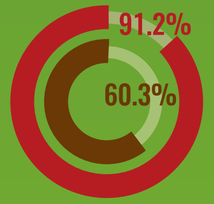
CATCH TRIAL

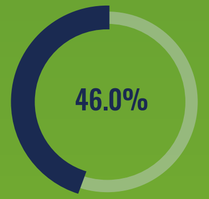
Coil **A**pplication **T**rial in **CH**ina (ClinicalTrials.gov Identifier: NCT02990156)

- Prospective, multi-center, randomized controlled trial for premarket approval.
- **336** patients enrolled and allocated to control arm and Numen™ arm.
- **10** centers enrolled.

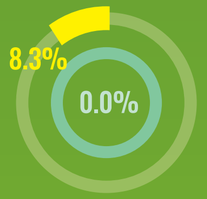
SAFETY & EFFICACY



6M-SUCCESSFUL OCCLUSION RATE*
6M-COMPLETE OCCLUSION RATE*



MEAN PACKING DENSITY*



6M-RECANALIZATION RATE*
6M-RETREATMENT RATE*

OBJECTIVES

To assess the safety and efficacy of Numen™ coil Embolization System for the treatment of intracranial aneurysm.

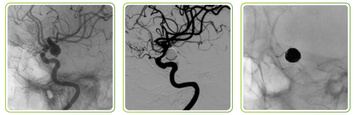
RESULTS

- Achieved 91.2% successful occlusion rate and 60.3% complete occlusion rate at 6 month follow-up.
- Mean packing density is 46.0%.
- Overall recanalization rate and retreatment rate are 8.3% and 0.0% respectively.

CONCLUSIONS

The CATCH Trial shows that Numen™ coil Embolization System is safe and effective for the treatment of the intracranial aneurysms.

CASE 1 **Packing density: 61%**

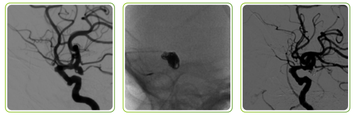


A 68-year-old female presented with a ruptured right P-Com aneurysm. The wideneck aneurysm measured 7.3×9.5mm.

MicroFrame: 12×29
MicroFill: 10×40, 8×30
MicroFinish: 8×35, 5×20, 5×20, 4×10, 4×10, 4×10, 3×10
Enterprise: 4.5×22

6 Month follow-up shows complete neck coverage and complete occlusion of aneurysm.

CASE 2 **Packing density: 43%**



A 80-year-old female presented with a ruptured right P-Com aneurysm. The wide-neck aneurysm measured 4.5×3.5mm.

MicroFinish: 4×8, 2×6, 1.5×3
MicroFill: 2×6, 2×6

6 Month follow-up shows complete occlusion of aneurysm and P-Com patency.

*Successful occlusion rate is defined as the proportion of subjects with a Raymond score of Raymond I or Raymond II, i.e., aneurysm occlusion degree around 95%-100%.
*Complete occlusion rate of aneurysm is defined as the proportion of subjects whose aneurysm occlusion degree is 100% with Raymond I score.
*Mean packing density was calculated using an on-line system available at www.angiocalc.com.
Recanalization rate of aneurysm is defined as the proportion of subjects with decreased aneurysm occlusion at follow-up compared with those immediately after the procedure.
*Retreatment was performed by the criteria set by each institution.

MicroFrame

Product Catalog Number	Coil diameter (mm)	Coil length (cm)	Primary Coil OD (inch)
3D0406FR	4	6	0.012 inch
3D0408FR		8	
3D0410FR		10	
3D0415FR		15	
3D4H08FR	4.5	8	
3D4H10FR		10	
3D4H14FR		14	
3D4H18FR		18	
3D0508FR	5	8	
3D0510FR		10	
3D0515FR		15	
3D0520FR		20	
3D0610FR	6	10	
3D0615FR		15	
3D0620FR		20	
3D0625FR		25	
3D0712FR	7	12	0.013 inch
3D0718FR		18	
3D0724FR		24	
3D0730FR		30	
3D0815FR	8	15	
3D0820FR		20	
3D0826FR		26	
3D0835FR		35	
3D0916FR	9	16	
3D0922FR		22	
3D0928FR		28	
3D0935FR		35	
3D1020FR	10	20	
3D1026FR		26	
3D1032FR		32	
3D1040FR		40	
3D1127FR	11	27	0.014 inch
3D1132FR		32	
3D1229FR	12	29	
3D1234FR		34	
3D1332FR	13	32	
3D1337FR		37	
3D1435FR	14	35	
3D1441FR		41	
3D1538FR	15	38	
3D1543FR		43	
3D1640FR	16	40	
3D1646FR		46	
3D1844FR	18	44	
3D1851FR		51	
3D2050FR	20	50	
3D2058FR		58	
3D2256FR	22	56	
3D2264FR		64	
3D2461FR	24	61	
3D2470FR		70	

MicroFill

Product Catalog Number	Coil diameter (mm)	Coil length (cm)	Primary Coil OD (inch)
1D0101HL	1	1	0.010inch
1D0102HL		2	
1D0103HL		3	
1D1H01HL	1.5	1	
1D1H02HL		2	
1D1H03HL		3	
1D1H04HL		4	
1D1H06HL		6	
1D0201HL	2	1	
1D0202HL		2	
1D0203HL		3	
1D0204HL		4	
1D0206HL		6	
1D0208HL		8	
1D2H03HL	2.5	3	
1D2H04HL		4	
1D2H06HL		6	
1D2H08HL		8	
1D0304HL	3	4	
1D0306HL		6	
1D0308HL		8	
1D0310HL		10	
1D0315HL		15	
1D3H04HL	3.5	4	
1D3H06HL		6	
1D3H08HL		8	
1D3H10HL		10	
1D3H15HL		15	
1D0406HL	4	6	0.012 inch
1D0408HL		8	
1D0410HL		10	
1D0415HL		15	
1D0420HL		20	
1D0506HL	5	6	
1D0508HL		8	
1D0510HL		10	
1D0515HL		15	
1D0520HL		20	
1D0525HL		25	
1D0606HL	6	6	
1D0608HL		8	
1D0610HL		10	
1D0615HL		15	
1D0620HL		20	
1D0625HL		25	
1D0630HL		30	
1D0715HL	7	15	
1D0720HL		20	
1D0730HL		30	
1D0740HL		40	
1D0820HL	8	20	
1D0830HL		30	
1D0840HL		40	
1D0930HL	9	30	
1D0940HL		40	
1D1030HL	10	30	
1D1040HL		40	
1D1045HL		45	
1D1230HL	12	30	0.014 inch
1D1240HL		40	
1D1250HL		50	
1D1255HL		55	
1D1430HL	14	30	
1D1440HL		40	
1D1450HL		50	
1D1455HL		55	
1D1630HL	16	30	
1D1640HL		40	
1D1650HL		50	
1D1655HL		55	
1D1830HL	18	30	
1D1840HL		40	
1D1850HL		50	
1D1855HL		55	
1D2030HL	20	30	
1D2040HL		40	
1D2050HL		50	
1D2055HL		55	

MicroFinish

Product Catalog Number	Coil diameter (mm)	Coil length (cm)	Primary Coil OD (inch)
3D0102FN	1	2	0.010inch
3D0103FN		3	
3D1H02FN	1.5	2	
3D1H03FN		3	
3D1H04FN		4	
3D0202FN	2	2	
3D0203FN		3	
3D0204FN		4	
3D0206FN		6	
3D0208FN		8	
3D2H03FN	2.5	3	
3D2H04FN		4	
3D2H06FN		6	
3D2H08FN		8	
3D0304FN	3	4	
3D0306FN		6	
3D0308FN		8	
3D0310FN		10	
3D0315FN		15	
3D3H06FN	3.5	6	
3D3H08FN		8	
3D3H10FN		10	
3D3H15FN		15	
3D0406FN	4	6	
3D0408FN		8	
3D0410FN		10	
3D0415FN		15	
3D4H08FN	4.5	8	
3D4H10FN		10	
3D4H14FN		14	
3D4H18FN		18	
3D0508FN	5	8	
3D0510FN		10	
3D0515FN		15	
3D0520FN		20	
3D0610FN	6	10	
3D0615FN		15	
3D0620FN		20	
3D0625FN		25	
3D0712FN	7	12	
3D0718FN		18	
3D0724FN		24	
3D0730FN		30	
3D0815FN	8	15	
3D0820FN		20	
3D0826FN		26	
3D0835FN		35	

NumenFR™

Description	Product Catalog Number
NumenFR™ detachment system	E101

INDICATIONS FOR USE:
Numen™ Coil Embolization System is intended to endovascularly obstruct or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels.
Numen™ Coil Embolization System is indicated for endovascular embolization of:
- Intracranial aneurysms
- Other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistula.
- Arterial and venous embolization in the peripheral vasculature.

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MicroPort NeuroTech

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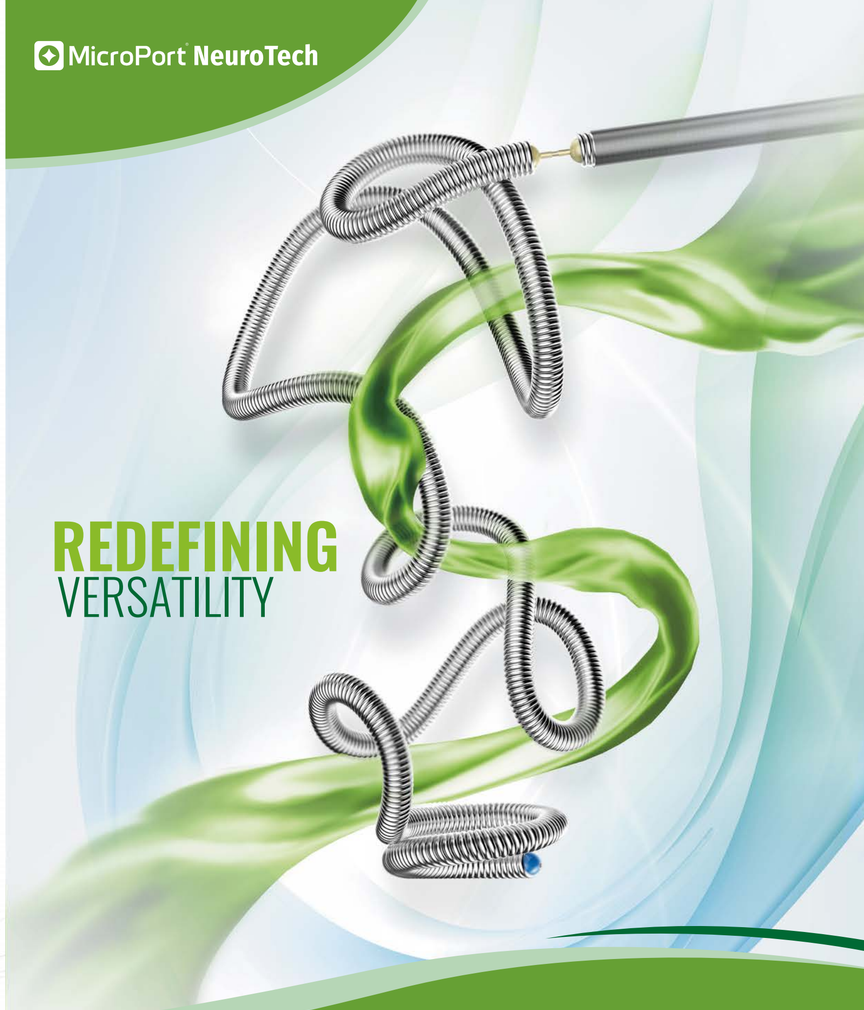
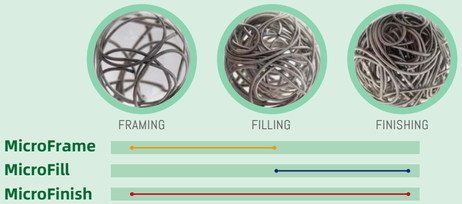
REDEFINING
VERSATILITY



NUMEN™
Coil Embolization System

VERSATILITY

Comprehensive portfolios offer optimal coils in all stages during coil embolization procedure.



SHAPE

Ω+S structure is designed to achieve **uniform distribution and robust neck coverage**.

First 1.5 loop minimizes the risk of coil protrusion.

Ω shape provides predictable and stable basket.

S shape allows subsequent loops to pack open spaces.

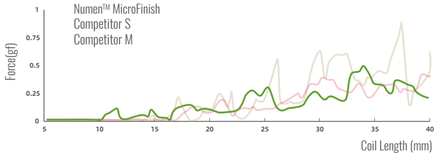
CONFORMABILITY

Conform to various aneurysm morphologies and pack remnant spaces with exceptional conformability.

Saccular Aneurysm | Aneurysm with daughter sac | Bilobed Aneurysm

SOFTNESS*

High-level coil softness ensures stable, low forces against the aneurysm wall.



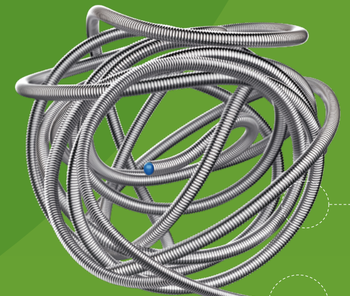
*Data on file.

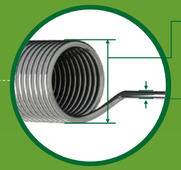
COIL DESIGN

VARIETY

Numen™ coil offers **8** grades of softness by combining **7** filament wire diameters with **4** coil primary diameters. Softness design is based on the theory of coil stiffness (k-factor theoretically represents for coil softness).

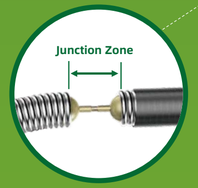
$$K \propto \frac{(\text{Filament Wire Diameter})^4}{(\text{Number of turns per unit length}) X (\text{Primary Coil Diameter})}$$





Primary Coil Diameter
Range: 0.010inch-0.014inch

Filament Wire Diameter
Range: 0.00125inch-0.00350inch



STABILITY

Junction zone between coil and delivery wire greatly affects the microcatheter stability during the coiling procedure.
Numen™ coil has very **short junction zone** which provides stable filling and safe finishing with less kickback.

MicroFill 1mm-3.5mm
MicroFinish 1mm-8mm

MicroFill 4mm-20mm
MicroFrame 4mm-24mm

BALANCE

Two types of stretch resistance design to ensure the balance between robust tensile strength and excellent softness.

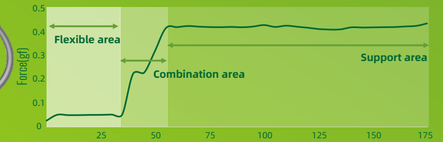
DELIVERY WIRE DESIGN

SMOOTHNESS

Numen™ delivery wire promises stable and smooth coil delivery with Hyper-coil design which balances between pushability and trackability.

RESULTS ON PUSHABILITY

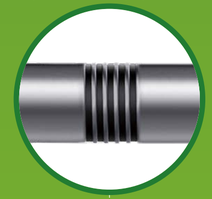
*Data on file.



3 levels of gradual softness throughout entire delivery wire ensure balanced performance between pushability and trackability.

CONVENIENCE

The raised fluoro-saver marker provides tactile feedback, designed to reduce radiation exposure time for patients and physicians.



RELIABILITY

NumenFR™ detachment system

Reliable, fast and simplified electrolytic detachment with real-time feedback and ergonomic handle.