

Penumbra
SMART COIL.

Progressively
soft



Ingeniously
practical

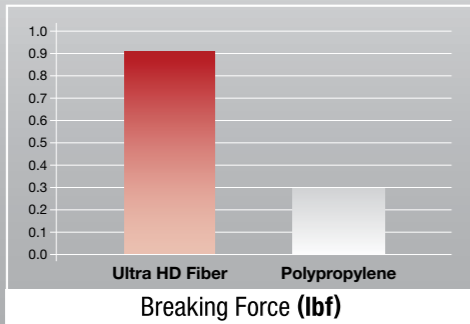
Penumbra 



10 Microcatheter
Compatible

Ultra Stretch Resistance

- High-tech Ultra HD Fiber is 3x stronger than current SR material^a



a. Scientific data on file at Penumbra, Inc.: Ultra HD Fiber vs. Polypropylene SR material

Exceptional Softness for Coil Conformability

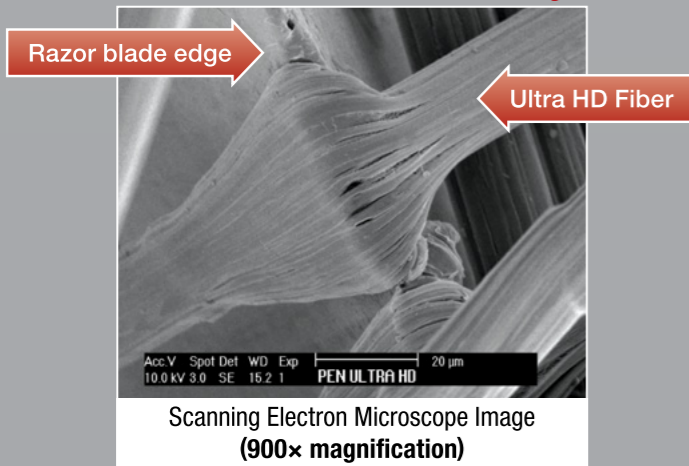
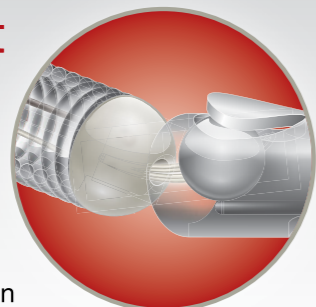


Image taken by and on file at Penumbra, Inc.

Consistent Instant Detachment

- True instant detachment using Ultra HD Fiber
- Detachment interface articulates 360° to reduce catheter deflection



Progressive Softness

Made possible with SmartCore technology

Distal

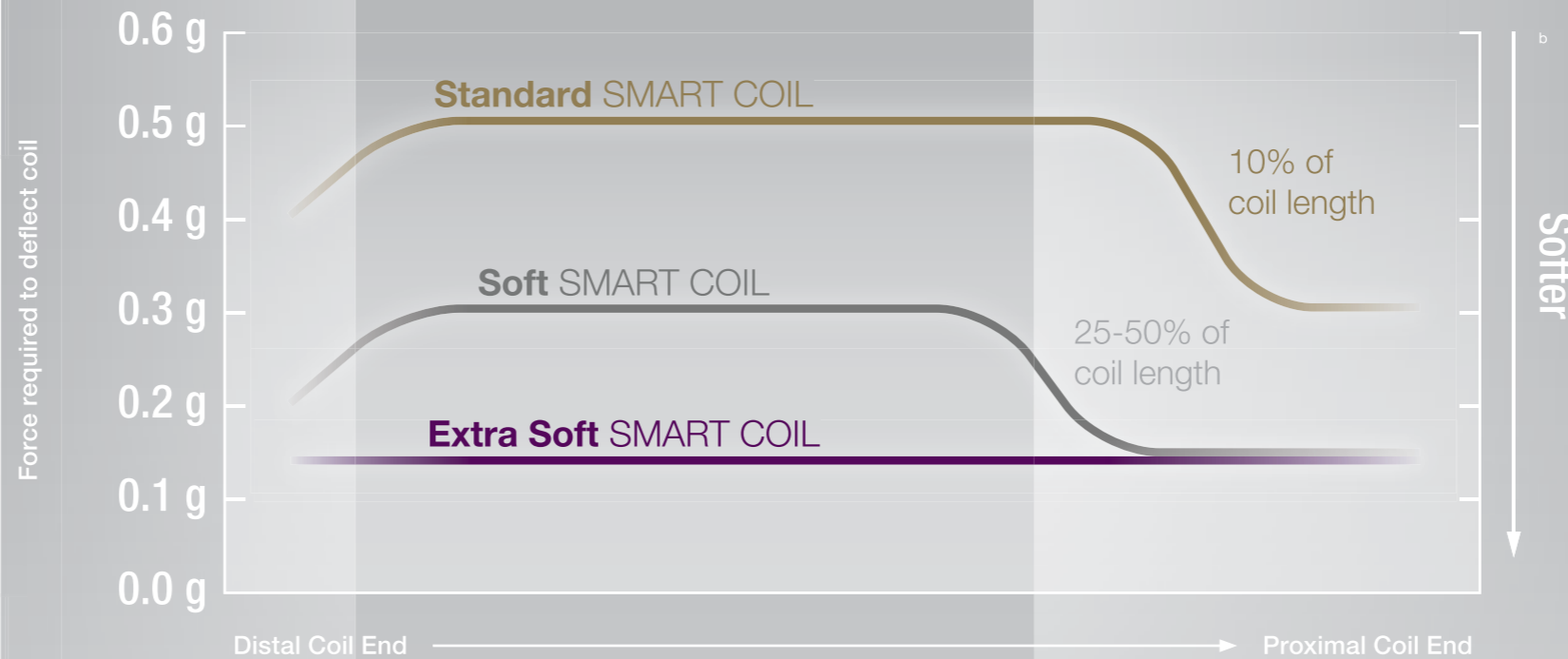
Distal coil loop is designed to be **soft and atraumatic**

Proximal

Coil becomes **progressively softer** as it is deployed

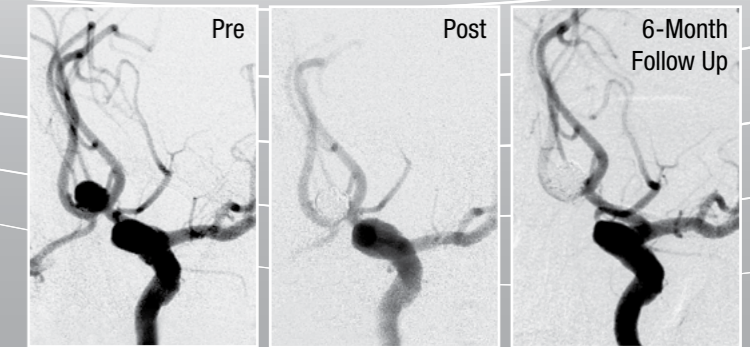


Magnified photo of 1 mm x 3 cm SMART COIL displaying accurate complex shape



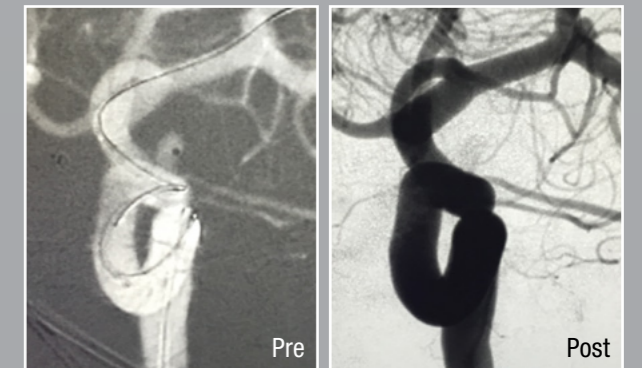
b. Scientific data on file at Penumbra, Inc.

Case Examples

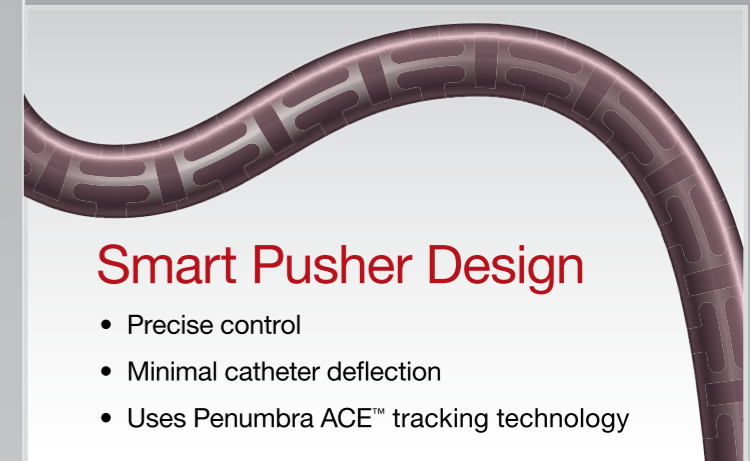


7 mm ACom Aneurysm

First follow-up performed in Europe, October 2015



5 x 2 mm ICA Aneurysm



Smart Pusher Design

- Precise control
- Minimal catheter deflection
- Uses Penumbra ACE™ tracking technology

Images used with permission. Consents on file at Penumbra, Inc.

Penumbra SMART COIL

10

10 Microcatheter
Compatible

STANDARD			SOFT			EXTRA SOFT			WAVE™ EXTRA SOFT		
Catalog Number	Secondary Diameter (mm)	Length (cm)	Catalog Number	Secondary Diameter (mm)	Length (cm)	Catalog Number	Secondary Diameter (mm)	Length (cm)	Catalog Number	Secondary Diameter (mm)	Length (cm)
400SMTSTD0408	4	8	400SMTSFT0203	2	3	400SMTXSFT0101	1	1	400SMTHXSFT0101	1	1
400SMTSTD0510	5	10	400SMTSFT0304	3	4	400SMTXSFT011H	1	1.5	400SMTHXSFT0102	1	2
400SMTSTD0515	5	15	400SMTSFT0306	3	6	400SMTXSFT0102	1	2	400SMTHXSFT0103	1	3
400SMTSTD0615	6	15	400SMTSFT0308	3	8	400SMTXSFT0103	1	3	400SMTHXSFT1H01	1.5	1
400SMTSTD0620	6	20	400SMTSFT3H08	3.5	8	400SMTXSFT0104	1	4	400SMTHXSFT1H02	1.5	2
400SMTSTD0715	7	15	400SMTSFT0406	4	6	400SMTXSFT1H02	1.5	2	400SMTHXSFT1H03	1.5	3
400SMTSTD0725	7	25	400SMTSFT0408	4	8	400SMTXSFT1H03	1.5	3	400SMTHXSFT0202	2	2
400SMTSTD0820	8	20	400SMTSFT0410	4	10	400SMTXSFT1H04	1.5	4	400SMTHXSFT0203	2	3
400SMTSTD0830	8	30	400SMTSFT4H10	4.5	10	400SMTXSFT0202	2	2	400SMTHXSFT0204	2	4
			400SMTSFT0506	5	6	400SMTXSFT0203	2	3	400SMTHXSFT0206	2	6
			400SMTSFT0510	5	10	400SMTXSFT0204	2	4	400SMTHXSFT0208	2	8
			400SMTSFT0515	5	15	400SMTXSFT0206	2	6	400SMTHXSFT2H04	2.5	4
			400SMTSFT0610	6	10	400SMTXSFT0208	2	8	400SMTHXSFT2H06	2.5	6
			400SMTSFT0615	6	15	400SMTXSFT2H03	2.5	3	400SMTHXSFT2H08	2.5	8
			400SMTSFT0715	7	15	400SMTXSFT2H04	2.5	4	400SMTHXSFT0304	3	4
			400SMTSFT0820	8	20	400SMTXSFT2H06	2.5	6	400SMTHXSFT0306	3	6
			400SMTSFT0930	9	30	400SMTXSFT2H08	2.5	8	400SMTHXSFT0308	3	8
						400SMTXSFT0304	3	4	400SMTHXSFT0406	4	6
						400SMTXSFT0306	3	6	400SMTHXSFT0408	4	8
						400SMTXSFT0308	3	8	400SMTHXSFT0410	4	10
						400SMTXSFT3H06	3.5	6	400SMTHXSFT0510	5	10
						400SMTXSFT3H08	3.5	8			
						400SMTXSFT0406	4	6			
						400SMTXSFT0408	4	8			
						400SMTXSFT0410	4	10			
						400SMTXSFT4H12	4.5	12			

SMART PLUS STANDARD

Catalog Number	Secondary Diameter (mm)	Length (cm)
400SMTSTD0920	9	20
400SMTSTD0930	9	30
400SMTSTD1045	10	45
400SMTSTD1160	11	60
400SMTSTD1260	12	60
400SMTSTD1360	13	60
400SMTSTD1460	14	60
400SMTSTD1660	16	60
400SMTSTD1860	18	60

Penumbra SMART COIL Detachment Handle



Catalog Number	Description
SCH1	Smart Coil Detachment Handle

Product availability varies by country.

Please contact your local Penumbra representative for more information.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Prior to use, please refer to the Instructions for Use.

Indication For Use

The Penumbra Smart Coil® System is indicated for the embolization of:

- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae
- Arterial and venous embolizations in the peripheral vasculature

Contraindications

There are no known contraindications.

Warnings

The Penumbra Smart Coil System should only be used by physicians who have received appropriate training in interventional techniques.

Precautions

- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may compromise the structural integrity of the device or increase the risk of contamination or infection leading to device failure and/or cross-infection and potential patient injury, illness or death.
- Do not use kinked or damaged devices. Do not use opened or damaged packages. Return all damaged

devices and packaging to the manufacturer/distributor.

- Standard and Soft configurations of Smart Coils are designed with Nitinol wire inside the platinum outer coil. The safety and effectiveness of this device has not been evaluated in patients with Nitinol allergy.
- Use prior to the "Use By" date
- Use device in conjunction with fluoroscopic guidance
- Do not advance or withdraw the device against resistance without careful assessment of the cause using fluoroscopy
- Moving or torquing the device against resistance may result in damage to the vessel or device
- Maintain a constant infusion of an appropriate flush solution

Potential Adverse Events

Potential complications include but are not limited to:

Acute occlusion, air embolism, allergic reaction and anaphylaxis from contrast media, aneurysm rupture, arteriovenous fistula, coagulopathy, coil herniation into parent vessel, death, device malfunction, distal embolization, emboli, embolic stroke and other cerebral ischemic events, false aneurysm formation, hematoma or hemorrhage at access site of entry, incomplete aneurysm occlusion, infection, intima dissection, intracranial hemorrhage, ischemia, myocardial infarction, neurological deficits including stroke, parent artery occlusion, peripheral thromboembolic events, post-embolization syndrome, premature device detachment, recanalization, renal failure, respiratory failure, revascularization, thromboembolic episodes, vessel spasm, thrombosis, dissection or perforation

Penumbra

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