

FLOW DIVERSION. SIMPLIFIED.

FRED™ Device

The new standard of ease and simplicity in flow diversion treatment.

FRED Device

EASY TO USE

- **PRECISE:** Immediate opening and redeployability allow for exact placement
- **RELIABLE:** Dependable conformability and wall apposition in tortuous anatomies
- **VERSATILE:** Long lengths, large diameters, and 21 system options

HEADWAY™ 21 or 27 Microcatheter

DESIGNED WITH DUO TECHNOLOGY

- Low Profile OD for dual catheter technique in FRED Device + coil cases
- Remarkable trackability for easy access to target site in difficult anatomies

SOFIA™ EX or SOFIA™ Catheter

DESIGNED WITH DUO TECHNOLOGY

- Excellent trackability for distal positioning and increased device control
- Extra stability for minimal tip movement when deploying and resheathing the FRED Device

FRED Device			TOTAL LENGTH / WORKING LENGTH IN DIFFERENT VESSEL DIAMETERS (mm)									
DEVICE	PRODUCT CODE	DEVICE SIZE (mm)		2.0mm	2.5mm	3.0mm	3.5mm	4.0mm	4.5mm	5.0mm	5.5mm	
		Unconstrained Diameter x Total Length										
FRED 21	FRED2508	2.5	X	13	15 / 11	13 / 8						
FRED 21	FRED2513	2.5	X	18	21 / 17	18 / 13						
FRED 21	FRED2520	2.5	X	25	32 / 28	25 / 20						
FRED 21	FRED2526	2.5	X	30	38 / 35	30 / 26						
FRED 21	FRED3009	3.0	X	13		16 / 12	13 / 9					
FRED 21	FRED3014	3.0	X	19		23 / 19	19 / 14					
FRED 21	FRED3021	3.0	X	27		34 / 29	27 / 21					
FRED 21	FRED3027	3.0	X	32		41 / 37	32 / 27					
FRED 27	FRED3507	3.5	X	13			16 / 10	13 / 7				
FRED 27	FRED3511	3.5	X	17			22 / 17	17 / 11				
FRED 27	FRED3516	3.5	X	22			30 / 24	22 / 16				
FRED 27	FRED3524	3.5	X	31			40 / 34	31 / 24				
FRED 27	FRED3536	3.5	X	40			54 / 49	40 / 36				
FRED 27	FRED4007	4.0	X	13				16 / 10	13 / 7			
FRED 27	FRED4012	4.0	X	18				24 / 18	18 / 12			
FRED 27	FRED4017	4.0	X	23				31 / 26	23 / 17			
FRED 27	FRED4026	4.0	X	32				43 / 37	32 / 26			
FRED 27	FRED4038	4.0	X	44				58 / 53	44 / 38			
FRED 27	FRED4508	4.5	X	15					18 / 11	15 / 8		
FRED 27	FRED4513	4.5	X	20					26 / 19	20 / 13		
FRED 27	FRED4518	4.5	X	25					34 / 27	25 / 18		
FRED 27	FRED4528	4.5	X	34					45 / 39	34 / 28		
FRED 27	FRED4539	4.5	X	45					62 / 56	45 / 39		
FRED 27	FRED5009	5.0	X	15						18 / 12	15 / 9	
FRED 27	FRED5014	5.0	X	21						26 / 20	21 / 14	
FRED 27	FRED5019	5.0	X	26						35 / 28	26 / 19	
FRED 27	FRED5029	5.0	X	36						48 / 41	36 / 29	
FRED 27	FRED5514	5.5	X	22							28 / 22	22 / 14
FRED 27	FRED5526	5.5	X	32							46 / 38	32 / 26

HEADWAY 21 and 27 Microcatheters	PRODUCT CODE	DISTAL ID (in)	PROXIMAL ID (in)	DISTAL OD (Fr/in)	PROXIMAL OD (Fr/in)	USABLE LENGTH (cm)	DISTAL MARKERS	TIP SHAPE
	MC212156S	0.021	0.021	2.1 / 0.026	2.5 / 0.033	156	2	Straight
	MC272156S	0.027	0.027	2.6 / 0.034	3.1 / 0.041	156	2	Straight

SOFIA EX Intracranial Support Catheter	PRODUCT CODE	DISTAL ID (in)	PROXIMAL ID (in)	DISTAL OD (Fr/in)	PROXIMAL OD (Fr/in)	USABLE LENGTH (cm)	DISTAL SOFT LENGTH (cm)	TIP SHAPE
	ISC5105ST	0.058	0.058	5.2 / 0.068	5.4 / 0.071	105	9	Straight
	ISC5115ST	0.058	0.058	5.2 / 0.068	5.4 / 0.071	115	9	Straight

SOFIA Distal Access Catheter	PRODUCT CODE	DISTAL ID (in)	PROXIMAL ID (in)	DISTAL OD (Fr/in)	PROXIMAL OD (Fr/in)	USABLE LENGTH (cm)	DISTAL SOFT LENGTH (cm)	TIP SHAPE
	DA5115ST	0.055	0.055	5.1 / 0.067	5.2 / 0.068	115	17	Straight
	DA5125ST	0.055	0.055	5.1 / 0.067	5.2 / 0.068	125	17	Straight
	DA6115ST	0.070	0.070	6.2 / 0.0815	6.3 / 0.0825	115	19	Straight

FRED System Product Indications:

The Flow Re-Direction Endoluminal Device (FRED) System is indicated for use with or without embolic coils for the treatment of intracranial aneurysms that are not amenable to treatment with surgical clipping with parent vessels that are ≥ 2.0 mm and ≤ 5.0 mm in diameter.

Contraindications:

Use of the FRED 27 system or FRED 21 system is contraindicated under these circumstances: Patients in whom anticoagulant, anti-platelet therapy, or thrombolytic drugs are contraindicated; patients with known hypersensitivity to metal such as nickel-titanium and metal jewelry; patients with anatomy that does not permit passage or deployment of the FRED system; patients with an active bacterial infection; patients with a pre-existing stent in place at the target aneurysm.

For Professional Use Only

RX Only: Federal law restricts this device to sale by or on the order of a physician.

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 devices. The SOFIA Catheter is not intended for use in coronary arteries.



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MicroVention Worldwide
Innovation Center
35 Enterprise
Aliso Viejo, CA 92656 USA
+1.714.247.8000
1.800.990.8368
microvention.com