

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. INTENDED USE/INDICATIONS FOR USE The MAMBA™ and MAMBA™ Flex Microcatheter is intended to provide support to facilitate the placement of guidewires in the coronary vasculatures, and can be used to exchange one guidewire for another. The microcatheter is also intended to assist in the delivery of contrast media into the coronary vasculatures. CONTRAINDICATIONS This device should not be used in neurovasculature. WARNINGS • The microcatheter is to be used over a guidewire. Use of the microcatheter ahead of a guidewire may result in device damage and/or vessel trauma. • Proximal marks should be used to gauge microcatheter position within the guide catheter to avoid over-advancement of the microcatheter. • Use of this product in narrow or tortuous vessels or over-torqueing the device in challenging anatomy increases risk of vessel trauma including perforation. • Advancement of the microcatheter under resistance may cause microcatheter and/or vessel damage. • Advancement of the microcatheter through a stented vessel can damage the microcatheter and/or cause stent displacement. • If a blocked/damaged lumen is encountered, e.g. when flushing with saline, infusing with contrast or advancing over a guidewire, the microcatheter should be replaced with a new device. Failure to do so may result in catheter rupture, guidewire lockup, or arterial injury. • It is recommended that this product only be used at a medical institution capable of promptly performing emergency open-heart surgery. PRECAUTIONS • Flush and wipe down device with sterilized saline prior to use to ensure smooth movement of guidewire. • Ensure all appropriate accessories are securely attached to the microcatheter prior to flushing. • The microcatheter should not be advanced ahead of the guidewire to avoid device damage. • Always verify tip position before injecting contrast. • Prior to advancing or withdrawing microcatheter, loosen hemostasis valve to avoid damage. • Do not over tighten Y-adapter/hemostasis valve to avoid microcatheter damage. • Ensure removal of quidewire prior to contrast injection. • Flush microcatheter after contrast injection to avoid quidewire lockup. • Withdrawing device too quickly or with too much force could cause the device to stretch or the tip to separate. • This product has not been tested for alcohol or drug delivery. ADVERSE EVENTS • Allergic reaction • Arrhythmia • Cardiac tamponade • Cardiogenic shock • Death • Embolism • Fever • Hematoma • Hemorrhage • Infection • Myocardial infarction/ischemia • Pericardial effusion • Radiation exposure • Renal failure • Stroke • Thrombosis • Vasospasm • Vessel trauma, including dissection, perforation, or arteriovenous fistula

REFERENCES

1. ASAHI INTECC USA, INC. ASAHI Corsair Pro. Available at: http://asahi-inteccusa-medical.com/medical-product/asahi-corsair-pro/. Accessed July 26, 2018.

use can be found in the product labeling supplied with each device. Information for the use only in

countries with applicable health authority product registrations. Material not intended for use in France.

IC-627402-AA Printed in Germany by medicalvision.

2. Teleflex Incorporated. Teleflex Turnpike Catheters. Product Brochure available at: https://www.teleflex.com/usa/product-areas/interventional/coronary-interventions/turnpikecatheters/.

Accessed July 26, 2018.

3. Terumo Medical Corporation. FINECROSS® MG Coronary Micro-Guide Catheter. Available at: http://www.terumois.com/products/catheters/finecross.html. Accessed July 26, 2018.

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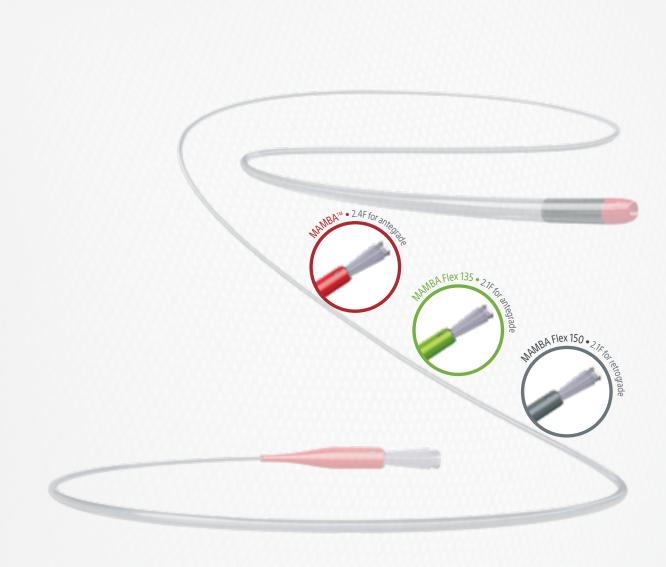


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INTEGRATED TIP

MAMBA™ Microcatheter's unique integrated tip is engineered with a Tapered Coil that extends to within less than 1 mm of the distal tip, providing a flexible metal backbone that is designed for maximum durability, guidewire support, and torque transmission for exceptional deliverability.

Two low-profile options available for a variety of clinical needs:

- 2.4F MAMBA for outstanding antegrade push and support
- 2.1F MAMBA Flex for excellent deliverability through tortuous anatomy

TIP DURABILITY

With the support of a metal coil – where other microcatheters have only polymer – the MAMBA Microcatheters' integrated tip is designed to minimize failure and maximize wire backup support.

Mamba's Tapered
Coil ends <1mm
from the distal tip,
providing enhanced
torque transmission
at the tip for improved
deliverability.

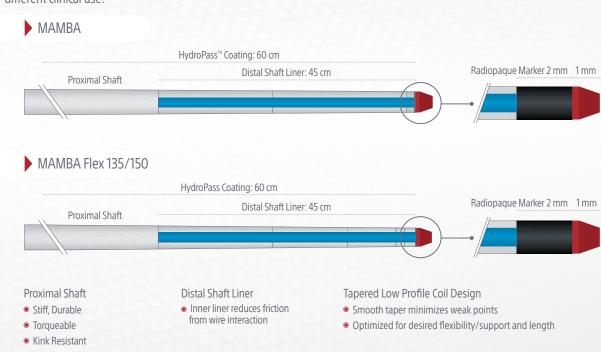


CROSSING PROFILE



TAPERED COIL

MAMBA and MAMBA Flex Microcatheters are engineered with unique Tapered Coil profiles to optimize each device for different clinical use:



TAPERED COIL

MAMBA[™] Microcatheter's game-changing proprietary Tapered Coil is optimized for exceptional pushability and torque transmission without compromising on flexibility or profile, providing outstanding delivery and support in a variety of clinical scenarios.



Constructed from 11 individually tapered filars that extend from hub to tip, the innovative Tapered Coil provides a flexible distal shaft as the filars taper, while maintaining a continuous metal backbone for impressive push and support.



3 taper zones optimize MAMBA for pushability and wire support







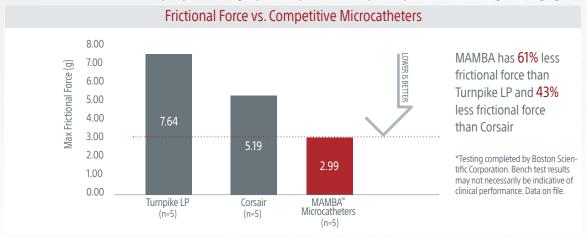


zone 3



HYDROPASS™ HYDROPHILIC COATING

Our most durable and lubricious hydrophilic coating, HydroPass provides unsurpassed performance for long, challenging cases.



PROXIMAL HUB

MAMBA's large, colored hubs are easy to identify and ergonomically designed for controlled maneuverability and torque.

Optimized for:	Antegrade Support	Antegrade Tortuosity	Retrograde		
	119	110	11		
			16		
		1			
MAMBA	MAMBA Flex 135	MAMBA Flex 150			

PRODUCT SPECIFICATIONS

MAMBA™ Micr	ocatheter							
		//						
Order Number (GTIN)	Ref/Catalog Number	Lesion Entry Profile	Crossing Profile	Proximal Shaft Profile	Distal I.D. (in/mm)	Proximal I.D. (in/mm)	Usable Length (cm)	Compatible Guidew Diameter (in/mm
8714729940265	H749 392871352 0	1.4F	2.4F	2.9F	0.018/.46	0.023/.58	135	0.014/.36
MAMBA Flex 1	135 Microcathete	r						
		//		_				b
Order Number (GTIN)	Ref/Catalog Number	Lesion Entry Profile	Crossing Profile	Proximal Shaft Profile	Distal I.D. (in/mm)	Proximal I.D. (in/mm)	Usable Length (cm)	Compatible Guidew Diameter (in/mm
8714729940302	H749 392871356 0	1.4F	2.1F	2.9F	0.018/.46	0.023/.58	135	0.014/.36
MAMBA Flex 1	150 Microcathete	r						
		//		_				
Order Number (GTIN)	Ref/Catalog Number	Lesion Entry Profile	Crossing Profile	Proximal Shaft Profile	Distal I.D. (in/mm)	Proximal I.D. (in/mm)	Usable Length (cm)	Compatible Guidew Diameter (in/mm
8714729940340	H749 392871502 0	1.4F	2.1F	2.9F	0.018/.46	0.023/.58	150	0.014/.36