-titanium).

2.3 Description of the ACCLINO® flex plus Stent

2.3.1 Description of the devices

The ACCLINO® flex plus Stent (in the following the device) is a self-expanding device for the treatment of vessel wall bulges in the brain (intracranial aneurysms). These bulges can break (rupture) at any time and therefore are a risk for you. The device is used with another material (embolisation materials) to clot the bulge and reduce the risk of breaking. The device is placed before the bulge in your brain. It expands before and after the bulge. Through the open cells or behind of the device, a metal wire or another substance can be coiled up in the bulge. The device prevents that the metal wire or other substance gets out of the bulge. The blood naturally clots then in the bulge and closes it.

For tracing of the device, the device has three markers (Platinum-Iridium) visible for the X-Ray. The device remains in your body, as it cannot be removed easily.

The device is placed in you using a transport wire. This wire consists of Nitinol, plastics and platinum iridium, tungsten, gold and steel. You can safely be examined in the MRI. Still, you should inform any doctor about your condition.

2.3.2 Description of the accessories

There are no accessories for the device other than standard operation tools. The device is implanted using a very small tube that enters the body mostly at the femoral artery. From there, the small tube is directed until it reaches the vessel wall bulge (aneurysm).

2.4 Risks and warnings

Contact your healthcare professional, if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional, if needed.
Please take your medicine prescribed by your doctor as scheduled. If not, it can affect the success of the surgery.

2.4.1 Residual risks and undesirable effects

The manufacturer employed a risk management system according to the International Standardization Organization Norm 14971:2019, which is the industry standard. The risk management of the ACCLINO® flex plus Stent does not reveal unacceptable residual risks.

As adverse effects or injuries may occur during or after the operation, Acandis specifies the following possible complications and undesirable side effects for their intracranial stents as follows:

- General complications which can happen during operations inside the blood vessel (endovascular treatments) and / during X-rays of blood vessels (angiographies) (e.g. small tears within inner vessel walls with high rupture risk ((pseudo-) aneurysm), rupture of or bleeding from vessel wall bulge (aneurysm), bleeding (in the brain) ((intracerebral) hemorrhage), vessel closure due to blood clotting consisting of air or foreign body or plaque or clotted blood (embolism (air, foreign body, plaque or thrombus)), fever, tear in the wall of a blood vessel (vessel dissection), hole in the vessel (vessel perforation), blood vessel bursts open (vessel rupture), vessel narrowing (vessel stenosis), vessel closure due to clotting (vessel occlusion or thrombosis) build-up of fluid in the brain (cerebral oedema), infection, stroke or tissue death due to restriction in blood supply ((cerebral) ischemia / infarction), delayed bleeding after some time (secondary hemorrhage), response to x-ray stress (radiation exposure), bleeding in the brain (subarachnoid hemorrhage), stroke (thromboembolic event), temporary blockage of blood flow to the brain (transient ischaemic attack), contraction of the blood vessel (vasospasm)
- General complications with drugs that prevent blood clots and drugs that improve x-ray sight in vessels (antiplatelet agents/anticoagulants, anaesthetics and contrast agents) for example resulting in poor functioning of the kidneys (renal insufficiency)
- Side effects due to vessel entry (e.g. bruise (haematoma) or bleeding at the puncture site, pain and / or infection at puncture site)
- Possible side effects that can happen in treatment with the stent, stent delivery / implantation (e.g. transport wire breakage, stent breakage, stent folding, wrong position of stent (incorrect placement), stent cannot be inserted into catheter, stent cannot be deployed, stent cannot be drawn back into catheter, stent bending, stent does not detach from transport wire, stent moves within vessel (stent migration), not complete opening of the stent (insufficient opening), stent is not pressed firmly against the vessel wall (insufficient wall apposition), treatment is not as fast as wanted (delayed treatment), target area is not reachable or it is unsafe to reach, insertion of an extra stent (additional stenting))
- Possible side effects that are related with the stent (e.g. local allergies to the materials used in the stent, narrowing of the blood vessel within the stent (in-stent stenosis), tissue death because of the closure of a branch of a blood vessel (perforator infarction), reoperation, stent closure (stent occlusion / thrombosis), not completely closed vessel wall bulge (incomplete aneurysm occlusion), closure of a branch of a blood vessel (occlusion of perforators or branching vessels), movement of the coil through the openings of the stent

(coil migration through the stent mesh), increased pressure on the wall of the blood vessel (increased stress to the vessel wall), local defense reaction of the body (local inflammatory reaction), body-wide allergic reaction (systemic hypersensitivity), brain inflammation (cerebritis).

- Not normal function of a body area after brain damage (Neurological deficits) (e.g. speech impediment (dysphasia), weakening of one side of the body (hemiparesis), paralysis of one side of the body (hemiplegia), reduced vision (impaired vision), weakening of the eye muscles (oculomotor paresis), speech disorders)
- Death

2.4.2 Warnings and precautions

The manufacturer states that the physician must inform the patient about the following:

- Please take the medicine your doctor prescribes to you.

2.4.3 Other relevant aspects of safety

No field safety corrective action or field safety notice related to the ACCLINO® flex plus Stent are published.

2.5 Summary of clinical evaluation and post-market clinical follow-up

The ACCLINO® flex plus Stent from Acandis is a CE-marked medical device for implantation in the vessels of the brain, if you suffer from a vessel wall bulge. The product is available on the market since 2016. The stent is a passive device, it does not emit energy during the treatment. The material of which the stent is manufactured, Nitinol, is used since several decades for medical devices and has a very good biocompatibility. The stents are designed to stay a long time in the body, as a removal of the devices after treatment completion is not feasible.

Since the CE-marking, the ACCLINO® flex plus Stent has a proven track record of safety and performance. This track record is summarized in the clinical evaluation report, a document evaluating the clinical safety and performance of the device, which is crucial for the CE-marking. Safety and performance are evaluated on the basis of clinical data. In the case of the ACCLINO® flex plus Stent the clinical data comprise publications in scientific journals and surveillance of the devices after marketing (Post-Market Surveillance) and will be detailed in the following.

The scientific literature on the ACCLINO® flex plus Stent comprises studies and investigations conducted by practitioners and scientists.

In summary, the published literature concludes that the ACCLINO® flex plus Stent has a good safety profile and offers the performance intended by the manufacturer Acandis. Therefore, the ACCLINO® flex plus Stent meets the requirement for performance, a prerequisite for CE-marking according to the current European legislation on medical devices.

During the clinical evaluation, the published literature on the ACCLINO® flex plus Stent was combined through a statistic method, called pooled-proportion analysis, to better compare the performance of the product with other products and alternative methods for the treatment of a vessel bulge in the brain. The analysis showed that the ACCLINO® flex plus Stent was equally good or better than other products or methods to treat vessel bulges in the brain.

The safety of the treatment of vessel bulges by the ACCLINO® flex plus Stent was assessed in the clinical evaluation through the review of several product-specific documents, including a

risk analysis and the comprehensive Instructions for Use, as well as test reports on biological testing. From this review, it can be concluded that the device fulfills the biological requirements. Based on these documents it can be summarized that the procedural and product-specific risks, corresponding warnings and precautions are adequately provided for the user and offer information on risks associated with the ACCLINO® flex plus Stent. Thus, the ACCLINO® flex plus Stent meets the requirement for safety, a prerequisite for CE-marking according to the current European legislation on medical devices. Potential risks of the ACCLINO® flex plus Stent are acceptable residual risks for the patient. The main risks are described and documented in detail in the scientific literature, thus being known to the medical expert. Therefore, by complying with all warnings and precautions, the ACCLINO® flex plus Stent offers an acceptable benefit-risk profile.

2.6 Therapeutic alternatives for stent-assisted coiling

Considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

Vessel wall bulges (aneurysms) are dangerous and often need to be treated.

Alternatives of treating a vessel wall bulge is the use of metal wires without a stent securing the position of the wires (simple coiling). Also, using a balloon which is removed after the metal wires are in place is an option (balloon-assisted coiling) or the vessel wall bulge can be clipped from the outside (surgical clipping).

Your healthcare professional chooses treatment fitting to the kind of vessel wall bulge you have.

2.7 Suggested profile and training for users

The device shall only be used by a professional user.

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