EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Catheter, Stents, Stent Delivery Systems and endovascular Medical Devices for neurological, cardiological and peripheral Applications according to Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	516802 MR2
Certificate unique ID	170738217
Effective date	2019-03-12
Expiry date	2022-06-28
Frankfurt am Main	2019-03-12

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 516802 MR2
Certificate unique ID: 170738217
Effective date: 2019-03-12

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

Device family	Device	Class	GMDN
Microcatheter	NeuroSlider®	III	10691
Embolisation Device/System	Derivo®	III	46352
	Derivo® mini	III	46352
Catheter	NeuroBridge®	III	17846
PTA Balloon Catheter	NeuroSpeed®	III	17184
Acclino® Stent	Acclino® flex Stent	III	46352
	Acclino® flex Stent System	III	46352
	Acclino® flex plus Stent	III	46352
	Acclino® flex plus Stent System	III	46352
	Acclino® peripher Stent	IIb	46352
	Acandis® BTK flex Stent	IIb	46352
Accero® Stent	Accero® Stent	III	46352
	Accero® Stent System	III	46352
Aperio® Recanalisation Device	Aperio® Thrombectomy Device	III	61779
	Aperio® Hybrid Thrombectomy Device	III	61779
Credo® Stent	Credo® Stent	III	46352

CERTIFICATE

This is to certify that the company

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design and Development, Manufacturing, Sales and Final Control of Product Categories Catheters, Stents, Stent Delivery Systems and endovascular Medical Devices for neurosurgical cardiological and peripheral Applications

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

EN ISO 13485 : 2016

Certificate registration no.	516802 MP2016
Certificate unique ID	170704275
Effective date	2018-06-19
Expiry date	2021-06-18
Frankfurt am Main	2018-06-19

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Akkreditierungsstelle
D-ZM-16021-01-00

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Declaration of Conformity

according to directive 93/42/EEC

Product	**Aperio® Hybrid Thrombectomy Devices** Product listing see page 2
Class	**III** **Rule 7, bullet point 2,** **according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/61779**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60443 Frankfurt Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 516327 MRA valid until 2024-02-27
Declaration of Conformity valid until	2021-02-02

Pforzheim, 2020-03-03

.....

Stefan Höfele,
Director Regulatory Affairs

Declaration of Conformity Aperio® Hybrid Thrombectomy Device

Product listing

Article number	Name	Size
01-000704	Aperio® Hybrid Thrombectomy Device	3.5mm x 28mm
01-000705	Aperio® Hybrid Thrombectomy Device	4.5mm x 30mm
01-000706	Aperio® Hybrid Thrombectomy Device	4.5mm x 40mm
01-000707	Aperio® Hybrid Thrombectomy Device	4.5mm x 50mm
01-000708	Aperio® Hybrid Thrombectomy Device	6.0mm x 40mm
01-000709	Aperio® Hybrid Thrombectomy Device	6.0mm x 50mm

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

that the design of the following device(s)

Aperio® Thrombectomy Device
Aperio® Hybrid Thrombectomy Device
Aperio® Hybrid[17] Thrombectomy Device

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.
This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 516802 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:
STED_CE-Approval_Aperio-E_A dated 24.10.2018
STED_CE-Approval_Aperio Hybrid-E_A.pdf dated 24.10.2018
411_18e_Report_TFR_Sterilization Inpac_V1 dated 2019-09-23
STED_CE-Approval_Aperio Hybrid17-E_A.pdf dated 2019-10-24

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report:
411_18e_Report_TFR_Sample dated 28.02.2019
411_18e_Report_TFR_ Aperio Hybrid.docx dated 12.03.2019
10_411_18e_Report_TFR_SterilizationInpac_V1 dated 2019-10-19
0_411_18e_Report_TFR_AperioHybrid17.docx dated 2020-03-27

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	516327 MRA
Certificate unique ID	170767275
Effective date	2020-03-27
Expiry date	2024-02-27
Frankfurt am Main	2020-03-27

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

PERFECT INTERPLAY

APERIO® Hybrid Thrombectomy Device

- Effective hybrid-cell design for fast flow restoration
- Outstanding visibility for maximum control and safety
- Broad range of sizes for tailored treatment options

αcandis®

ENGINEERING STROKE SOLUTIONS

APERIO® Hybrid Thrombectomy Device

The hybrid cell design combined with perfect visibility lead to utmost safety and reliability during procedure – for fast flow restoration.

PERFECT INTERPLAY.

RELIABLE

The APERIO® Hybrid Thrombectomy Device is the third generation of Acandis® stent retriever featuring the proven hybrid cell design.

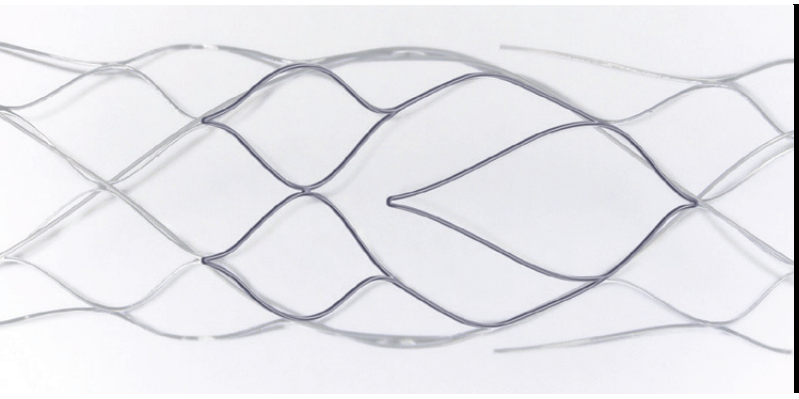
Small closed cells ensure a perfect vessel wall apposition and expansion into the clot. Large open cells with integrated anchoring elements assure efficient clot retention for reliable and atraumatic retrieval even in tortuous vessel anatomies. In combination, these two cell designs build up a functional segment.

VARIABLE

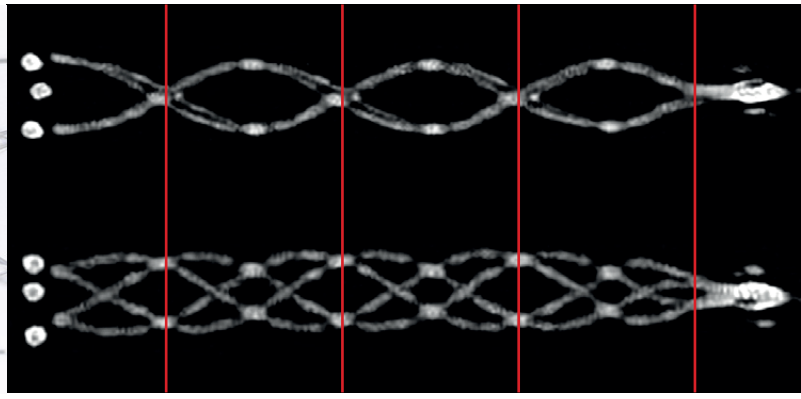
The broad range of sizes enables the treatment of vessel diameters from 1.5 mm up to 5.5 mm.

All sizes are suitable with 0.021“ microcatheter.

Due to repeating functional segments the device working length can be adapted.



Functional segment of the APERIO® Hybrid Thrombectomy Device



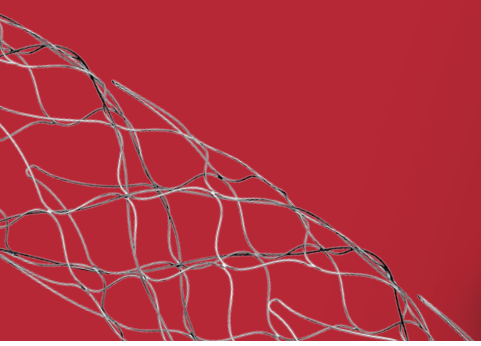
APERIO® Hybrid Thrombectomy Device (6.0 x 50 mm) – functional segments

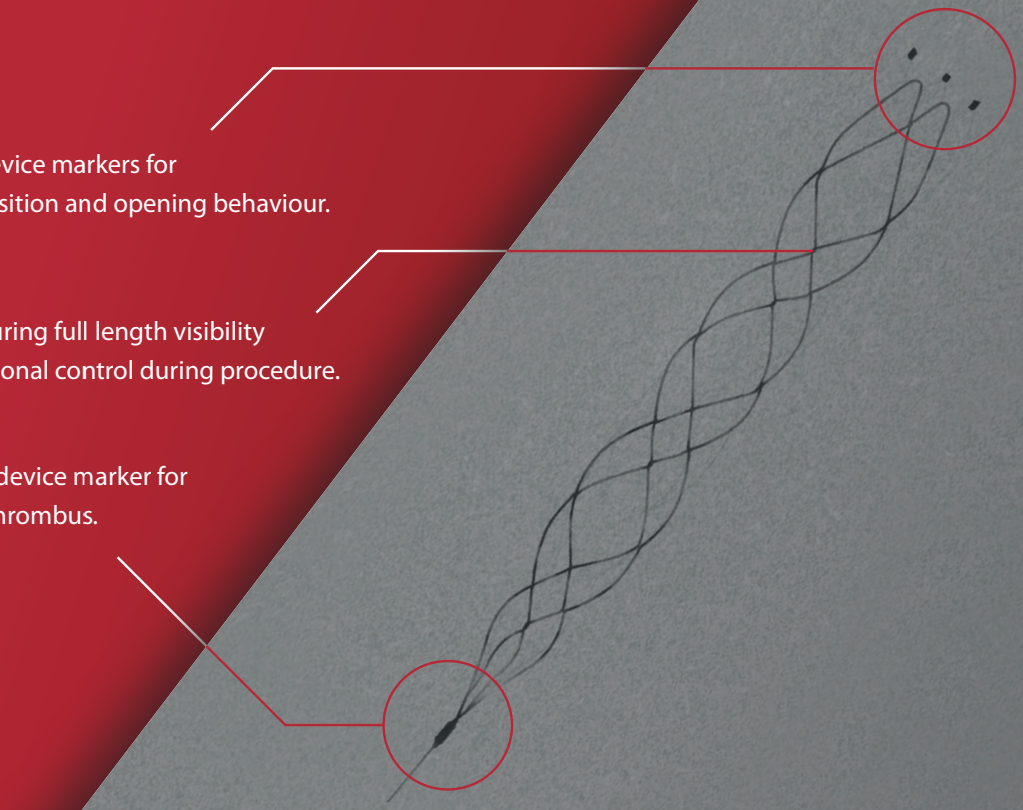
Simple and clear visibility concept for maximum control and assurance

Three distal platinum iridium device markers for permanent control of device position and opening behaviour.

Two radiopaque DFT wires featuring full length visibility for precise alignment and additional control during procedure.

One proximal platinum iridium device marker for precise positioning within the thrombus.





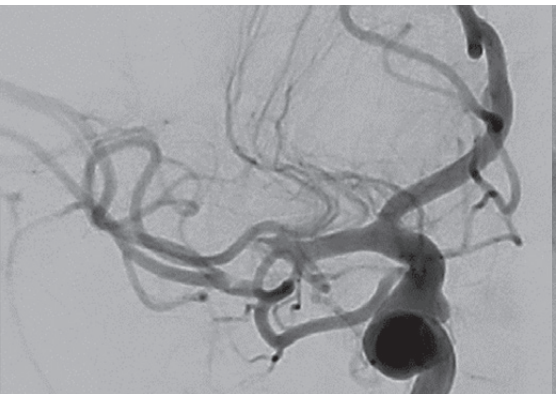
SAFE

Thanks to the proven hybrid cell design and the excellent full length visibility, the APERIO® Hybrid Thrombectomy Device leads to a maximum in safety and reliablitity during the procedure.

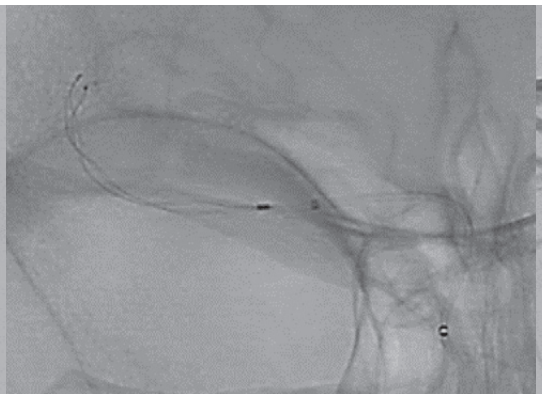
EFFICIENT

The constant and balanced radial force over the intended vessel diameter allows a gentle and highly efficient clot removal.[1]

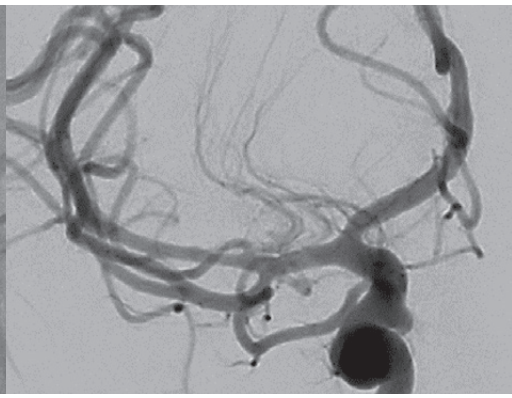
[1] Machi P, Jourdan F, Ambard D, et al Experimental evaluation of stent retrievers' mechanical properties and effectiveness, Journal of NeuroInterventional Surgery 2017;9:257-263.



Pre treatment
Total occlusion of middle cerebral artery



Treatment
with APERIO® Hybrid Thrombectomy Device 4.5 x 30 mm



Post treatment
Final result after first pass

Images are courtesy of Dr. Christoph Kabbasch, University Hospital, Cologne

ORDERING INFORMATION

Labelled APERIO® Hybrid Dimensions (mm)	Reference Number	Device Diameter (mm)	Device Length* (mm)	Recommended Vessel Diameter (mm)	Required Microcatheters for Delivery (Inch)
3.5 x 28	01-000704	3.5	28	1.5 – 3.0	0.021
4.5 x 30	01-000705	4.5	30	2.0 – 4.0	0.021
4.5 x 40	01-000706	4.5	40	2.0 – 4.0	0.021
4.5 x 50	01-000707	4.5	50	2.0 – 4.0	0.021
6.0 x 40	01-000708	6.0	40	3.5 – 5.5	0.021 – 0.027
6.0 x 50	01-000709	6.0	50	3.5 – 5.5	0.021 – 0.027

* Average length within intended vessel diameter

Recommended Microcatheters

Product Name	Reference Number	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)	Tip Shape
NeuroSlider® 21	01-000273	0.021	2.4 / 2.5	155	Straight
NeuroSlider® 27	01-000274	0.027	3.0 / 3.1	155	Straight

Recommended Intermediate Catheters

Product Name	Reference Number	ID (Inch)	OD dist. OD prox. (French / Inch)	Usable / Total Length (cm)	Tip Shape
NeuroBridge® 52	01-000518	0.052	5.0 / 0.066 5.3 / 0.070	105 / 111	Multi-Purpose 25°
	01-000511	0.052	5.0 / 0.066 5.3 / 0.070	115 / 121	Multi-Purpose 25°
	01-000512	0.052	5.0 / 0.066 5.3 / 0.070	125 / 131	Multi-Purpose 25°
	01-000513	0.052	5.0 / 0.066 5.3 / 0.070	135 / 141	Multi-Purpose 25°
NeuroBridge® 65	01-000519	0.065	6.1 / 0.080 6.3 / 0.083	105 / 111	Multi-Purpose 25°
	01-000514	0.065	6.1 / 0.080 6.3 / 0.083	115 / 121	Multi-Purpose 25°
	01-000515	0.065	6.1 / 0.080 6.3 / 0.083	125 / 131	Multi-Purpose 25°

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09-000100 EN 10/2019

The New Fully Radiopaque Aperio Hybrid Stent Retriever: Efficient and Safe? An Early Multicenter Experience

Marius Kaschner[1], Thorsten Lichtenstein[2], Daniel Weiss[1], Bernd Turowski[1], Lukas Goertz[2,3], Claudia Kluner[4], Marc Schlamann[2], Christian Mathys[1,4,5], Christoph Kabbasch[2]

■ OBJECTIVE: **To investigate the visibility, safety, and efficacy of the full-length radiopaque Aperio Hybrid stent retriever (APH) in mechanical thrombectomy of large vessel occlusions.**

■ METHODS: **Multicentric retrospective analysis of patients with stroke, treated with the APH due to an acute ischemic stroke by large vessel occlusions in the anterior or posterior circulation, was performed. We focused on technical and angiographic parameters including device visibility, perfusion results (modified thrombolysis in cerebral infarction scale [mTICI]), procedural times, periprocedural complications, and favorable clinical outcome (modified Rankin Scale, 0–2) at discharge and after 90 days.**

■ RESULTS: **A total of 48 patients (male: n = 22, 45.8%, mean age 73 years [standard deviation (SD), ±15], median baseline National Institutes of Health Stroke Scale: 15 [2–36], 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. 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. APH radiopacity was rated as good and very good in 97.9% (47 of 48).**

■ CONCLUSIONS: **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.**

INTRODUCTION

Mechanical thrombectomy (MT) in acute ischemic stroke treatment caused by large vascular occlusions (LVO) has evolved into the gold standard of care.[1,2] Mechanical retrieval of the vessel occluding clot may lead to reliable and fast vessel recanalization. The superiority of stent-retriever–based thrombectomy over intravenous thrombolysis (IVT) alone was demonstrated in numerous large, randomized,

Key words
- Aperio Hybrid
- Ischemic stroke
- Mechanical thrombectomy
- Recanalization
- Stent retriever

Abbreviations and Acronyms
APH: Aperio Hybrid stent retriever
ARISE II: Analysis of Revascularization in Ischemic Stroke with EmboTrap
ASPECTS: Alberta Stroke Program Early CT Score
CT: Computed tomography
DFT: Drawn filled tubing
IVT: Intravenous thrombolysis
LVO: Large vascular occlusions
mRS: Modified Rankin Scale
MT: Mechanical thrombectomy
mTICI: Modified thrombolysis in cerebral infarction
NIHSS: National Institutes of Health Stroke Scale
RCT: Randomized controlled trial
SAH: Subarachnoid hemorrhage
sICH: Symptomatic intracranial hemorrhage

From the [1]Medical Faculty, Department of Diagnostic and Interventional Radiology, University Duesseldorf, Duesseldorf; [2]Institute for Diagnostic and Interventional Radiology, and [3]Center for Neurosurgery, Faculty of Medicine and University Hospital Cologne, University of Cologne, Cologne; [4]Institute of Radiology and Neuroradiology, Evangelisches Krankenhaus, University of Oldenburg; and [5]Research Center Neurosensory Science, Carl von Ossietzky Universität Oldenburg, Oldenburg, Germany

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All listed authors contributed to the work. M. Kaschner and T. Lichtenstein contributed equally and share first authorship. C. Mathys and C. Kabbasch contributed equally and share the last authorship.

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*Journal homepage: **www.journals.elsevier.com/world-neurosurgery***

*Available online: **www.sciencedirect.com***

recanalization appear to be in the range of comparable stent-retriever publications.

Full structural radiopacity would allow a more targeted deployment of the APH and delineation of the stent retriever. From a procedural point of view, visualization of just the distal markers would be sufficient but a reliable detection of clot integration and clot displacement requires full-length visibility of the stent structures. Moreover, during retrieval there is no visual control of the clot-stent interaction in conventional nitinol retrievers as the predecessor Aperio. Compared with the Aperio, the APH is one of few stent retrievers that allow visualization of the clot-strut interaction during both deployment and retrieval.[11,12] As a result of full-length visibility, a potential failure of the thrombectomy maneuver might be detected at an early stage and enables us to adapt or modify the procedure, for example, obvious nonintegration of the clot within the stent retriever just sliding past it or visible straightening of the target vessel without relative movement of the stent retriever that may indicate increased force transmitted to the vessel, with the risk of structural damage. In our cases in which pushability of the device was rated as "poor" and "very poor" (4.2%, 2 of 48) and positioning of the APH as "poor" (2.1%, 1 of 48), the added DFT wires were supposed to increase the resistance during the delivery and deployment of the APH stent retriever via the microcatheter. This assumption is in accord with reports of an international survey performed among the members of the World Federation of Interventional and Therapeutic.[23] In this context, a final assessment of friction or resistance during delivery and deployment of the device, and evaluation of the used material in combination with the APH (e.g., microcatheters, aspiration catheters), should be subject to a prospective evaluation.

CONCLUSIONS

This early multicenter experience demonstrated that the recently introduced APH yielded high rates of favorable and excellent reperfusion in cerebral LVO in conjunction with lesional aspiration in the setting of acute stroke. Clinical outcome after 90 days seems to be in line with published literature. The absence of device-related procedural complications reflects a high safety profile. Full-length visibility of the APH may allow the detection of the alignment of the device with the clot and may guide procedural adaptation by control of the actual stent-clot or stent-vessel interaction. These promising initial results will be further evaluated in a German multicentric registry.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Marius Kaschner: Writing - original draft, Data curation, Investigation. **Thorsten Lichtenstein:** Writing - original draft, Data curation, Investigation. **Daniel Weiss:** Data curation, Formal analysis. **Bernd Turowski:** Data curation, Formal analysis. **Lukas Goertz:** Data curation, Formal analysis. **Claudia Kluner:** Data curation, Formal analysis. **Marc Schlamann:** Data curation, Formal analysis. **Christian Mathys:** Writing - review & editing, Data curation, Project administration, Investigation, Validation, Supervision. **Christoph Kabbasch:** Conceptualization, Writing - review & editing, Data curation, Project administration, Investigation, Validation, Supervision.

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Conflict of interest statement: C. Kabbasch reports personal fees from Acandis and personal fees from Microvention, outside the submitted work. The remaining authors have no conflicts to report.

All data will be made available on request in an anonymized manner.

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