

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

xcandis®

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.

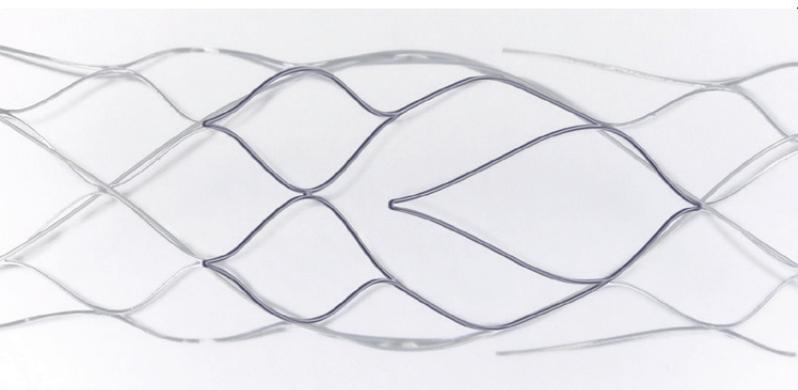
Small closed cells ensure a perfect vessel wall apposition and expansion into the clot. Large open cells with integrated anchoring elements assure efficient clot retention for reliable and atraumatic retrieval even in tortuous vessel anatomies. In combination, these two cell designs build up a functional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

VARIABLE

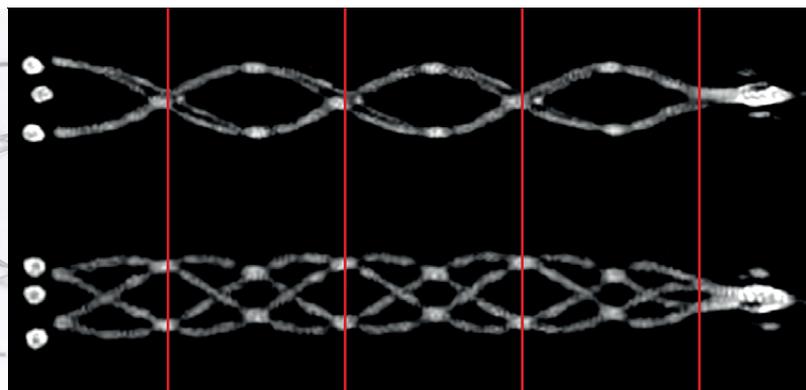
The broad range of sizes enables the treatment of vessel diameters from 1.5 mm up to 5.5 mm.

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



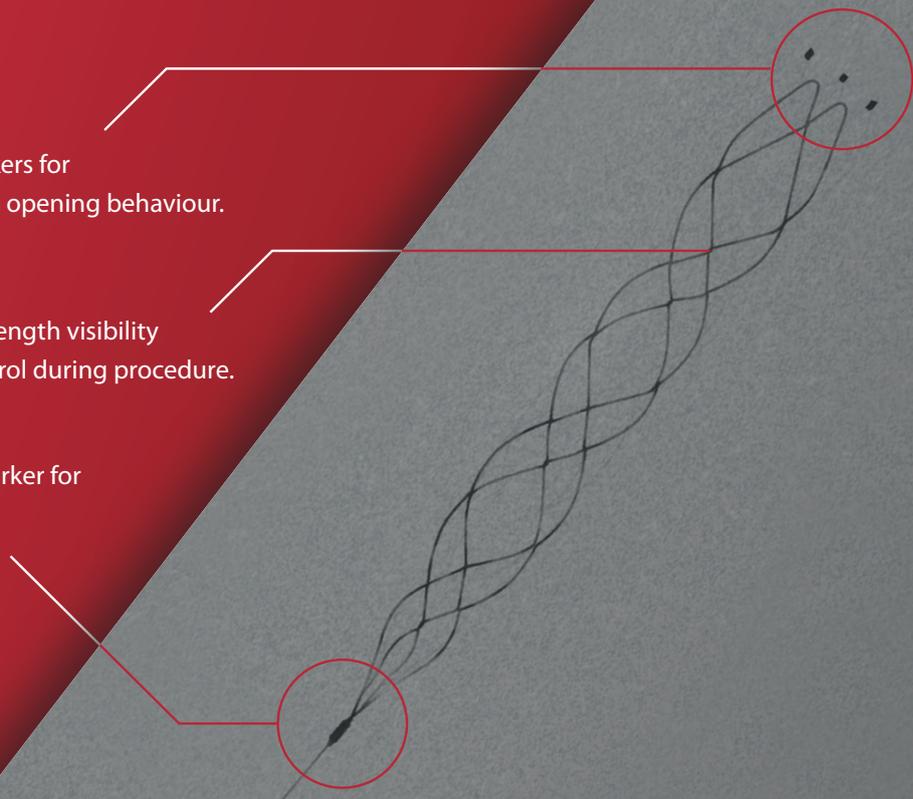
APERIO® Hybrid Thrombectomy Device (6.0 x 50 mm) – functional segments

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.



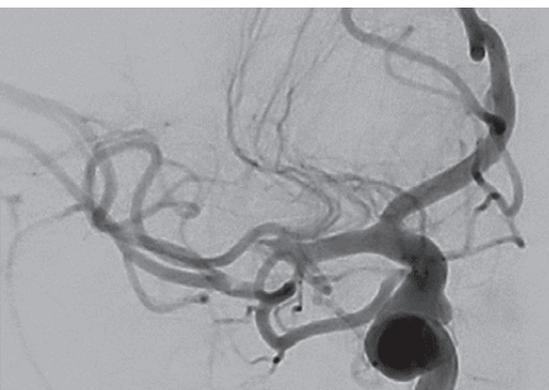
SAFE

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 reliability during the procedure.

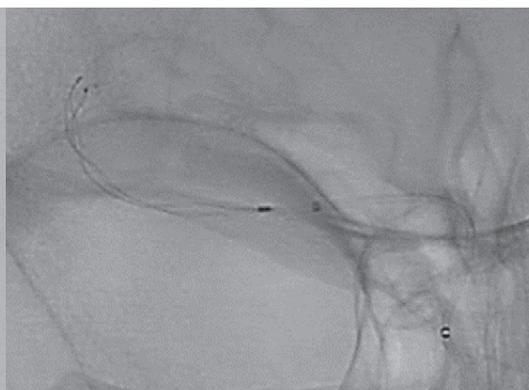
EFFICIENT

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

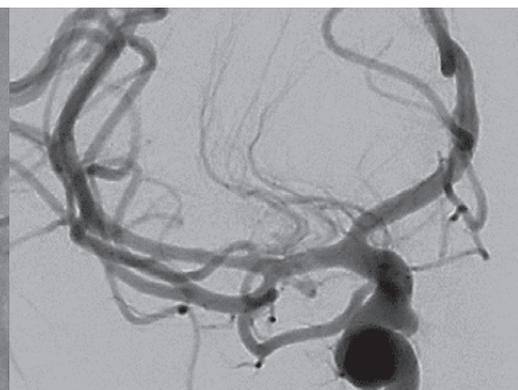
¹ Machi P, Jourdan F, Ambard D, et al Experimental evaluation of stent retrievers' mechanical properties and effectiveness, Journal of NeuroInterventional Surgery 2017;9:257-263.



*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*

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. / 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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ORDERING INFORMATION | APERIO® Hybrid^{17|21}

Labelled APERIO® Hybrid ^{17 21} Dimensions (mm)	Reference Number	Device Diameter (mm)	Device Length* (mm)	Recommended Vessel Diameter (mm)	Required / Recommended Microcatheters for Delivery (Inch)
2.5 × 16	01-000713	2.5	16	1.0 – 2.0	0.0165 – 0.021 NeuroSlider® 17 DLC NeuroSlider® 21 DLC
2.5 × 28	01-000710	2.5	28	1.0 – 2.0	
3.5 × 28	01-000711	3.5	28	1.5 – 3.0	
4.5 × 30	01-000712	4.5	30	2.0 – 4.0	
4.5 × 40	01-000715	4.5	40	2.0 – 4.0	0.021 – 0.027 NeuroSlider® 21 DLC NeuroSlider® 27 (DLC)
4.5 × 50	01-000716	4.5	50	2.0 – 4.0	
6.0 × 40	01-000717	6.0	40	3.5 – 5.5	
6.0 × 50	01-000718	6.0	50	3.5 – 5.5	

* Average length within intended vessel diameter

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

Marius Kaschner¹, Thorsten Lichtenstein², Daniel Weiss¹, Bernd Turowski¹, Lukas Goertz^{2,3}, Claudia Kluner⁴, Marc Schlamann², Christian Mathys^{1,4,5}, Christoph Kabbasch²

■ **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

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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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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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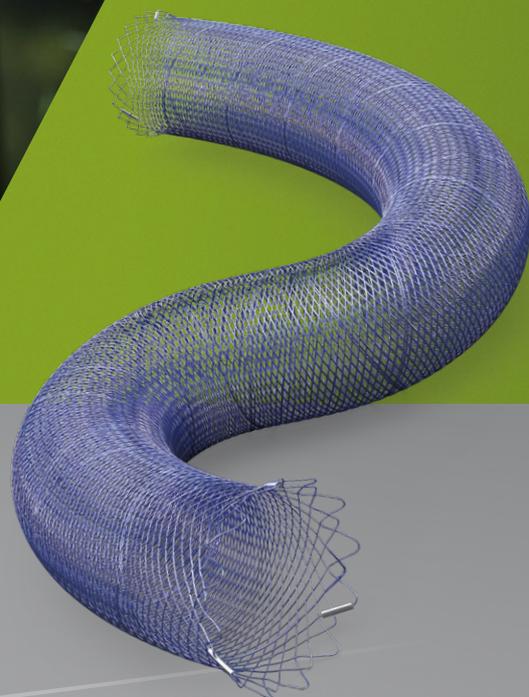
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VISIBLE ADAPTABILITY

DERIVO® Embolisation Device



- Unique visibility
- 2.5 mm to 6.0 mm vessel diameter
- True self-expansion



xcandis®

ENGINEERING STROKE SOLUTIONS



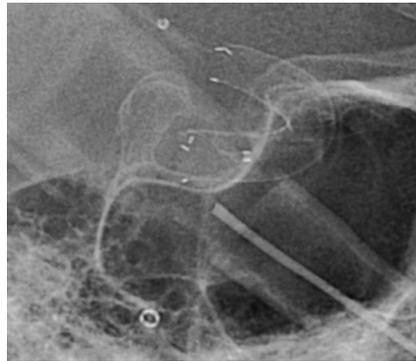
Proven Technology – Safe and Efficient

New composite wire concept for outstanding visibility of the DERIVO® contour

Treatment of left saccular ICA aneurysm with DERIVO® 5.0 mm x 20 mm



Excellent visibility of DERIVO® contour even in front of dense bone structures. View inside the lumen is possible.



Opening of DERIVO® in tight curve is clearly visible.

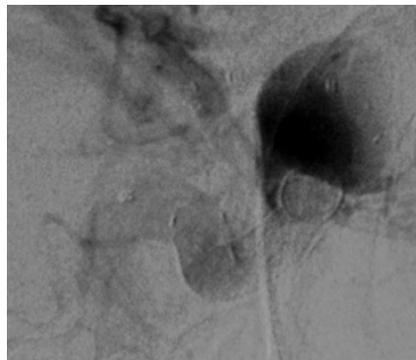
Images by courtesy of: Prof. Reith, Department of Neuroradiology, Saarland University Hospital, Homburg, Germany

Balanced mechanical properties for excellent clinical performance

Treatment of large right ICA aneurysm with DERIVO® 4.0 mm x 30 mm



Perfect wall apposition: DERIVO® contour follows exactly the tortuous shape of the vessel.



Immediate flow diversion effect after DERIVO® placement.



Excellent visibility of fully released DERIVO®.

Images by courtesy of: Dr. Prothmann, Klinikum rechts der Isar, Department of Diagnostic and Interventional Neuroradiology, Technical University Munich, Germany



Advanced technology for the treatment of intracranial aneurysms

UNIQUE VISIBILITY

- Completely visible device contour
- Nitinol Composite Wires with Platinum core
- Three Platinum-Iridium X-Ray markers on both ends

BROADEST RANGE

nominal device length from 15 mm – 60 mm, also available in 6 mm \varnothing

- 3D Sizing Support for best flow diversion properties
- Long lengths to avoid telescoping
- Intended vessel diameters from 2.5 mm up to 6 mm

EXCEPTIONAL RELIABILITY

- Secure wall apposition because of flared ends & closed distal ends
- Better corrosion resistance and lower thrombogenicity¹ due to BlueXide® Surface Finishing
- Outstanding flexibility combined with well-balanced radial force

¹ results from in-vitro testings

FLOW – WHERE IT SHOULD BE

Acandis® is using the latest technological developments to ensure a smooth, reliable and precise treatment of intracranial aneurysms with the DERIVO® Embolisation Device.

BlueXide® Surface Finishing

The Acandis® proprietary BlueXide® Surface Finishing Technology ensures less friction during delivery through the microcatheter as well as during expansion, making the opening of the device smooth and reliable. This finishing contributes to better corrosion resistance which might lead to lower thrombogenicity.

Nitinol Composite Wires

The entire device consists of Nitinol Composite Wires with Platinum core leading to an outstanding visualisation of the contour and shape of the device under fluoroscopy.

X-Ray Markers

Three Platinum-Iridium X-Ray markers are positioned on each end of the DERIVO® Embolisation Device for an accurate placement.

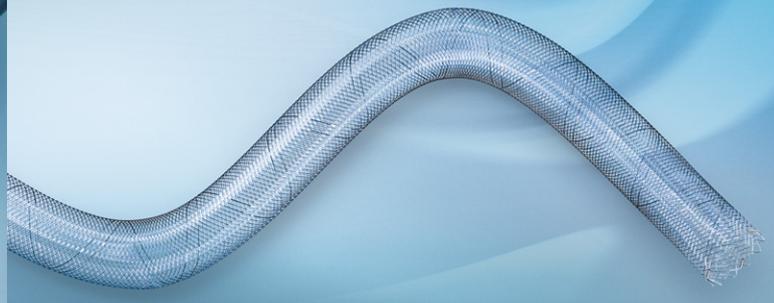
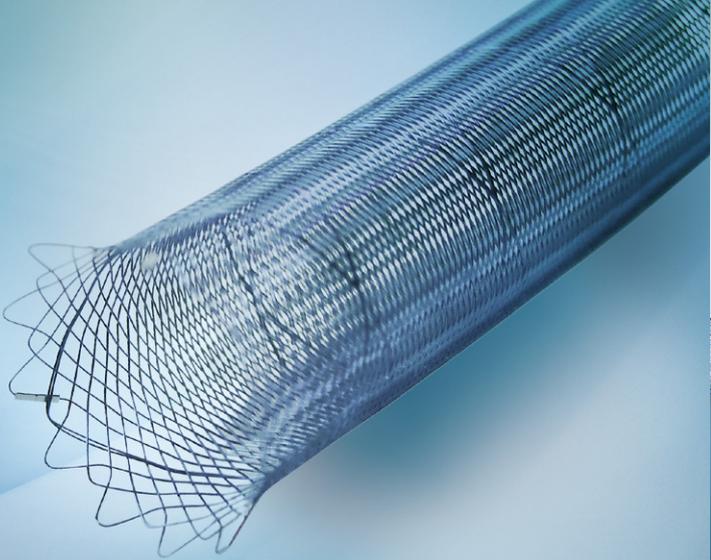
Closed Distal Ends

The closed distal ends of the DERIVO® Embolisation Device help in delivering the device smoothly and releasing it simply, as they create less friction during the delivery through the microcatheter. Additionally these ends are less traumatic, even if the implant is oversized in the distal part of the vessel.

Flared Ends

The DERIVO® Embolisation Device has flared ends for a secure wall apposition immediately after the initial distal opening, while the foreshortening on the proximal end is reduced.





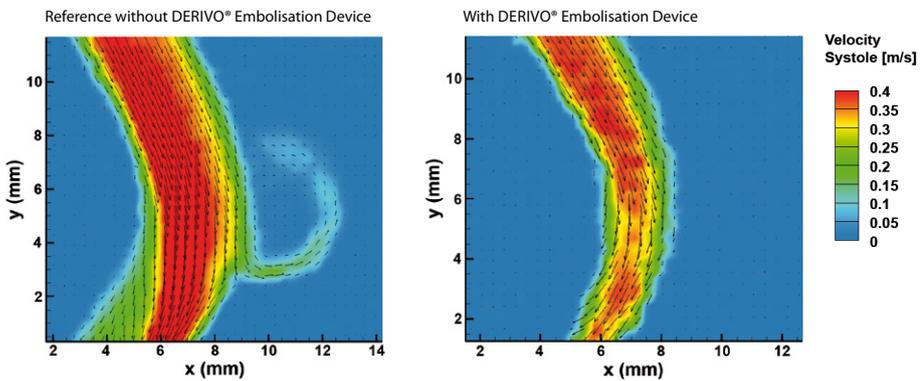
Flow Diversion

The mesh density enables flow diversion away from the aneurysm while maintaining the flow into the side branches. Particle Image Velocimetry (PIV) proves the effectiveness of the DERIVO® Embolisation Device flow diversion properties.

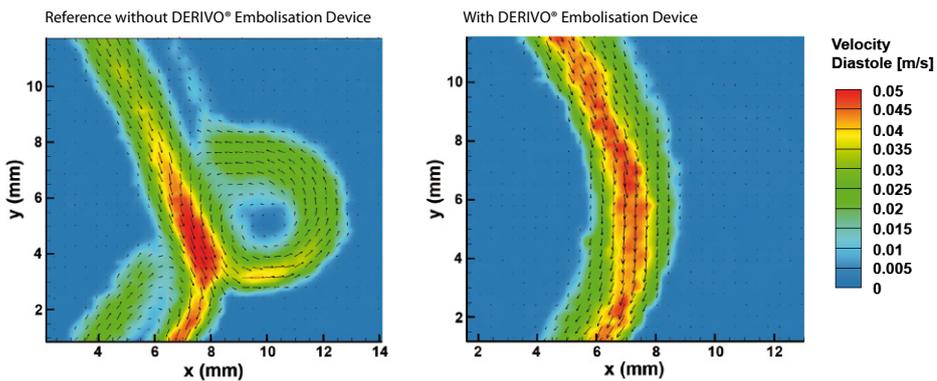
Vessel Wall Conformability

The braiding design ensures a good vessel wall conformability, even in highly variable vessel diameters and in tortuous anatomies.

Velocity during Systole



Velocity during Diastole



Particle Image Velocimetry (PIV) by courtesy of: Dept. of Cardiovascular Engineering RWTH Aachen (CVE/AME)

PROCEDURE – RELIABLE AND EFFECTIVE

s.e.c.u.r.e. GP Technology

The DERIVO® Embolisation Device is equipped with a Nitinol transport wire using the s.e.c.u.r.e. GP Technology engineered to meet the demands of a reliable and effective procedure.

S- safe

E- enhanced

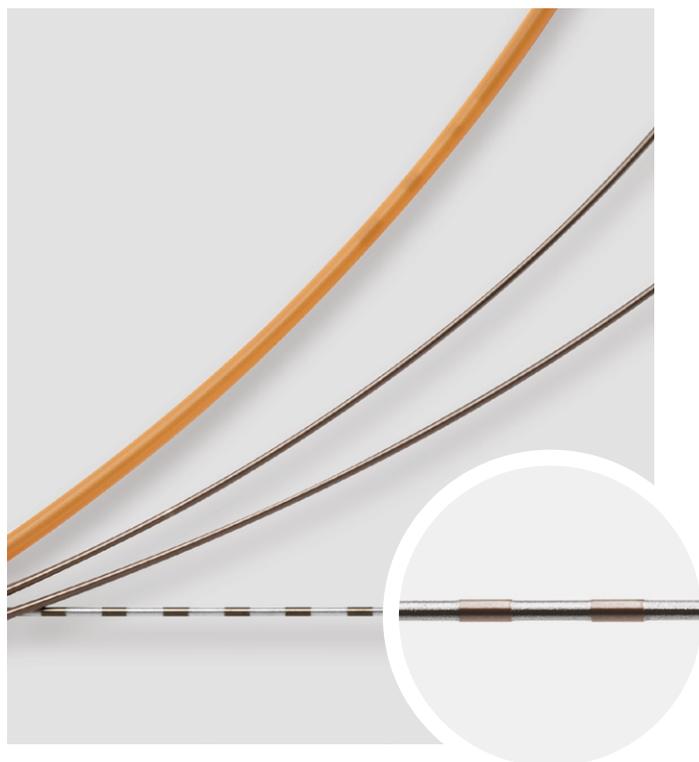
C- controlled

U- unique

R- reliable

E- effective

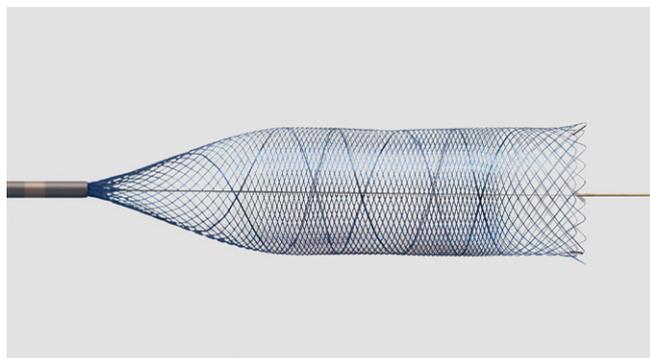
The sleek surface of the transport wire changes into a unique – optically and tactile perceptible – checkered surface at the fluoroscopy marker point, to enhance the grip and push for a controlled and safe placement of the DERIVO® Embolisation Device.



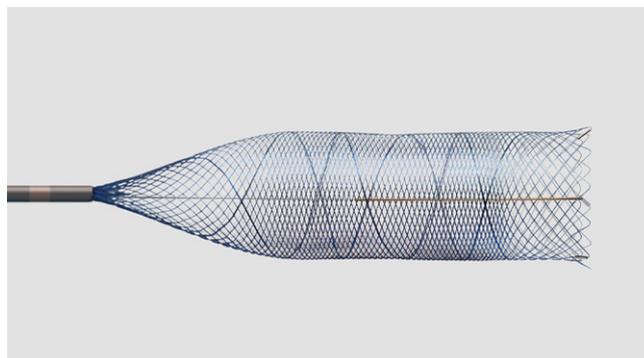
Resheathability

The device can be safely recaptured and repositioned if an adjustment and superior placement is needed.

Tip Design



With tip – for additional distal support and retention of device access after release.



Without tip (only applicable for 40 mm and 50 mm device lengths) – for more flexibility and tip control in the treatment of long lesions.

SIZING SUPPORT CHART – DERIVO® EMBOLISATION DEVICE

Labelled DERIVO® Dimensions (mm)	Reference Number		Unconstrained DERIVO® Dimensions (mm)	DERIVO® Lengths in corresponding Intended Use Diameters (mm)		
		Ø	3.7	3.5	3.0	2.5
3.5 × 15	01-000408	Device Length	10	15	20	25
3.5 × 20	01-000409		13	20	27	32
3.5 × 25	01-000410		16	25	35	41
3.5 × 30	01-000411		19	30	41	48
3.5 × 40	01-000415		25	40	53	66
		Ø	4.2	4.0	3.5	3.0
4.0 × 15	01-000381	Device Length	11	15	20	25
4.0 × 20	01-000330		14	20	27	32
4.0 × 25	01-000335		17	25	35	41
4.0 × 30	01-000340		20	30	41	48
4.0 × 40	01-000360		26	40	53	66
		Ø	4.7	4.5	4.0	3.5
4.5 × 15	01-000382	Device Length	11	15	20	25
4.5 × 20	01-000331		14	20	27	32
4.5 × 25	01-000336		17	25	35	41
4.5 × 30	01-000341		20	30	41	48
4.5 × 40	01-000361		26	40	53	66
		Ø	5.2	5.0	4.5	4.0
5.0 × 15	01-000383	Device Length	11	15	20	23
5.0 × 20	01-000332		14	20	27	32
5.0 × 25	01-000337		17	25	35	41
5.0 × 30	01-000342		20	30	41	48
5.0 × 40	01-000362		26	40	53	62
5.0 × 50	01-000363		34	50	68	82
		Ø	5.7	5.5	5.0	4.5
5.5 × 15	01-000384	Device Length	11	15	20	23
5.5 × 20	01-000333		14	20	27	32
5.5 × 25	01-000338		17	25	35	41
5.5 × 30	01-000343		20	30	41	48
5.5 × 40	01-000364		26	40	53	62
5.5 × 50	01-000365		34	50	68	82
		Ø	6.2	6.0	5.5	5.0
6.0 × 15	01-000385	Device Length	11	15	20	23
6.0 × 20	01-000334		14	20	27	32
6.0 × 25	01-000339		17	25	35	41
6.0 × 30	01-000344		20	30	41	48
6.0 × 40	01-000366		26	40	53	62
6.0 × 50	01-000367		34	50	68	82

Note: all indicated lengths can vary within a tolerance range of +/- 1mm

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	20	01-000409		
	25	01-000410		
	30	01-000411		
	40	01-000415*		
4.0	15	01-000381	3.0 – 4.0	
	20	01-000330		
	25	01-000335		
	30	01-000340		
	40	01-000360*		
4.5	15	01-000382	3.5 – 4.5	
	20	01-000331		
	25	01-000336		
	30	01-000341		
	40	01-000361*		
5.0	15	01-000383	4.0 – 5.0	
	20	01-000332		
	25	01-000337		
	30	01-000342		
	40	01-000362*		
	50	01-000363*		
5.5	15	01-000384	4.5 – 5.5	
	20	01-000333		
	25	01-000338		
	30	01-000343		
	40	01-000364*		
	50	01-000365*		
6.0	15	01-000385	5.0 – 6.0	
	20	01-000334		
	25	01-000339		
	30	01-000344		
	40	01-000366*		
	50	01-000367*		

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Implantation of Large Diameter (5.5–6 mm) Derivo Embolization Devices for the Treatment of Cerebral Aneurysms

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Abstract

Background The efficacy of flow diverters is dependent upon robust wall apposition in the parent artery. Usage in large caliber cerebral vessels has therefore been limited as few implants with diameters >5 mm exist. We present our initial experience in treating cerebral aneurysms using the 5.5 mm and 6 mm diameter implants of the Derivo embolization device (DED).

Methods Our prospectively maintained institutional database was reviewed to identify patients in whom a >5 mm DED was implanted between November 2016 and February 2021. The primary efficacy outcome was complete or near-complete aneurysm occlusion at 6 months (O’Kelly-Marotta, OKM, C–D, adapted for magnetic resonance angiography). Safety outcomes included 30-day major morbidity defined as modified Rankin Score (mRS) 3–5, mortality, serious adverse events and procedural complications.

Results A total of 21 large diameter DEDs were deployed in 18 patients (age 59.5 ± 14.1 years), harboring 19 unruptured aneurysms. Of the aneurysms 14 (73.7%) were saccular in morphology (sac diameter 10.9 ± 5.5 mm, neck diameter 6.8 ± 3.1 mm), 3 (15.8%) aneurysms were dissecting, 1 (5.3%) iatrogenic pseudoaneurysm and 1 (5.3%) fusiform. Aneurysm locations were: ICA (internal carotid artery) ($n=17$); (7 cavernous, 4 paraophthalmic, 2 paraclinoid, 1 petrous, 2 communicating, 1 cervical); vertebrobasilar ($n=2$). Adjunct stenting to optimize proximal wall apposition was undertaken in 5 (27.8%) patients. At 6 months 75% of patients followed-up met the primary efficacy endpoint (OKM C–D). There were no serious adverse events, 30-day major morbidity (mRS 3–5) or mortality.

Conclusion Implantation of large diameter (5.5 mm and 6 mm) DEDs into capacious cerebral vessels to treat a range of complex aneurysms is safe and technically feasible but may require adjunct stenting to optimize proximal wall apposition. Short-term efficacy of this device subset is comparable to previous DED and other flow diverter studies. Long-term follow-up and comparative studies are required for further assessment.

Keywords Flow diverter · Stent · Intracranial aneurysm · Embolization · Endovascular

Abbreviations

CTA Computed tomography angiography,
DED Derivo embolization device,
DSA Digital subtraction angiography,

EVT Endovascular treatment,
ICA Internal carotid artery,
MRA Magnetic resonance angiography,
OKM O’Kelly-Marotta,
PED Pipeline embolization device,
SAH Subarachnoid hemorrhage

All authors approved the final version of the manuscript for submission.

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Introduction

Since the introduction of flow diverters into the neurointerventional armamentarium there has been a paradigm shift in the treatment of large, giant, wide-necked, dissecting and fusiform aneurysms [1]. The principle mechanism is aneurysm exclusion from the circulation by creating

impedance to blood flow at the vessel wall defect with subsequent hemodynamic decoupling between the normal vessel and aneurysm lumen [2]. Robust wall apposition in the parent artery promotes endothelialization, prevents endoleaks and is a key determinant of aneurysm obliteration [3, 4].

Although there has been continued expansion in the number of available devices, only a few implants with diameters greater than 5 mm are available [5]. This has limited the use of flow diverters in anatomies where the maximum unconstrained opening diameter of the stent is less than that of the parent artery. The Derivo embolization device (DED) (Acandis, Pforzheim, Germany) is a second-generation flow diverter braided from 48 nitinol wires with an inner platinum core to improve visibility and a further 3 radiopaque markers at the distal and proximal ends. It is available in lengths between 15 and 50 mm, diameters between 3.5 and 6 mm, and can be resheathed to its point of no-return if repositioning is required.

Recently published DED multicentric series and single-arm trials have yielded promising short-term clinical and angiographic outcomes; however, data pertaining to device and parent vessel diameter and device size cannot be gleaned from these studies [6–8]. Furthermore, reports on the usage of large diameter flow diverter stents are scarce [9]. Therefore, we sought to present our experience and evaluate short-term efficacy and feasibility with 5.5 and 6 mm DEDs for the treatment of cerebral aneurysms.

Methods

Study Design

The prospectively maintained electronic database at a regional neurosciences center (Hull Royal Infirmary, Hull, UK) was reviewed to identify patients treated with 5.5 and 6 mm DEDs between November 2016 and February 2021. In accordance with our institutional and Health Research Authority (United Kingdom) guidelines, ethical approval was not required given the retrospective observational nature of the study and non-personally identifiable data. The study was performed in accordance with the 1964 Declaration of Helsinki and its later amendments.

Primary Efficacy End-point

The primary efficacy outcome was near-complete or complete aneurysm occlusion at 6 months. Evaluation was performed by time-of-flight MRA and contrast-enhanced MRA which are noninvasive and have sensitivities and specificities comparable with DSA [10, 11]. The degree of aneurysm filling was graded using the O'Kelly-Marotta (OKM) scale

(A=total, B=subtotal, C=entry remnant, D=no filling) [12]. The OKM grades C and D were considered to meet the primary efficacy end-point.

Safety Outcomes

The primary end-point for clinical safety was the absence of 30-day major morbidity defined as modified Rankin Score (mRS) 3–5 and mortality. Serious adverse events were screened using the electronic patient records, which included any new neurological deficit and stroke. Periprocedural complications were additionally recorded irrespective of clinical effect. The DSA images were evaluated by the operating neurointerventionalist. Difficulties in device delivery, the use of adjunct devices including coils, thromboembolic and access site complications were assessed. Follow-up MRI scans were also evaluated for evidence of new ischemic lesions as reported by the consultant neuro-radiologist in comparison to prior preprocedure baseline MRI.

Procedural Details

The decision for endovascular treatment of aneurysms was achieved by consensus between neurointerventionalists and vascular neurosurgeons taking into consideration the estimated lifetime rupture risk, clinical symptoms and patient wishes after informed consultation on the risk and benefits of treatment. The choice of technique, implant and the use of adjunctive devices was left to the operator's discretion. The diameter and length of the stent was based on 3D-DSA volume rendered images, considering the size and morphology of the aneurysm and parent vessel.

Patients were premedicated with dual antiplatelets (aspirin 300 mg and either ticagrelor 180 mg or clopidogrel 600 mg), usually the day prior to the procedure. Dual antiplatelets were maintained for 3 months (aspirin 75 mg once a day and either ticagrelor 90 mg twice a day or clopidogrel 75 mg once a day), with aspirin 75 mg once a day being administered life-long. Antiplatelet testing was not routinely performed. Systematic intravenous heparin was administered (typically 5000 IU), adjusted to body weight. Procedures were performed with the patient under general anesthesia utilizing a dedicated neurointerventional bi-plane angiography system (Allura Xper FD, Philips Healthcare, Amsterdam, The Netherlands).

A standardised triaxial, transfemoral approach was utilized. A 0.088" Asahi Fubuki (Asahi Intecc, Tokyo, Japan) guide-catheter was positioned in the ipsilateral cervical internal carotid artery (ICA). The 5Fr or 6Fr intermediate (distal access/intracranial support) catheter used in both anterior and posterior circulations was either a CAT5 or CAT6 (Stryker Neurovascular, Fremont, CA, USA)

or Navien 0.058"/0.072" (Navien, Covidien, Irvine, CA, USA). We endeavored to place the intermediate catheter as close to the intended landing zone to optimize stability during stent delivery.

The DED was deployed through a 0.027" microcatheter: Via27 (Sequent Medical/MicroVention Terumo, Tustin, CA, USA) or Phenom 027 (Medtronic, Dublin, Ireland). In cases requiring adjunctive coiling, this was performed through either an Excelsior SL10 (Stryker, Kalamazoo, MI, USA) or Echelon (Covidien/Medtronic). The decision to perform adjunct coiling at the discretion of the operator, taking into consideration aneurysm size, location, morphology and the requirement for scaffolding support during stent delivery to reduce the risk of device foreshortening or prolapse. In select cases requiring adjunct stenting to correct suboptimal wall apposition of the DED proximal end, this was done using a second DED or a Solitaire AB stent (eV3, Irvine, CA, USA).

Statistical Analysis

Descriptive and comparative statistical analyses were performed using SPSS (Version 23.0; IBM, Armonk, NY, USA). Categorical variables were presented as numbers and percentages. Continuous variables were presented as means \pm SD.

Results

Baseline Patient and Aneurysm Characteristics

A total of 18 patients (14 females, 4 males; age 59.5 ± 14.1 years) harboring 19 aneurysms were included. Of the aneurysms 14 (73.7%) were saccular in morphology (sac diameter 10.9 ± 5.5 mm, neck diameter 6.8 ± 3.1 mm), 3 (15.8%) aneurysms were dissecting (2 of which were iatrogenic), 1 (5.3%) iatrogenic pseudoaneurysm and 1 (5.3%) was fusiform. Aneurysm locations were: cavernous ICA ($n=7$), paraophthalmic ICA ($n=4$), paraclinoid ICA ($n=2$), petrous ICA ($n=1$), communicating ICA ($n=2$), cervical ICA ($n=1$), vertebral ($n=1$) and basilar ($n=1$). All aneurysms were considered unruptured with the exception of one iatrogenic pseudoaneurysm that presented with hemorrhagic otorrhea (patient 17). Baseline aneurysm characteristics and clinical presentation are presented in Table 1.

Procedural Results and Efficacy Outcomes

In total, 21 DEDs were deployed, 16 (76.2%) of which were 5.5 mm diameter implants and 5 (23.8%) being 6 mm diameter implants: 19 devices were deployed in 16 patients in the internal carotid artery (ICA) and 2 devices were deployed in 2 patients in the vertebrobasilar system. The mean number

Table 1 Baseline aneurysm characteristics and clinical presentation

Patient No	Aneurysm type	Clinical presentation and symptoms	Location	Aneurysm, max. diameter, mm	Aneurysm neck size, mm
1	Saccular	Headache/diplopia	Left cavernous ICA	10	5.3
2	Fusiform	Asymptomatic/Incidental	Right paraclinoid ICA	6.2	–
3	Saccular	Otalgia	Right cavernous ICA	9	7
4	Saccular	Asymptomatic/Incidental	Left PCOM	10	8
5	Saccular	Asymptomatic/Incidental	Left paraclinoid ICA	9	5
6	Saccular	3rd cranial nerve palsy	Right cavernous ICA	25	14
7	Dissecting	Infarct of left upper pons	Basilar	6.3	–
8	Saccular	3rd Cranial nerve palsy	Left PCOM (recurrence, previously coiled)	6	5
9	Saccular (partially thrombosed)	Headache, 3rd cranial nerve palsy	Right cavernous ICA	19	–
10	Saccular	Headache	Left paraophthalmic ICA	7.5	6
11	Saccular	Headache, 3rd cranial nerve palsy	1) Left cavernous ICA 2) Left para-ophthalmic	14 4	13 3
12	Dissecting (iatrogenic)	Iatrogenic	Right cervical ICA	6.5	–
13	Saccular	Asymptomatic/Incidental	Left paraophthalmic ICA	9	7
14	Saccular	Diplopia, headache	Left cavernous ICA	16	6
15	Dissecting (iatrogenic)	Iatrogenic	Left cavernous ICA	5.3	–
16	Saccular	Asymptomatic/Incidental	Left paraophthalmic ICA	7.5	4.5
17	Iatrogenic pseudoaneurysm	Iatrogenic Hemorrhagic otorrhea	Left petrous ICA	5.7	–
18	Saccular	Asymptomatic/Incidental	Left VA	7	5

ICA Internal carotid artery, PCOM Posterior communicating artery, VA Vertebral artery

of devices deployed per patient and per aneurysm were 1.2 and 1.1, respectively. The cohort parent vessel distal landing zone was $4.5\text{ mm} \pm 0.6\text{ mm}$ and the proximal landing zone $5.4\text{ mm} \pm 0.5\text{ mm}$. Adjunct intrasaccular coiling was undertaken for 6 (out of 14) saccular aneurysms (42.9%). Adjunct stenting to optimize proximal wall apposition was undertaken in 5 (27.8%) patients. In 2 (11.1%) patients with iatrogenic dissecting aneurysms a second DED was telescoped to achieve double mesh density.

The 6-month follow-up MRAs were available for 16 out of 19 (84.2%) aneurysms. Of these, 12 (75%) demonstrated near-complete or complete occlusion. One aneurysm (patient 3) which initially demonstrated subtotal filling (OKM-B) was retreated with a third stent (PED) and completely occluded on follow-up at 24 months. The sole fusiform aneurysm (patient 2) remodeled and remained stable at the 24-month follow-up. There were no cases of in-stent stenosis or occlusion. Representative cases are illustrated in

Figs. 1 and 2. Parent vessel size, device dimensions and efficacy outcomes are summarized in Table 2.

Safety Outcomes

There was no major 30-day morbidity (mRS 3-5) or mortality in this patient cohort. There was one pseudoaneurysm at the femoral arterial access site which was repaired surgically. No other serious adverse events, including new neurological deficits and stroke, were identified in the patient records. Procedural DSA images did not reveal evidence of a thromboembolic event nor did any of the 6-month follow-up MRI scans demonstrate evidence of an interval ischemic lesion/infarct when compared to preprocedure baseline MRI. In 5 (27.8%) patients there was suboptimal opening of the proximal end of the DED and/or “fish mouthing” which was corrected using adjunct stenting. Periprocedural complications and safety outcomes are listed in Table 2.

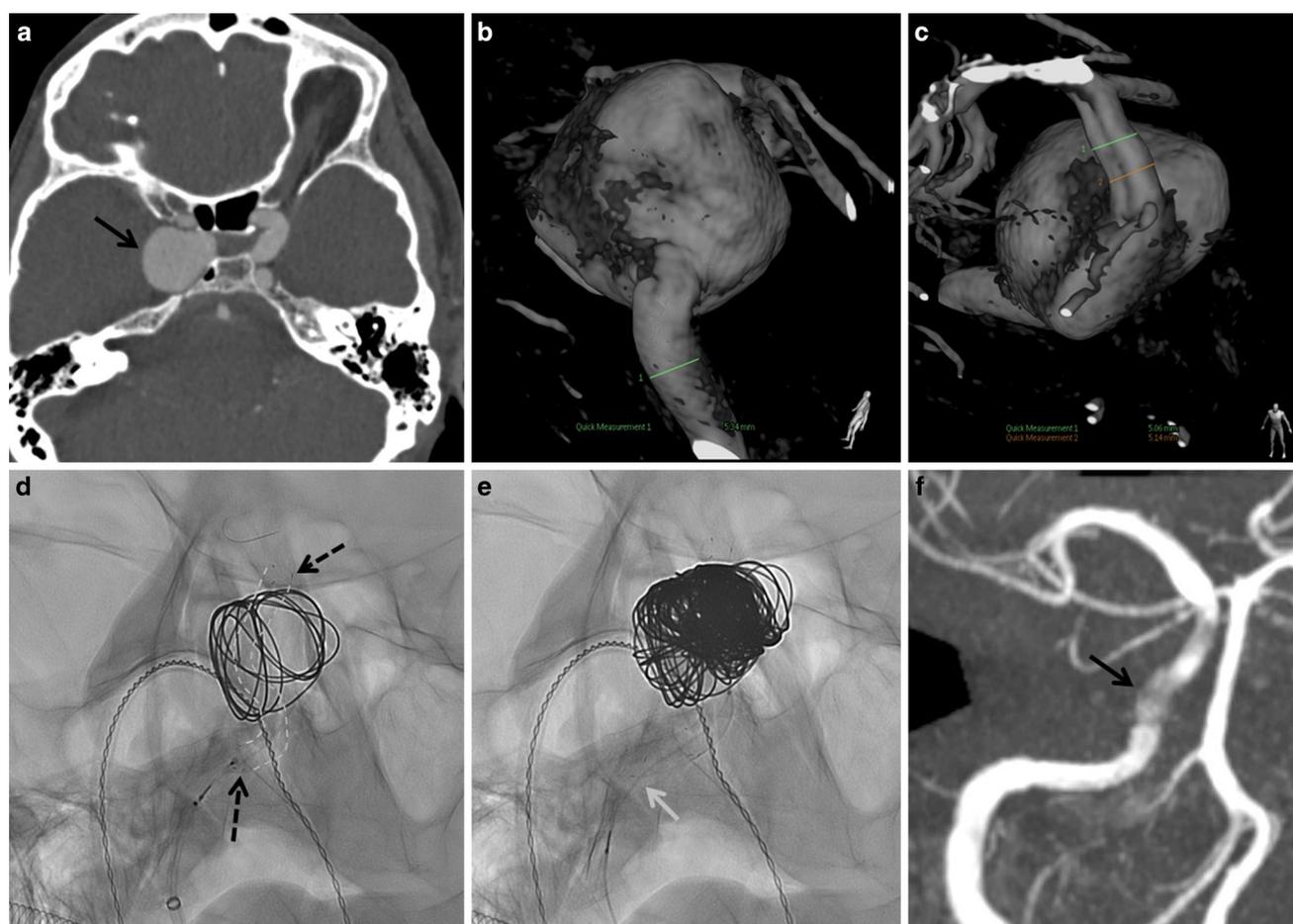


Fig. 1 Patient 6 presented with 3rd cranial nerve palsy. **a** CTA revealed a right cavernous ICA aneurysm measuring 25 mm in maximum diameter. Volume rendered 3D-DSA images illustrating the proximal (**b**) and distal (**c**) parent vessel artery diameters. **d** Initial 5.5×30 DED delivered (dashed white lines identify position, dashed black arrows identify markers) with adjunct coiling of the sac performed through a jailed SL-10 microcatheter to provide structural support for the stent. Mild proximal “fish mouthing” was corrected with a second 6×20 mm DED (solid white arrow in **e** indicates proximal markers). **f** Follow-up MRA demonstrates complete aneurysm occlusion at the cavernous ICA (solid black arrow)

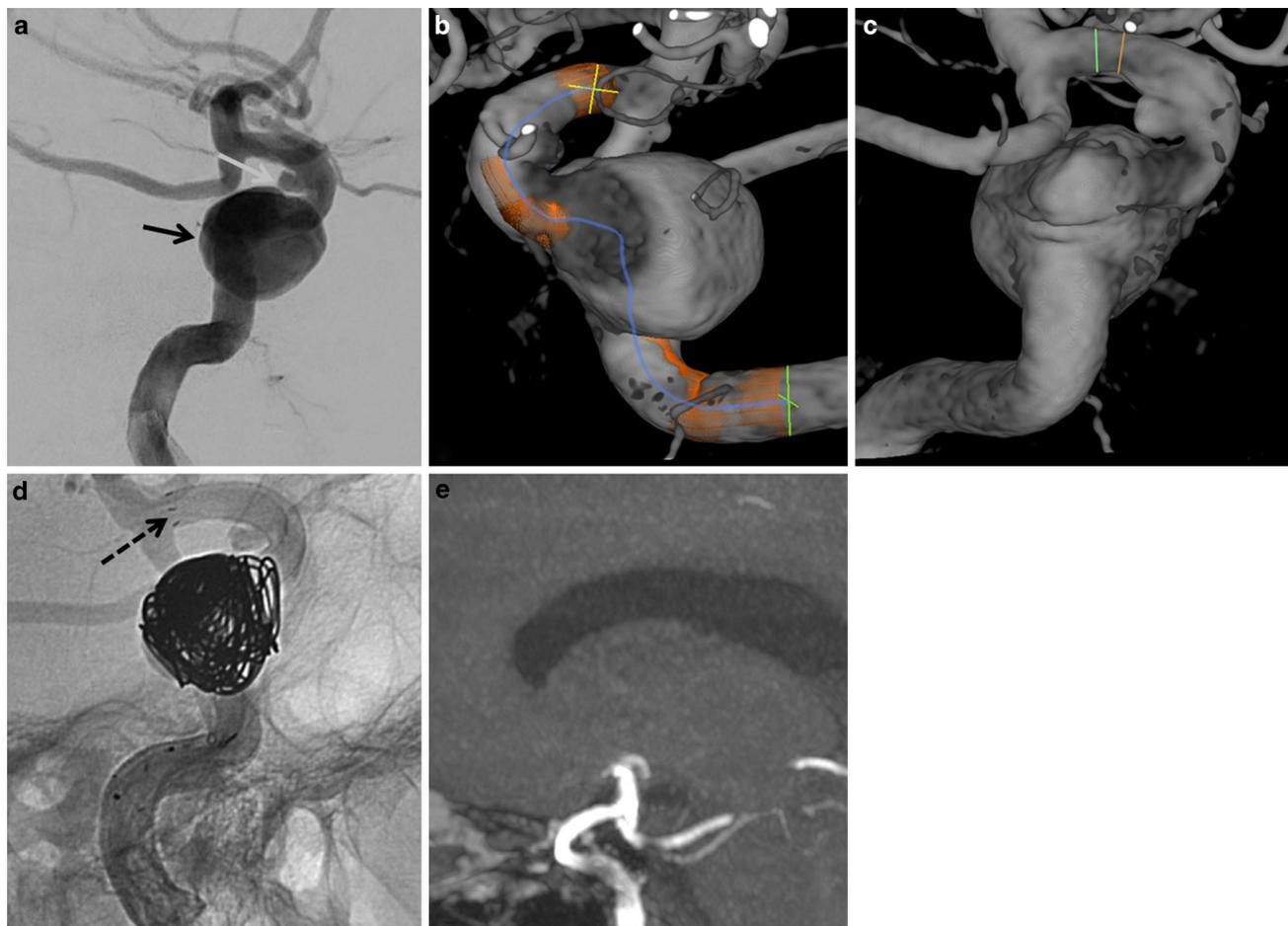


Fig. 2 Patient 11 presented with right 3rd cranial nerve palsy and worsening headaches. **a** Initial DSA reveals a 14 mm left cavernous ICA aneurysm (*solid black arrow*) and a smaller 4 mm left paraophthalmic ICA aneurysm (*solid white arrow*). **b** and **c** 3D-DSA volume rendered images illustrating aneurysm and parent vessel size/morphology. **d** A 6 × 50 mm DED was deployed covering both aneurysms with good wall apposition. Adjunct coiling of the cavernous ICA aneurysm was performed through to provide architectural support during stent delivery. **e** Follow-up MRA demonstrating complete occlusions of both aneurysms

Discussion

In this single center observational study, we assessed the feasibility and short-term efficacy of 5.5 and 6 mm implants of the DED in the treatment of a range of cerebral aneurysms. Whilst there exist a number of studies reporting on angiographic and clinical outcomes of the DED, to our knowledge none have specifically reported outcomes for large diameter devices [6–8, 13]. In recent series where the DED was used to treat ruptured and dissecting aneurysms all devices implanted were ≤ 5 mm [14, 15]. Furthermore, DED is one of the few flow diverters currently used with diameters in 5.5 and 6 mm. From the commonly available flow diverters, the Flow-Redirection Endoluminal Device (FRED; Microvention) and the SILK stent (Balt Extrusion, Montmorency, France) are also available in a 5.5 mm diameter however similar to the DED, studies reporting on outcomes have not specifically assessed this size of implant precluding cross-manufacturer comparisons [16–20].

Procedural Outcomes

In our compiled experience, 21 large diameter DEDs were implanted into 18 patients to treat 19 cerebral aneurysms. A variety of aneurysm subtypes (saccular, fusiform and dissecting) were represented in the cohort reflecting the expanding utilization of flow diverters [21]. The saccular aneurysms included were on average large (10.9 ± 5.5 mm) and wide-necked (6.8 ± 3.1), which is an established indication for flow diversion [22, 23]. Although their use in posterior circulation, fusiform and dissecting aneurysms may carry increased treatment-related complications they offer an effective treatment option when conventional methods are unfeasible [24–26]. Out of 17 anterior circulation aneurysms in this cohort 7 (41.2%) arose from the cavernous ICA which represents a higher proportion than the 9.8% presented in the Brazilian DED registry [7]. This is not unsurprising given the relatively capacious geometry

Table 2 Parent vessel and device size, procedural complications and follow-up efficacy outcomes

Patient No	Distal landing zone max. diameter, mm	Proximal landing zone max. diameter, mm	DED size, mm (DxL)	Adjunct devices	Anti-platelet regime	Periprocedural complications/difficulties	Occlusion OKM grade (A–D) at 6-month follow-up	Occlusion OKM grade (A–D) at 24-month follow-up
1	4.3	5.5	5.5 × 20	Coils (to provide scaffold for stent)	Aspirin Clopidogrel	Angioseal-related femoral occlusion, surgically repaired	D	D
2	3.8	5.3	5.5 × 25	–	Aspirin Clopidogrel	–	C	C
3	5.5	6.0	5.5 × 25	Coils (to provide scaffold for stent) Solitaire 6 × 20 Pipeline 5 × 18	Aspirin Clopidogrel	Small endoleak of the proximal end of the flow diverter, treated with 6 × 20 mm Solitaire 2nd flow diverter treatment at 9 months, initially attempted using DED 6 × 30 (proximal segment failed to open). Pipeline 5 × 18 eventually deployed	B	D
4	5.3	5.6	5.5 × 20	–	Aspirin Clopidogrel	–	A	A
5	4.5	5.4	5.5 × 25	Coils (to provide scaffold for stent and view to reduce risk of delayed SAH)	Aspirin Clopidogrel	–	D	D
6	5.1	5.4	5.5 × 30 6 × 20	Coils (to provide scaffold for stent)	Aspirin Ticagrelor	Proximal fish mouting of initial 5.5 × 30 stent, 2nd DED 6 × 20 telescoped	D	–
7	4.4	4.9	6 × 50	Right VA PVO (coils)	Aspirin Ticagrelor	–	D	–
8	4.6	5.5	5.5 × 25	–	Aspirin Ticagrelor	–	B	B
9	4.7	5.1	5.5 × 25	Solitaire 5.5 × 20	Aspirin Ticagrelor	Sub-optimal proximal apposition, re-inforced with Solitaire 5 × 20 stent	D	D
10	4.3	5.5	5.5 × 25	Coils (to provide scaffold for stent and view to reduce risk of delayed SAH) Solitaire 6 × 20	Aspirin Ticagrelor	Sub-optimal proximal apposition, endoleak, re-enforced with Solitaire 6 × 20 stent	D	D
11	3.5	6.1	6 × 50	Coils (to provide scaffold for stent)	Aspirin Ticagrelor	–	D	–
12	5.1	5.3	6 × 30	–	Aspirin Ticagrelor	–	–	–
13	3.9	5.3	5.5 × 25	Solitaire 6 × 20	Aspirin Ticagrelor	Sub-optimal proximal apposition, re-enforced with Solitaire 6 × 20	B	–
14	5.3	5.4	5.5 × 25	–	Aspirin Ticagrelor	6 × 30 initially attempted but proximal fish-mouthing/ribboning	–	–

Table 2 (Continued)

Patient No	Distal landing zone max. diameter, mm	Proximal landing zone max. diameter, mm	DED size, mm (DxL)	Adjunct devices	Anti-platelet regime	Periprocedural complications/difficulties	Occlusion OKM grade (A-D) at 6-month follow-up	Occlusion OKM grade (A-D) at 24-month follow-up
15	3.9	4.0	5.5 × 25 5.5 × 30	-	Aspirin Ticagrelor	Initial attempts with pipeline and Evolve failed. 2nd DED telescoped to achieve double mesh density across dissected segment	D	-
16	3.5	5.3	5.5 × 25	-	Aspirin Ticagrelor	-	D	-
17	4.6	4.6	5.5 × 30 5.5 × 30	-	Aspirin Ticagrelor	2nd DED telescoped to achieve double mesh density across dissected segment	D	-
18	3.9	6.1	6 × 30	-	Aspirin Ticagrelor	-	-	-

DED Derivo embolization device, DxL Diameter × Length, OKM O'Kelly-Marotta, PVO Parent vessel occlusion, SAH Subarachnoid hemorrhage, VA Vertebral artery

of the cavernous segment [27] and the selection for large diameter implants in our study.

Although final device size was left to the discretion of the individual operator, the maximum diameters of the parent vessel proximal and distal landing zones were key determinants of implant selection. Undersized devices carry the potential risk of an endoleak whereas substantially oversized devices may reduce flow-diversion efficacy [28, 29]. In 3 (out of 18) patients the proximal and distal landing zone measurements on 3D-DSA volume rendered images were <5.0mm; however, a larger device was used to account for the maximum diameter of the dilated diseased parent vessel (patients 7 and 15) and size underestimation due to vasospasm (patient 17).

Adjunct intrasaccular coiling was undertaken in 6 aneurysms in this series. In 4 (out of 6) of these cases the aneurysm was located was at the cavernous ICA and the primary reason to use adjunct coils was to provide a scaffold for the stent and to reduce the risk of the device foreshortening or prolapse. There is also some evidence that adjunct coiling may expedite and improve occlusion outcomes; however, whether this reduces delayed subarachnoid hemorrhage is undetermined [30]. Adjunct stenting was undertaken in 5 cases to optimize wall apposition which may also improve occlusion rates [31]. Similar to Taschner et al. [8] we found the proximal part of the device particularly prone to fish mouthing/suboptimal expansion; however, it is not possible to draw conclusions from our study whether the rates are significantly higher with the use of the 5.5 and 6mm devices.

Efficacy Outcomes

Of the 16 aneurysms with follow-up MRA at 6 months, 12 (75%) demonstrated near-complete or complete occlusion (OKM-C or D). These results are similar to flow diverter studies in general with a meta-analysis by Brinjikji et al. reporting a 6-month complete occlusion rate of 76% [32]. Our findings are also comparable with the Brazilian DED registry which reported a 6-month occlusion rate of 80.7% (113 of 140 aneurysms) with the smaller sac size in their cohort (6.7 ± 5.1 mm) potentially accounting for some of the difference [7]. Direct comparison with the higher rates of near-complete or complete occlusion rate of 89% (79/89) reported by Taschner et al. is difficult due to the longer follow-up time point (median 12.4 ± 5.84 months) [8]. Furthermore, given that we specifically assessed large diameter stents which arguably have their own unique deployment challenges to achieve satisfactory wall apposition and therefore aneurysm healing, the results from our preliminary experience are promising.

Whilst DSA remains the gold standard for the detection of aneurysm recurrence it carries the risk of ionising radia-

tion and stroke which accumulates over time with sequential DSA follow-up. A recent cross-modality meta-analysis concluded that MRA can reliably be used to follow up aneurysms treated with flow diverters with 86% sensitivity and 95% specificity for time-of-flight MRA, and 90% sensitivity and 92% specificity for contrast-enhanced MRA [33]. Although potentially cumbersome, we employ both techniques at our institution as they provide complementary information and the addition of contrast may mitigate potential false positive results on time-of-flight MRA of in-stent thrombosis due to stent-induced signal loss and false positive intra-aneurysmal flow due to T1-weighted hyperintensity of thrombus [11].

Limitations

The study presented is limited by its single-center retrospective design but provides a real-world sense of efficacy, limitations and associated technical challenges when using select 5.5 and 6 mm diameter DED implants. Secondly, the overall sample size was small but is comparable to previous series assessing the feasibility of the device for specific indications [14]. Furthermore, to the best of our knowledge this is the first study specifically reporting on the use of flow diverters >5 mm in diameter. Thirdly, only short-term 6-month MRA follow-up was available for most patients which precludes assessment of medium and long-term efficacy. Fourth, procedural DSA and follow-up MRA data were self-assessed thereby introducing potential bias. Lastly, the absence of follow-up DSA may impair the reliability of comparison with previous studies.

Conclusion

Implantation of large diameter (5.5 and 6 mm) DEDs into capacious cerebral vessels to treat a range of complex aneurysms is safe and technically feasible but may require adjunct stenting to optimize proximal wall apposition. Short-term efficacy of this device subset is comparable to previous DED and other flow diverter studies. Long-term follow-up and comparative studies are required for further assessment.

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Conflict of interest W. Butt, C.-N. Kim, R. Ramaswamy, A. Smith and P. Maliakal declare that they have no competing interests.

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BRILLIANT HIGH-FLYER

ACCERO® Stent

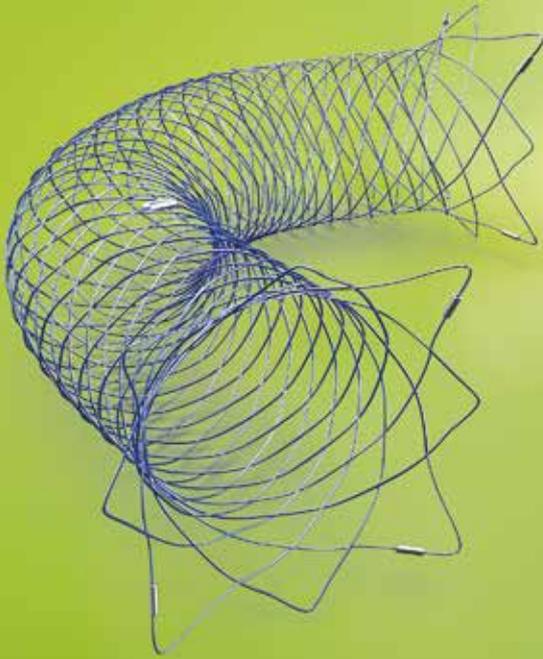


- Self-expanding braided stent
- BlueXide® surface finishing
- Excellent opening behaviour & adaptability
- Brilliant visibility

xcandis®

ENGINEERING STROKE SOLUTIONS

ACCERO® Stent



ACCERO® Stent is a highly visible, braided self-expanding stent with BlueXide® surface technology.

ADAPTIVE

The stent has an excellent opening behaviour and an advanced wall apposition at the ends. Our engineers designed a high radial resistive force to ensure reliable coil retention.

EASY TO USE

The ACCERO® can be delivered through 0.0165"-0.0170" microcatheters and double lumen balloon guidecatheters* and can be resheathed more than 95% of its length.

** contact Acandis for detailed microcatheter compatibility information*

Captions:

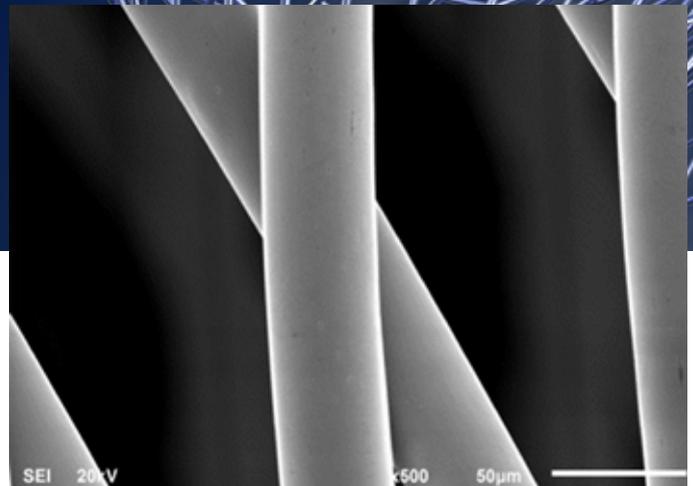
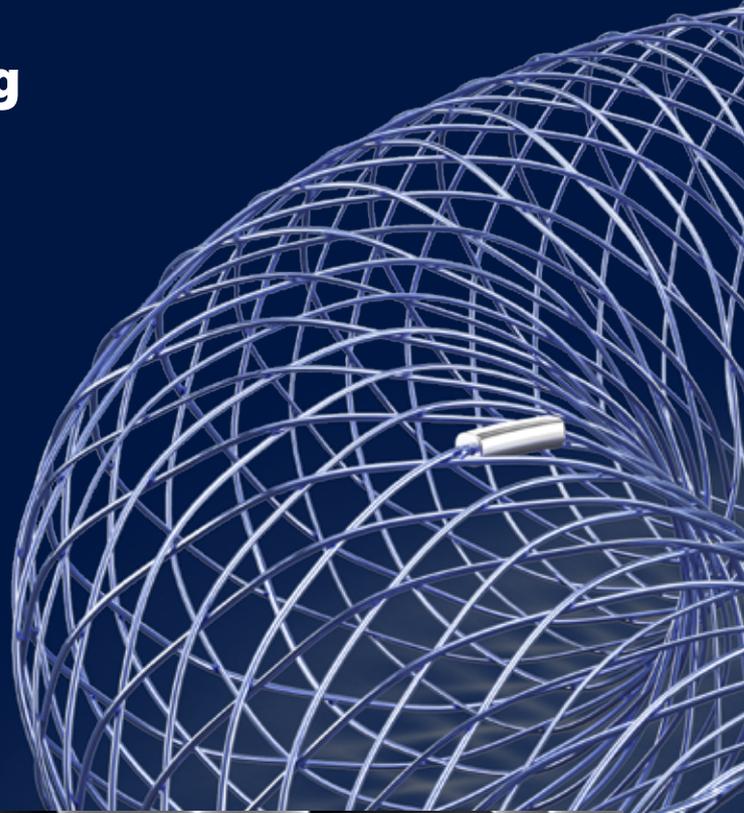
1,2 Stent assisted coiling with ACCERO® Stent



BlueXide® Surface Finishing

The Acandis® proprietary BlueXide® surface finishing aims to optimize hemocompatibility and facilitates stent delivery by:

- Corrosion protective BlueXide® surface ensures an extremely **low Nickel ion release**.
- High Oxygen and Nitrogen intensity of the protective Titanium Oxide/Oxynitride film **reduces platelet adhesion and favours endothelialization** compared to native oxide and therefore results in improved vessel healing.
- Smooth surface of Nitinol wires favours **excellent opening behaviour and low delivery force**.

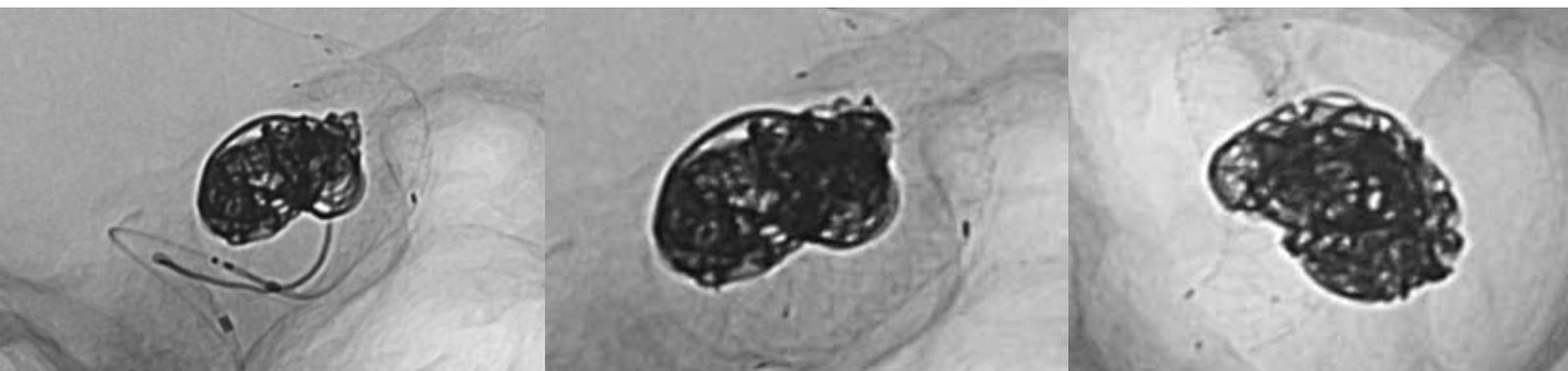


SEM (scanning electron microscope) image of the surface

VISIBLE

Enhanced radiopacity of the Platinum-Nitinol composite wire allow the visibility of the entire contour of the stent. Three additional Platinum markers at each end plus the middle marker allow an accurate placement.

STENT ASSISTED COILING WITH ACCERO®



Initial Deployment of ACCERO® 4.5 x 20 mm

ACCERO® fully deployed

Final Angio

ORDERING INFORMATION

Labelled ACCERO® Stent Ø (mm)	Labelled ACCERO® Stent Length (mm)	Reference Number	Recommended Vessel Ø (mm)	Recommended MC for Delivery (inch)
2.5	10	01-000800	1.5 – 2.5	0.0165-0.017
	15	01-000801		
	20	01-000802		
3.5	10	01-000806	2.5 – 3.5	
	15	01-000807		
	20	01-000808		
	25	01-000841		
4.5	15	01-000813	3.5 – 4.5	
	20	01-000814		
	25	01-000842		

Product Name	Reference Number*	ID (inch)	OD dist. / prox. (French)	Usable Length (cm)
NeuroSlider® 17	01-000272	0.0165	1.9 / 2.1	155

* For availability please contact your local representative from Acandis®.

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www.acandis.com

ORDERING INFORMATION | ACCERO®

Labelled ACCERO® Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required / Recommended Microcatheters for Delivery (Inch)
2.5 × 10	01-000800	2.5	10	1.5 – 2.5	0.0165 – 0.017 NeuroSlider® 17 DLC
2.5 × 15	01-000801	2.5	15	1.5 – 2.5	
2.5 × 20	01-000802	2.5	20	1.5 – 2.5	
3.0 × 10	01-000803	3.0	10	2.0 – 3.0	
3.0 × 15	01-000804	3.0	15	2.0 – 3.0	
3.0 × 20	01-000805	3.0	20	2.0 – 3.0	
3.5 × 10	01-000806	3.5	10	2.5 – 3.5	
3.5 × 15	01-000807	3.5	15	2.5 – 3.5	
3.5 × 20	01-000808	3.5	20	2.5 – 3.5	
3.5 × 25	01-000841	3.5	25	2.5 – 3.5	
4.0 × 15	01-000810	4.0	15	3.0 – 4.0	
4.0 × 20	01-000811	4.0	20	3.0 – 4.0	
4.0 × 25	01-000845	4.0	25	3.0 – 4.0	

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UNIQUE FLEXIBILITY

ACCLINO® flex plus Stent



- Improved visibility
- New range for more treatment options
- For microcatheters with 0.0165 – 0.021" ID

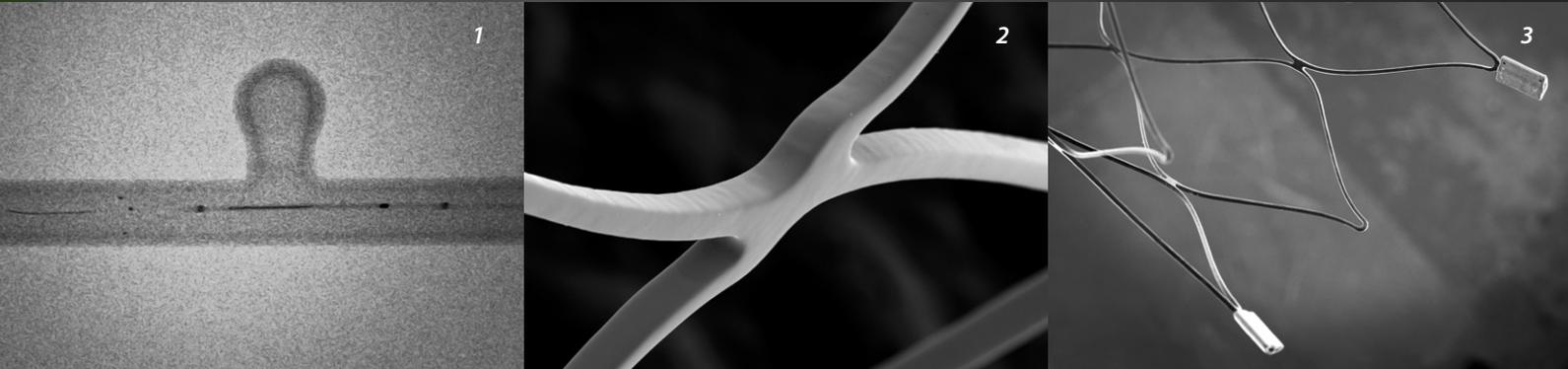
xcandis®

ENGINEERING STROKE SOLUTIONS



UNIQUE FLEXIBILITY

The optimised asymmetric cell design of the closed cell laser-cut Stent ensures the highest flexibility in its class. The Stent displays enhanced expansion behaviour, excellent vessel wall apposition and optimal conformability even in tortuous vessel anatomies.

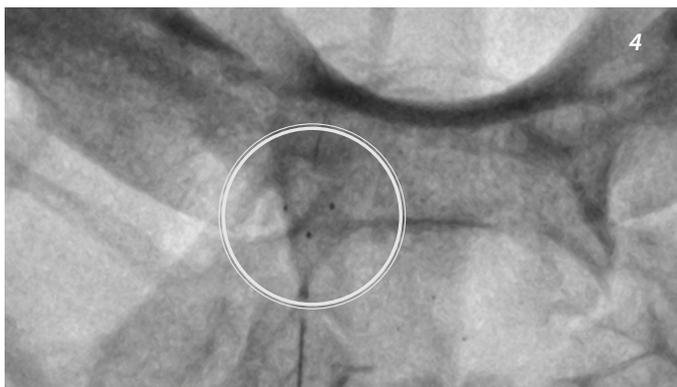
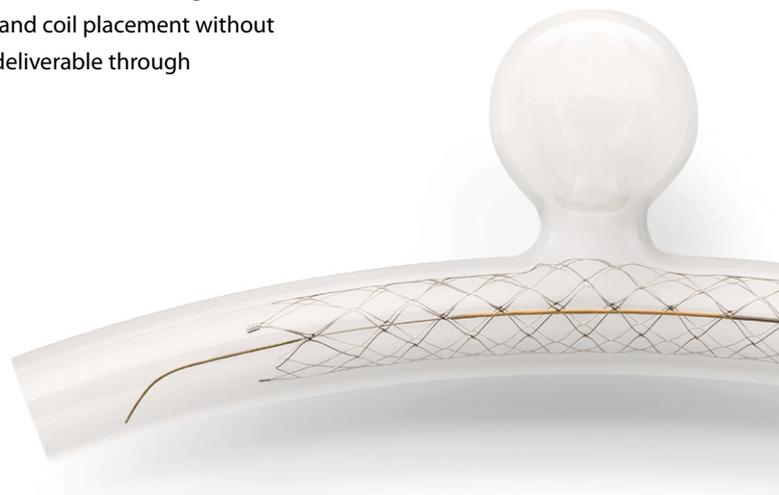


MORE TREATMENT OPTIONS

The new ACCLINO® flex plus Stent provides an increased range and is suitable for vessel diameters from 1.5 to 6.0 mm. For an easy handling all sizes from 3.0 – 5.5 mm are deliverable through microcatheters with 0.0165" – 0.017" ID. This allows a sequential stent and coil placement without the changing of the microcatheter. The 6.5 mm diameter devices are deliverable through microcatheters with 0.021" ID.

NEW X-RAY MARKER

Visibility leads to maximum safety. **The three flat Platinum-Iridium X-ray markers on each end of the ACCLINO® flex plus Stent and the two golden transport wire markers** support a safe and precise placement under fluoroscopy.



Captions:

- 1 Improved visibility
- 2 SEM (scanning electron microscope) image of the surface
- 3 Three low profile Platinum-Iridium X-ray markers
- 4 Good visibility even behind solid bone structures



Highly flexible self-expanding nitinol Stent for the treatment of intracranial aneurysms

FLEXIBLE

- Excellent vessel wall apposition and exceptional conformability
- Enhanced expansion behaviour due to balanced radial force and adaptive cell geometry

SECURE & VISIBLE

- Improved X-ray marker concept
- Maximum vessel lumen patency
- Low thrombogenicity

RELIABLE

- Enhanced delivery and accurate placement
- Resheathability

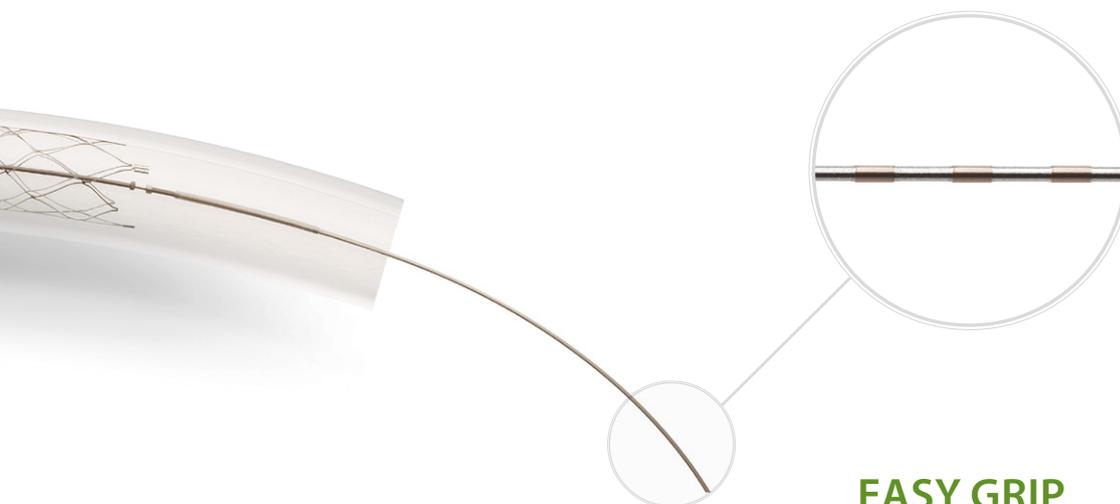
REPOSITIONABLE

The proximal transport wire markers indicate the “point of no return” up to where the Stent can be resheathed securely. The ACCLINO® flex plus Stent can be recaptured and repositioned up to 90% of its length – if needed.

REDUCED THROMBOGENICITY

The perfectly electropolished stent cell connectors, only between 50 to 70 µm thin, occupy minimal space in the vessel lumen and lead to a low thrombogenicity¹.

¹ (Brassel et. Al, *j Neurointervent Surg* 2016. 0:1-6)



EASY GRIP

The sleek surface of the transport wire changes into a unique gripped surface, perceptible visually and by touch at the fluoroscopy marker point, to enhance the grip and push for a controlled and safe placement.

ORDERING INFORMATION | ACCLINO® flex plus

Labelled ACCLINO® flex plus Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required / Recommended Microcatheters for Delivery (Inch)	
HRF 3.0 × 15 3.0 × 20 3.0 × 25 3.0 × 30 3.0 × 35	01-001122	3.0	15	1.5–2.5	0.0165 – 0.017 NeuroSlider® 17 NeuroSlider® 17 DLC	
	01-001123	3.0	20	1.5–2.5		
	01-001124	3.0	25	1.5–2.5		
	01-001125	3.0	30	1.5–2.5		
	01-001126	3.0	35	1.5–2.5		
3.5 × 15 3.5 × 20 3.5 × 25 3.5 × 30 3.5 × 35	01-001132	3.5	15	1.5–3.0		
	01-001133	3.5	20	1.5–3.0		
	01-001134	3.5	25	1.5–3.0		
	01-001135	3.5	30	1.5–3.0		
	01-001136	3.5	35	1.5–3.0		
HRF 4.0 × 15 4.0 × 20 4.0 × 25 4.0 × 30 4.0 × 35	01-001142	4.0	15	2.5–3.5		
	01-001143	4.0	20	2.5–3.5		
	01-001144	4.0	25	2.5–3.5		
	01-001145	4.0	30	2.5–3.5		
	01-001146	4.0	35	2.5–3.5		
4.5 × 15 4.5 × 20 4.5 × 25 4.5 × 30 4.5 × 35	01-001152	4.5	15	2.5–4.0		
	01-001153	4.5	20	2.5–4.0		
	01-001154	4.5	25	2.5–4.0		
	01-001155	4.5	30	2.5–4.0		
	01-001156	4.5	35	2.5–4.0		
HRF 5.0 × 15 5.0 × 20 5.0 × 25 5.0 × 30 5.0 × 35	01-001162	5.0	15	3.0–4.5		
	01-001163	5.0	20	3.0–4.5		
	01-001164	5.0	25	3.0–4.5		
	01-001165	5.0	30	3.0–4.5		
	01-001166	5.0	35	3.0–4.5		
5.5 × 20 5.5 × 25 5.5 × 30 5.5 × 35	01-001173	5.5	20	3.5–5.0		
	01-001174	5.5	25	3.5–5.0		
	01-001175	5.5	30	3.5–5.0		
	01-001176	5.5	35	3.5–5.0		
6.5 × 20 6.5 × 25 6.5 × 30 6.5 × 35	01-001193	6.5	20	4.0–6.0		0.021 NeuroSlider® 21 NeuroSlider® 21 DLC
	01-001194	6.5	25	4.0–6.0		
	01-001195	6.5	30	4.0–6.0		
	01-001196	6.5	35	4.0–6.0		
HRF 8.0 × 20* 8.0 × 30* 8.0 × 40* 8.0 × 60*	01-001213	8.0	20	6.0–7.0		0.027 NeuroSlider® 27 (DLC)
	01-001215	8.0	30	6.0–7.0		
	01-001217	8.0	40	6.0–7.0		
	01-001221	8.0	60	6.0–7.0		

HRF: High Radial Force – compared to ACCLINO® flex plus Stents within the same recommended vessel diameter.

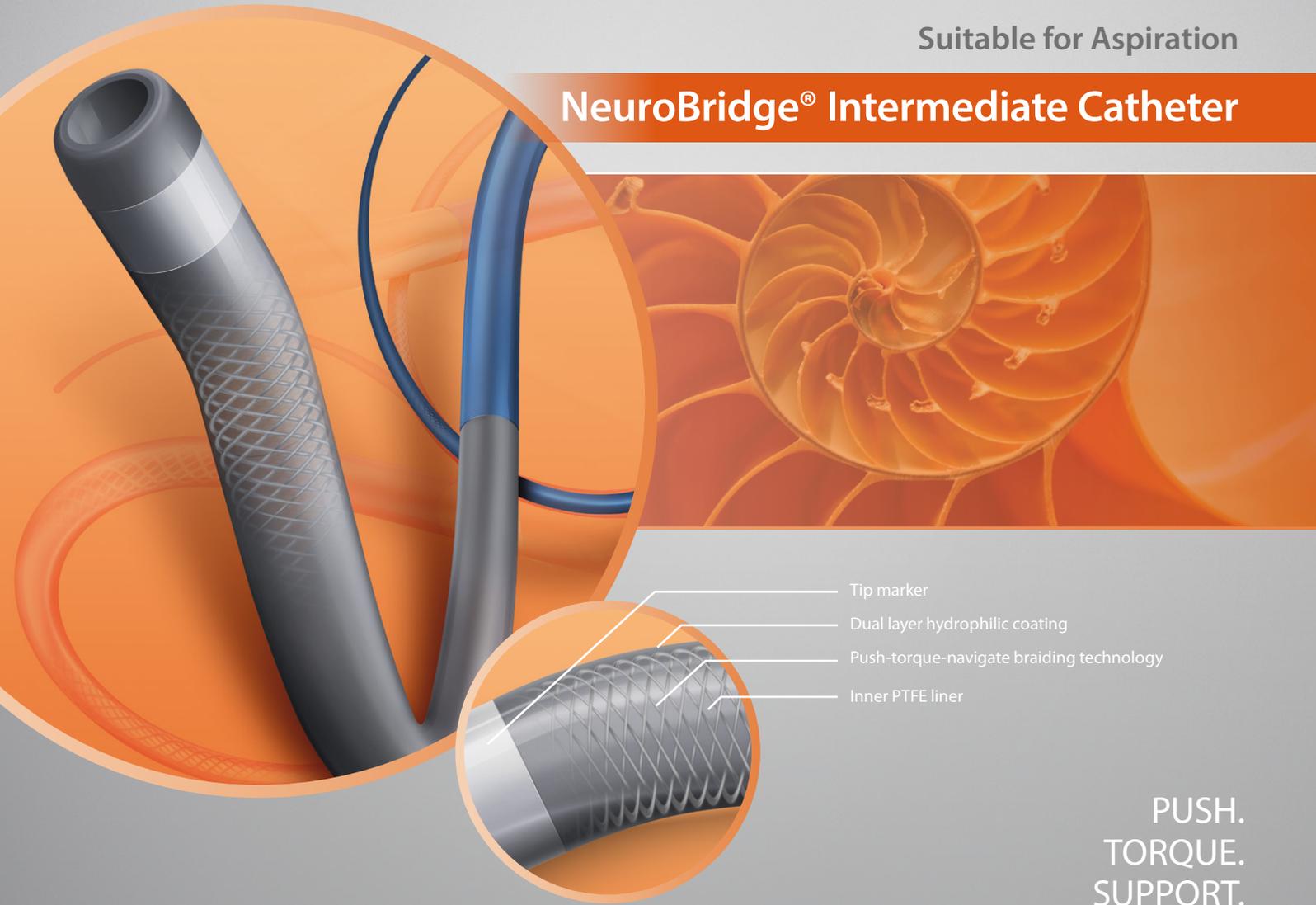
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CE 0297

Suitable for Aspiration

NeuroBridge® Intermediate Catheter



Tip marker

Dual layer hydrophilic coating

Push-torque-navigate braiding technology

Inner PTFE liner

PUSH.
TORQUE.
SUPPORT.

xcandis®

ENGINEERING STROKE SOLUTIONS

FEATURES AND BENEFITS OF THE NeuroBridge®

PUSH.

- Proximal shaft stiffness leads to superior pushability
- Dual layer hydrophilic coating ensures enhanced lubricity and durability

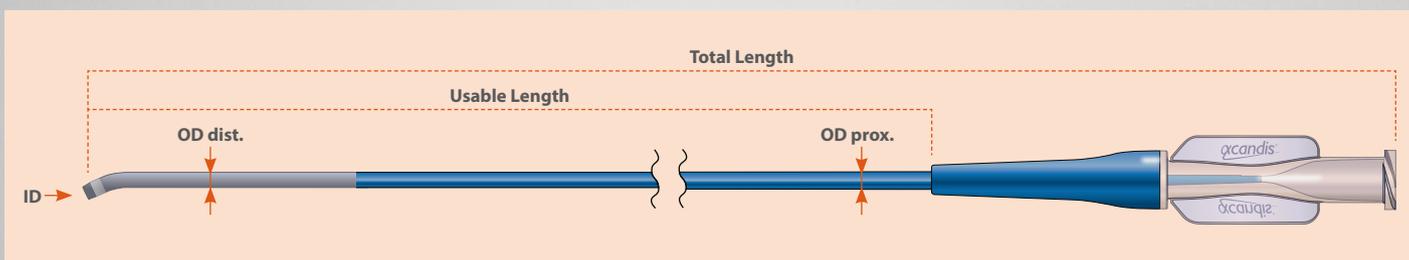
TORQUE.

- Push-torque-navigate braiding technology induces excellent torquability
- Multi polymer shaft construction consisting of 5 different zones with smooth transition from hub to tip ensures precise navigation and optimized torque control
- 25° multi-purpose tip shape enables an easy and safe vessel targeting

SUPPORT.

- Robust inner lumen leads to enhanced stability and safety for strong and powerful aspiration
- Special braiding construction ensures overall increased kink and ovalization resistance
- Soft, rounded and flexible tip allows atraumatic access even through tortuous anatomies
- Low friction inner PTFE liner assures smooth passage and safe delivery of microcatheters

SPECIFICATIONS



ORDERING INFORMATION

Product Name	Reference Number	ID (Inch)	OD dist. (French/Inch)	OD prox. (French/Inch)	Usable Length (cm)	Total Length (cm)	Tip Shape
NeuroBridge® 39	01-000508	0.039	3.9/0.051	4.2/0.055	125	131	Multi-Purpose 25°
NeuroBridge® 39	01-000509	0.039	3.9/0.051	4.2/0.055	135	141	Multi-Purpose 25°
NeuroBridge® 39	01-000510	0.039	3.9/0.051	4.2/0.055	145	151	Multi-Purpose 25°
NeuroBridge® 52	01-000518	0.052	5.0/0.066	5.3/0.070	105	111	Multi-Purpose 25°
NeuroBridge® 52	01-000511	0.052	5.0/0.066	5.3/0.070	115	121	Multi-Purpose 25°
NeuroBridge® 52	01-000512	0.052	5.0/0.066	5.3/0.070	125	131	Multi-Purpose 25°
NeuroBridge® 52	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°
NeuroBridge® 65	01-000514	0.065	6.1/0.080	6.3/0.083	115	121	Multi-Purpose 25°
NeuroBridge® 65	01-000515	0.065	6.1/0.080	6.3/0.083	125	131	Multi-Purpose 25°

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MOVING ELEGANCE

NeuroSlider® Microcatheter DLC



- Superior torqueability and pushability
- Smooth and safe device delivery
- Longlasting tip shape retention

ADVANCE.

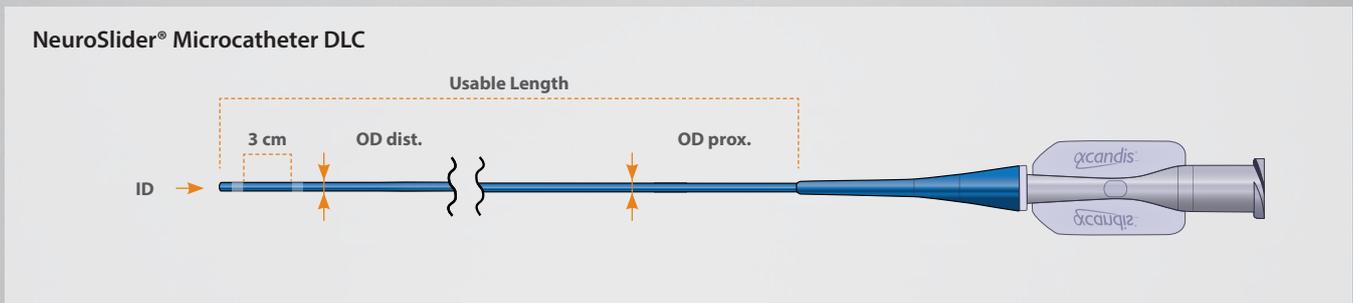
- Dual layer hydrophilic coating ensures outstanding lubricity and durability.
- Braiding / coiling reinforcement induces superior torqueability and significant reduction of ovalisation and elongation.

NAVIGATE.

- Shapeable tip with lasting shape retention allows excellent distal navigation even in tortuous anatomies.
- Multi polymer construction consisting of different flexibility zones with smooth transitions from maximum stability at the hub to maximum flexibility at the tip permits precise and effective navigation.

DELIVER.

- Inner PTFE liner minimises friction and allows a controlled and safe delivery of therapeutic and diagnostic agents.
- Advanced hub design with a transparent window results in a precise device transfer into the hub.



ORDERING INFORMATION

Product Name	Reference Number	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)	Tip Shape	Tip Marker
NeuroSlider® 17	01-000272	0.0165	1.9 / 2.1	155	Straight (shapeable)	2
NeuroSlider® 17 DLC	01-000282	0.0165	1.9 / 2.3	155	Straight (shapeable)	2
	01-000283	0.0165	1.9 / 2.3	160	Straight (shapeable)	2
	01-000284	0.0165	1.9 / 2.3	167	Straight (shapeable)	2
NeuroSlider® 21	01-000273	0.021	2.4 / 2.5	155	Straight (shapeable)	2
NeuroSlider® 21 DLC	01-000292	0.021	2.2 / 2.6	155	Straight (shapeable)	2
	01-000293	0.021	2.2 / 2.6	160	Straight (shapeable)	2
	01-000294	0.021	2.2 / 2.6	167	Straight (shapeable)	2
NeuroSlider® 27 (DLC)	01-000274	0.027	3.0 / 3.6	155	Straight (shapeable)	1

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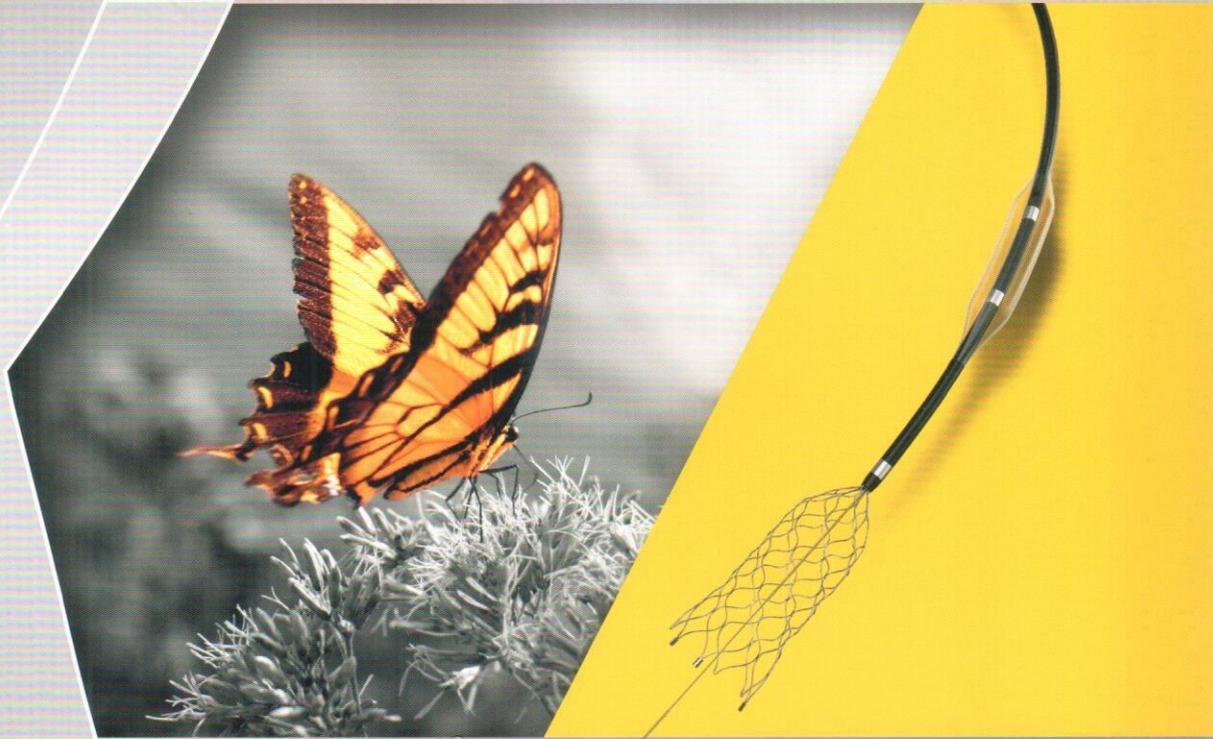
CE 0297

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SIMPLY UNIQUE

ICAD* Treatment with

NeuroSpeed® PTA Balloon Catheter and CREDO® Stent



- Over-the-wire system

8.84cm OTW (over-the-wire)

- Flexible self-expanding highly visible stent
- Deliverable through 0.0165" NeuroSpeed® PTA Balloon Catheter

* ICAD Intracranial Atherosclerotic Disease

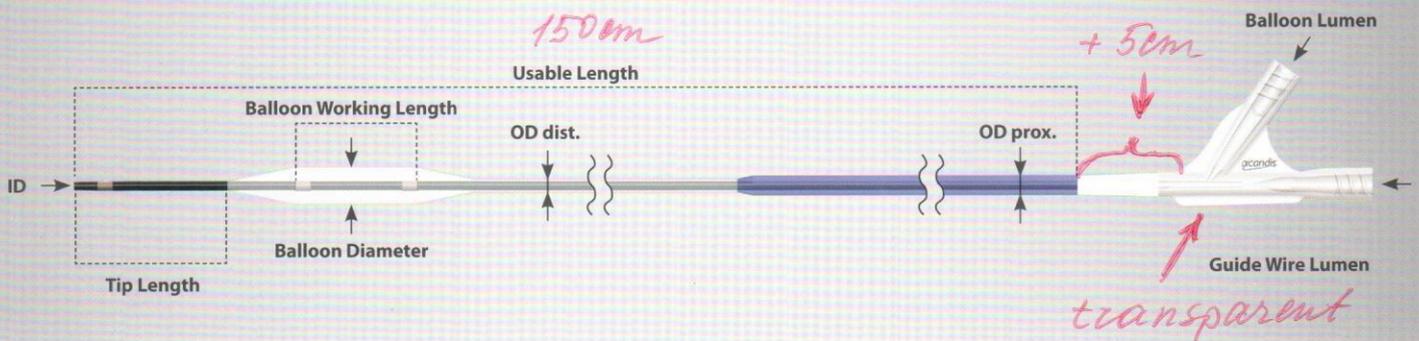
xcandis®

ENGINEERING STROKE SOLUTIONS

NeuroSpeed® PTA Balloon Catheter



FEW SIZES – BIG IMPACT



FLEXIBLE

The NeuroSpeed® PTA Balloon Catheter is ideal for gentle and controllable PTA of intracranial stenosis.

If stent placement is required for stabilisation of the stenotic lesion, the CREDO® Stent can be delivered through the low-profile NeuroSpeed® PTA Balloon Catheter without exchange manoeuvre.

SMOOTH

The NeuroSpeed® PTA Balloon Catheter features a slim entrance profile and double hydrophilic coating.

The flexible 10 mm tip, with distal tip X-ray marker, ensures atraumatic access and easy navigation. With a usable length of 150 cm, it is possible to reach more distal vessels.

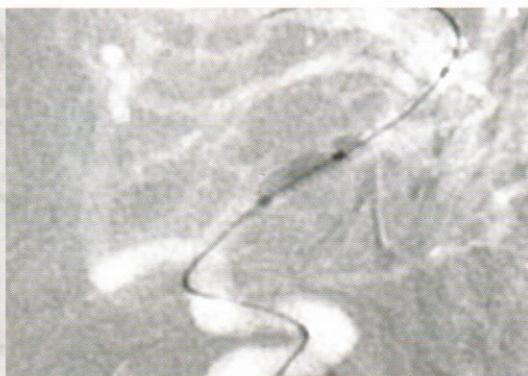
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duble stratificat*

EFFECTIVE

The semi-compliant balloon material of the NeuroSpeed® PTA Balloon Catheter enables a precise and controllable inflation behaviour for gentle and effective dilation. The portfolio consist of only 6 sizes with nominal balloon diameters ranging from 1.5 to 4.0 mm.



Initial degree of stenosis 80 %
Pre Dilatation



NeuroSpeed® PTA Balloon Catheter 2.0 x 8 mm
Inflation



Final degree of stenosis ~ 10 %
Post Dilatation

ORDERING INFORMATION

www.acandis.com

Labelled CREDO® Dimensions (mm)	Reference Number	Stent Diameter (mm)	Stent Length (mm)	Recommended Vessel Diameter (mm)	Required Catheter for Delivery
3.0 × 15	01-000930	3.0	15	2.0–2.5	NeuroSpeed® PTA Balloon Catheter
3.0 × 20	01-000931	3.0	20	2.0–2.5	NeuroSpeed® PTA Balloon Catheter
4.0 × 15	01-000940	4.0	15	2.5–3.5	NeuroSpeed® PTA Balloon Catheter
4.0 × 20	01-000941	4.0	20	2.5–3.5	NeuroSpeed® PTA Balloon Catheter
5.0 × 15	01-000950	5.0	15	3.5–4.5	NeuroSpeed® PTA Balloon Catheter
5.0 × 20	01-000951	5.0	20	3.5–4.5	NeuroSpeed® PTA Balloon Catheter

Labelled NeuroSpeed® Dimensions (mm)	Reference Number	Balloon Diameter (mm)	Balloon Working Length (mm)	ID (Inch)	OD dist. / prox. (French)	Usable Length (cm)
1.5 × 8	01-000605	1.5	8	0.0165	2.7 / 3.7	150
2.0 × 8	01-000600	2.0	8	0.0165	2.7 / 3.7	150
2.5 × 8	01-000601	2.5	8	0.0165	2.7 / 3.7	150
3.0 × 8	01-000602	3.0	8	0.0165	2.7 / 3.7	150
3.5 × 8	01-000603	3.5	8	0.0165	2.7 / 3.7	150
4.0 × 8	01-000604	4.0	8	0.0165	2.7 / 3.7	150

dimensioni

Inflation Pressure (bar)	NeuroSpeed® Diameter (mm)					
	1.5	2.0	2.5	3.0	3.5	4.0
2.0	1.21	1.72	2.09	2.42	3.06	3.26
4.0	1.37	1.84	2.33	2.78	3.25	3.72
6.0	1.50*	2.00*	2.50*	3.00*	3.50*	4.00*
8.0	1.67	2.16	2.65	3.22	3.69	4.23
10.0	1.85	2.27	2.75	3.38	3.83	4.37
12.0	2.02	2.39	2.87	3.54	3.97**	4.53**
14.0	2.20**	2.52**	2.98**	3.73**	-	-

* Nominal pressure ** Rated burst pressure

All changes or modifications, may they be technical or other, or changes in the availability of products are expressly reserved.

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