
VESALIO™
CHANGING OUTCOMES
CHANGING LIVES
Designed for 1st PASS SUCCESS with ALL Clot Types
VESALIO™
NeVa™
LV-MKT-010-Rev C

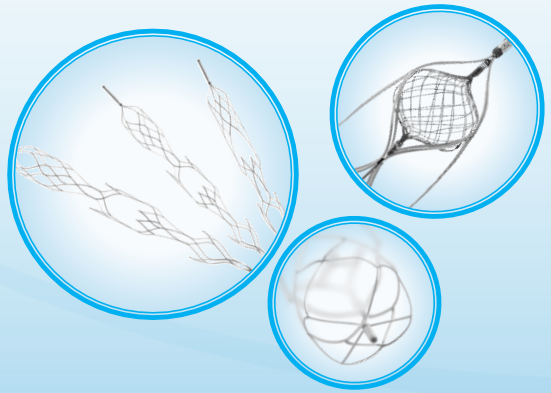
# VESALIO CHANGING OUTCOMES CHANGING LIVES

## 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
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

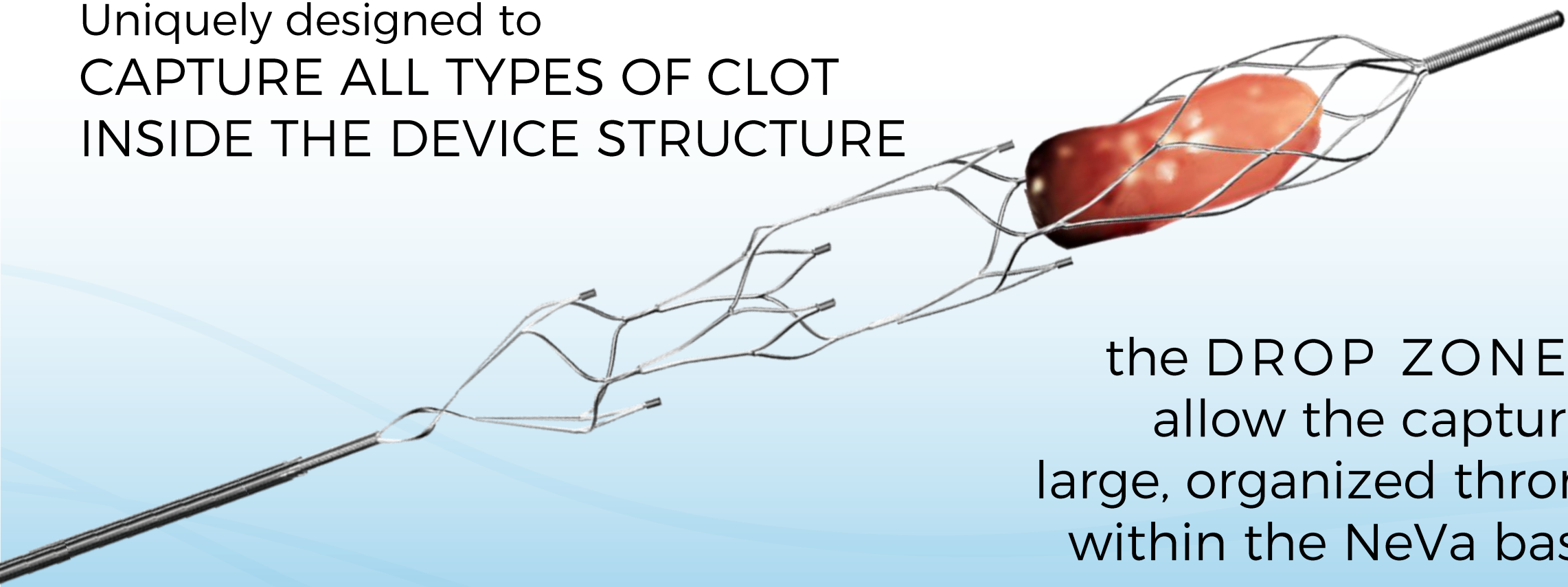
Designed for **1st PASS SUCCESS** with **ALL Clot Types**

NeVa™

ESALIO™

# NeVa™ DROP ZONE™ THE CLOT INSIDE

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

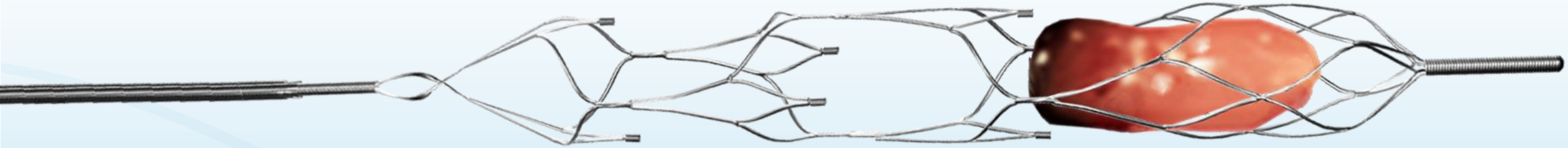


the DROP ZONES™
allow the capture of
large, organized thrombi
within the NeVa basket

# 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

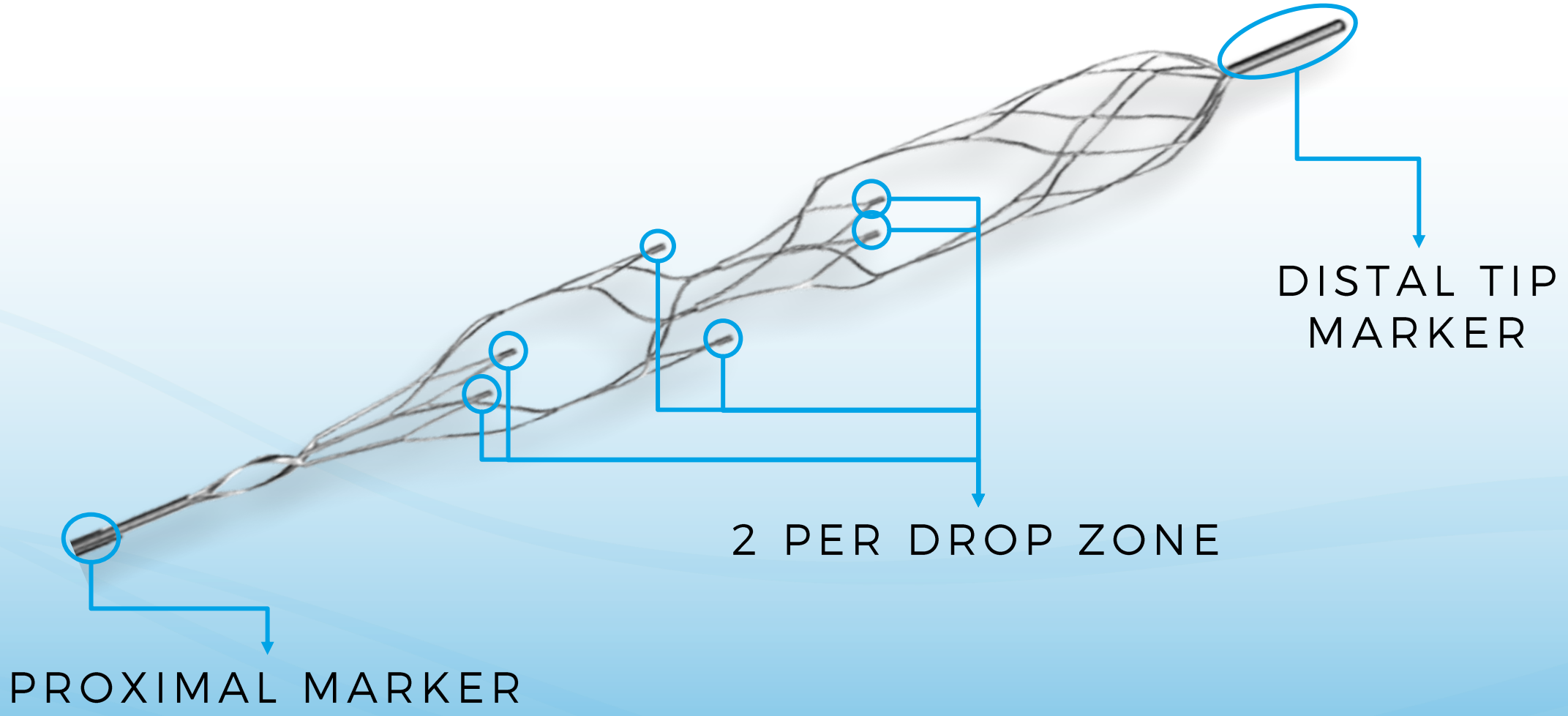
### DROP ZONE MARKERS

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

### CLOSED DISTAL TIP

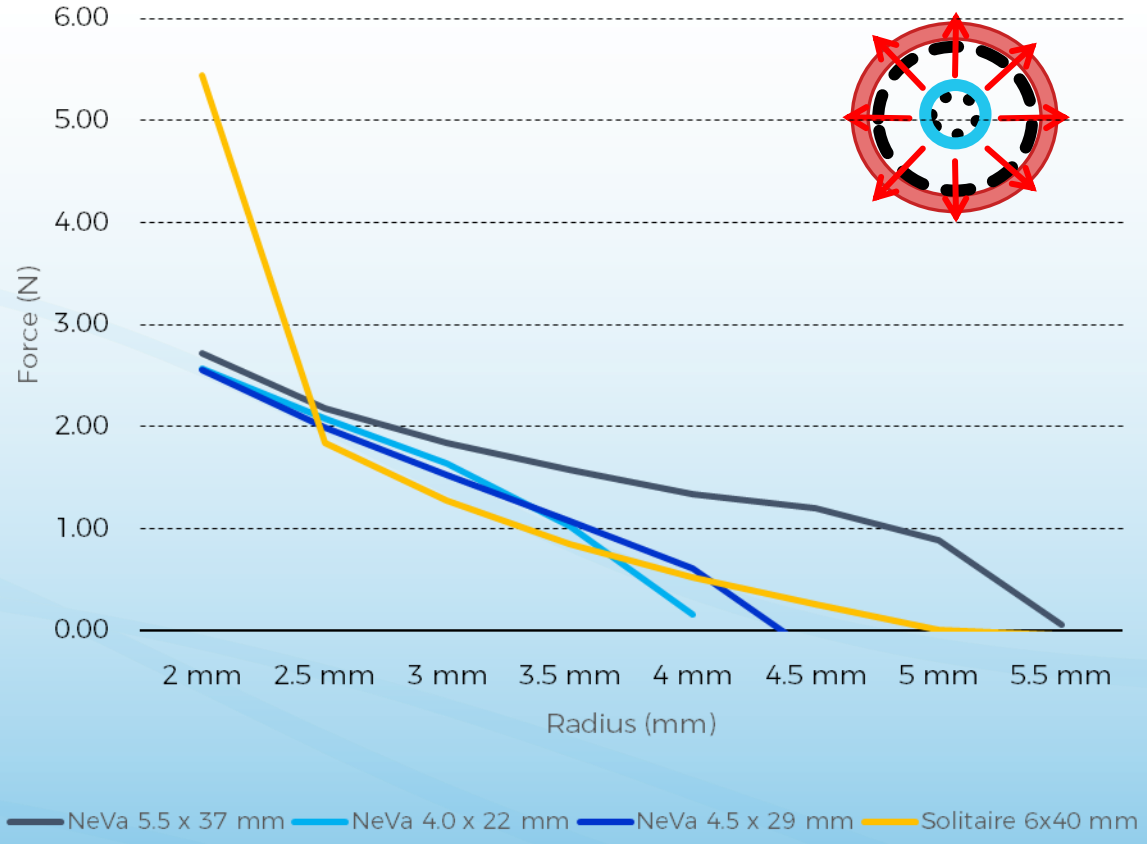
Clot gets inside, clot stays inside!

# Neva™ DROP ZONE™ THE CLOT INSIDE

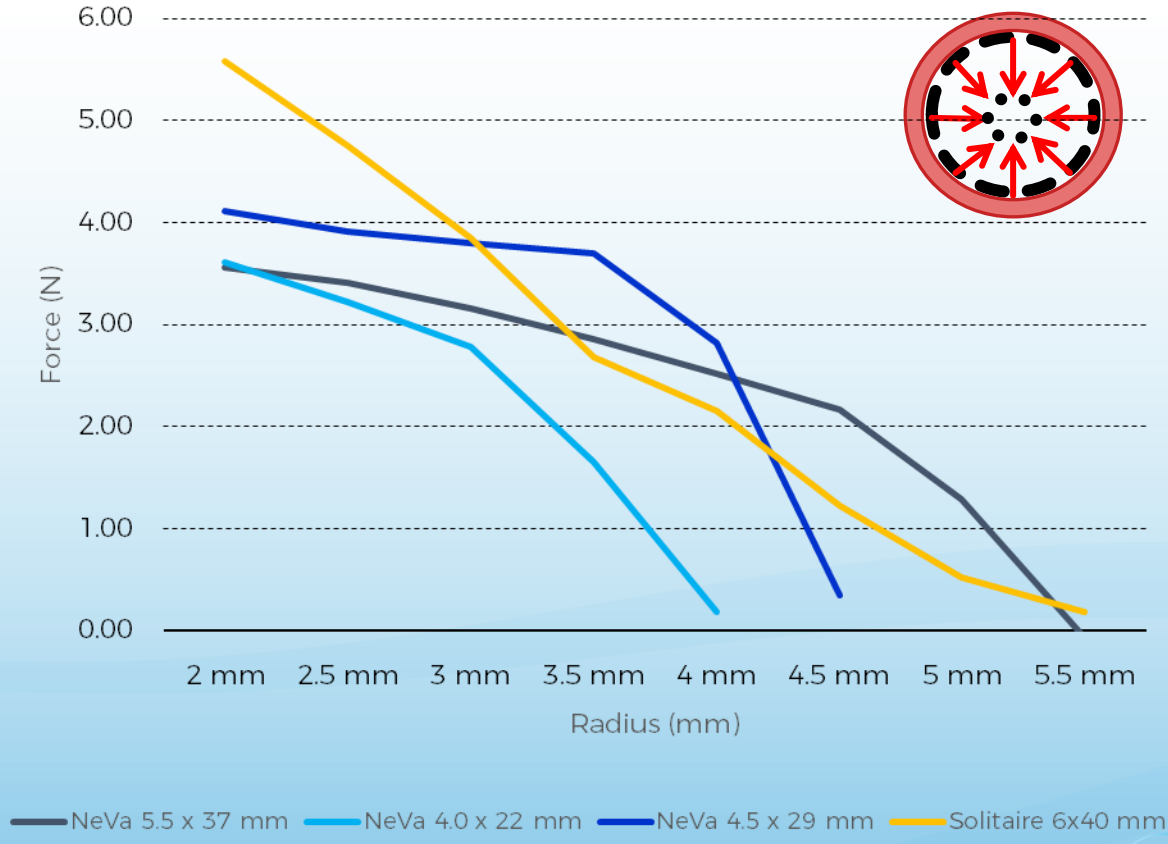


# OPTIMIZED RADIAL FORCE BALANCED WITH LARGE OPENINGS & CLOSED ENDS

## Expansive Radial Force



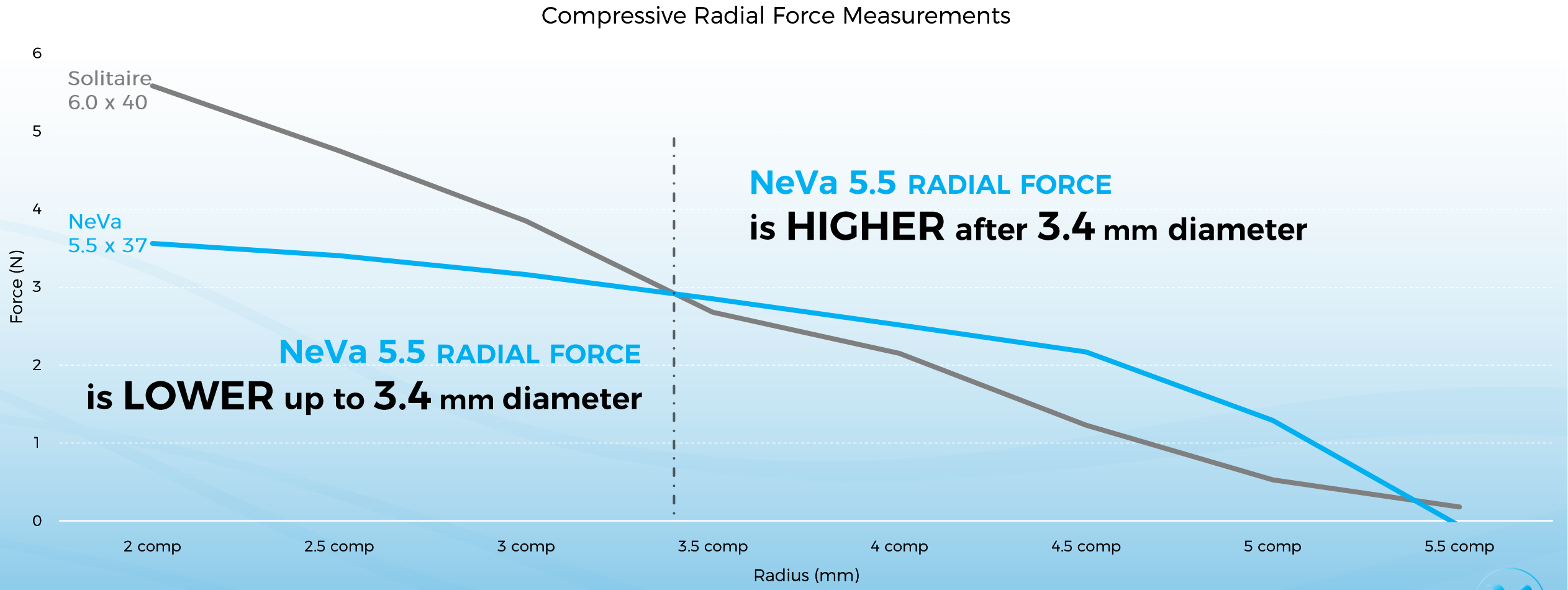

## Compressive Radial Force





Source: Data on file at Vesalio

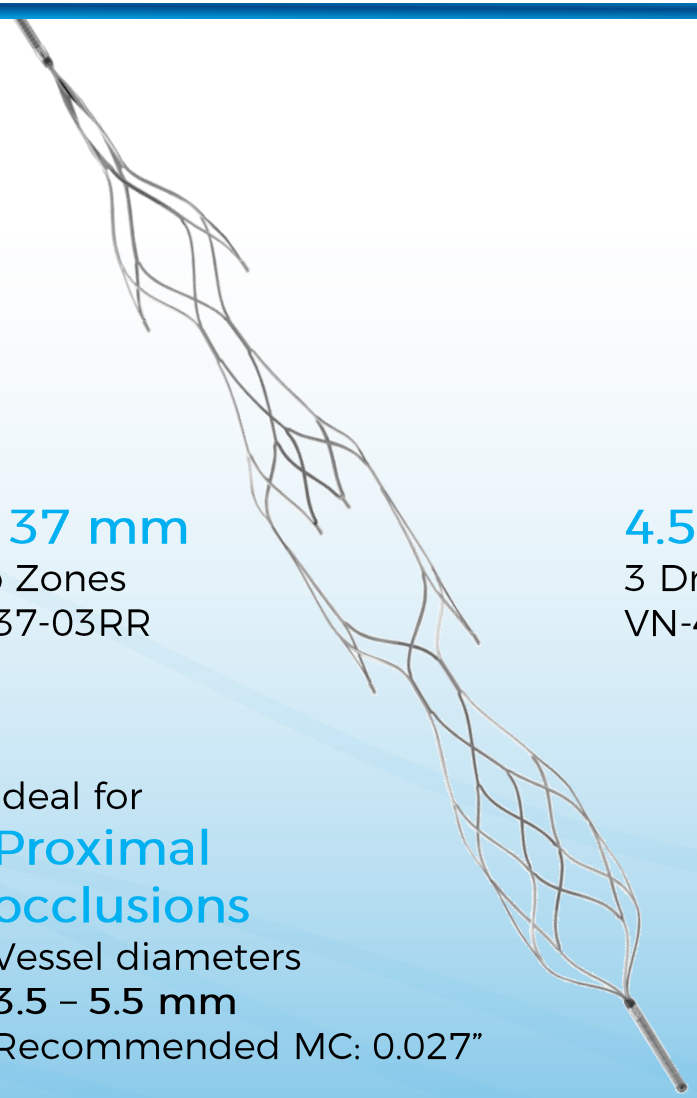
# NEVA 5.5 COMPRESSIVE RADIAL FORCE COMPARED TO SOLITAIRE 6.0






Testing on file at Vesalio

# Neva™ MULTIPLE PASSES ENGINEERED INTO ONE

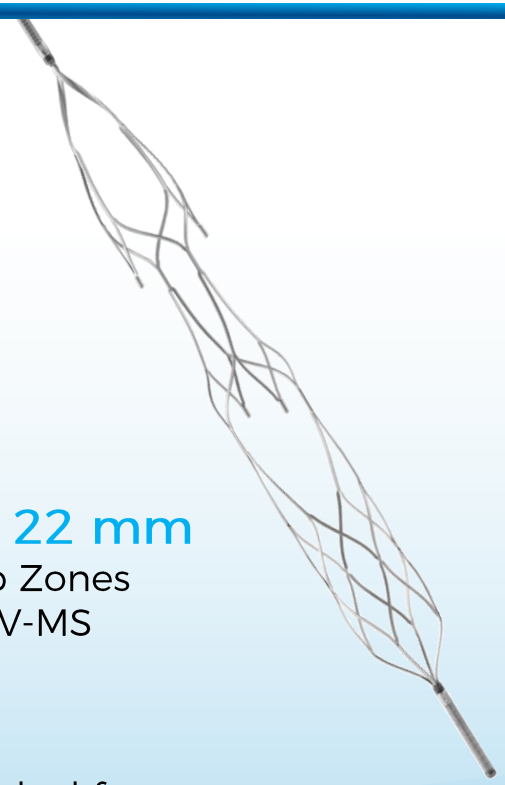


**5.5 x 37 mm**
3 Drop Zones
VN-5537-03RR

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”

# CLINICAL DATA

Designed for 1st PASS SUCCESS with ALL Clot Types

Neva™

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EXPERIMENTAL TESTING

# 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™
EXPERIMENTAL TESTING

# 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

# NeVa™ 1ST PASS RATES TRENDING HIGH

CLINICAL RESULTS

## META-ANALYSIS[1] published in 2021

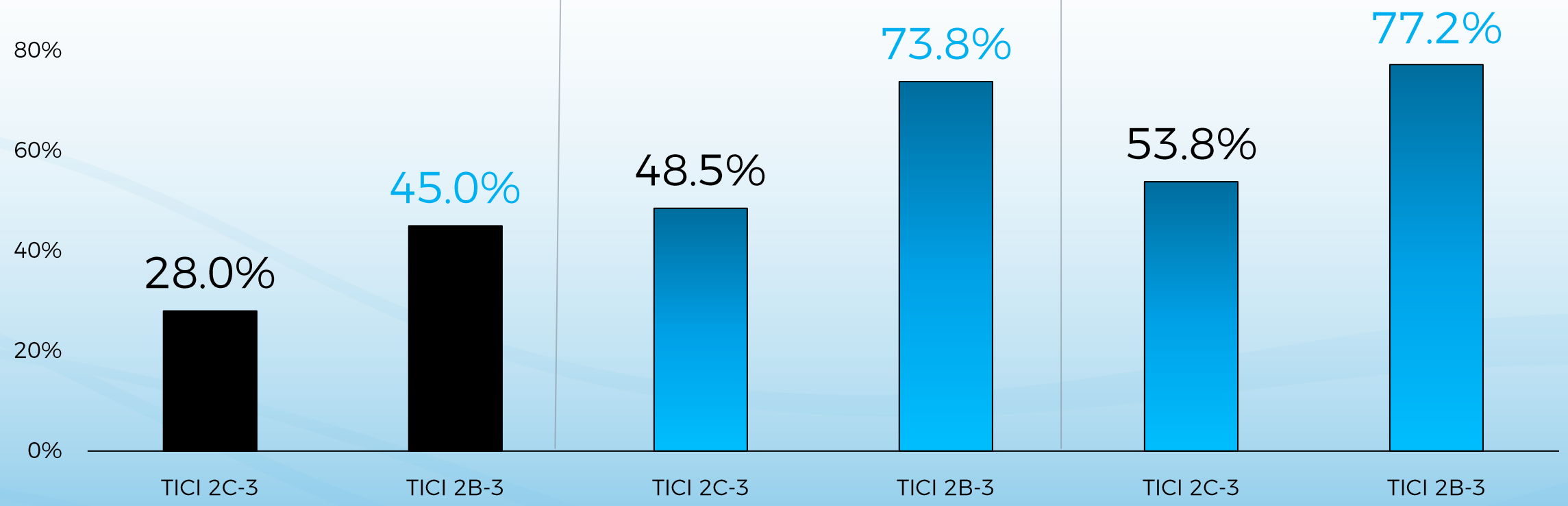
16870 patients, 67 clinical series

## NeVa CLEAR study Presented in 2023[2]

107 patients (mITT), 25 centers

## NeVa largest published patient series in 2022[3]

145 patients, single center





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.

# PRIMARY RESULTS FROM THE CLEAR STUDY OF A NOVEL STENT RETRIEVER WITH DROP ZONE TECHNOLOGY


Albert J Yoo, Texas Stroke Inst, Plano, TX

Christoph Maurer, Augsburg, Augsburg, Germany

Raul G Nogueira, Univ of Pittsburgh, Pittsburgh, PA

Laurent Spelle, Bicetre Univ Hosp, Paris, France

Audrius Sirvinskas, Vilnius, Vilnius, Lithuania

Jordi Blasco, Hosp Clinic Barcelona, Barcelona, Spain

Adnan H Siddiqui, Univ at Buffalo, Buffalo, NY

Diogo C Haussen, Emory Univ, Atlanta, GA

Arturo Consoli, Hosp Foch, Paris, France

Alberto Maud, Texas Tech Univ, El Paso, TX

Maher Sahnoun, CHU Reims, Reims, France

Serdar Geyik, Istanbul Aydin Univ, Istanbul, Turkey

Tareq Kass-Hout, Univ of Chicago, Chicago, IL

Ricardo Hanel, Baptist, Jacksonville, FL

Demetrius Lopes, Advocate Aurora Health, Park Ridge, IL

Eugene Lin, Mercy St. Vincent, Toledo, OH

Muhammad Asif Taqi, Vasc. Neurology of S.Cal, Thousand Oaks, CA

Timothy Ryan Miller, Univ of Maryland, Baltimore, MD

Keith Woodward, Fort Sanders, Fort Sanders, TN

M. Imran Chaudry, Greenville, Mt. Pleasant, SC

Joshua Bentley, Southeast Health, Dothan, AL

Jens Fiehler, Uni Medical Ctr Hamburg-Eppendorf, Hamburg, Germany

Michael Froehler, Vanderbilt, Nashville, TN

Osama Zaidat, Mercy Health St. Vincent Hosp, Toledo, OH

Laurent Pierot, CHU Reims, Reims, France

Ameer E Hassan, Valley Baptist Medical Ctr, Harlingen, TX

Marc Ribo, Val d'Hebron, Barcelona, Spain

Aamir Badruddin, Community Healthcare, Munster, IN

Shazam Muhammad Hussain, Cleveland Clinic, Cleveland, OH

Christoph Groden, Univsmedizin Mannheim, Mannheim, Germany

Christian Ramsey, Baptist Health, Lexington, KY

Arsida Bajrami, Istanbul Aydin Univ, Istanbul, Turkey

Rishi Gupta, Wellstar Health System, Marietta, GA



Journal of Interventional Surgery

Published Online First: 02 December 2023. doi: 10.1136/jnis-2023-020960

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


Neva™

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# OBJECTIVES

1. Demonstrate the efficacy and safety of the NeVa device for revascularization of LVOs
2. Assess the comparative performance of the NeVa device versus existing stent retriever devices

# STUDY DESIGN

Prospective, multi-center, open label, single arm, FDA-regulated IDE study

## POPULATION:

- AIS patients treatable within 8 hours of onset
- 18-85 yrs
- NIHSS 8-25
- ASPECTS 6-10
- intracranial LVO including ICA, M1/M2 MCA, and vertebrobasilar arteries
- IV-tPA ≤3h of TLKW

# STUDY ENDPOINTS

## PRIMARY EFFICACY ENDPOINT

- Rate of successful reperfusion (eTICI 2b-3) within 3 NeVa passes without rescue
- Primary non-inferiority analysis (mITT population)
- Performance goal: 72% with non-inferiority margin of -10%

## PRIMARY SAFETY ENDPOINT

- All-cause mortality at 90 days and/or symptomatic ICH (sICH) at 24 hours post procedure (ECASS III)

## SECONDARY ENDPOINTS: (HIERARCHICAL TESTING)

- First pass eTICI 2b-3 with NeVa
- eTICI 2b-3 after all NeVa passes (no rescue)
- eTICI 2c-3 after all NeVa passes (no rescue)
- 90-day good outcome (mRS 0-2)

# METHODOLOGY

- mITT population was used for the analysis of efficacy endpoints:
  - All subjects that met eligibility criteria and used the 4.0x22mm, 4.5x29mm or the 5.5x37mm NeVa devices
  - N=107

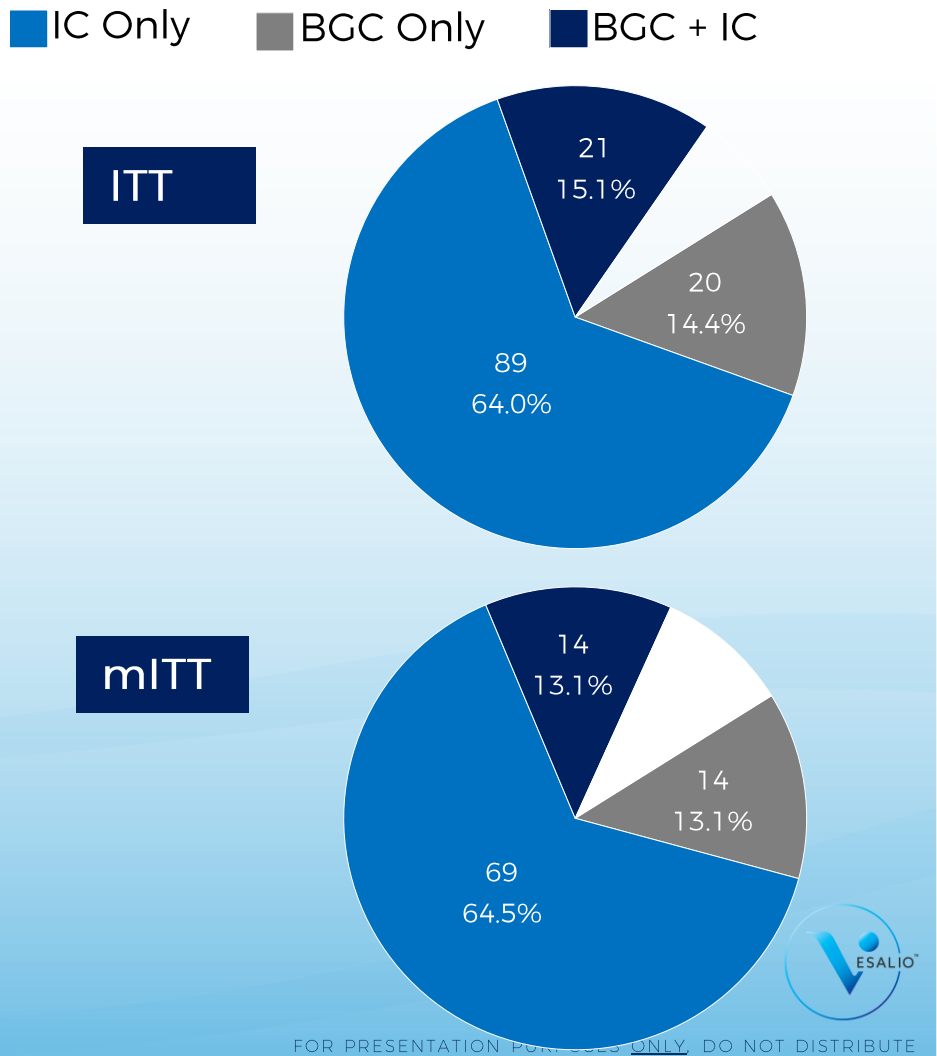
- ITT population was used for the analysis of safety endpoints
  - All subjects that got treated with the NeVa devices, including those that did not meet eligibility criteria
  - N=139

- Performance Goal (PG): defined using ARISE 2 and TIGER trials

# SUMMARY OF RESULTS

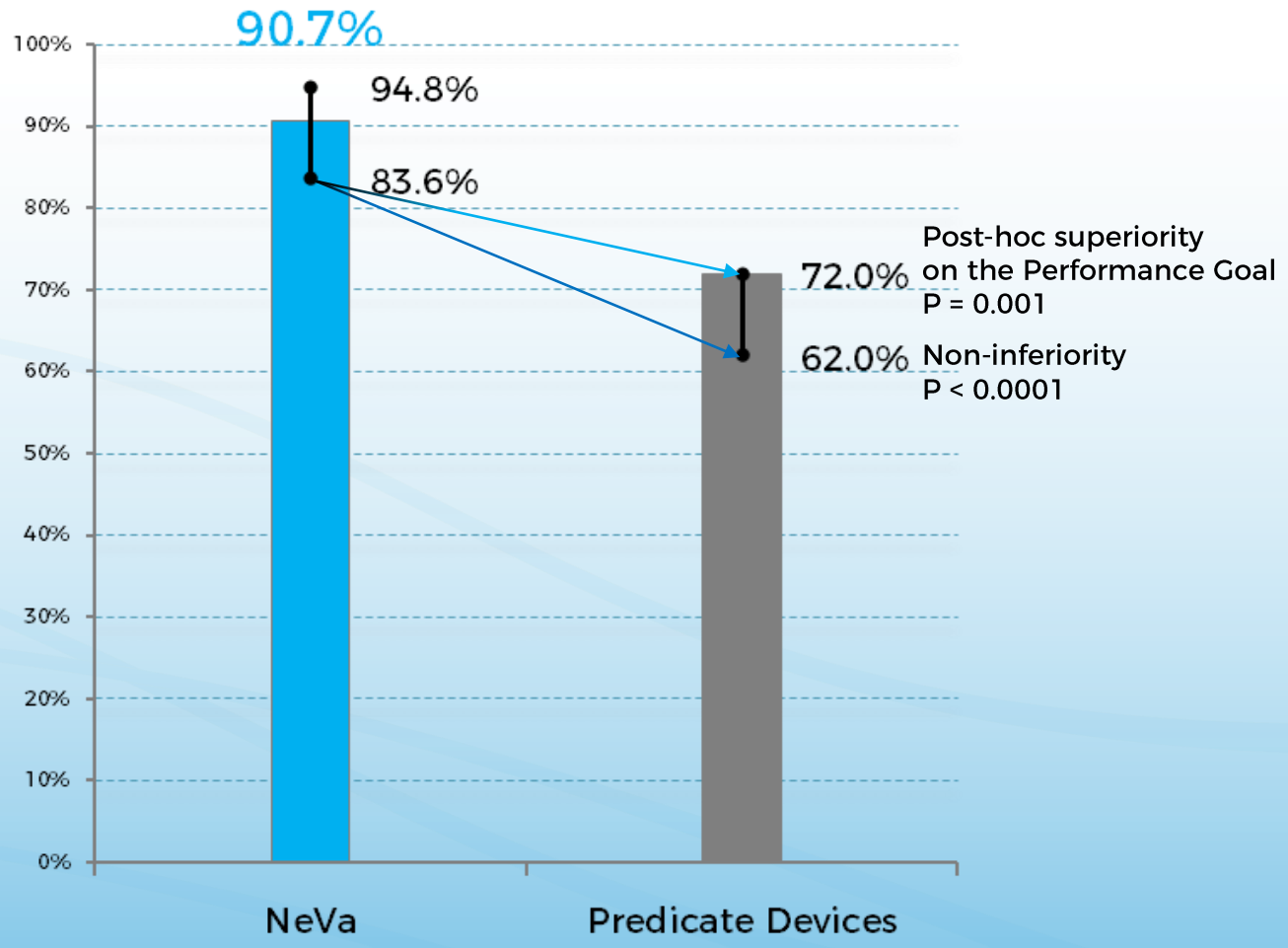
| PARAMETER | ITT/ SAFETY (n = 139) | mITT (n = 107) |
|---|---|---|
| **Age**, mean (SD) | 66.7 (12.8) | 65.1 (13.2) |
| **Baseline NIHSS**, median (IQR) | 16 (12-20) | 16 (12-20) |
| **Baseline CT ASPECTS**, median (IQR) | 9 (8-10) | 9 (8-10) |
| **IV tPA administration**, n (%) | 71 (51.1%) | 59 (55.1%) |
| **PROCEDURAL CHARACTERISTICS** | | |
| **Last known well to arterial puncture** min; median (IQR) | 202 (138-294) | 181 (131-252) |
| **Arterial puncture to first device pass** min; median (IQR) | 18 (11-25) | 18 (11-25) |
| **Procedure duration** min; median (IQR) | 32 (20-51) | 35 (22-52) |
| **PRIMARY OCCLUSIVE LOCATION** | | |
| **Intracranial ICA**, n (%) | 14 (10.1%) | 10 (9.3%) |
| **MCA-M1**, n (%) | 86 (61.9%) | 66 (61.7%) |
| **MCA-M2**, n (%) | 37 (26.6%) | 30 (28.0%) |
| **Basilar**, n (%) | 1 (0.7%) | 1 (0.9%) |
| **PCA**, n (%) | 1 (0.7%) | 0 (0.0%) |

## USE OF ANCILLIARY DEVICES FOR FLOW CONTROL



# eTICI 2B-3 WITHIN 3 PASSES

## Primary efficacy endpoint (mITT, n=107)




NeVa successfully demonstrated non-inferiority to the performance goal based on predicate devices (prespecified primary efficacy analysis)

NeVa further demonstrated post hoc superiority to the predicate performance goal

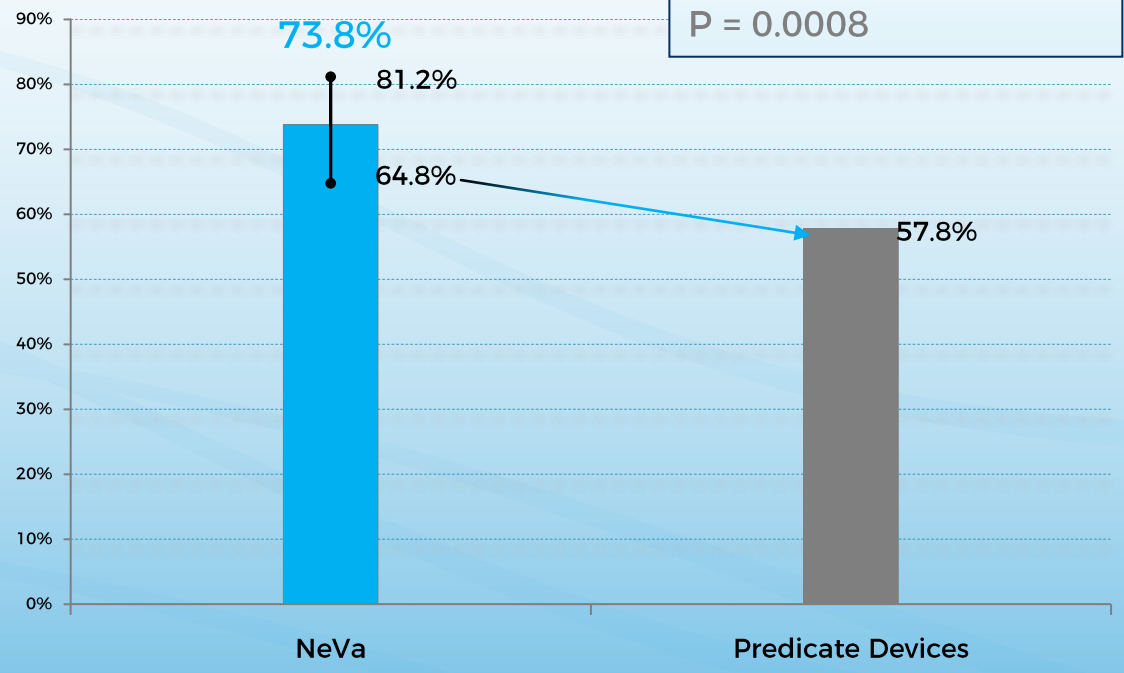
# FIRST-PASS REPERFUSION

## Key secondary efficacy endpoint (mITT, n=107)

**NeVa achieved a superior rate of first pass successful reperfusion compared to predicate devices** - prespecified secondary endpoint hierarchical testing

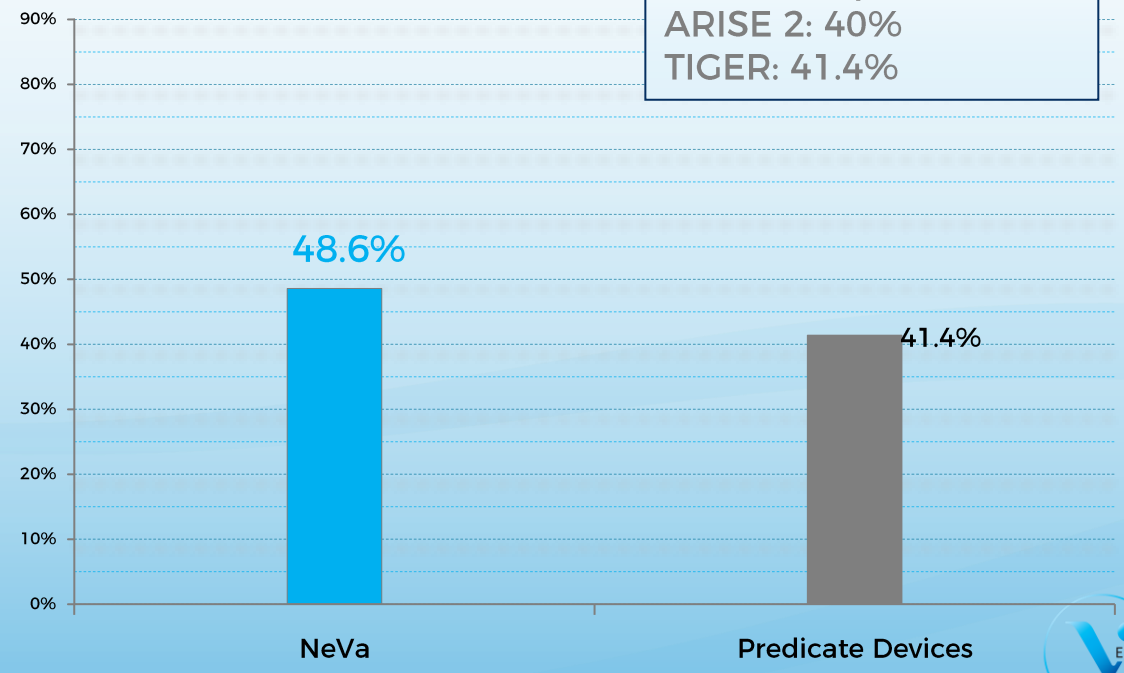
### SUCCESSFUL RECANALIZATION
### % eTICI 2B-3

Superiority on the Performance Goal
P = 0.0008




### EXCELLENT RECANALIZATION
### % eTICI 2C-3

Numerically higher than both predicates:
ARISE 2: 40%
TIGER: 41.4%



# FIRST-PASS REPERFUSION

Key secondary efficacy endpoint (mITT, n=107)

**NeVa achieved a superior rate of first pass successful reperfusion compared to predicate devices** - prespecified secondary endpoint hierarchical testing

**SUCCESSFUL RECANALIZATION**
% eTICI 2B-3

≈7.5/10

**EXCELLENT RECANALIZATION**
% eTICI 2C-3

≈5/10

# OTHER

## ADDITIONAL ANGIOGRAPHIC EFFICACY ENDPOINTS

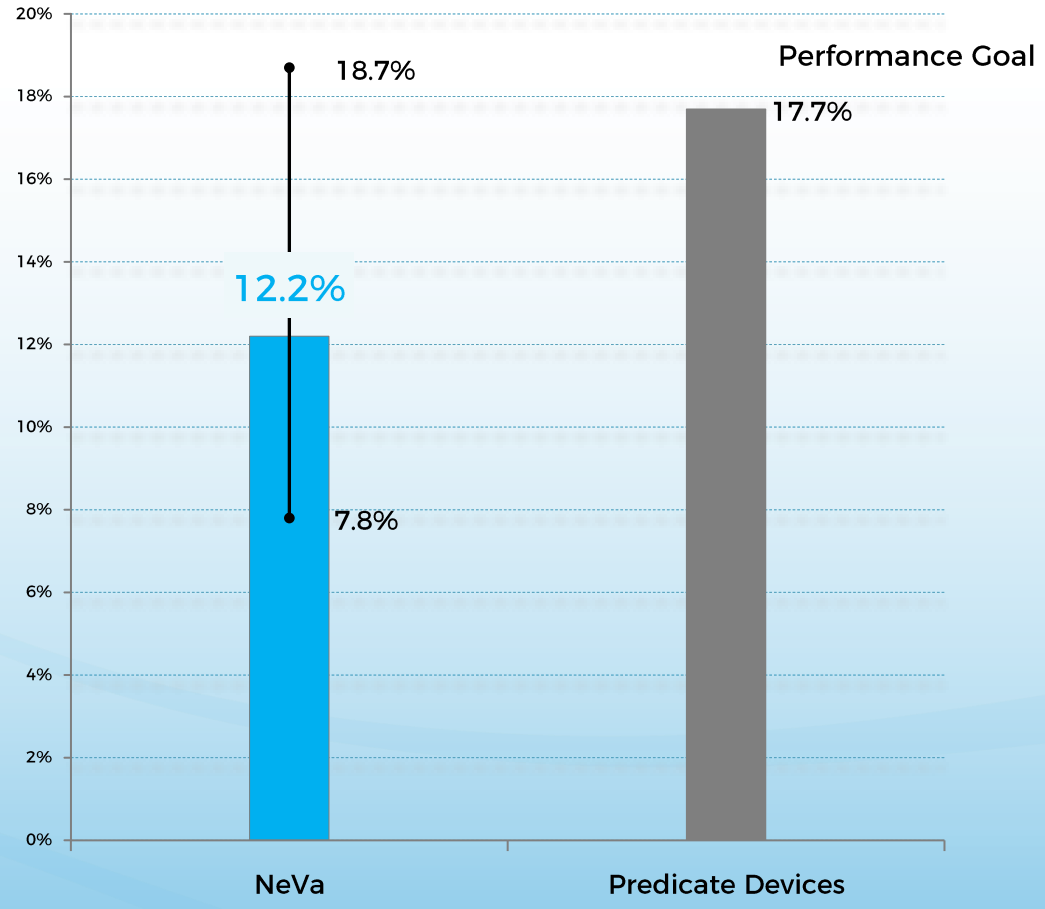
| | mITT (n = 107) | PREDICATE DEVICE VALUES | P VALUE |
|---|---|---|---|
| **Successful Reperfusion after all passes** (eTICI 2B-3) – n, % | 102 (95.3%) | 95.7% | 0.85 |
| **Excellent Reperfusion after all passes** (eTICI 2C-3) – n, % | 76 (71.0%) | 71.8% | 0.86 |

## PROCEDURAL STATISTICS

| | |
|---|---|
| **Use of Rescue Therapy** – n, % | 4 (3,7%) |
| **Time from arterial puncture to 1st device pass (min)**, median (IQR) | 18 (11 – 25) |
| **Procedure Duration (min)**, median (IQR) | 32 (20 – 51) |
| **Number of Passes**, median (IQR) | 1 (1 – 2) |

# COMPOSITE OF 90-DAY ALL-CAUSE MORTALITY AND/OR 24-H sICH

Primary safety endpoint (ITT, n=139)



# OTHER SAFETY ENDPOINTS

| Percent of subjects | ITT | 95% Confidence Interval |
|---|---|---|
| **deceased at Day 90** | 9.4% | 5.5% - 15.3% |
| **experiencing sICH at 24 hrs post-procedure** | 5.0% | 2.5% - 10.0% |
| **with > 4-point increase in NIHSS score at 24 hrs post-procedure** | 5.0% | 2.5% - 10.0% |
| **with > 4-point increase in NIHSS score at day 5-10/ Discharge** | 2.9% | 1.1% - 7.2% |
| **experiencing PRSAEs** (procedure-related serious adverse events) | 4.3% | |
| **experiencing DRSAEs** (device-related serious adverse events) | 3.6% | |

NeVa-related SAEs:

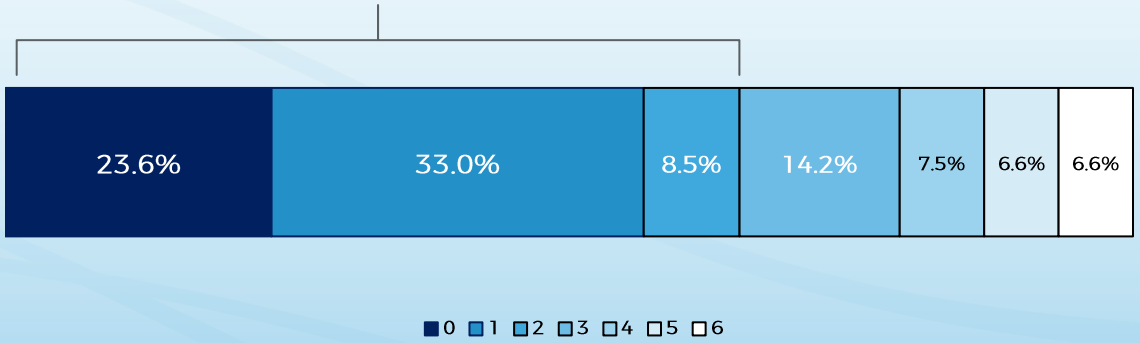
Vasospasm (2), aSAH (1),
SAH (2), vessel perforation (1)

# CLINICAL OUTCOMES

## 90-day outcomes with NeVa were superior to predicate studies in exploratory analysis

### 90-DAY MRS ≤ 2
(mITT, n=106)

**65.1%**
**vs. PG: 54.7%, P = 0.03**

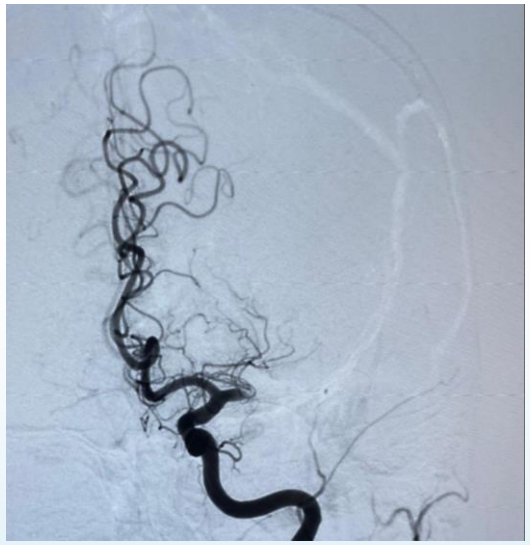


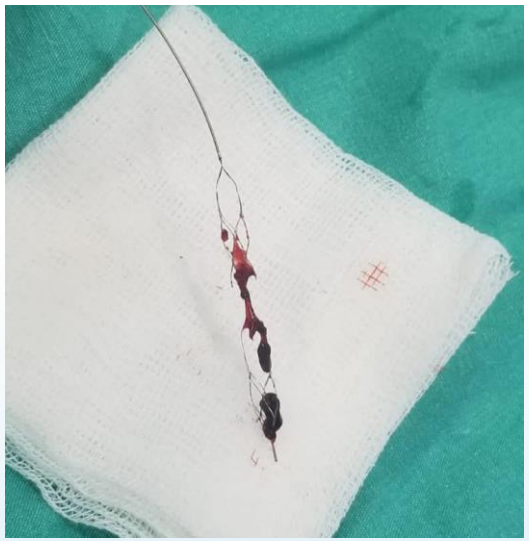

### OTHER CLINICAL OUTCOMES
(mITT, n=107)

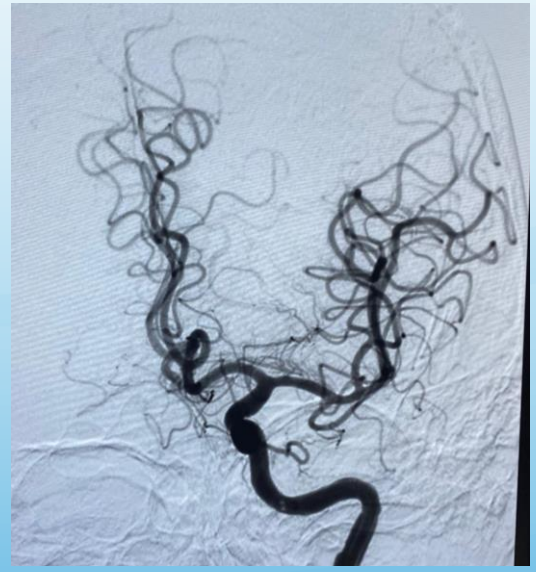
| | |
|---|---|
| **NIHSS at 24-hours**, median (IQR) | 4 (1-8) |
| **NIHSS change from baseline to 24-hrs**, median (IQR) | -10 (-15 to -5) |
| **NIHSS at 5-10 days or discharge**, median (IQR) | 2 (0-5) |
| **NIHSS change from baseline to 5-10 days or discharge**, median (IQR) | -11 (-17 to -8) |

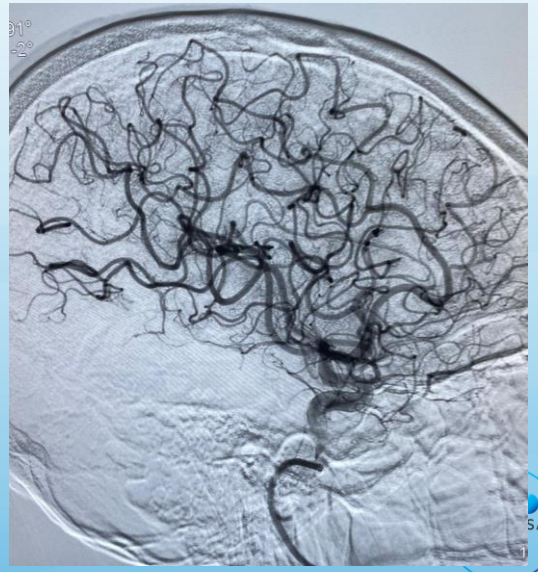
# CONCLUSION

- The CLEAR study demonstrates that the NeVa stent retrievers are effective and safe for the revascularization of LVOs in AIS
  - Substantial equivalence to predicate devices (eTICI 2b-3) in primary non-inferiority analysis
  - Statistically superior to predicate devices (eTICI 2b-3) in post hoc analysis
- Statistically superior to predicate devices for first pass successful reperfusion (eTICI 2b-3)
- Clinical outcomes at 90 days were superior to predicate studies in exploratory analysis









# EVALUATION

Designed for 1st PASS SUCCESS with ALL Clot Types

Neva™

VESALIO™

# 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

# NeVa™ 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 >

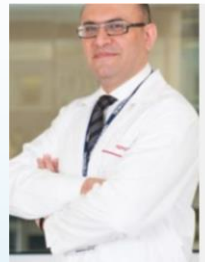
## SINGLE NEVA RESCUES KISSING RETRIEVERS

*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 >

# THANK YOU

Designed for 1st PASS SUCCESS with ALL Clot Types

Neva™

VESALIO™