CERTIFICATE

This is to certify that the company

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

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

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Devices and Microspheres.

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.	487703 MP2016
Certificate unique ID	170736547
Effective date	2019-11-14
Expiry date	2022-11-13
Frankfurt am Main	2019-11-14

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

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

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:

Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires) and Accessories, Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres and Detachment Controller Units as listed in 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.	411133 MR2
Certificate unique ID	170752398
Effective date	2019-10-07
Expiry date	2022-11-02
Frankfurt am Main	2019-10-07

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.

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Production Sites:

1.
MicroVention, Inc.
35 Enterprise,
Aliso Viejo, CA 92656
United States of America

2.
MicroVention, Inc.
1311 Valencia Ave.
Tustin, CA 92780
United States of America

3.
MicroVention Costa Rica, S.R.L.
Zona Franca Coyol
Alajuela,
Costa Rica

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	V-Trak® Detachable Embolization Coils System	MicroPlex® Platinum Detachable Embolization Coils - Helical – Standard Helical-Reg. and Soft 10 & 18, - HyperSoft® 10 & 3D - Complex 10 & 18 - Compass 10 & 18, - COSMOS® 10 & 18 - VFC™	III	1,2,3
		HydroCoil® Platinum/Hydrogel Detachable Embolization Coils - HydroCoil® 10 & 14 & 18, - HydroSoft® 10 - HydroFill® - HydroFrame® 10 & 18 - HydroSoft 3D	III	1,2,3
	AZUR® Peripheral Coil System	AZUR® HydroCoil Detachable Embolization Coils 18 & 35 AZUR® HydroCoil Pushable Embolization Coils 18 & 35 AZUR® Framing Detachable Coils 18 & 35 AZUR® Injectable Coil System 18 & 35 AZUR Detachable 18 AZUR PURE Pushable Coil System 18 & 35 AZUR CX Detachable 18 & 35	IIb	1,2,3
Detachment Controller Units		V-Grip® Detachment Controller V-Grip® PLUS Detachment Controller WEB Detachment Controller AZUR® Detachment Controller	IIa IIa IIa IIa	1,2 1,2 1,2 1,2
Intravascular Access Devices		Traxcess® 14 Guidewire Traxcess® 14 EX Guidewire Traxcess® 14 SELECT Guidewire Traxcess® 7 Mini Guidewire Traxcess® 7 Mini XSoft Guidewire Traxcess® Docking Wire	III IIa	2 2

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Catheters		Chaperon® Guiding Catheter System	III	2
		Headway® 17 Advanced Soft Microcatheter		2,3
		Headway® 17 Advanced Microcatheter		2,3
		Headway® 21 Microcatheter		2,3
		Headway® 27 Microcatheter		2,3
		Headway Duo Microcatheter		2,3
		Scepter C™ Occlusion Balloon Catheter		1,2,3
		Scepter XC™ Occlusion Balloon Catheter		1,2,3
		Scepter Mini™ Occlusion Balloon Catheter		1,2
		SOFIA™ Distal Access Catheter		1,2,3
		SOFIA™ Select Catheter		1,2,3
		SOFIA™ PLUS Catheter		1,2,3
		SOFIA™ Flow PLUS Catheter		1,2,3
		SOFIA™ Guiding Catheter		1,2,3
		SOFIA™ Flow Catheter		1,2,3
		SOFIA® EX Catheter		1,2,3
		KANSHAS Drug Coated Balloon		1
		VIA™ 17 Microcatheter		2
		VIA™ 21 Microcatheter		2
		VIA™ 27 Microcatheter		2
		VIA™ 33 Microcatheter		2
		Wedge Microcatheter		2,3
Stents		LVIS™ Intraluminal Support Device	III	1,2,3
		LVIS Jr.™ Intraluminal Support Device		
		LVIS™ EVO Intraluminal Support Device		
		FRED® Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED Jr.® Flow Re-Direction Endoluminal Device		1,2,3
		CASPER™ RX Carotid Artery Stent System		1,2,3
		Roadsaver Carotid Artery Stent System		1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170752398
Effective date: 2019-10-07

MicroVention, Inc.

1311 Valencia Ave.
Tustin, CA, 92780
United States of America

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Peripheral Vascular Stent System		CASPER™ Peripheral Vascular Stent System	IIb	1,2,3
		RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2,3
Liquid Embolic System Microspheres		PHIL™ Liquid Embolic System	III	1,2
		HydroPearl Microspheres	IIb	1,2
		LifePearl Microspheres	III	1,2
		BioPearl® Microspheres	III	1,2
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,2,3
		Nanoparasol Embolic Protection System		
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1,2
Aspiration Tubing Kit		Aspiration Tubing Kit	Is	2
Aspiration Syringe Kit		Aspiration Syringe Kit	Is	2
AZUR Vascular Plug		AZUR Vascular Plug	IIb	1,2
PG Pro Microcatheter		PG Pro Microcatheter	IIa	1,2

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention Europe SARL

30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

that the design of the following device(s)

FRED™ Flow Re-Direction Endoluminal Devices
FRED Jr. ™ Flow Re-Direction Endoluminal Devices
FRED X™ Flow Re-Direction Endoluminal Devices
FRED OMEGA™ Flow Re-Direction Endoluminal Devices

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. 487703 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:
FRED-FRED Jr STED.docx dated 2019-02-22
FRED-FRED Jr-FRED X STED_29Jan2020_Clean Copy.docx dated 2020-01-29
ST012 Rev B FRED Product family STED.pdf dated 2021-04-10

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

Examination report:
411_18e_Report_TFR_Sample_Version 6.docx dated 2019-06-24
411_18e_Report_TFR_FRED Change FRED X 2020.docx dated 2020-03-23
411_18e_Report_TFR_FRED Change FRED OMEGA 2021.docx dated 2021-04-29

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

Certificate registration no.	502357 MRA
Certificate unique ID	170775718
Effective date	2021-04-29
Expiry date	2024-05-26
Frankfurt am Main	2021-04-29

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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 DECLARATION OF CONFORMITY

RF 19-0025 Rev. B
DC Number:DC20-03704

We, MicroVention Europe SARL, located in Saint-Germain-en-Laye, France, declare according to Directive 93/42/EEC Annex II under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Council Directive 93/42/EEC

Conformity Assessment Procedure Performed:

EC Design Examination Certificate ☒ (Annex II.4) 502357 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
FRED® Flow Re-Direction Endoluminal Device FRED® Jr. Flow Re-Direction Endoluminal Device FRED® X™ Flow Re-Direction Endoluminal Device	*See attached list*	Class III – Annex IX, Rule 8 Subclause 2	46352

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA MicroVention Costa Rica, S.R.L. Zona Franca Coyol Alajuela, Costa Rica MicroVention, Inc. 35 Enterprise Aliso Viejo, California 92656 USA	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration applies to all device(s) specified above distributed from the signature date forward.

J. Kulinets

Irina Kulinets
Sr. Vice President, Regulatory Affairs,
Quality, Clinical Research
MicroVention Europe SARL

Saint-Germain-en-Laye, France
Place of Issue

6/23/2020
Date of Issue

Certificate Expiry Date: 26 May 2024

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
Siège Social : 30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) 20 Quater rue Schnapper – 78100 Saint-Germain-en-Laye
Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 - E-mail : contact-europe@microvention.com

EC DECLARATION OF CONFORMITY

FRED, FRED Jr and FRED X Flow Re-Direction Endoluminal Device
Model Numbers

FRED			
FRED3507	FRED4007	FRED4508	FRED5009
FRED3509	FRED4009	FRED4511	FRED5011
FRED3511	FRED4012	FRED4513	FRED5014
FRED3513	FRED4014	FRED4518	FRED5019
FRED3516	FRED4017	FRED4524	FRED5026
FRED3524	FRED4026	FRED4528	FRED5029
FRED3536	FRED4038	FRED4539	FRED5514
			FRED5519
			FRED5526
FRED Jr.			
FREDJR2508	FREDJR2518	FREDJR3009	FREDJR3019
FREDJR2509	FREDJR2519	FREDJR3010	FREDJR3020
FREDJR2510	FREDJR2520	FREDJR3011	FREDJR3021
FREDJR2511	FREDJR2521	FREDJR3012	FREDJR3022
FREDJR2512	FREDJR2522	FREDJR3013	FREDJR3023
FREDJR2513	FREDJR2523	FREDJR3014	FREDJR3024
FREDJR2514	FREDJR2524	FREDJR3015	FREDJR3025
FREDJR2515	FREDJR2525	FREDJR3016	FREDJR3026
FREDJR2516	FREDJR2526	FREDJR3017	FREDJR3027
FREDJR2517		FREDJR3018	
FRED X			
XFRED3507	XFRED4007	XFRED4508	XFRED5009
XFRED3509	XFRED4009	XFRED4511	XFRED5011
XFRED3511	XFRED4012	XFRED4513	XFRED5014
XFRED3513	XFRED4014	XFRED4518	XFRED5019
XFRED3516	XFRED4017	XFRED4524	XFRED5026
XFRED3524	XFRED4026	XFRED4528	XFRED5029
XFRED3536	XFRED4038	XFRED4539	XFRED5514
			XFRED5519
			XFRED5526
XFRED2508	XFRED2518	XFRED3009	XFRED3019
XFRED2509	XFRED2519	XFRED3010	XFRED3020
XFRED2510	XFRED2520	XFRED3011	XFRED3021
XFRED2511	XFRED2521	XFRED3012	XFRED3022
XFRED2512	XFRED2522	XFRED3013	XFRED3023
XFRED2513	XFRED2523	XFRED3014	XFRED3024
XFRED2514	XFRED2524	XFRED3015	XFRED3025
XFRED2515	XFRED2525	XFRED3016	XFRED3026
XFRED2516	XFRED2526	XFRED3017	XFRED3027
XFRED2517		XFRED3018	

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
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Tél. : +33 (0)1 39 21 77 46 – Fax : +33 (0)1 39 21 16 01 - E-mail : contact-europe@microvention.com

FRED® Jr.

Flow Re-Direction Endoluminal Device

PRODUCT SIZES

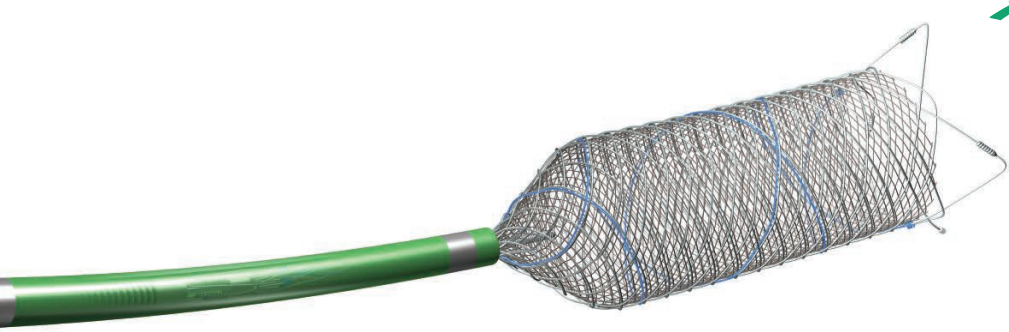
One unit per box.

Fully Open Implant Diameter	Product Code	*Working Length (mm) / Total Length (mm) at Target Vessel Diameters (mm)			Crimped Length *Inside Microcatheter (mm)*	% Foreshortening *At Fully Open Implant Diameter*
		2.0	2.5	3.0		
2.5	FREDJR2508	11 / 15	8 / 13		18	27
2.5	FREDJR2513	17 / 21	13 / 18		26	33
2.5	FREDJR2520	28 / 32	20 / 25		40	38
2.5	FREDJR2526	35 / 38	26 / 30		49	39
3.0	FREDJR3009		12 / 16	9 / 13	20	32
3.0	FREDJR3014		19 / 23	14 / 19	30	38
3.0	FREDJR3021		29 / 34	21 / 27	46	42
3.0	FREDJR3027		37 / 41	27 / 32	56	44

* Outer device total length (including flared ends) and inner device working length (marked by helical strands), constrained in vessel.

DELIVERED THROUGH:

Headway® 21 Microcatheter

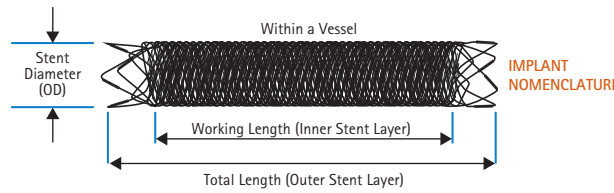


MicroVention® TERUMO

EMEA

FRED® Jr.

Flow Re-Direction Endoluminal Device



EFFECTIVE METAL SURFACE AREA

One unit per box.

Fully Open Implant Diameter	Product Code	*Effective Metal Surface Area (%) at Target Vessel Diameters (mm)		
		2.0	2.5	3.0
2.5	FREDJR2508	29	31	
2.5	FREDJR2513	30	31	
2.5	FREDJR2520	29	33	
2.5	FREDJR2526	30	32	
3.0	FREDJR3009		25	28
3.0	FREDJR3014		25	28
3.0	FREDJR3021		25	28
3.0	FREDJR3027		26	29

* Effective Metal Surface Area (%) measured for the inner stent, which provides flow diversion.

The FRED® and FRED® Jr. systems are CE Marked. The FRED Jr. system is not approved in the United States. The FRED system is limited by United States law to investigational use only.

INDICATIONS FOR USE:
The system is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED and FRED Jr. system may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

CE 0297

MicroVention® TERUMO

MicroVention, Inc.
Worldwide Headquarters PH +1.714.247.8000
1311 Valencia Avenue
Tustin, CA 92780, USA
MicroVention UK Limited PH +44 (0) 191 258 6777
MicroVention Europe, S.A.R.L. PH + 33 (1) 39 21 77 46
MicroVention Deutschland Gmbh PH +49 211 210 798-0
Web **microvention.com**

FRED®

Flow Re-Direction Endoluminal Device

PRODUCT SIZES

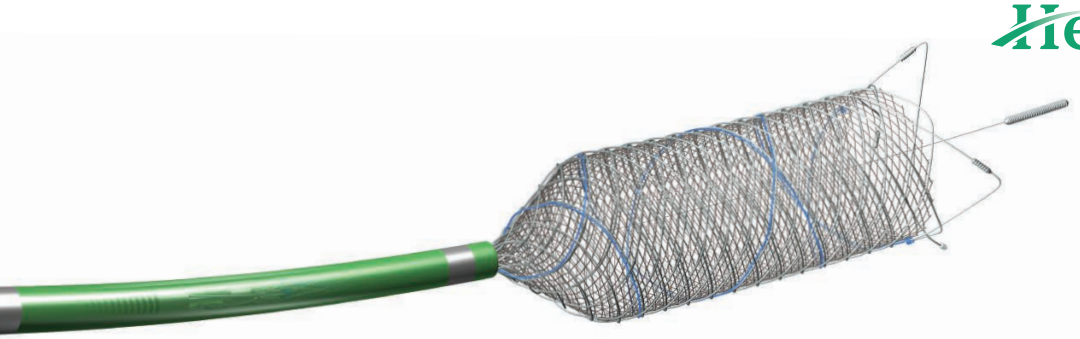
One unit per box.

Fully Open Implant Diameter	Product Code	*Working Length (mm) / Total Length (mm) at Target Vessel Diameters (mm)						Crimped Length *Inside Microcatheter (mm)*	% Foreshortening *At Fully Open Implant Diameter*
		3.0	3.5	4.0	4.5	5.0	5.5		
3.5	FRED3507	10 / 16	7 / 13					21	39
3.5	FRED3511	17 / 22	11 / 17					32	47
3.5	FRED3516	24 / 30	16 / 22					44	49
3.5	FRED3524	34 / 40	24 / 31					61	48
3.5	FRED3536	49 / 54	36 / 40					83	52
4.0	FRED4007		10 / 16	7 / 13				24	42
4.0	FRED4012		18 / 24	12 / 18				36	49
4.0	FRED4017		26 / 31	17 / 23				49	53
4.0	FRED4026		37 / 43	26 / 32				69	53
4.0	FRED4038		53 / 58	38 / 44				94	55
4.5	FRED4508			11 / 18	8 / 15			27	43
4.5	FRED4513			19 / 26	13 / 20			41	51
4.5	FRED4518			27 / 34	18 / 25			55	55
4.5	FRED4528			39 / 45	28 / 34			77	56
4.5	FRED4539			56 / 62	39 / 45			105	57
5.0	FRED5009				12 / 18	9 / 15		28	44
5.0	FRED5014				20 / 26	14 / 21		44	53
5.0	FRED5019				28 / 35	19 / 26		60	56
5.0	FRED5029				41 / 48	29 / 36		84	57
5.5	FRED5514					22 / 28	14 / 22	48	54
5.5	FRED5526					38 / 46	26 / 32	83	59

* Outer device total length (including flared ends) and inner device working length (marked by helical strands), constrained in vessel.

DELIVERED THROUGH:

Headway® 27 Microcatheter

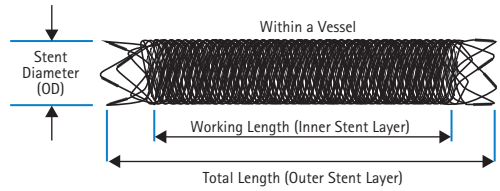


MicroVention® TERUMO

EMEA

FRED®

Flow Re-Direction Endoluminal Device



IMPLANT NOMENCLATURE

EFFECTIVE METAL SURFACE AREA

One unit per box.

Fully Open Implant Diameter	Product Code	*Effective Metal Surface Area (%) at Target Vessel Diameters (mm)					
		3.0	3.5	4.0	4.5	5.0	5.5
3.5	FRED3507	35	42				
3.5	FRED3511	34	43				
3.5	FRED3516	34	44				
3.5	FRED3524	30	38				
3.5	FRED3536	31	36				
4.0	FRED4007		32	39			
4.0	FRED4012		31	40			
4.0	FRED4017		32	42			
4.0	FRED4026		28	37			
4.0	FRED4038		28	34			
4.5	FRED4508			30	37		
4.5	FRED4513			30	40		
4.5	FRED4518			29	39		
4.5	FRED4528			26	36		
4.5	FRED4539			26	33		
5.0	FRED5009				28	33	
5.0	FRED5014				28	36	
5.0	FRED5019				28	36	
5.0	FRED5029				25	33	
5.5	FRED5514					25	34
5.5	FRED5526					25	36

* Effective Metal Surface Area (%) measured for the inner stent, which provides flow diversion.

The FRED® and FRED® Jr. systems are CE Marked. The FRED Jr. system is not approved in the United States. The FRED system is limited by United States law to investigational use only.

INDICATIONS FOR USE:
The system is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED and FRED Jr. system may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

CE 0297

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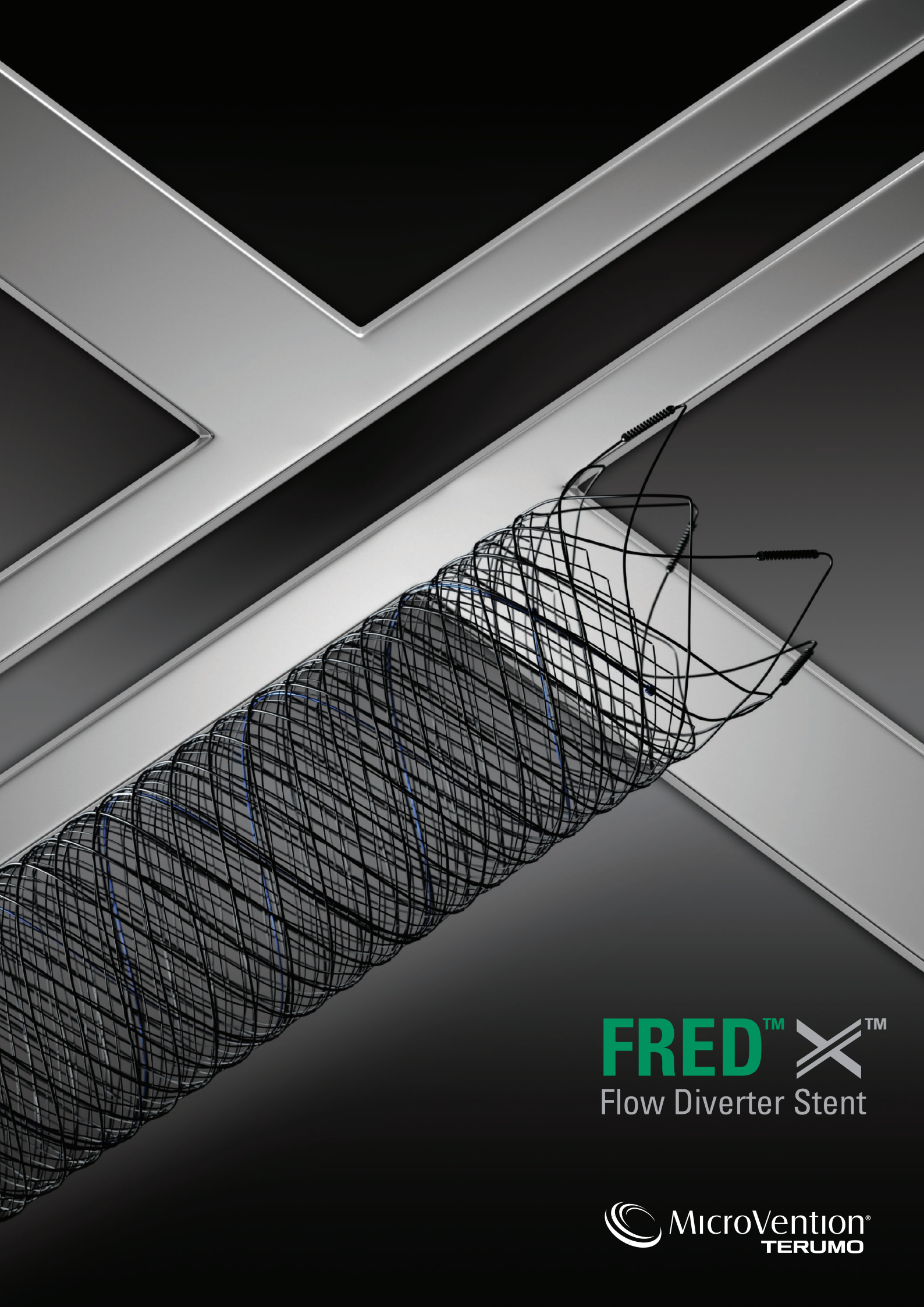
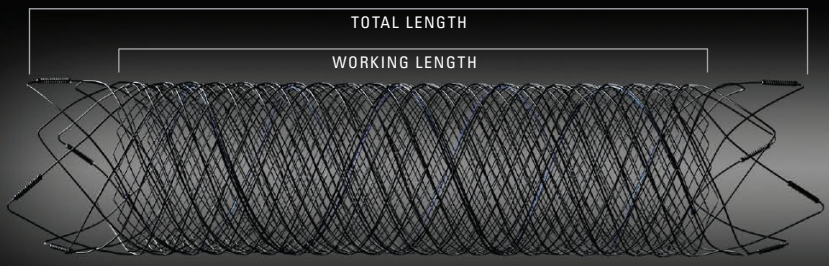


FRED™ X™

Flow Diverter Stent

MicroVention® TERUMO

FRED™ X™
Flow Diverter Stent



DEVICE	PRODUCT CODE	DEVICE SIZE (mm) *Unconstrained Diameter x Total Length*	WORKING LENGTH / TOTAL LENGTH IN DIFFERENT VESSEL DIAMETERS (mm)							
			2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm
FRED X 21	XFRED2508	2.5 x 13	11 / 15	**8 / 13**						
	XFRED2513	2.5 x 18	17 / 21	**13 / 18**						
	XFRED2520	2.5 x 25	28 / 32	**20 / 25**						
	XFRED2526	2.5 x 30	35 / 38	**26 / 30**						
	XFRED3009	3.0 x 13		12 / 16	**9 / 13**					
	XFRED3014	3.0 x 19		19 / 23	**14 / 19**					
	XFRED3021	3.0 x 27		29 / 34	**21 / 27**					
	XFRED3027	3.0 x 32		37 / 41	**27 / 32**					
FRED X 27	XFRED3507	3.5 x 13			10 / 16	**7 / 13**				
	XFRED3511	3.5 x 17			17 / 22	**11 / 17**				
	XFRED3516	3.5 x 22			24 / 30	**16 / 22**				
	XFRED3524	3.5 x 31			34 / 40	**24 / 31**				
	XFRED3536	3.5 x 40			49 / 54	**36 / 40**				
	XFRED4007	4.0 x 13				10 / 16	**7 / 13**			
	XFRED4012	4.0 x 18				18 / 24	**12 / 18**			
	XFRED4017	4.0 x 23				26 / 31	**17 / 23**			
	XFRED4026	4.0 x 32				37 / 43	**26 / 32**			
	XFRED4038	4.0 x 44				53 / 58	**38 / 44**			
	XFRED4508	4.5 x 15					11 / 18	**8 / 15**		
	XFRED4513	4.5 x 20					19 / 26	**13 / 20**		
	XFRED4518	4.5 x 25					27 / 34	**18 / 25**		
	XFRED4528	4.5 x 34					39 / 45	**28 / 34**		
	XFRED4539	4.5 x 45					56 / 62	**39 / 45**		
	XFRED5009	5.0 x 15						12 / 18	**9 / 15**	
	XFRED5014	5.0 x 21						20 / 26	**14 / 21**	
	XFRED5019	5.0 x 26						28 / 35	**19 / 26**	
	XFRED5029	5.0 x 36						41 / 48	**29 / 36**	
	XFRED5514	5.5 x 22							22 / 28	**14 / 22**
	XFRED5526	5.5 x 32							38 / 46	**26 / 32**

DEVICE	PRODUCT CODE	DISTAL ID (in)	PROXIMAL ID (in)	DISTAL OD (Fr/in)	PROXIMAL OD (Fr/in)	LENGTH (cm)
HEADWAY™ 21 and 27 Microcatheters	MC212156S	0.021	0.021	2.1 / 0.026	2.5 / 0.033	156
	MC272156S	0.027	0.027	2.6 / 0.034	3.1 / 0.041	156
SOFIA™ EX Intracranial Support Catheter	ISC5105ST	0.058	0.058	5.2 / 0.068	5.4 / 0.071	105
	ISC5115ST	0.058	0.058	5.2 / 0.068	5.4 / 0.071	115
SOFIA™ Distal Access Catheter	DA5115ST	0.055	0.055	5.1 / 0.067	5.2 / 0.068	115
	DA5125ST	0.055	0.055	5.1 / 0.067	5.2 / 0.068	125
	DA6115ST	0.070	0.070	6.2 / 0.0815	6.3 / 0.0825	115

FRED X Indications for Use: The FRED X System is intended for endovascular embolization of intracranial neurovascular aneurysms. The FRED X System may also be used with embolic coils for the treatment of intracranial neurovascular lesions.

HEADWAY Microcatheter Indications for Use: The HEADWAY Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

SOFIA EX Catheter Indications for Use: The SOFIA EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Catheter is not intended for use in coronary arteries.

SOFIA Catheter Indications for Use: The SOFIA Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA Catheter is not intended for use in coronary arteries. Moreover, the SOFIA Catheter is intended for use in removal/aspiration of emboli and thrombi from selected blood vessels in the arterial system, including the peripheral and neuro vasculatures.

For Healthcare professional use only.

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