




CHANGING OUTCOMES CHANGING LIVES

**Neva**™ **NET**

Designed to Maximize Clot Retention



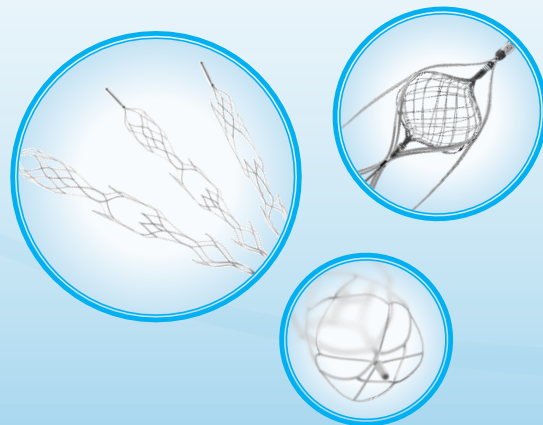
VESALIO CHANGING OUTCOMES CHANGING LIVES

2017 Founded by physicians treating stroke

- NeVa design freeze and establishment of Vesalio in 2017
- 34 Issued & 50+ Filed Patents

2018 Set on resolving vascular occlusions

- Commercial launch of NeVa in Europe



2022 Improving, perfecting, diversifying portfolio

- U.S. FDA Approval for Vasospasm (NeVa VS)
- CE marking of NeVa NET - the 1st SR device with integrated distal filter in thrombectomy
- CE marking of enVast - the 1st SR-type device approved in STEMI

2023 Commercial Expansion and Success

- International commercialization in over 50 countries, expanding into new global regions
- U.S. commercialization with NeVa VS
- 10000th device milestone

Vesalio is advancing the care of patients suffering from vascular occlusion by providing physicians superior technology designed to improve clinical outcomes

WHY DEVELOP ANOTHER STENT-RETRIEVER

1

TREAT ALL OCCLUSIONS

From soft, friable clots that easily disintegrate to hard, fibrin-rich clots that are impenetrable

2

IMPROVE PROCEDURAL PERFORMANCE

1st Pass Success
Faster time to recanalization
Higher TICI 2c/3 rates

3

PROVIDE EASE OF USE

Real-time feedback during retrieval
Synergy with all access philosophies

TO ACHIEVE BETTER PATIENT OUTCOMES

FIRST PASS EFFECT = BETTER PATIENT OUTCOMES

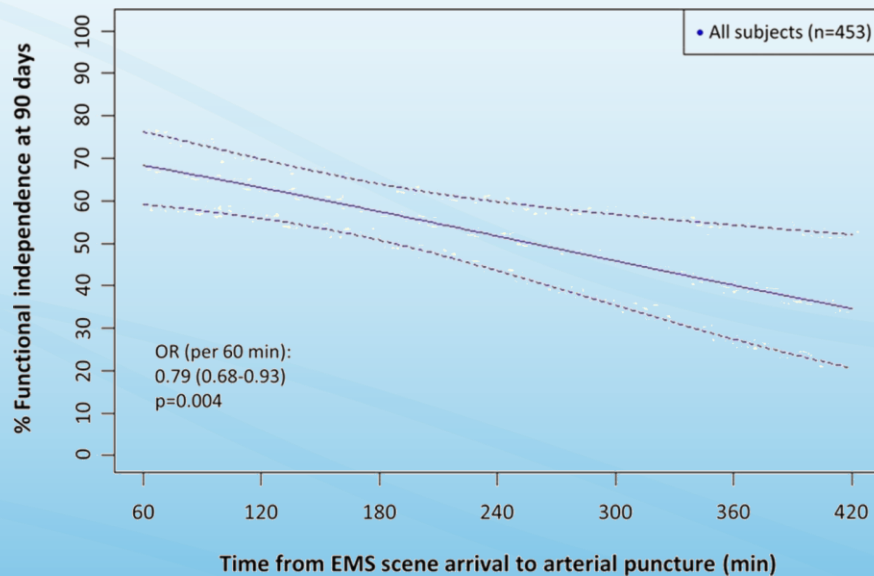
Faster recanalization:
TIME is BRAIN

Lower complication
rates

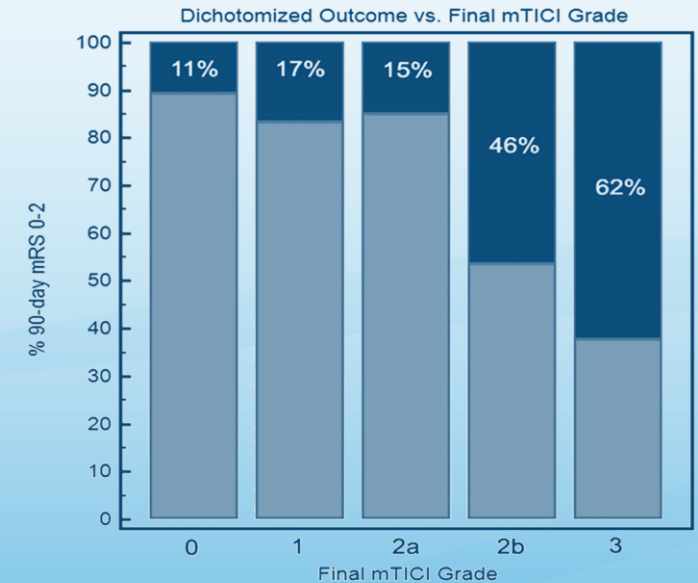
Impact of complete
recanalization

Each hour delay to treatment is associated with a 5.5% absolute decline in the likelihood of achieving good outcome¹

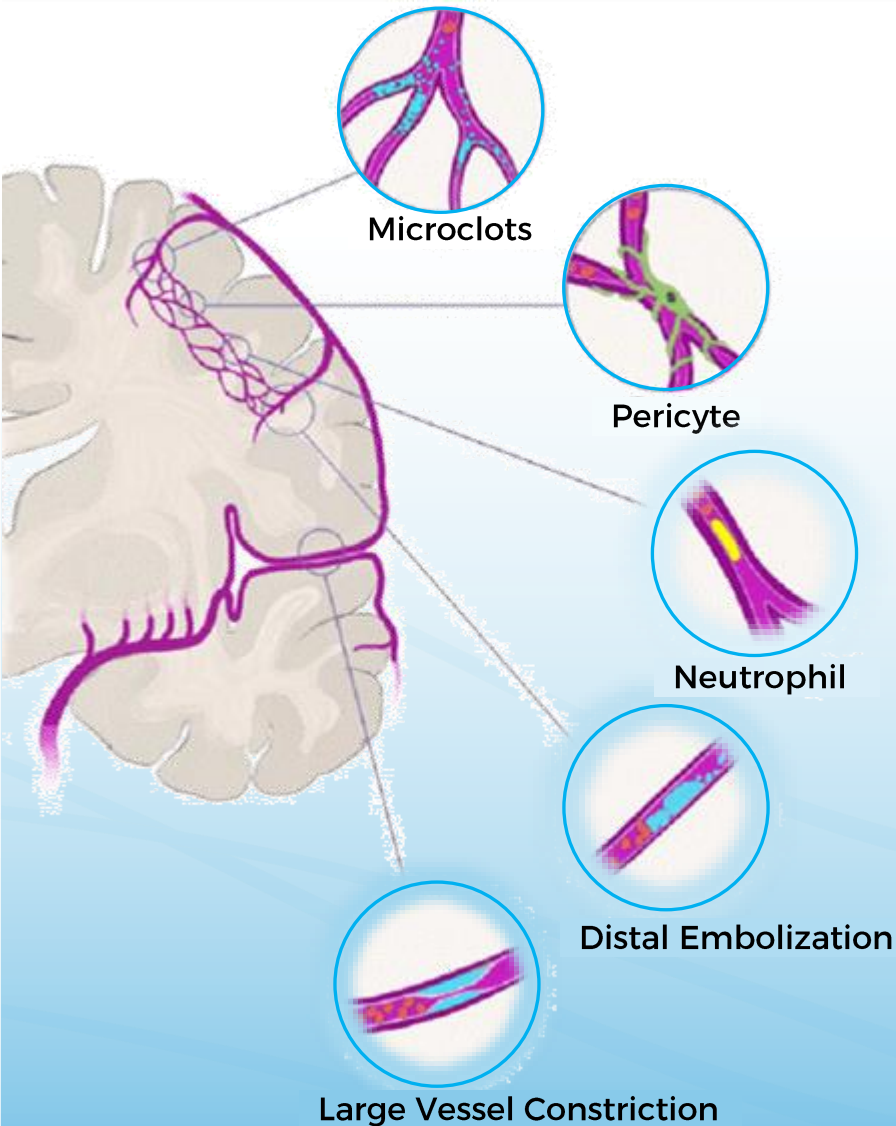
Proportion of good outcomes by mTICI grade² (P<0.0001 for overall comparison)



- Good outcome (mRS 0 - 2)
- Poor outcome (mRS 3 - 6)



RECANALIZATION ≠ REPERFUSION



Recanalization: restoring blood flow in the macro vessel

Reperfusion: blood flow & oxygenation at tissue level

- Restoring blood flow to the occluded vessel does not guarantee full tissue reperfusion
- Reperfusion failure significantly attenuates the beneficial effect of recanalization and severely affects functional recovery of stroke patients
- The mechanisms of reperfusion failure are not fully understood
- Furthermore, after recanalization in stroke patients, a primary clot can break, dislodge, and occlude distal arterial branches further downstream

DESIGN

NevaTM

Designed for 1st PASS SUCCESS with ALL Clot Types



CONVENTIONAL STENT-RETRIEVERS



Work by **pinning** the clot to the artery wall and **dragging** it down

In most cases, clot penetration is **partial**

Hard clots simply slide outside the basket and **remain in place**

CONVENTIONAL STENT-RETRIEVERS

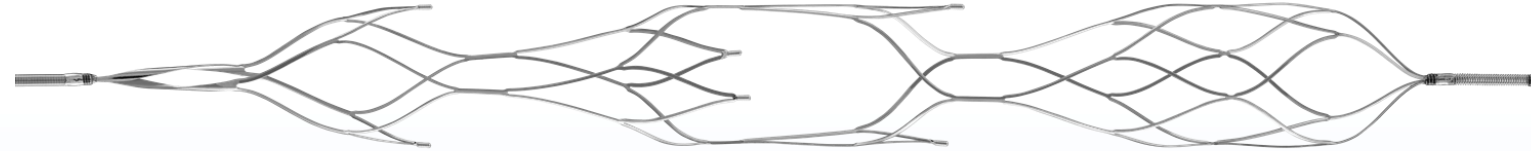


Up to 40% of thrombectomies result in clot particles escaping to distal or previously unaffected vascular territories, adversely affecting outcomes

Open-ended designs do not protect against the risk of clot escape to distal vasculature

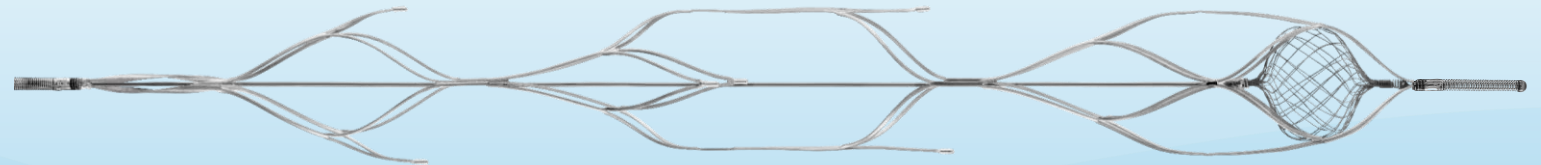
DROP ZONE™ THE CLOT INSIDE

Ne^va™



Uniquely designed to CAPTURE ALL TYPES OF CLOT INSIDE THE DEVICE STRUCTURE

Ne^va™ NET

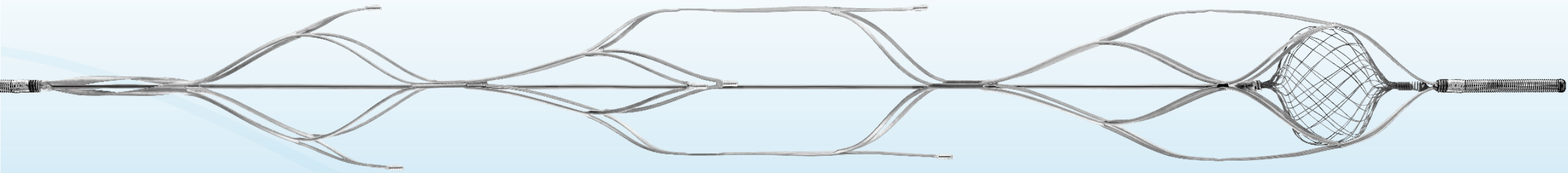


The first and only integrated microfilter designed to MAXIMIZE CLOT RETENTION

A DESIGN TARGETING FIRST PASS SUCCESS WITH MAXIMIZED REPERFUSION

DROP ZONES™

3 Drop Zones offset at 90° work by acting as clot pockets: entry points to capture thrombi inside



BALANCED DESIGN

Optimized radial force balanced with large openings & closed ends

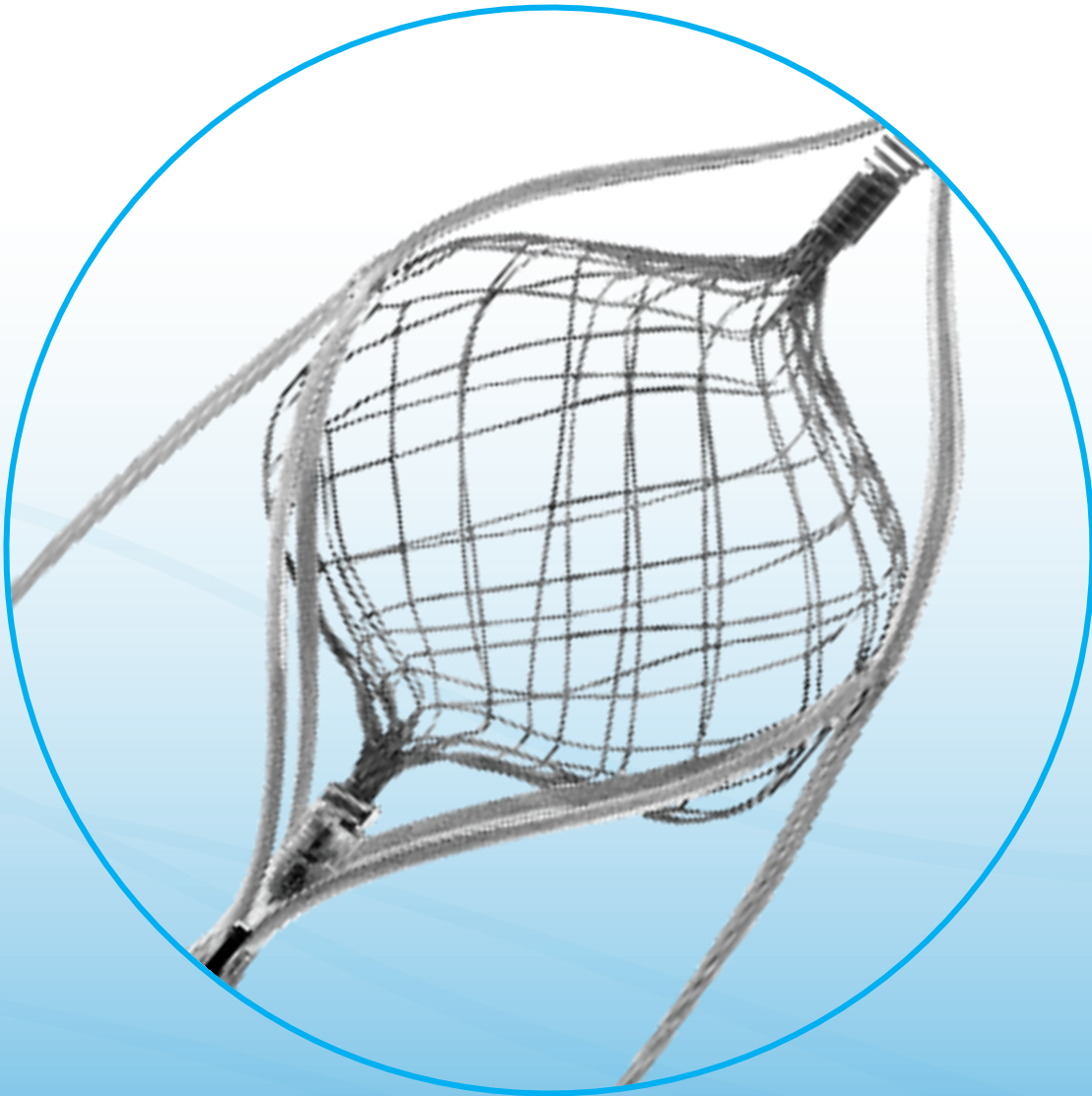
DROP ZONE MARKERS

2 per Drop Zone, for real-time feedback during retrieval

CLOSED TIP WITH NET PROTECTION

Clot gets inside, clot stays inside!

A SINGULAR MICRO FILTRATION TECHNOLOGY



32 intricately braided
nitinol strands of
.00125" creating a filter
with an average pore
size of $385.3 \pm 68 \mu\text{m}$

Currently
Available

5.5 x 37 mm

3 Drop Zones
VN-5537-03NR

Ideal for
**Proximal
occlusions**

Vessel diameters
3.5 – 5.5 mm
Recommended MC: 0.027"

Coming
soon

4.0 x 30 mm

3 Drop Zones
VN-4030-03NR

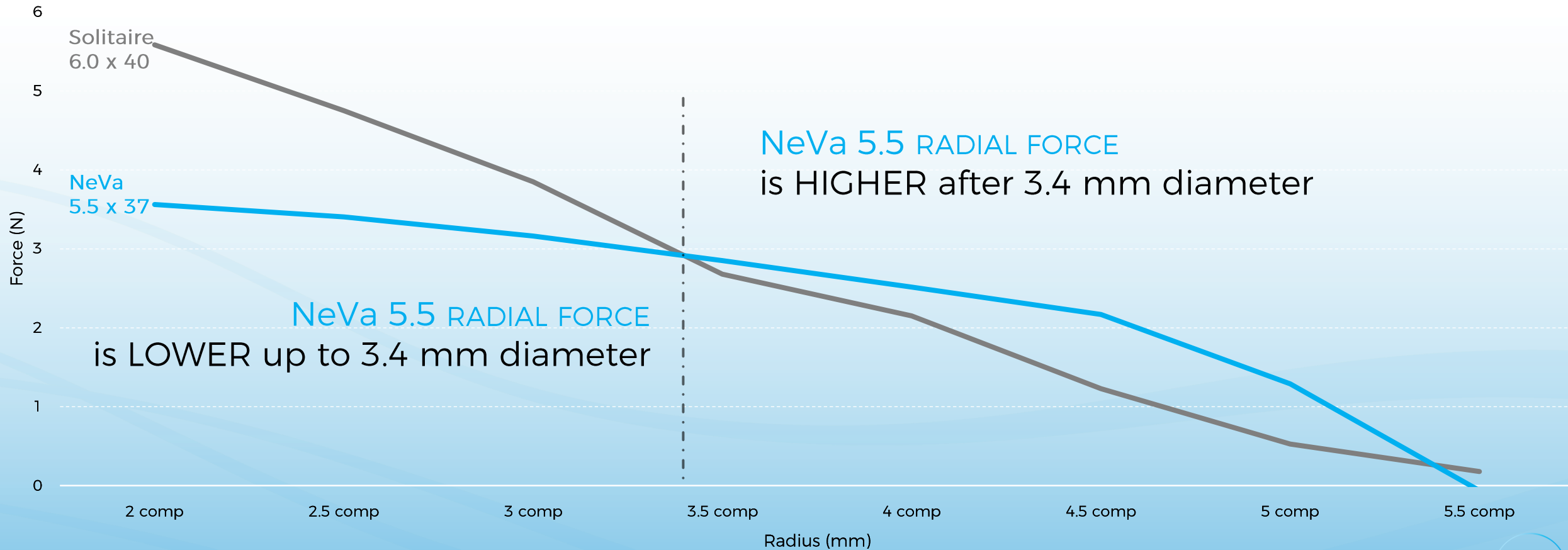
Ideal for
**MCA
occlusions**

Vessel diameters
2.0 – 4.5 mm
Recommended MC: 0.021"



NEVA 5.5 COMPRESSIVE RADIAL FORCE COMPARED TO SOLITAIRE 6.0

Compressive Radial Force Measurements



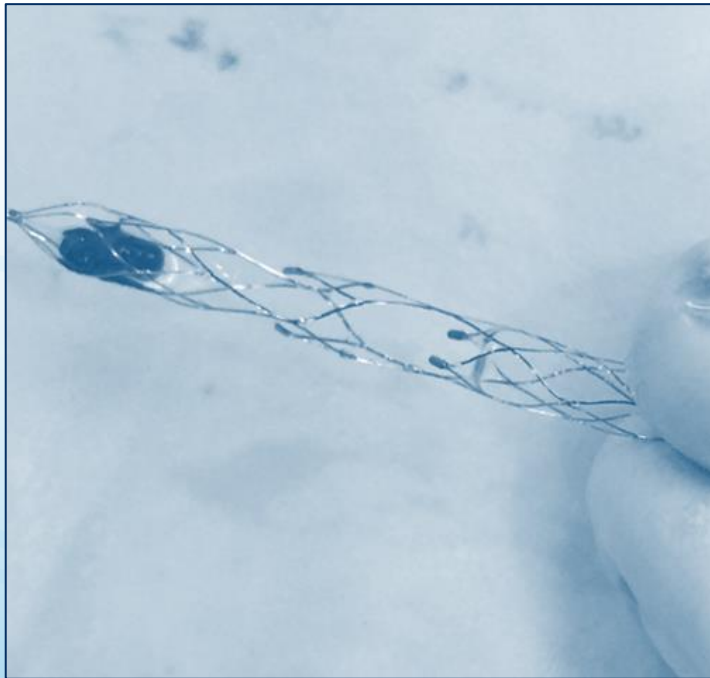
CLINICAL DATA

Neva™ & Neva™ NET



NEVA SHOWED 97% RECANALIZATION SUCCESS WITH 1.2 PASSES ACROSS ALL CLOT TYPES

Early animal study with NeVa



Clot Type	Soft	Hard	Ultra Hard	All Clots
Clot morphology	Whole Blood "RED" Clot	Plasma Rich "WHITE" Clot	Clot modeled from ONYX 500	RED, WHITE and ONYX 500
N =	19	5	11	35
Length of clots - mm	10-40	6-12	4-12	4-40
1 st Pass TICI 3	84%	60%	55%	71%
Final TICI 3	89%	NR	82%	83%
Final TICI 2b/3	100%	100%	91%	97%
Average # of passes for final recanalization	1,05	1,00	1,63	1,23

NEVA CONSISTENTLY EFFECTIVE AT REMOVING ORGANIZED CLOTS

Data from Machi et al. Journal of Neuro-Int. Surgery, 2016¹

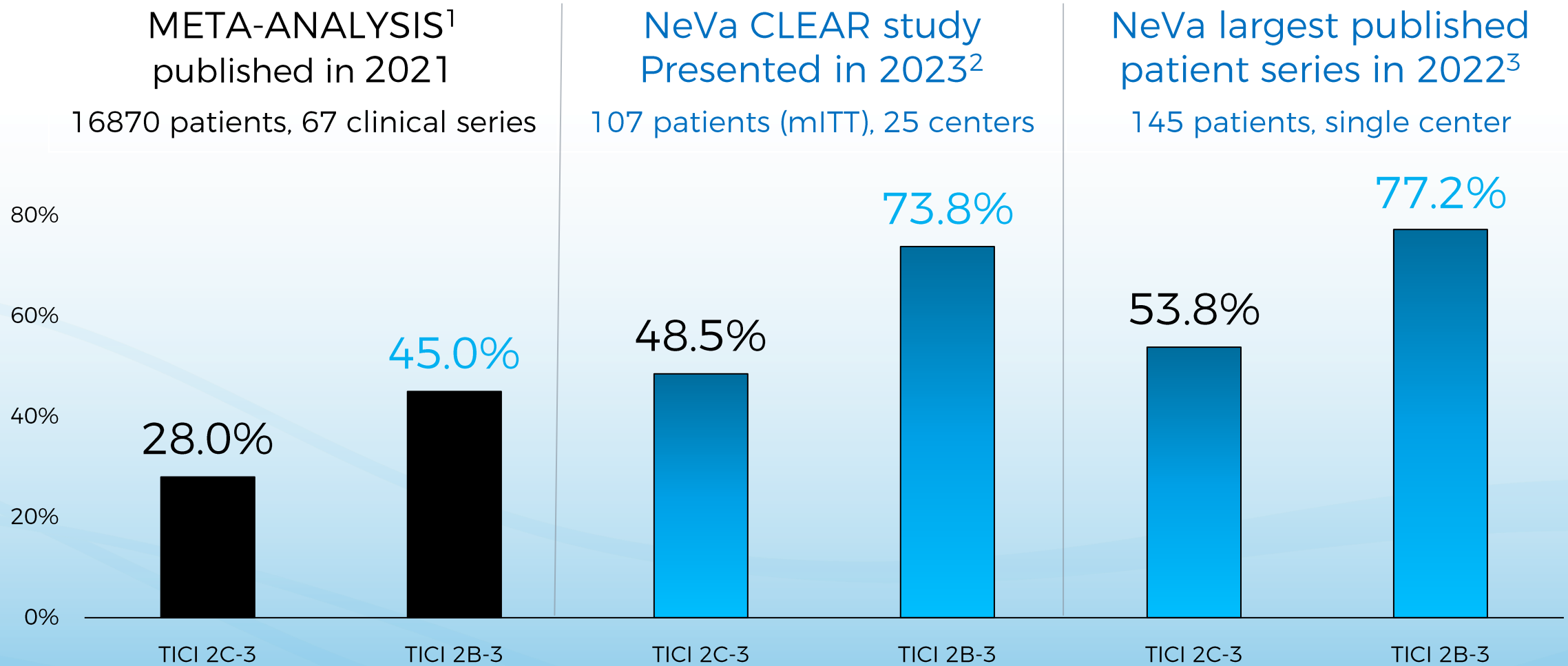
“All stent retrievers failed when interacting with large white thrombi (≥ 6mm)”

Solitaire*:	0/5	Trevo:	0/5
Embotrap*:	0/5	Eric:	0/5
Preset*:	0/5	Preset LT:	0/5
Catch*:	0/5	Separator 3D:	0/5
Revive*:	0/5	Mindframe:	0/5

Data from Machi P, et al., “Experimental evaluation of the NeVa™ thrombectomy device a novel stent retriever conceived to improve efficacy of organized clot removal”, Journal of Neuroradiology. 2018²

**NeVa: 6/10 successful
complete removals
of white thrombi ≥ 6 mm**

NEVA 1ST PASS RATES TRENDING HIGH



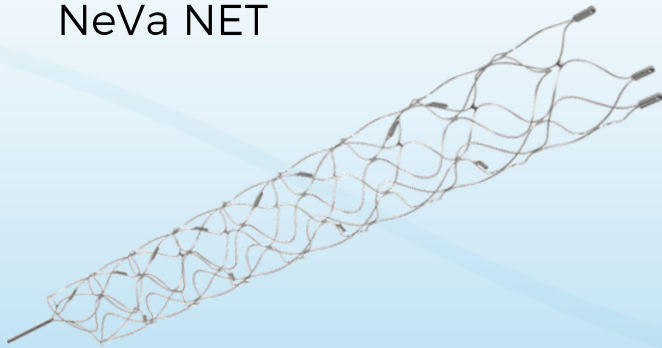
1. Abbasi M, Liu Y, Fitzgerald S, et al. Systematic review and meta-analysis of current rates of first pass effect by thrombectomy technique and associations with clinical outcomes. J Neurointerv Surg. 2021;13:212-216.
 2. Yoo AJ, Geyik S, Froehler MT, et al. Primary results from the CLEAR study of a novel stent retriever with drop zone technology. Journal of NeuroInterventional Surgery. Published Online First: 02 December 2023. doi: 10.1136/jnis-2023-020960
 3. Bajrami A, Ertugrul O, Senadim S, Erdem E, Baltacioglu F, Geyik S. First pass results of mechanical thrombectomy with two-drop zone NeVaTM device. Interv Neuroradiol. 2022 Oct 30;15910199221135309. doi: 10.1177/15910199221135309. PMID: 36314456.



NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY



NeVa NET



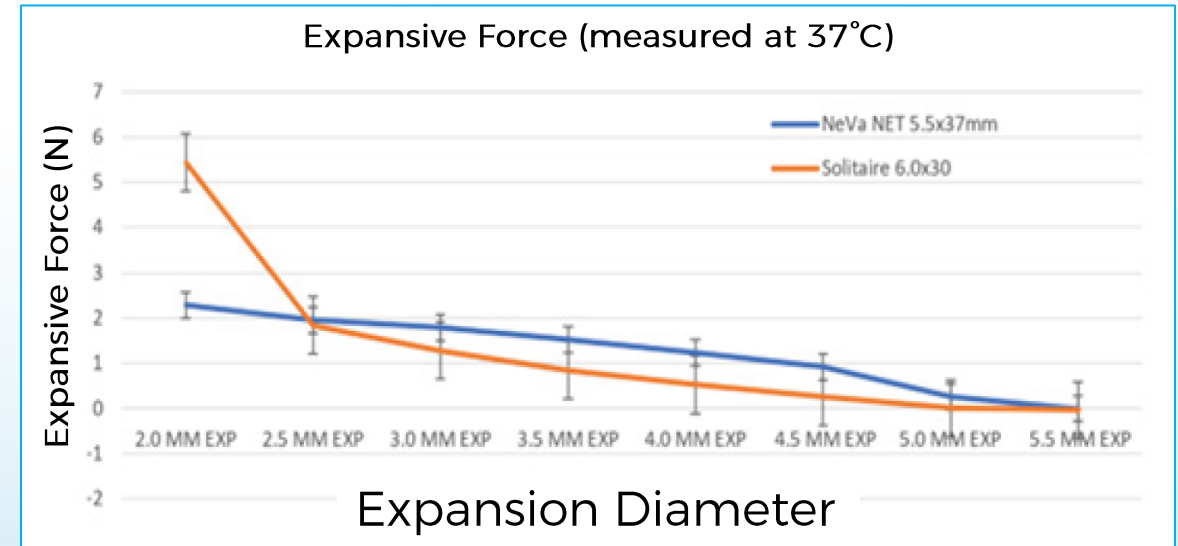
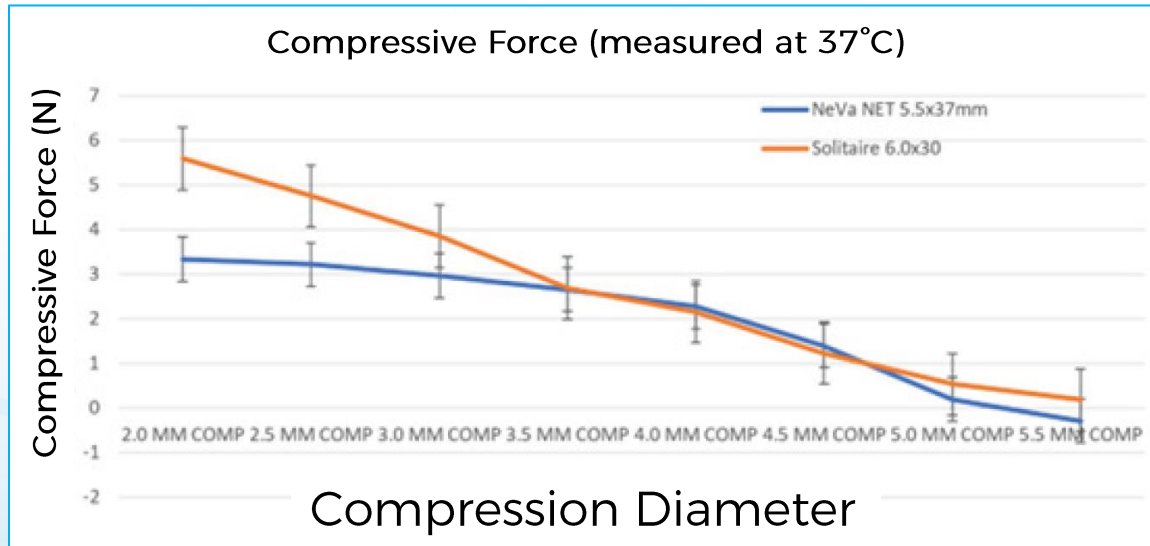
Solitaire

A randomized evaluation comparing NeVa NET to SOLITAIRE in in-vivo and in-vitro studies:

1. Radial force measurements on 10 NeVa NET and 4 Solitaire™ 6×30 mm units
2. Animal studies comparing NeVa NET to Solitaire 6×40 mm and 4×40 mm to assess acute vascular injury, vasospasm and thrombogenicity during thrombectomy
3. A randomized comparison in a closed loop vascular model to quantify first pass effect and distal emboli generated during 20 MCA thrombectomies

NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY

RADIAL FORCE COMPARISONS



- The radial resistive force was very similar between 3.5 & 5.5mm
- Below 3.5mm, Solitaire generated progressively higher radial force

- The chronic outward radial force was similar between 2.5 & 5.5mm
- Below 2.5mm, Solitaire demonstrated progressively higher outward radial force

NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY

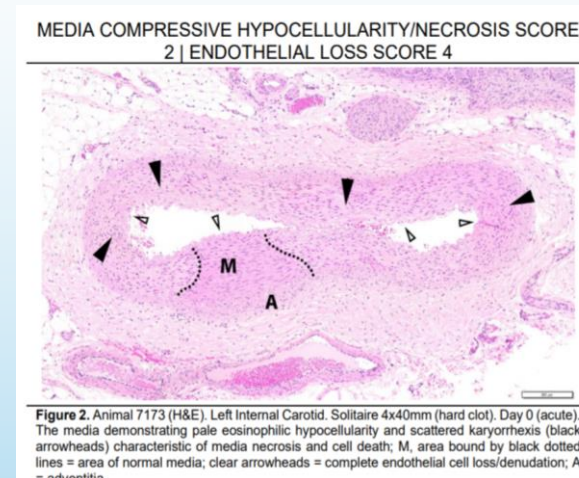
VASCULAR INJURY SCORES NEARLY IDENTICAL

The injury scores were nearly identical and primarily related to endothelial loss, occasional IEL disruption and limited medial injury

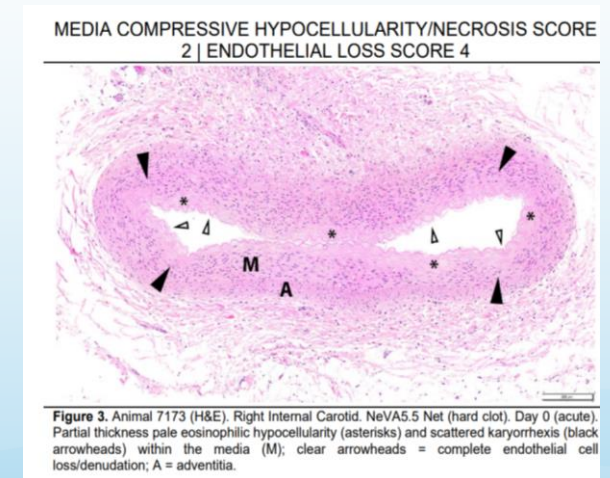
- Soft and hard platelet rich thrombus were delivered in 6 vascular territories
- Vessel sizes ranged from 1.8 to 3.4 mm
- NeVa NET 5.5mm compared to Solitaire 4x40 in vessels < 3mm and Solitaire 6x40 in vessels > 3mm
- 4 retrievals performed in each vessel
- Harvested vessels analyzed by an independent veterinary pathologist and compared for thrombectomy induced acute vascular injury

Example

B. Solitaire™ 4x40



A. NeVa NET™ 5.5x30



- A = adventitia,
- M = media
- ▲ = scattered hypocellularity and karyorrhexis
- ▽ = endothelial loss
- * = pale eosinophilic hypocellularity

NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY

VASOSPASM & THROMBOGENICITY

- The vasospasm study demonstrated findings comparable with predicate devices
- Vasospasm scores were nearly identical after four thrombectomies in multiple similar-sized swine arteries
- The addition of the internal filter did not result in increased thrombogenicity in the non-heparinized swine model. In the randomized flow model study.



NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY

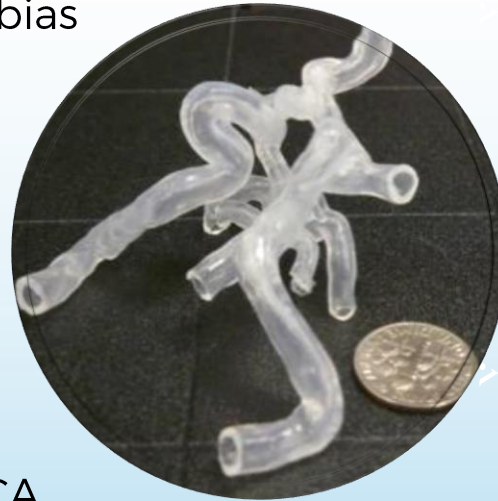
EXPERIMENTAL SET UP

EXPERIMENT DESIGN

- NeVa NET (5.5 x 37) vs Solitaire Platinum (6.0 x 40)
- Block randomization to eliminate bias
- 10 experiments per device
- Each device used up to 3 times

DEVICES and TECHNIQUES

- 0.027" MC
- 0.088" long sheath placed in the ICA
- 0.018" guidewire
- Aspiration via syringe for the duration of retrieval into the long sheath to avoid any effect from stripping the clot off the device



A MODEL MIMICKING VASCULAR OCCLUSION

- a human vascular replica
- a friable clot model of medium stiffness
 - length: 7mm, diameter: 4.3mm
 - prone to fragmentation, selected specifically to mimic the worst-case scenario
- a physiologically relevant mock circulation flow loop
- collection reservoirs for ACA and MCA territories

M-TICI DETERMINATION

- Fluoroscopic and direct visualization to determine mTICI score after each pass
- No angiography to avoid contrast interfering with particle count

NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY THROMBECTOMIES AND RECANALIZATION RATES

Table showing each thrombectomy

NeVa NET			Solitaire		
Run	TICI	#of Passes	Run	TICI	#of Passes
1	3	1	2	3	1
4	3	1	3	2	2
5	3	1	6	2	2
8	3	1	7	3	1
10	3	1	9	3	1
12	3	1	11	3	1
13	3	1	14	2	2
16	3	1	15	3	1
18	3	1	17	3	1
19	3	1	20	2	3
average		1	average		1.5

First-Pass Complete Recanalization Rates



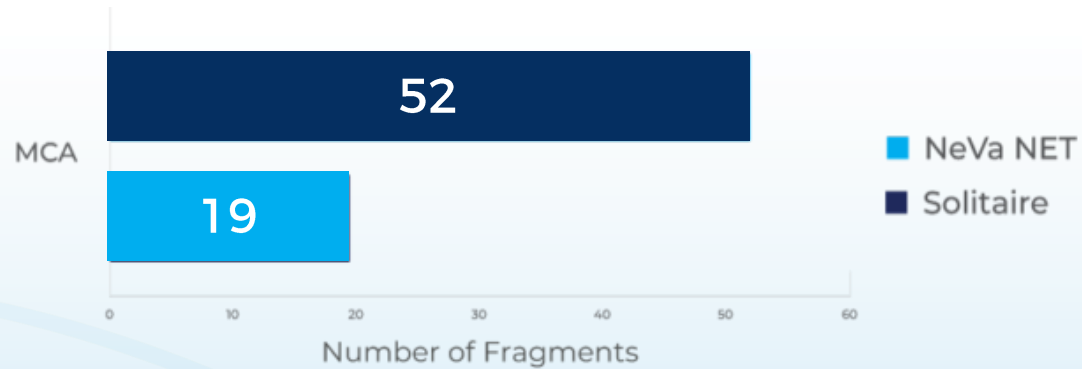
➤ NeVa NET required less passes than Solitaire to achieve TICI 3 reperfusion (p = 0.0344)



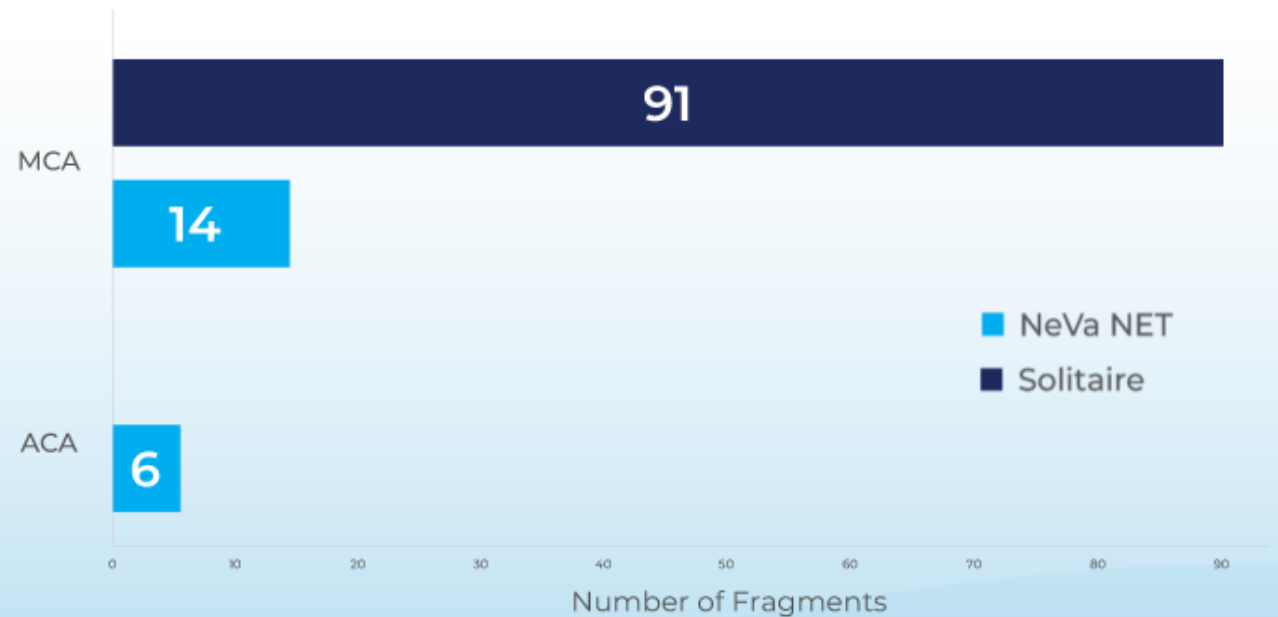
NEVA NET PRECLINICAL SAFETY & EFFICACY STUDY

DISTAL EMBOLIZATION RESULTS

Clot Fragments > 1 mm



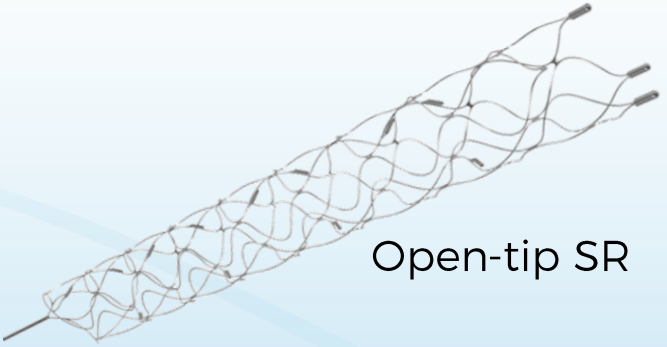
Clot Fragments of 0.2 – 1 mm



➤ Solitaire generated 4-fold more clot fragments > 1 mm vs NeVa NET (p = 0.034, Wilcoxon rank sum)

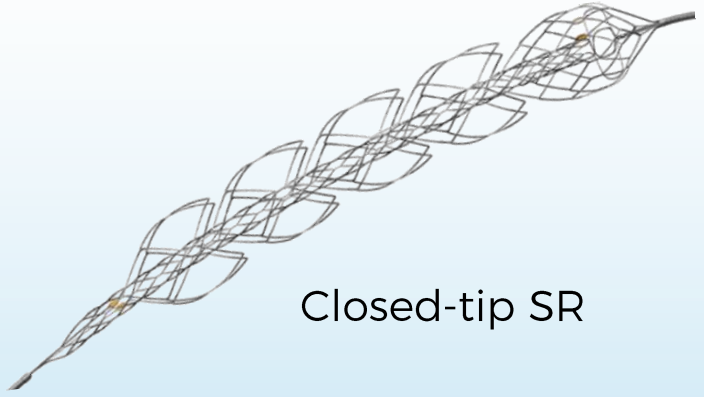
➤ Overall more fragments were generated with Solitaire vs NeVa NET (p = 0.048)

A RANDOMIZED IN VITRO EVALUATION COMPARING THREE STENT RETRIEVER TIP DESIGNS IMPACT ON 1ST-PASS RECANALIZATION & DISTAL EMBOLIZATION



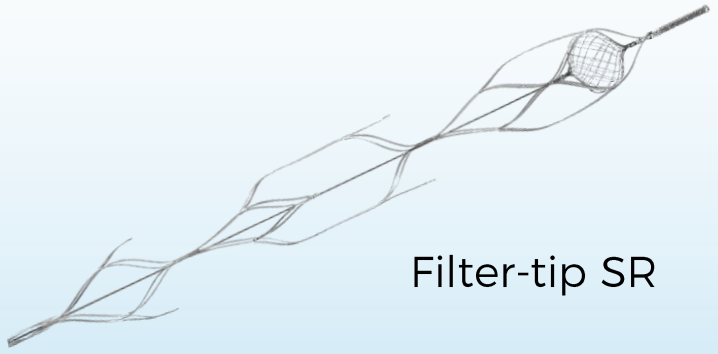
Open-tip SR

Solitaire 6.0x40 mm
+ 0.021" microcatheter & BGC



Closed-tip SR

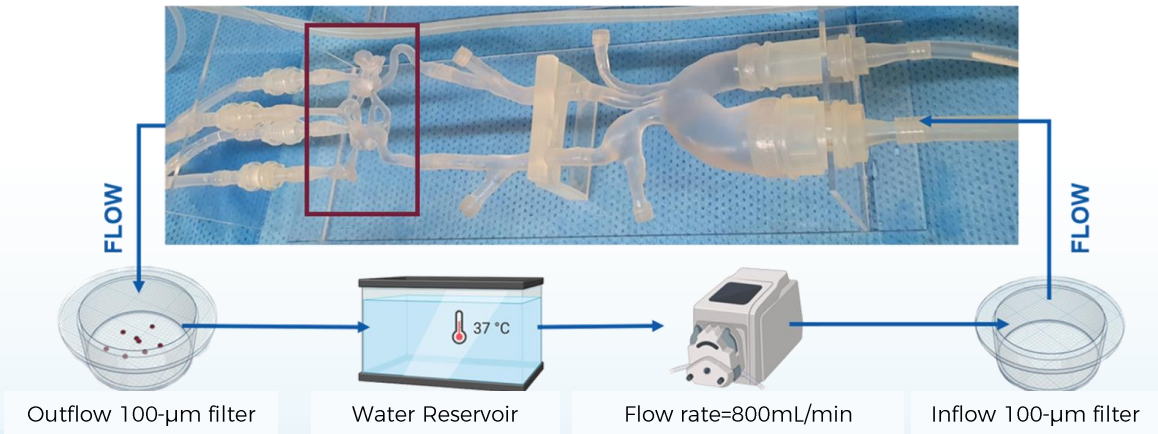
Embotrap II 5.0x33 mm
+ 0.021" microcatheter & BGC



Filter-tip SR

NeVa NET 5.5x37 mm
+ 0.027" microcatheter & BGC

A RANDOMIZED IN VITRO EVALUATION EXPERIMENTAL SET-UP



Binarization and segmentation



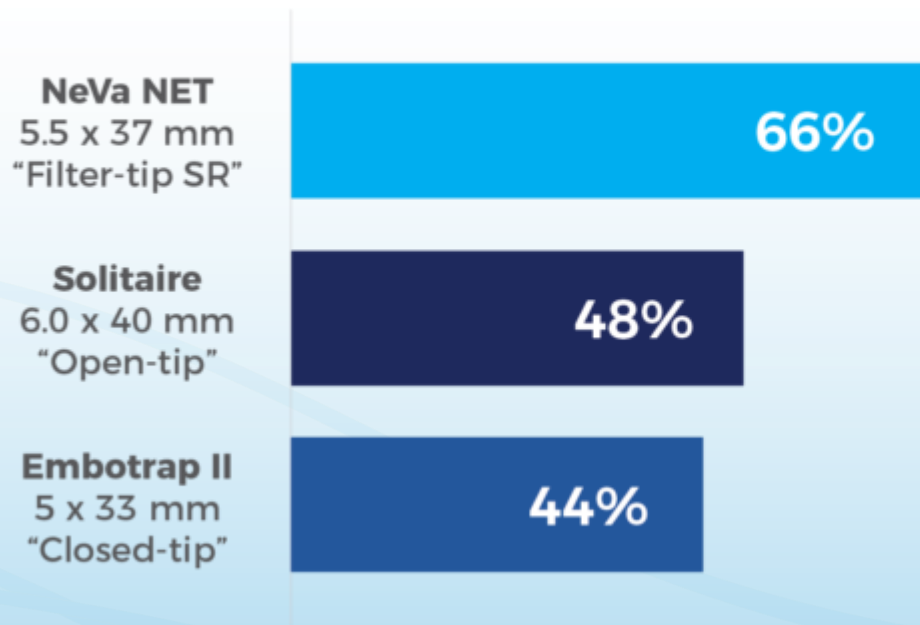
- Largest distal embolus' Feret diameter
- Total count of large distal emboli (>1mm)
- Total count of distal emboli (>100µm)

Stiff-friable clot analog (low SR engagement, fragment-prone)

- Middle-distal M1-MCA occlusions
- Randomized into one of the three treatment arms.
- BGC under proximal flow arrest and continuous aspiration
- 50 single-attempt cases/ treatment arm
- Distal emboli (>100 µm) collected and analyzed after each experiment

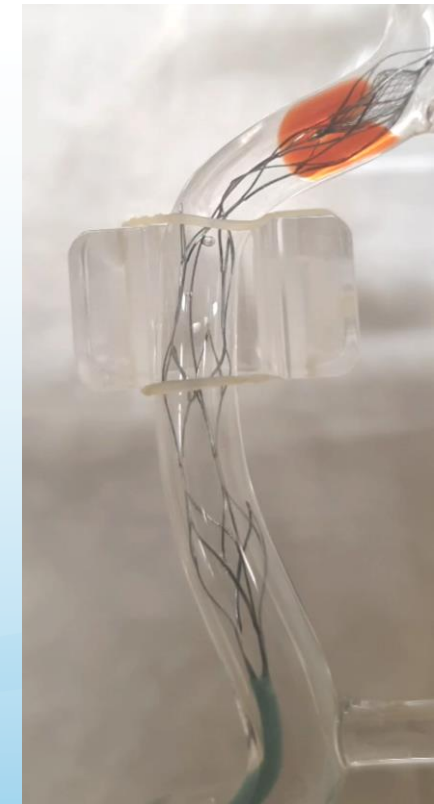
A RANDOMIZED IN VITRO EVALUATION FIRST PASS RECANALIZATION RATES

First-Pass Recanalization Rates

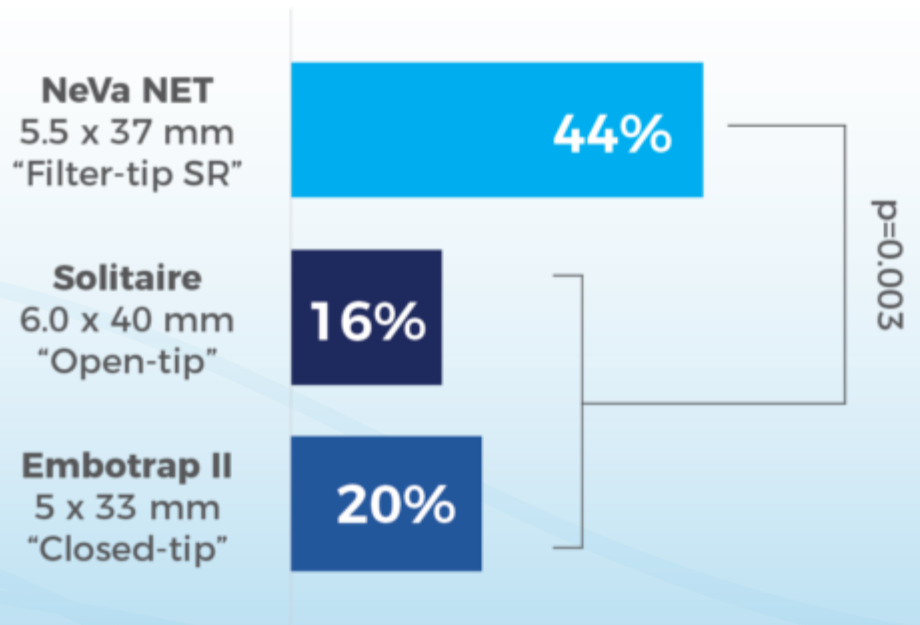


Filter-tip SR achieved a non-significantly higher first-pass recanalization rate than open-tip SR and closed-tip SR. (66% vs 48% vs 44%; P=0.064)

Clot Engagement at distal tip



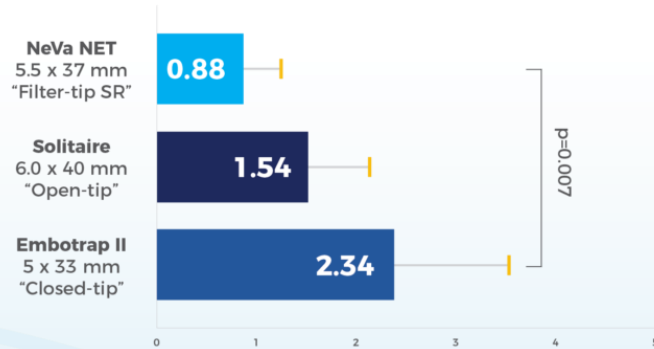
A RANDOMIZED IN VITRO EVALUATION PREVENTION OF EMBOLIZATION BY CLOT FRAGMENTS > 1 MM



Filter-tip SR was significantly better at preventing clot fragments >1mm from embolizing distal territories. (44% vs 16% vs 20%; P=0.003)

A RANDOMIZED IN VITRO EVALUATION OTHER RESULTS ON DISTAL EMBOLIZATION

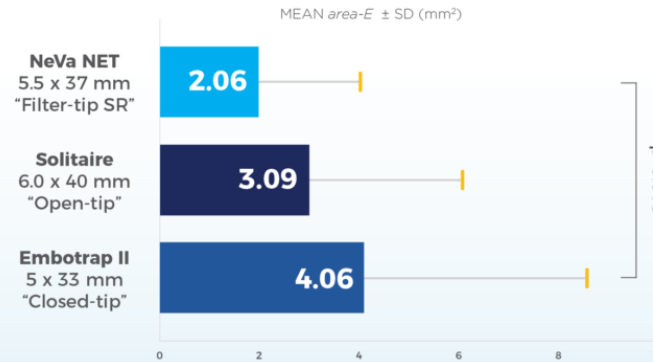
Frequency of Large Emboli (Count-E>1mm)



The frequency of large emboli was significantly lower in the filter-tip arm than in the closed-tip arm (count-E >1 mm=0.88±1.2 vs 2.34±3.38; P=0.007)

No significant differences were found in pairwise comparisons between open (count- E>1 mm=1.54±2.07) versus closed-tip or filter-tip SRs.

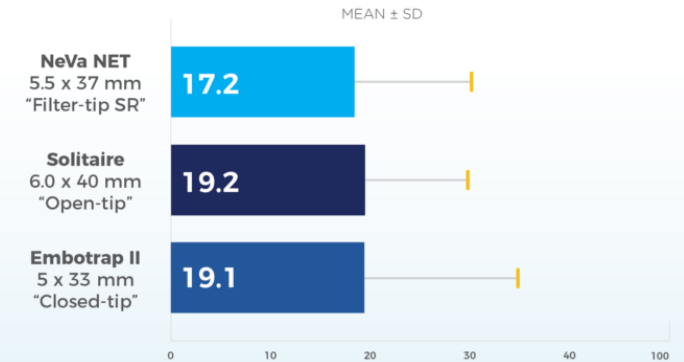
Total Area of Emboli



Total area of emboli was significantly smaller in the filter-tip arm than in the closed-tip arm (E=2.06±1.85 mm² vs 4.06±4.80 mm²; P=0.013).


No significant differences were found in pairwise comparisons between open (area-E=3.09±3.12 mm²) versus closed-tip or filter-tip SRs.

Total Emboli Count (Count-E)



In total emboli count, the differences were not significant between treatment arms (open-tip= 19.2±13.1, closed-tip= 19.1±10.7, filter-tip= 17.2±13.0; P=0.660).

CASES



Neva[™] NET

Designed to Maximize Clot Retention



CASE 1

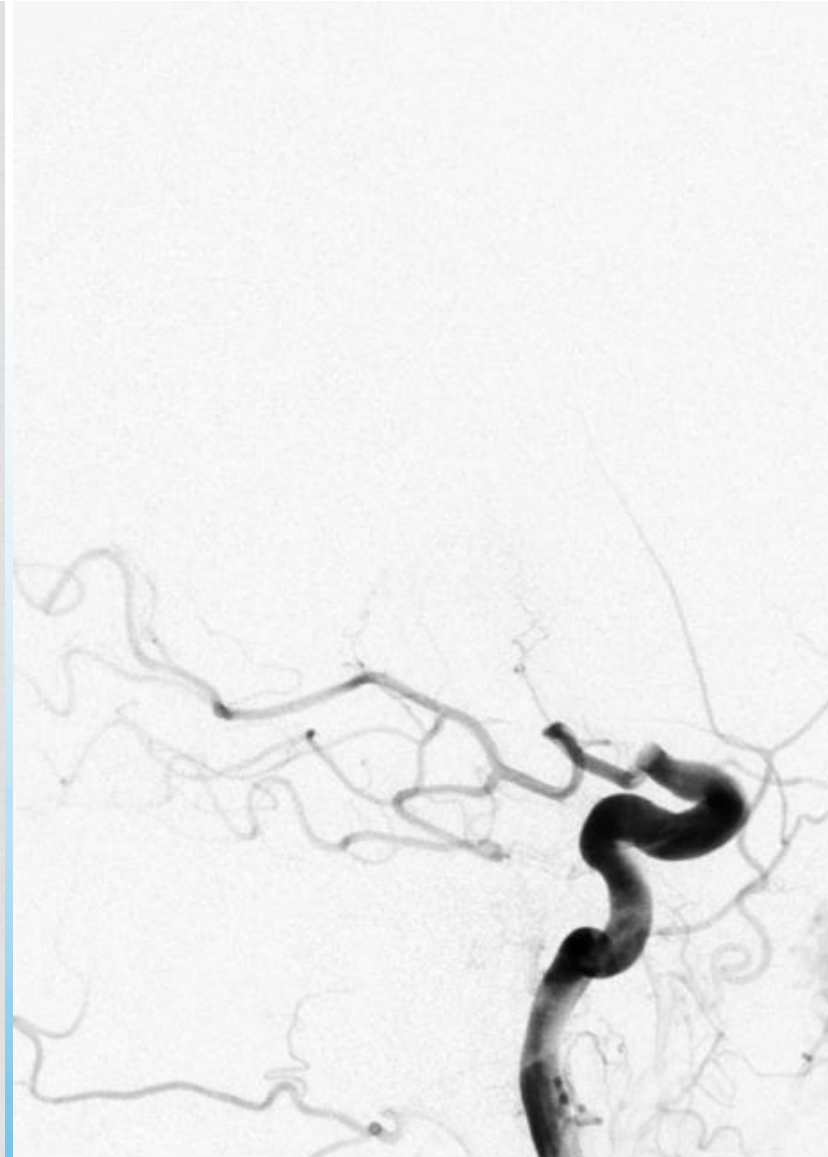
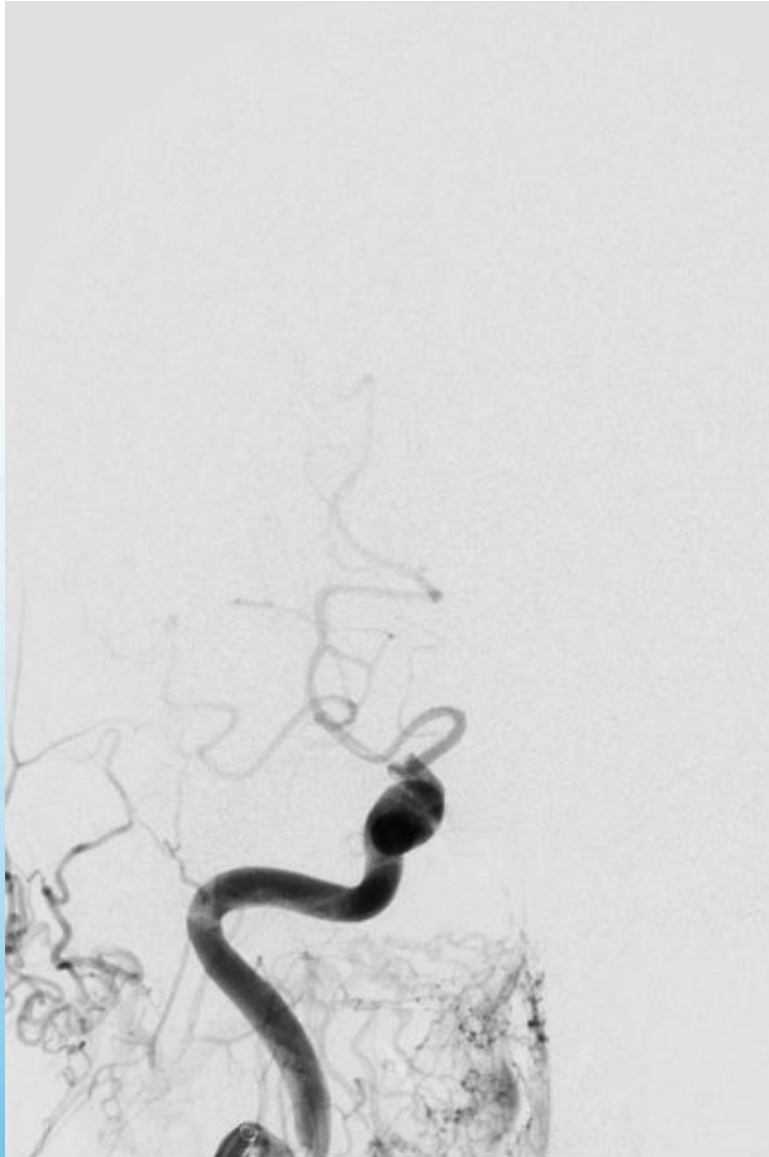
➤ Behme, Daniel



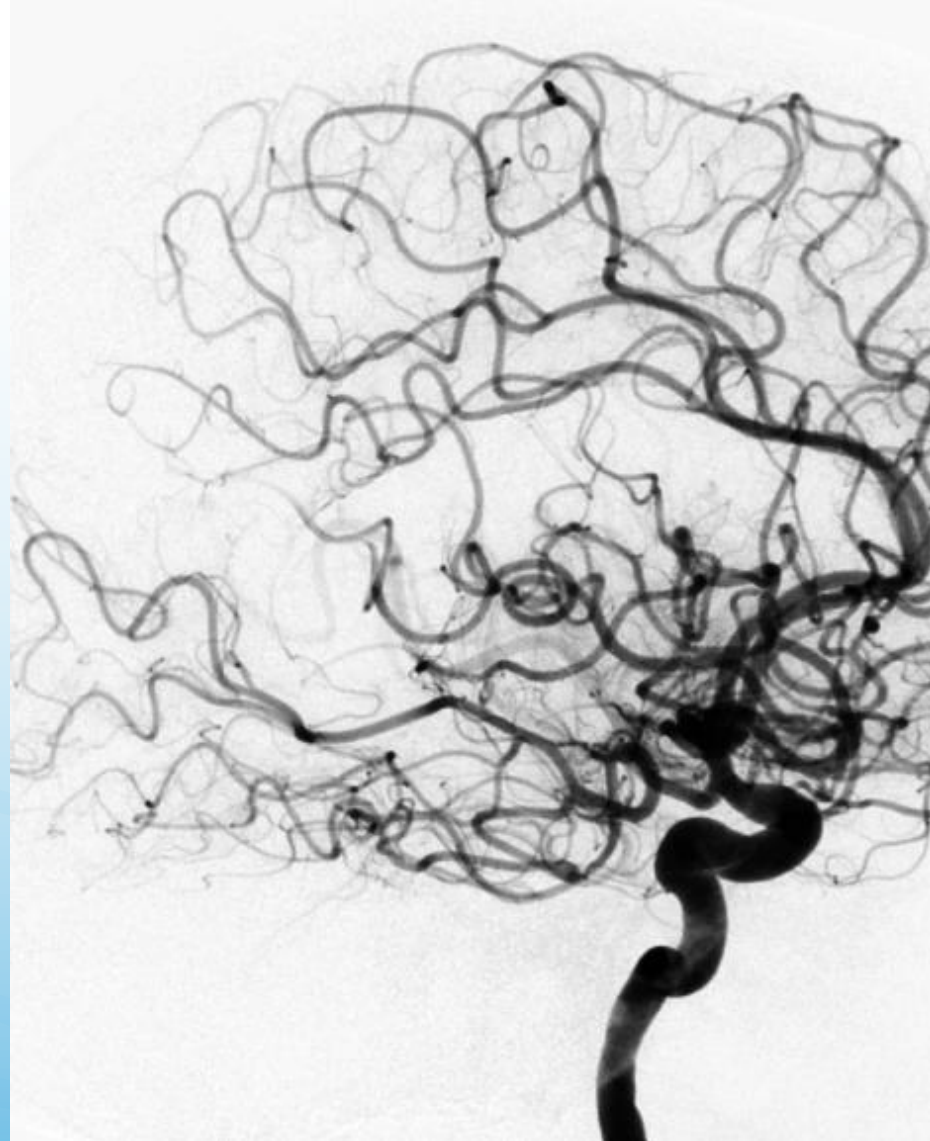
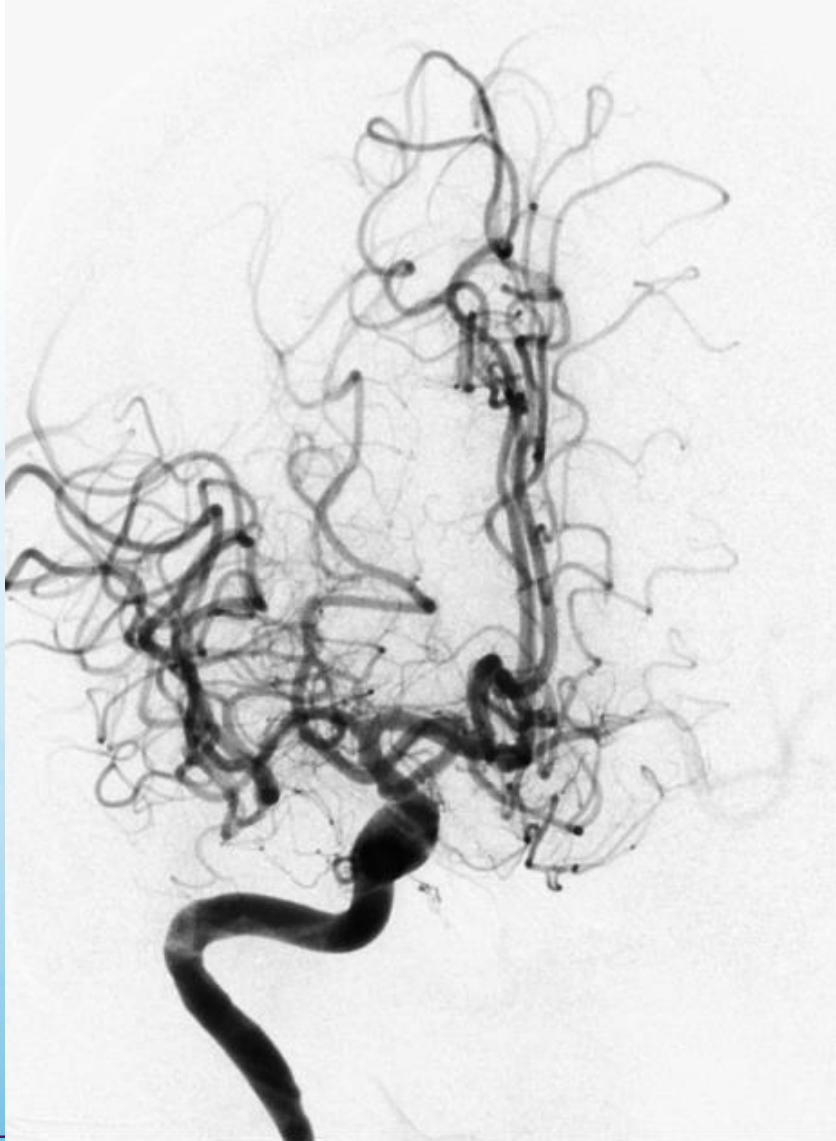
76YO FEMALE, RIGHT CAROTID T OCCLUSION 30 MIN FROM ONSET TO CT, NIHSS 16



76YO FEMALE, RIGHT CAROTID T OCCLUSION 30 MIN FROM ONSET TO CT, NIHSS 16



76YO FEMALE, RIGHT CAROTID T OCCLUSION 30 MIN FROM ONSET TO CT, NIHSS 16



CASE 2

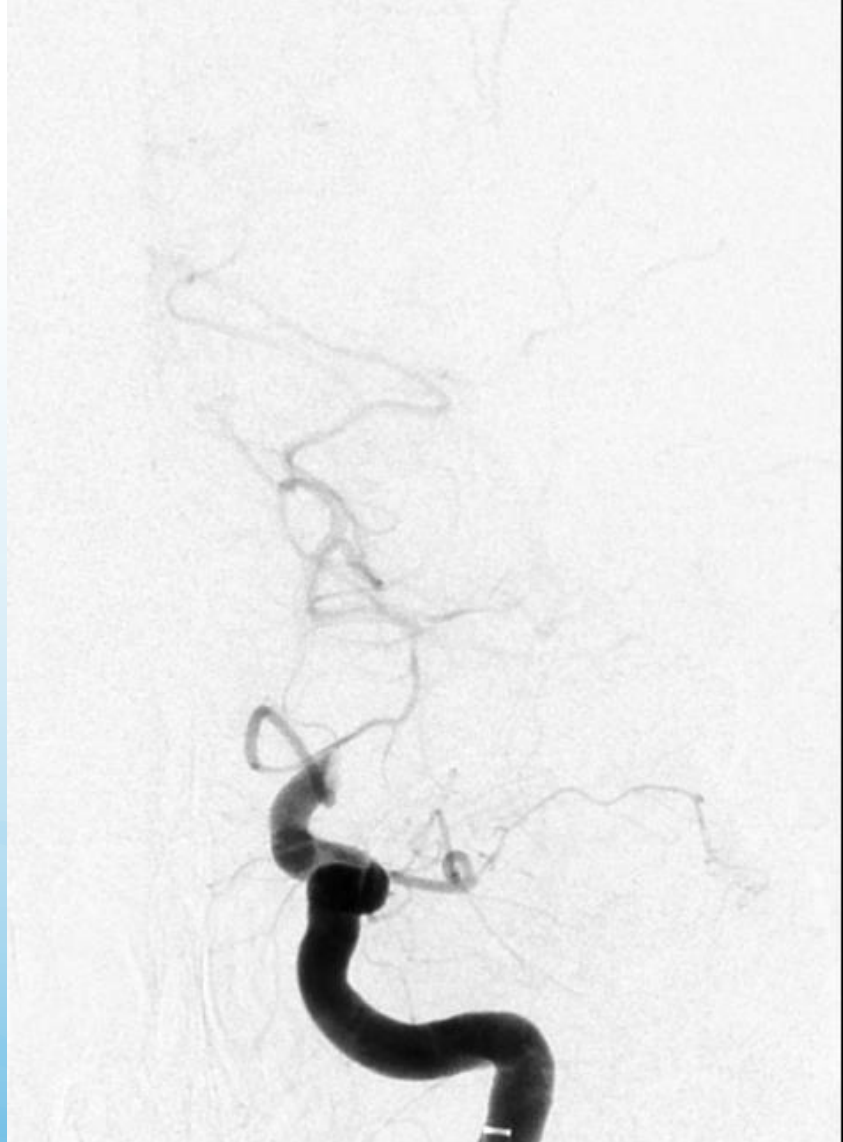
➤ Behme, Daniel



84YO MALE, LEFT CAROTID T OCCLUSION SO ADMISSION 1H, NIHSS 19

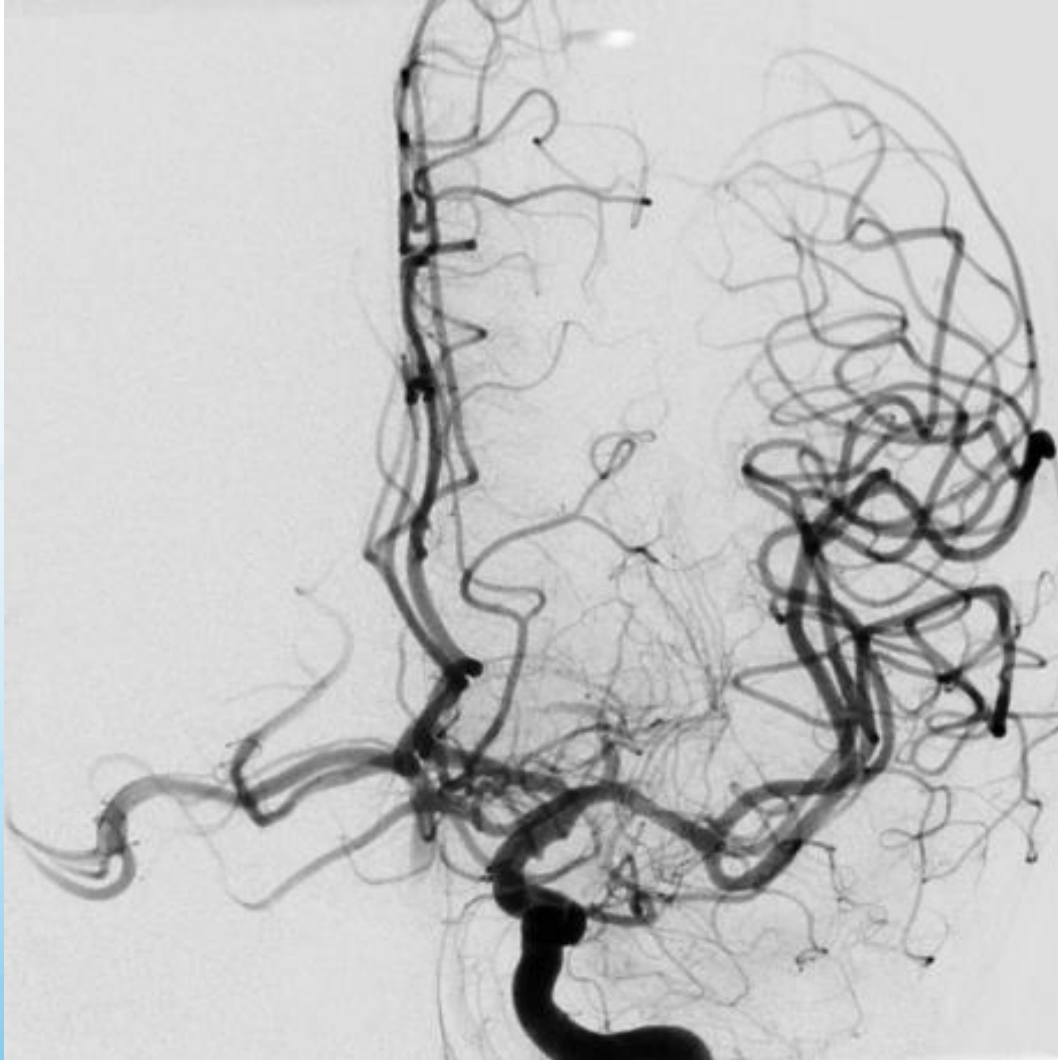


84YO MALE, LEFT CAROTID T OCCLUSION SO ADMISSION 1H, NIHSS 19



FG2
HEADWAY 27

84YO MALE, LEFT CAROTID T OCCLUSION SO ADMISSION 1H, NIHSS 19



CASE 3

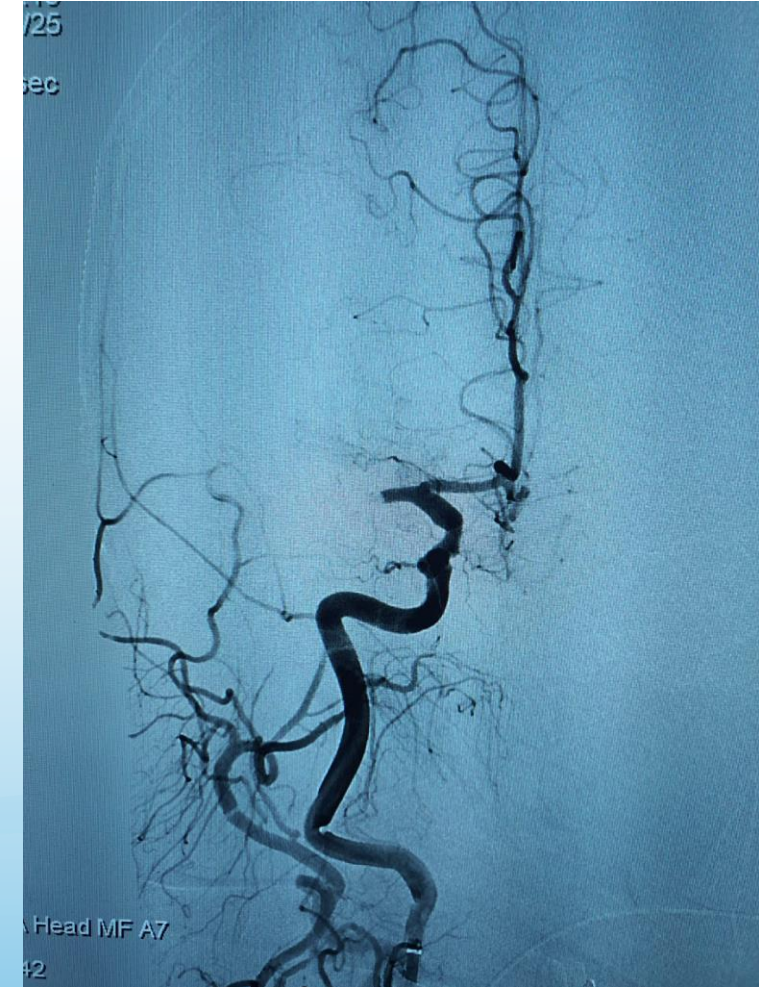
➤ Kalousek, Vladimir



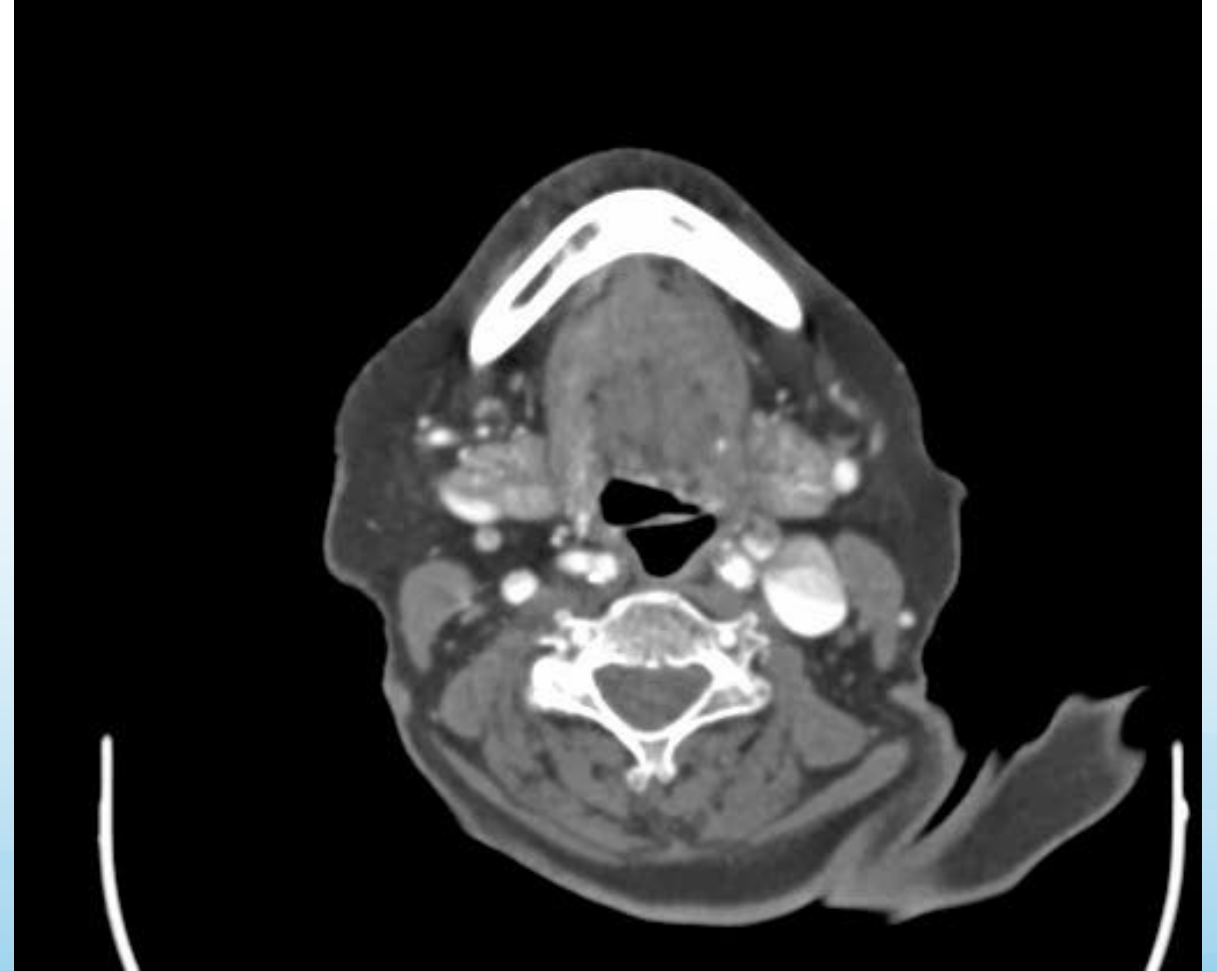
Klinički bolnički centar
SESTRE MILOSRDNICE

86YO FEMALE, MCA-M1 OCCLUSION RIGHT SIDE, UNKNOWN SYMPTOM ONSET, NIHSS 12

- Referred with an IV-tPA (drip & ship) from primary care centre
- Time of symptom onset: unknown
- 18:30: Stroke alert received
- 19:40: Admitted with further deteriorated neurological status



86YO FEMALE, MCA-M1 OCCLUSION RIGHT SIDE, UNKNOWN SYMPTOM ONSET, NIHSS 12



86YO FEMALE, MCA-M1 OCCLUSION RIGHT SIDE, UNKNOWN SYMPTOM ONSET, NIHSS 12



86YO FEMALE, MCA-M1 OCCLUSION RIGHT SIDE, UNKNOWN SYMPTOM ONSET, NIHSS 12

0.027" micro-catheter,
co-aspiration with a
0.071" ID-DAC

➤ Full recan in 1 pass



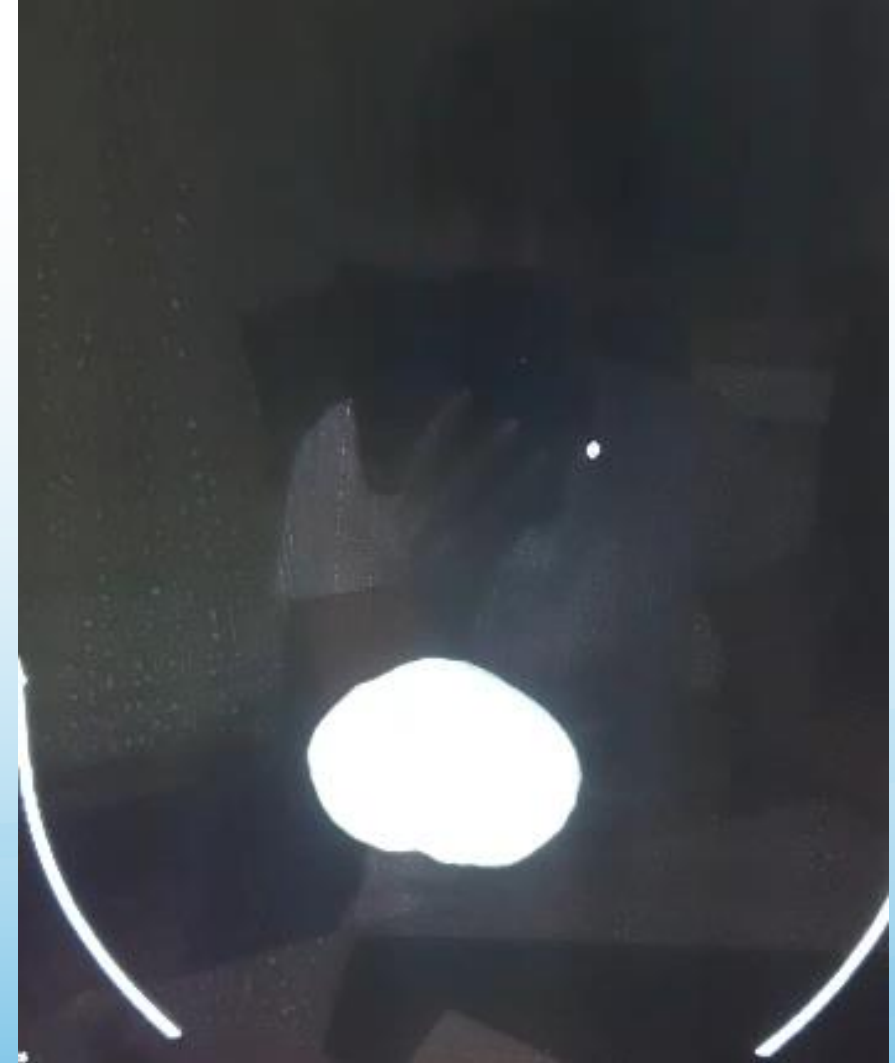
86YO FEMALE, MCA-M1 OCCLUSION RIGHT SIDE, UNKNOWN SYMPTOM ONSET, NIHSS 12



86YO FEMALE, MCA-M1 OCCLUSION RIGHT SIDE, UNKNOWN SYMPTOM ONSET, NIHSS 12

a demarcation of the ischemic lesion was observed in the right peri-insular region and the basal ganglia on the post-op CT

- no ICH observed on the control CT
- patient discharged with an NIHSS of 3



CASE 4

➤ Kalousek, Vladimir



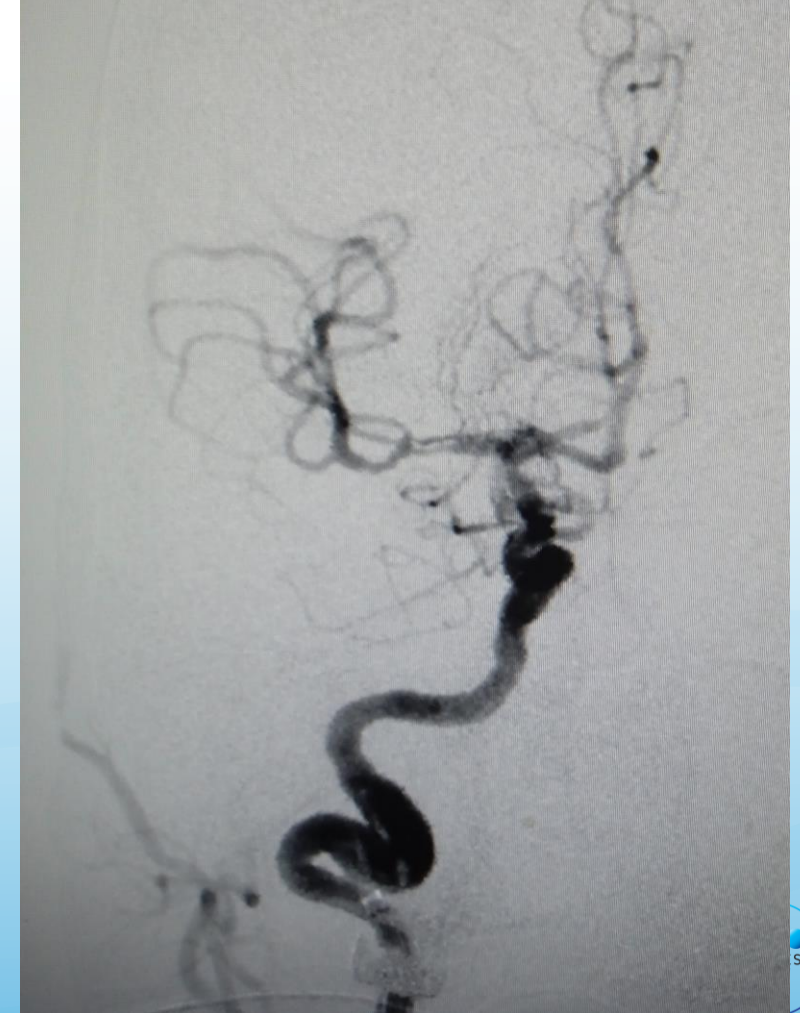
Klinički bolnički centar
SESTRE MILOSRDNICE

FEMALE, ICA-TIP-MCA-M1-M2 OCCLUSION

OCCLUSION



Recanalization after the
NeVa NET pass:





CASE 5

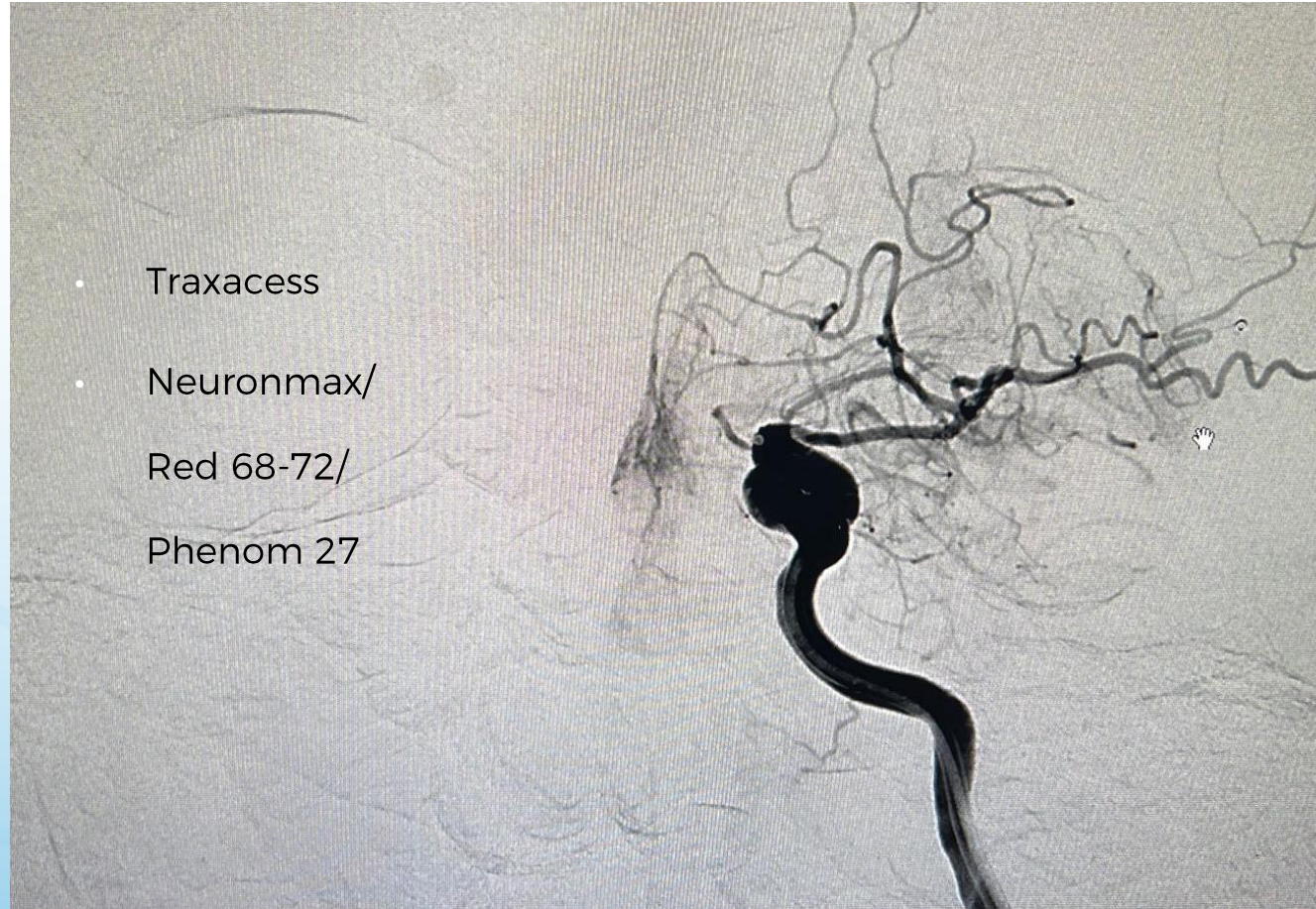
➤ Kalousek, Vladimir



Klinički bolnički centar
SESTRE MILOSRDNICE

62 YO MALE, LEFT ICA-TIP OCCLUSION, NIHSS 17

First Pass



62 YO MALE, LEFT ICA-TIP OCCLUSION, NIHSS 17

First Pass



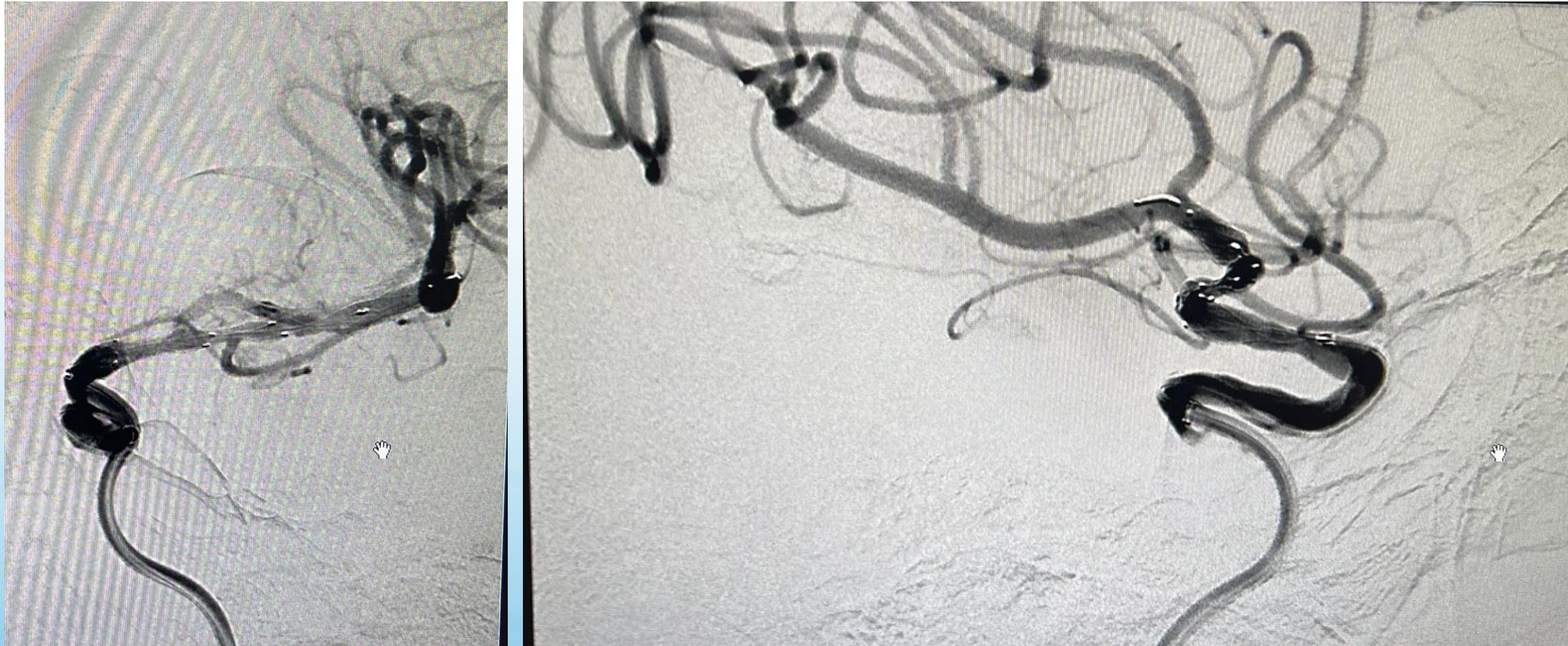
62 YO MALE, LEFT ICA-TIP OCCLUSION, NIHSS 17

First Pass



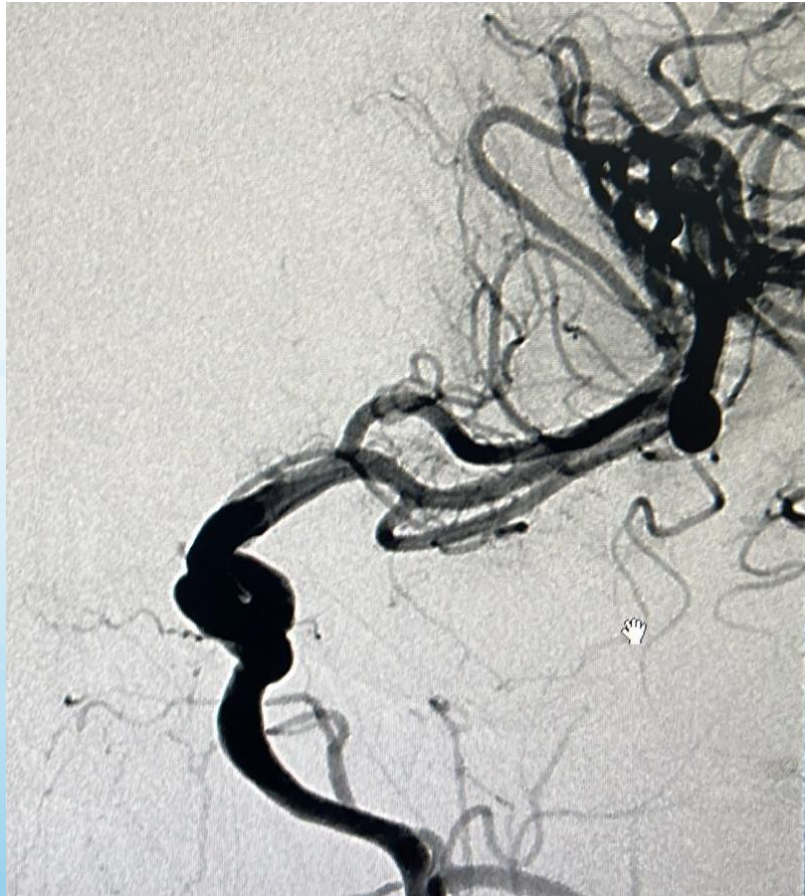
62 YO MALE, LEFT ICA-TIP OCCLUSION, NIHSS 17

2nd pass: NeVa NET in more proximal position to capture the whole clot



62 YO MALE, LEFT ICA-TIP OCCLUSION, NIHSS 17

2nd pass: NeVa NET in more proximal position to capture the whole clot



62 YO MALE, LEFT ICA-TIP OCCLUSION, NIHSS 17 POST-PROCEDURE NIHSS: 14



CASE 6

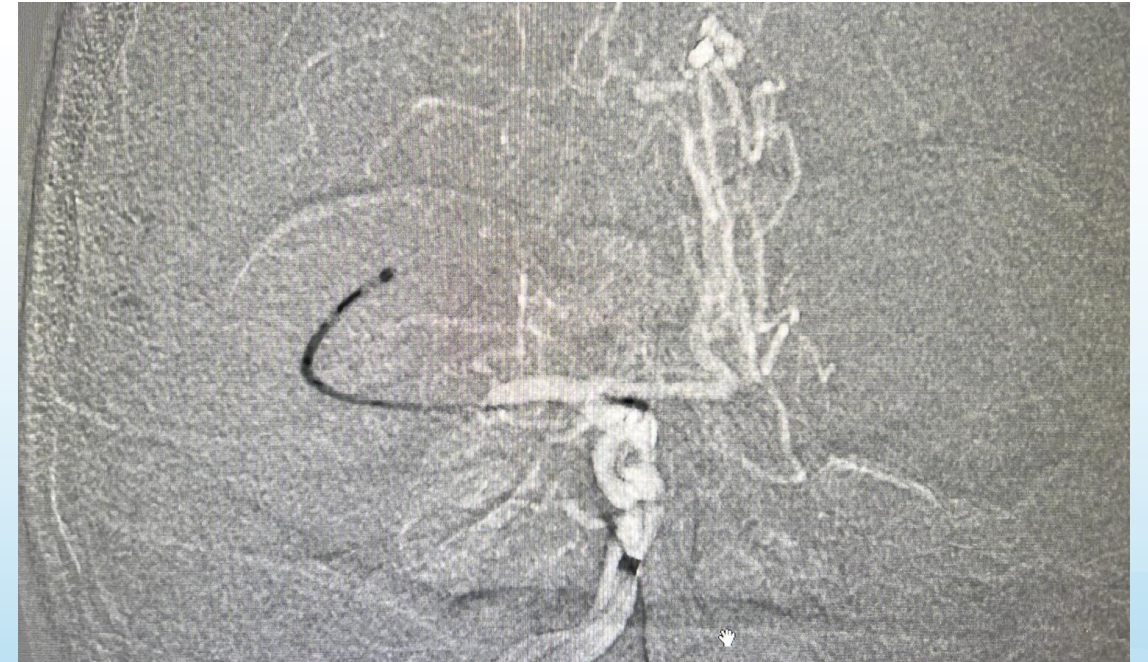
➤ Kalousek, Vladimir



Klinički bolnički centar
SESTRE MILOSRDNICE

75 YO FEMALE, M1 OCCLUSION, NIHSS 17

First Pass



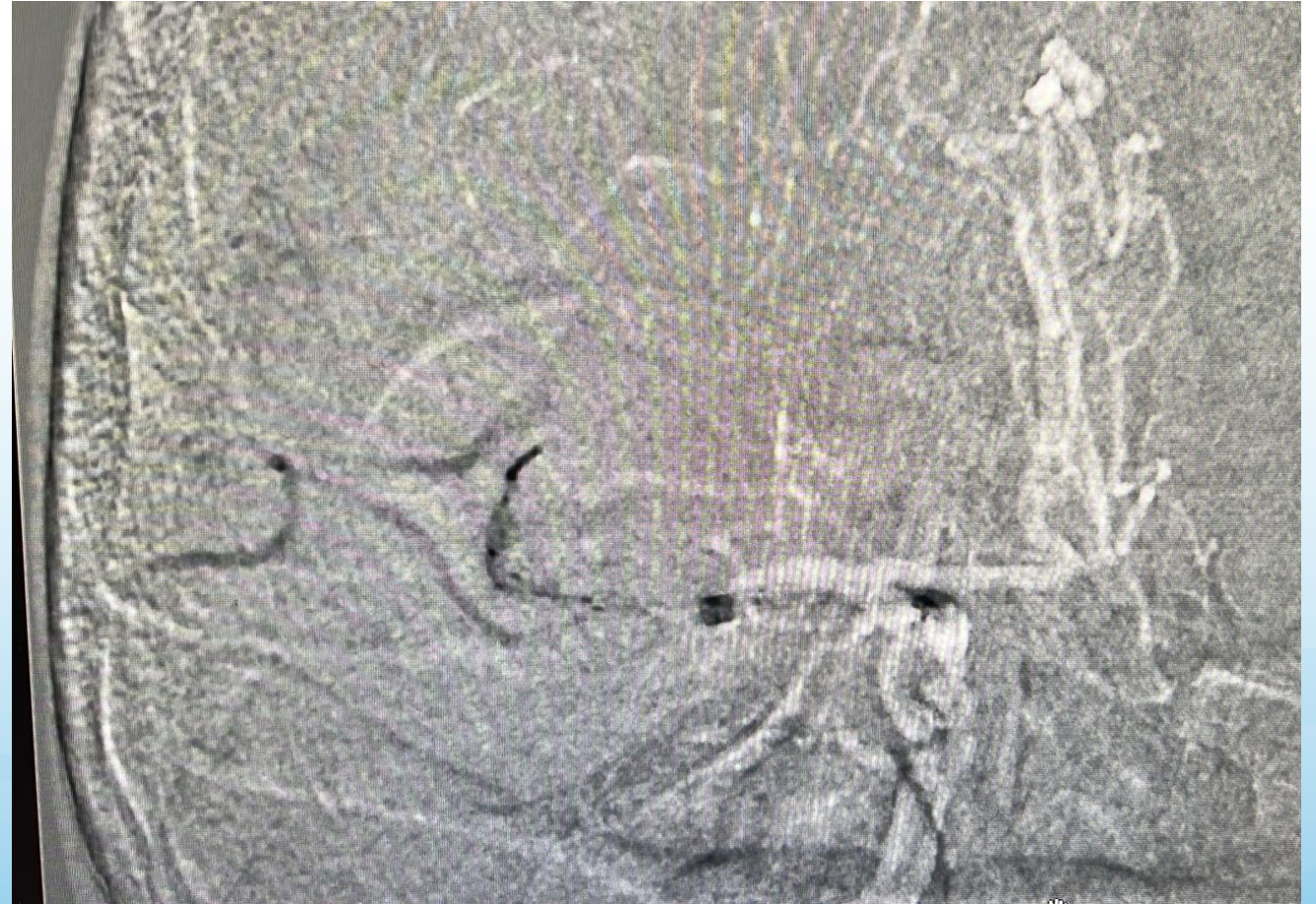
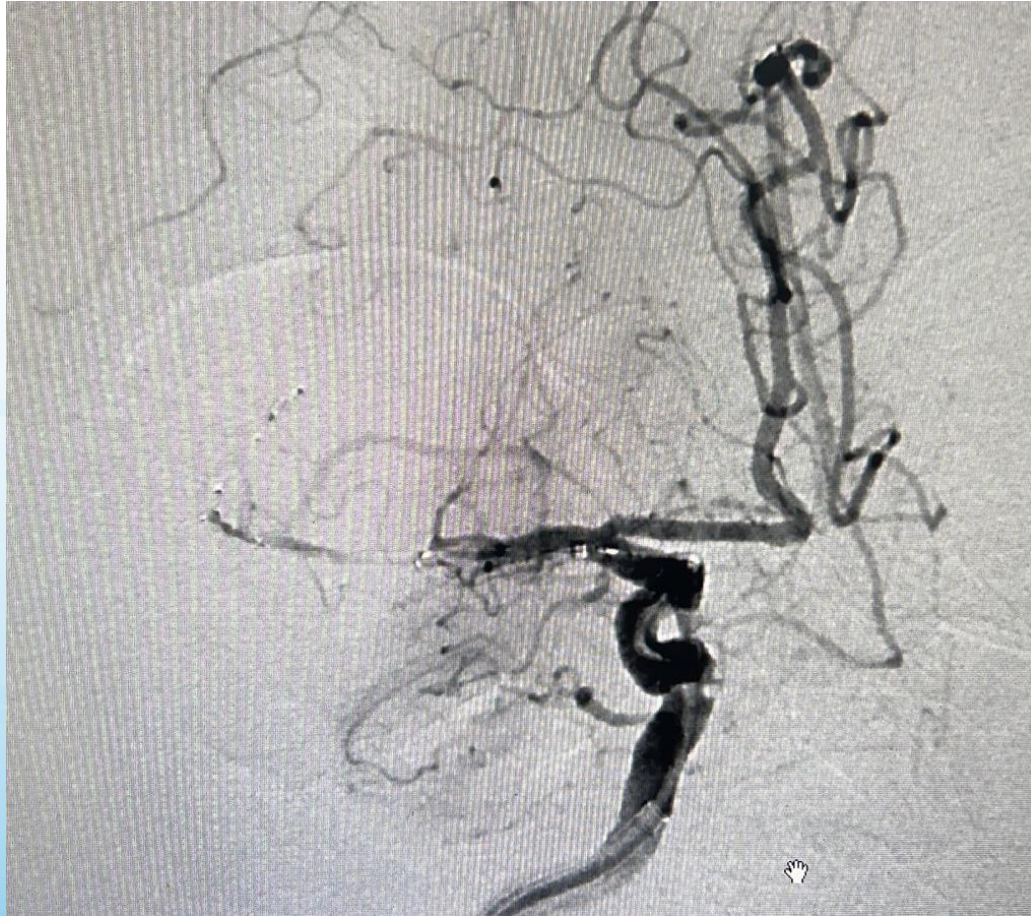
75 YO FEMALE, M1 OCCLUSION, NIHSS 17

First Pass



75 YO FEMALE, M1 OCCLUSION, NIHSS 17

First Pass



75 YO FEMALE, M1 OCCLUSION, NIHSS 17

First Pass

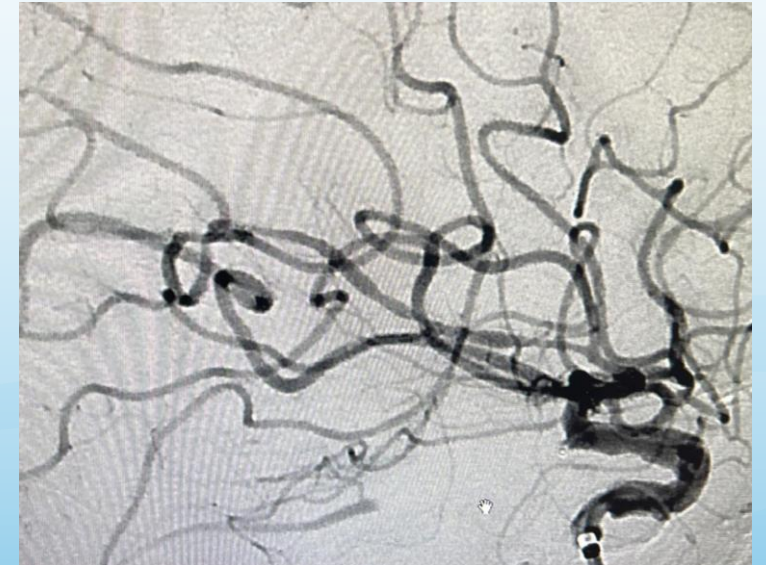


75 YO FEMALE, M1 OCCLUSION, NIHSS 17



Additionally, occlusion of the pericallosal artery was treated with a smaller SR

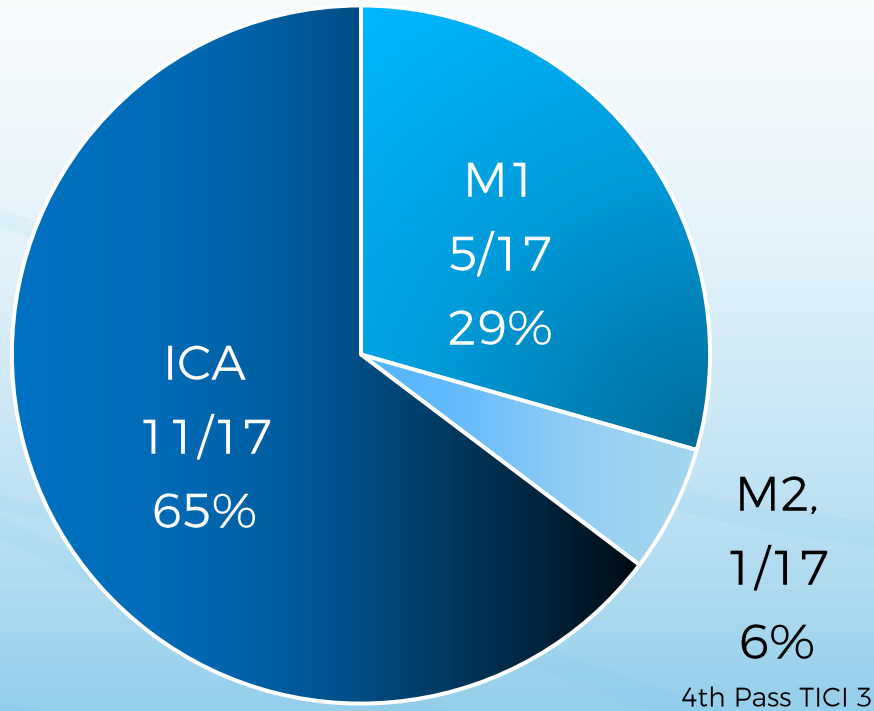
➤ Post-procedure NIHSS: 15



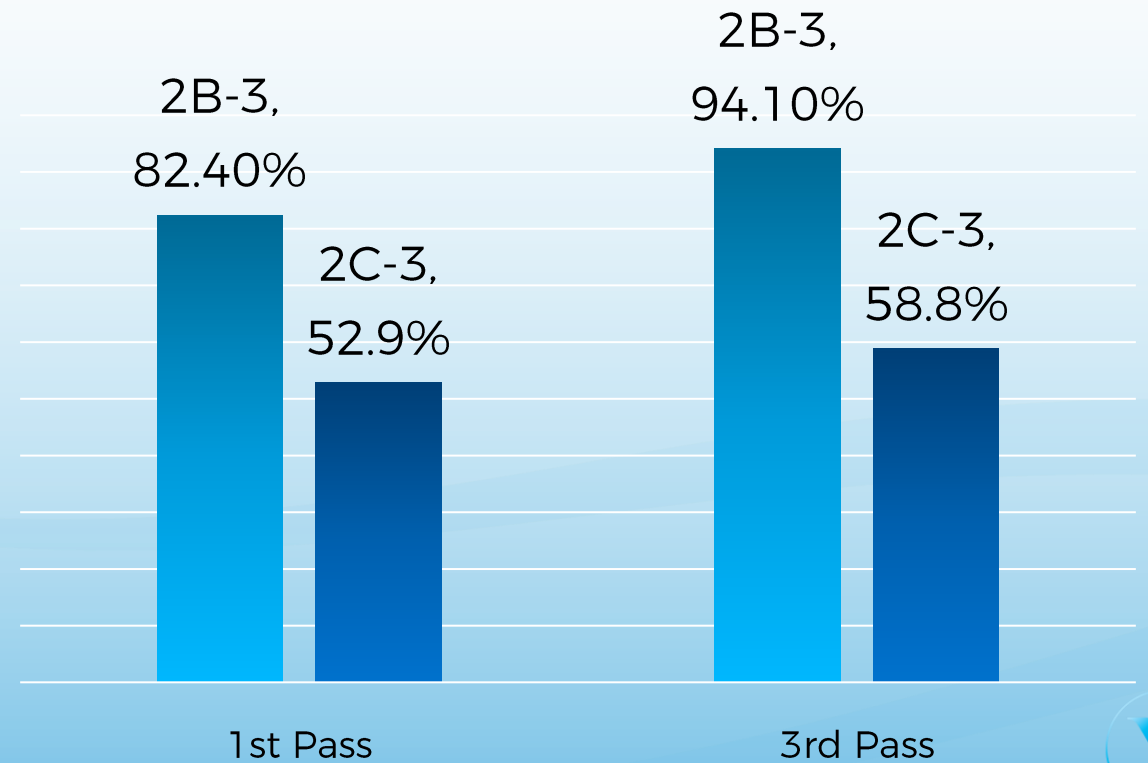
EARLY CLINICAL STUDY EXPERIENCE

To date 17 patients have been treated with NeVa NET 5.5 in post-market observational clinical studies


Lesion Location



Recanalization Results



EVALUATION

**Neva**™ **NET**

Designed to **Maximize Clot Retention**



Proposal:

Retrospective analysis of 10 consecutive incoming AIS patients

No particular patient exclusion criteria except choosing anatomy according to available sizes, hospital protocol to be followed, but recommend to start with standard cases to gain familiarity

Tips & tricks training before use

Expectations:

Use NeVa NET as first line treatment

At least 3 attempts to achieve TICl 2c/3 before trying an alternative device

A simple form to fill for each case

CLINICAL CASES

<https://www.vesalio.com/clinical-cases/>



A PROXIMAL OCCLUSION: ONE AND DONE

Right ICA Tip Occlusion, 1st Pass Success

NeVa 4.5 x 37 mm

Prof Geyik, Aydin University, Istanbul, TURKEY

[READ CASE STUDY >](#)



1ST PASS IN BASILAR WAKE UP STROKE

Basilar Occlusion, 1st Pass Success

NeVa 4.5 x 29 mm

Dr Sirvinskas, Republic University, Vilnius, LITHUANIA

[READ CASE STUDY >](#)



1ST PASS SUCCESS WITH 3 DROP ZONES

Left M1 Occlusion, first pass success

NeVa 4.5 x 29 mm

Dr Maurer, University Hospital, Augsburg, GERMANY

[READ CASE STUDY >](#)



1ST PASS SUCCESS AFTER CAROTID BLOWOUT REPAIR

Left M2 Occlusion, first pass success through the carotid stent graft

NeVa 4.0 x 22 mm

Prof Kizilkilic, Dr Korkmaz, Cerrahpasa University, Istanbul, TURKEY

[READ CASE STUDY >](#)



1ST PASS IN STROKE WITH UNKNOWN ONSET

Right M1 Occlusion, 1st Pass Success

NeVa 4.0 x 30 mm

Dr. Kalousek, Sisters Charity Hospital, Zagreb, Croatia

[READ CASE STUDY >](#)



NEVA IN TANDEM STROKE

Tandem Occlusion, two single-pass retrievals, case from LINNC MASTERCLASS

NeVa 4.0 x 30 mm

Prof Spelle, Prof Moret, Dr Mihalea, Neuri Bicetre, Paris, FRANCE

[WATCH CASE >](#)



IMPACT OF 1ST PASS SUCCESS IN EARLY ONSET STROKE

Left M1 Occlusion, first pass success

NeVa 4.0 x 30 mm

Prof Mayer, University Hospital, Jena, GERMANY

[READ CASE STUDY >](#)



WAKE UP STROKE 1ST PASS SUCCESS

Left M1 Occlusion, 1st Pass Success

NeVa 4.0 x 30 mm

Prof Geyik, Aydin University Hospital, Istanbul, TURKEY

[READ CASE STUDY >](#)



SINGLE NEVA RESCUES KISSING RETRIEVERS

Carotid T Occlusion, 1st Pass Success after 2 failed attempts with the kissing-stents technique

NeVa 6.0 x 44 mm

Dr Tomasello, Vall d'Hebron, Barcelona, SPAIN

[READ CASE STUDY >](#)



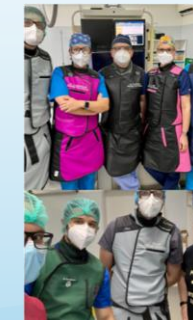
NEVA TO THE RESCUE

Left M2 Occlusion, single pass rescue after failure of 2 different devices

NeVa 4.0 x 22 mm

Prof Geyik, Aydin University, Istanbul, TURKEY

[READ CASE STUDY >](#)



NEW! NEVA SAVES THE DAY AFTER A 5-PASS ORDEAL

Left M1 Occlusion Success

NeVa™ 4.5 x 37 mm

Bucharest University Emergency Hospital Stroke Team

[READ CASE STUDY >](#)



NEW! NEVA IN AN I-TYPE ICA WITH MANY SURPRISES

Live case transmission from iCureStroke 2022

NeVa™ 4.5 x 37 mm

Prof Geyik & Dr Bajrami, Aydin University Hospital, Istanbul, TURKEY

[WATCH CASE >](#)



THANK YOU

Neva™ & Neva™ NET

