VESALIO

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**

NeVa™

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
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**

DESIGN

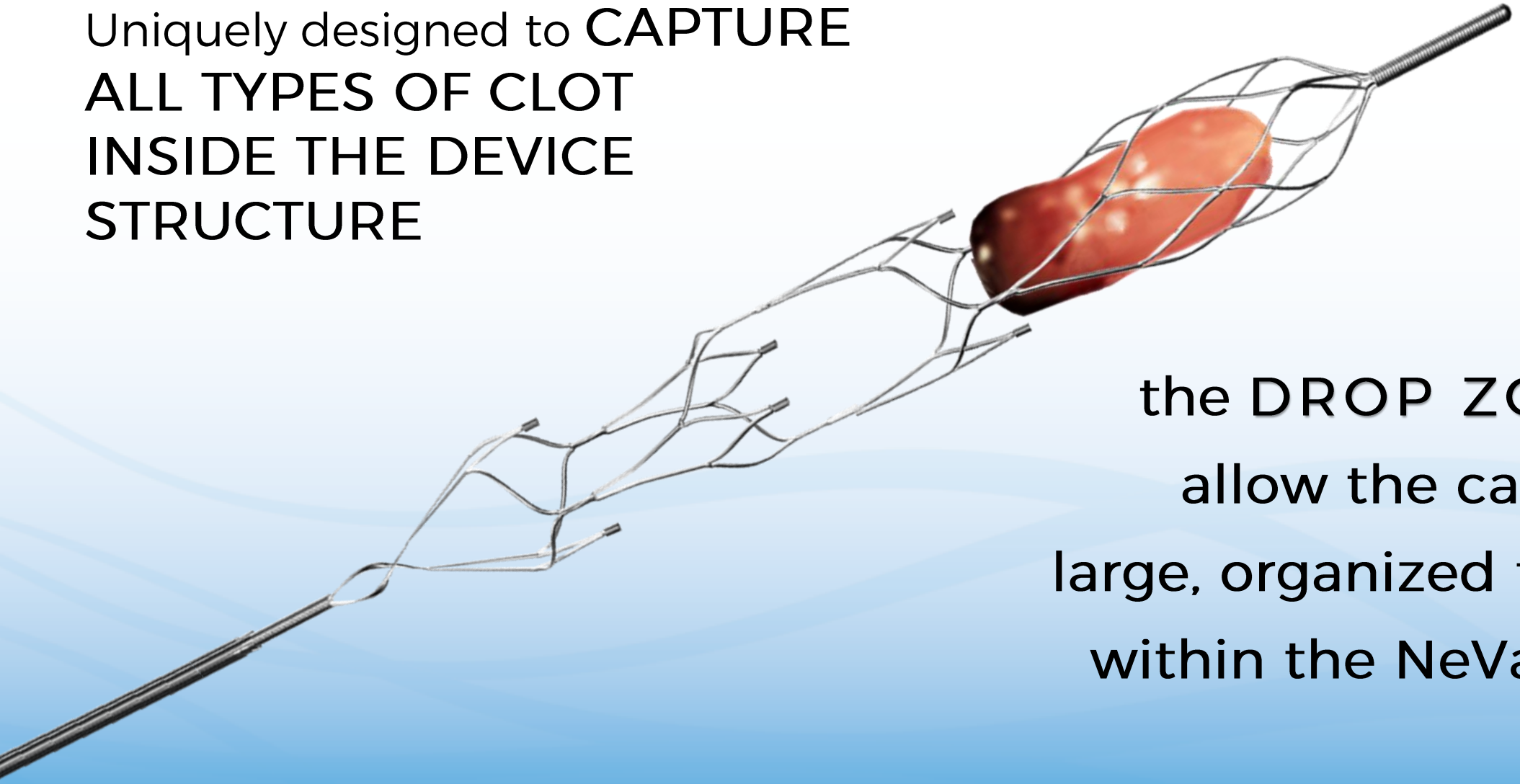
Designed for 1st PASS SUCCESS with ALL Clot Types

Neva™

VESALIO™

DROP ZONE™ THE CLOT INSIDE

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

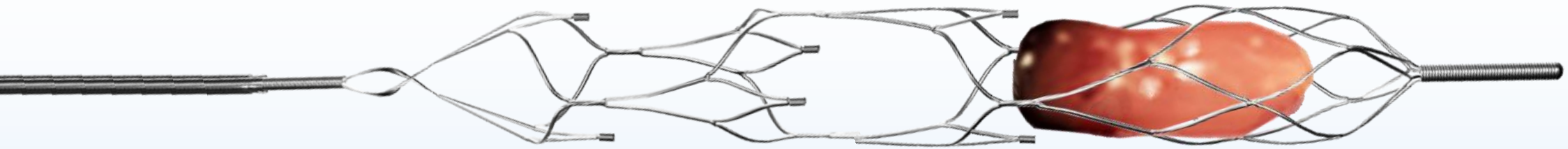


the **DROP ZONES™**
allow the capture of
large, organized thrombi
within the NeVa basket

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

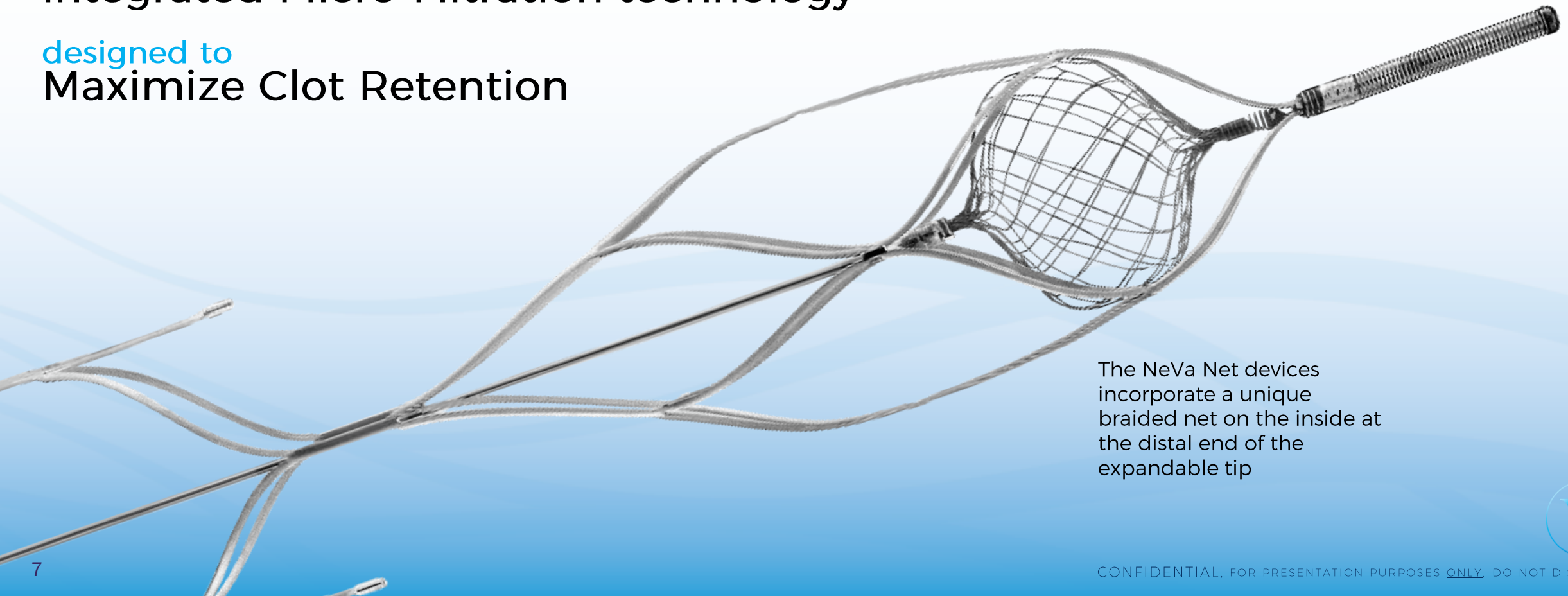
Clot gets inside, clot stays inside!

NeVa NET

THE NEXT FRONTIER IN THROMBECTOMY

the first and only
integrated Micro-Filtration technology

designed to
Maximize Clot Retention



The NeVa Net devices incorporate a unique braided net on the inside at the distal end of the expandable tip

MULTIPLE PASSES ENGINEERED INTO ONE

5.5 x 37 mm
3 Drop Zones
VN-5537-03RR

Ideal for
Proximal occlusions
Vessel diameters
3.5 – 5.5 mm
Recommended MC: 0.027”

4.5 x 29 mm
3 Drop Zones
VN-4529-03RR

Ideal for
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 mm
Recommended MC > 0.021”

NeVa NET

THE NEXT FRONTIER IN THROMBECTOMY

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”

4.0 x 30 mm
3 Drop Zones
VN-4030-03NR

Ideal for
MCA occlusions
Vessel diameters
2.0 – 4.5 mm
Recommended MC > 0.027”

CLINICAL DATA

Designed for 1st PASS SUCCESS with ALL Clot Types

Neva™

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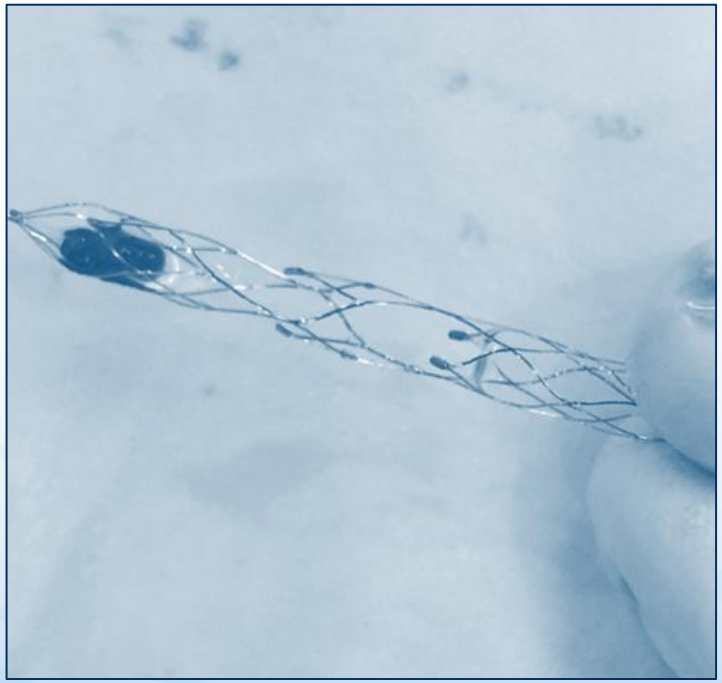
Neva™

ANIMAL LAB RESULTS

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
1st 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

Ulm A.J. et al. Interventional Neurology 2018;7:205–217

NeVa™

IN VITRO RESULTS

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. 2018[2]

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

1. Machi P, et al. Journal of NeuroInterventional Surgery. 2016; 0:1–7 -- * Some versions of these devices were able to minimally displace clots 1-2 times in 5, without succeeding in removing them; 2. Machi P, et al. Journal of Neuroradiology. April 2018

1ST PASS RATES TRENDING HIGH

META-ANALYSIS[1] published in 2021

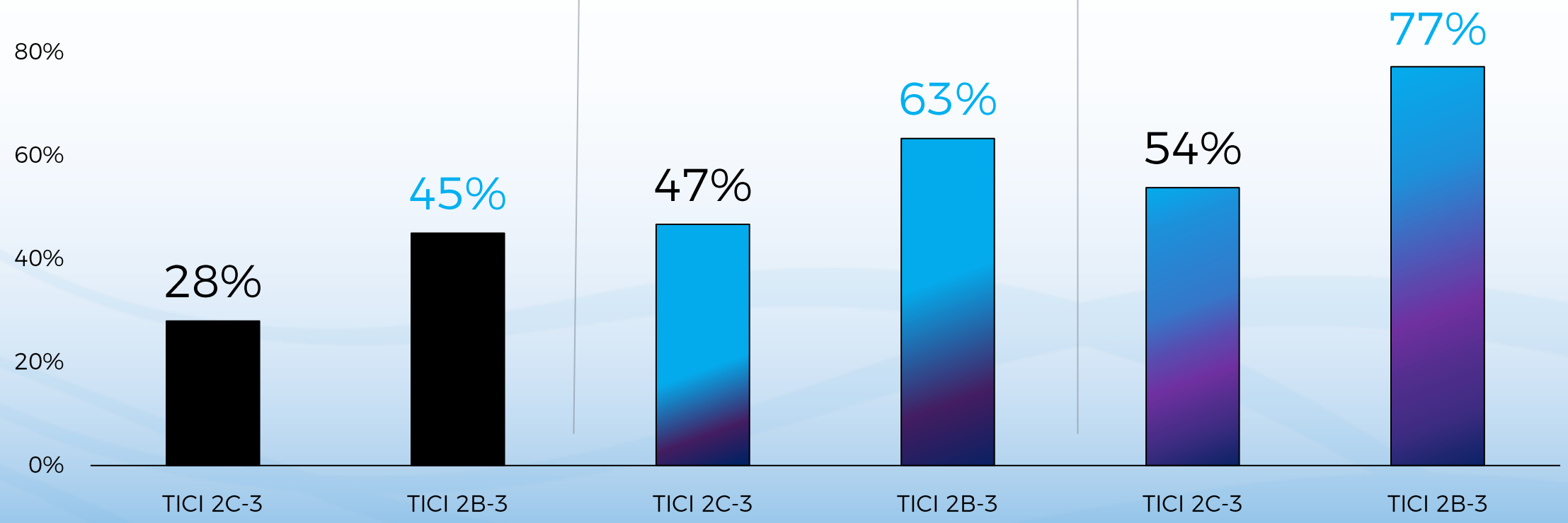
16870 patients, 67 clinical series

NeVa FIRST-IN-HUMAN[2] published in 2018

30 patients

NeVa LATEST PUBLISHED patient series in 2022[3]

145 patients



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

3. Bajrami et al. Interventional Neuroradiology Oct 2022

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

	n	First Pass TICI 2C/3	First Pass TICI 2B/3	Final TICI 2C3	Final TICI 2B/3	Mean # of passes to achieve final TICI	Median # of passes to achieve final TICI (IQR)
Ribo et al.	30	*14/30* 47%	*19/30* 63%	*19/30* 63%	*28/30* 93%	1.7	
Akpinar et al.	118	*53/118* 45%	*67/118* 57%	*86/118* 73%	*113/118* 96%		1 (1-2)
Borgreffe et al.	29	*14/29* 48%	*16/118* 55%	*21/29* 72%	*29/29* 100%	2.4	
Bajrami et al.	145	*78/145* 54%	*112/145* 77%	*126/145* 87%	*142/145* 98%	1.8	
Total	322	*159/322* **49%**	*214/322* **66%**	*252/322* **78%**	*312/322* **97%**		

- M. Ribo, et al., Journal of Neuroradiology May 2019
- Akpinar, Cetin K., et al., Interventional Neuroradiology, July 2020
- Borggrefe et al. World Neurosurg. Dec. 2020
- Bajrami et al. Interventional Neuroradiology Oct 2022

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

	2B/3	2C/3
First Pass	19/30 → 63%	14/30 → 47%
Final Recanalization	28/30 → 93%	19/30 → 63%

Average # of passes for final recan → 1.7

<u>Patient Outcomes</u>

- 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: <u>70% clot incorporation into device basket</u>

M. Ribo, J. Macho, J. Zamarro, P. Machi, D. Hernandez, J. Blasco, A. Tomasello, Journal of Neuroradiology May 2019 – vol. 46

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

	2B/3	2C/3	
First Pass	61/80 → 57%	46/80 → 45%	Median # of passes for final recan → 1 (IQR 1–2)
Final Recanalization	77/80 → 96%		

Favorable functional outcome (mRS ≤ 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

Akpinar, Cetin K., et al. "Favorable First-Pass Recanalization Rates with NeVa™ Thrombectomy Device in Acute Stroke Patients: Initial Clinical Experience." Interventional Neuroradiology, July 2020, doi:10.1177/1591019920938223

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

Borggrefe et al. World Neurosurg. 2020 Dec 22:S1878-8750(20)32642-5. doi: 10.1016/j.wneu.2020.12.075.

1ST LINE TREATMENT – ANTERIOR
145 PATIENTS -SINGLE-CENTER

	2B/3	2C/3
First Pass	112/145→ 77%	78/145 → 54%
Final Recanalization	142/145→ 98%	126/145→ 87%

Average # of passes for final recan → 1.8

Patient Outcomes:

- 24 hour mean NIHSS:
  - 6 (IQR 0-33)
  - average decrease of 10 points compared to initial presentation
- 30-day mRS 0-2: 89 (60.7%)
- 90-day mRS 0-2: 97 (66.9%)

Safety Data:

- No device-related adverse events
- No significant vasospasm
- HT-1: 29.7% (n=43), HT-2: 7.6% (n=11), PH-1: 2.8% (n=4)
- no perforation or extravasation observed during any procedure
- asymptomatic SAH identified on follow-up imaging: 4.8%(n=7)

• Bajrami et al. Interventional Neuroradiology Oct 2022

EVALUATION

Designed for 1st PASS SUCCESS with ALL Clot Types

Neva™

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NeVa™ EVALUATE

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

Nevia™

VESALIO™

SUPPLEMENTARY INFORMATION

Radial Force	NeVa Markers	Example Cases & Clots by NeVa

Designed for **1st PASS SUCCESS** with **ALL Clot Types**

NeVa™

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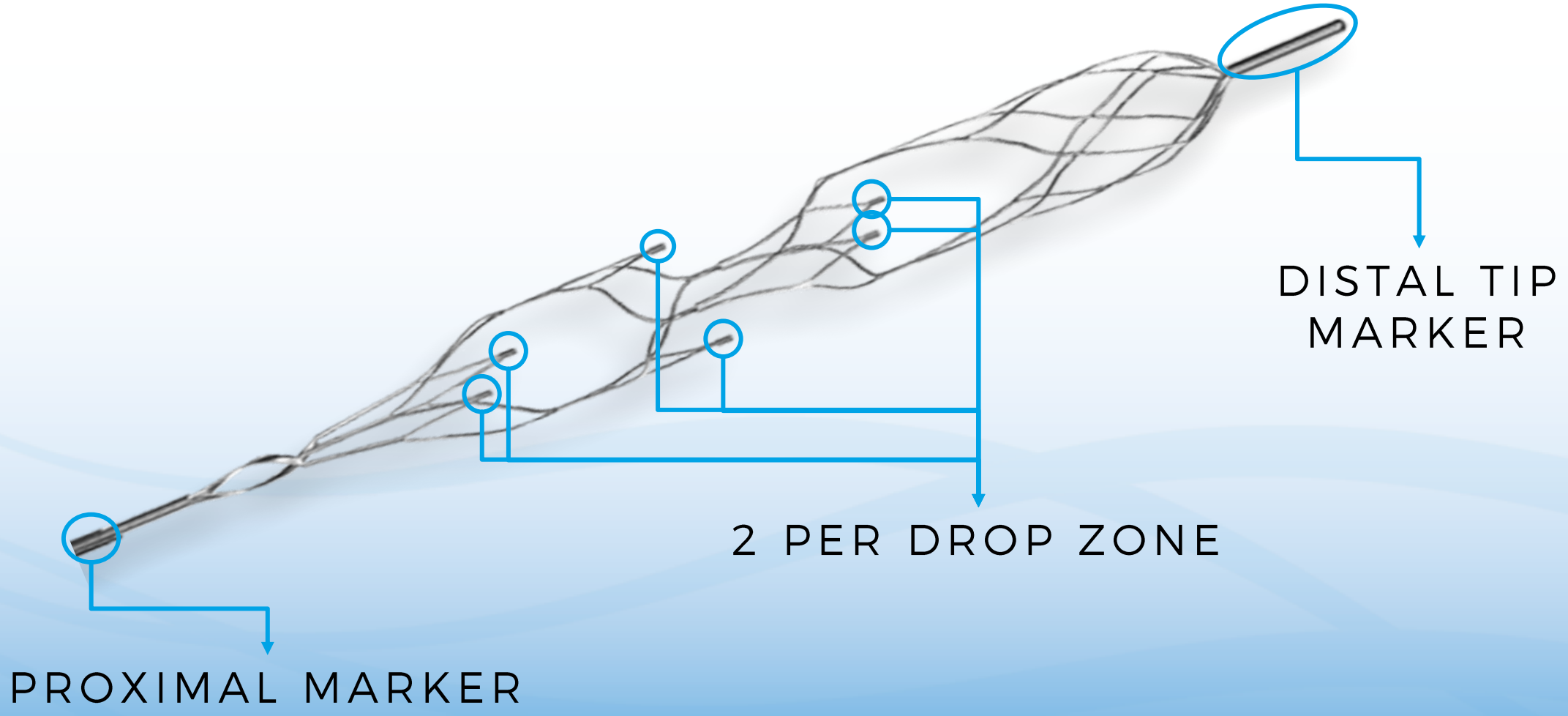
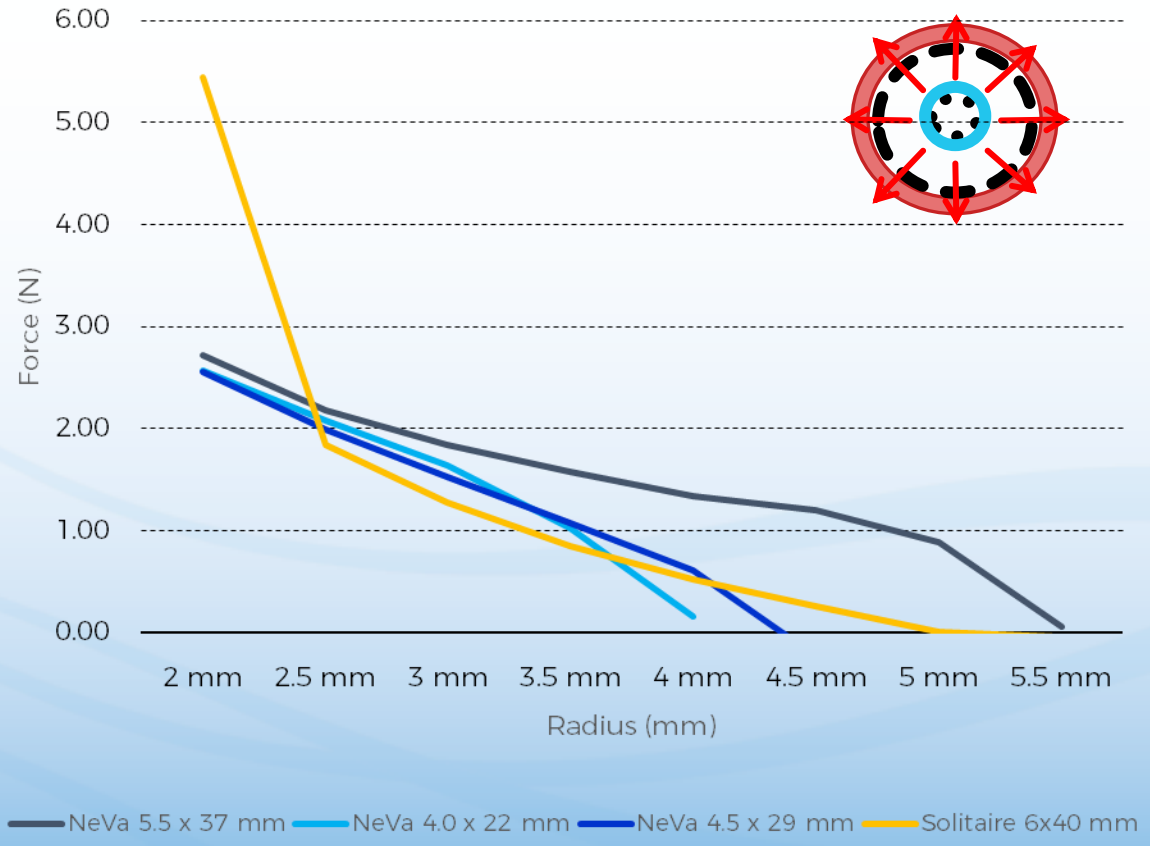
NeVa™ DROP ZONE™ THE CLOT INSIDE

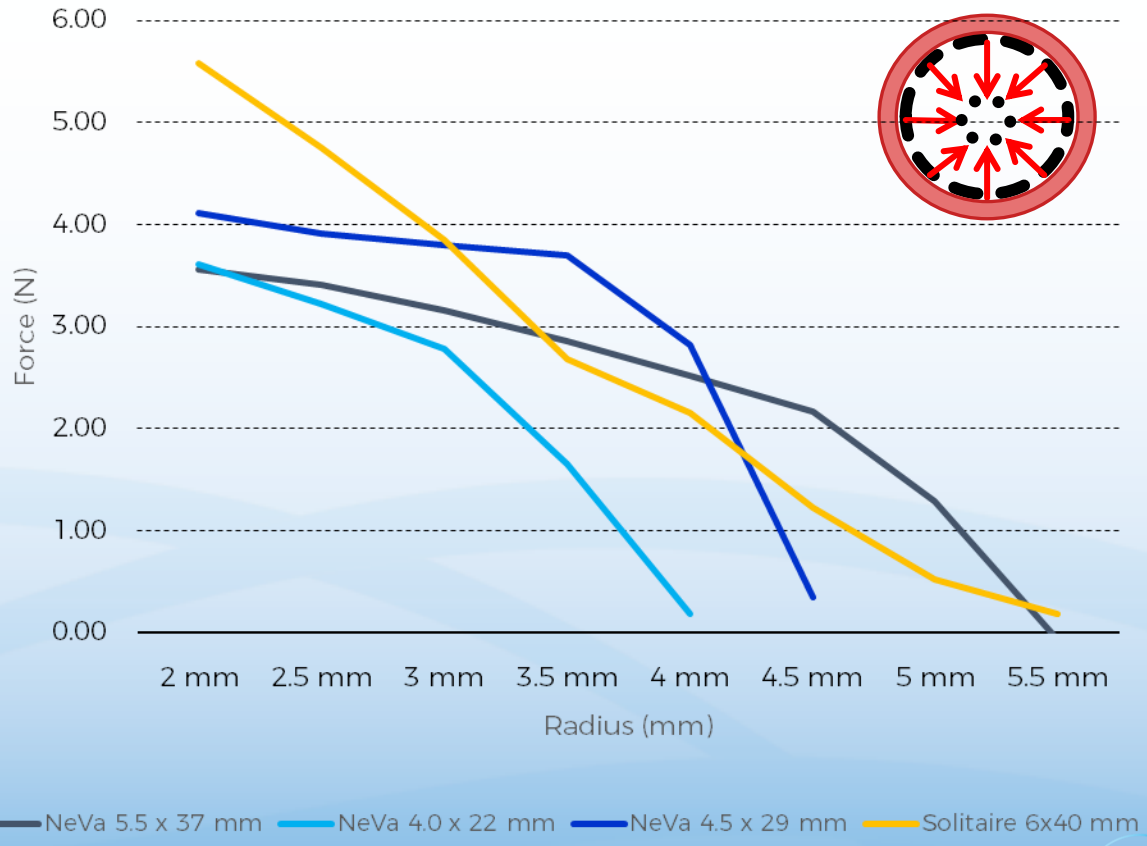


OPTIMIZED RADIAL FORCE BALANCED WITH LARGE OPENINGS & CLOSED ENDS

Expansive Radial Force

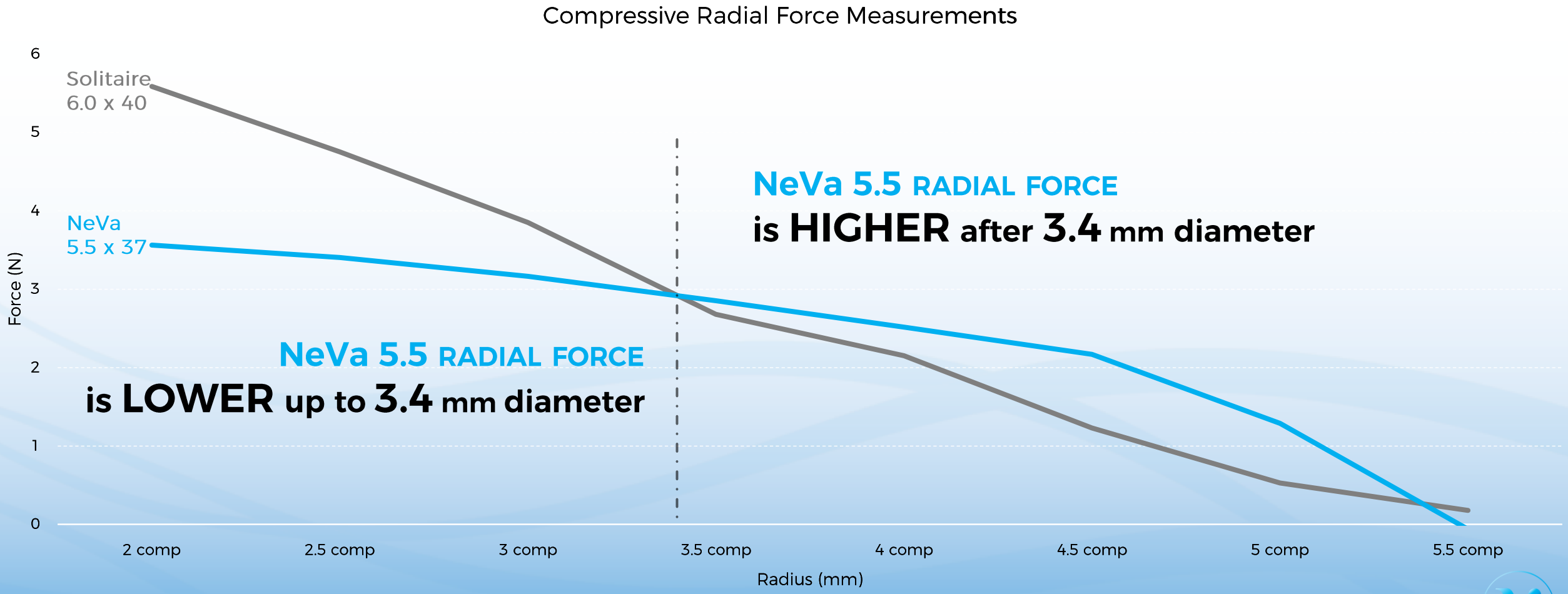


Compressive Radial Force



Source: Data on file at Vesalio

THE LARGEST NEVA SIZE (5.5) RADIAL FORCE COMPARED TO SIMILAR SIZED STENT RETRIEVER



Testing on file at Vesalio

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 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

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 Occlussion, 1st Pass Success

NeVa 4.0 x 30 mm

Prof Geyik, Aydin University Hospital, Istanbul, TURKEY

READ CASE STUDY >

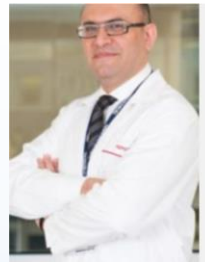
SINGLE NEVA RESCUES KISSING RETRIEVERS

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 >



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

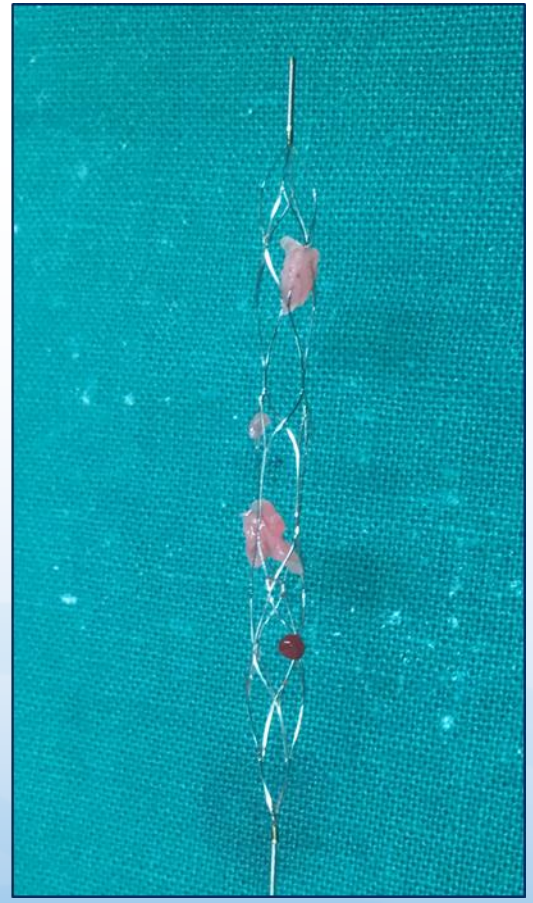
NeVa™ 4.5 x 37 mm

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

WATCH CASE >

NeVa™ DROP ZONE™ THE CLOT INSIDE



 Source: Clots retrieved during VESALIO CLOT INTERACTION WORKSHOP, Madrid, 17-18 April 2018