ENGINEERING STROKE SOLUTIONS

Summary of Safety and Clinical Performance:

NeuroBridge® 39 / 52 / 65 Catheter

Acandis GmbH

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

Identifier: 2100

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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 NeuroBridge.
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 is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the NeuroBridge nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1.1 Device identification and general information

Device trade name(s)	– **NeuroBridge® 39:** # 01-000508, -509, -510 – **NeuroBridge® 52:** # 01-000511, -512, -513 – **NeuroBridge® 65:** # 01-000514, -515
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	426065033NeuroBridge3L
Medical device nomenclature	– UMDNS: 17-846 (catheters, intravascular, guiding) – GMDN: 17846 (vascular guide-catheter, single use) – EMDN: C010499 (Anqioqraphv and Hemodynamics Devices – Other)
Class of device	Class III medical device, as defined in Medical Device Regulation (MDR) EU 2017/745, Annex VIII, rule 7, point 2
Year of first CE certificate	NeuroBridge was first CE-marked according to MDD in 2013
Authorized representative	not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297).

1.2 Intended use of the NeuroBridge

Intended purpose	– The NeuroBridge is intended for introducing interventional and diagnostic instruments into peripheral, coronary and cerebral vessels. – In addition, it can be used as a diagnostic angiography catheter. – Furthermore, it is intended for the removal or aspiration of fresh, soft emboli and thromboses from arterial vessels including cerebral vessels.
Indication(s)	The NeuroBridge is intended for the diagnostics or treatment of peripheral, coronary and cerebrovascular diseases that can be treated endovascularly.
Targeted population(s)	Intended user: The NeuroBridge should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional radiology
	Patient target group:

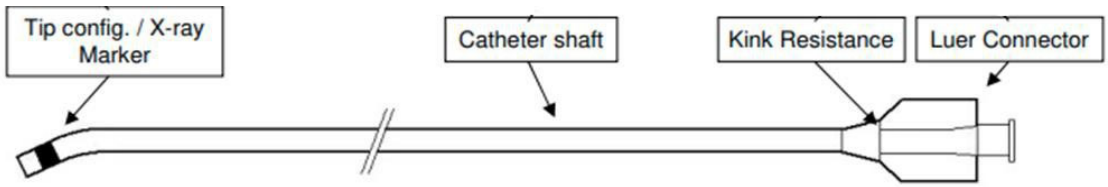
	No special patient populations defined but patients with contraindications are to be excluded.
Contra-indications and/or limitations	The NeuroBridge is contraindicated for patients who present in the angiography with anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity. General contraindications in connection with endovascular and/or angiographic treatments must be taken into consideration. No limitations are mentioned in the IFU

1.3 Device description

1.3.1 Description of the NeuroBridge

The NeuroBridge is a single-lumen, distally open catheter. The rigidity of the catheter shaft decreases in a distal direction, thus making it possible to easily reach distal and tortuous vessel sections. At its proximal end, the catheter is equipped with a standard Luer connection for attaching accessories. An x-ray marker at the distal end makes visibility easier du ring fluoroscopy. The outer surface of the catheter has a hydrophilic coating for improved lubricity. The sizes are specified on the label.

The NeuroBridge is provided sterile and for single use only.



	NeuroBridge 39	NeuroBridge 52	NeuroBridge 65
Outer diameter, distal (F)	3.9	5.0	6.1
Outer diameter, proximal (F)	4.2	5.3	6.3
Inner diameter, nominal (inch)	0.039	0.052	0.065
Shaft, working length (cm)	125 / 135 / 145	115 / 125 / 135	115 / 125
Tip shape	Multi-purpose 25°, length 20 cm		

1.3.2 Previous generations of the NeuroBridge

The first generation of the NeuroBridge received CE approval according to MDD in November 2013.

1.3.3 Description of the accessories

No accessories.

1.3.4 Description of other devices and products used in combination

Compatible with standard guide wire, RHV (rotating hemostatic valve), syringe, guiding catheter/sheath.
Combination with Acandis NeuroSlider (DLC) recommended.

1.4 Risks and warnings

1.4.1 Residual risks and undesirable effects

According to the risk management, after risk-mitigating measures there are no unacceptable residual risks. As adverse effects or injuries may occur peri-interventionally, Acandis specifies the following possible complications and undesirable side effects for their NeuroBridge.
Possible complications, among others, include the following:

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Pseudo)aneurysm, Rupture of or bleeding from aneurysm, (Intracerebral) hemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, (Arteriovenous) fistula, Vessel dissection, Vessel perforation, Vessel rupture, (Abrupt) vessel occlusion or thrombosis, Infection, (Cerebral) ischemia/infarction, Secondary hemorrhage, Reactions due to radiation exposure, Subarachnoid hemorrhage, Thromboembolic event/stroke, Vasospasm)
- General complications in connection with antiplatelet agents/ anticoagulants, anesthetics and contrast agents (e.g. Renal insufficiency)
- Complications in connection with vessel entry (e.g. Hematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during catheter delivery (e.g. Aspiration of thrombus not possible, Failed recanalization, Catheter breakage, Incorrect catheter placement, Catheter cannot be withdrawn, Catheter bending, Catheter collapses near tip, Catheter compression, Catheter damage, Therapeutic or diagnostic aids cannot be used, Delayed treatment, Target area inaccessible or cannot be accessed safely)
- Other complications in connection with the catheter (e.g. Allergic reactions to the catheter material, (Distal) embolization including previously unaffected areas, Vessel collapse during aspiration, Thrombus fragmentation)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

Quantitative data on the occurrence of complications can be drawn from respective scientific publications on the topic of endovascular treatment and diagnosis, known to the medical experts.

1.4.2 Warnings and precautions

Warnings

- The NeuroBridge should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional radiology.
- No special patient populations defined but patients with contraindications are to be excluded.
- Before use, the product needs to be carefully checked to ensure there is no transportation damage. Under no circumstances should damaged or kinked catheters be used.
- The infusion pressure must not exceed the values given in the flow table. Exceeding these values may cause cracks/ruptures in the catheter. After using contrast agents, ensure that the catheter is adequately flushed.
- If the infusion flow is interrupted, no attempt must be made to correct this by applying a high-pressure infusion. Instead, the catheter must be removed in order to determine what caused the blockage or it must be replaced by a new catheter.
- On no account should you continue advancing the catheter if you encounter resistance without first finding out the cause, as otherwise you could damage the catheter or perforate the vessel.
- Intraluminal instruments must never be moved against resistance within the catheter. The application of too much force against resistance may lead to damage (e.g. cracks/ruptures) to the instrument or injury to the vessel wall.
- When using additional devices and substances, the manufacturer’s instructions must be observed in each case.
- Compatibility of the NeuroBridge with liquid embolisates cannot be guaranteed. It is not suitable for liquid embolisates based on cyanoacrylate and dimethyl sulfoxide (DMSO).
- A corresponding treatment with anticoagulant and antiplatelet agents must be performed in accordance with well-established medical standards.
- If the catheter is incorrectly positioned at the vessel wall, excessive aspiration can lead to vessel injuries. Prior to aspiration, check the position of the distal catheter tip using a fluoroscopic method.
- 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 product 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 expiration date printed (see label).
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation 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 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 hydrophilic coating of the outer surface of the catheter must be kept hydrated to maintain its lubricious properties.
- Once the catheter is inside the body, it should only be moved under fluoroscopy. Do not remove the catheter without checking how the tip reacts.
- The manufacturers' instructions for use should be observed for all devices and substances used together with the catheter.
- The NeuroBridge must be handled carefully to minimize the risk of injury.

1.4.3 Other relevant aspects of safety

The total complaint rate is 0.07 % and the total incident rate is 0 % since market approval. The medical benefit continues to outweigh the residual risk. There were also no relevant hits on unduly or unknown risks of the NeuroBridge in the databases of competent authorities.

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 devices

No clinical data of equivalent devices from other manufacturers were used for the clinical evaluation. However, the clinical performance and safety of the NeuroBridge was demonstrated using clinical data of similar devices, which show that the generic device group of vascular guide/aspiration catheters comprises safe and efficacious devices for state-of-the-art treatment and diagnostic. The similar devices comprise the Distal Access Catheter (Stryker, Kalamazoo, MI, USA), its successor AXS Catalyst (Stryker Neurovascular, Fremont, CA, USA) and SOFIA Plus (MicroVention, Inc., Aliso Viejo, CA, USA). These devices were used as

equivalent devices for the CE-marking of the NeuroBridge under the provisions of the MDD. Under the provisions of the MDR, the use of equivalent devices is not deemed feasible, but the clinical data on the generic device group is sufficient to demonstrate safety and performance. Vascular guide/aspiration catheters for endovascular treatment and diagnosis are low-risk, well-established class III devices with a positive benefit-risk profile. As the NeuroBridge is a typical device of this generic device group, the data from the generic device group are therefore also applicable to the NeuroBridge.

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

Relevant clinical data generated from the previously used equivalent devices were still included in the clinical evaluation report of the NeuroBridge. The similar devices were used in the clinical evaluation report to demonstrate the safety and efficacy of vascular guide/aspiration catheters. The state-of-the-art shows the effectiveness of the Distal Access Catheter (DAC) for a variety of neuro-interventional procedures (Colby GP et al., 2013).
Vascular guide/aspiration catheters are now available from many manufacturers in many variations of size and diameter, as well as name: distal access catheter, distal aspiration catheter, intermediate catheter, intracranial support catheter or siphon catheter - to name but a few (Harrigan MR and Deveikis JP, 2018; Ruiz AM et al., 2019; Marnat G et al., 2019).

The devices are used for many different neuro-endovascular procedures, or as accessories during the procedures, such as endovascular thrombectomy, angiography or endovascular aneurysm treatment, with even more uses branching out. Therefore, the clinical data give an overview of procedures and the associated safety and performance.
For the clinical evaluation, several publications on the use of other distal access catheters such as the similar products were identified and assessed. Most authors reported about the use of distal access catheters in embolization of aneurysms and thrombus aspiration. Fewer publications described the use of distal access catheters in the embolization of arteriovenous malformations, endovascular recanalization and angiography. In total, their use was described as being effective for all described treatments. Furthermore, the procedures were often simplified using distal access catheters, thus resulting in shorter procedure times. Distal access catheters also provided better manipulation control of microcatheters. Due to their good

technical performance and clinical efficaciousness, distal access catheters in all their variants are accepted as clinical standard tools which are presented in guidelines and textbooks on the subject of endovascular treatment. The success rate of interventions using distal access catheters ranged from 88 % to 100 %. In most publications; it is stated that there were no complications associated with the use of distal access catheters. All reviewed studies demonstrated that the use of endovascular guide and aspiration catheters seems to be safe, feasible, and effective with good technical and clinical results. Based on the reviewed clinical literature, endovascular guide or aspiration catheters can be considered safe in the given indications. Application of endovascular techniques represents a valid treatment option (e.g. for mechanical thrombectomy) and is mostly associated with higher revascularization rates when compared to intravenous thrombolysis. Current literature and guidelines provide comprehensive information on contraindications, complications and critical aspects of different endovascular procedures and angioplasty.

The clinical literature comprises four publications using the 6 Fr NeuroBridge catheter, or combinations of catheters. Civlan and colleagues report the use of the device in a case report, treating one patient with an unruptured aneurysm. The second publication Dange and colleagues describes the use of the device in 13 patients with 14 aneurysms. Of these, 13 aneurysms were unruptured and 1 aneurysm was ruptured. Altunbulak published a case report with one patient treated for a pseudo-aneurysm, whereas Weiss and colleagues reported a retrospective study with 21 patients with intracranial aneurysms, which were treated with several differen catheters. In all publications no complications associated with the devices were reported. The authors did not disclose the technical success, but as no complaints on the use of the devices were reported, a technical success of 100 % was assumed in all publications. Civlan reports that the treatment improved the symptoms during the first postoperative month, which encompasses the complete follow-up of the publication (Civlan SS et al., 2022). Dange and Roy rate the treatment as a clinical success, as at the median follow-up of 3 months, all patients were functionally independent (modified Rankin scale score of ≤ 2) (Dange NN & Roy JM, 2022). Altunbulak reported that after the treatment, at follow-up time points at one week, 3-months and 7-months and one-year, cerebral angiograms revealed no evidence of a residual aneurysm and patency of the internal carotid artery was observed (Altunbulak HI et al., 2024). Weiss et al. did not report on the safety or performance of the Acandis Neurobridge in general, but the absence of any complications or performance issues reported by the authors shows that the devices performed as intended (Weiss D et al., 2024). These reports show the safe and efficacious clinical use of the Acandis NeuroBridge.

Still, adequate training and knowledge of the materials, techniques and handling of complications is mandatory to perform these procedures safely and successfully. However,

the experienced user is aware of the putative risks and complications and knows how to circumvent and to handle.

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

Due to the established nature of endovascular catheters and their use for various procedures, no general open questions on their safety and performance are currently evident. PMCF measures are suspended because the current expertise with the NeuroBridge catheter does not facilitate the need for PMCF activities.

1.5.3.3 Clinical data in medical device databases

The medical device registries “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 NeuroBridge. The searches were conducted on September 14, 2022 for the time period June 2014 to September 30, 2022, on October 26, 2023 for the time period September 01, 2022 to October 26, 2023 and on March 24, 2025 for the time period October 27, 2023 to March 24, 2025 (BfArM) or February 28, 2025 (MAUDE).

The BfArM database search revealed no entries concerning the NeuroBridge. The MAUDE database search revealed very few entries regarding death, injuries or malfunctions of the similar devices DAC (Distal Access Catheter), its successor device AXS Catalyst (both Stryker Neurovascular, Fremont, CA, USA) (Stryker, Kalamazoo, MI, USA) and the SOFIA Plus Aspiration Catheter (MicroVention, Inc., Aliso Viejo, CA, USA. The most device- and procedure-related problems were vessel dissection, device fracture and missing device components, resulting in intracranial hemorrhage, obstruction/occlusion, paralysis, dysphasia, stroke and vessel perforation. However, the reported events are known complications with endovascular procedures.

1.5.4 An overall summary of the clinical performance and safety

The clinical literature identified in the CER, together with the data collected from PMS on the NeuroBridge show the clinical performance and safety of the device. The state-of-the-art and clinical data on the generic device group shows that the devices are safe and efficacious medical devices for various indications. As the Acandis NeuroBridge can be considered a standard device in line with the generic device group, the clinical evidence is also applicable to it.

The clinical evaluation of the NeuroBridge is based upon several product-specific documents, including risk analysis and comprehensive instructions for use, as well as various test reports, amongst others, verifying the devices' biocompatibility.
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 NeuroBridge and its clinical application. Complications directly associated with the catheter cannot be ruled out completely. The basic design, as well as the material used for the device, has been successfully applied for several years. The risks described in the literature and the instructions for use are consistent. Thus, the NeuroBridge meets the requirement for safety. Also, no evidence on unduly or unknown risks of the NeuroBridge was identified in the CER.
According to the risk management, the product is safe for treatment and the medical benefits outweigh the residual risk. It can be concluded that risks which may be associated with the intended use of the NeuroBridge constitute acceptable risks when weighed against the benefits to the patient according to the clinical data presented in the scientific literature, the PMS as well as the risk analysis. The main risks are described and documented in detail in the scientific literature, thus being known to trained physicians Therefore, by complying with all warnings and precautions, the NeuroBridge offer an acceptable benefit/risk profile.
The regular PMS data show very low complaint rates.

In conclusion, the Acandis NeuroBridge 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

Due to the established nature of endovascular catheters and their use for various procedures, no general open questions on their safety and performance are currently evident. PMCF measures are suspended because the current expertise with the NeuroBridge catheter does not facilitate the need for PMCF activities.

1.6 Therapeutic alternatives for endovascular treatments using vascular guide/aspiration catheters

Identified alternatives to endovascular treatment using vascular guide/aspiration catheters is the treatment by open surgery.

1.7 Suggested profile and training for users

The NeuroBridge may only be used by physicians who have the required background knowledge and experience in the field of interventional radiology.

1.8 Reference to harmonized standards and common specifications

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

Mnemonic	Number	Title	Revision
EN	556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2001+AC:2006
EN	868-2	Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods	2017
EN ISO	10555-1	Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2013 + Amd 1:2017), cited as 2018	2013+A1:2017
EN ISO	10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	2020
EN ISO	10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2009
EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	2021
EN ISO	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	2018
EN ISO	10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008 + Cor 1:2009 + Amd 1:2019)	2008 + AC:2009 +A1:2022
EN ISO	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2009
EN ISO	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)	2017
EN ISO	10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	2014
EN ISO	10993-2	Biological evaluation of medical devices - Part 2: 2022 Animal welfare requirements (ISO 10993-2:2022)	2022
EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10	2020
EN ISO	11135	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014+Amd.1:2018)	2014+A1:2019
EN ISO	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	2017
EN ISO	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)	2017
EN ISO	11139	Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)	2018
EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)	2020/A11: 2022

Mnemonic	Number	Title	Revision
EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)	2020/A11: 2022
EN ISO	11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	2018+A1:2021
EN ISO	13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016+AC:2018+ A11:2021
EN	13868	Test methods for kinking of single lumen catheters and medical tubing	2002
EN ISO	14644-5	Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2004)	2004
EN ISO	14644-4	Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2022)	2022
EN ISO	14644-3	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)	2019
EN ISO	14644-2	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	2015
EN ISO	14644-1	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)	2015
ISO	14698-2	Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data TECHNICAL CORRIGENDUM 1	2003/Cor. 1:2004
ISO	14698-1	Cleanroom and associated controlled environments - Biocontamination control - Part 1: General principles and methods	2003
EN ISO	14971	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	2019+A11:2021
EN ISO	15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2021)	2021
EN	17141	Cleanrooms and associated controlled environments - Biocontamination control	2020
EN ISO	20417	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, corrected version 2021-12)	2021
EN	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1+COR1:2016+A1:2020)	2015+AC:2015+ A1:2020
EN ISO	80369-7	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)	2021

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

2 Information for the patient

This part of the SSCP is not deemed necessary for the NeuroBridge.

3 Bibliography

No.	Citation
1	Altunbulak HI, Altunbulak AY, Balci S, Berker M, Arat A. Use of a new low-profile coronary stent graft for the treatment of intracranial carotid blow-out. J Cerebrovasc Endovasc Neurosurg. 2024 Dec;26(4):399-404.
2	Civlan S, Yakar F, Coskun ME, Sato K. Endovascular occlusion of giant serpentine aneurysm: A case report and literature review. J Cerebrovasc Endovasc Neurosurg. 2022 Mar;24(1):51-57.
3	Colby GP, Lin LM, Huang J, Tamargo RJ, Coon AL. Utilization of the Navien distal intracranial catheter in 78 cases of anterior circulation aneurysm treatment with the Pipeline embolization device. J Neurointerv Surg. 2013 Nov;5.
4	Dange NN, Roy JM. Initial Experience with the Contour Device in the Treatment of Ruptured Intracranial Wide-necked Bifurcation Aneurysms: A Single-operator, Multicenter Study. Neurol India. 2022 Sep-Oct;70(5):2059-2064.
5	Harrigan, M. R., & Deveikis, J. P. General considerations for neurointerventional procedures. In Handbook of cerebrovascular disease and neurointerventional technique. Humana Press, Cham. 2018. Chapters 2, 4, 6, 12.
6	Ruiz AM, Sheharyar A, Ortega-Gutierrez S. Chapter 5: Arterial Access and Intermediate Catheters: Procedural and Technical Considerations. In: Samaniego EA, Hasan D: Acute Stroke Management in the Era of Thrombectomy. Springer Nature Switzerland AG 2019
7	Weiss D, Vach M, Ivan VL, Muhammad S, Hofmann BB, Neyazi M, Turowski B, Kaschner M. Comparison of antithrombogenic coated and uncoated flow diverters in ruptured and unruptured cerebral aneurysms. J Neuroimaging. 2025 Jan-Feb;35(1):e13253.