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>

Digitally signed by Roibu Tatiana
Date: 2022.10.01 12:42:15 EEST
Reason: MoldSign Signature
Location: Moldova

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-1663222957295, ID:21063733 din 15.09.2022 privind aplicarea procedurii pentru atribuirea contractului privind achiziționarea consumabilelor angiografice conform necesităților IMSP Institutul de Medicină Urgentă 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: 01.10.2022

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 consumabilelor angiografice conform necesităților IMSP Institutul de Medicină Urgentă pentru anul 2022 prin procedura de achiziție licitație deschisă, pentru o durată de 60 zile, (șaizeci zile), respectiv până la data de 05.12.2022 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 01.10.2022

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>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1663222957295,
ID:21063733

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate pentru produsele oferite în cadrul licitației prenonate privind achiziționarea consumabilelor angiografice conform necesităților IMSP Institutul de Medicină Urgentă pentru anul 2022 va constitui la momentul livrării nu mai puțin de 80% din termenul total de valabilitate.

Cu respect,

Director Tatiana Roibu

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

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

LISTA FONDATORILOR
SRL TEHNOMEDICA

Fondator unic: Roibu Tatiana

IDNP: date cu caracter personal

Data prezentării 19.04.2022 13:56:22

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2021 - 31.12.2021

Entitatea: SRL "TEHNOMEDICA"
Cod CUIÎO: 37700778
Cod IDNO: 1002600053256

Sediul:
MD:
Raionul(municipiul): 102, DDF CENTRU
Cod CUATM: 0130, SEC.CENTRU
Strada:

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: 022601102
WEB:
E-mail:
Numele și coordonatele al contabilului-șef: Dl (dna) Popescu Ecaterina Tel. 069153407

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

Persoanele responsabile de semnarea situațiilor financiare* Popescu Ecaterina

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la 31.12.2021

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	0	0
	2. Imobilizări necorporale în exploatare, total	020	319	255
	din care: 2.1. concesiuni, licențe și mărci	021	0	0
	2.2. drepturi de autor și titluri de protecție	022	0	0
	2.3. programe informatice	023	0	0
	2.4. alte imobilizări necorporale	024	319	255
	3. Fond comercial	030	0	0
	4. Avansuri acordate pentru imobilizări necorporale	040	2861138	3906847
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	2861457	3907102
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060	0	0
	2. Terenuri	070	0	0
	3. Mijloace fixe, total	080	2174915	1775960
	din care: 3.1. clădiri	081	1038156	929187
	3.2. construcții speciale	082	0	0
	3.3. mașini, utilaje și instalații tehnice	083	34609	18080
	3.4. mijloace de transport	084	1042950	806787

A.	3.5. inventar și mobilier	085	0	0
	3.6. alte mijloace fixe	086	59200	21906
	4. Resurse minerale	090	0	0
	5. Active biologice imobilizate	100	0	0
	6. Investiții imobiliare	110	0	0
	7. Avansuri acordate pentru imobilizări corporale	120	0	0
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2174915	1775960
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140	0	0
	2. Investiții financiare pe termen lung în părți afiliate, total	150	0	0
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151	0	0
	2.2 împrumuturi acordate părților afiliate	152	0	0
	2.3 împrumuturi acordate aferente intereselor de participare	153	0	0
	2.4 alte investiții financiare	154	0	0
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160	0	0
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170	0	0
	2. Creanțe ale părților afiliate pe termen lung	180	0	0
	inclusiv: creanțe aferente intereselor de participare	181	0	0
	3. Alte creanțe pe termen lung	190	0	0
	4. Cheltuieli anticipate pe termen lung	200	0	0
	5. Alte active imobilizate	210	0	0
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220	0	0
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	5036372	5683062
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	4996	4996
	2. Active biologice circulante	250	0	0
	3. Producția în curs de execuție	260	0	0
	4. Produse și mărfuri	270	1326025	491017
	5. Avansuri acordate pentru stocuri	280	0	0
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	1331021	496013
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	1022910	2800290
	2. Creanțe ale părților afiliate curente	310	0	0
	inclusiv: creanțe aferente intereselor de participare	311	0	0
	3. Creanțe ale bugetului	320	6546	6546
	4. Creanțele ale personalului	330	0	0
	5. Alte creanțe curente	340	0	0
	6. Cheltuieli anticipate curente	350	13569	2114
	7. Alte active circulante	360	31297	
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	1074322	2808950
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380	700000	0
	2. Investiții financiare curente în părți afiliate, total	390	0	0
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391	0	0
	2.2. împrumuturi acordate părților afiliate	392	0	0
	2.3. împrumuturi acordate aferente intereselor de participare	393	0	0

	2.4. alte investiții financiare în părți afiliate	394	0	0
	Total investiții financiare curente (rd.380 + rd.390)	400	700000	0
	IV. Numerar și documente bănești	410	6916759	6867356
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	10022102	10172319
	TOTAL ACTIVE (rd.230 + rd.420)	430	15058474	15855381
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social și neînregistrat**			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	(0)	(0)
	3. Capital neînregistrat	460	0	0
	4. Capital retras	470	(0)	(0)
	5. Patrimoniul primit de la stat cu drept de proprietate	480	0	0
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500	0	0
	III. Rezerve			
	1. Capital de rezervă	510	0	0
	2. Rezerve statutare	520	0	0
	3. Alte rezerve	530	0	0
	Total rezerve (rd.510 + rd.520 + rd.530)	540	0	0
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	0
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	14705486	12203358
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	2864668
	4. Profit utilizat al perioadei de gestiune	580	X	(0)
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	14705486	15068026
	V. Rezerve din reevaluare	600	0	0
	VI. Alte elemente de capital propriu	610	0	0
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	14710886	15073426
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630	0	0
	2. Împrumuturi pe termen lung	640	0	0
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641	0	0
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642	0	0
	2.2. alte împrumuturi pe termen lung	643	0	0
	3. Datorii comerciale pe termen lung	650	0	0
	4. Datorii față de părțile afiliate pe termen lung	660	0	0
	inclusiv: datorii aferente intereselor de participare	661	0	0
	5. Avansuri primite pe termen lung	670	0	0
	6. Venituri anticipate pe termen lung	680	0	0
	7. Alte datorii pe termen lung	690	0	0
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700	0	0
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710	0	0

E.	2. Împrumuturi pe termen scurt, total	720	0	0
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	721	0	0
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722	0	0
	2.2. alte împrumuturi pe termen scurt	723	0	0
	3. Datorii comerciale curente	730	149510	288048
	4. Datorii față de părțile afiliate curente	740	0	0
	inclusiv: datorii aferente intereselor de participare	741	0	0
	5. Avansuri primite curente	750	0	0
	6. Datorii față de personal	760	977	100
	7. Datorii privind asigurările sociale și medicale	770	0	0
	8. Datorii față de buget	780	197101	493807
	9. Datorii față de proprietari	790	0	0
	10. Venituri anticipate curente	800	0	0
	11. Alte datorii curente	810	0	0
	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	347588	781955
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830	0	0
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840	0	0
	3. Provizioane pentru impozite	850	0	0
	4. Alte provizioane	860	0	0
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870	0	0
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	15058474	15855381

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2021 pînă la 31.12.2021

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	16620028	21962759
din care: venituri din vînzarea produselor și mărfurilor	011	13778008	19347659
venituri din prestarea serviciilor și executarea lucrărilor	012	2842020	2615100
venituri din contracte de construcție	013	0	0
venituri din contracte de leasing	014	0	0
venituri din contracte de microfinanțare	015	0	0
alte venituri din vînzări	016	0	0
Costul vînzărilor, total	020	12527753	16833673
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	11595535	16054470
costul serviciilor prestate și lucrărilor executate terților	022	932218	779203
costuri aferente contractelor de construcție	023	0	0
costuri aferente contractelor de leasing	024	0	0
costuri aferente contractelor de microfinanțare	025	0	0
alte costuri aferente vînzărilor	026	0	0
Profit brut (pierdere brută) (rd.010 - rd.020)	030	4092275	5129086
Alte venituri din activitatea operațională	040	986	1238
Cheltuieli de distribuire	050	0	
Cheltuieli administrative	060	1569273	1518335
Alte cheltuieli din activitatea operațională	070	17430	79468

Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	2506558	3532521
Venituri financiare, total	090	1257613	365919
din care: venituri din interese de participare	091	0	0
inclusiv: veniturile obținute de la părțile afiliate	092	0	0
venituri din dobînzi	093	0	0
inclusiv: veniturile obținute de la părțile afiliate	094	0	0
venituri din alte investiții financiare pe termen lung	095	0	0
inclusiv: veniturile obținute de la părțile afiliate	096	0	0
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097	0	0
venituri din ieșirea investițiilor financiare	098	0	0
venituri aferente diferențelor de curs valutar și de sumă	099	1257613	365919
Cheltuieli financiare, total	100	666851	603812
din care: cheltuieli privind dobînzile	101	0	0
inclusiv: cheltuielile aferente părților afiliate	102	0	0
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103	0	0
cheltuieli aferente ieșirii investițiilor financiare	104	0	0
cheltuieli aferente diferențelor de curs valutar și de sumă	105	666851	603812
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	590762	-237893
Venituri cu active imobilizate și excepționale	120	0	0
Cheltuieli cu active imobilizate și excepționale	130	0	0
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140	0	0
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	590762	-237893
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	3097320	3294628
Cheltuieli privind impozitul pe venit	170	410288	429960
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	2687032	2864668

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2021 pînă la 31.12.2021

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	0	0	5400
	2. Capital nevărsat	020	(0)	(0)	(0)	(0)
	3. Capital neînregistrat	030	0	0	0	0
	4. Capital retras	040	(0)	(0)	(0)	(0)
	5. Patrimoniul primit de la stat cu drept de proprietate	050	0	0	0	0
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5400	0	0	5400
II.	**Prime de capital**	070	0	0	0	0
III.	**Rezerve**					
	1. Capital de rezervă	080	0	0	0	0
	2. Rezerve statutare	090	0	0	0	0
	3. Alte rezerve	100	0	0	0	0
	Total rezerve (rd.080 + rd.090 + rd.100)	110	0	0	0	0

IV.	**Profit (pierdere)**					
	1. Corecții ale rezultatelor anilor precedenți	120	X	0	0	0
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	14705486	0	2502128	12203358
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	2864668	0	2864668
	4. Profit utilizat al perioadei de gestiune	150	X	(0)	(0)	(0)
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	14705486	2864668	2502128	15068026
V.	**Rezerve din reevaluare**	170	0	0	0	0
VI.	**Alte elemente de capital propriu**	180	0	0	0	0
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	14710886	2864668	2502128	15073426

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2021 pînă la 31.12.2021

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	17211991	23444192
Plăți pentru stocuri și servicii procurate	020	13370873	18993827
Plăți către angajați și organe de asigurare socială și medicală	030	554000	456668
Dobînzi plătite	040	0	0
Plata impozitului pe venit	050	414542	331089
Alte încasări	060	2220519	1598942
Alte plăți	070	5025576	3293285
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	67519	1968265
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090	0	0
Plăți aferente intrărilor de active imobilizate	100	0	0
Dobînzi încasate	110	0	0
Dividende încasate	120	0	0
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130	0	0
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140	0	0
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150	630000	800000
Plăți aferente rambursării creditelor și împrumuturilor	160	830000	0
Dividende plătite	170	2019064	2512000
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180	0	0
Alte încasări (plăți)	190	0	0
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-2219064	-1712000
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-2151545	256265
Diferențe de curs valutar favorabile (nefavorabile)	220	401419	-305668
Sold de numerar la începutul perioadei de gestiune	230	8666885	6916759
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	6916759	6867356

Documente atașate - Notă explicativă (fișierul pdf)

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

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. № A2218603 **din** от 28.09.2022

1. Destinația / Назначение

PENTRU PARTICIPAREA LA PROCEDURI PRIVIND ACHIZIȚIILE 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 13.10.2022

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

Șef DDF CENTRU
Funcția/Должность

Digitally signed by Iasinschi Veronica
Date: 2022.09.29 08:38:02 EEST
Reason: MoldSign Signature
Location: Moldova
Semnătura/Подпись

Veronica IASINSCHI
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: Fodor V.
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 28.09.2022 ora 14:48:57 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (304,54)

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-1663222957295,
ID:21063733

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante pentru produsele oferite în cadrul licitației prenonate privind achiziționarea consumabilelor angiografice conform necesităților IMSP Institutul de Medicină Urgentă 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-1663222957295,
ID:21063733

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

Numerele de înregistrare se regăsesc în anexa la prezenta declarație.

Cu respect,

Director Tatiana Roibu

DM000196479	DISPOZITIV DE EMBOLIZARE	Derivo	4,0 mm 20 mm	**01-000330**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196480	DISPOZITIV DE EMBOLIZARE	Derivo	4,5 mm 20 mm	**01-000331**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196481	DISPOZITIV DE EMBOLIZARE	Derivo	5,0 mm 20 mm	**01-000332**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196482	DISPOZITIV DE EMBOLIZARE	Derivo	5,5 mm 20 mm	**01-000333**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196483	DISPOZITIV DE EMBOLIZARE	Derivo	6,0 mm 20 mm	**01-000334**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196484	DISPOZITIV DE EMBOLIZARE	Derivo	4,0 mm 25 mm	**01-000335**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196485	DISPOZITIV DE EMBOLIZARE	Derivo	4,5 mm 25 mm	**01-000336**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196486	DISPOZITIV DE EMBOLIZARE	Derivo	5,0 mm 25 mm	**01-000337**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196487	DISPOZITIV DE EMBOLIZARE	Derivo	5,5 mm 25 mm	**01-000338**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196488	DISPOZITIV DE EMBOLIZARE	Derivo	6,0 mm 25 mm	**01-000339**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196489	DISPOZITIV DE EMBOLIZARE	Derivo	4,0 mm 30 mm	**01-000340**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196490	DISPOZITIV DE EMBOLIZARE	Derivo	4,5 mm 30 mm	**01-000341**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196491	DISPOZITIV DE EMBOLIZARE	Derivo	5,0 mm 30 mm	**01-000342**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196492	DISPOZITIV DE EMBOLIZARE	Derivo	5,5 mm 30 mm	**01-000343**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196493	DISPOZITIV DE EMBOLIZARE	Derivo	6,0 mm 30 mm	**01-000344**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196509	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	4,0 mm 40 mm	**01-000360**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196510	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	4,5 mm 40 mm	**01-000361**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196511	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	5,0 mm 40 mm	**01-000362**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196512	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	5,0 mm 50 mm	**01-000363**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019

DM000196513	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	5,5 mm 40 mm	**01-000364**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196514	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	5,5 mm 50 mm	**01-000365**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196515	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	6,0 mm 40 mm	**01-000366**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196516	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	6,0 mm 50 mm	**01-000367**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196530	DISPOZITIV DE EMBOLIZARE	Derivo	4,0 mm 15 mm	**01-000381**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196531	DISPOZITIV DE EMBOLIZARE	Derivo	4,5 mm 15 mm	**01-000382**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196532	DISPOZITIV DE EMBOLIZARE	Derivo	5,0 mm 15 mm	**01-000383**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196533	DISPOZITIV DE EMBOLIZARE	Derivo	5,5 mm 15 mm	**01-000384**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196534	DISPOZITIV DE EMBOLIZARE	Derivo	6,0 mm 15 mm	**01-000385**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196543	DISPOZITIV DE EMBOLIZARE	Derivo	3,5 mm 15 mm	**01-000408**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196544	DISPOZITIV DE EMBOLIZARE	Derivo	3,5 mm 20 mm	**01-000409**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196545	DISPOZITIV DE EMBOLIZARE	Derivo	3,5 mm 25 mm	**01-000410**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196546	DISPOZITIV DE EMBOLIZARE	Derivo	3,5 mm 30 mm	**01-000411**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019
DM000196550	DISPOZITIV DE EMBOLIZARE FĂRĂ VÂRF	Derivo	3,5 mm 40 mm	**01-000415**	Germania	ACANDIS GMBH	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-8	22-01-2019

VISIBLE ADAPTABILITY

DERIVO® Embolisation Device

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

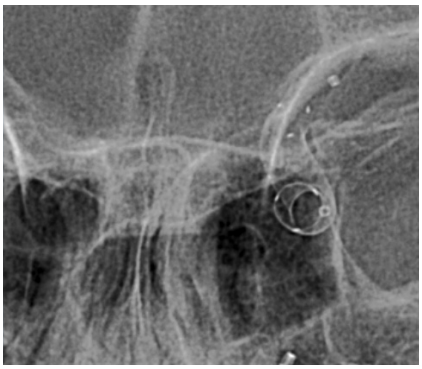
αcandis®

ENGINEERING STROKE SOLUTIONS

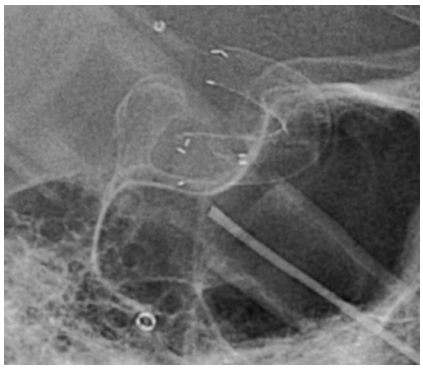
Proven Technology – Safe and Efficient

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.

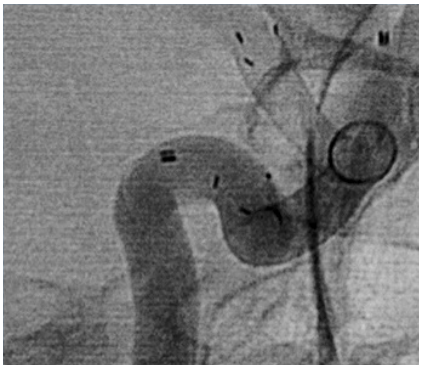


Opening of DERIVO® in tight curve is clearly visible.

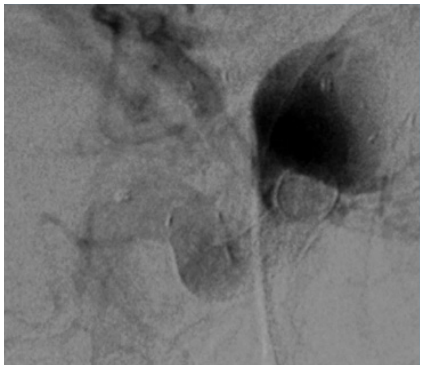
Images by courtesy of: Prof. Reith, Department of Neuroradiology, Saarland University Hospital, Homburg, Germany

Balanced mechanical properties for excellent clinical performance

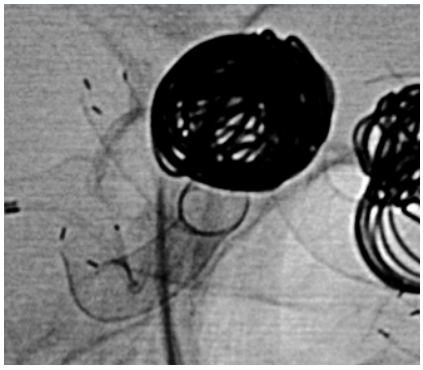
Treatment of large right ICA aneurysm with DERIVO® 4.0 mm x 30 mm



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

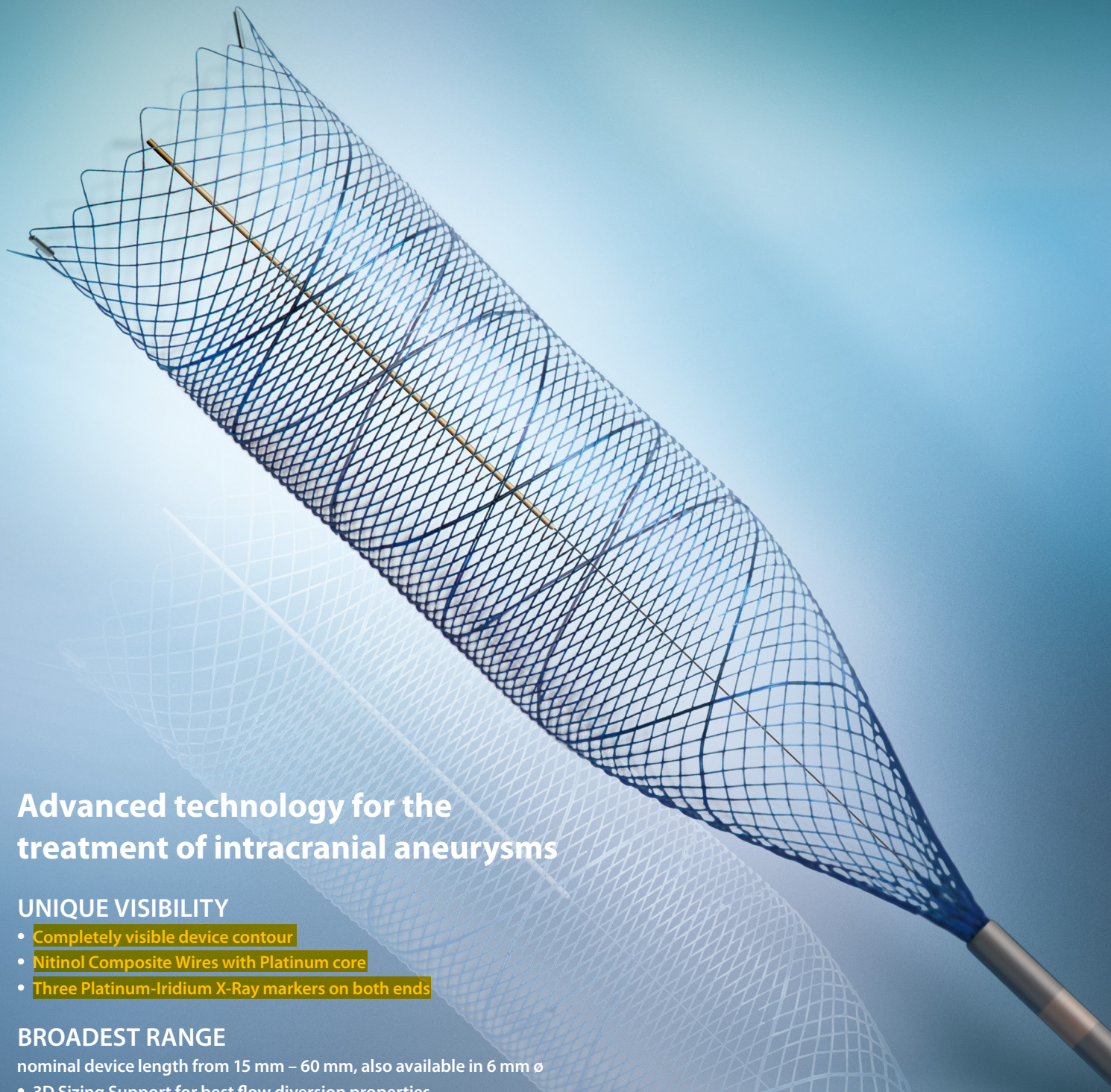


Immediate flow diversion effect after DERIVO® placement.



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.

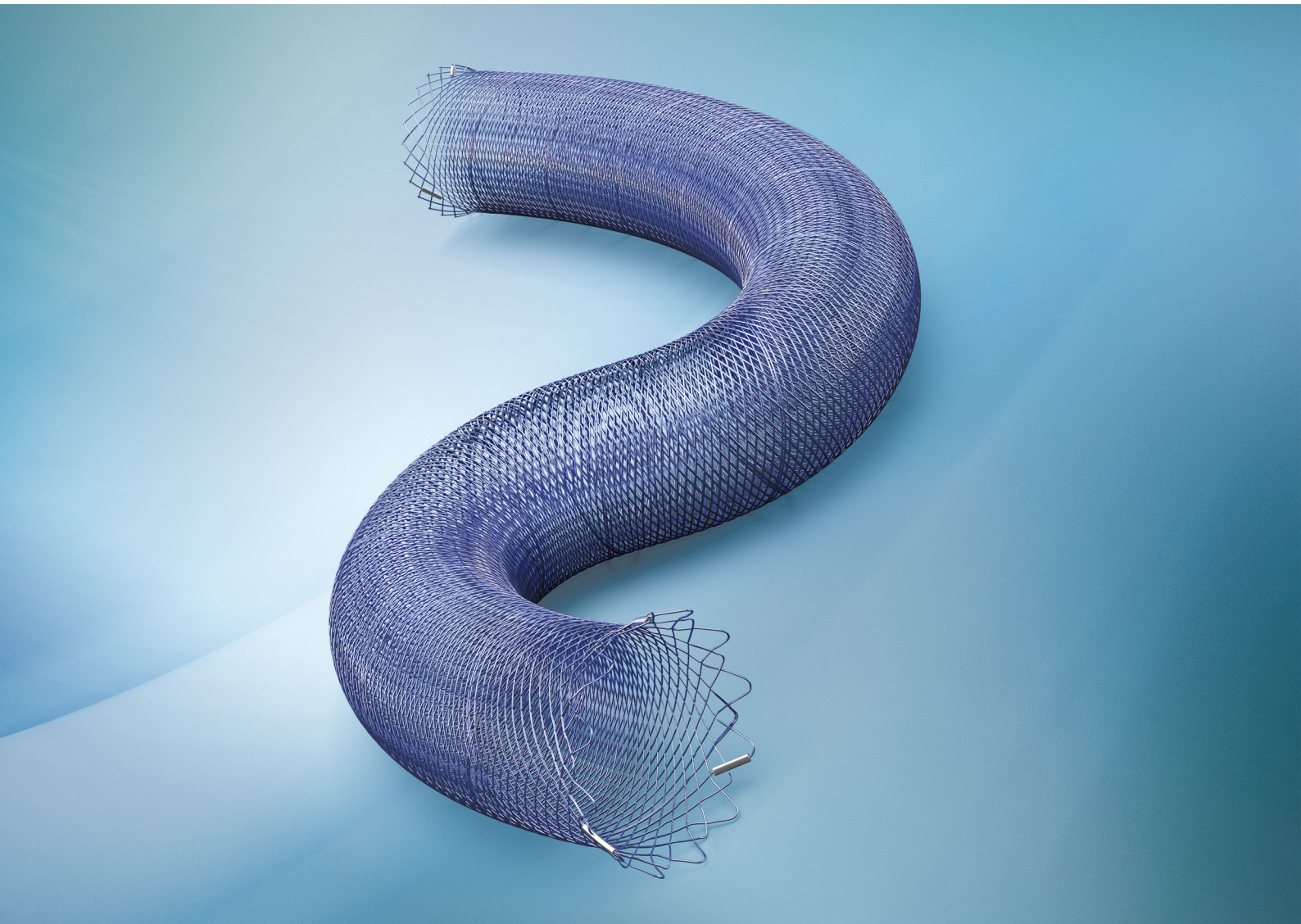
BlueXide® Surface Finishing
The Acandis® proprietary BlueXide® Surface Finishing Technology ensures less friction during delivery through the microcatheter as well as during expansion, making the opening of the device smooth and reliable. This finishing contributes to better corrosion resistance which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

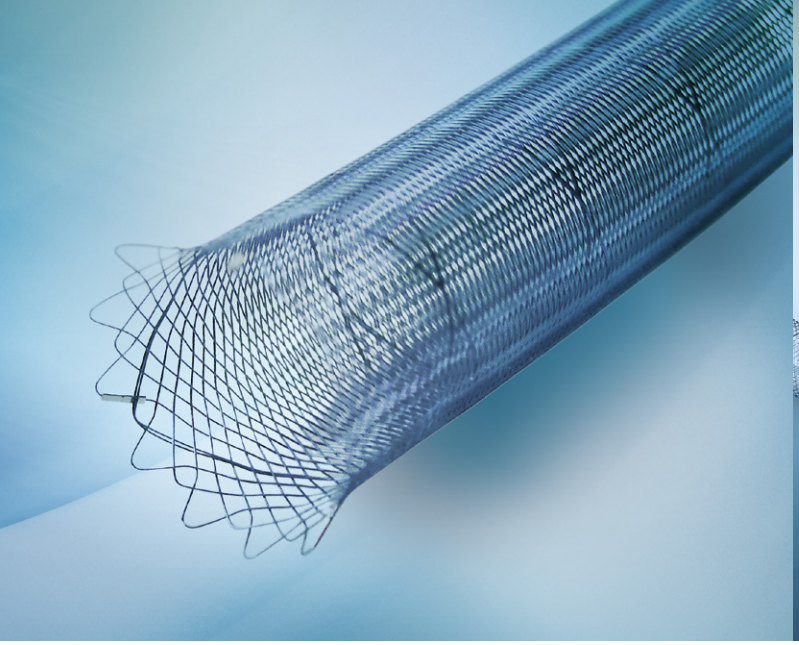
Nitinol Composite Wires
The entire device consists of Nitinol Composite Wires with Platinum core leading to an outstanding visualisation of the contour and shape of the device under fluoroscopy.

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.





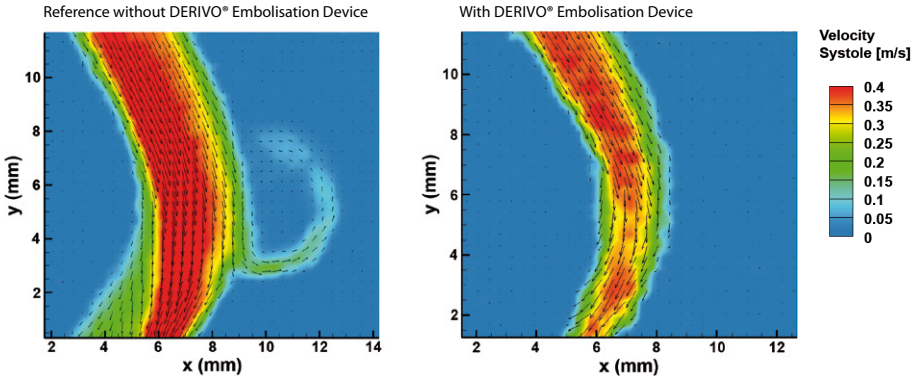
Flow Diversion

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.

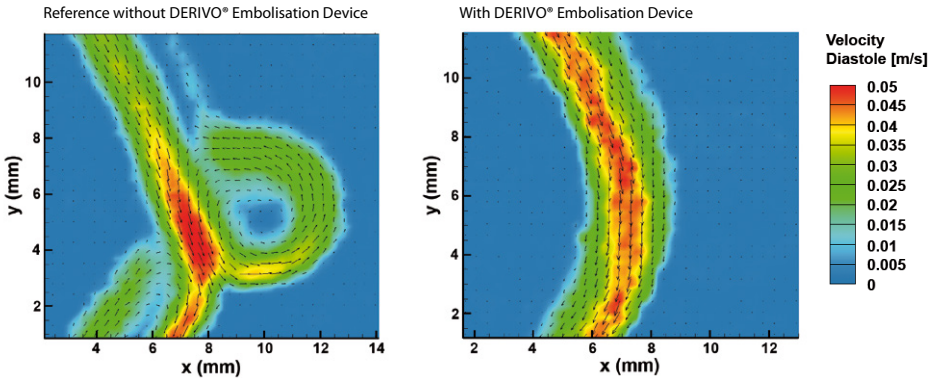
Vessel Wall Conformability

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

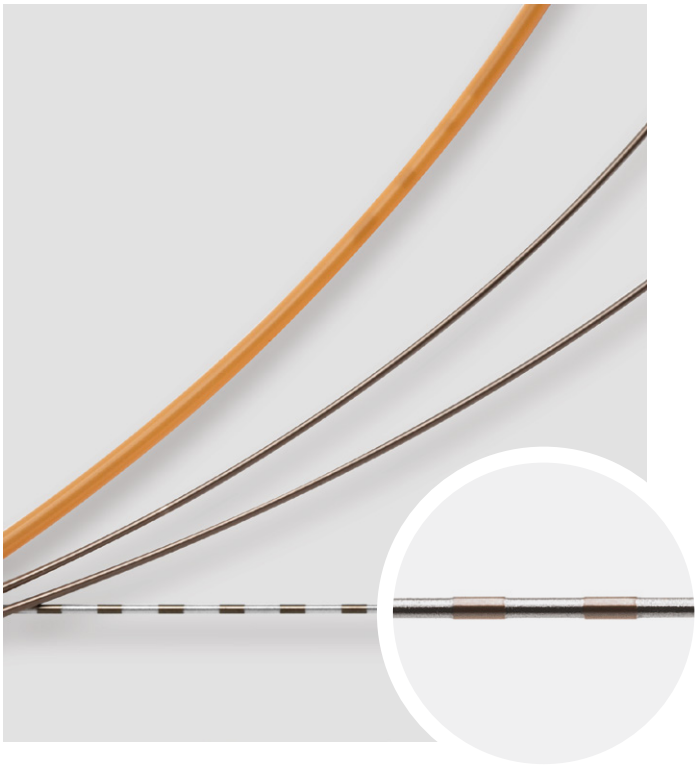
C- controlled

U- unique

R- reliable

E- effective

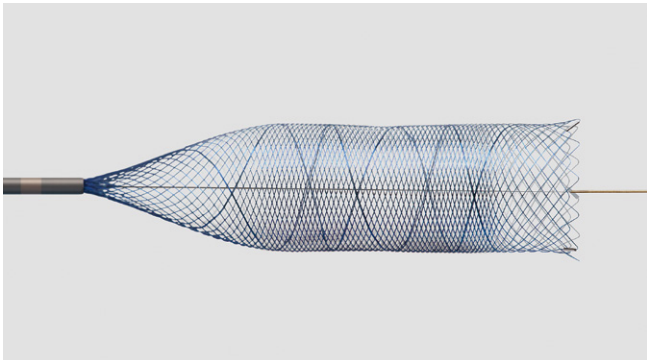
The sleek surface of the transport wire changes into a unique – optically and tactile perceptible – checkered surface at the fluoroscopy marker point, to enhance the grip and push for a controlled and safe placement of the DERIVO® Embolisation Device.



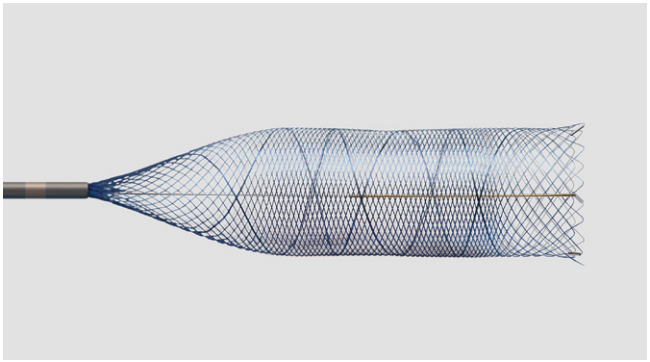
Resheathability

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.

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4.0	15	01-000381	3.0 – 4.0	
	20	01-000330		
	25	01-000335		
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ORIGINAL ARTICLE

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

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Abstract

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

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

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

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

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

Abbreviations

CTA Computed tomography angiography,
DED Derivo embolization device,
DSA Digital subtraction angiography,
EVT Endovascular treatment,
ICA Internal carotid artery,
MRA Magnetic resonance angiography,
OKM O'Kelly-Marotta,
PED Pipeline embolization device,
SAH Subarachnoid hemorrhage

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

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Introduction

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

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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.

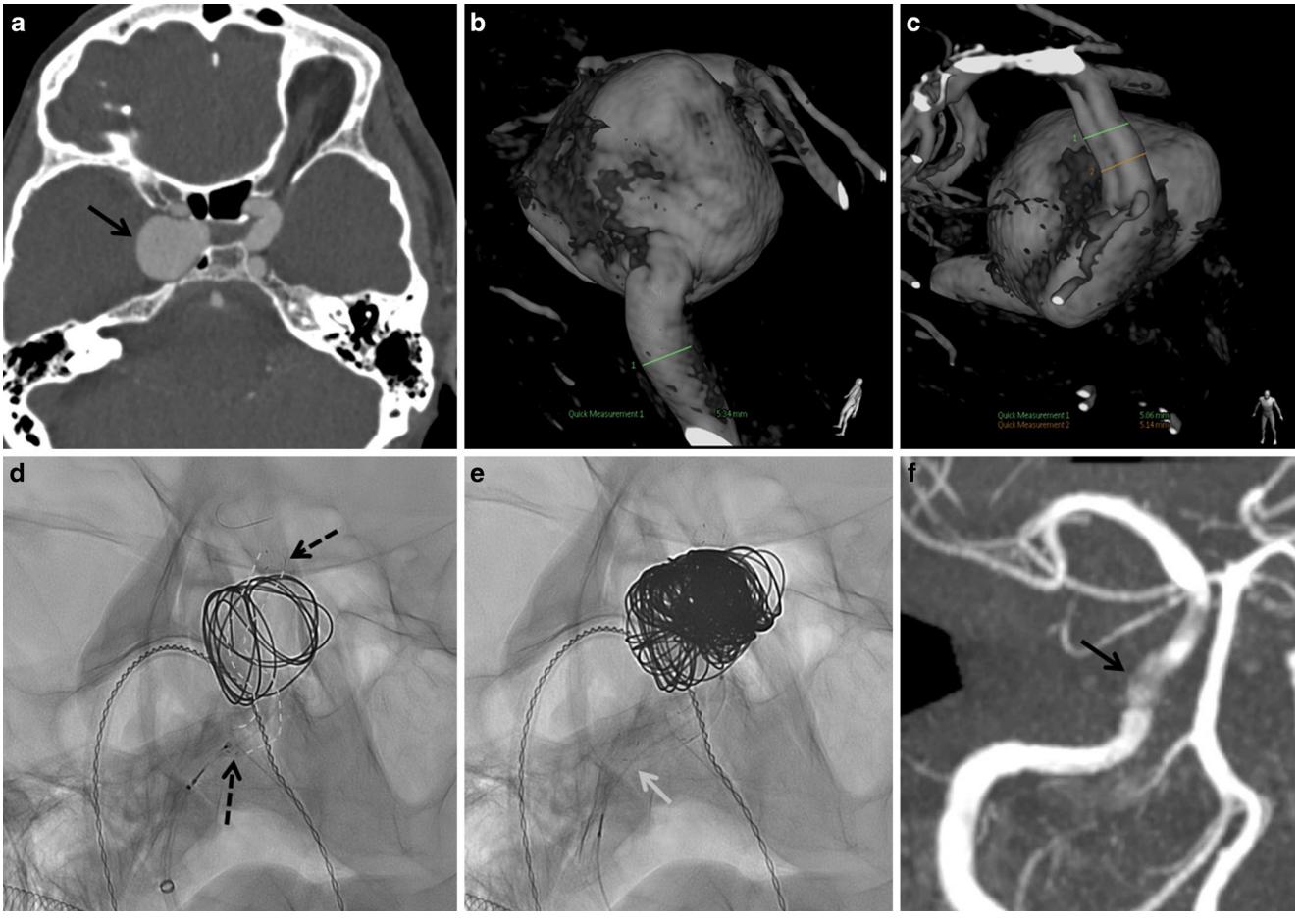

Fig. 1 Patient 6 presented with 3rd cranial nerve palsy. **a** CTA revealed a right cavernous ICA aneurysm measuring 25 mm in maximum diameter. Volume rendered 3D-DSA images illustrating the proximal (**b**) and distal (**c**) parent vessel artery diameters. **d** Initial 5.5 × 30 DED delivered (*dashed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

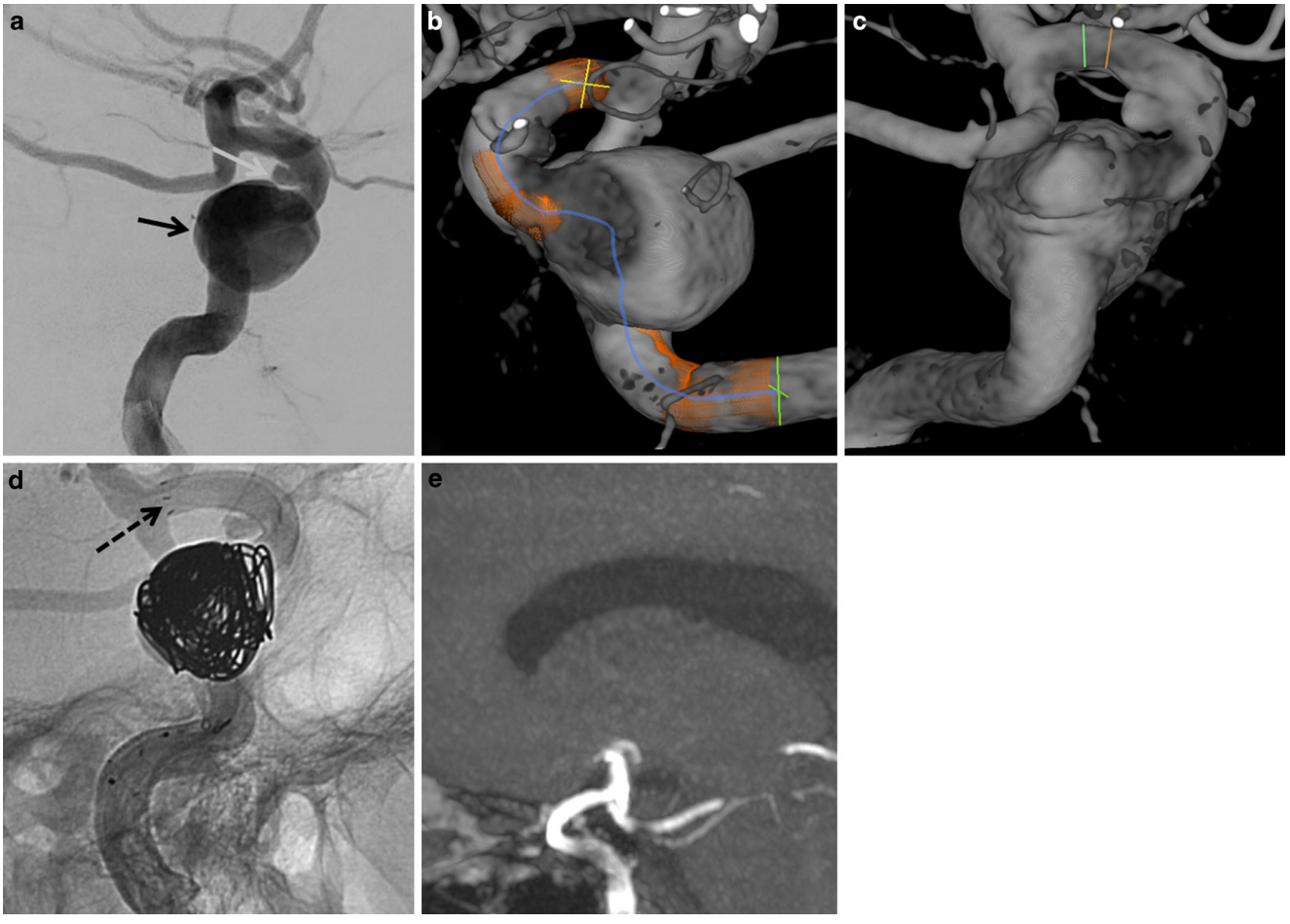

Fig. 2 Patient 11 presented with right 3rd cranial nerve palsy and worsening headaches. **a** Initial DSA reveals a 14 mm left cavernous ICA aneurysm (*solid black arrow*) and a smaller 4 mm left paraophthalmic ICA aneurysm (*solid white arrow*). **b** and **c** 3D-DSA volume rendered images illustrating 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.

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

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