TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 7
la Documentația standard nr.115
din 15.09.2021

CERERE DE PARTICIPARE

Către **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr. *ocds-b3wdp1-MD-1637321868736, ID:21047154 din 21.12.2021* privind aplicarea procedurii pentru atribuirea contractului privind *achiziționarea de consumabile angiografice pentru cabinetul Neuroradiologie Intervențională al IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022*, noi, *Tehnomedica SRL,* am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării: 20.12.2021

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind *achiziționarea de consumabile angiografice pentru cabinetul Neuroradiologie Intervențională al IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022* prin procedura de achiziție licitație deschisă, pentru o durată de 160 zile, (una sută șaizeci zile), respectiv până la data de 30.05.2022 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 21.12.2021

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

F/COM/CC/23/02

Nr. CIF26-842.2020
Data: 13 Februarie 2020

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**

L.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

Mobiasbanca - OTP Group S.A. • Capital Social: 100 000 000 MDL • Număr de înregistrare de stat – 1002600006089
bd. Ştefan cel Mare şi Sfînt 81A • MD-2012 Chişinău, Moldova • telefon: +373 22 256 456 • e-mail: info@mobiasbanca.md • www.mobiasbanca.md

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1002600053256

Data înregistrării **17.04.2002**

Data eliberării **16.02.2005**

Bolboceanu Adela, registrator de stat
Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT 109 L.Ș.

MD 0027040

LISTA FONDATORILOR

SRL „TEHNOMEDICA”

Fondator unic: Roibu Tatiana

IDNP: 0992606484592

Nr. de contact: +37369909500

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2121180 **din** / от 09.12.2021

1. Destinația / Назначение

PENTRU PARTICIPARE LA PROCEDURI DE ACHIZIȚII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
TEHNOMEDICA S.R.L.	1002600053256
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Ciuflea nr.38 bl.1	0130-SEC.CENTRU

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 24.12.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Centru — **Funcția**/Должность

Semnătura/Подпись

Albina IȘCOVA — **Numele și prenumele**/Фамилия и имя

L.Ș/ М.П.

Executor: Gavajuc V. — **Numele și prenumele**/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 09.12.2021 ora 8:51:46
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

Data prezentării 21.04.2021 14:23:33

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2020 - 31.12.2020

Entitatea: TEHNOMEDICA S.R.L.
Cod CUIÎO: 37700778
Cod IDNO: 1002600053256

Sediul:
MD: 2001
Raionul(municipiul): 102, DDF CENTRU
Cod CUATM: 0130, SEC.CENTRU
Strada: SECTORUL CENTRAL STR.Ciuflea nr.38 bl.1

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37369153407
WEB:
E-mail: ecaterin.popescu@gmail.com
Numele și coordonatele al contabilului-șef: Dl (dna) Popescu Ecaterina Tel. 022601102

Numărul mediu al salariaților în perioada de gestiune: 5 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Roibu Tatiana

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE **I. Imobilizări necorporale**			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020	407	319
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024	407	319
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040	1404169	2861138
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	1404576	2861457
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2364772	2174915
	din care: 3.1. clădiri	081	1147126	1038156
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	28036	34609
	3.4. mijloace de transport	084	1128114	1042950

A.	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	61496	59200
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2364772	2174915
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	3769348	5036372
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	31417	4996
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	1242672	1326025
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	1274089	1331021
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	1090879	1022910
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	48364	6546
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340	838	
	6. Cheltuieli anticipate curente	350	5421	13569
	7. Alte active circulante	360	63104	31297
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	1208606	1074322
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380	150000	700000
	2. Investiții financiare curente în părți afiliate, total	390		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400	150000	700000
	IV. Numerar și documente bănești	410	8666885	6916759
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	11299580	10022102
	TOTAL ACTIVE (rd.230 + rd.420)	430	15068928	15058474
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social și neînregistrat**			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	14214199	12018454
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	2687032
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	14214199	14705486
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	14219599	14710886
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care: 2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	275321	149510
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	249170	
	6. Datorii față de personal	760		977
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	324838	197101
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810		
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	849329	347588
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	15068928	15058474

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2020 pînă la 31.12.2020

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	21436657	16620028
din care: veniturи din vînzarea produselor și mărfurilor	011	17775775	13778008
veniturи din prestarea serviciilor și executarea lucrărilor	012	3660882	2842020
veniturи din contracte de construcție	013		
veniturи din contracte de leasing	014		
veniturи din contracte de microfinanțare	015		
alte venituri din vînzări	016		
Costul vînzărilor, total	020	15063379	12527753
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	15063379	11595535
costul serviciilor prestate și lucrărilor executate terților	022		932218
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	6373278	4092275
Alte venituri din activitatea operațională	040	41518	986
Cheltuieli de distribuire	050	8704	
Cheltuieli administrative	060	2164450	1569273
Alte cheltuieli din activitatea operațională	070		17430
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	4241642	2506558

Venituri financiare, total	090	741192	1257613
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	741192	1257613
Cheltuieli financiare, total	100	680243	666851
din care: cheltuieli privind dobînzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	680243	666851
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	60949	590762
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	60949	590762
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	4302591	3097320
Cheltuieli privind impozitul pe venit	170	569409	410288
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	3733182	2687032

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2020 pînă la 31.12.2020

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010	5400			5400
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5400			5400
II.	**Prime de capital**	070				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	14214199		2195745	12018454
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	2687032		2687032
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	14214199	2687032	2195745	14705486
V.	**Rezerve din reevaluare**	170				
VI.	**Alte elemente de capital propriu**	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	14219599	2687032	2195745	14710886

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2020 pînă la 31.12.2020

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	24785768	17211991
Plăți pentru stocuri și servicii procurate	020	14966422	13370873
Plăți către angajați și organe de asigurare socială și medicală	030	596384	554000
Dobînzi plătite	040		
Plata impozitului pe venit	050	408570	414542
Alte încasări	060	1459997	2220519
Alte plăți	070	4278234	5025576
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	5996155	67519
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150	992852	630000
Plăți aferente rambursării creditelor și împrumuturilor	160	330000	830000
Dividende plătite	170	1968000	2019064
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-1305148	-2219064
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	4691007	-2151545
Diferențe de curs valutar favorabile (nefavorabile)	220	-80398	401419
Sold de numerar la începutul perioadei de gestiune	230	4056276	8666885
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	8666885	6916759

Documente atașate - Notă explicativă (fișierul pdf)

Versiune de imprimare
Salvare

Recipisa

Respondent
Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2020
Data prezentarii: 21.04.2021
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 21.04.2021 14:23:33

Versiune de imprimare
Salvare

Recipisa 2

Respondent
Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2020
Data prezentarii: 21.04.2021
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.04.2021 18:24:30

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1637321868736,
ID:21047154 din 21.12.2021

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante/beneficiarului pentru produsele oferite în cadrul licitației prenonate privind ***achiziționarea de consumabile angiografice pentru cabinetul Neuroradiologie Intervențională al IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022.***

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1637321868736,
ID:21047154 din 21.12.2021

Declarație privind înregistrarea dispozitivelor medicale

Prin prezenta, declarăm că, produsele oferite în cadrul licitației deschise prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md

Cu respect,

Director Tatiana Roibu

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1637321868736,
ID:21047154 din 21.12.2021

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate la momentul livrării a produselor oferite în cadrul licitației prenonate privind ***achiziționarea de consumabile angiografice pentru cabinetul Neuroradiologie Intervențională al IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022*** va constitui cel puțin 80% din termenul total de valabilitate a acestora, dar nu mai mic de 12 luni.

Cu respect,

Director Tatiana Roibu

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01966**

Issued To: **Mölnlycke Health Care AB**
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

...making excellence a habit.™

By Royal Charter

Certificate No: CE 01966

Certificate Scope:

Those aspects of manufacture related to securing and maintaining sterility of absorbent tracheostomy dressing, sterile scar management dressing and transparent adhesive IV film dressing.

Those aspects of manufacture related to securing and maintaining sterility of negative pressure wound therapy (NPWT) accessories, surgical and equipment drapes and surgical gowns.

Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with article 12 of the MDD.

First Issued: **1998-06-29** Date: **2018-05-30** Expiry Date: **2023-06-28**

...making excellence a habit.™

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mölnlycke Health Care AB
Box 13080
Gamlestadsvägen 3C
SE-402 52 Göteborg
Sweden

Holds Certificate Number: **MD 83345**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves.
The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-07-21
Effective Date: 2018-11-28
Latest Revision Date: 2018-11-26
Expiry Date: 2021-11-27

...making excellence a habit.™

Certificate No: **MD 83345**

Location	Registered Activities
Mölnlycke Health Care AB Box 13080 Gamlestadsvägen 3C SE-402 52 Göteborg Sweden	The design, development, manufacture, marketing, sales and distribution of sterile wound and scar dressings, porcine collagen wound dressings, open wound products, cavity dressings, polyurethane foam with and without additives for incorporation into medical devices, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and support, sterile wound irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves. The design, development, manufacture, marketing, sales and distribution of single patient use Negative Pressure wound therapy pumps and accessories. Distribution of laparoscopic instruments.
Molnlycke Health Care Pty Ltd Level 4 12 Narabang Way Belrose New South Wales 2085 Australia	The provision of sales, marketing, and distribution of sterile wound and scar dressings, open wound products, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non-sterile textile bandages and supports, sterile irrigation solutions, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non-sterile medical gloves and sterile surgical gloves and laparoscopic instruments.

Original Registration Date: 2004-07-21

Effective Date: 2018-11-28

Latest Revision Date: 2018-11-26

Expiry Date: 2021-11-27

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

This is to certify that:

Mölnlycke Health Care AB
Gamlestadvägen 3 C
S-402 52
Göteborg
Sweden

Holds Certificate No: **FM 39247**

and operates a Quality Management System which complies with the requirements of ISO 9001:2000 for the following scope:

The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves.

The design, development and manufacture of pharmaceuticals and other healthcare products.

For and on behalf of BSI:

Managing Director, BSI Management Systems (CEMEA)

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

UKAS QUALITY MANAGEMENT 003

Certificate No: **FM 39247**

Location	***Registered Activities***
Mölnlycke Health Care AB Gamlestadsvägen 3 C S-402 52 Göteborg Sweden	The design, development and manufacture of sterile wound and scar dressings, open wound products, wound management gels, cavity dressings, swabs, sponges, sterile alcohol wipes, skin care products, non sterile textile bandages and supports, sterile wound irrigation solutions, abdominal towels, operation sets, surgical and equipment drapes, procedure packs, surgical gowns and other medical staff clothing for use in the patient environment, sterile and non sterile medical gloves and sterile surgical gloves. The design, development and manufacture of pharmaceuticals and other healthcare products.
Mölnlycke Health Care Oy PO Box 76 Saimaankatu 6 Mikkeli FIN 50101 Finland	Manufacture of swabs, sponges, towels, wound dressings, open wound products, scar dressings and procedure packs.
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt 160 Bangplee Industrial Estate Bangna-Trad Rd Samutprakarn Bansaothong 10540 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB T/A Mölnlycke Health Care SA Parc Industrial B-4300 Waremme Belgium	Manufacture of sterile drapes, operating sets and procedure packs.
Mölnlycke Health Care Klinipro s.r. Na Novem Poli 382 Prumyslova zona Karvina Karvina - State Mesto 733 01 Czech Republic	Manufacture of surgical drapes and procedure packs.

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

Certificate No: **FM 39247**

Location	***Registered Activities***
Mölnlycke Health Care AB Mölnlycke Health Care (Thailand) Lt Amata Nakorn (Bang Pakong) Industrial Estate 700/461 Moo Bangha-Trad Rd. KM.57 Tambol Donhuaroh, Amphur Muang Chonburi 20000 Thailand	Manufacture of surgical drapes and sets, equipment drapes, surgical and protective gowns and other staff clothing.
Mölnlycke Health Care AB Tubiton House Medlock Street Oldham OL1 3HS United Kingdom	The design, development and manufacture of sterile wound dressings, non sterile textile bandages and supports, procedure packs, sterile irrigation solutions, sterile alcohol wipes, skin care products, pharmaceuticals and other healthcare products.
Mölnlycke Health Care AB Lot 9, Lorong Perusahaan 4 Kulim Industrial Estate PO Box 52, 09000 Kulim Kedah Darulaman Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Plot 204 Kawasan Perindustrian Kula Ketil Phas II 09300 Kula Ketil Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.
Mölnlycke Health Care AB Lot B5 & B6 Kawasan Perindustrian Miel Batang Kali Phase II 44300 Batang Kali Malaysia	The design, development and manufacture of sterile and non sterile medical gloves and sterile surgical gloves.

Originally registered: **31/03/1998** Latest Issue: **10/01/2007**

Title: Mölnlycke Procedure Trays MDD Article 12 (former Class IIa trays)

We, Mölnlycke Health Care AB, Gamlestadsvägen 3C, Box 13080, SE-402 52 Göteborg, Sweden being the assembler of the following declare that the procedure packs listed in the attached schedule are in conformity with the provisions of Article 12 in the Council Directive 93/42/EEC of 14 June 1993, as amended by 2007/47/EEC, concerning medical devices, the Medical Devices Act SFS 1993:584 and the Swedish Medical Product Agency regulations and guidelines: Medical Devices, LVFS 2003:11, as amended by LVFS 2009:18.

Trade Name: *Mölnlycke® Procedure Trays*

The mutual compatibility of each device within the Mölnlycke Health Care procedure packs has been verified in accordance with the relevant instructions for use provided by the manufacturer of each device and / or the approved indications for use of each device.

Where appropriate, the relevant instructions for use are provided.

Procedure packs are assembled in accordance with a documented quality management system and therefore, subject to internal controls and inspection prior to release that ensures the safety, quality and performance of the procedure pack.

Sterilisation after assembly:	*EtO, Ethylene Oxide*
CE certificate	*CE 01966*
Certificate issued by	*BSi (0086)*

For sterilised procedure packs, the sterilisation process is performed in accordance with the manufacturer(s)' instructions and follows the procedures of Annex V of 93/42/EEC.

For systems and procedure packs, the intervention of the notified body is limited to the aspects of the procedure relating to the obtaining of sterility.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person
RA Manager, Medical Devices

Product reference	Product Name	Product Description / included devices	GMDN code
See products linked to this document in the ERP system.			

Product name, article number, manufacturer and notified body number for each device included in the system or procedure pack can be found in the BOM in the ERP system.

Signed for and on behalf of Mölnlycke Health Care

Authorised Signatory:

Name of signing person

RA Manager, Medical Devices

Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany

erklären in eigener Verantwortung, dass das/die Produkt/e

hereby declare in our own responsibility that the product/s

Procedure Kits

(Artikelnummern siehe Anlage)

Procedure Kits

(article numbers see attachment)

a) die gegenseitige Kompatibilität der Geräte in Übereinstimmung mit den Anweisungen des Herstellers geprüft wird, und dass alle Operationen in Übereinstimmung mit diesen Anweisungen ausgeführt werden, und das

a) mutual compatibility of the devices in accordance with the manufacturers instructions is proven and that all operations are carried out in accordance with these instructions, and that

b) das System oder die Behandlungseinheit verpackt und sachdienliche Informationen für die Nutzer, einschließlich der einschlägigen Informationen von den Herstellern mitgeliefert werden; und

b) the system or procedure pack is packed and supplied with relevant information to users incorporating relevant information from the manufacturers; and

c) die gesamte Tätigkeit in geeigneter Weise intern überwacht und kontrolliert wird.

c) the whole activity is subjected to appropriate methods of internal control and inspection.

d) (Falls das System / Behandlungseinheit sterilisiert wird).
Die Sterilisation ist gemäß den Anweisungen des Herstellers erfolgt.

d) (If the system / procedure pack has been sterilised).
The sterilisation has been carried out in accordance with the manufacturer's instructions.

Diese Erklärung basiert auf der Grundlage

declaration is made on basis of

- Artikel 12 Absatz 2 der Medizinprodukte Richtlinie 93/42/EWG
- Paragraph 10 des Medizinproduktegesetzes (Medizinproduktegesetz, 7. August 2002)

- Article 12 part 2 of Medical Device Directive 93/42/EEC
- Paragraph 10 of Medical Devices Act (Medizinproduktegesetz, 7. August 2002)

Dieses Zertifikat ist gültig für die im Anhang I genannten Procedure Kits hergestellt von der B. Braun Melsungen AG, 34209 Melsungen, Deutschland

This certificate is valid for the procedure kits mentioned in the Attachment I manufactured by B. Braun Melsungen AG, 34209 Melsungen, Germany

Datum der ersten Erklärung
2015-01

Date of first declaration
2015-01

Gültig bis
2024-05-26

Valid until
2024-05-26

Berlin, 2020-05-19

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VS

Berlin, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Enthält Komponenten der Klasse/ contains components of Class
5010687	Hahnbankset Uni Münster	Hahnbankset Uni Münster	IIa
5010690	Feinnadelset KH-Stuttgart	Feinnadelset KH-Stuttgart	IIa
5010691	Angiodyn Coroset Villingen-Schwenningen	Angiodyn Coroset Villingen-Schwenningen	IIa
5010701	Coroset Nagold	Coroset Nagold	IIa
5010709	PTCA Set	PTCA Set	IIa
5010714	Port-Punktionsset	Port-Punktionsset	IIa
5010720	EP-Set	EP-Set	IIa
5010727	Laser-Set, KSSP Aarau	Laser-Set, KSSP Aarau	IIa
5010744	Toimenpidesetti Seinäjoe ks, röntgen	Toimenpidesetti Seinäjoe ks, röntgen	IIa
5010764	Angiodynset 3FRR35 15360	Angiodynset 3FRR35 15360	IIa
5010778	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	Angio-Neuro-Set Heinrich-Braun-Krankenhaus	IIa
5010782	Pädiatrie-Set Uni Homburg	Pädiatrie-Set Uni Homburg	IIa
5010783	Set steril pentru Angiografie	Set steril pentru Angiografie	IIa
5010786	Hybrid Set Hirslanden Zürich	Hybrid Set Hirslanden Zürich	IIa
5010794	Angiosetti PHKS, ELFYS	Angiosetti PHKS, ELFYS	IIa
5010800	Bowl 90ml, Round, Blue	Bowl 90ml, Round, Blue	I
5010801	Tab. Neuro / Angiograpfia – H. Egas Moniz	Tab. Neuro / Angiograpfia – H. Egas Moniz	IIa
5010804	Epiduraalsetti Vaasan ks	Epiduraalsetti Vaasan ks	IIa
5010805	EPU Set HZ Dresden	EPU Set HZ Dresden	IIa
5010806	Hahnbankset Nagold	Hahnbankset Nagold	IIb
5010808	Contrast-Saver HKZ Rotenburg	Contrast-Saver HKZ Rotenburg	IIa
5010811	NNI – Angiography Set	NNI – Angiography Set	IIa
5010817	UNI-Set_Novomed	UNI-Set_Novomed	IIa
5010820	Angiodyn-Schale, 60 ml, transp.	Angiodyn-Bowl, 60 ml, transp.	Is
5010830	Cover Drape 90 X 90 CM	Cover Drape 90 X 90 CM	I
5010833	Sahlgrenska Sotra	Sahlgrenska Sotra	IIa
5010840	Kidney Dish Blue	Kidney Dish Blue	I
5010850	Cover Drape 152 X 228 CM	Cover Drape 152 X 228 CM	I
5010860	Angiodyn-Schale, 120 ml, transp.	Angiodyn-Bowl, 120 ml, transp.	Is
5010868	PTCA Set Bad Rothenfelde	PTCA Set Bad Rothenfelde	IIa
5010871	Angiodyn HKL-Set Bad Tölz	Angiodyn HKL-Set Bad Tölz	IIa
5010874	Untersuchungskittel, Gr. XL	Untersuchungskittel, Gr. XL	Is
5010878	Skejby højre side pakke	Skejby højre side pakke	IIa
5010880	Paineemittaussetti malli 2	Paineemittaussetti malli 2	IIb

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

Manufacturer: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): **Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168177

Valid from: 2020-05-06
Valid until: 2024-05-26

Date, 2020-05-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 012974 0606 Rev. 00

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA guide wires and sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial punture cannula, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713160067

Valid from: 2019-10-08
Valid until: 2022-09-30

Date, 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 012974 0606 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

./.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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® Recanalisation Device
Aperio® Thrombectomy Device
Aperio® Hybrid 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

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

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	170738074
Effective date	2019-03-12
Expiry date	2024-02-27
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,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

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,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

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)

Derivo® Embolisation Device and Derivo® Embolisation System
Derivo® 2 Embolisation Device and Derivo® Embolisation System
Derivo® mini Embolisation Device/ Derivo® mini Embolisation System

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_Derivo Embolisation Device-E_A dated 2018-06-22
STED_CE-Approval_Derivo mini Embolisation Device-E_A dated 2018-09-10
STED_CE-Approval_Derivo Embolisation Device-E_A dated 2019-08-15
411_18e_Report_TFR_Sterilization Inpac_V1 dated 2019-09-23
STED_CE-Approval_Derivo 2 Embolisation Device-E_A dated 2019-10-02

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

Examination report:
411_18e_Report_TFR_Derivo_V1 dated 2018-08-26
411_18e_Report_TFR_Derivo_V2 dated 2018-11-11
411_18e_Report_TFR_Derivo_V3 dated 2019-09-06
10_411_18e_Report_TFR_SterilizationInpac_V1 dated 2019-10-19
0_411_18e_Report_TFR_Derivo2_V1.docx dated 2020-03-26

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

Certificate registration no.	513562 MRA
Certificate unique ID	170767288
Effective date	2020-03-26
Expiry date	2023-08-25
Frankfurt am Main	2020-03-26

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

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:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	516802 MP2016
Certificate unique ID	170774421
Effective date	2021-06-19
Expiry date	2024-06-18
Frankfurt am Main	2021-04-28

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

410.90.en Version 1.0

Declaration of Conformity

according to directive 93/42/EEC

Product	**DERIVO® 2 Embolisation Device & System** Product listing see page 2 et seqq.
Class	**III** **Rule 8, according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/46352**
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 2024-05-26
EC Design Examination Certificate	No. 513562 MRA valid until 2023-08-25
Declaration of Conformity valid until	2023-08-25

Pforzheim, 2021-05-25

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity DERIVO® 2 Embolisation Device & System

Product listing

Article number	Name	Size
01-107001	DERIVO® 2 Embolisation Device short tip	2.5 mm x 10 mm
01-107002	DERIVO® 2 Embolisation Device short tip	2.5 mm x 15 mm
01-107003	DERIVO® 2 Embolisation Device short tip	2.5 mm x 20 mm
01-107004	DERIVO® 2 Embolisation Device short tip	2.5 mm x 25 mm
01-107005	DERIVO® 2 Embolisation Device short tip	3.0 mm x 10 mm
01-107006	DERIVO® 2 Embolisation Device short tip	3.0 mm x 15 mm
01-107007	DERIVO® 2 Embolisation Device short tip	3.0 mm x 20 mm
01-107008	DERIVO® 2 Embolisation Device short tip	3.0 mm x 25 mm
01-107009	DERIVO® 2 Embolisation Device short tip	3.5 mm x 10 mm
01-107010	DERIVO® 2 Embolisation Device short tip	3.5 mm x 15 mm
01-107011	DERIVO® 2 Embolisation Device short tip	3.5 mm x 20 mm
01-107012	DERIVO® 2 Embolisation Device short tip	3.5 mm x 25 mm
01-107013	DERIVO® 2 Embolisation Device	3.5 mm x 30 mm
01-107014	DERIVO® 2 Embolisation Device	4.0 mm x 15 mm
01-107015	DERIVO® 2 Embolisation Device	4.0 mm x 20 mm
01-107016	DERIVO® 2 Embolisation Device	4.0 mm x 25 mm
01-107017	DERIVO® 2 Embolisation Device	4.0 mm x 30 mm
01-107018	DERIVO® 2 Embolisation Device	4.5 mm x 15 mm
01-107019	DERIVO® 2 Embolisation Device	4.5 mm x 20 mm
01-107020	DERIVO® 2 Embolisation Device	4.5 mm x 25 mm
01-107021	DERIVO® 2 Embolisation Device	4.5 mm x 30 mm
01-107022	DERIVO® 2 Embolisation Device	5.0 mm x 15 mm
01-107023	DERIVO® 2 Embolisation Device	5.0 mm x 20 mm
01-107024	DERIVO® 2 Embolisation Device	5.0 mm x 25 mm
01-107025	DERIVO® 2 Embolisation Device	5.0 mm x 30 mm
01-107026	DERIVO® 2 Embolisation Device	5.5 mm x 15 mm
01-107027	DERIVO® 2 Embolisation Device	5.5 mm x 20 mm
01-107028	DERIVO® 2 Embolisation Device	5.5 mm x 25 mm
01-107029	DERIVO® 2 Embolisation Device	5.5 mm x 30 mm

Article number	Name	Size
01-107030	DERIVO® 2 Embolisation Device	6.0 mm x 15 mm
01-107031	DERIVO® 2 Embolisation Device	6.0 mm x 20 mm
01-107032	DERIVO® 2 Embolisation Device	6.0 mm x 25 mm
01-107033	DERIVO® 2 Embolisation Device	6.0 mm x 30 mm
01-107034	DERIVO® 2 Embolisation Device short tip	3.5 mm x 30 mm
01-107035	DERIVO® 2 Embolisation Device short tip	3.5 mm x 40 mm
01-107036	DERIVO® 2 Embolisation Device short tip	4.0 mm x 20 mm
01-107037	DERIVO® 2 Embolisation Device short tip	4.0 mm x 25 mm
01-107038	DERIVO® 2 Embolisation Device short tip	4.0 mm x 30 mm
01-107039	DERIVO® 2 Embolisation Device short tip	4.0 mm x 40 mm
01-107040	DERIVO® 2 Embolisation Device short tip	4.5 mm x 20 mm
01-107041	DERIVO® 2 Embolisation Device short tip	4.5 mm x 25 mm
01-107042	DERIVO® 2 Embolisation Device short tip	4.5 mm x 30 mm
01-107043	DERIVO® 2 Embolisation Device short tip	4.5 mm x 40 mm
01-107044	DERIVO® 2 Embolisation Device short tip	5.0 mm x 20 mm
01-107045	DERIVO® 2 Embolisation Device short tip	5.0 mm x 25 mm
01-107046	DERIVO® 2 Embolisation Device short tip	5.0 mm x 30 mm
01-107047	DERIVO® 2 Embolisation Device short tip	5.0 mm x 40 mm
01-107048	DERIVO® 2 Embolisation Device short tip	5.0 mm x 50 mm
01-107049	DERIVO® 2 Embolisation Device short tip	5.5 mm x 20 mm
01-107050	DERIVO® 2 Embolisation Device short tip	5.5 mm x 25 mm
01-107051	DERIVO® 2 Embolisation Device short tip	5.5 mm x 30 mm
01-107052	DERIVO® 2 Embolisation Device short tip	5.5 mm x 40 mm
01-107053	DERIVO® 2 Embolisation Device short tip	5.5 mm x 50 mm
01-107054	DERIVO® 2 Embolisation Device short tip	6.0 mm x 20 mm
01-107055	DERIVO® 2 Embolisation Device short tip	6.0 mm x 25 mm
01-107056	DERIVO® 2 Embolisation Device short tip	6.0 mm x 30 mm
01-107057	DERIVO® 2 Embolisation Device short tip	6.0 mm x 40 mm
01-107058	DERIVO® 2 Embolisation Device short tip	6.0 mm x 50 mm
01-107059	DERIVO® 2 Embolisation Device	7.0 mm x 20 mm
01-107060	DERIVO® 2 Embolisation Device	7.0 mm x 25 mm
01-107061	DERIVO® 2 Embolisation Device	7.0 mm x 30 mm

Article number	Name	Size
01-107062	DERIVO® 2 Embolisation Device	8.0 mm x 20 mm
01-107063	DERIVO® 2 Embolisation Device	8.0 mm x 25 mm
01-107064	DERIVO® 2 Embolisation Device	8.0 mm x 30 mm
01-107065	DERIVO® 2 Embolisation Device short tip	7.0 mm x 20 mm
01-107066	DERIVO® 2 Embolisation Device short tip	7.0 mm x 25 mm
01-107067	DERIVO® 2 Embolisation Device short tip	7.0 mm x 30 mm
01-107068	DERIVO® 2 Embolisation Device short tip	7.0 mm x 40 mm
01-107069	DERIVO® 2 Embolisation Device short tip	7.0 mm x 50 mm
01-107070	DERIVO® 2 Embolisation Device short tip	8.0 mm x 20 mm
01-107071	DERIVO® 2 Embolisation Device short tip	8.0 mm x 25 mm
01-107072	DERIVO® 2 Embolisation Device short tip	8.0 mm x 30 mm
01-107073	DERIVO® 2 Embolisation Device short tip	8.0 mm x 40 mm
01-107074	DERIVO® 2 Embolisation Device short tip	8.0 mm x 50 mm
01-107101	DERIVO® 2 Embolisation System short tip	2.5 mm x 10 mm
01-107102	DERIVO® 2 Embolisation System short tip	2.5 mm x 15 mm
01-107103	DERIVO® 2 Embolisation System short tip	2.5 mm x 20 mm
01-107104	DERIVO® 2 Embolisation System short tip	2.5 mm x 25 mm
01-107105	DERIVO® 2 Embolisation System short tip	3.0 mm x 10 mm
01-107106	DERIVO® 2 Embolisation System short tip	3.0 mm x 15 mm
01-107107	DERIVO® 2 Embolisation System short tip	3.0 mm x 20 mm
01-107108	DERIVO® 2 Embolisation System short tip	3.0 mm x 25 mm
01-107109	DERIVO® 2 Embolisation System short tip	3.5 mm x 10 mm
01-107110	DERIVO® 2 Embolisation System short tip	3.5 mm x 15 mm
01-107111	DERIVO® 2 Embolisation System short tip	3.5 mm x 20 mm
01-107112	DERIVO® 2 Embolisation System short tip	3.5 mm x 25 mm
01-107113	DERIVO® 2 Embolisation System	3.5 mm x 30 mm
01-107114	DERIVO® 2 Embolisation System	4.0 mm x 15 mm
01-107115	DERIVO® 2 Embolisation System	4.0 mm x 20 mm
01-107116	DERIVO® 2 Embolisation System	4.0 mm x 25 mm
01-107117	DERIVO® 2 Embolisation System	4.0 mm x 30 mm
01-107118	DERIVO® 2 Embolisation System	4.5 mm x 15 mm

Article number	Name	Size
01-107119	DERIVO® 2 Embolisation System	4.5 mm x 20 mm
01-107120	DERIVO® 2 Embolisation System	4.5 mm x 25 mm
01-107121	DERIVO® 2 Embolisation System	4.5 mm x 30 mm
01-107122	DERIVO® 2 Embolisation System	5.0 mm x 15 mm
01-107123	DERIVO® 2 Embolisation System	5.0 mm x 20 mm
01-107124	DERIVO® 2 Embolisation System	5.0 mm x 25 mm
01-107125	DERIVO® 2 Embolisation System	5.0 mm x 30 mm
01-107126	DERIVO® 2 Embolisation System	5.5 mm x 15 mm
01-107127	DERIVO® 2 Embolisation System	5.5 mm x 20 mm
01-107128	DERIVO® 2 Embolisation System	5.5 mm x 25 mm
01-107129	DERIVO® 2 Embolisation System	5.5 mm x 30 mm
01-107130	DERIVO® 2 Embolisation System	6.0 mm x 15 mm
01-107131	DERIVO® 2 Embolisation System	6.0 mm x 20 mm
01-107132	DERIVO® 2 Embolisation System	6.0 mm x 25 mm
01-107133	DERIVO® 2 Embolisation System	6.0 mm x 30 mm
01-107134	DERIVO® 2 Embolisation System short tip	3.5 mm x 30 mm
01-107135	DERIVO® 2 Embolisation System short tip	3.5 mm x 40 mm
01-107136	DERIVO® 2 Embolisation System short tip	4.0 mm x 20 mm
01-107137	DERIVO® 2 Embolisation System short tip	4.0 mm x 25 mm
01-107138	DERIVO® 2 Embolisation System short tip	4.0 mm x 30 mm
01-107139	DERIVO® 2 Embolisation System short tip	4.0 mm x 40 mm
01-107140	DERIVO® 2 Embolisation System short tip	4.5 mm x 20 mm
01-107141	DERIVO® 2 Embolisation System short tip	4.5 mm x 25 mm
01-107142	DERIVO® 2 Embolisation System short tip	4.5 mm x 30 mm
01-107143	DERIVO® 2 Embolisation System short tip	4.5 mm x 40 mm
01-107144	DERIVO® 2 Embolisation System short tip	5.0 mm x 20 mm
01-107145	DERIVO® 2 Embolisation System short tip	5.0 mm x 25 mm
01-107146	DERIVO® 2 Embolisation System short tip	5.0 mm x 30 mm
01-107147	DERIVO® 2 Embolisation System short tip	5.0 mm x 40 mm
01-107148	DERIVO® 2 Embolisation System short tip	5.0 mm x 50 mm
01-107149	DERIVO® 2 Embolisation System short tip	5.5 mm x 20 mm
01-107150	DERIVO® 2 Embolisation System short tip	5.5 mm x 25 mm

Article number	Name	Size
01-107151	DERIVO® 2 Embolisation System short tip	5.5 mm x 30 mm
01-107152	DERIVO® 2 Embolisation System short tip	5.5 mm x 40 mm
01-107153	DERIVO® 2 Embolisation System short tip	5.5 mm x 50 mm
01-107154	DERIVO® 2 Embolisation System short tip	6.0 mm x 20 mm
01-107155	DERIVO® 2 Embolisation System short tip	6.0 mm x 25 mm
01-107156	DERIVO® 2 Embolisation System short tip	6.0 mm x 30 mm
01-107157	DERIVO® 2 Embolisation System short tip	6.0 mm x 40 mm
01-107158	DERIVO® 2 Embolisation System short tip	6.0 mm x 50 mm
01-107159	DERIVO® 2 Embolisation System	7.0 mm x 20 mm
01-107160	DERIVO® 2 Embolisation System	7.0 mm x 25 mm
01-107161	DERIVO® 2 Embolisation System	7.0 mm x 30 mm
01-107162	DERIVO® 2 Embolisation System	8.0 mm x 20 mm
01-107163	DERIVO® 2 Embolisation System	8.0 mm x 25 mm
01-107164	DERIVO® 2 Embolisation System	8.0 mm x 30 mm
01-107165	DERIVO® 2 Embolisation System short tip	7.0 mm x 20 mm
01-107166	DERIVO® 2 Embolisation System short tip	7.0 mm x 25 mm
01-107167	DERIVO® 2 Embolisation System short tip	7.0 mm x 30 mm
01-107168	DERIVO® 2 Embolisation System short tip	7.0 mm x 40 mm
01-107169	DERIVO® 2 Embolisation System short tip	7.0 mm x 50 mm
01-107170	DERIVO® 2 Embolisation System short tip	8.0 mm x 20 mm
01-107171	DERIVO® 2 Embolisation System short tip	8.0 mm x 25 mm
01-107172	DERIVO® 2 Embolisation System short tip	8.0 mm x 30 mm
01-107173	DERIVO® 2 Embolisation System short tip	8.0 mm x 40 mm
01-107174	DERIVO® 2 Embolisation System short tip	8.0 mm x 50 mm

Declaration of Conformity

according to directive 93/42/EEC

Product	**APERIO® Hybrid$^{17/21}$ 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 2024-05-26
EC Design Examination Certificate	No. 516327 MRA valid until 2024-02-27
Declaration of Conformity valid until	2024-02-27

Pforzheim, 2021-05-25

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity APERIO® Hybrid$^{17/21}$ Thrombectomy Device

Product listing

Article number	Name	Size
01-000713	APERIO® Hybrid^{17} Thrombectomy Device	2.5mm x 16mm
01-000714	APERIO® Hybrid^{17} Thrombectomy Device	2.5mm x 18mm
01-000710	APERIO® Hybrid^{17} Thrombectomy Device	2.5mm x 28mm
01-000711	APERIO® Hybrid^{17} Thrombectomy Device	3.5mm x 28mm
01-000712	APERIO® Hybrid^{17} Thrombectomy Device	4.5mm x 30mm
01-000715	APERIO® Hybrid^{21} Thrombectomy Device	4.5mm x 40mm
01-000716	APERIO® Hybrid^{21} Thrombectomy Device	4.5mm x 50mm
01-000717	APERIO® Hybrid^{21} Thrombectomy Device	6.0mm x 40mm
01-000718	APERIO® Hybrid^{21} Thrombectomy Device	6.0mm x 50mm

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 2024-05-26
EC Design Examination Certificate	No. 516327 MRA valid until 2024-02-27
Declaration of Conformity valid until	2024-02-27

Pforzheim, 2021-05-25

.....

Stefan Höfele,
Director Regulatory Affairs

Declaration of Conformity APERIO® Hybrid Thrombectomy Device

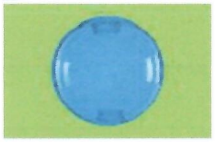
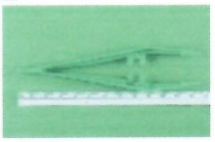
Product listing

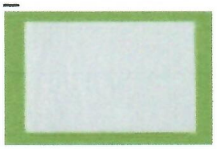
Article number	Name	Size
01-000704	APERIO® Hybrid Thrombectomy Device	3.5mm x 28mm
01-000705	APERIO® Hybrid Thrombectomy Device	4.5mm x 30mm
01-000706	APERIO® Hybrid Thrombectomy Device	4.5mm x 40mm
01-000707	APERIO® Hybrid Thrombectomy Device	4.5mm x 50mm
01-000708	APERIO® Hybrid Thrombectomy Device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

Mölnlycke

Tray ID	97038757
Tray name	SET INTERVENTII RADIOGRAFICE
Colour code	
Speciality filter	ENDOVASCULAR
Intervention filter	Coronary or Peripher
Hospital filter	Tehnomedica SRL

	Description	Qty
	Crepe paper 60x60cm 60g/m2 White	1
	Angio drape 240x330cm 2 adh.ap.5x7cm 2 adh.ap.7x9cm Transp. panels	1
	Kidney bowl 800ml Yellow	1
	Adh. op towel 50x50cm	1
	Banded bag 75cm Circ. Elast. Transp.	1
	Absorbent towel 34x50cm	1

	Bowl 250ml Graduated red	1
	Bowl 2500ml Polypropylene Blue Guidewire W/tabs	1
	Specimen cup 120ml Polyethylene Transp. Blue screw-on lid	1
	Gallipot 120ml Transparent	1
	Forceps tweezer plastic green	1
	Forceps 12cm plastic green	1
	Banded bag 140cm Circ. Elast. Transp.	2
	Surg.glove latex 7.0 PF 2/1 Biogel Surgeons	1
	Surg.glove latex 7.5 PF 2/1 Biogel Surgeons	2

–	Surg.glove latex 8.0 PF 2/1 Biogel Surgeons	1
– 	Surgical gown Primary Standard Perfomance XL 127cm	1
– 	Hand towel 47x38cm	2
– 	Surgical gown Primary Standard Perfomance XL 127cm	1
– 	Hand towel 47x38cm	2
– 	Reinforced Table Cover 150 x 190 wrapping	1

Article number 5010783

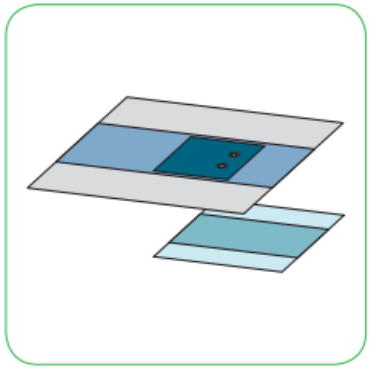
B|BRAUN

Angiographic syringe 12 ml	1
Puncture Needle 1,3 x 70 mm, 18G	1
Scalpel Cutfix fig. 11	1
Guidewire J3FC-FS175-035	1
Compress gauze 10 x 10 cm, 12-ply	30
Sterican Cannula 0,80 x 40 mm, 21G	2
Sterican Cannula 0,70 x 30 mm, 22G	1

Syringe Omnifix 2 ml, Luer Lock	1
Syringe Omnifix 5 ml, Luer Lock,	1
Syringe Omnifix 10 ml, Luer Lock,	1
Syringe Omnifix 20 ml, Luer Lock,	1
Guidewire bowl 2500 ml, blue	1
Cover drape 100 x 150 cm	1
Combidyn tubing 150 cm, red	1
Rotator m/m	1
Manifold 3-fold, OFF, 35 bar	1
Tape for fixation "Japan"	2
Contrast Media System 180 cm	1
Infusionsystem ventilated 190 cm	1

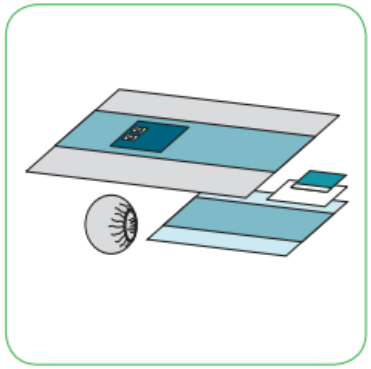
"TEHNOMEDICA" S.R.L. IDNO 1002600053256

ANGIOGRAPHY SET 8/16 65213



Ref. No.	Qty	Description
	1	Angiography Drape 240x320 cm, reinforcement 90x110 cm, ap. 6x9 cm
	1	Table Cover 150x190 cm, abs. 75x190 cm

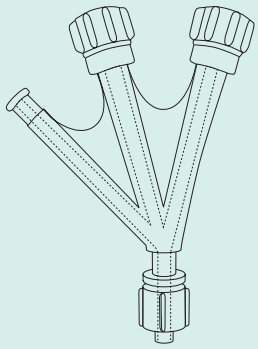
ANGIOGRAPHY SET -/10 698220



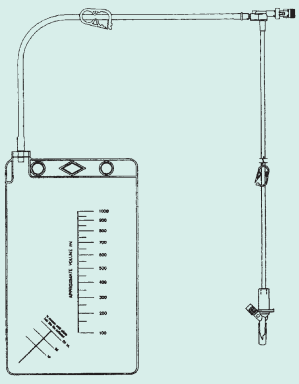
Ref. No.	Qty	Description
	1	Angiography Drape 240x370cm, ap. 7x10cm (2), patched
	1	Adhesive OP-Towel 50x50cm
	1	Banded Bag 140cm circular
	1	Absorbent Towel 34x50cm
	1	Table Cover 150x190 cm, abs. 75x190 cm

Accessories for PTCA

Y-Connector, PTCA-Set, Fluid Collection System



	Code-Number	Sales unit-pcs.
Y-Connector For all interventional techniques – with rotational adaptor and Touhy-Borst-valve – 9.5F lumen		
Y-connector with plastic insertion tool	**5021693**	10
Double Y-connector with plastic insertion tool	**5020743**	5
Unique Kissing BiBalloon adaptor For simultaneous and/or sequential dilatation of bifurcation lesions - innovative approach for multiple dilatation techniques - final kissing balloon inflation		
Kissing BiBalloon adaptor	**5014760**	25
PTCA-Kit 1 – Y-connector with metal insertion tool – Torquer, luminescent wire grip for all diameters up to 0.022" – Inflation Device for PTCA (622510)		
PTCA-Kit 1	**622511**	1
PTCA-Kit 2 – Y-connector with metal insertion tool – Torquer, luminescent wire grip for all diameters up to 0.022"		
PTCA-Kit 2	**5028550**	10
Bifurcation Kit – Inflation device – Double Y-Connector – Kissing Balloon adaptor – Insertion tool and torquer		
Bifurcation Kit	**5028904**	1



Fluid Collection System – aspiration of liquids (saline solution, contrast media) – secure disposal of aspiration liquid in a closed container (bag) – tubing length to dual check valve: 190 cm – tubing length to container: 180 cm – container volume: 1000 ml		
Fluid Collection System	**5010555**	**50**

Customized kits on request. Please ask your B. Braun clinical specialist.

VISIBLE ADAPTABILITY

DERIVO® Embolisation Device

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

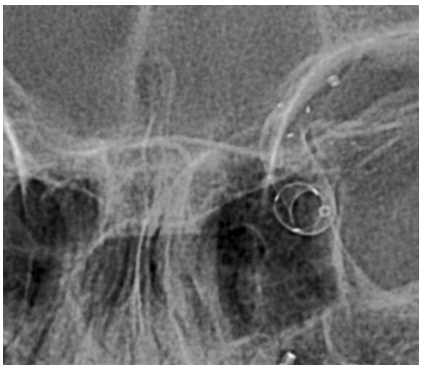
αcandis®

ENGINEERING STROKE SOLUTIONS

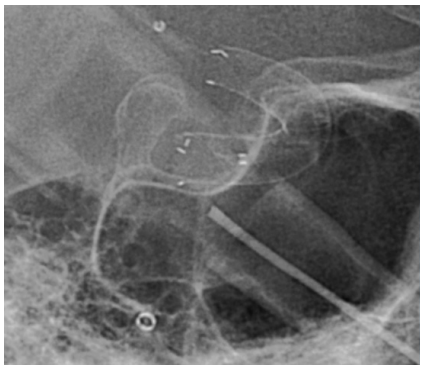
Proven Technology – Safe and Efficient

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.

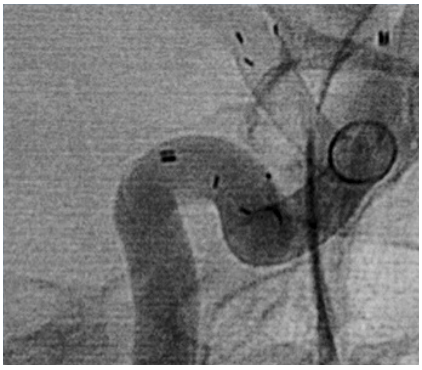


Opening of DERIVO® in tight curve is clearly visible.

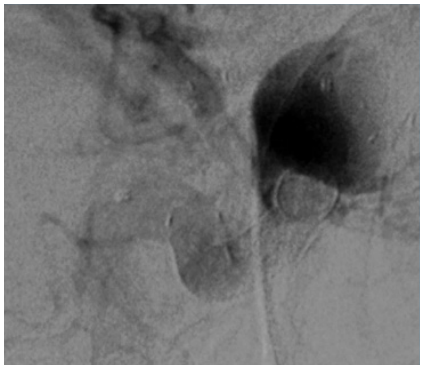
Images by courtesy of: Prof. Reith, Department of Neuroradiology, Saarland University Hospital, Homburg, Germany

Balanced mechanical properties for excellent clinical performance

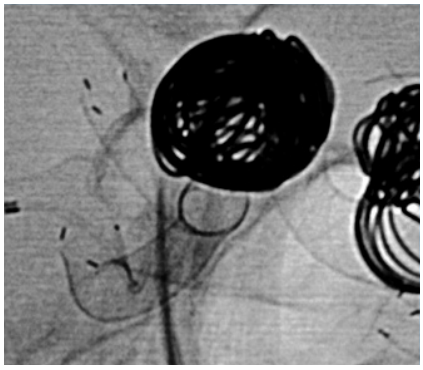
Treatment of large right ICA aneurysm with DERIVO® 4.0 mm x 30 mm



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

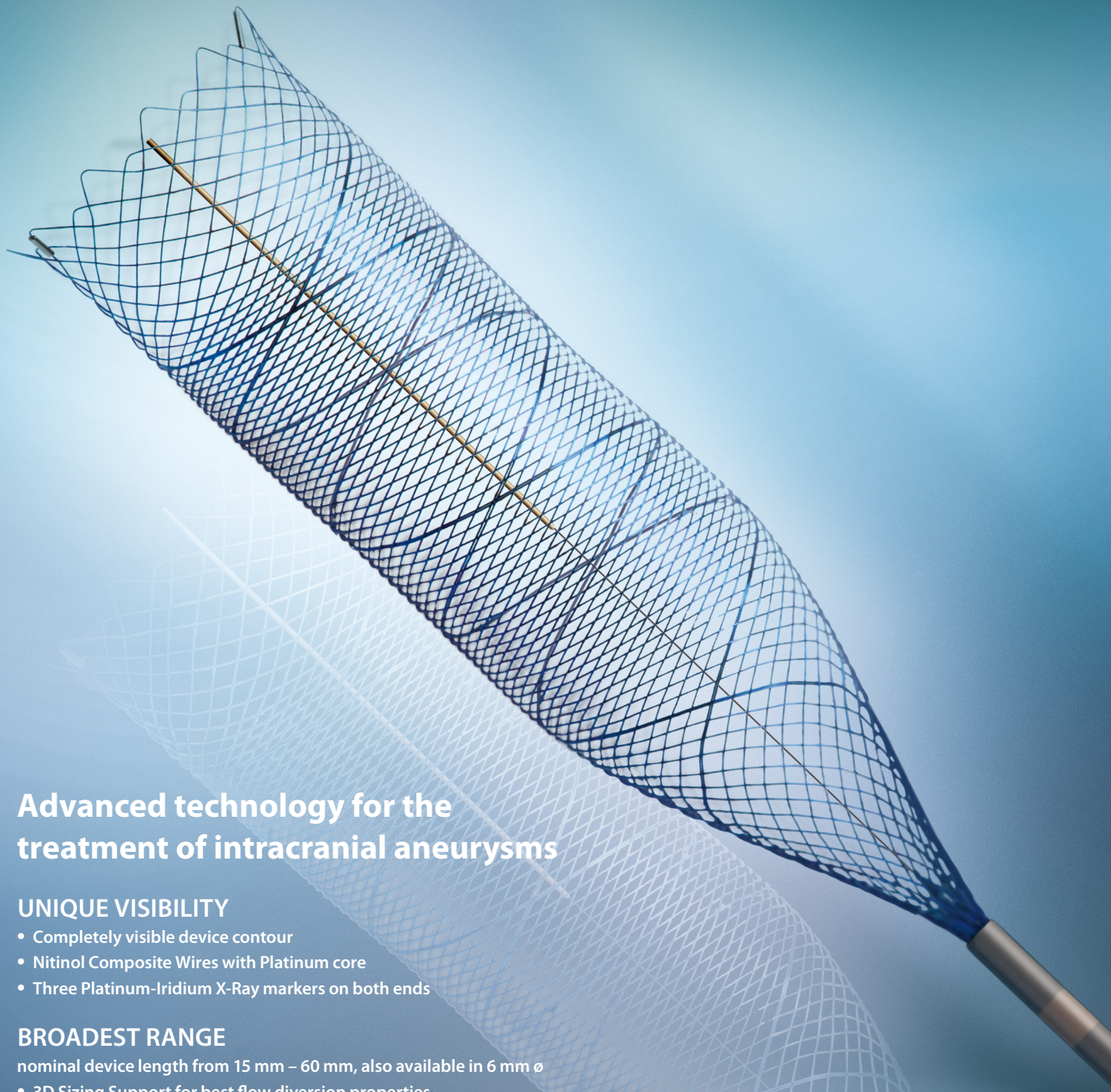


Immediate flow diversion effect after DERIVO® placement.



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 ø

- 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 thrombogenicity[1] 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.

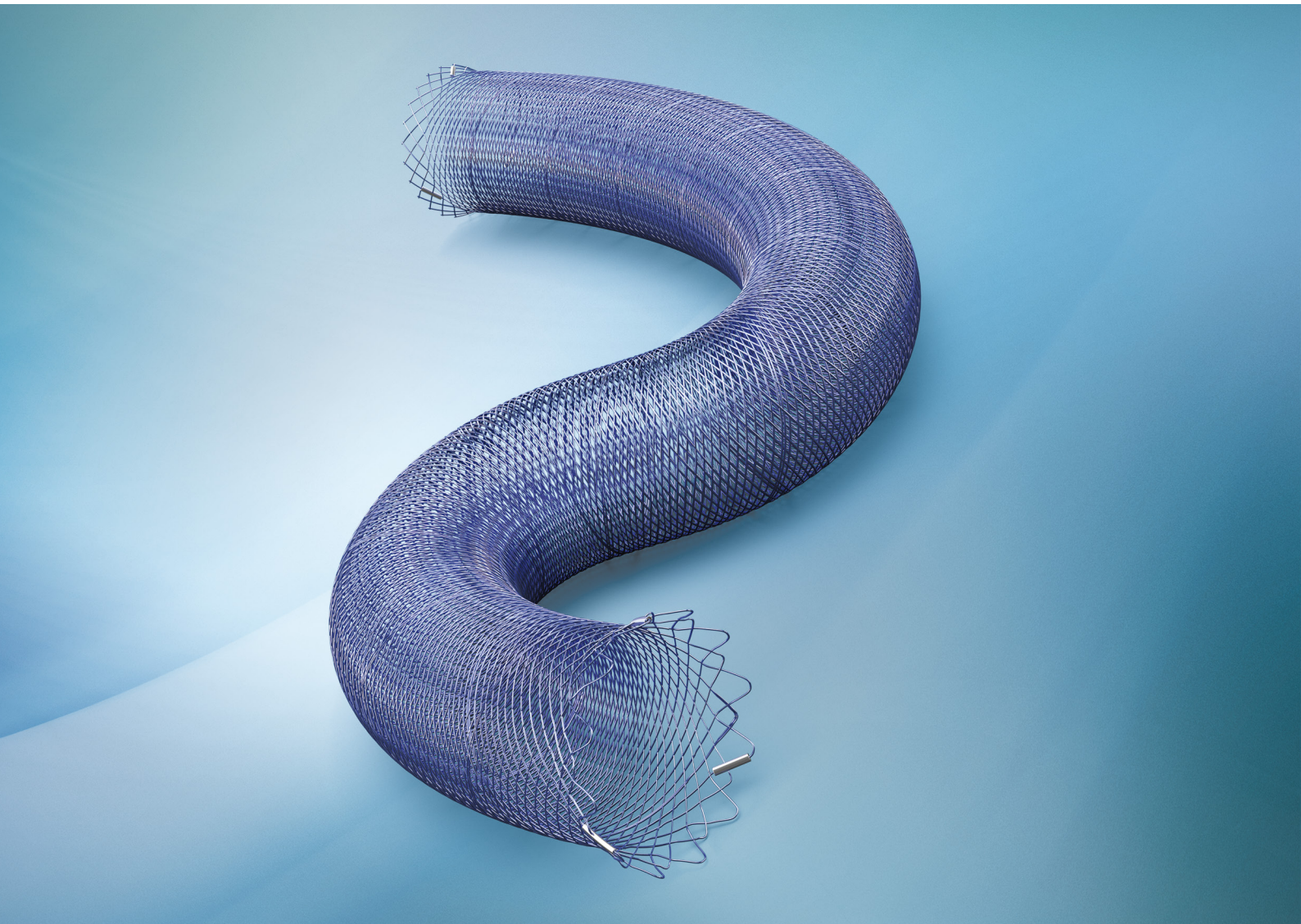
BlueXide® Surface Finishing
The Acandis® proprietary BlueXide® Surface Finishing Technology ensures less friction during delivery through the microcatheter as well as during expansion, making the opening of the device smooth and reliable. This finishing contributes to better corrosion resistance which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

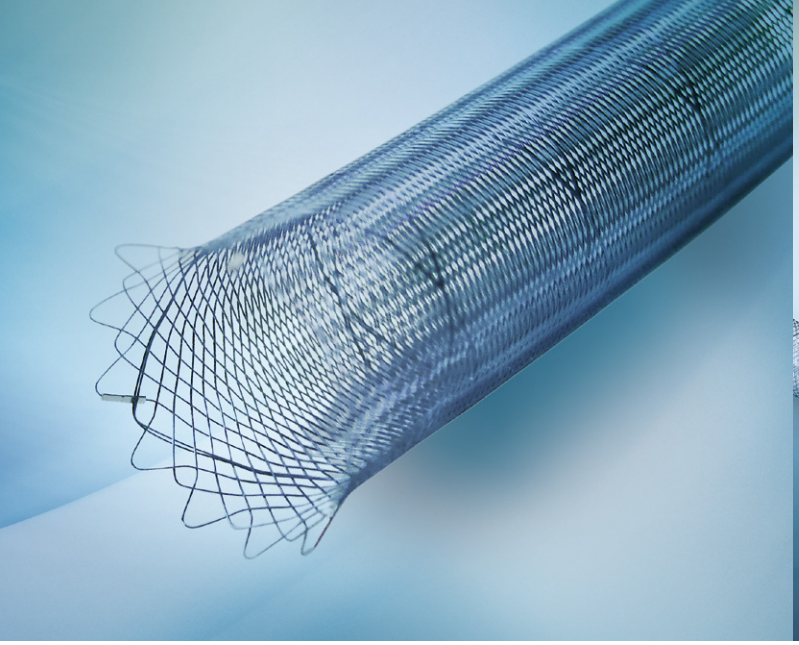
Nitinol Composite Wires
The entire device consists of Nitinol Composite Wires with Platinum core leading to an outstanding visualisation of the contour and shape of the device under fluoroscopy.

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.





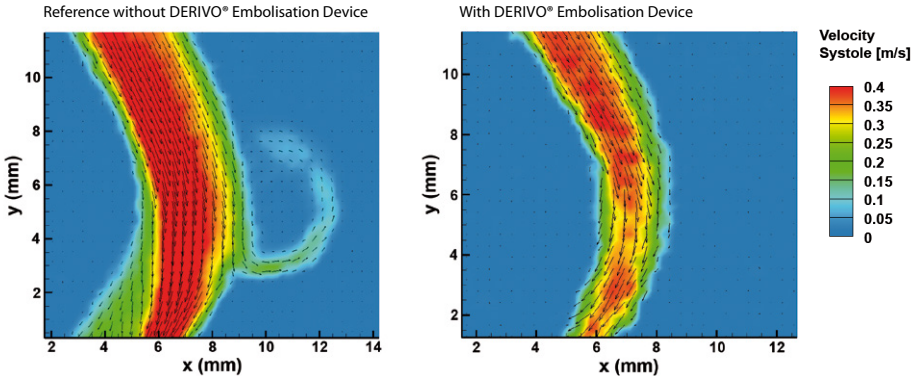
Flow Diversion

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.

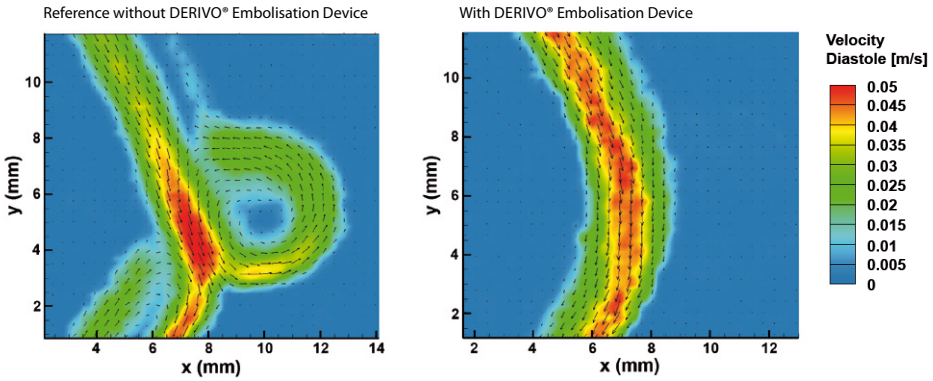
Vessel Wall Conformability

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

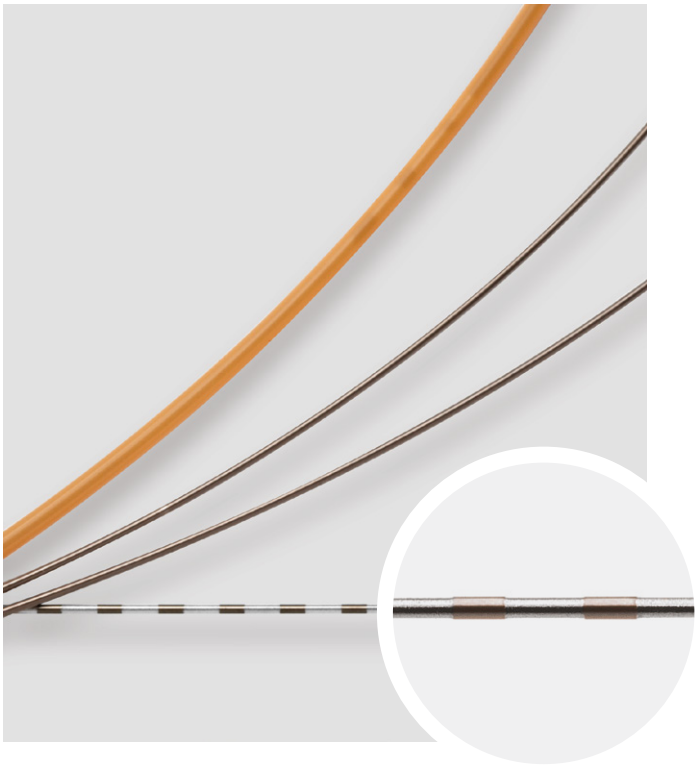
C- controlled

U- unique

R- reliable

E- effective

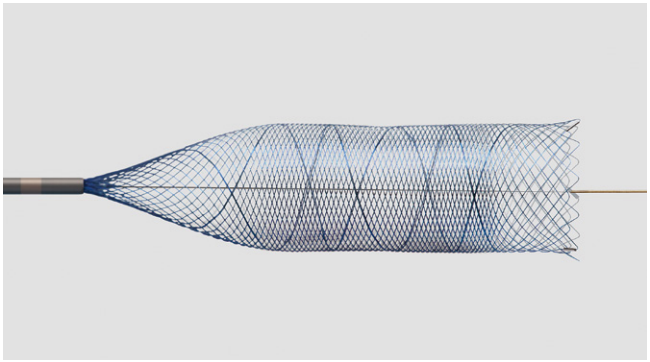
The sleek surface of the transport wire changes into a unique – optically and tactile perceptible – checkered surface at the fluoroscopy marker point, to enhance the grip and push for a controlled and safe placement of the DERIVO® Embolisation Device.



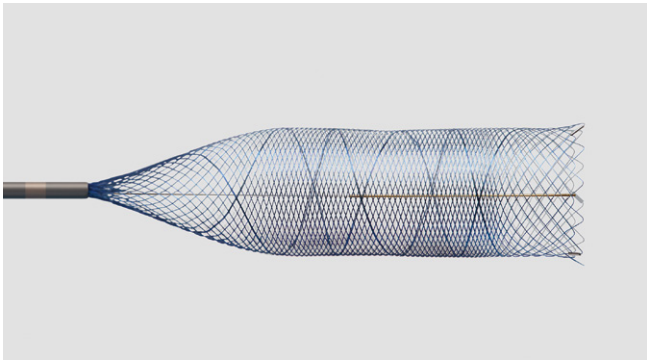
Resheathability

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

For optimal case preparation, Acandis also offers software-based 3D Sizing Support.

For further information please contact the Clinical Support Team: **clinical-support@acandis.com**

ORDERING INFORMATION

Labelled DERIVO® Diameter (mm)	Labelled DERIVO® Length (mm)	Reference Number	Recommended Vessel Diameter (mm)	Required Microcatheter for Delivery ** (inch)
3.5	15	01-000408	2.5 – 3.5	0.027
	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*		

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

* Indicated on package as „without Tip" as the tip always stays inside the stent for the 40 mm and 50 mm length
** Please contact your local Acandis® representative for information on compatible microcatheters

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

CE 0297

ACANDIS GmbH
Theodor-Fahrner-Str. 6
75177 Pforzheim
Germany

Tel: +49 7231 155 00 0
Fax: +49 7231 155 00 129
E-Mail: info@acandis.com
www.acandis.com

09-000052 EN 09/2017

Clin Neuroradiol
https://doi.org/10.1007/s00062-021-01086-2

ORIGINAL ARTICLE

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

Waleed Butt[1,2] · Cha-ney Kim[1] · Rajesh Ramaswamy[1] · Aubrey Smith[1] · Paul Maliakal[1]

Received: 25 April 2021 / Accepted: 7 August 2021

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.

✉ Waleed Butt
mohammad.butt2@nuh.nhs.uk

[1] Interventional Neuroradiology, Hull Royal Infirmary, Hull University Teaching Hospitals NHS Trust, Hull, UK

[2] Interventional Neuroradiology, Queens Medical Centre, Nottingham University Hospitals NHS Trust, Nottingham, UK

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

Published online: 08 September 2021

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 neuroradiologist 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 withe 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 5 Fr or 6 Fr 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 ± 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	14	13
			2) Left para-ophthalmic	4	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 mm ± 0.6 mm and the proximal landing zone 5.4 mm ± 0.5 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 morality 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.

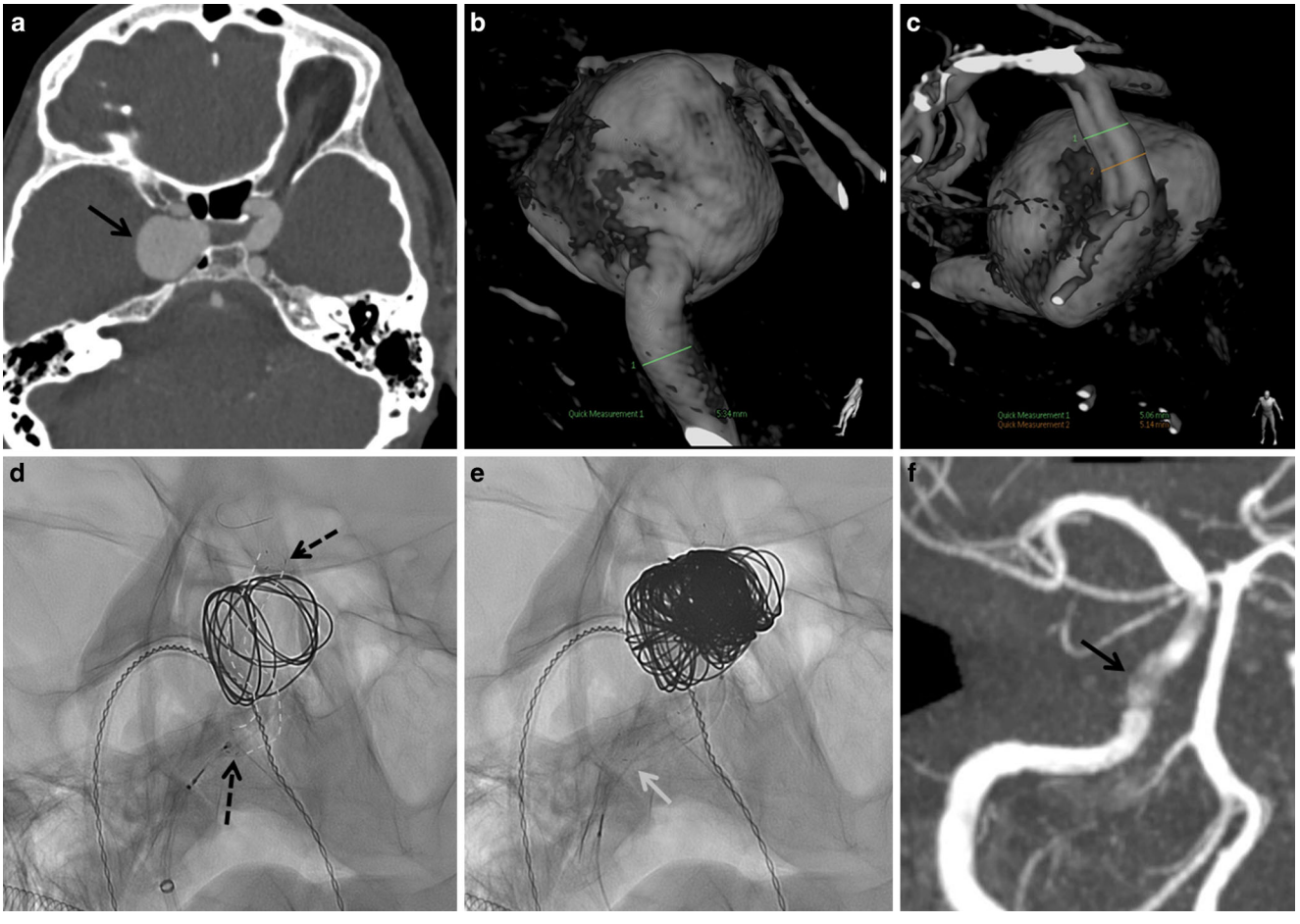


Fig. 1 Patient 6 presented with 3rd cranial nerve palsy. **a** CTA revealed a right cavernous ICA aneurysm measuring 25 mm in maximum diameter. Volume rendered 3D-DSA images illustrating the proximal (**b**) and distal (**c**) parent vessel artery diameters. **d** Initial 5.5 × 30 DED delivered (*dashed 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*)

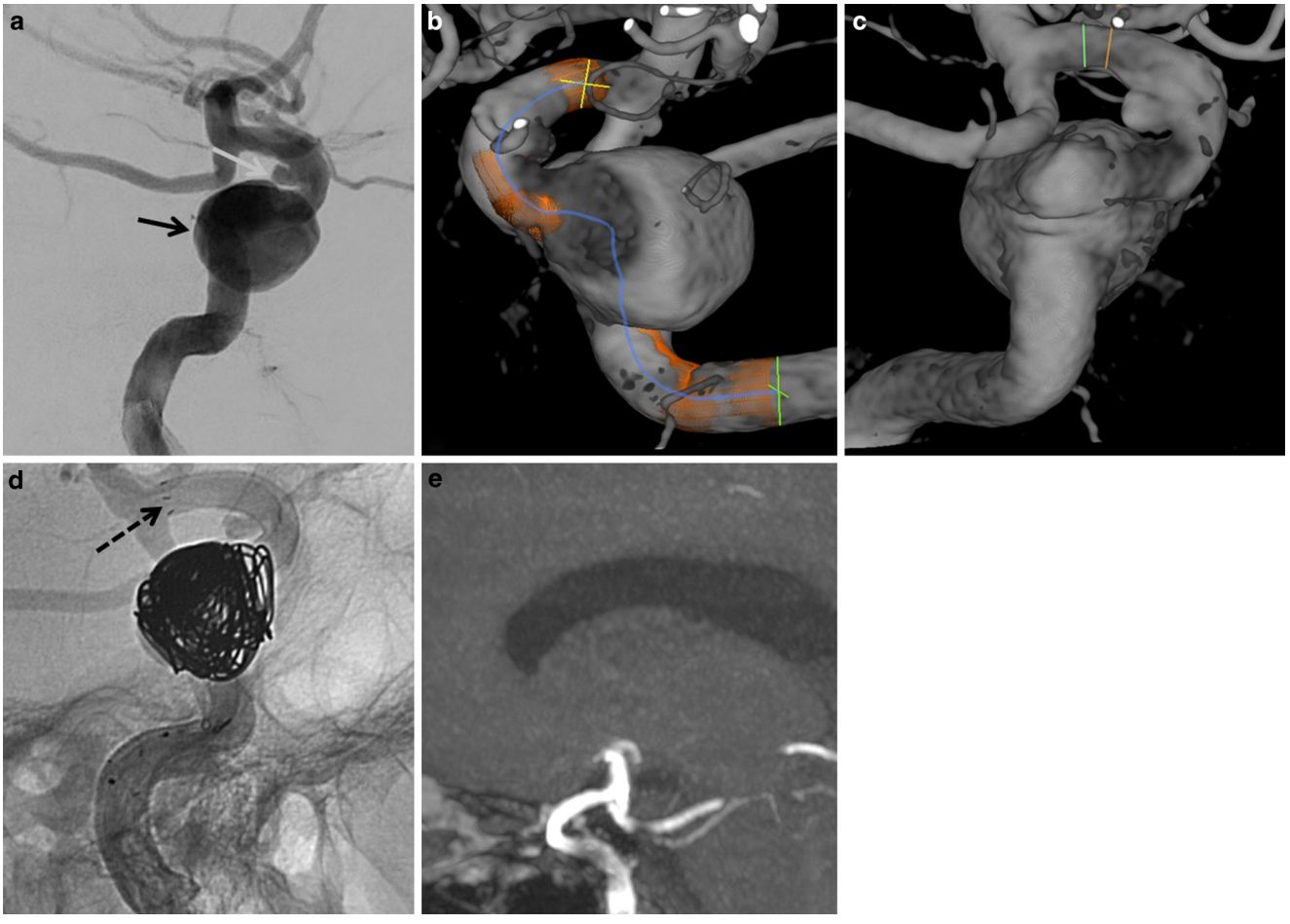


Fig. 2 Patient 11 presented with right 3rd cranial nerve palsy and worsening headaches. **a** Initial DSA reveals a 14 mm left cavernous ICA aneurysm (*solid black arrow*) and a smaller 4 mm left paraophthalmic ICA aneurysm (*solid white arrow*). **b** and **c** 3D-DSA volume rendered images illustrating 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 complied 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 8 mm residuum	A 9 mm residuum
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 mouthing 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 (4 mm remnant)	B Stable
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 < 5.0 mm; 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 6 mm 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.

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

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

References

1. Wakhloo AK, Gounis MJ. Revolution in aneurysm treatment: flow diversion to cure aneurysms: a paradigm shift. Neurosurgery. 2014;61 Suppl 1:111–20.
2. Lieber BB, Gounis MJ. The physics of endoluminal stenting in the treatment of cerebrovascular aneurysms. Neurol Res. 2002;24 Suppl 1:S33–42.
3. Rouchaud A, Ramana C, Brinjikji W, Ding YH, Dai D, Gunderson T, Cebral J, Kallmes DF, Kadirvel R. Wall Apposition Is a Key Factor for Aneurysm Occlusion after Flow Diversion: A Histologic Evaluation in 41 Rabbits. AJNR Am J Neuroradiol. 2016;37:2087–91.
4. Aquarius R, de Korte A, Smits D, Gounis M, Verrijp K, Driessen L, Leenders W, de Vries J. The Importance of Wall Apposition in Flow Diverters. Neurosurgery. 2019;84:804–10.
5. Dandapat S, Mendez-Ruiz A, Martínez-Galdámez M, Macho J, Derakhshani S, Foa Torres G, Pereira VM, Arat A, Wakhloo AK, Ortega-Gutierrez S. Review of current intracranial aneurysm flow diversion technology and clinical use. J Neurointerv Surg. 2021;13:54–62.
6. Kraus B, Goertz L, Turowski B, Borggrefe J, Schlamann M, Dorn F, Kabbasch C. Safety and efficacy of the Derivo Embolization Device for the treatment of unruptured intracranial aneurysms: a multicentric study. J Neurointerv Surg. 2019;11:68–73.
7. Trivelato FP, Abud DG, Ulhôa AC, Waihrich ES, Abud TG, Castro Afonso LH, Nakiri GS, de Castro GD, Parente BSM, Dos Santos Silva R, Manzato LB, Bonadio LE, Viana DC, Vanzin JR, Baccin CE, Rezende MTS. Derivo Embolization Device for the Treatment of Intracranial Aneurysms. Stroke. 2019;50:2351–8.
8. Taschner CA, Stracke CP, Dorn F, Kadziolka KB, Kreiser K, Solymosi L, Pham M, Buhk JH, Turowski B, Reith W, Elsheikh S, Meckel S, Janssen H, Hammer A, Beuing O, Jansen O, Urbach H, Knauth M, Jenkner C, Chapot R. Derivo embolization device in the treatment of unruptured intracranial aneurysms: a prospective multicenter study. J Neurointerv Surg. 2021;13:541–6.
9. Martínez-Galdámez M, Rodríguez C, Hermosín A, Crespo-Vallejo E, Monedero G, Chaviano J, Zheng B. Internal Carotid Artery Reconstruction with a "Mega Flow Diverter": First Experience with the 6×50 mm DERIVO Embolization Device. Neurointervention. 2018;13:133–7.
10. Xiang S, Fan F, Hu P, Yang K, Zhai X, Geng J, Ji Z, Lu J, Zhang H. The sensitivity and specificity of TOF-MRA compared with DSA in the follow-up of treated intracranial aneurysms. J Neurointerv Surg. 2021. https://doi.org/10.1136/neurintsurg-2020-016788.
11. Boddu SR, Tong FC, Dehkharghani S, Dion JE, Saindane AM. Contrast-enhanced time-resolved MRA for follow-up of intracranial aneurysms treated with the pipeline embolization device. AJNR Am J Neuroradiol. 2014;35:2112–8.
12. O'kelly CJ, Krings T, Fiorella D, Marotta TR. A novel grading scale for the angiographic assessment of intracranial aneurysms treated using flow diverting stents. Interv Neuroradiol. 2010;16:133–7.
13. Akgul E, Onan HB, Akpinar S, Balli HT, Aksungur EH. The DERIVO Embolization Device in the Treatment of Intracranial Aneurysms: Short- and Midterm Results. World Neurosurg. 2016;95:229–40.
14. Goertz L, Dorn F, Kraus B, Borggrefe J, Schlamann M, Forbrig R, Turowski B, Kabbasch C. Safety and efficacy of the Derivo Embolization Device for the treatment of ruptured intracranial aneurysms. J Neurointerv Surg. 2019;11:290–5.
15. Kaschner MG, Petridis A, Turowski B. Single-center experience with the new generation Derivo Embolization Device in ruptured dissecting and blister aneurysms. Acta Radiol. 2020;61:37–46.
16. Killer-Oberpfalzer M, Kocer N, Griessenauer CJ, Janssen H, Engelhorn T, Holtmannspötter M, Buhk JH, Finkenzeller T, Fesl G, Tren-

kler J, Reith W, Berlis A, Hausegger K, Augustin M, Islak C, Minnich B, Möhlenbruch M. European Multicenter Study for the Evaluation of a Dual-Layer Flow-Diverting Stent for Treatment of Wide-Neck Intracranial Aneurysms: The European Flow-Redirection Intraluminal Device Study. AJNR Am J Neuroradiol. 2018;39:841–7.
17. Guimaraens L, Vivas E, Saldaña J, Llibre JC, Gil A, Balaguer E, Rodríguez-Campello A, Cuadrado-Godia E, Ois A. Efficacy and safety of the dual-layer flow-diverting stent (FRED) for the treatment of intracranial aneurysms. J Neurointerv Surg. 2020;12:521–5.
18. Pierot L, Spelle L, Berge J, Januel AC, Herbreteau D, Aggour M, Piotin M, Biondi A, Barreau X, Mounayer C, Papagiannaki C, Lejeune JP, Gauvrit JY, Derelle AL, Chabert E, Costalat V. SAFE study (Safety and efficacy Analysis of FRED Embolic device in aneurysm treatment): 1-year clinical and anatomical results. J Neurointerv Surg. 2019;11:184–9.
19. Shankar JJ, Tampieri D, Iancu D, Cortes M, Agid R, Krings T, Wong J, Lavoie P, Ghostine J, Shettar B, Ritchie K, Weill A. SILK flow diverter for complex intracranial aneurysms: a Canadian registry. J Neurointerv Surg. 2016;8:273–8.
20. Berge J, Biondi A, Machi P, Brunel H, Pierot L, Gabrillargues J, Kadziolka K, Barreau X, Dousset V, Bonafé A. Flow-diverter silk stent for the treatment of intracranial aneurysms: 1-year follow-up in a multicenter study. AJNR Am J Neuroradiol. 2012;33:1150–5.
21. Kan P, Sweid A, Srivatsan A, Jabbour P. Expanding Indications for Flow Diverters: Ruptured Aneurysms, Blister Aneurysms, and Dissecting Aneurysms. Neurosurgery. 2020;86(Suppl 1):S96–103.
22. Kallmes DF, Brinjikji W, Cekirge S, Fiorella D, Hanel RA, Jabbour P, Lopes D, Lylyk P, McDougall CG, Siddiqui A. Safety and efficacy of the Pipeline embolization device for treatment of intracranial aneurysms: a pooled analysis of 3 large studies. J Neurosurg. 2017;127:775–80.
23. Chalouhi N, Starke RM, Yang S, Bovenzi CD, Tjoumakaris S, Hasan D, Gonzalez LF, Rosenwasser R, Jabbour P. Extending the indications of flow diversion to small, unruptured, saccular aneurysms of the anterior circulation. Stroke. 2014;45:54–8.
24. Cagnazzo F, Lefevre PH, Derraz I, Dargazanli C, Gascou G, di Carlo DT, Perrini P, Ahmed R, Hak JF, Riquelme C, Bonafe A, Costalat V. Flow-Diversion Treatment for Unruptured Nonsaccular Intracranial Aneurysms of the Posterior and Distal Anterior Circulation: A Meta-Analysis. AJNR Am J Neuroradiol. 2020;41:134–9.
25. Toth G, Bain M, Hussain MS, Moskowitz S, Masaryk T, Rasmussen P, Hui F. Posterior circulation flow diversion: a single-center experience and literature review. J Neurointerv Surg. 2015;7:574–83.
26. Wang CB, Shi WW, Zhang GX, Lu HC, Ma J. Flow diverter treatment of posterior circulation aneurysms. A meta-analysis. Neuroradiology. 2016;58:391–400.
27. Rai AT, Hogg JP, Cline B, Hobbs G. Cerebrovascular geometry in the anterior circulation: an analysis of diameter, length and the vessel taper. J Neurointerv Surg. 2013;5:371–5.
28. Mut F, Cebral JR. Effects of flow-diverting device oversizing on hemodynamics alteration in cerebral aneurysms. AJNR Am J Neuroradiol. 2012;33:2010-6.
29. Zhou G, Su M, Yin YL, Li MH. Complications associated with the use of flow-diverting devices for cerebral aneurysms: a systematic review and meta-analysis. Neurosurg Focus. 2017;42:E17.
30. Bender MT, Jiang B, Campos JK, Lin LM, Beaty N, Vo CD, Zarrin DA, Caplan JM, Huang J, Tamargo RJ, Colby GP, Coon AL. Single-stage flow diversion with adjunctive coiling for cerebral aneurysm: outcomes and technical considerations in 72 cases. J Neurointerv Surg. 2018;10:843–50.
31. Ocal O, Peker A, Balci S, Arat A. Placement of a Stent within a Flow Diverter Improves Aneurysm Occlusion Rates. AJNR Am J Neuroradiol. 2019;40:1932–8.
32. Brinjikji W, Murad MH, Lanzino G, Cloft HJ, Kallmes DF. Endovascular treatment of intracranial aneurysms with flow diverters: a meta-analysis. Stroke. 2013;44:442–7.
33. Ahmed SU, Mocco J, Zhang X, Kelly M, Doshi A, Nael K, De Leacy R. MRA versus DSA for the follow-up imaging of intracranial aneurysms treated using endovascular techniques: a meta-analysis. J Neurointerv Surg. 2019;11:1009–14.

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.

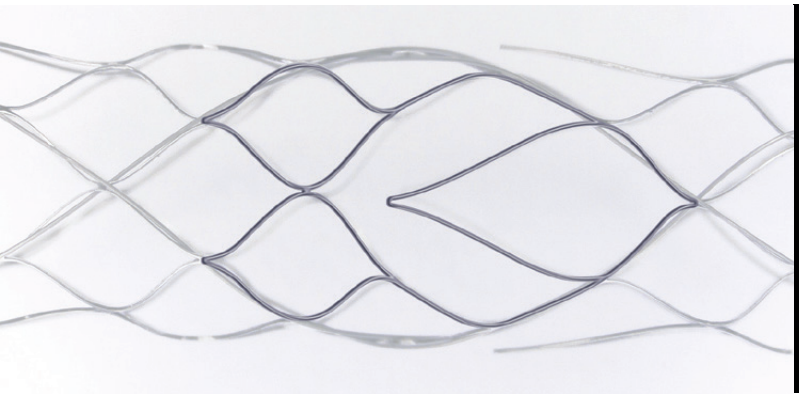
Small closed cells ensure a perfect vessel wall apposition and expansion into the clot. Large open cells with integrated anchoring elements assure efficient clot retention for reliable and atraumatic retrieval even in tortuous vessel anatomies. In combination, these two cell designs build up a functional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

VARIABLE

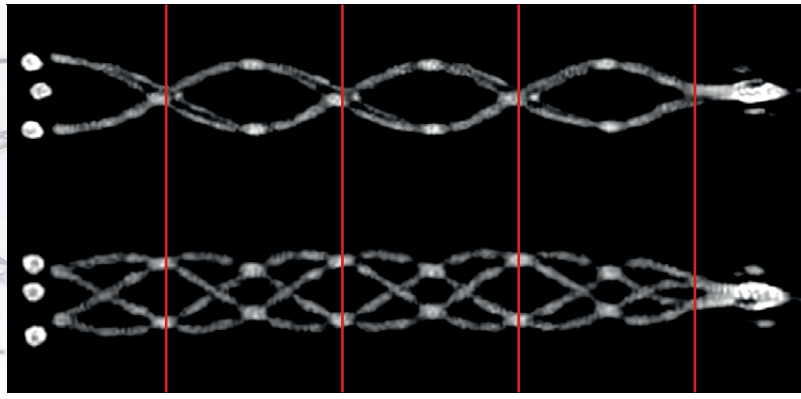
The broad range of sizes enables the treatment of vessel diameters from 1.5 mm up to 5.5 mm.

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



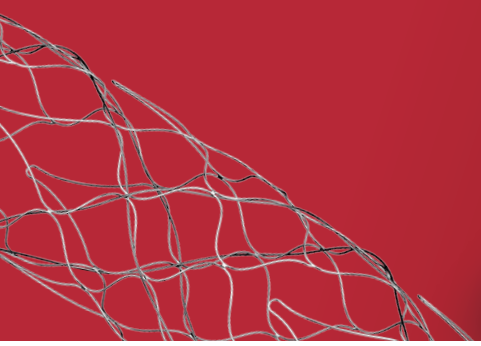
APERIO® Hybrid Thrombectomy Device (6.0 x 50 mm) – functional segments

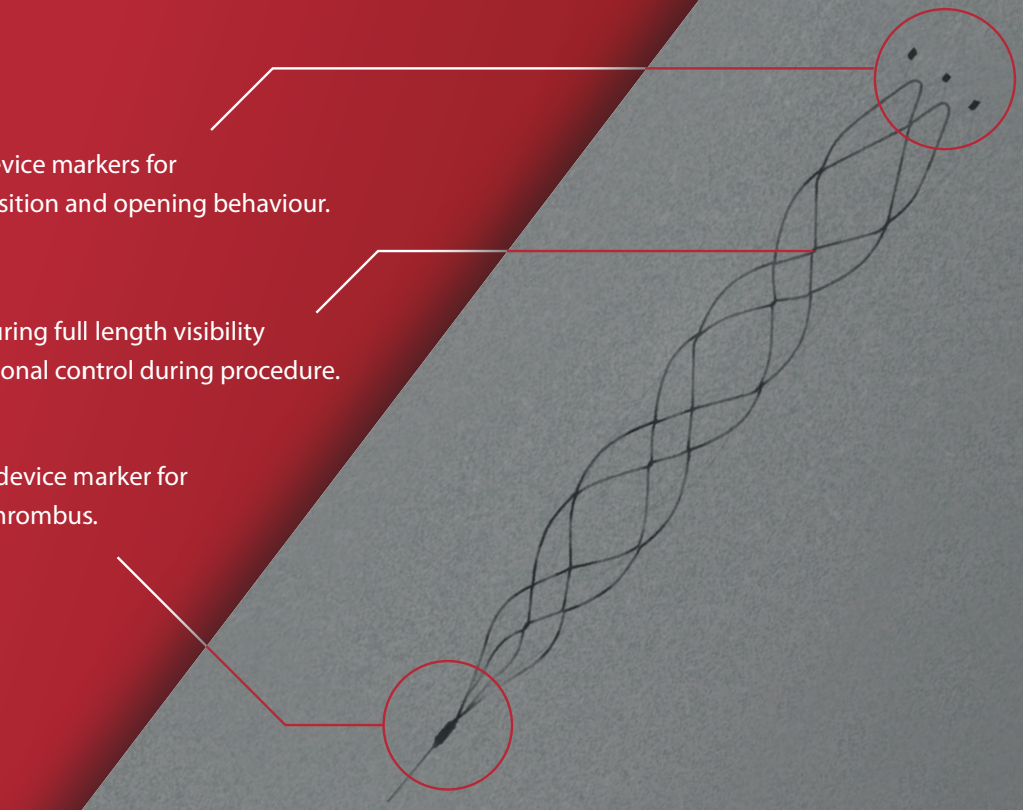
Simple and clear visibility concept for maximum control and assurance

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.





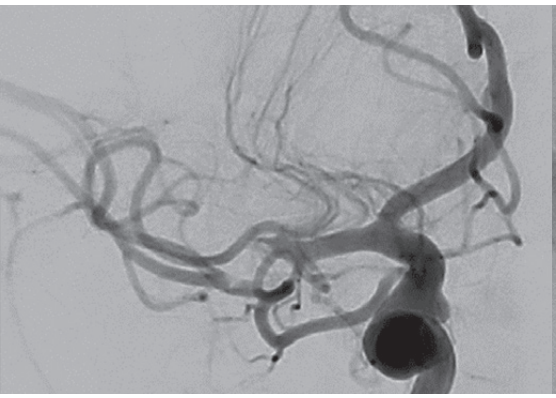
SAFE

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.

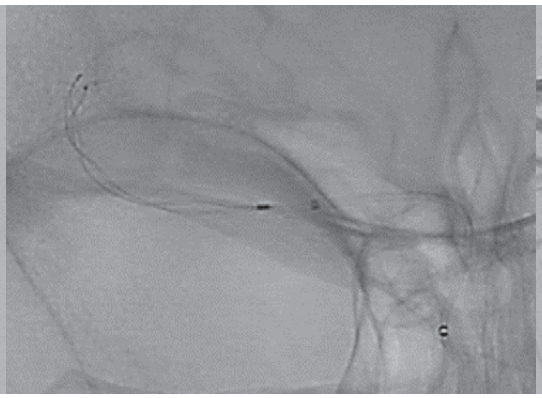
EFFICIENT

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

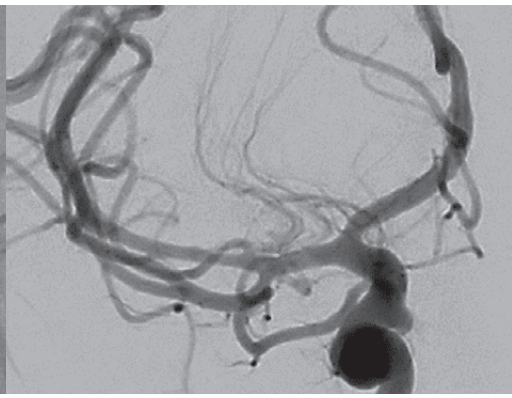
[1] Machi P, Jourdan F, Ambard D, et al Experimental evaluation of stent retrievers' mechanical properties and effectiveness, Journal of NeuroInterventional Surgery 2017;9:257-263.



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°

Distributed by:

acandis®
ENGINEERING STROKE SOLUTIONS

CE 0297

ACANDIS GmbH
Theodor-Fahrner-Str. 6
75177 Pforzheim
Deutschland

Tel: +49 7231 155 00 0
Fax: +49 7231 155 00 129
E-Mail: info@acandis.com
www.acandis.com

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

To whom correspondence should be addressed: Christoph Kabbasch, M.D. [E-mail: christoph.kabbasch@uk-koeln.de]

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.

Citation: World Neurosurg. (2020). https://doi.org/10.1016/j.wneu.2020.05.104

*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.

REFERENCES

1. Turc G, Bhogal P, Fischer U, et al. European Stroke Organisation (ESO)—European Society for Minimally Invasive Neurological Therapy (ESMINT) guidelines on mechanical thrombectomy in acute ischemic stroke [e-pub ahead of print]. *J Neurointerv Surg* https://doi.org/10.1136/neurintsurg-2018-014569, accessed February 16, 2020.

2. Powers WJ, Rabinstein AA, Ackerson T, et al. 2018 Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2018;49:E46-E110.

3. Berkhemer OA, Fransen PSS, Beumer D, et al. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med*. 2015;372:11-20.

4. Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med*. 2015;372:1009-1018.

5. Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. 2015;372:1019-1030.

6. Saver JL, Goyal M, Bonafe A, et al. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. *N Engl J Med*. 2015;372:2285-2295.

7. Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. 2015;372:2296-2306.

8. Riedel CH, Zimmermann P, Jensen-Kondering U, Stingele R, Deuschl G, Jansen O. The importance of size. *Stroke*. 2011;42:1775-1777.

9. Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. *N Engl J Med*. 2018;378:11-21.

10. Albers GW, Marks MP, Kemp S, et al. Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. *N Engl J Med*. 2018;378:708-718.

11. Pfaff J, Rohde S, Engelhorn T, Doerfler A, Bendszus M, Möhlenbruch MA. Mechanical thrombectomy using the new Solitaire™ Platinum stent-retriever: reperfusion results, complication rates and early neurological outcome. *Clin Neuroradiol*. 2019;29:311-319.

12. Kabbasch C, Mpotsaris A, Chang D-H, et al. Mechanical thrombectomy with the Trevo ProVue device in ischemic stroke patients: does improved visibility translate into a clinical benefit? *J Neurointerv Surg*. 2016;8:778-782.

13. Kaschner MG, Weiss D, Rubbert C, et al. 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*. 2019;40:1443-1451.

14. Humphries W, Hoit D, Doss VT, et al. Distal aspiration with retrievable stent assisted thrombectomy for the treatment of acute ischemic stroke. *J Neurointerv Surg*. 2015;7:90-94.

15. Zaidat OO, Castonguay AC, Nogueira RG, et al. TREVO stent-retriever mechanical thrombectomy for acute ischemic stroke secondary to large vessel occlusion registry. *J Neurointerv Surg*. 2018;10:516.

16. Brouwer PA, Yeo LLL, Holmberg A, et al. Thrombectomy using the EmboTrap device: core laboratory-assessed results in 201 consecutive patients in a real-world setting. *J Neurointerv Surg*. 2018;10:964.

17. Kabbasch C, Mpotsaris A, Liebig T, et al. First-in-man procedural experience with the novel EmboTrap® revascularization device for the treatment of ischemic stroke—a European multicenter series. *Clin Neuroradiol*. 2016;26:221-228.

18. Zaidat OO, Bozorgchami H, Ribó M, et al. Primary results of the multicenter ARISE II study (Analysis

of Revascularization in Ischemic Stroke with EmboTrap). *Stroke*. 2018;49:1107-1115.

19. Yi HJ, Lee DH, Kim SU. Effectiveness of Trevo stent retriever in acute ischemic stroke. *Medicine*. 2018;97:e10747.

20. Zaidat OO, Castonguay AC, Gupta R, et al. North American Solitaire Stent Retriever Acute Stroke registry: post-marketing revascularization and clinical outcome results. *J Neurointerv Surg*. 2014;6:584.

21. Singer OC, Haring H-P, Trenkler J, et al. Age dependency of successful recanalization in anterior circulation stroke: the ENDOSTROKE study. *Cerebrovasc Dis*. 2013;36:437-445.

22. Kallenberg K, Solymosi L, Taschner CA, et al. Endovascular stroke therapy with the Aperio thrombectomy device. *J Neurointerv Surg*. 2016;8:834.

23. Berg R van den, Mayer TE. International survey on neuroradiological interventional and therapeutic devices and materials. *Interv Neuroradiol*. 2015;21:646-652.

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.

Received 24 March 2020; accepted 12 May 2020

Citation: World Neurosurg. (2020). https://doi.org/10.1016/j.wneu.2020.05.104

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

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

1878-8750/$ - see front matter