



# CERTIFICATE



This is to certify that the company

### **MicroVention**, Inc.

1311 Valencia Ave. Tustin, CA, 92780 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	170758666
Effective date	2019-11-17
Expiry date	2022-11-16
Frankfurt am Main	2019-11-17

### **DQS Medizinprodukte GmbH**

We leve

Sigrid Uhlemann Managing Director

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



Dr. Thomas Feldmann Head of Certification Body







## MicroVention, Inc.

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

Location

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

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

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.

Design, Development, Manufacturing and

Distribution of Embolization Prostheses and

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 DECLARATION OF CONFORMITY

FD08-011/W

We, MicroVention, Inc., located in Tustin, California, USA declare according to Directive 93/42/EEC Annex II (incl. section 4.) 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.

Directives 93/42/EEC Council Directive Concerning Medical Devices

Conformity Assessment Route EC Design Examination:

435827 MRA (Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code	
Headway 17 Advanced Soft Microcatheter	MC172150S				
Headway 17 Advanced Microcatheter	MC172150STX, MC17215045X, MC17215090X, MC172150AX, MC172150BX, MC172150CX, MC172150DX, MC172150WX, MC172150JX, MC172150SX	III – Annex 9, rule 7	2018-12-19	10691	
Headway 21 Microcatheter	MC212150S, MC212156S				
Headway 27 Microcatheter	MC272150S, MC272156S				
Headway Duo	MC162156S, MC162167S				
Wedge Microcatheter	MCWED21160	III – Annex 9, rule 8	2018-12-19	10691	

#### Manufacturer/

Production Site: MicroVention, Inc. 1311 Valencia Avenue Tustin, CA 92780 USA Notified Body: DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body Number: 0297 EU Representative:

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

<u>Production Site:</u> MicroVention Costa Rica Zona Franca Coyol

Alajuela, Costa Rica

#### Intended Use:

The Headway Microcatheter (Headway 17 Advanced Soft, Headway 17 Advanced, 21 & 27) 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.

The Headway Duo Microcatheter is intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

The Wedge 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 to assist in the delivery of interventional devices, such as the SOFIA 6F Catheter, in the neurovasculature.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Tustin, CA 92780, USA

Place of Issue

19-012-20

Salvadore Palomares Director, Regulatory Affairs MicroVention, Inc.

Expiry Date: 2022-12-19

Page 1 of 1

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



## **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	<b>156cm Headway<sup>®</sup> Duo</b> microcatheter compatible with coils and ≤0.014" OD guidewires 0.0165" body ID microcatheter with low profile distal tip
	<b>167cm Headway<sup>®</sup> Duo</b> 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**, Inc. **Worldwide Headquarters** 1311 Valencia Avenue Tustin, CA 92780, USA **MicroVention UK Limited** MicroVention Europe, S.A.R.L. MicroVention Deutschland GmbH Web

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0297





# **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, Detachment Controller Units, Syringe Kits, Stents, Clot and Foreign Body Retrieval Devices, Intravascular Access Devices (Occlusion Balloon Catheters, Micro Catheters, Guidewires), Liquid Embolic System, EPS Embolic Protection System, Microspheres and Aneurysm Embolization Device 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	170711729
Effective date	2018-06-11
Expiry date	2022-11-02
Frankfurt am Main	2018-06-11

### DQS Medizinprodukte GmbH

Mblu

Sigrid Uhlemann Managing Director

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

Dr. Thomas Feldmann Head of Certification Body

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

Prepared for Romania





### MicroVention, Inc.

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

### **Production Sites:**

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

2.

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

3.

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







## 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 <sup>®</sup> Detachable Embolization Coils System	MicroPlex <sup>®</sup> Platinum Detachable Embolization Coils - Helical IStandard Helical-Reg. and Soft 10 & 18, - HyperSoft <sup>®</sup> 10 & 3D - Complex 10 & 18 - Compass 10 & 18, - COSMOS <sup>®</sup> 10 & 18 - VFC <sup>™</sup>		1,2,3
		HydroCoil <sup>®</sup> Platinum/Hydrogel Detachable Embolization Coils - HydroCoil <sup>®</sup> 10 & 14 & 18, - HydroSoft <sup>®</sup> 10 - HydroFill <sup>®</sup> - HydroFrame <sup>®</sup> 10 & 18 - HydroSoft 3D	111	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	llb	1,2,3
Detachment Controller		V-Grip® Detachment Controller V-Grip® PLUS Detachment	lla Ila	1 1
Units		Controller WEB Detachment Controller AZUR® Detachment Controller	lla Ila	1 1







## MicroVention, Inc.

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

Device Groups:	Device Family:	Devices:	Risk Class	Production Site
Intravascular Access Devices		Traxcess <sup>®</sup> 14 Guidewire Traxcess <sup>®</sup> 14 EX Guidewire Traxcess <sup>®</sup> 14 SELECT Guidewire Traxcess <sup>®</sup> 7 Mini Guidewire Traxcess <sup>®</sup> 7 Mini XSoft Guidewire	III	1
		Traxcess <sup>®</sup> Docking Wire	lla	1
Catheters		Chaperon <sup>®</sup> Guiding Catheter	111	1
		System Headway <sup>®</sup> 17 Advanced Soft		1,3
		Microcatheter Headway <sup>®</sup> 17 Advanced Microcatheter		1,3
		Headway <sup>®</sup> 21 Microcatheter		1,3 1,3
		Headway <sup>®</sup> 27 Microcatheter Headway Duo Microcatheter Scepter C <sup>™</sup> Occlusion Balloon Catheter		1,3 1,3
		Scepter XC <sup>™</sup> Occlusion Balloon Catheter		1,3
		SOFIA Distal Access Catheter SOFIA Select Catheter SOFIA PLUS Catheter SOFIA Flow PLUS Catheter SOFIA Flow Catheter SOFIA Flow Catheter KANSHAS Drug Coated Balloon VIA 117 Microcatheter VIA 121 Microcatheter VIA 127 Microcatheter VIA 133 Microcatheter		1,2,3 1,2,3 1,2,3 1,2,3 1,2,3 1,2,3 1,2,3 1,2,3 1
		Wedge Microcatheter		1







## 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 LVIS Jr.™ Intraluminal Support Device	Ш	1,2,3
		FRED® Flow Re-Direction Endoluminal Device FRED Jr.® Flow Re-Direction Endoluminal Device CASPER IRX Carotid Artery Stent	111	1,3 1,3 1,3 1,3 1,3
		System Roadsaver Carotid Artery Stent System		1,3
Peripheral vascular		CASPER Peripheral Vascular Stent System	llb	1,3
stent system		RENZAN Peripheral Vascular Stent System	llb	1,3
Clot Retriever		ERIC <sup>™</sup> Retrieval Device	111	1,2
Liquid Embolic System		PHIL <sup>™</sup> Liquid Embolic System	Ш	1
Microspheres		HydroPearl Microspheres LifePearl Microspheres	llb III	1 1,2
Embolic Protection Device (EPS)		Empro Embolic Protection System Nanoparasol Embolic Protection System	III	1,2,3
Aneurysm Embolization Device		WEB IAneurysm Embolization System	Ш	1





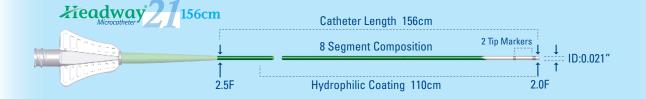
and during lengthy procedures

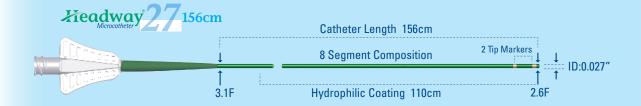


## **SPECIFICATIONS**

# Headway<sup>®</sup> 21 & 27 (156cm) Microcatheter Microcatheter with Hydrophilic Coating

Packed 1 per box; includes shaping mandrel and introducer sheath							
Product Name	Description Product Code		<b>ID</b> (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
Headway 27 156cm	Straight	MC272156S	0.027	STR	156	3.1 / 2.6	2







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



✓ Facilitate access to the lesion

- ✓ Smooth device trackability
- ✓ Controlled device delivery



#### **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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**MicroVention**, Inc. **Worldwide Headquarters** 1311 Valencia Avenue Tustin, CA 92780 USA **MicroVention UK Limited** MicroVention Europe, S.A.R.L. **MicroVention Deutschland GmbH** Web

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## **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	<b>156cm Headway<sup>®</sup> Duo</b> microcatheter compatible with coils and ≤0.014" OD guidewires 0.0165" body ID microcatheter with low profile distal tip
	<b>167cm Headway<sup>®</sup> Duo</b> 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



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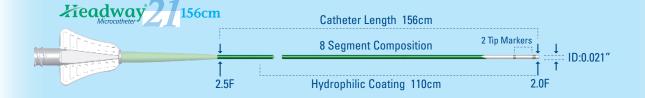
and during lengthy procedures

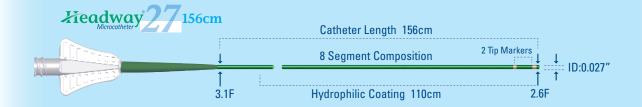


## **SPECIFICATIONS**

# Headway<sup>®</sup> 21 & 27 (156cm) Microcatheter Microcatheter with Hydrophilic Coating

Packed 1 per box; includes shaping mandrel and introducer sheath								
Product Name	Description	Description Product Code		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	
Headway 27 156cm	Straight	MC272156S	0.027	STR	156	3.1 / 2.6	2	







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



✓ Facilitate access to the lesion

- ✓ Smooth device trackability
- ✓ Controlled device delivery



#### **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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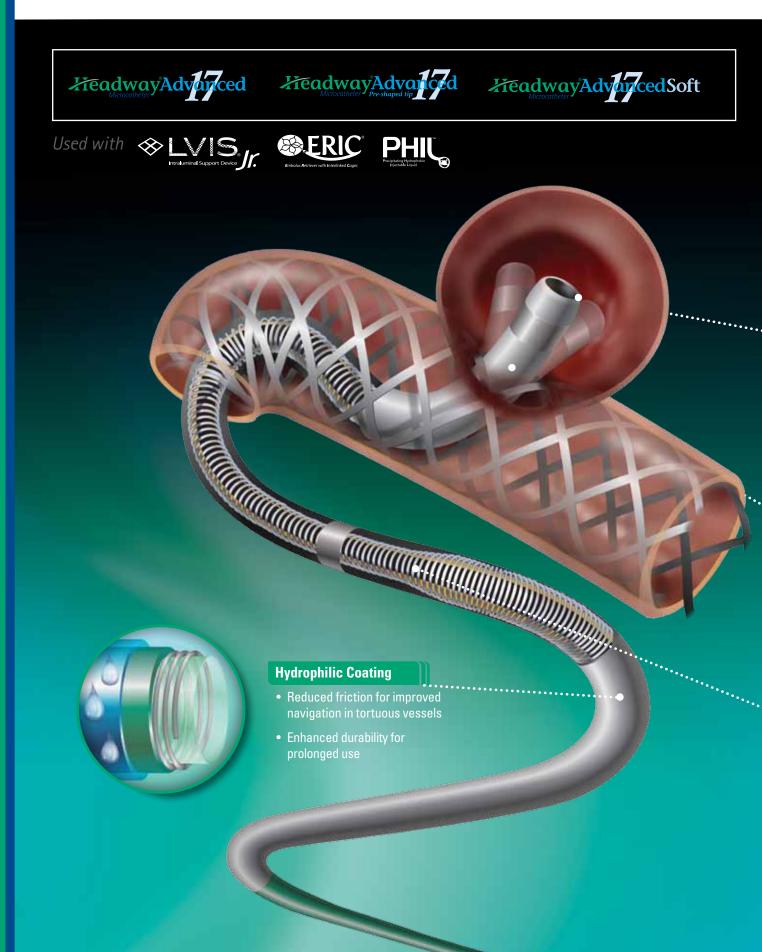
Trackability / Shape Retention / Durability







## **HEADWAY® MICROCATHETER - N**



## **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



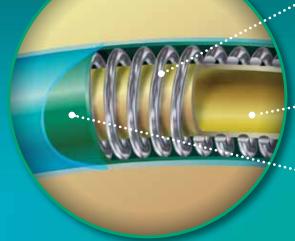
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#### Designed for Tip Shapability

- 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**











### **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



CHOOSE YOUR SIZE &

LEVEL OF

SOFTNESS

## **A Complete Range of Sizes & Softness**

Headway<sup>®</sup> 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<sup>®</sup> and LVIS<sup>®</sup> Jr. Intraluminal Support Devices, FRED<sup>®</sup> System flow diverting stents, ERIC<sup>®</sup> Retrieval Devices, and embolic coils. Headway microcatheters are also PHIL<sup>™</sup> Liquid Embolic System and DMSO compatible.

### **SOFT SUPPORT ZONE**

Soft support zone for greater sensitivity to coil delivery force

*X***ieadwayAdvanced**Soft

**Headway**Advanced





Headway 2



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

### ENHANCED SUPPORT ZONE

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

## **SPECIFICATIONS**

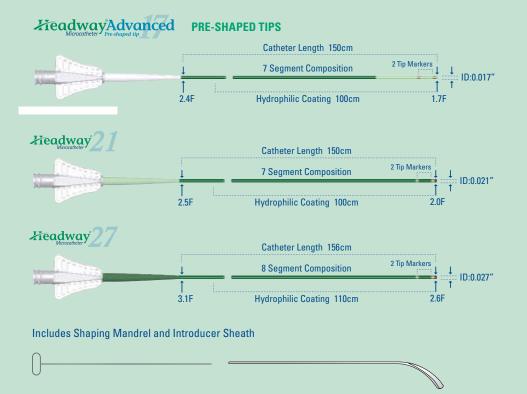
## **Headway**<sup>®</sup>

Microcatheter with Hydrophilic Coating

1 per box. Includes shaping mandrel and introducer sheath.							
Product Name	Description	Product Code	<b>ID</b> (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.

ADVANCED & ADVANCED 'SOFT' Catheter Length 150cm Catheter Length 150cm 2 Tip Markers 2 Tip Markers 1 D:0.017" 2.4F Hydrophilic Coating 100cm 1.7F





www.microvention.com

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Microcatheter

**CE** 0297