ESALIO

DRIVEN TO ADVANCE PATIENT CARE
IN VASCULAR OCCLUSION BY
PROVIDING PHYSICIANS SUPERIOR TECHNOLOGY
DESIGNED TO IMPROVE CLINICAL OUTCOMES

Designed for 1st PASS SUCCESS with ALL Clot Types

ESALIO"

WHY DEVELOP ANOTHER STENT-RETRIEVER

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 TIME TO RECANALIZATION HIGHER TICI 2C/3 RATES 3

PROVIDE EASE OF USE

REAL TIME FEEDBACK

DURING RETRIEVAL

SYNERGISTIC WITH ALL

ACCESS PHILOSOPHIES

TO ACHIEVE BETTER PATIENT OUTCOMES



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







Neva Drop zonem the clot inside

Uniquely designed to CAPTURE

ALL TYPES OF CLOT INSIDE THE DEVICE

STRUCTURE

the DROP ZONES™ allow the capture of large, organized thrombi within the NeVa basket



Neva a design targeting 1st pass success

DROP ZONES™

2 or more 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

SMART MARKERS

2 per drop zone, for real-time feedback during retrieval

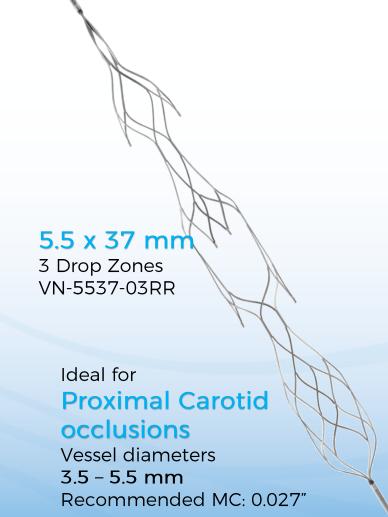
CLOSED DISTAL TIP

Clot gets inside, clot stays inside!





Neva Multiple passes engineered into one



4.5 x 29 mm 3 Drop Zones VN-4529-03RR Ideal for ICA tip & MCA occlusions Vessel diameters 2.0 - 4.5 mm Recommended MC > 0.021"

4.0 x 22 mm 2 Drop Zones 30020V-MS Ideal for

Distal M1, M2, ACA, PCA occlusions Vessel diameters 2.0 - 3.5 mmRecommended MC > 0.021"

CLINICAL DATA

Designed for 1st PASS SUCCESS with ALL Clot Types

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97% RECANALIZATION SUCCESS WITH 1.2 PASSES ACROSS ALL CLOT TYPES



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	





CONSISTENT EFFECTIVENESS AT REMOVING ORGANIZED CLOTS

Data from Machi et al. Journal of Neuro-Int. Surgery, 2016 ¹

"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

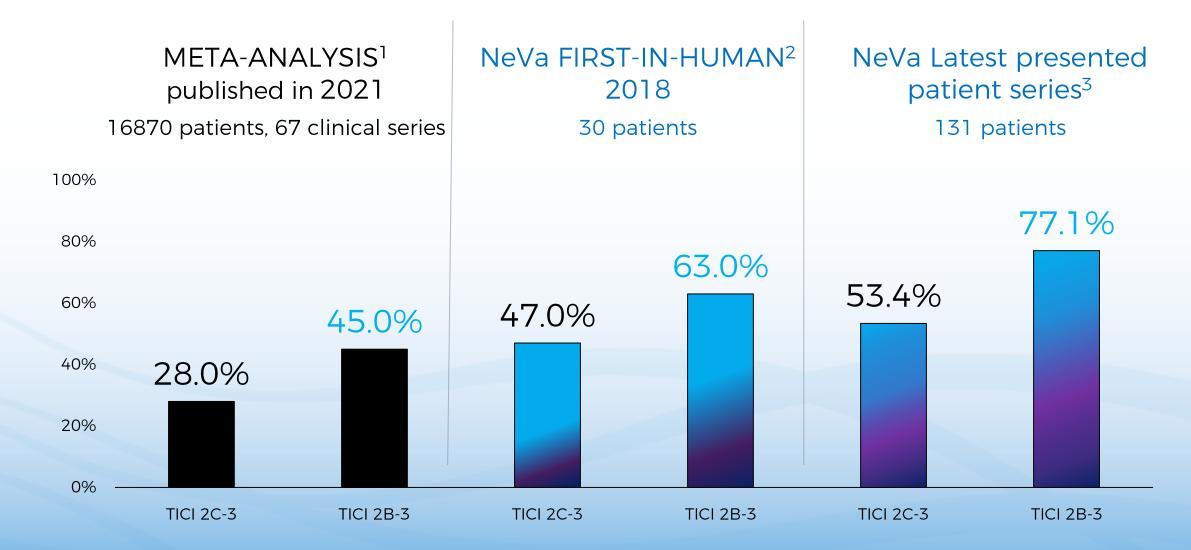
Revive*: 0/5 Mindframe: 0/5

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



SUMMARY OF CLINICAL DATA 348 CASES WITH FIRST-LINE NEVA USE

First-pass TICI 2C/3 rates

Lowest reported: 45%

Highest reported: 63%

First-pass TICI 2B/3 rates:

Lowest reported: 55%

Highest reported: 77%

> Final recan rates:

Lowest reported: 93%

Highest reported: 100%

> Technique:

93.6% (326/348) done under local aspiration

6.4% (22/348) done with BGC

0% combination technique

Mean number of passes for final recan:

ranging from 1.5 - 1.8

^{*297} first-line case experience includes 3 publications + 2 large series presentations: • Akpinar, Cetin K., et al., Interventional Neuroradiology, July 2020

M. Ribo, et al., Journal of Neuroradiology May 2019

S. Geyik, Presented at iCureStroke, Feb. 2020

A. Sirvinskas, Presented at ESMINT, Sept. 2020



1ST LINE TREATMENT ON "ALL" COMERS 30 PATIENTS -MULTI-CENTER

2B/3 2C/3

First Pass

Final Recanalization

19/30 **→ 63**%

28/30 **> 93**%

14/30 **→ 47**%

19/30 **→ 63**%

Average # of passes for final recan $\rightarrow 1.7$

Patient Outcomes

- Mean NIHSS @ 24hr: 7
- 90 day mRS < 2 : 53%
- Zero NeVa related adverse events & sICH

- NeVa was effective with both balloon guide and local aspiration strategies
- In the 40 passes where the info was available: 70% clot incorporation into device basket





1ST LINE TREATMENT – ANTE & POSTERIOR 118 PATIENTS -MULTI-CENTER

2B/3

2C/3

First Pass

61/80 **→ 56.8**%

46/80 **44.9**%

Median # of passes

Final Recanalization

77/80 **→ 95.8**%

for final recan \rightarrow 1 (IQR 1-2)

Favorable functional outcome (mRS \leq 2):

- 53% in the "first-pass" subgroup
- 42.4% in the total patient population.

Procedure related complications:

- Symptomatic ICH: 3.3%
- Asymptomatic ICH: 13.6%
- Embolization into new territory: 1.7%
- Dissection that did not require stenting: 1.7 %

Flow Control strategies preferred:

- 92.4% of cases done with distal aspiration (Solumbra: Aspiration catheter + NeVa)
- Balloon Guide Catheter used only in 13.6% of cases





1ST LINE TREATMENT - ANTERIOR 131 PATIENTS -SINGLE-CENTER

2B/3

2C/3

First Pass

101/131 → **77.1**%

70/131 **→ 53.4**%

Average # of passes for final recan $\rightarrow 1.8$

Final Recanalization

128/131 **→ 97.6**%

113/131→ **86.2**%

Patient Outcomes:

- 24 hour mean NIHSS: 7
- mRS scores available in 67 patients
- mRS 0-1: 43 (61.2%)
- mRS 0-2: 48 (71.6%)
- 1 month mortality: 7.5%

Safety Data:

- No device-related serious adverse events
- Asymptomatic ICH (HT): 36 pts (27.4%)
- SAH: 4 pts (3%), mild and asymptomatic

FOCUS ON 38 ICA-cases:

- 21 patients (55 %) were recanalized in 1 pass
- 17 were TICI 3
- 4 was TICI 2C
- Only 1 patient required 6 passes
- Addition of a 2nd SR for the distal M2 occlusion





1ST LINE & RESCUE TREATMENT – M1 29 PATIENTS -SINGLE-CENTER

	2B/3	2C/3
First Pass	55 %	48%
1-2 passes	79 %	62 %
Final Recanalization	100%	72 %

Patient Outcomes:

- Median NIHSS scores decreased from 16 to 12 after treatment
- 90-day mRS < 2 : 31%

Safety Data:

- 1 asymptomatic carotico-cavernous fistula
- asymptomatic M2 dissection
- 1 sICH
- Procedure-related vasospasm rate: 48% (no negative impact observed on outcomes)



RESCUE TREATMENT - ANTERIOR 6 PATIENTS - SINGLE-CENTER

TICI>2B WAS ACHIEVED IN 5/6 AND IN 1.2 PASSES

	Occlusion	NEVA USED AT	Tici Score before NeVa Use	NUMBER OF NEVA PASSES REQUIRED FOR FINAL TICI SCORE	Tici Score after NeVa Use
1	M1	3 rd Pass	2A →	1 NeVa pass →	2B
2	M1	3 rd Pass	0 >	1 NeVa pass →	2B
3	ICA/M1	3 rd Pass	0 >	1 NeVa pass →	2C
4	M1	3 rd Pass	2A →	1 NeVa pass →	2C
5	M1/M2	2 nd Pass	0 →	2 NeVa passes →	2C
6	M1	3 rd Pass	2A →	1 NeVa pass →	2A





Ne 1ST LINE TREATMENT - ANTE &POSTERIOR 40 PATIENTS -SINGLE-CENTER

	TICI 3	TICI 2C+	TICI 2B+	1st Pass rates
	13/30 → 43%	19/30 → 63%	20/30 → 66%	2 DZ NEVA 30 cases
	7/10 → 70%	9/10 → 90%	10/10 → 100%	3 & 5 DZ NEVA 10 cases
Mean no. of passes for final recanalization	TICI 3	TICI 2C+	TICI 2B+	<u>Final rates</u>
1.5	19/30 → 63%	26/30 → 86%	28/30 → 93%	2 DZ NEVA 30 cases
1.0	7/10 → 70%	9/10 → 90%	10/10 → 100%	3 or 5 DZ NEVA 10 cases

EVALUATION

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Proposal:

Retrospective analysis of 10 consecutive incoming AIS patients

No particular patient exclusion criteria, hospital protocol to be followed, but recommend to start with standard cases to gain familiarity with NeVa

NeVa tips & tricks training before use

Expectations:

Use NeVa as first line treatment

At least 3 attempts to achieve TICI 2b/3 before trying an alternative device

A simple form to fill for each case



THANK YOU

Designed for 1st PASS SUCCESS with ALL Clot Types

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SUPPLEMENTARY INFORMATION

RADIAL FORCE

SMART MARKERS

EXAMPLE CASES & CLOTS BY NEVA

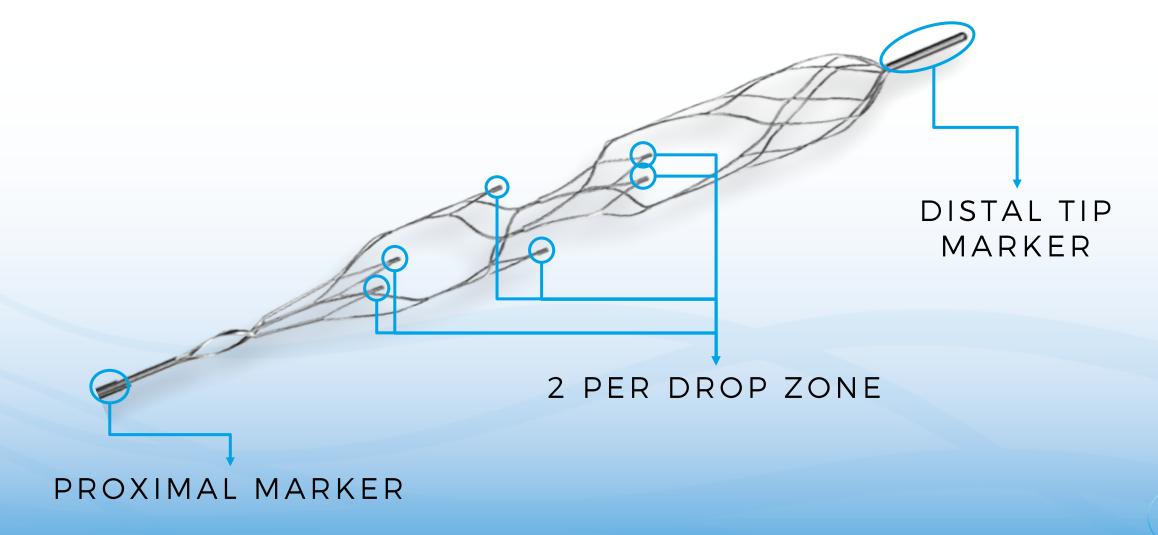
Designed for 1st PASS SUCCESS with ALL Clot Types

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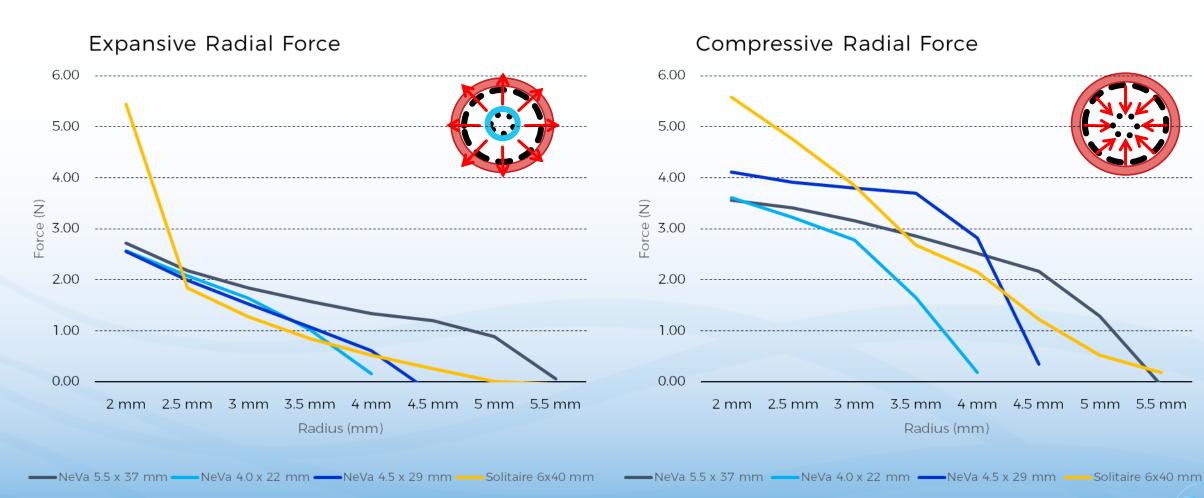


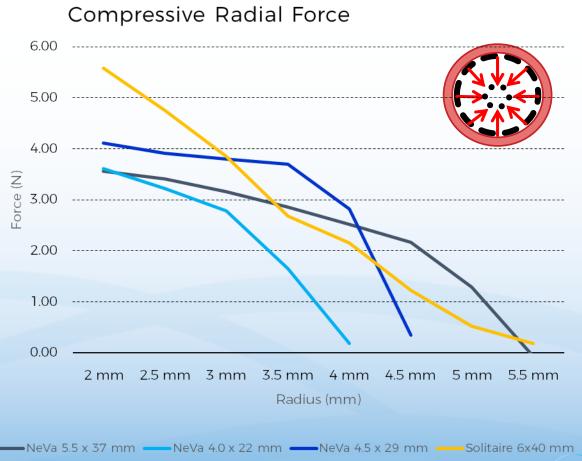
Neva Drop Zonem the CLOT Inside





OPTIMIZED RADIAL FORCE BALANCED WITH LARGE OPENINGS & CLOSED ENDS







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



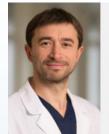
A PROXIMAL OCCLUSION: ONE AND DONE

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 Korkmazer, 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

READ CASE STUDY >



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 IST PASS SUCCESS

Left M1 Occlussion. 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 >



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

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 >





Neva DROP ZONETH THE CLOT INSIDE

