MicroVention
TERUMO

Trackability / Shape Retention / Durability

Used with

LVIS
Intraluminal Support Device

LVIS Jr.
Intraluminal Support Device

FRED
Flow Re-Direction Endoluminal Device

ERIC
Embolus Retriever with Interlinked Cages

PHIL
Precipitating Hydrophobic Injectable Liquid

Headway®
Microcatheter

Headway® Microcatheter

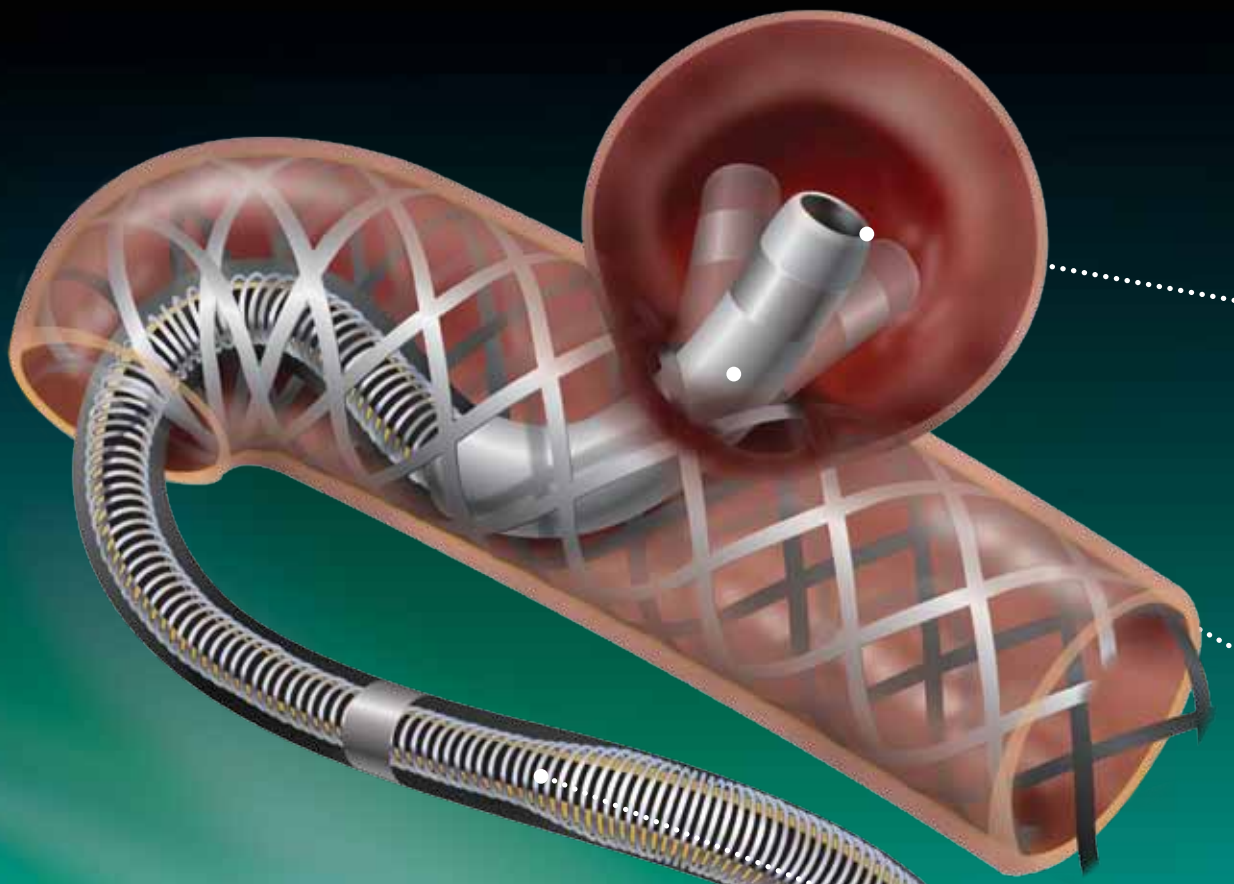
HEADWAY® MICROCATHETER - N

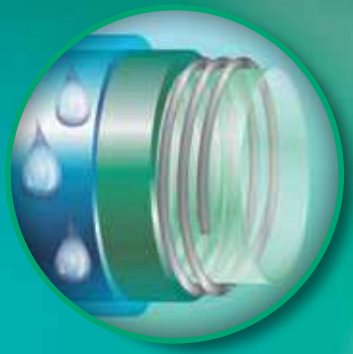
Headway® Advanced 17 Microcatheter

Headway® Advanced 17 Microcatheter Pre-shaped tip

Headway® Advanced Soft 17 Microcatheter

Used with LVIS® Jr. Intraluminal Support Device · ERIC® Embolus Retriever with Interlinked Cages · PHIL™ Precipitating Hydrophobic Injectable Liquid





Hydrophilic Coating

- Reduced friction for improved navigation in tortuous vessels
- Enhanced durability for prolonged use

EXT GENERATION CATHETER PERFORMANCE WITH IMPRO

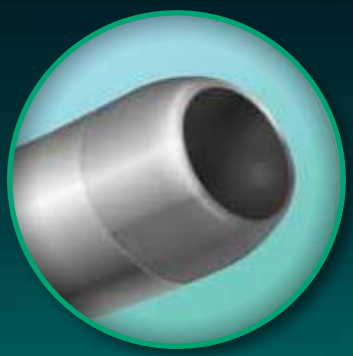
Innovative Catheter Construction

Headway 17 *The unique construction of the Headway 17 microcatheter combines 7 progressive segments with a tapered PTFE liner and an atraumatic soft tip for enhanced performance in challenging anatomies. Two levels of softness and superior tip shapability allow for an optimized configuration for every procedure.*

Headway 21 and 27 *The multi-segmented design of the Headway 21 and 27 microcatheters provides superb trackability and resistance to elongation, while the combination of a tight-pitch coil reinforcement and PTFE inner liner allows for the delivery of stents in a smooth, controlled manner.*

Rounded Tip

- Atraumatic soft tip facilitates smooth catheter advancement
- Rounded shape allows easier navigation through a deployed stent

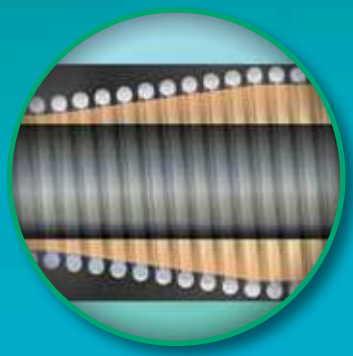


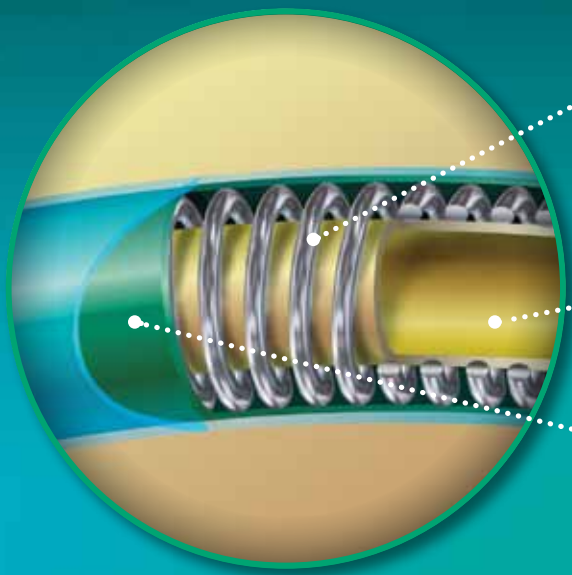
Designed for Tip Shapability

- Easy to shape with steamer
- Advanced technology for better shape retention on distal tip

Tapered PTFE Liner with Coil Reinforcement

- Tapered liner design allows true 1:1 push/pull control
- Tight-pitch coil reinforcement resists ovalization while maintaining maximum flexibility





VED TRACKABILITY AND CONTROL

MicroVention® TERUMO

Headway® 21 Microcatheter

Used with LVIS® Intraluminal Support Device

Headway® 27 Microcatheter

Used with FRED®

Coil Reinforced Catheter

- Tight pitch coil wind resists kinking and ovalization while maintaining maximum flexibility

PTFE Liner

- Lubricious, yet durable inner liner for smooth stent delivery

Robust Catheter Body

- Offers enhanced resistance to stretching and elongation while delivering stents or other less flexible devices

Headway® Microcatheter

A Complete Range of Sizes & Softness

Headway® microcatheters offer a wider selection of access solutions. With three sizes, two levels of support and three pre-shaped tip options available, there is a Headway microcatheter available for use in nearly any procedure. All Headway microcatheters are designed to optimize the performance of LVIS® and LVIS® Jr. Intraluminal Support Devices, FRED® System flow diverting stents, ERIC® Retrieval Devices, and embolic coils. Headway microcatheters are also PHIL™ Liquid Embolic System and DMSO compatible.

CHOOSE YOUR SIZE & LEVEL OF SOFTNESS

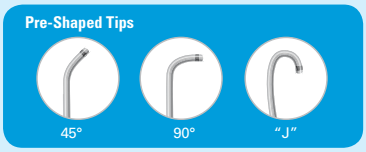
SOFT SUPPORT ZONE

Soft support zone for greater sensitivity to coil delivery force

Headway® Advanced Soft 17 Microcatheter

Headway® Advanced 17 Microcatheter

Headway® Advanced 17 Microcatheter Pre-shaped tip



Headway® 21 Microcatheter

Headway® 27* Microcatheter

ENHANCED SUPPORT ZONE

More support in the distal shaft to reduce catheter movement in challenging anatomy and ensure accurate device delivery.

**Also available in 156cm hybrid braid/coil design version for improved flow diverter delivery experience.*

SPECIFICATIONS

Headway®

Microcatheter with Hydrophilic Coating

1 per box. Includes shaping mandrel and introducer sheath.

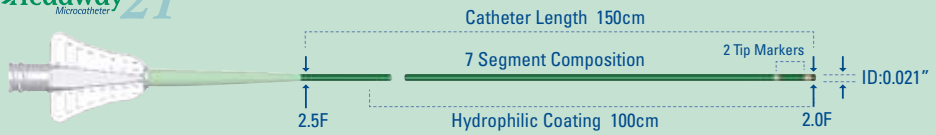
Product Name	Description	Product Code	ID (inches)	Tip Shape	Usable Length (cm)	OD Prox./Distal (French)	Tip Markers
Headway17 Advanced 'Soft'	Straight	MC172150S	0.017	STR	150	2.4 / 1.7	2
Headway17 Advanced	Straight	MC172150SX	0.017	STR	150	2.4 / 1.7	2
Headway17 Advanced	Pre-shaped tip 45	MC17215045X	0.017	45	150	2.4 / 1.7	2
Headway17 Advanced	Pre-shaped tip 90	MC17215090X	0.017	90	150	2.4 / 1.7	2
Headway17 Advanced	Pre-shaped tip J	MC172150JX	0.017	J	150	2.4 / 1.7	2
Headway21	Straight	MC212150S	0.021	STR	150	2.5 / 2.0	2
Headway27	Straight	MC272150S	0.027	STR	150	3.1 / 2.6	2
Headway27	Straight	MC272156S	0.027	STR	156	3.1 / 2.6	2

Dead space of Headway® 17 microcatheter is 0.41cc and 0.26cc with MicroVention hub adaptor.

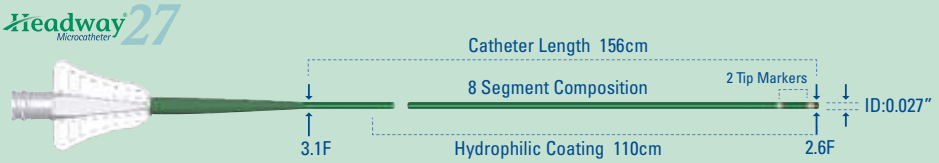
Headway 17 Microcatheter — ADVANCED & ADVANCED 'SOFT'

Headway Advanced 17 Microcatheter Pre-shaped tip — PRE-SHAPED TIPS

Headway 21 Microcatheter



Headway 27 Microcatheter



Includes Shaping Mandrel and Introducer Sheath

MicroVention® TERUMO

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F +44 (0) 191 258 5999

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F +33 (1) 39 21 16 01

MicroVention Deutschland GmbH
Hildebrandtstr. 4 F
D-40215, Düsseldorf
Germany
PH +49 211 210 798-0
F +49 211 210 798-29

Headway Duo microcatheter

Innovative Catheter Technology

Unique braid/coil construction for the lowest profile of any 0.014"/ 0.012" guidewire compatible catheter

Headway® Duo Microcatheter

Microcatheter with Hydrophilic Coating

1 per box; includes shaping mandrel and introducer sheath

Product Name	Product Code	ID Body/Tip (inches)	Tip Shape	Usable Length (cm)	Flexible Distal Length (cm)	OD Prox./Dist. (French)	Dead Space	Tip Markers
Headway Duo, 156cm	MC162156S	0.0165 / 0.0165	STR	156	9	2.1 / 1.6	0.34 ml	2
Headway Duo, 167cm	MC162167S	0.0165 / 0.013	STR	167	9	2.1 / 1.3	0.35 ml	1

Features

Benefits

Hybrid Braid/Coil Design

Tight pitch coil provides lumen integrity and bending flexibility
Proximal braid provides firmness and a torqueable catheter body
Resists kinking and ovalization

Small OD, Large ID

156cm Headway® Duo microcatheter compatible with coils and ≤0.014" OD guidewires
0.0165" body ID microcatheter with low profile distal tip

167cm Headway® Duo microcatheter compatible with ≤0.014"/≤0.012" (proximal/distal OD) guidewires
0.0165" body ID microcather with 0.013" ID distal tapered tip

Superior Trackability

True 1:1 push/pull while tracking through tortuous anatomy

Liquid Embolic Compatibility

Compatible with PHIL™ Liquid Embolic, Onyx™ Liquid Embolic, nBCA and DMSO
High burst strength (700 psi)
Long length allows distal lesion access

Soft Distal Tip

Smooth, atraumatic tracking
Excellent tip "painting" ability

MicroVention TERUMO

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CE 0297

MM268(I) Rev.C 8/14

Headway 156cm Microcatheter

Now with Headway Duo microcatheter Technology

Hybrid braid/coil construction to improve stent delivery experience

Headway 21 Microcatheter 156cm

LVIS Intraluminal Support Device
ERIC Embolus Retriever with Interlinked Cages
FRED Jr. Flow Re-Direction Endoluminal Device
Sofia Distal Access Catheter

Headway 27 Microcatheter 156cm

FRED Flow Re-Direction Endoluminal Device
Sofia Distal Access Catheter

Hybrid Braid & Coil Design

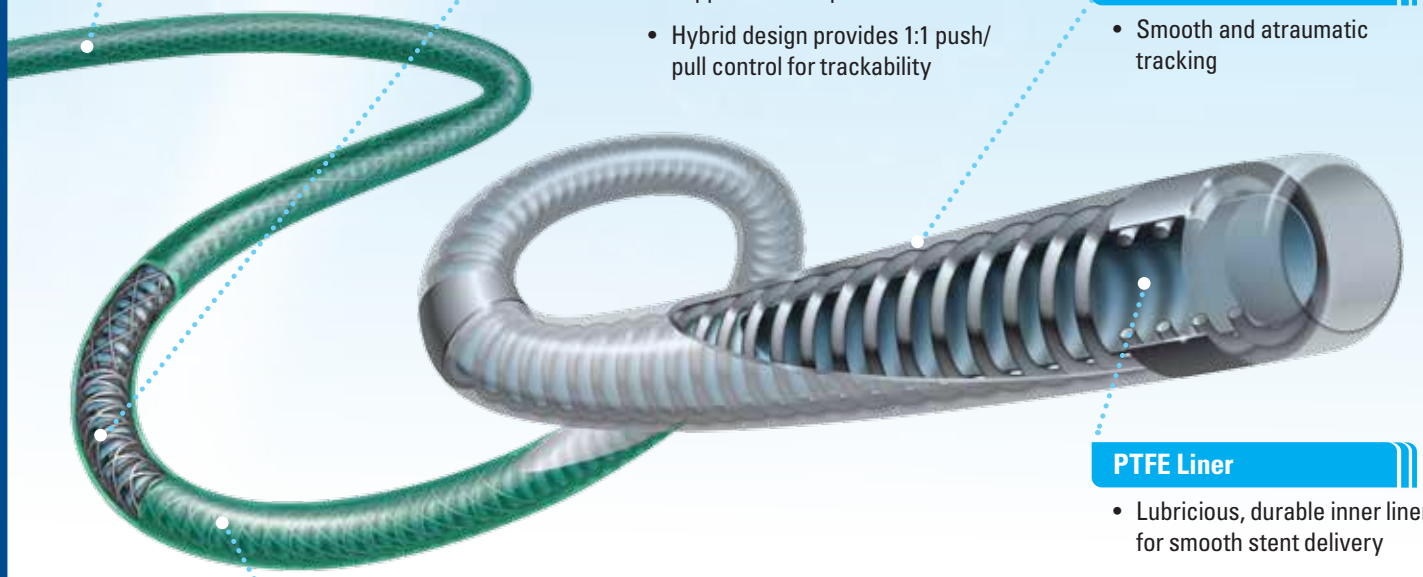
- Coil reinforcement provides lumen integrity, bending flexibility and excellent shape retention
- Proximal variable braid reinforcement provides support and torque control
- Hybrid design provides 1:1 push/pull control for trackability

Stretch Resistant Shaft

- For stability and prevention of catheter body twisting

Soft Distal Shaft

- Smooth and atraumatic tracking



PTFE Liner

- Lubricious, durable inner liner for smooth stent delivery

Lubricious Hydrophilic Coating

- Reduced friction during navigation in tortuous anatomy and during lengthy procedures

MicroVention TERUMO

SPECIFICATIONS

Headway® 21 & 27 (156cm) Microcatheter

Microcatheter with Hydrophilic Coating

Packed 1 per box; includes shaping mandrel and introducer sheath

Product Name	Description	Product Code	ID (inches)	Tip Shape	Usable Length (cm)	OD Prox./Distal (French)	Tip Markers
Headway 21 156cm	Straight	MC212156S	0.021	STR	156	2.5 / 2.0	2
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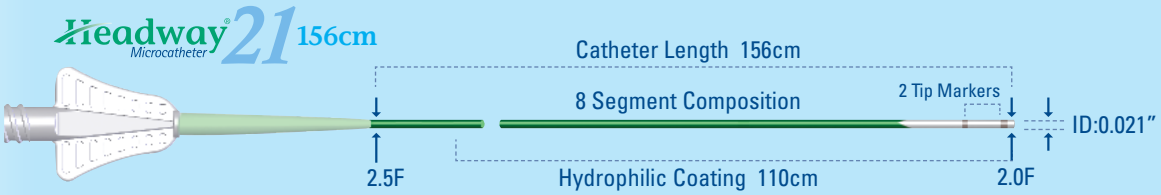

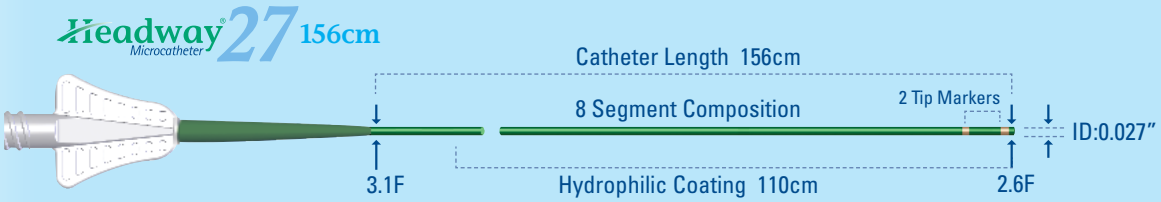

Headway Duo microcatheter

Technology

Hybrid Braid/Coil Design

Features

- Proximal column strength for stability and torqueability
- 156cm working length with distal flexible transitions
- Resistance to kinking and ovalization
- Resistance to stretching
- Resistance to twisting

Benefits

✓Facilitate access to the lesion

✓Smooth device trackability

✓Controlled device delivery

MicroVention TERUMO

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.

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Headway 156cm Microcatheter

Now with Headway Duo microcatheter Technology

Hybrid braid/coil construction to improve stent delivery experience

Headway 21 Microcatheter 156cm

LVIS Intraluminal Support Device
ERIC Embolus Retriever with Interlinked Cages
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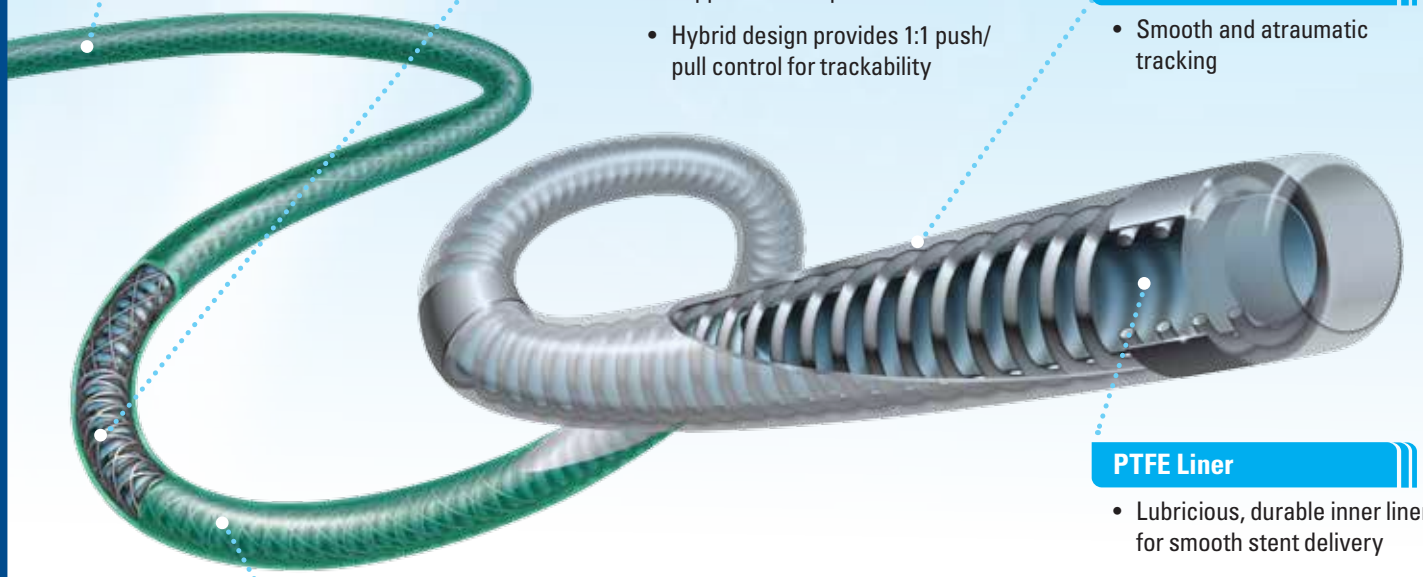

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MicroVention TERUMO

SPECIFICATIONS

Headway® 21 & 27 (156cm) Microcatheter

Microcatheter with Hydrophilic Coating

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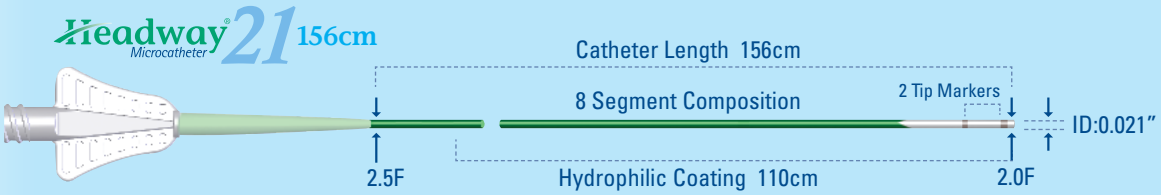

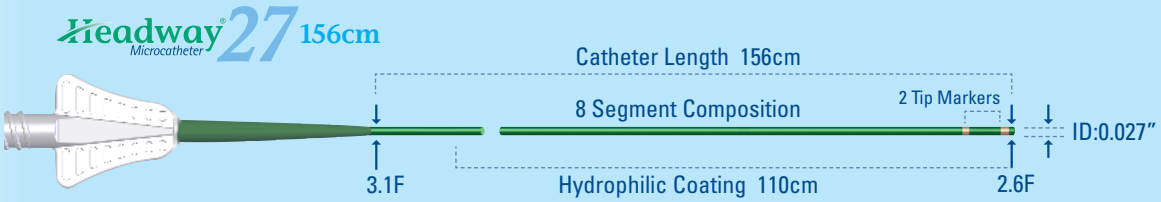

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Headway Duo microcatheter

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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, Aspiration Devices, 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	170776096
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

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.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

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: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolization Prothese	MicroPlex Coil System (MCS) & HydroCoil Embolic System (HES) with V-Trak Delivery System	MicroPlex 10 Platinum Coil System (MCS) Endovascular Embolization Coil - Cosmos10 - HyperSoft 3D - HyperSoft Helical - Helical 10 - VFC - Compass 10 - Complex 10	III	1,2,3
		MicroPlex 18 Platinum Coil System (MCS) Endovascular Embolization Coil - Cosmos 18 - Helical 18 - Compass 18 - Complex 18	III	1,2,3
		HydroCoil 10 Embolic System (HES) Endovascular Embolization Coil - HydroFrame 10 - HydroSoft Helical - HydroSoft 3D - HydroFill	III	1,2,3
		HydroCoil 18 Embolic System (HES) Endovascular Embolization Coil - HydroFrame 18	III	1,2,3
	AZUR® Peripheral Coil System	AZUR® HydroCoil Detachable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® HydroCoil Pushable Embolization Coils 18 & 35	IIb	1,2,3
		AZUR® Framing Detachable Coils 18 & 35	IIb	1,2,3
		AZUR® Injectable Coil System 18 & 35	IIb	1,2,3
		AZUR Detachable 18	IIb	1,2,3
		AZUR PURE Pushable Coil System 18 & 35	IIb	1,2,3
		AZUR CX Detachable 18 & 35	IIb	1,2,3
		AZUR Vascular Plug	IIb	1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Detachment Controller Units		V-Grip® Detachment Controller	IIa	1,2
		V-Grip® PLUS Detachment Controller	IIa	1,2
		WEB Detachment Controller	IIa	1,2
		AZUR® Detachment Controller	IIa	1,2
Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires)		Traxcess® 14 Guidewire	III	1,2
		Traxcess® 14 EX Guidewire	III	1,2
		Traxcess® 14 SELECT Guidewire	III	1,2
		Traxcess® 7 Mini Guidewire	III	1,2
		Traxcess® 7 Mini XSoft Guidewire	III	1,2
		Traxcess® Docking Wire	IIa	1,2
		Chaperon® Guiding Catheter System	III	2
		Headway® 17 Advanced Soft Microcatheter	III	1,2,3
		Headway® 17 Advanced Microcatheter	III	1,2,3
		Headway® 21 Microcatheter	III	1,2,3
		Headway® 27 Microcatheter	III	1,2,3
		Headway Duo Microcatheter	III	1,2,3
		Scepter C™ Occlusion Balloon Catheter	III	1,2,3
		Scepter XC™ Occlusion Balloon Catheter	III	1,2,3
		Scepter Mini™ Occlusion Balloon Catheter	III	1,2,3
		SOFIA™ Distal Access Catheter	III	1,2,3
		SOFIA™ Select Catheter	III	1,2,3
		SOFIA™ PLUS Catheter	III	1,2,3
		SOFIA™ Flow PLUS Catheter	III	1,2,3
		SOFIA™ Guiding Catheter	III	1,2,3
		SOFIA™ Flow Catheter	III	1,2,3
		SOFIA® EX Catheter	III	1,2,3
		KANSHAS Drug Coated Balloon	III	1
		VIA™ 17 Microcatheter	III	1,2
		VIA™ 21 Microcatheter	III	1,2
		VIA™ 27 Microcatheter	III	1,2
		VIA™ 33 Microcatheter	III	1,2
		Wedge Microcatheter	III	1,2,3
		PG Pro Microcatheter	IIa	1,2,3

Annex to certificate
Certificate registration No.: 411133 MR2
Certificate unique ID: 170776096
Effective date: 2021-04-29

MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Stents		LVIS™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ Intraluminal Support Device	III	1,2,3
		LVIS™ X™ Intraluminal Support Device	III	1,2,3
		LVIS™ Jr. X™ Intraluminal Support Device	III	1,2,3
		LVIS™ EVO™ X™ Intraluminal Support Device	III	1,2,3
		FRED™ Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED Jr.™ Flow Re-Direction Endoluminal Device	III	1,2,3
		FRED X™ Flow Re-Direction Endoluminal Devices	III	1,2,3
		FRED OMEGA™ Flow Re-Direction Endoluminal Devices	III	1,2,3
		CASPER™ RX Carotid Artery Stent System	III	1,2,3
		Roadsaver Carotid Artery Stent System	III	1,2,3
Peripheral Vascular Stent System		RENZAN™ Peripheral Vascular Stent System	IIb	1,2,3
Clot Retriever		ERIC™ Retrieval Device	III	1,2,3
Liquid Embolic System		PHIL™ Liquid Embolic System	III	1,2
Microspheres		HydroPearl Microspheres	IIb	1,2
		LifePearl Microspheres	III	1,2
		BioPearl® Microspheres	III	1

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MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Embolic Protection Device (EPS)		Empro Embolic Protection System	III	1,3
		Nanoparasol Embolic Protection System	III	1,3
Aneurysm Embolization Device		WEB™ Aneurysm Embolization System	III	1,2
Aspiration Kit		Aspiration Tubing Kit	Is	1,2
		Aspiration Syringe Kit	Is	1,2
BOBBY™ Balloon Guide Catheter		BOBBY™ Balloon Guide Catheter	III	1,2

CERTIFICATE

This is to certify that the company

MicroVention, Inc.

35 Enterprise
Aliso Viejo, CA, 92656
United States of America

with the organizational units/sites as listed in the annex

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

Scope:
Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.

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.	411133 MP2016
Certificate unique ID	170780788
Effective date	2022-07-07
Expiry date	2024-09-26
Frankfurt am Main	2022-07-07

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

DQS IS A MEMBER OF
IQNET

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

Annex to certificate
Certificate registration No.: 411133 MP2016
Certificate unique ID: 170780788
Effective date: 2022-07-07

MicroVention, Inc.

35 Enterprise
Aliso Viejo, CA, 92656
United States of America

Location	Scope
497135 **MicroVention, Inc.** 35 Enterprise Aliso Viejo, CA, 92656 United States of America	Design, Development, Manufacturing and Distribution of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheters, Guiding and Aspiration Catheters, Microcatheters and Guidewires), Stents, Clot and Foreign Body Retrieval Devices, Liquid Embolic System, Embolic Protection System, Aneurysm Embolization Device, Microspheres, Aspiration Devices and Detachment Controller Units.
499088 **MicroVention Costa Rica, S.R.L.** **Production Site** Zona Franca Coyol Alajuela Costa Rica	Manufacturing of Embolization Prostheses and Accessories, Intravascular Access Devices (Occlusion Balloon Catheter, Guiding and Aspiration Catheters, and Microcatheters), Stents, Clot and Foreign Body Retrieval Devices, Embolic Protection System, and Aspiration Devices.

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

MicroVention, Inc.

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

that the design of the following device(s)

Headway Microcatheters in the variants as listed in Annex

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. 411133 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: RF17-0003C HW-W dated 2018-10-15

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

Examination report: 411_18e_Report_TF_Headway_2018_V1 dated 2018-12-08

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

Certificate registration no.	435827 MRA
Certificate unique ID	170729002
Effective date	2019-01-09
Expiry date	2024-01-08
Frankfurt am Main	2018-12-08

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.

411.23 Version 1.0

Annex to certificate
Certificate registration No.: 435827 MRA
Certificate unique ID: 170729002
Effective date: 2019-01-09

MicroVention, Inc.

EGA Headway

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

Headway Microcatheters	Headway 17 Advanced Microcatheter Headway 17 Advanced Soft Microcatheter Headway 21 Microcatheter Headway 27 Microcatheter Headway Duo Microcatheter Wedge Microcatheter

EC DECLARATION OF CONFORMITY

RF20-0015A (replacing FD08-011)

We, MicroVention, Inc., located in Tustin, California, USA, 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) 435827 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 411133 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
Headway 17 Advanced Soft Microcatheter	MC172150S	III – Annex 9, rule 7	10691
Headway 17 Advanced Microcatheter	MC172150STX, MC17215045X, MC17215090X, MC172150JX, MC172150SX		
Headway 21 Microcatheter	MC212150S, MC212156S		
Headway 27 Microcatheter	MC272150S, MC272156S		
Headway Duo Microcatheter	MC162156S, MC162167S		
Wedge Microcatheter	MCWED21160	III – Annex 9, rule 8	10691

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

MicroVention Inc. 1311 Valencia Avenue, Tustin, California, 92780, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com

EC DECLARATION OF CONFORMITY

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.

I. Kulinets

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

Tustin, CA, USA
Place of Issue

6/18/2020
Date of Issue

Certificate Expiry Date: 2024-01-08

MicroVention Inc. 35 Enterprise, Aliso Viejo, California, 92656, USA
Tel : 714-247-8000 – Fax : 714-247-8005 www.microvention.com