ENGINEERING STROKE SOLUTIONS

Summary of safety and clinical performance:

APERIO Hybrid^{17}/Hybrid^{21} Thrombectomy Device

Acandis GmbH

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

Identifier: 2800

Table of contents

1 Information for the professional user

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the APERIO Hybrid[17] Thrombectomy Device and the APERIO Hybrid[21] Thrombectomy Device, together referred to as APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device.

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 APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals (chapter 1).
The second part of the SSCP is not required for the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device (chapter 2).

1.1 Device identification and general information

Device trade name(s)	**APERIO Hybrid[17] Thrombectomy Device** (Article no. 01-000710, 01-000711, 01-000712, 01-000713) **APERIO Hybrid[21] Thrombectomy Device** (Article no. 01-000715, 01-000716, 01-000717, 01-000718)
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	426065033APERIOHy1721LJ
Medical device nomenclature	UMDNS: 17-461 (Stents, vascular) GMDN: 61779 (Thrombectomy wire-net) EMDN: C010499 (Angiography and Hemodynamics Devices – Other)
Class of device	Class III, Rule 7, bullet point 2, according to MDR annex VIII
Year of first CE certificate	Hybrid[17]: on the European market since March 2020 Hybrid[21]: on the European market since May 2021
Authorized representative	not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297).

1.2 Intended use of the device

Intended purpose	The APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device is intended for restoring arterial blood flow in occluded vessels.
Indication(s)	The APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device is intended for the treatment of patients with diagnosed acute ischemic stroke following a vascular occlusion. Patients in whom intravenous thrombolysis fails or does not constitute a suitable treatment are also candidates for treatment with the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device.
Targeted population(s)	Intended user: The APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device should only be used by physicians who have the required background knowledge and experience in the field of interventional neuroradiology.
	Patient target group: There are no specific restrictions based on age, weight, health status or ethnicity. The decision on whether a patient is eligible for treatment with the product lies solely with the intended user.
Contra-indications and/or limitations	Usage is contraindicated for the following patients: – Patients in whom a dissection of the carotid artery has been verified. – Patients who are hypersensitive to nickel-titanium. – Patients with occlusions in vessels whose diameter is outside the recommended vessel diameter (see label). – Patients in whom the obstruction (such as stenosis proximal to the occlusion to be treated) cannot be safely removed due to anatomical conditions or angiopathologies. No limitations are mentioned in the IFU.

1.3 Device description

1.3.1 Description of the Product

The APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device consists of a self-expanding, laser-cut stent made of Nitinol (a nickel-titanium alloy) that is connected to the transport wire at the proximal end. There are three platinum/iridium markers at the distal end of the device and two at the proximal end. In order to simplify placement under fluoroscopy, continuous radiopaque Nitinol (a nickel-titanium alloy) wires with a platinum core are attached along the stent. The device is preloaded in an introducer. The sizes are specified on the packaging label.

The devices are characterized by a stent-like design with a combination of a closed and open cell design, called hybrid cell design. The small closed cells ensure a good vessel wall apposition and improved expansion in the clot. The large open cells with integrated anchoring elements shall assure clot retrieval even in tortuous vessels.

Sizes Hybrid[17]	2.5 x 16 / 2.5 x 28, intended vessel diameters 1.0 – 2.0 mm 3.5 x 28, intended vessel diameters 1.5 – 3.0 mm 4.5 x 30 mm, intended vessel diameters 2.0 – 4.0 mm
Sizes Hybrid[21]	4.5 x 40 / 4.5 x 50 mm, intended vessel diameters 2.0 – 4.0 mm 6.0 x 40 / 6.0 x 50 mm, intended vessel diameters 3.5 – 5.5 mm
Sterility	Yes, EtO sterilized, for single-use
Generic device group	Thrombectomy devices

The device will be navigated to the target region over a fitting microcatheter that is placed distal to the thrombus by pushing the transport wire. The device will then be unfolded by retracting the microcatheter. The device expands into the clot and can then be retrieved with the integrated clot into the aspiration catheter or together with the aspiration catheter into the sheath.

1.3.2 Previous generations

Predecessor products of the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device are the APERIO (first generation, on the market since May 2014) and the APERIO Hybrid (second generation, on the market since March 2019).

1.3.3 Accessories

A microcatheter with a matching inner diameter, intended for use in combination with the Acandis microcatheter NeuroSlider DLC 17 / 21 / 27.

1.3.4 Combination with other devices

APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device is used in combination with microcatheters and medical devices for neurovascular angiography.

1.3.5 Complications, warnings, cautions and precautions

1.3.6 Possible complications

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Pseudo)aneurysm, (Intracerebral) haemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, (Arteriovenous) fistula, Vessel dissection, Vessel perforation, Vessel rupture, Vessel stenosis, Vessel trauma, (Abrupt) vessel occlusion or thrombosis, Cerebral oedema, Infection, Cerebritis, (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, anaesthetics and contrast agents (e.g. Renal insufficiency, Allergic reaction)

- Complications in connection with vessel entry (e.g. Haematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during device delivery (e.g. Device deformation, Device collapse, Device breakage, Wrong device positioning, Device cannot be inserted into catheter, Device cannot be deployed, Device cannot be drawn back into catheter, Failed recanalisation, Insufficient opening behaviour, Delayed treatment, Target area inaccessible or cannot be accessed safely)
- Other complications in connection with the device (e.g. (Local) Allergic reactions to the device material, (Distal) embolisation including previously unaffected areas, Perforator infarction, Thrombus fragmentation, Occlusion of perforators or branch vessels, Increased stress to the vessel wall, Local inflammatory reactions, Systemic hypersensitivity)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

From the systematic review of the scientific literature and PMCF measures, only scarce quantitative data on the occurrence of complications with the APERIO generations could be obtained. The overall mortality rates across the studies reviewed were in mean 17.4 % (early-hospital and overall mortality during hospital stay, pooled; APERIO Hybrid[17] early-hospital / overall mortality 4.2 % - 18.9 %) without procedure-related deaths. The overall mortality rate for the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device was 9.8 % in the completed HYBRID study. No device-related event was reported in the HYBRID study. Under the most commonly reported complications fall subarachnoid hemorrhage (SAH), hemorrhagic infarction, symptomatic intracranial hemorrhage (sICH), asymptomatic SAH, vasospasm and parenchymal hematoma. Procedural complications such as emboli to new territories (ENT) that causing SAH, dissections as well as perforation only occasionally occur. According to the literature, the following occurrence rates of complication were reported:

	APERIO Hybrid[17] / Hybrid[21]
embolization into previously unaffected territories	1.4 % (Goertz L et al., 2022) 1.7 % (Dorn F et al., 2025) 4.1 % (Dunkerton et al., 2025)
asymptomatic hemorrhagic	4.2 % (Goertz L et al., 2022) 13.5 % (Dorn F et al., 2025)
SAH	6.3 % (Goertz L et al., 2022) 12.6 % (Dorn F et al., 2025)
sICH	0 % (Dorn F et al., 2025) 0 % (Klüner C et al., 2025) 2.8 % (Goertz L et al., 2022) 3.1 % (Dunkerton S et al., 2025)

Such complication rates are in accordance with those of similar devices intended for mechanical thrombectomy.

1.3.7 Cautions, warnings and precautions

Cautions

- The accessory must be selected according to the medical experience of the physician and recommendations on the label!
- The product is only compatible with accessories that comply with the manufacturer's specifications on the label and in the instructions for use!
- The device must not be partially deployed!
- The device must not be pushed out of the introducer!
- Ensure that the system is free from air!
- Do not dispose of the introducer before you have fully completed the procedure!
- Do not apply excessive force!
- On no account whatsoever should you continue advancing the device if you encounter resistance!
- Do not attempt to move the device distally if you have already started deploying it! This could have undesirable side effects!
- If you are not able to retract the stent retriever, you should not use excessive force. Try to enclose the stent retriever in the guide catheter by pushing the guide catheter forward. Then remove the entire system (stent retriever and guide catheter)!
- Do not attempt to recanalise the vessel using the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device more than three times!

Warnings

- The APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device should be applied only by physicians who have the necessary background knowledge and experience in the field of interventional neuroradiology.
- 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 device if you encounter resistance without first finding out the cause as otherwise you could damage the instrument or perforate a vessel.
- Do not attempt to recanalise the vessel using the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device more than three times. A new device must be used after three attempts.
- Use a new microcatheter for each new APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device.
- The device 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 is 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.
- 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.
- In order to minimise potential complications during and after the intervention, attention should be paid to careful medication treatment in accordance with the current guidelines from the medical societies.
- Throughout the entire procedure, permanent flushing must be maintained between the:
  - insertion sheath and guide catheter
  - guide catheter and microcatheter
  - microcatheter and guide wire or transport wire of the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device

1.3.8 Other relevant aspects of safety

There were no recalls, CAPAs, FSCAs or trends. In the collection period from September 2024 to August 2025 the overall complaint rate is 0.07 %. The medical benefit continues to outweigh the residual risk.

There were also no relevant hits on unduly or unknown risks of the APERIO devices in the databases of competent authorities.

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

1.4.1 Summary of clinical data related to equivalent devices

No clinical data of equivalent devices from other manufacturers were used for the clinical evaluation. Since the variants of the APERIO family have an identical clinical application, identical principle of operation and all are made of Nitinol, the clinical evaluation was conducted by using the clinical data of all three generations of the APERIO Thrombectomy Devices and evaluated them together.

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

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

1.4.3 Summary of clinical data from other sources

1.4.3.1 Clinical data in the literature

1.4.3.1.1 Clinical data on the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device (third generation of APERIO device family)

Table 1: Clinical data on the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device. ACA: anterior cerebral artery, AE: adverse event, APH: APERIO Hybrid Thrombectomy Device, APH17: APERIO Hybrid[17] Thrombectomy Device, ASPECTS: Alberta Stroke Program Early CT Score, CT: computed tomography, ENT: emboli to new territories, ENI: early neurological improvement, FPE: first pass effect, HI: hemorrhagic infarction, MR: magnetic resonance, MT: mechanical thrombectomy, mRS: Modified Rankin Scale, NIHSS: National Institutes of Health Stroke Scale, PH: parenchymal hematoma, rt-PA: recombinant tissue plasminogen activator, SAH: subarachnoid hemorrhage, sICH: symptomatic intracranial hemorrhage, TICI: thrombolysis in cerebral infarction.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Goertz L et al., 2022 Safety and efficacy of the novel low-profile APERIO Hybrid[17] for treatment of proximal and distal vessel occlusion in acute ischemic stroke: a multi-center experience	**APERIO Hybrid[17] Thrombectomy Device (AP17)**	**71** [32 / 39 / 73 years]	- The AP17 was rated “good” and “very good” in terms of marker visibility, device visibility, and transfer into microcatheter (100 %). “Resheathing of introducer” and “resheathing of microcatheter” were rarely necessary (n=13/n=14) and mainly rated “good” and “very good”. Pushability into microcatheter (93.8 %), positioning of stent retriever (96.9 %) and device deployment (96.5 %) were rated “good” and “very good” with one to four cases which were rated “poor” (6.2 %) - Overall favorable recanalization (TICI≥2b) was achieved in 92.7 % (63/68) and excellent	- Patients were treated by the AP17 with the following occlusion patterns: carotid-T in 8 cases (11.3 %), M1-segment in 16 (22.5 %), M2-segment in 29 (40.8 %), anterior cerebral artery 3 (4.2 %) and basilar or posterior cerebral artery in 15 (21.1 %). - The mean diameter of the occluded vessels was 1.9 ± 0.5 mm. Prior to thrombectomy, 25 patients (35.2 %) received IVT according to the guidelines of the German Neurological Society - Periprocedural embolization into previously unaffected territories by fragmented or lost clots did occur in one patient (1.4 %). Asymptomatic	The AP17 was associated with a reasonable safety and efficacy profile for both proximal and distal vessel occlusions. These results may contribute to establish mechanical thrombectomy for distal occlusions. Furthermore, the study indicates high

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
			recanalization (TICI≥2c) was achieved in 69.2 % (47/68). Overall favorable first-pass recanalization (TICI≥2b) was achieved in 75.6 % (28/37) and excellent first-pass recana-lization (TICI≥2c) was achieved in 59.4 % (22/37). A rescue maneuver was only necessary in two patients (2.8 %). - Overall mean groin-puncture-to-recanalization-time in that proceeding from femoral access to final recanalization was 59±34 min. Intraarterial rt-PA was administered in five patients (7.0 %). The posttreatment median ASPECTS in follow-up CT after 16-24 hours was 9 (7 –10). The overall mean number of stent retriever passes was 3±2. - All patients were available for follow-up at discharge, forty-two patients (59.2 %) were available for follow-up at three-months and twenty-nine were lost to follow-up (40.8 %). Favorable functional outcome at discharge was achieved in 50.7 % (35/71) patients and in 69.0 % (29/42) after three months.	hemorrhagic transformations (HI-1, HI-2) were observed in three patients (4.2 %) and asymptomatic, mild SAH, Fisher 2, in five patients (6.3 %) in follow–up CT or MR imaging 16-24 hours after the MT. Parenchymal hematoma (PH-1) did not occur. Two (2.8 %) patients suffered of sICH as result of a reperfusion injury. Rescue maneuvers were performed in three patients (4.2 %). - In the first case, after successful recanalization of a M2-occlusion, a new occlusion occurred in the pericallosal artery, which was successfully recanalized with direct aspiration (3MAX Reperfusion Catheters, Penumbra Inc.). In the second case, a distal M2 occlusion could not be recanalized and, in addition, vasospasm occurred, so direct aspiration (3MAX Reperfusion Catheters, Penumbra Inc.) was attempted in this case as well. In the third case, inadvertent detachment of a conventional APH occurred, which was used as rescue treatment after unsuccessful reperfusion of the right ACA with an AP17.	favorable and excellent reperfusion rates and low complication rates with the AP17. In addition, these results encourage the use of low-profile stent retrievers for MT and might contribute to expand the indications of MT to distal occlusions in the near future.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
			- A higher first and final TICI score correlated positively with an improved patient outcome at discharge.	- Overall, early in-hospital mortality was 17.4 % (12/71) and procedure-related deaths did not occur. - In summary, recanalization rates, NIHSS scores and mRS scores were not significantly different between the different occlusion sites. The mean number of passes was significantly lower in the M2-group (2±1) than in the M1 group (3±3; p=0.043).	
Dorn F et al., 2025 REcanalization of Distal Cerebral Vessels In Acute Stroke Using ApeRio (REVISAR) *Note: Results display PMCF study "REVISAR" conducted by Acandis*	**APERIO Hybrid [17] Thrombectomy Device (AP17)** or APERIO Thrombectomy Device **AP17:** **2.5x16 15 Pat.** **2.5x18 1 Pat.** **2.5x28 36 Pat.** **3.5x28 30 Pat.** **4.5x30 21 Pat.** **4.5x50 -**	**119** [60 / 59 / 71.7 years]	- Successful recanalization with one to three passes (TICI 2b/3) was achieved in 81.5 %. In those with four to six passes, TICI 2b/3 was reached in 3.3 % and with other techniques in 15 %. - The overall success for recanalization was 95.8 %. - First pass success was achieved in 63.9 %, in 19.3 % after two passes and in 0.8 % after three passes. - The 90-day mRS 0 – 2 was 79 %.	- Recanalization of distal cerebral vessels in acute stroke in M2 and M3 segments of MCA, A2 and A3 segments of ACA, P2 and P3 segments of PCA - APERIO or APERIO Hybrid17 was used as first-line technique. - There was no sICH, but 13.5 % asymptomatic intracranial hemorrhage and 12.6 % SAH. - Emboli to new territories occurred in 1.7 % and in-hospital mortality in 4.2 % of cases.	APERIO and APERIO Hybrid[17] were both safe and effective first-line devices for mechanical thrombectomy in medium vessel occlusion stroke with high rates of successful recanalization.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
	Total: 103 AP17 devices used				
Klüner C et al., 2025 Safety, Technical and Clinical Success of the Aperio Hybrid Thrombectomy Device in Acute Ischemic Stroke, a Prospective Post-market Clinical Follow-up Study (HYBRID) *Note: Results display PMCF study "HYBRID" conducted by Acandis*	APERIO Hybrid / **Hybrid[17|21]** *Note: It was not distinguished which devices were used exactly.*	**173** [101 / 72 / 73.2 years]	- mTICI ≥ 2b was achieved in 84.4 % with APERIO Hybrid/Hybrid[17/21] alone, 47.4 % thereof with first pass success. - The overall mTICI ≥ 2b was 97.1 %. - 90-day mRS 0 – 2 was seen in 68.8 %.	- Thrombectomy in acute ischemic stroke in the anterior and posterior circulation (MCA, ICA, ACA, BA, PCA) - Additional intracranial techniques included pure aspiration (5.8 %), intracranial percutaneous transluminal angioplasty with stenting (5.8 %) and alternative stent retriever (5.8 %). - There was no sICH, despite stent retriever oversizing in 79.8 % of cases.	The APERIO Hybrid/ Hybrid[17/21] was effective and safe. Technical success, primary safety and clinical outcomes surpassed earlier registries on different stent retrievers of the same and earlier generations.
Ozdemir G et al., 2025	Solitaire™ X, **APERIO**	**Total: 603**	- mTICI 2b–3 was achieved in 61.4 % (medium vessel occlusion) vs. 64.3 % (large vessel	- Endovascular treatment of medium vessel occlusions, large vessel occlusions and rescue	Endovascular treatment of medium

Reference [Author, title]	**Used device**	**Included patient no. [female / male / average age]**	**Effectiveness end point / technical success**	**Safety end points / technical notes / periprocedural complications**	**Overall conclusion**
Primary vs. Rescue Medium Vessel Occlusions: Comparative Clinical Outcomes in Patients with Acute Ischemic Stroke	**Hybrid/Hybrid[17|21]**, and CATCH/CATCH Mini/CATCHVIEW *Note: There was no distinction between the results of the different stent retrievers*	medium vessel occlusion group: **202** [102 / 100 / 71.26 years] large vessel occlusion group: 401 [208 / 193 / 67.28 years]	occlusion) and complete reperfusion (mTICI 3) in 32.7% vs. 31.4%, respectively. - At 90-day follow-up, medium vessel occlusions achieved more mRS 2 (29.2 %) and large vessel occlusions more mRS 1 (14 %), reperfusion rates were similar.	medium vessel occlusions in A1-A3, M2-M3, P1-P3, fetal PCA and PICA - Mechanical thrombectomy was done with the stent retrievers Solitaire™ X (Medtronic, Dublin, Ireland), APERIO® Hybrid/Hybrid[17|21] (Acandis, Pforzheim, Germany), and CATCH/CATCH Mini/CATCHVIEW (Balt, Montmorency, France). - Of the medium vessel occlusion cases, 58.9 % were primary and 41.1 % rescue occlusions. - Mortality was numerically lower in MeVO (9.4% vs. 13.5%) but not statistically significant - Rescue cases had worse 90-day outcomes and higher mortality (21.7 % vs. 0.8 %). - Intracranial hematoma occurred in 17.3 % with medium vessel occlusion vs. 17.2 % with large vessel occlusion.	vessel occlusions was feasible, effective and safe, but rescue cases were associated with poorer outcomes and markedly higher mortality.
Dunkerton S et al., 2025 REAL-WORLD EXPERIENCE OF	**6×50 mm APERIO Hybrid[21] stent-retriever**	**127** [n.a. / n.a. / n.a. years]	- FPE was achieved in 55%, with successful reperfusion (TICI ≥2b) in 85% and complete reperfusion (TICI 3) in 36%. - ENI occurred in 21% of patients.	- sICH was observed in 3.1%, and embolization to new territory in 4.1%. - mortality was 18.9%.	The 6×50 mm APERIO stent-retriever, when

Reference [Author, title]	**Used device**	**Included patient no. [female / male / average age]**	**Effectiveness end point / technical success**	**Safety end points / technical notes / periprocedural complications**	**Overall conclusion**
THE LARGE 6–50 APERIO STENT-RETRIEVER: EVALUATION OF EFFECTIVENESS AND SAFETY *Note: Presented only as abstract in J NeuroIntervent Surg*			- At 90-day follow-up, 41% achieved functional independence (mRS 0–2)	- Ordinal logistic regression identified age, baseline NIHSS, and embolization to new territory as significant predictors of poor outcome.	combined with aspiration, demonstrated high technical success and favorable safety in routine clinical practice. These findings support its effectiveness as a front-line device for LVO thrombectomy.

1.4.3.1.2 Clinical data on the APERIO Thrombectomy Device and APERIO Hybrid Thrombectomy Device (first and second generation of APERIO device family)

Table 2: Clinical data on the first and second generation of the APERIO device family. ADAPT: Direct aspiration first-pass technique, AP: APERIO Thrombectomy Device, APH: APERIO Hybrid Thrombectomy Device, ASPECTS: Alberta Stroke Program Early CT Score, BA: basilar artery, CS: Collateral Score, CT: computed tomography, CTA: CT angiography, ET: Endovascular treatment, FO: favorable clinical outcome, GP: globus pallidus, HI: hemorrhagic infarction, ICA: internal carotid artery, IVT: intravenous thrombolysis, LSA: left subclavian artery, LVO: large vessel occlusion, MCA: middle cerebral artery, mRS: Modified Rankin Scale, NIHSS: National Institutes of Health Stroke Scale, PH: parenchymal hematoma, PICA: Posterior inferior cerebellar artery, rCBVR: relative cerebral blood volume ratio, rt-PA: recombinant tissue plasminogen activator, SAH: subarachnoid hemorrhage, sICH: symptomatic intracranial hemorrhage, TICI: thrombolysis in cerebral infarction, WM_{MCA}: white matter in the territory of the middle cerebral artery.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Kallenberg K et al., 2016 Endovascular stroke therapy with the APERIO Thrombectomy Device	**APERIO Thrombectomy Device** *(outer diameter of 4.5 mm and a usable length of 35 – 40 mm)*	**119** [68 / 51 / n.m.]	- The median thrombus length was 15 mm (range 1.5–20 mm) and the average time from device insertion to recanalization was 30 min (range 5–120 min). - The median number of device deployments was two (range 1 – 6). In 10 % of patients (twelve cases), more than one thrombectomy device was used as the previously applied stent retriever was not successful. In ten cases, the APERIO was the first-line device. - Blood flow restoration (Thrombolysis In Cerebral Infarction (TICI) 2–3) was achieved in 85%. In the majority of cases complete clot removal was achieved (TICI 0, 12 %; TICI 1, 2 %; TICI 2a, 14 %; TICI 2b, 18 %; TICI 3, 53 %).	- In more than 33 % of cases, an occlusion of the carotid artery was treated. - In 16 cases, an occlusion of the internal carotid artery (ICA) was treated. - In 50 cases, a thrombus in M1 and in seven cases an embolus occluding the M2 segment of the MCA was removed. In 18 cases, the basilar artery was treated with the APERIO Thrombectomy Device. - Fourteen percent of patients were not administered any additional peri-procedural anticoagulant. A body weight-adjusted rtPA dose was administered in 62 %. Patients were treated with i.v. rtPA only in a bridging fashion in 22 % of cases. In 40 % of cases, patients received a combined i.v/i.a. medication. The remaining 24 % of the patient collective was treated with anticoagulant drugs during the procedure. - In 10 % of cases, thrombectomy procedural complications occurred with three dissections, one vessel perforation causing SAH, one idiopathic SAH, four cases of vasospasm, one device rupture and one idiopathic case in which subarachnoid contrast agent was present in post-	- APERIO Thrombectomy Device is an effective and adequately safe tool to reopen occluded cerebral vessels in acute stroke situations. - The recanalization rate of the APERIO is similar to that of other stent systems that were evaluated in other trials (SWIFT: Solitaire 89 %; MERCI 67 %; SWIFT PRIME: Solitaire 88 %; Trevo: Trevo 92 %; Trevo II: Trevo 92 %, MERCI 77 %; IMS III: MERCI 73 %)

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
				interventional CT. The dissections emerged in the extracranial arteries only (one in the ICA and one in the vertebral artery). - In three cases, more than two devices from different manufacturers were deployed. In two patients, the vessel was successfully reopened after the deployment of multiple devices. However, in the majority (ten out of twelve cases) of the multi-device deployment, the target vessel remained clogged. In one case, SAH emerged after the application of multiple stent retrievers.	
Kaschner MG et al., 2019a One-year single-center experience with the APERIO thrombectomy device in large vessel occlusion in the anterior circulation: safety, efficacy, and clinical outcome	**APERIO device** *(4.5 × 40 mm were used in 42 patients, 4.5 × 30 mm in 37 patients, and of 3.5 × 28 mm in three patients)*	**82** [49 / 33 / 77 years]	- The overall mean time to final recanalization proceeding from femoral access to final revascularization was 52.3 ± 34.8 min. - The mean of stent retriever passes was 2.6. - The median baseline NIHSS was 14, and the median pre-treatment mRS was 5. Baseline median ASPECTS was 10. A major revascularization (TICI ≥ 2b) was achieved in 85.3 %. - First-pass final recanalization (TICI 2b – 3) was achieved in 43.9 % (36/82). In all cases, the APERIO was the first-line stent retriever device, recanalization procedures could be completed without using more than one stent retriever device. - A final TICI ≥ 2c was achieved in 54.9 %. The post-treatment median ASPECTS was 6. Out of 82 patients treated with the APERIO, 68 (82.9 %) were available for a follow-up after three months. A favorable clinical outcome according to the mRS scale	- There were ICA occlusion in three (3.1 %), carotid-T in two (2.1 %), M1 in 63 (64.9 %), tandem occlusion in 14 (14.4 %), and proximal M2 segment occlusion in 15 (15.5 %) patients. Of 97 patients, 82 (85.6 %) underwent thrombectomy using the APERIO stent retriever. - The overall early mortality was 17 % (14/82). The overall mortality after three months was 22.1 % (15/68). There was no procedure-related death. Post-procedural sICH due to hemorrhagic infarction occurred in six patients (7.3 %). Asymptomatic hemorrhagic transformation or parenchymal hematoma was observed in 15 patients (18.3 %) and asymptomatic SAH in six patients (7.3 %). Embolization of previously unaffected territories by fragmented or lost clots was observed in one case (1.2 %). In another patient, bleeding due to perforation of the right femoral communicating artery after groin puncture occurred. Patients with failed first-line intention to treat had a high rate of good clinical outcome (66.6 %, (2/6)) despite a low rate of favorable recanalization rates (TICI ≥ 2b = 50 %) due to bias from the small sample size.	- The APERIO device achieved high rates of successful reperfusion in large-vessel occlusions in the anterior circulation with local aspiration techniques in the setting of acute stroke. - The absence of device-related procedural complications demonstrated an adequate safety profile of the device

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
			(mRS 0 – 2) was achieved in 41.2 % (28/68) patients.		
Müller-Eschner M et al., 2019 Introducing the New 3.5/28 Microstent Retriever for Recanalization of Distal Cerebral Arteries in Acute Stroke	**APERIO thrombectomy device** *(3.5 x 28 mm)*	**22** [10 / 12 / 61 years]	- Evaluation of the angiographic data revealed a TICI score of 0 before treatment in seven patients and a TICI score of 1 in two patients. In seven vessels treated with the APERIO 3.5 x 28 alone, a TICI score C 2b could be achieved. In two vessels, a recanalization rate of TICI 2a was observed - A mean number of 1.5 passages has been performed. Mean procedure time from first to final angiograms was 81.1 ± 42.1 min. - TICI before treatment was 0 in all 13 patients *(used as additional device, see technical notes*). In the 13 patients treated with a combination of devices, the overall TICI score was 3 in two patients, 2b in nine patients, and 2a in two patients. In this group, TICI 3 of the vessel treated with the APERIO 3.5 x 28 could be achieved in five patients and TICI 2b in four patients, resulting in a successful recanalization rate of 84.6 % (11 out of 13). Persisting occlusion of the target vessel (TICI 0) was observed in three patients. - The mean time for procedures with the APERIO 3.5 x 28 as an additional device was 100.2 ± 37.9 min. - The overall median NIHS score at admission was 8.5 (range 0 – 20).	- 11 of all 22 patients (6/14 distal occlusions and 5/8 proximal occlusions) received IVT prior to thrombectomy. - The mean vessel diameter was 1.6 ± 0.11 mm. - In nine patients/ten vessels, (one patient received a thrombectomy with the APERIO 3.5 x 28 in two separate vessels) the APERIO 3.5 x 28 was used first-line and the mechanical recanalization was performed using the APERIO 3.5 x 28 alone. In these patients, the primary targets were smaller vessels (M2 segment n = 7, A3 segment n = 1, hypoplastic BA n = 1, and P1 segment n = 1). In four patients, additional ICA stent retriever implantation was necessary due to an ipsilateral proximal high-grade stenotic lesion to achieve successful recanalization. - In 13 patients, the APERIO 3.5 x 28 was used as an additional device and in eleven patients, second due to secondary or remaining occlusion of peripheral arteries (M2 segment n = 9, A1 segment n = 1, P2 segment n = 2, and PICA n = 1) after thrombectomy of a proximal artery. In two patients with primary peripheral occlusion, the APERIO 3.5 x 28 was used as the first-line device and dragged the thrombus in proximal cerebral arteries, where a larger stent retriever was additionally used to remove the proximal thrombus remnants. In these patients, a mean number of 1.3 passages with the APERIO 3.5 x 28 had been performed.	Data suggest that mechanical thrombectomy of distal cerebrovascular occlusions in small cerebral arteries using the APERIO 3.5 x 28 is feasible and safe and results in good recanalization rates and clinical outcome data

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
			Median NIHSS at discharge was 2 (range 0 – 21). The median mRS at discharge was 2 (range 0 – 6). A favorable clinical outcome (mRS ≤ 2) was achieved in twelve patients (54.5 %) and a moderate outcome (mRS 3 or 4) was noted in three patients (16.6 %). Poor outcome (mRS 5 or 6) was observed in seven patients (31.8 %).	- Two patients died during the hospital stay due to pneumonia. Mild vasospasm was observed in 5 out of 22 patients, which subsided quickly. In the follow-up CT imaging obtained 24 h after thrombectomy, one patient exhibited parenchymal bleeding in the corpus callosum after mechanical recanalization of the peri-callosal artery.	
Kaschner MG et al., 2018b Mechanical thrombectomy in MCA-mainstem occlusion in patients with low NIHSS scores	**Stent retriever thrombectomy device APERIO** *(4.5 × 40 mm or 3.5 × 28 mm)*	**30** [17 / 13 / 71.5 years]	- A favorable recanalization rate (TICI 2b – 3), was achieved in 29 patients. Embolization to other vascular territories was not observed. In the remaining patient with unsuccessful recanalization (TICI2a) of a right-sided M1 occlusion, good collateralization could be confirmed by digital subtraction angiography. - Despite a pre- and post-interventional ASPECTS of 5, this patient's NIHSS improved from 5 to 0 and mRS from 3 to 1 at discharge. The median NIHSS score of the 30 included patients was 4 before mechanical thrombectomy. At discharge, median NIHSS score changed from 4 to 1 ($p < 0.001$), median mRS decreased from 2 to 1 ($p < 0.001$).	- Thirty patients with MCA M1 occlusion, exhibiting a pre-therapeutic NIHSS score of 1 to 5 - Stent retrieval with the APERIO combined with local thrombo-aspiration via a 5Fr or 6Fr intracranial intermediate catheter at the MCA- mainstem was performed. The overall median thrombus length was 14 mm (range 5 to 22 mm), and 14 mm for patients receiving i.v bridging lysis, as well. - Patients were discharged or moved to another hospital after 2 to 25 days (median: 9). In one patient (3.3 %), a reperfusion hematoma of the basal ganglia occurred after M1 revascularization (TICI 3). Small or confluent petechial infarction without space-occupying effect and without clinical deterioration was found in 5/30 patients (16.7 %). No deaths occurred. Median ASPECTS of the 30 patients was 10 in the pre interventional non-contrast-enhanced CT imaging and 9 at the 24-hour follow-up imaging.	In patients presenting with low NIHSS score due to M1 occlusion, mechanical thrombectomy could be performed safely, technically very successfully, and with a favorable outcome
Kaschner MG et al., 2019b Predictors for basal ganglia viability after mechanical thrombectomy in	**APERIO System** (n = 85; 92.4 %)	**92** [53 / 39 / 72 years]	- TICI 2b and 3 recanalization was achieved in 86.9 %. Mean time from symptom onset to initial CT perfusion imaging was 99.9 min (SD ± 78.7) and to first flow in the M1 segment 220.8 min (SD ± 91.5).	- Among APERIO, the Solitaire stent retriever (Medtronic) in six (6.5 %) and in one (1,1 %) case with a Trevo stent retriever system treatment was performed. - Procedurally, the occluded vessel was probed by a microcatheter through a 5Fr or 6Fr intermediate catheter and in elongated	Extended MCA-mainstem occlusion generally causes broad BG infarction. Yet, BG integrity after technically effective mechanical thrombectomy in

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
proximal middle cerebral artery occlusion				vessel anatomy an additional 8F guiding-catheter was used. Mechanical thrombectomy was subsequently performed using the above-mentioned stent-retriever systems. - There was no significant correlation between BG viability and pre-treatment factors (admission NIHSS, i.v. rtPA), procedural factors (i.a. rtPA, duration from onset to recanalization), and recanalization rate (TICI). Hemorrhagic transformation of white matter and cortical region of the MCA territory correlated significantly with decreased BG viability. The authors identified no anatomical variants of BG collateralization in any patient in final digital subtraction angiography scan after successful mechanical thrombectomy.	complete MCA occlusion was observed in several patients. Further, CTA collateral score and higher relative cerebral blood volume ratio (rCBVR) were predictive for BG viability in stroke patients after successful mechanical thrombectomy in prolonged complete MCA-mainstem and LSA occlusion
Ivan VL et al., 2020 Mechanical thrombectomy in acute middle cerebral artery M2 segment occlusion with regard to vessel involvement	**APERIO Device** *(4.5 × 40mm, 4.5 × 30 mm, or 3.5 × 28 mm)*	**57** [34 / 23 / 73 years]	- Successful reperfusion (TICI2b-3) was found in 49 patients (86.0 %), whereas four patients (7 %) had persistent occlusion after multiple attempts of endovascular treatment. Partial or complete recanalization (TICI 2b-3) was more frequently achieved in patients with occlusion of M2-vessels supplying the central and parietal/temporal areas (n = 19, cohort C 100 %) compared to other cohorts (cohort A 78.6 %, cohort B 79.2 %) without statistical difference (p = 0.8). - Favorable early clinical outcome (mRS 0-2) was achieved in n = 19 (37.7 %). Compared to admission, mRS at discharge improved significantly (median (admission) 5 vs. median (discharge) 4, p < 0.001).	- 75.4 % (n = 43) underwent IVT - Patients were grouped according to the localization of the M2-occlusion (Cohort A (n = 14): central region only, B (n = 24): central region and involvement of frontal vessels, C (n = 19): parietal, occipital, and/or temporal vessels). Differences in proximal (M2-trunk, n = 34) and distal (M2- branches, n = 23) occlusions were also examined. - Except for one case of sole direct aspiration, a combination of distal access catheters and stent retriever thrombectomy in conjunction with distal aspiration was routinely performed. Eleven different interventionalists performed endovascular treatment within the selected period of time and had Considerable experience in endo-vascular procedures like the thrombectomy with a median experience of 3.2 years. - Stent retriever thrombectomy were combined with distal aspiration via 5F or 6F	- Endovascular treatment in patients with acute M2-occlusion is safe and leads to a significant clinical improvement at discharge. - No significant differences in clinical outcomes or complications were found with regard to the localization of the M2-occlusion

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
				intra-cranial distal access catheter (SOFIA, MicroVention, Düsseldorf, Germany) at the affected M2-segment was performed - Six (10.5 %) patients suffered from symptomatic intracranial hemorrhage during treatment or hospitalization. Four patients died (7.0 %). No significant differences in favorable clinical outcome (mRS ≤ 2: Cohort A 42.9 %, B 50.0 %, C 16.7 %, p = 0.4; χ2-test) or peri-interventional complications were found regarding vessel involvement.	
Lande R, 2020 Predictors of basal ganglia preservation (original title: Prädiktoren für den Erhalt der Basalganglien)	**APERIO Stent Retrievers** *(4.5 x 40 mm, 4.5 x 30 mm and 3.5 x 28 mm)*	**92**	- The result was the survival of the basal ganglia, verified by way of CT-scan the day after. Significant correlations were documented between the ratio of the relative cerebral blood volume rCBVratio (rCBVinfarcted/rCBVhealthy) and the survival of the entity of the globus pallidus (GP) and the white matter in the territory of the middle cerebral artery (WMMCA)	Lande states that the basal ganglia are extremely important as a control center for coordination of motor behavior. For the most part, they are supplied with blood by end arteries, the lenticulostriate arteries. End arteries do not show any anastomosis so that the ischemia time is expected to be only a few minutes. Despite this fact, survival of the basal ganglia is observed in about 50 % of patients with M1 segment occlusions of the MCA treated by thrombectomy. From this contradiction, Lande derived the following hypotheses: - There are factors (predictors), which relate to the survival of the basal ganglia. - The assumption that the lenticulostriate arteries are functional end arteries is wrong - Isolated M1-occlusions were included in the study, as well as combinations between M1 occlusions and additional carotid T occlusions or ICA occlusions - Sofia 5-Fr from MicroVention, Düsseldorf, Germany, 6-Fr Navien Intracranial Support Catheter (Medtronic, Dublin, Ireland) and 5F and 6F Neurobridge catheters from Acandis were used for thrombo-aspiration.	The author concluded that CS correlates with the survival of the GP, Putamen and WM_{MCA}. There is a minor negative relation between the blood glucose level and the survival of GP, Putamen and WM_{MCA}. Other factors such as pre-existing conditions, time until reperfusion and lysis therapy did not show any correlation. These findings may contribute to the selection of patients for thrombectomy

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
				- The relationship between the quantitative volumetric analysis of the affected and regular hemisphere was examined. Additional factors analyzed were the collateralization according to a Collateral Score (CS), time until the reperfusion of the M1 segment, lysis therapy, blood glucose level and risk factors as well as pre-existing conditions	
Kaschner M et al., 2020 The New Fully Radiopaque APERIO Hybrid Stent Retriever: Efficient and Safe? An Early Multicenter Experience	**APERIO Hybrid Stent Retriever (APH)** *(4.5 x 50 mm in 7 Pt., 4.5 x 40 mm in 32 Pt., and 4.5 x 30 mm in 9 Pt.)*	**48** [26 / 22 / 73 years]	- Median NIHSS score:15 (n = 25, 52.1 % received additional intravenous thrombolytics) were treated with the APH with a mean number of 2 device passes (SD, +3) in APH-only cases (n = 41). The median time from groin puncture to the final mTICI was 54 minutes (SD, +33). - In 46 patients (95.8 %), mTICI 2b-3 was achieved (mTICI 2c, 12.5 %; mTICI 3, 47.9 %). - Favorable outcome (modified Rankin Scale <2) was achieved in 15 (32.6 %) patients at discharge and in 11 of the 30 (36.7 %) patients available for 90-day follow-up. - APH radiopacity was rated as good and very good in 97.9 % (47 of 48).	- Symptomatic intracranial hemorrhage was recorded in 3 of 48 cases (6.3 %). Difficulties during device delivery and/or deployment occurred in 6.3 % (3 of 48). - APH-related adverse events did not occur. - Overall mortality during hospital stay was 21.7 % (10 of 46). Procedure-related deaths did not occur.	Mechanical thrombectomy with the APH appeared feasible, efficient, and safe. Full-length device radiopacity may facilitate thrombectomy or support to adapt the course of action during retrieval if required.
Vogt ML et al., 2021 Safety and Effectiveness of the New Generation APERIO Hybrid Stent-retriever Device in Large Vessel Occlusion Stroke	**APERIO Device (AP,** *148 Pt.***)** **APERIO Hybrid Stent Retriever (APH,** *150 Pt.***)**	**298** [161 / 137 / 78 years]	- Successful recanalization (eTICI≥ 2b67) was achieved in 112 (75.7 %) patients of the AP group and in 119 (79.3 %) patients of the APH group, revealing no significant differences in recanalization rates between the two devices (p= 0.450). - A median of 2 passages (IQR 1–3) were needed to achieve successful recanalization in both groups.	- Observational retrospective study of APERIO vs. new generation APERIO Hybrid (APH) stent-retriever device for mechanical thrombectomy in large vessel occlusion (LVO) stroke. - Primary effectiveness endpoint was successful recanalization eTICI ≥ 2b67 - Primary safety endpoint was occurrence of hemorrhagic complications after MT. Secondary	In the specific example of the APERIO stent-retriever device, further technological developments of the new generation device were not associated with disadvantages with respect to typical

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
			- In 8/150 (5.3 %) patients treated with the new generation APH recanalization was not successful despite using different bail-out thrombectomy devices (vs. 2/148, 1.4 %, patients in the AP group, p= 0.056). - In 4/148 (2.7 %) patients treated with the AP and in 6/150 (4.0 %) patients treated with the new generation APH device secondary distal occlusions occurred within the same territory after thrombectomy of the primary target LVO lesion and were treated with secondary distal thrombectomy. In these cases, distal recanalization was possible using a smaller thrombectomy device (Catch Mini 3× 15mm, Balt, France) in 2/4 patients of the AP group and in 6/6 patients of the APH group. - In 5/150 (3.3 %) patients treated with the new generation APH device successful recanalization was achieved only after switching to another thrombectomy device vs. 3 (2.0 %) treated with the AP. - Neither the median number of stent-retriever passages needed to achieve final recanalization, time from groin puncture to first pass (40 min), time from groin puncture to final recanalization (92 min) nor the number of cases in which successful recanalization could only be achieved by using a different stent-retriever as bail-out device differed between both groups.	outcome measures were time from groin puncture to first pass and successful reperfusion, and the total number of passes needed to achieve the final recanalization result. - Postinterventional hemorrhagic complications and particularly subarachnoid hemorrhage as the entity possibly associated with stent-retriever device type was significantly less frequent in the group treated with the APH: 29.7 % for AP and 16.0 % for APH; p= 0.005; however, rates of symptomatic hemorrhage with clinical deterioration and in domo mortality were not statistically different (21/148, 14.2 % vs. 28/150, 18.7 %).	observational indicators of safety or effectiveness

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Weiss D et al., 2022 Mechanical thrombectomy in stroke patients with acute occlusion of the M1- compared to the M2-segment: Safety, efficacy, and clinical outcome	**APERIO Stent Retriever (APERIO Thrombectomy Device)**	**174** [103 / 71 / 76 years]	- Most patients achieved a complete or substantial revascularization after mechanical recanalization (TICI scale 2b-3; 87.7 %). - Seventy-nine (45.4 %) patients showed a favorable outcome (mRS ≤2) and ninety-three (54.6 %) patients a poor outcome (mRS ≥3).	- M1-division of MCA was the most frequently occluded vessel (n = 141, 81.0 %). Proximal M2-segment was occluded in 22 (12.6 %) cases and distal M2-segment was occluded in 11 (6.3 %) cases. Median ASPECT-Score at admission was 10 (IQR 9–10) and median NIHSS at admission was 14 (IQR 9–17). - 64 patients were undergoing ET alone (36.8 %) and 110 combined with intravenous thrombolysis (IVT) (63.2 %). Of all patients with a M2-occlusion, 8 (24.2 %) were initially treated with ADAPT. - Overall complication rate (after 24 h) was 28.7 % (50 patients). 121 had no complications. 22 patients develop hemorrhagic infarction 1/2 or parenchymal hematoma (PH)1. Eleven patients developed a symptomatic intracerebral hemorrhage (PH-2) and 17 patients a subarachnoid hemorrhage. - No procedural complications such as perforation, dissection, or emboli to new territories occurred in patients treated with a stent retriever TE and with ADAPT. - There were no significant group differences in 3-month mRS, mTICI scale, or complication rates between M1- and M2-occlusions nor between proximal and distal M2-occlusions. - Binary logistic regression in patients with M1-occlusions showed a sub-stantial explanation of variance (NR2=0.35). NIHSS (p=0.009) and Maas Score as parameter for collateralization (p=0.01) appeared as significant contributing parameters. Binary logistic regression in M2-occlusions showed a high explanation of variance (NR2=0.50) of mRS but no significant factors.	Clinical outcome and procedural safety of patients with M2-occlusions undergoing ET are comparable to those of patients with M1-occlusions. Clinical outcome of patients with M1-occlusions undergoing ET is primarily influenced by the initial neurological deficit and the collateralization of the occlusions. By contrast, clinical outcome in patients with M2-occlusions undergoing ET is more multifactorial.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Weiss D et al., 2022 A fully radiopaque hybrid stent retriever versus a precursor device: Outcome, efficacy, and safety in large vessel stroke	**APERIO thrombectomy device**; 20 Pat. (AP) **APERIO Hybrid stent retriever**; 31 Pat. (APH)	**51** [33 / 18 / 73 years]	- Visibility of the APH was rated “good” and “very good” in terms of marker visibility (100%) and device contour visibility (97.9 %). In 2 of 48 (4.2 %) cases, pushability of the device was rated as “poor” or “very poor” and positioning of the APH was rated “poor” in 1 of 48 cases (2.1%) due to increased force to advance the device within the microcatheter. - Overall favorable revascularization (mTICI ≥ 2b) was achieved in 100% (51/51) including a first pass revascularization rate (mTICI ≥ 2b) of 58.8 % (30/51). When the AP was used, final favorable revascularization (mTICI ≥ 2b) was achieved in 100 % (20/20) and first pass favorable revascularization (mTICI ≥ 2b) was achieved in 60% (12/20). Final mTICI ≥ 2b was achieved in 100 % (31/31) and first pass mTICI ≥ 2b was achieved in 58.1 % (18/31) when the APH was used as exclusive device. There were no significant group differences between APH and AP regarding final favorable revascularization. - The overall mean number of stent retriever passes was 2 ± 1. Whenever APH was used exclusively, the mean number of maneuvers accounted to 2 ± 1 and 2 ± 1 when AP was used. - Overall mean groin-puncture-to-recanalization time in that proceeding from femoral access to final revascularization was 52 ± 32	- The primary endpoint was final favo-rable recanalization defined as the modified thrombolysis in cerebral infarction (mTICI) scale of ≥2b. The secondary outcome parameters contained first-pass favorable reperfusion rate, favorable clinical outcome (FO, modified Rankin Scale [mRS] 0-2) after 3 months, and complication rates including sympto-matic intracranial hemorrhage with neurological deterioration (National Institutes of Health Stroke Scale [NIHSS] worsening >4) within 24 hours after intervention, periprocedural subarachnoid hemorrhages, embolisms into new territories, dissections, and material defects as well as evaluation of technical difficulties. - No device-related procedural complications were noted. - Periprocedural embolization into previously unaffected territories by fragmented or lost clots and angio-graphically apparent SAH did not occur. Asymptomatic hemorrhagic transformation or parenchymal hema-toma (HI-1, HI-2, PH-1) was observed in 6 patients (11.7 %) and asymptomatic, mild SAH (Fisher 1) in 3 patients (9.8 %) in follow-up CT or MRI 16-24 hours after the MT. Two (3.9 %) patients suffered parenchymal hematomas (PH-2), as result of a reperfusion injury. - No device-related adverse events occurred. There were no significant group differences between APH and AP regarding the complication rate and correlations between the use of APH and complication rate showed a nonsignificant correlation with a small effect size.	Comparable clinical outcome, efficacy, and safety of the AP and the recently introduced APH were demonstrated. Both devices appeared feasible, efficient, and safe with regard to endovascular treatment in large vessel occlusion. Overall, both devices yielded high rates of favorable and excellent reperfusion in cerebral LVO in conjunction with lesional aspiration in the setting of acute stroke and absence of device-related procedural complications. Furthermore, high rates of FO after 3 months were yielded for both devices. Full-length visibility of the APH may guide procedural adaptation by control of the actual stent-clot or stent-vessel interaction.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
			minutes. Intraarterial rt-PA was given in 0.0 %. The posttreatment median ASPECTS in follow-up CT after 16-24 hours was 6 (4-8). - Forty-four patients (86.3 %) were available for follow-up at discharge and 7 were lost for follow-up (13.7 %). Overall, FO at discharge according to the mRS scale (mRS ≤ 2) was achieved in 38.3 % (18/44) patients. - There were no significant group differences between APH and AP regarding favorable clinical outcome after 3 months, and correlations between the use of APH and FO after 3 months showed a nonsignificant correlation with a small effect size	- Overall, early mortality during hospital stay was 20.5 % (9/44) and procedure-related deaths did not occur.	
Remollo S et al., 2022 Combined Approach to Stroke Thrombectomy Using a Novel Short Flexible Aspiration Catheter with a Stent Retriever	**APERIO Hybrid Stent**	52 [31 / 21 / 75 years] *Note:* **27** Pat. (51.9 %) were treated with APERIO Hybrid	- After the first pass, 25 (48 %) patients had mTICI≥ 2c. At the end of the procedure, 47 (90.4 %) had mTICI≥ 2b and 35 (67.3 %) had mTICI≥ 2c. - Mean NIHSS score was 13at 24h and 5at discharge. At 90 days, 24 (46.2 %) patients were functionally independent (mRS 0–2).	- 14 (26.9 %) with terminal internal carotid artery occlusions, 26 (50 %) middle cerebral artery (MCA) segment M1 occlusions, and 12 (23.1 %) MCA segment M2 occlusions; median NIHSS score at admission was 19 (IQR: 13–22). - No serious device-related adverse events were observed. Symptomatic intracranial hemorrhage developed in 1 patient. *Note*: Numbers refer to the total patient population of 52 patients	Study data display good efficacy and safety for MIVI Q™ aspiration catheters used in combination with stent-retriever devices.
de Castro-Afonso LH et al., 2025 Thrombectomy for Anterior Circulation Stroke with a Hybrid Cell Design Stent Retriever	**APERIO Hybrid Stent**	**128** [69 / 59 / 72.2 years]	- eTICI 2b – 3 was 79.7 %, with first pass success in 29.7 % - mRS 0 – 2 was achieved in 52.3 % of cases.	- Thrombectomy for anterior circulation acute ischemic stroke in ICA, M1, M2 and carotid tandem - The mean procedure time was 62 min. - sICH occurred in 7 % of patients and SAH in 8.6 %. - Mortality at three months was 18.7 %.	The APERIO Hybrid stent retriever was safe and effective for thrombectomy of anterior circulation strokes. The outcomes of this study were similar to those of previous large thrombectomy studies.

Reference [Author, title]	Used device	Included patient no. [female / male / average age]	Effectiveness end point / technical success	Safety end points / technical notes / periprocedural complications	Overall conclusion
Castro-Afonso LH et al., 2025 Comparison of the Aperio Hybrid® and Solitaire FR/X® stents for anterior circulation stroke thrombectomy across different time periods: A propensity score-matched analysis of recanalization and symptomatic hemorrhage	**APERIO Hybrid Stent**	Total: 258 *Note:* **129** Pat. (50 %) [70 / 59 / 72.3 years] were treated with APERIO Hybrid	- The adjusted recanalization rates (TICI 2b-3) for the Aperio Hybrid and Solitaire FR/X were 79.8 % and 75.9 %.	- Among 455 patients treated, after PSM, 258 patients (129 per group) were analyzed. - adjusted sICH rates were 6.9 % and 6.2 %. - mortality 19.3 % in APERIO group and 28.7 % in Solitaire group.	In this observational study on thrombectomy for AIS, the Aperio Hybrid and Solitaire FR/X demonstrated similar rates of recanalization and symptomatic intracranial hemorrhage. However, due to significant selection bias, these results should be interpreted with caution.
Perez-Garcia C et al., 2025 Impact of double stent retriever configuration on first-pass effect in stroke	**APERIO Hybrid Stent**	**209** [122 / 87 / 76.1 years]	- The double stent retriever technique using the APERIO Hybrid achieved a first-pass effect eTICI 2c – 3 in 72.7 % of cases and a final successful recanalization rate of 99.5 %. - The Y-shaped configuration achieved a higher first pass recanalization. - mRS 0 – 2 at 90 days was 57.2 %.	- Double stent retriever recanalization in acute ischemic stroke in terminal ICA and MCA M1 - Rescue therapy was used in 14.8 % of cases including stent retriever + aspiration, single stent retriever use and rescue stent placement. - sICH occurred in 3.3 % of patients, dissection and vasospasm in 1 % each, distal emboli in the same territory in 4.3 %, vessel rupture in 0.5 % and SAH in 5.7 %. - Mortality was 15.1 %.	The findings support the efficacy of the double stent retriever technique, particularly the Y-shaped configuration, in achieving high recanalization rates on the first pass with an acceptable safety profile. This technique may offer clinical benefits for future acute ischemic stroke treatment protocols.

1.4.3.1.3 Summary and conclusion on safety and clinical performance

Available references on the APERIO Hybrid[17] includes two clinical studies and three case series on the APERIO first and second generation devices nine clinical investigations and six case series aiming at investigating the safety and performance of the APERIO generations (Table 1, Table 2). A total of at least 300 patients were treated with the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device, 829 patients were treated with the APERIO thrombectomy devices as well as at least 722 patients were treated using the APERIO Hybrid Thrombectomy Device (aka APERIO Hybrid Stent-retriever devices). The APERIO generations were used in current stroke therapy for restoring arterial blood flow in occluded vessels by mechanical thrombectomy.

In the literature, performance is mainly assessed using TICI scoring, NIHSS scoring or mRS scale. According to the identified literature, clinical success was high when the APERIO generations (including the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device) were deployed.

TICI scoring

Blood flow restoration was achieved in up to 81.5 – 87.7 % (TICI 2-3) (Kallenberg K et al., 2016, Kaschner MG et al., 2019a; Müller-Eschner M et al., 2019; Kaschner MG et al., 2019b; Weiss D et al., 2022; Dorn F et al., 2025, Klüner C et al., 2025, Dunkerton S et al., 2025) / 95.8 % (mTICI) (Kaschner M et al., 2020) / 90.4 % (Remollo S et al., 2022) as well as 100 % (Weiss D et al., 2022A). A first-pass final recanalization was achieved in 44 % as mentioned in one study (Kaschner MG et al., 2019a) / 58.8 % (Weiss D et al., 2022A). Vogt and colleagues reported on successful recanalization (eTICI≥ 2b67) in 75.7 % of patients treated with the APERIO Devices and 79.3 % with the APERIO Hybrid Devices (Vogt ML et al., 2021), 79.7 % - 79.8 % (eTICI 2b – 3) were reported by (de Castro-Afonso LH et al., 2025; Castro-Afonso LH et al., 2025) as well as 72.7 % (eTICI 2c – 3; Perez-Garcia C et al., 2025).

mRS scale

Furthermore, a favorable clinical outcome after a follow-up after three months / at discharge according to the mRS scale (mRS 0 – 2) was achieved in 36.7 % – 79 % of the patients (Kaschner MG et al., 2019a, Müller-Eschner M et al., 2019, Ivan VL et al., 2020, Kaschner M et al., 2020; Weiss D et al., 2022; Weiss D et al., 2022A, Remollo S et al., 2022; Dorn F et al., 2025; Klüner C et al., 2025; Dunkerton S et al., 2025; de Castro-Afonso LH et al., 2025; Perez-Garcia C et al., 2025). In one publication a poor outcome (mRS 5 or 6) was observed in 31.8 % of the patients after treatment (Müller-Eschner M et al., 2019).

NIHSS score

In several publications, NIHS score was assessed. The overall median NIHS score at admission was 8.5 (range 0 – 20). Median NIHSS at discharge was 2 (range 0 – 21) (Müller-Eschner M et al., 2019). Remollo et al reported on a mean NIHSS score at discharge of 5 (Remollo S et al., 2022). Another publication reported on a median NIHSS score of the included patients of 4 before mechanical thrombectomy. At discharge, median NIHSS score changed from 4 to 1 ($p < 0.001$) (Kaschner MG et al., 2018b).

Further information on performance is listed in Table 2.

APERIO Hybrid17/Hybrid21 separately

When considering the APERIO Hybrid17 separately, overall favorable recanalization (TICI≥2b) was achieved in 92.7 % (63/68) and excellent recanalization (TICI ≥ 2c) was achieved in 69.2 % (47/68) of the patients. Overall favorable first-pass recanalization (TICI≥2b) was achieved in 75.6 % (28/37) and excellent first-pass recanalization (TICI≥2c) was achieved in 59.4 % (22/37). A rescue maneuver was only necessary in two patients (2.8 %). Favorable functional outcome at discharge was achieved in 50.7 % (35/71) patients and in 69.0 % (29/42) after three months (Goertz L et al., 2022). Additional publications mentioned successful recanalization rates (TICI 2b/3) of the APERIO Hybrid17/Hybrid21 between 81.5 – 85 % (Dorn F et al., 2025; Klüner C et al., 2025; Dunkerton S et al., 2025). Furthermore, an early neurological improvement rate of 21 % was reported (Dunkerton S et al., 2025). 90-day functional independence (mRS 0–2) were reported between 41 – 79 % (Dorn F et al., 2025; Klüner C et al., 2025; Dunkerton S et al., 2025)

Technical success

Technical success was described as “time from device insertion to recanalization was 30 – 52.3 min / first to final angiograms 81.1 min”, “a median number of device deployments of two” with “a mean of stent retriever passes was 1.5 – 2.6” (Kallenberg K et al., 2016; Kaschner MG et al., 2019; Müller-Eschner M et al., 2019, Kaschner M et al., 2020, Vogt ML et al., 2021). Furthermore, the APERIO Hybrid Devices radiopacity was rated as good and very good in 97.9 of the cases (Kaschner M et al., 2020). Comparable results were mentioned in Weiss D et al., 2022. Further information on performance is listed in Table 2. When considering the APERIO Hybrid17 separately, the device was rated “good” and “very good” in terms of marker visibility, device visibility, and transfer into microcatheter (100 %). “Resheathing of introducer” and “resheathing of microcatheter” were rarely necessary (n=13/n=14) and mainly rated “good” and “very good”. Pushability into microcatheter (93.8 %), positioning of stent retriever (96.9 %) and device deployment (96.5 %) were rated “good” and “very good” with one to four cases

which were rated “poor” (6.2 %). Overall mean groin-puncture-to-recanalization-time in that proceeding from femoral access to final recanalization was 59 ± 34 min. Intraarterial rt-PA was administered in five patients (7.0 %). The post-treatment median ASPECTS in follow-up CT after 16-24 hours was 9 (7 –10). The overall mean number of stent retriever passes was 3 ± 2 (Goertz L et al., 2022).

From the presented data, it can be concluded that the APERIO device (including APERIO Hybrid[17] as well as APERIO Hybrid[21]) achieve the performances intended by Acandis.

Technical and clinical complication rates were low, and complications 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 APERIO device family (including APERIO Hybrid[17]; estimated for APERIO Hybrid[21]) seems to be within the expected and known range inherent to the general product group of thrombectomy devices for restoring arterial blood flow in occluded vessels.

In addition, almost all authors evaluated the APERIO generations as safe and efficient in the treatment for restoring arterial blood flow in occluded vessels by mechanical thrombectomy during current stroke therapy.

1.4.3.2 Clinical data obtained by clinical trials or PMCF-measures

Acandis was conducting two clinical trials, REVISAR and HYBRID (chapter 1.4.5). The results are available and described in the respective chapter.

1.4.3.3 Clinical data from medical device databases

BfArM (German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions)): Latest search on January 19, 2026:

- No entries concerning APERIO
- Concerning the similar device Trevo (Stryker, Fremont, CA, USA) in 2017 there were two batch recalls because labels and packaging contents did not match in 2017. In 2020 there were lot recalls due to an increased number of complaints involving fractures of the core wires resulting in stent retriever separation from the core wire during use. And in 2024 there was a recall because endotoxin levels could be elevated. There were no entries concerning the similar device Tigertriever.

MAUDE ("Manufacturer and User Facility Device Experience (MAUDE) Database, maintained by the United States' Food and Drug Administration). Latest search on January 19, 2026, searched time frame comprised January 2024 to December 2025.

- No entries concerning APERIO. The APERIO devices are not marketed in the USA.
- Concerning the similar devices there are several entries on the Trevo (Stryker, Fremont, CA, USA) and the Tigertriever (Rapid Medical, Yokneam, Israel). However, these entries deal with risks and complications inherent to the risk profile of the thrombectomy devices and the procedure of mechanical thrombectomy in selected patients with diagnosed acute ischemic stroke following a vascular occlusion. 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 thrombectomy devices which are comparable to the APERIO Hybrid17/Hybrid21 Thrombectomy Device. Thus, there is no allusion to an unfavorable risk profile of such systems in the field of routine clinical use. From this point of view, the APERIO Hybrid17/Hybrid21 Thrombectomy Device, its similar devices and devices from the same generic device group appear to be effective and safe for their intended use.

1.4.4 Overall summary of the clinical performance and safety

The clinical literature reflecting the state-of-the-art in current stroke therapy with mechanical thrombectomy devices, including the use of the APERIO generations (APERIO Thrombectomy Device, APERIO Hybrid Thrombectomy Device, APERIO Hybrid17/Hybrid21 Thrombectomy Device Thrombectomy Devices), together with the results from the searches in authority-maintained vigilance databases as well as the data collected from PMCF studies on the APERIO generations prove the clinical performance and safety of the APERIO generations (including APERIO Hybrid17/Hybrid21 Thrombectomy Device). The reviewed studies provide sound evidence that by using the APERIO Thrombectomy Devices from first and second generation as well as the APERIO Hybrid17/Hybrid21, in particular, a successful and safe mechanical thrombectomy to restore arterial blood flow in occluded vessels is feasible. It could be shown that the APERIO generations achieve technical and clinical success rates that are comparable to the well-established similar device from the generic device group. Therefore, the Acandis APERIO generations, especially the APERIO Hybrid17/Hybrid21 Thrombectomy Device, are suitable for their intended use, namely the restoring of the arterial blood flow in occluded vessels. Thus, it can be concluded that the APERIO generations (including APERIO

Hybrid[17]/Hybrid[21] Thrombectomy Device) achieve the performances intended by Acandis and meets the requirement for performance.

Acandis added the APERIO Hybrid[17] with the additional small diameter of 2.5 mm to provide adequate treatment for patients with small intracranial vessel diameters down to 1.0 mm. The APERIO Hybrid[21] was developed as range extension of the APERIO Hybrid[17], but is otherwise similar in its design and function. In addition, the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device include a newly designed locking mechanism between the transport wire and stent component that is not expected to affect clinical performance.

Complications, ranging from mild to severe, associated with the procedure and the devices themselves used for mechanical thrombectomy are thoroughly described in the literature, thus being known to the professional user. These complications encompass subarachnoid hemorrhage (SAH), hemorrhagic infarction, symptomatic intracranial hemorrhage (sICH), asymptomatic SAH, vasospasm and parenchymal hematoma. Procedural complications such as emboli to new territories (ENT) that causing SAH, dissections as well as perforation only occasionally occur. According to the literature on the APERIO generations, device-related complications do not occur. Therefore, no evidence on unduly or unknown risks of the APERIO generations were identified. The overall mortality rates across the studies reviewed were in mean 17.4 % (early-hospital and overall mortality during hospital stay, pooled; APERIO Hybrid[17] early-hospital mortality 4.2 % – 18.9 %) without procedure-related deaths. The overall mortality rate for the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device was 9,8 % in the currently completed HYBRID study.

Technical and clinical complication rates were low, and complications were within the known and manageable spectrum inherent to this kind of intervention. Hence, the safety profile of the APERIO generations (including the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device) seems to be within the expected and known range inherent to the generic product group of thrombectomy devices. The basic design, as well as the material used for the devices, have been successfully applied for several years. The APERIO generations (including the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device) were subjected to various pre-clinical and laboratory test reports according to harmonized standards with successful results. Thus, the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device as third generation of the APERIO devices meets the requirement for safety.

According to the clinical data presented in the scientific literature, the information gained from PMS and PMCF measures as well as the risk analysis, it can be concluded that risks which may be associated with the intended use of the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device 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 the scientific literature, thus being known to trained professional user. Therefore, by complying with all warnings and precautions, the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device offer an acceptable benefit-risk profile and meet the requirement for an acceptability of side effects and acceptable benefit-risk profile.

Table 3: Clinically relevant marketing claims made by Acandis

Marketing claim
For vessel diameters from 1.0 – 5.5 mm
Effective hybrid cell design
Visible throughout the entire length
Excellent full length visibility
Hybrid cell design for successful recanalisation
For distal thrombectomy
Compatible with 0.0165" – 0.027" ID microcatheters

The above-mentioned marketing claims are acceptable. They are supported by product specification, technical characteristics and literature (Goertz L et al., 2022; Dorn F et al., 2025; Klüner C et al., 2025; Ozdemir G et al., 2025; Dunkerton S et al., 2025).

In conclusion, the Acandis APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device could be shown to be in compliance with the General Safety and Performance Requirements (GSPRs) specified by the Medical Device Regulation (MDR) EU 2017/745 and the safety and performance of the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device can be confirmed.

1.4.5 Ongoing or planned post-market clinical follow-up

Acandis conducted two clinical trials, REVISAR and HYBRID.
The observational study REVISAR (NCT04479020) included the devices APERIO, APERIO Hybrid and APERIO Hybrid[17]. The recruitment was completed in September 2023. Technical success defined as mTICI ≥ 2b without any symptomatic intracranial hemorrhage and rescue therapy within 3 passes was achieved in 97 patients of the per protocol set (81.5 %; 95 % CI 74.5 – 88.5 %). Good clinical outcome after 90 days was seen as mRS < 3 in 94 patients of the per protocol set (79 %; 95 % CI 71.7 – 86.3 %). There were no cases of peri-procedural sICH associated with a worsening of the NIHSS ≥ 4 Points. Mortality after 90 days was very low and occurred in 5 patients (4.2 %).

The registry study HYBRID (NCT04457479) included the devices APERIO Hybrid and APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device. The recruitment was completed in June 2023. In the completed HYBRID study the technical success rate was 97% with a high rate of good clinical outcome after three months (68.8 %). Serious adverse events were seen in 22.5 % of patients, none of them were device-related.

1.5 Possible diagnostic of therapeutic alternatives

In the scientific literature chemical or drug-based recanalizing therapy with thrombolytics is described to restore the arterial flow as alternative to mechanical thrombectomy. However, the option for performing a mechanical thrombectomy should be especially considered in patients who cannot be treated with thrombolytics (Ringleb PA et al., 2015). Furthermore, if possible, mechanical thrombectomy should be performed in combination with systematic thrombolysis, unless clinical signs indicate otherwise (Ringleb PA et al., 2022).

1.6 Suggested profile and training for users

The APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device should be applied only by physicians who have the required background knowledge and experience in the field of interventional neuroradiology.

1.7 Reference to harmonized standards and common specifications applied

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	2024
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	2018
EN	868-9	Packaging for terminally sterilized medical devices – Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods	2018
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

Mnemonic	Number	Title	Revision
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: 2023)	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	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

Mnemonic	Number	Title	Revision
EN ISO	11138-1	Sterilization of health care products – Biological indicators – Part 1: General requirements (ISO 11138-1:2017)	2017
EN ISO	11138-2	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	2017
EN ISO	11139	Sterilization of health care products – Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018 + Amd 1:2024)	2018 + A1:2024
EN ISO	11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019 +Amd 1:2023)	2020 + A1:2023
EN ISO	11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2: 2019 +Amd 1:2023)	2020 + A1:2023
EN ISO	11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	2018+A1:2021
EN ISO	11737-2	Sterilization of health care products - Microbiological methods – Part 2: Tests of sterility 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

Mnemonic	Number	Title	Revision
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	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	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

2 Information for the patient

This part of the SSCP is not deemed necessary for the APERIO Hybrid[17]/Hybrid[21] Thrombectomy Device.

3 Bibliography

No.	Citation
1	Castro-Afonso LH, Trivelato FP, Wajnberg E, Waihrich ES, Abud TG, Alves SVB, Matsubara A, Rezende MTS, Araujo JFS, Nakiri GS, Abud DG. Comparison of the Aperio Hybrid® and Solitaire FR/X® stents for anterior circulation stroke thrombectomy across different time periods: A propensity score-matched analysis of recanalization and symptomatic hemorrhage. Interv Neuroradiol. 2025 May 13:15910199251342439.
2	de Castro-Afonso LH, Trivelato FP, Wajnberg E, Waihrich ES, Abud TG, Alves SVB, Matsubara A, Rezende MTS, Araujo JFS, Nakiri GS, Abud DG. Thrombectomy for Anterior Circulation Stroke with a Hybrid Cell Design Stent Retriever: A Multicenter Registry. J Neuroendovasc Ther. 2025;19(1):2024-0083. A
3	Dorn F, Borggrefe J, Kallenberg K, Ernst M, Behme D, Foerschler A, Kabbasch C, Liebig T, Turowski B, Nordmeyer H. REcanalization of Distal Cerebral Vessels In Acute Stroke Using ApeRio (REVISAR). J Neurointerv Surg. 2026 Jan 13;18(2):404-410.
4	Dunkerton S, Ghozy S, Mortimer A, Flood R, Cox A, Wareham J, Minks D. REAL-WORLD EXPERIENCE OF THE LARGE 6–50 APERIO STENT-RETRIEVER: EVALUATION OF EFFECTIVENESS AND SAFETY J NeuroIntervent Surg 2025;17(Suppl 2):A1–A195; 10.1136/jnis-2025-ESMINT.108 *Note: only abstract*
5	Goertz L, Weiss D, Abdullayev N, Moenninghoff C, Borggrefe J, Phung TH, Haage P, Schlamann M, Dorn F, Kaschner M, Kabbasch C, Nordmeyer H. Safety and efficacy of the novel low-profile APERIO Hybrid[17] for treatment of proximal and distal vessel occlusion in acute ischemic stroke: a multi-center experience. World Neurosurg. 2022 Aug 10:S1878-8750(22)01123-8.
6	Ivan VL, Rubbert C, Caspers J, Lee JI, Gliem M, Jander S, Turowski B, Kaschner M. Mechanical Thrombectomy in acute middle cerebral artery M2 segment occlusion with regard to vessel involvement. Neurological Sciences (2020), 41:3165 – 3173.
7	Kallenberg K, Solymosi L, Taschner CA, Berkefeld J, Schlamann M, Jansen O, Arnold S, Tomandl B, Knauth M, Turowski B. Endovascular stroke therapy with the APERIO Thrombectomy Device. J Neurointerv Surg. 2016 Aug;8(8):834-9.
8	Kaschner M, Lichtenstein T, Weiss D, Turowski B, Goertz L, Kluner C, Schlamann M, Mathys C, Kabbasch C. The New Fully Radiopaque Aperio Hybrid Stent Retriever: Efficient and Safe? An Early Multicenter Experience. World Neurosurg. 2020 Sep;141:e278-e288.
9	Kaschner MG, Caspers J, Rubbert C, Lande R, Kraus B, Lee JI, Gliem M, Jander S, Turowski B. Mechanical thrombectomy in MCA-mainstem occlusion in patients with low NIHSS scores. Interv Neuroradiol. 2018b Aug;24(4):398-404.
10	Kaschner MG, Lande R, Rubbert C, Caspers J, Lee JI, Gliem M, Jander S, Turowski B. Predictors for basal ganglia viability after mechanical thrombectomy in proximal middle cerebral artery occlusion. Clin Imaging. 2019b May 2;57:1-6.
11	Kaschner MG, Weiss D, Rubbert C, Lee JI, Gliem M, Jander S, Ivan V, Kraus B, Turowski B, Caspers J. One-year single-center experience with the APERIO thrombectomy device in large vessel occlusion in the anterior circulation: safety, efficacy, and clinical outcome. Neurol Sci. 2019a Jul;40(7):1443-1451.
12	Klüner C, Sundermann B, Iacoban CG, Behme D, Kallenberg K, Wunderlich O, Turowski B, Reith W, Liman T, Rusche T, Nordmeyer H, Mathys C. Safety, Technical and Clinical Success of the Aperio Hybrid Thrombectomy Device in Acute Ischemic Stroke, a Prospective Post-market Clinical Follow-up Study (HYBRID). Clin Neuroradiol. 2025 Oct 23.
13	Lande R. Thrombektomie: Prädiktoren für den Erhalt der Basalganglien. Dissertation, Heinrich-Heine-Universität Düsseldorf 2020.
14	Müller-Eschner M, You SJ, Jahnke K, Kammerer S, Foerch C, Pfeilschifter W, Lauer A, Berkefeld J, Wagner M. Introducing the New 3.5/28 Microstent Retrieverfor Recanalization of Distal Cerebral Arteries in Acute Stroke: Preliminary Results. Cardiovasc Intervent Radiol. 2019 Jan;42(1):101-109.

No.	Citation
15	Ozdemir G, Eren A, Kizildag N, Gundogdu OL, Ersoy AN, Korez MK, Sonmez LO, Ongun G, Unal N, Utku U. Primary vs. Rescue Medium Vessel Occlusions: Comparative Clinical Outcomes in Patients with Acute Ischemic Stroke. J Clin Med. 2025 Nov 12;14(22):8008.
16	Pérez-García C, Castaño M, Llibre JC, Vargas L, López-Frías A, Rosati S, López JL, Venegas J, González E, Fondevila J, Espinosa de Rueda M, Zamarro J, Baldi S, Díaz T, de la Rosa C, Chaviano Grajera J, Ballenilla Marco F, Cuba V, Muñoz Olmedo JM, Mendez JC, Remollo S, Bermejo R, Morales E, Gómez-Escalonilla C, Moreu M. Impact of double stent retriever configuration on first-pass effect in stroke: a multicenter study. J Neurointerv Surg. 2025 Nov 18;17(12):1294-1300.
17	Remollo S, Terceño M, Werner M, Castaño C, Hernández-Pérez M, Blasco J, San Román L, Daunis-I-Estadella P, Thió-Henestrosa S, Cuba V, Gimeno A, Puig J. Combined Approach to Stroke Thrombectomy Using a Novel Short Flexible Aspiration Catheter with a Stent Retriever : Preliminary Clinical Experience. Clin Neuroradiol. 2022 Jun;32(2):393-400.
18	Ringleb P., Köhrmann M., Jansen O., et al.: Akuttherapie des ischämischen Schlaganfalls, S2e-Leitlinie, 2022 Version 1.1, in: Deutsche Gesellschaft für Neurologie (Hrsg.), Leitlinien für Diagnostik und Therapie in der Neurologie. Online: www.dgn.org/leitlinien (abgerufen am 20.01.2025)
19	Ringleb PA, Hamann GF, Röther J, Jansen O, Groden C, Veltkamp R. Acute Therapy of the ishemic stroke – Supplement 2015 – Recanalizing Therapy. Published by the “Kommission Leitlinien der Deutschen Gesellschaft für Neurologie”, 2015.
20	Vogt ML, Kollikowski AM, Weidner F, Strinitz M, Feick J, Essig F, Neugebauer H, Haeusler KG, Pham M, Maerz A. Safety and Effectiveness of the New Generation APERIO® Hybrid Stent-retriever Device in Large Vessel Occlusion Stroke. Clin Neuroradiol. 2021 Dec 9.
21	Weiss D, Kabbasch C, Lichtenstein T, Turowski B, Kaschner M. A fully radiopaque hybrid stent retriever versus a precursor device: Outcome, efficacy, and safety in large vessel stroke. J Neuroimaging. 2022 Apr 12.
22	Weiss D, Rubbert C, Ivan VL, Lee JI, Gliem M, Jander S, Caspers J, Turowski B, G Kaschner M. Mechanical thrombectomy in stroke patients with acute occlusion of the M1- compared to the M2-segment: Safety, efficacy, and clinical outcome. Neuroradiol J. 2022 Jan 27:19714009211067403.