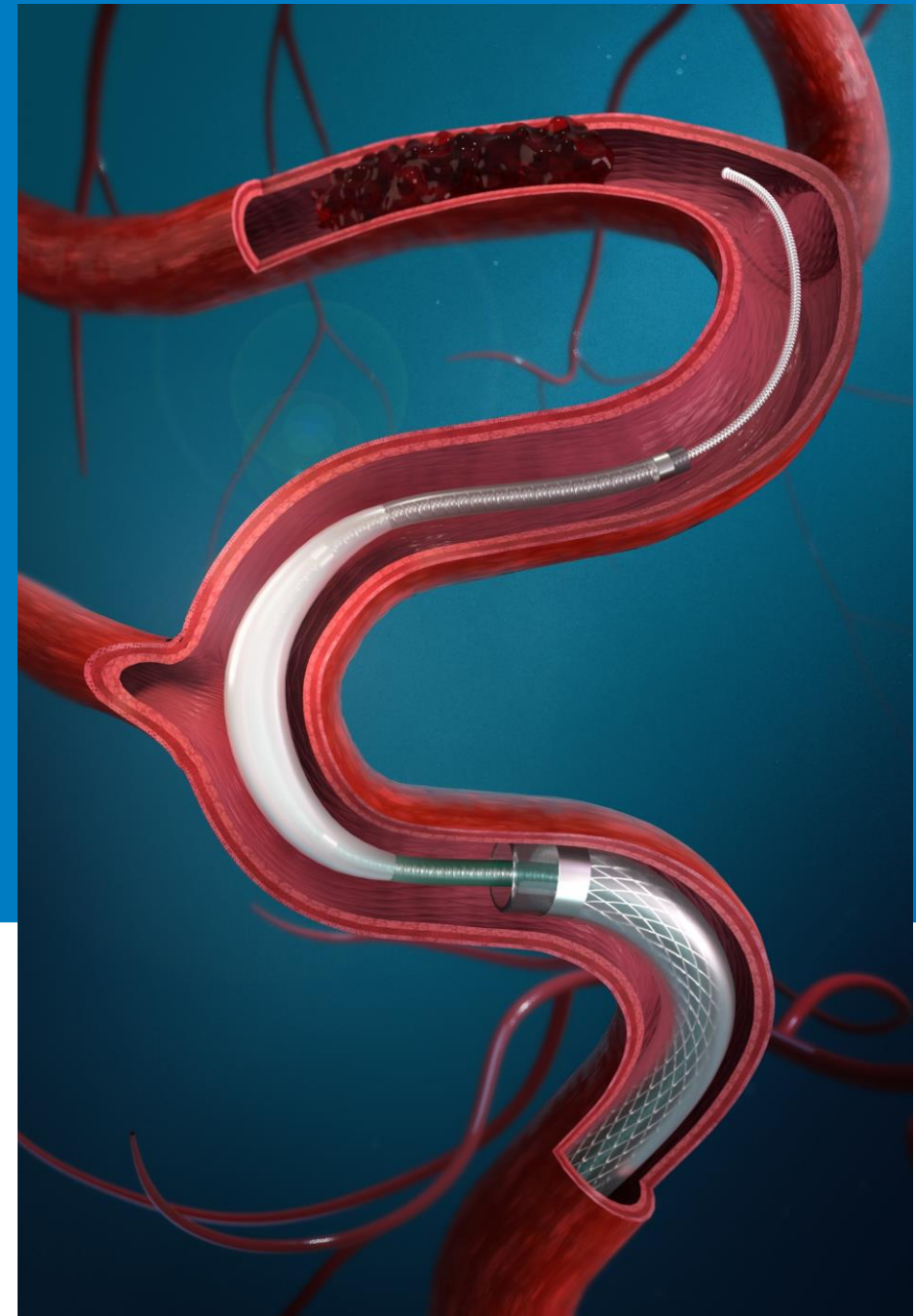




WEDGE™ MICROCATHETER

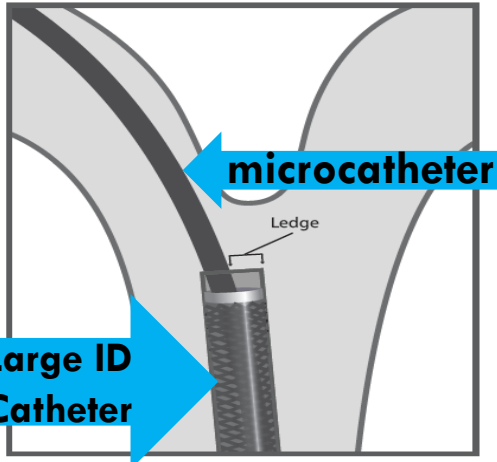
IN-SERVICE PRESENTATION

- **1.5cm** DISTAL TIP
- **160cm** WORKING LENGTH



Catheter Navigation Challenges

The "Ledge Effect"



Gap between microcatheter OD and large ID catheters creates "ledge" that can get caught at bifurcations

Catheter distal tip can't pass tortuous anatomy



Catheter distal tip can't pass Ophthalmic bifurcation



Catheter distal tip can't pass MCA/ACA bifurcation



Images courtesy of Dr. Markus Möhlenbruch, University Hospital, Heidelberg, Germany

Physician may be required to use larger devices (Penumbra® 3F 3MAX™ Catheter as inner catheter or 0.027" microcatheter) or multiple guidewires to overcome these challenges

Indication & Specifications

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.

WEDGE™ CATHETER
 Improve SOFIA® 6F Catheter Navigation Past Tortuous Anatomy

PRODUCT CODE	ID	TIP SHAPE	CATHETER LENGTH	TIP LENGTH	OD DISTAL	OD PROXIMAL	BULB WORKING LENGTH	BULB MAX OD	TIP MARKERS
MCWED21160	0.021"	Straight	160 cm	1.5 cm	0.026" 2.0 F 0.67 mm	0.033" 2.5 F 0.84 mm	1.1 cm	0.068" 5.1 F 1.73 mm	3

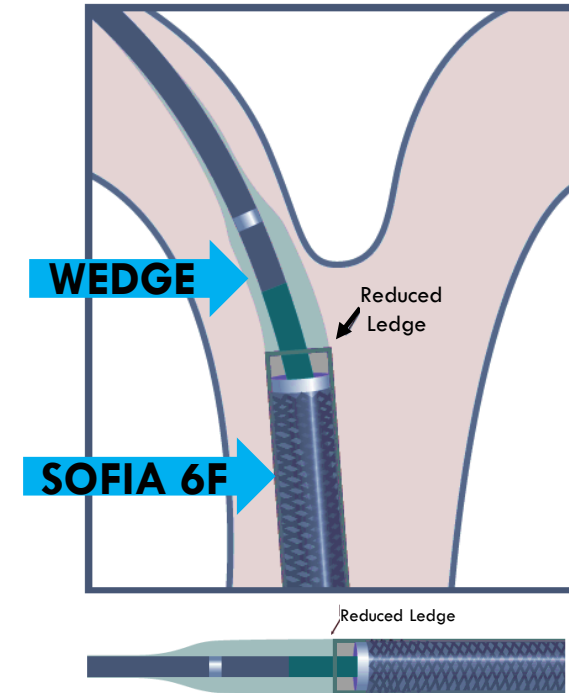
One unit per box, includes shaping mandrel and introducer sheath

The technical drawing illustrates the catheter's dimensions. The side view shows a total length of 160 cm, with a 1.5 cm distal tip. The proximal OD is 0.033" (2.5 F / 0.84 mm) and the distal OD is 0.026" (2.0 F / 0.67 mm). The bulb working length is 1.1 cm, and the bulb maximum OD is 0.068" (5.1 F / 1.73 mm). The distal tip features 3 marker bands. A cross-sectional view shows an inner diameter of 0.021".

Note: The Wedge Microcatheter with 1.5cm distal tip is not intended to deploy a stentriever.

Device Benefits

- ❑ Bulb segment's enlarged OD designed to reduce ledge effect with SOFIA 6F Catheter¹
- ❑ Wedge Catheter + SOFIA™ 6F Catheter expected to provide²:
 - ❖ Easier passage through ophthalmic and MCA/ACA bifurcations
 - ❖ Improved navigation to occlusion location
 - ❖ Minimized vessel trauma
- ❑ 0.021" ID compatible with 0.014" - 0.018" guidewires
- ❑ 160cm working length to ensure adequate distal length when using SOFIA 6F 131cm Catheter



¹Yoo AJ, Frei D, Tatshima S, et al. *J NeuroIntervent Surg* (2011). doi:10.1136/neurintsurg-2011-010080.

Spiotta AM, et al. *J NeuroIntervent Surg* 2015;7:2-7. doi:10.1136/neurintsurg-2013-011022.

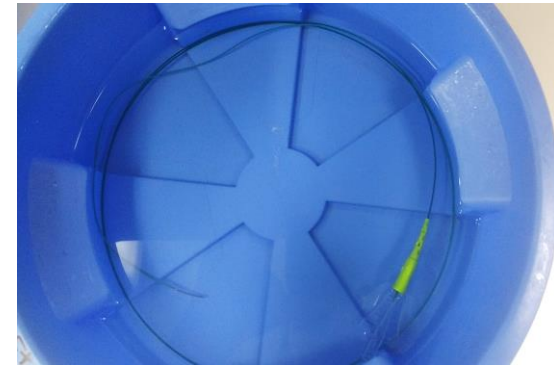
D.-H Kang, MD, Acute Ischemic Stroke, DOI 10.1007/978-981-10-0965-5_10.

²FDA 510(k) submission

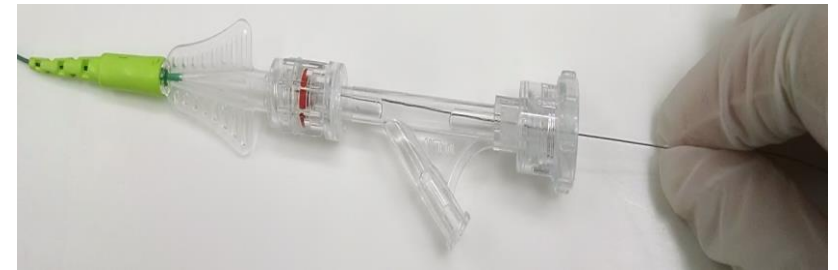
Device Preparation

□ STEP 1

- A. Prior to use, flush the Wedge Microcatheter lumen thoroughly and completely submerge into a bowl of heparinized saline
- B. Attach a rotating hemostatic valve (RHV) to the Wedge Microcatheter hub. Insert the distal section of the guidewire into the RHV attached to Wedge Microcatheter. Advance the guidewire until the distal tip is near the distal end of the Wedge Microcatheter



(A)



(B)

□ STEP 2

- C. Insert the introducer sheath with Wedge Microcatheter and guidewire into the RHV attached to the SOFIA 6F Catheter
- D. Advance the Wedge Microcatheter with guidewire slowly through the SOFIA 6F Catheter. Once the Wedge Microcatheter tip has been advanced at least 60cm, remove the introducer sheath



(C)

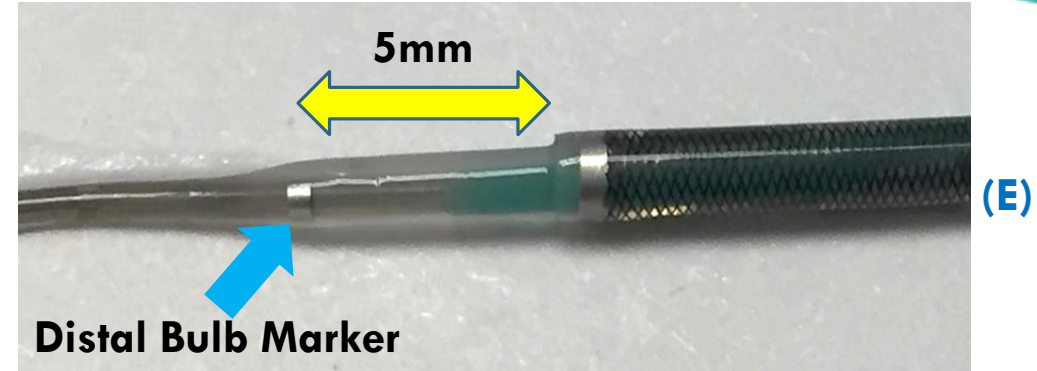


(D)

Device Preparation

□ STEP 3

- E. Advance the Wedge Microcatheter with guidewire through the SOFIA 6F Catheter until the Wedge Microcatheter's distal bulb marker is at least 5mm past the SOFIA 6F Catheter distal tip (in the middle of the Wedge Microcatheter "bulb" segment)



□ STEP 4

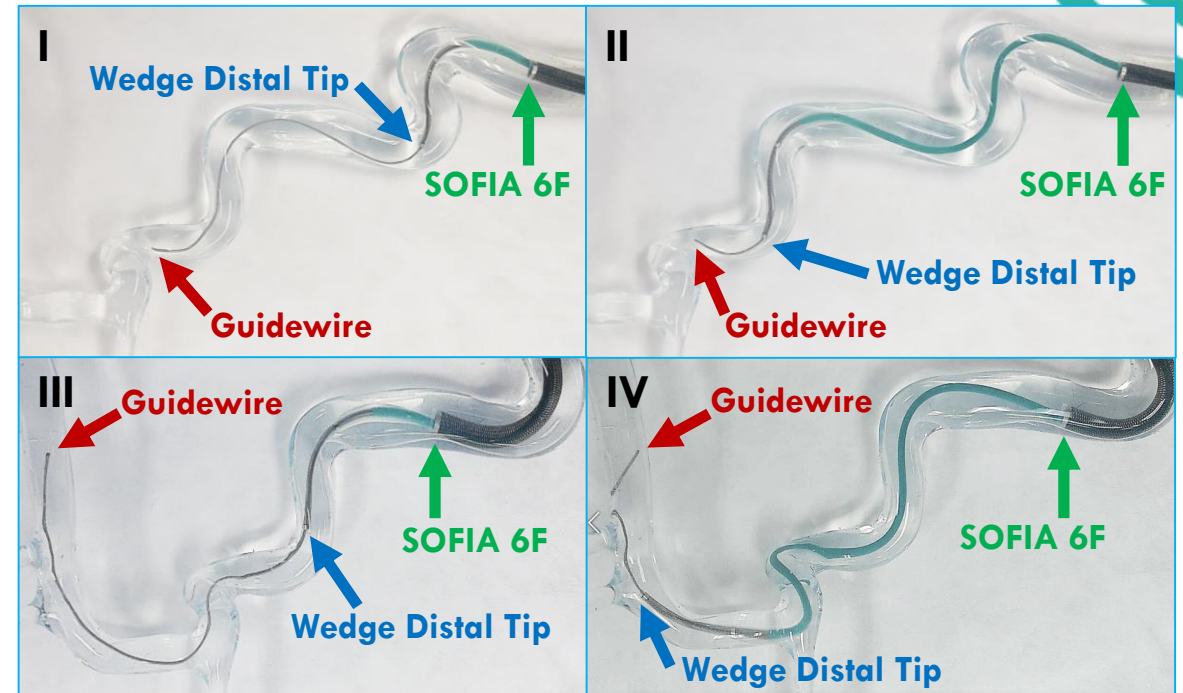
- F. Insert the introducer sheath with SOFIA 6F Catheter, Wedge Microcatheter, and guidewire into the RHV attached to the Guiding Sheath.
- G. Advance the SOFIA 6F Catheter with Wedge Microcatheter and guidewire slowly through the Guiding Sheath. Once the SOFIA 6F Catheter distal tip has advanced at least 60 cm, remove the Introducer sheath.



Navigation Recommendations

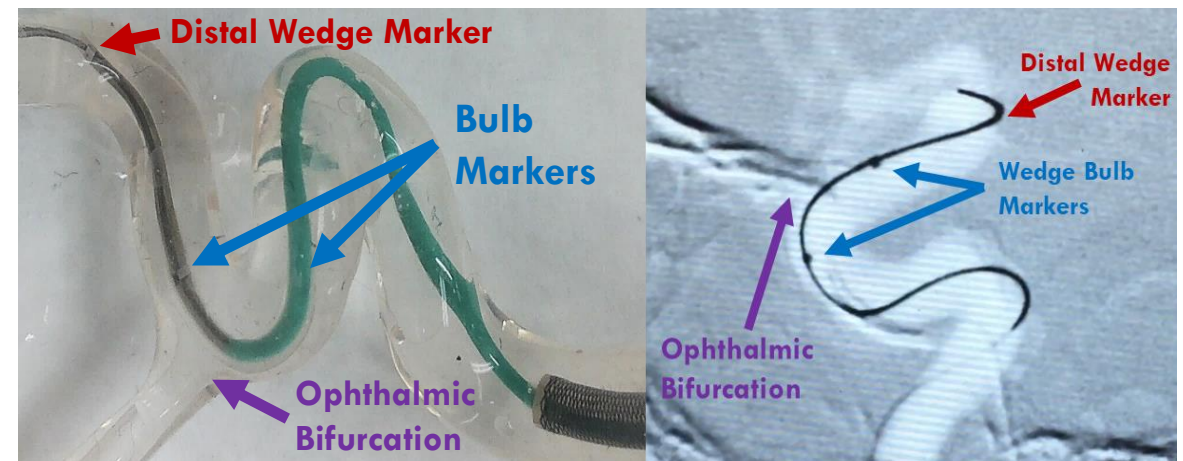
STEP 5

H. To navigate the SOFIA 6F Catheter to the desired vessel location, advance the guidewire a short distance, then advance the Wedge Microcatheter over the guidewire. Repeat this technique until the bulb segment of the Wedge Microcatheter reaches the target bifurcation



STEP 6

I. Position the Wedge Microcatheter's bulb segment across the bifurcation. Under fluoroscopy, ensure that each of the bulb's radiopaque markers is positioned on either side, equidistant from the middle of the bifurcation

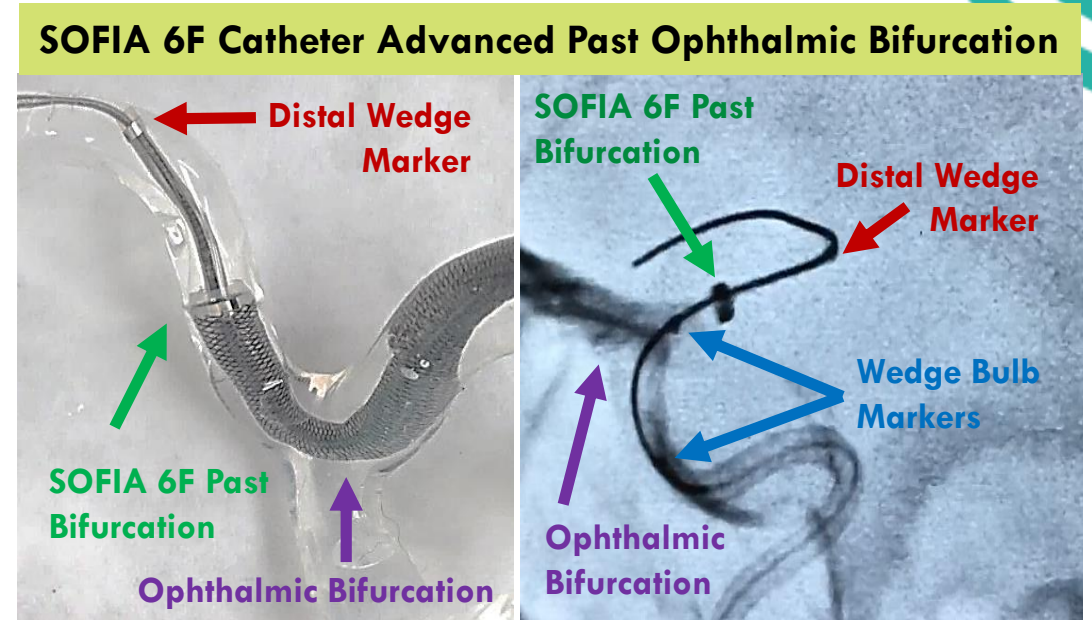


Wedge positioned across ophthalmic bifurcation

Navigation Recommendations

□ STEP 7

- J. With the bulb segment positioned at the desired location, hold the Wedge Microcatheter in place and advance the distal tip of the SOFIA 6F Catheter over the bulb segment completely past the bifurcation



(J)

□ STEP 8

- K. Once the SOFIA 6F Catheter has navigated completely past the bifurcation to the target vessel location, the guidewire and Wedge Microcatheter can be removed from the SOFIA 6F Catheter.





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Indications for Use:

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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.

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

This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures at medical facilities with the appropriate fluoroscopy equipment. The Wedge Microcatheter should only be used by physicians who have received appropriate training for the device.