Nevia™

DESIGNED FOR 1ST PASS SUCCESS WITH ALL CLOT TYPES

VESALIO & EXIMIA

are happy to welcome you to this

NeVa Induction Webinar

AGENDA:

- Why NeVa?
- Clinical Experience
- User Tips & Tricks
- Question & Answer Session

FIRST PASS SUCCESS GETS BETTER OUTCOMES

First Pass Effect - FPE (*full recanalization in the 1st Pass*) is the most powerful predictor of clinical outcome with best safety results

Zaidat et al., Journal of NeuroInterventional Surgery, 2015 → NASA* registry: 354 patients from 24 US centers

	First Pass Effect Group	Total Patient Population		
n	89 patients (*25% of total patient population*)	354 patients		**FPE: 25.1% of patients**
MCA occlusions	64.0%	52.5%		FPE more commonly observed in MCA occlusions
ICA occlusions	10.1%	27.7%		
BGCs use in the subgroup	64%	34.7%		FPE more commonly observed when balloon guide catheters were used
Median time to revascularization	34 min	60 min	*P=.0003*	Median time to revascularization was significantly faster in FPE group
mRS ≤ 2	**61.3%**	**35.3%**	*P=.013*	**Patient outcomes were significantly better in FPE group**

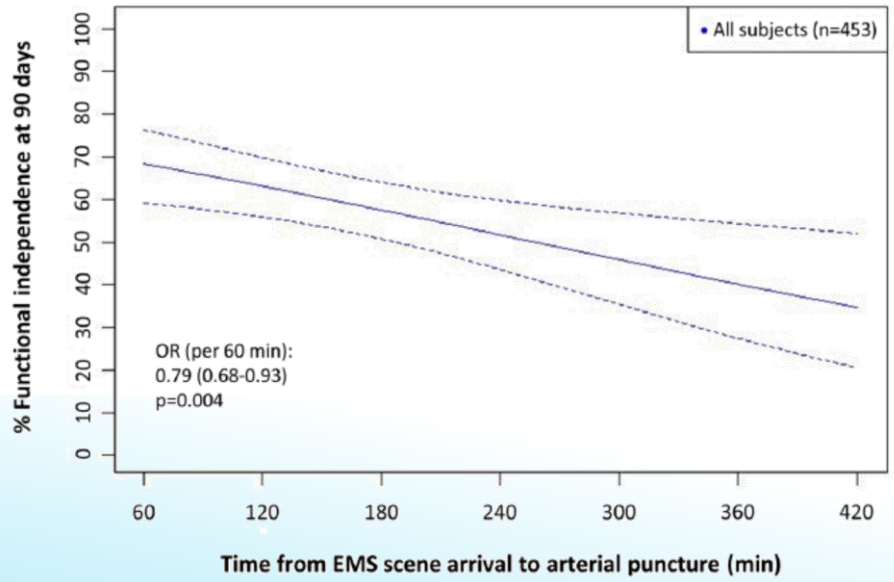
WHY DOES FIRST PASS SUCCESS GET BETTER OUTCOMES?

Faster recanalization: TIME is BRAIN

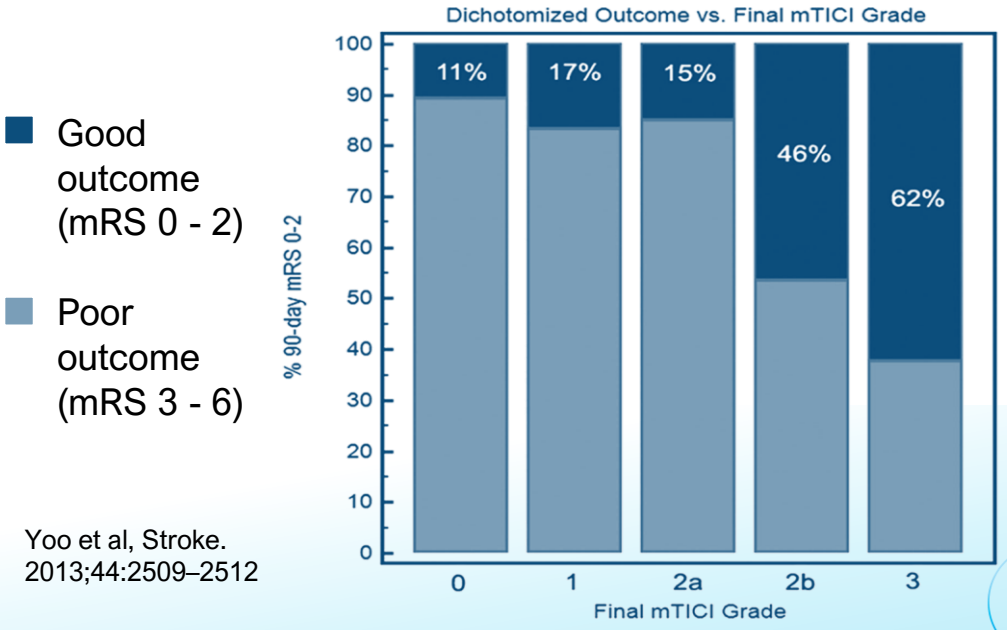
Lower complication rates

Impact of complete recanalization

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



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



Yoo et al, Stroke. 2013;44:2509–2512

WHY DEVELOP ANOTHER STENT-RETRIEVER

1
TREAT ALL OCCLUSIONS

FROM SOFT CLOTS
THAT EASILY DISINTEGRATE
TO HARD, FIBRIN-RICH CLOTS
THAT ARE IMPENETRABLE

2
IMPROVE PROCEDURAL PERFORMANCE

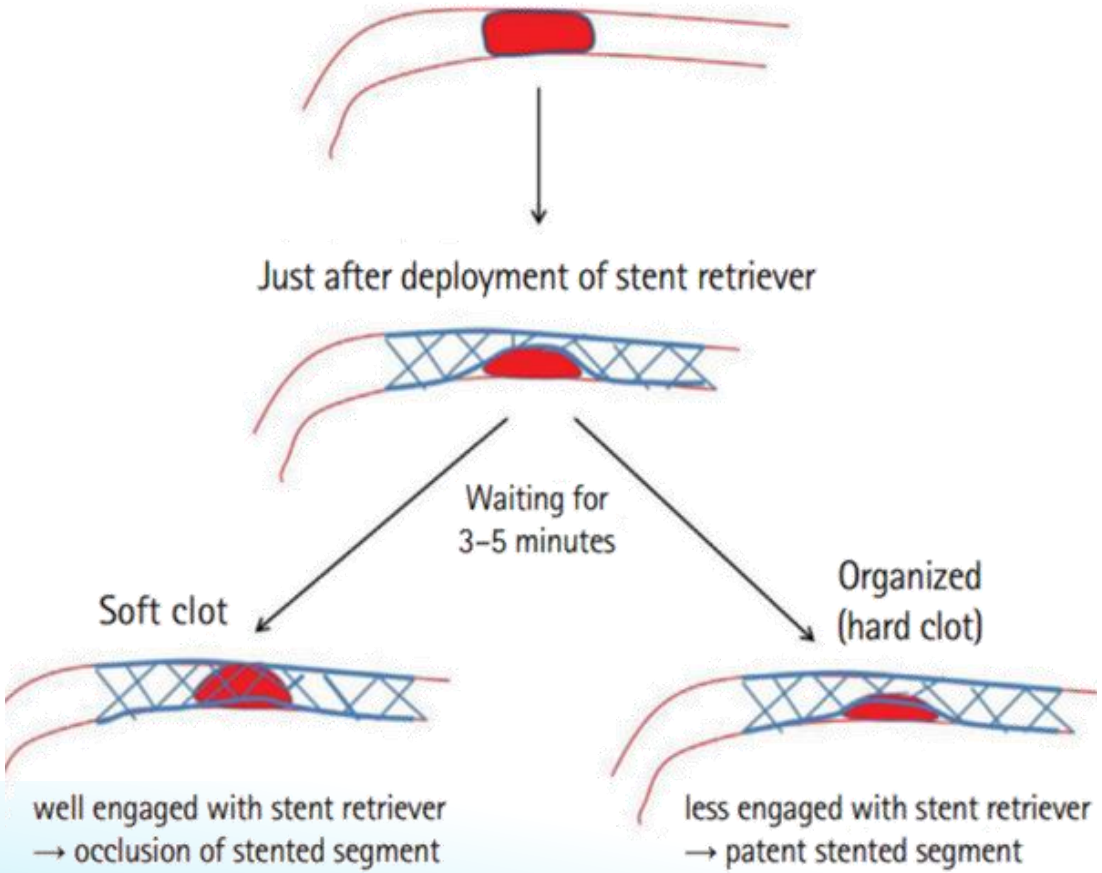
1ST PASS SUCCESS
TIME TO RECANALIZATION
HIGHER TICI 2C/3 RATES

3
PROVIDE EASE OF USE

REAL TIME FEEDBACK
DURING RETRIEVAL
SYNERGISTIC WITH ALL
ACCESS PHILOSOPHIES

TO ACHIEVE BETTER PATIENT OUTCOMES

CAUSES OF ENDOVASCULAR TREATMENT FAILURE



An organized *(hard, fibrin-rich)* clot is more resilient and less sticky than fresh *(soft, red blood cell-rich)* clots, **causing less engagement with a stent retriever and leading to clot missing during retrieval**, especially in the case of a tortuous arterial tree.

Furthermore, because an organized clot may cause more tension in the stent-retriever deployed segment of the parent artery, this **can also likely induce an arterial spasm**.

Byung Moon Kim, Causes and Solutions of Endovascular Treatment Failure, Journal of Stroke 2017;19(2):131-142. Published online: May 31, 2017

CAUSES OF ENDOVASCULAR TREATMENT FAILURE

During experimental evaluation of stent retrievers' mechanical properties and effectiveness, differences were observed in their interaction with white versus red clots:

FINDINGS:

- **Large white clots: could not be removed at all**
- **Smaller white clots:** variable results, clot was engaged - then disengaged and rolled between the device and the vessel wall
- **Red clots:** showed a tendency to fragment causing distal embolization
- Device's ability to maintain a constant radial pressure and wall apposition during retrieval played an important role

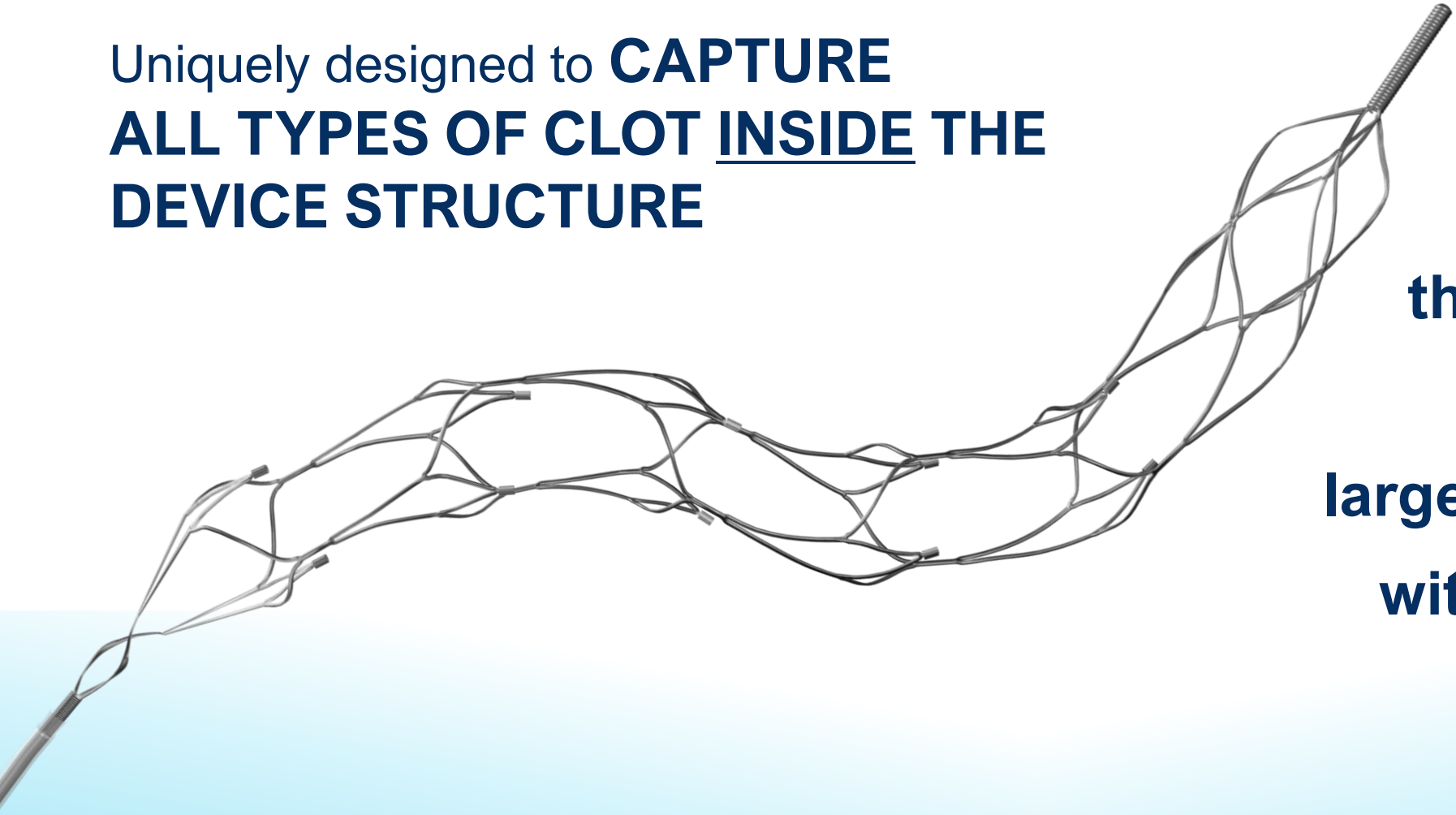
*"Devices did not expand when interacting with large white clots (6 mm). They remained constrained between the clot and the vessel wall. During retrieval, **devices slided over the clot without capturing it**. None of the devices tested could penetrate and remove large white thrombi."*

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

Machi P, et al., "Experimental evaluation of stent retrievers' mechanical properties and effectiveness", 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

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

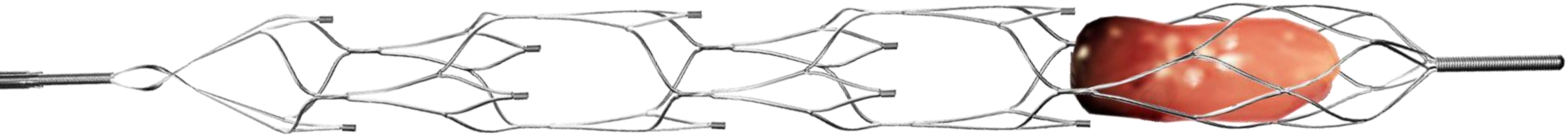


the DROP ZONES™
allow the capture of
large, organized thrombi
within the NeVa basket

A DESIGN TARGETING FIRST PASS SUCCESS

DROP ZONES™

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



CLOSED DISTAL TIP

Clot gets inside, clot stays inside!

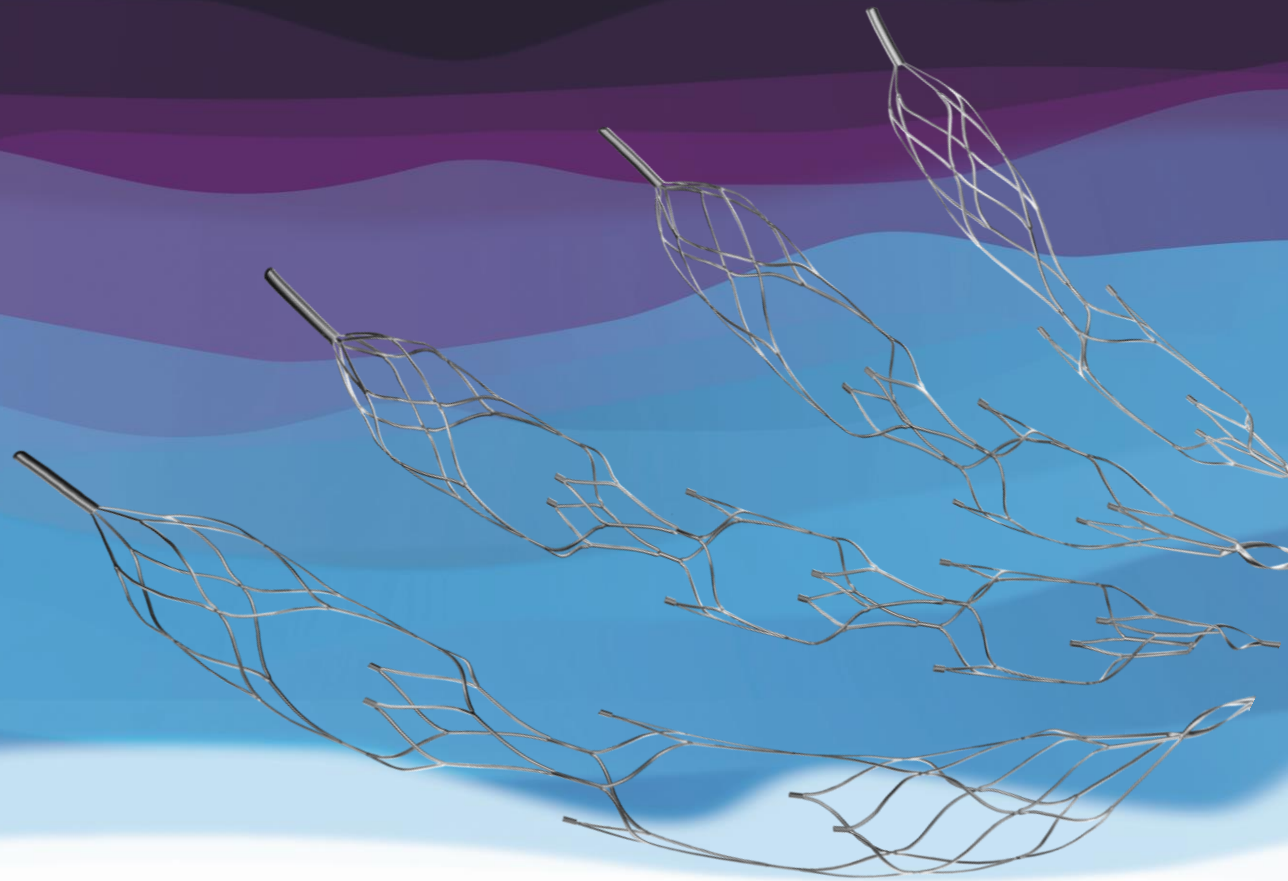
SMART MARKERS

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

BALANCED DESIGN

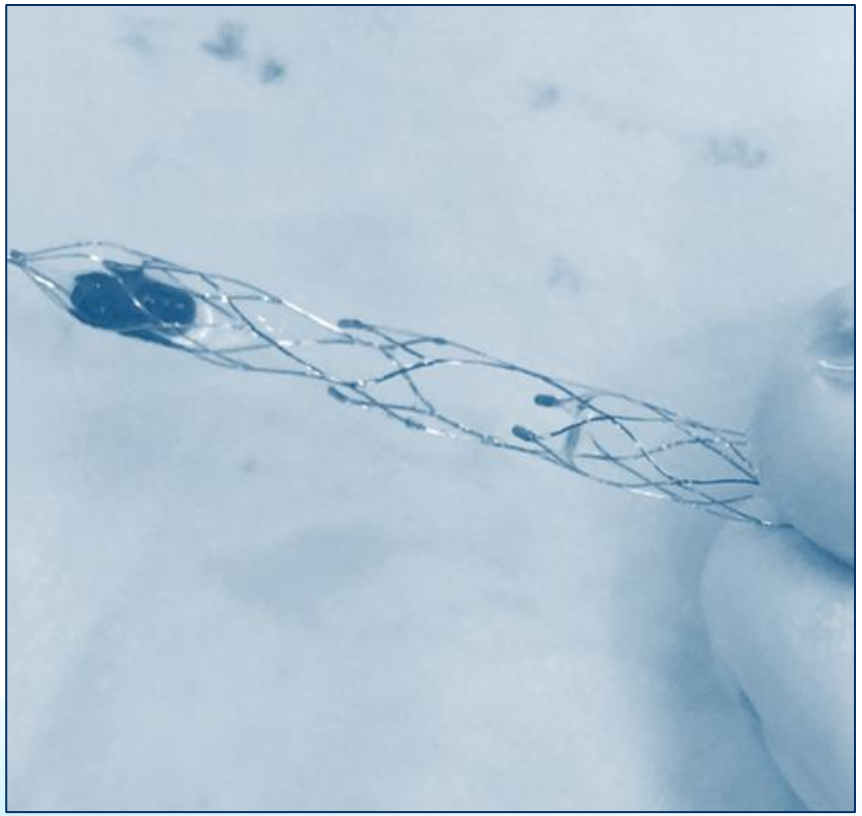
Optimized radial force balanced with large openings & closed ends

Clinical Experience with the NeVa™ thrombectomy device



97% RECANALIZATION SUCCESS WITH 1.2 PASSES ACROSS ALL CLOT TYPES

ANIMAL LAB RESULTS



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

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

CONSISTENT EFFECTIVENESS AT REMOVING ORGANIZED (WHITE) CLOTS

IN VITRO RESULTS

The same set up was used to test NeVa with large, hard clots:

2. Machi P, et al., 2018

- **NeVa: 6/10 successful complete removals of white thrombi ≥ 6 mm**
- The main difference versus other devices: Drop Zones, allowing for the lateral integration of clots
- The Neva devices demonstrated good wall apposition and resisted stretch related deformation during retrieval
- NeVa radial pressure values appear slightly higher in comparison to those of other stent retrievers

1. Machi P, et al., 2016

*""Devices did not expand when interacting with large white clots (6 mm). They remained constrained between the clot and the vessel wall. During retrieval, **devices slided over the clot without capturing it**. None of the devices tested could penetrate and remove large white thrombi."*

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2. 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. April 2018

USED AS FIRST LINE TREATMENT ON "ALL COMERS"

NeVa™

CLINICAL RESULTS
MULTI CENTER EXPERIENCE

30 patients

	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**

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

VESALIO™

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

USED AS FIRST LINE TREATMENT ON CONSECUTIVELY TREATED LVOS

NeVa™

CLINICAL RESULTS
MULTI CENTER EXPERIENCE

118 patients

	2B/3	2C/3
First Pass	61/80 → **56.8%**	46/80 → **44.9%**
Final Recanalization	77/80 → **95.8%**	

Median # of passes for final recan → **1** (IQR 1–2)

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

USED AS FIRST LINE TREATMENT ON ANTERIOR OCCLUSIONS

NeVa™

CLINICAL RESULTS
SINGLE CENTER EXPERIENCE

80 patients

	2B/3	2C/3	
First Pass	61/80 → **76.3%**	46/80 → **57.5%**	Average # of passes for final recan → **1.6**
Final Recanalization	77/80 → **96.3%**	72/80 → **90.0%**	

Safety Data

No NeVa related intra-procedural complications

- Difficulty of navigation via the MC due to significant tortuosity: 3.7%
- Mild asymptomatic SAH at 24hr follow up: 2.5%
- Asymptomatic petechial hemorrhage (HT1): 15%
- HT-2: 1.2%
- Parenchymal hemorrhage (PH-1): 1.2%

Patient Outcomes

Mean NIHSS @ 24 hours: **7 (*Range:* 0-33)**

30-day mRS ≤ 2 **51/80 (65%)**

obtained in 64 of 80 patients

90-day mRS ≤ 2 **55/80 (68.7%)**

obtained in 66 of 80 patients

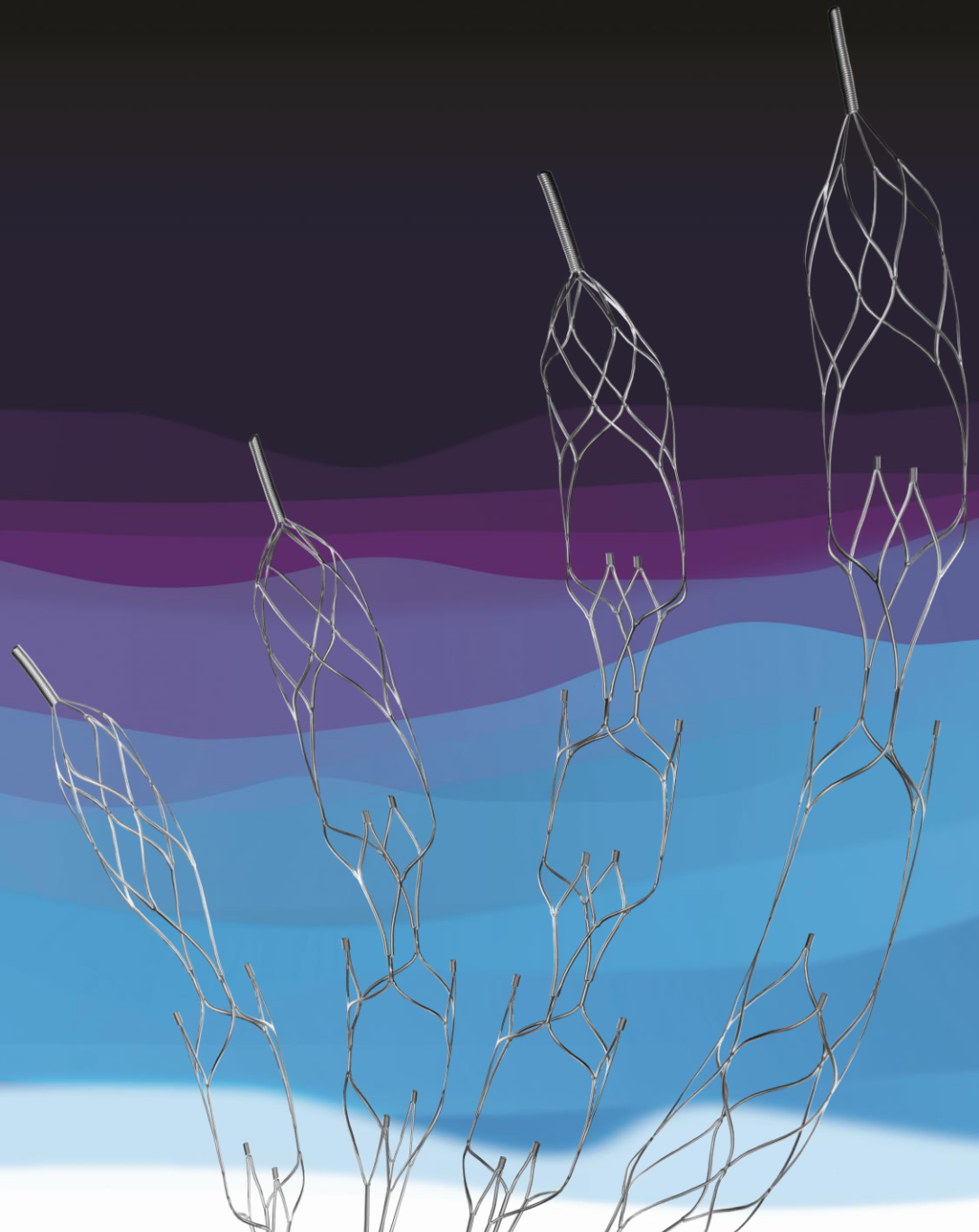
VESALIO™

S. Geyik, Presented at iCureStroke 2020, Submitted and pending publication

Nevia™

DESIGNED FOR **1ST PASS SUCCESS**
WITH **ALL CLOT TYPES**

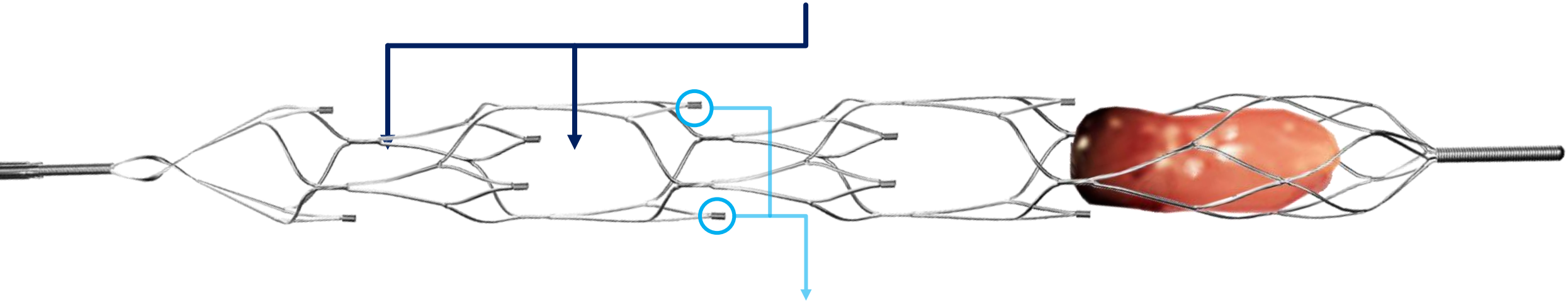
DROP ZONE TECHNIQUE™



NEVA THROMBECTOMY DEVICE

DROP ZONES™

2 or more Drop Zones offset at 90° work by acting as clot pockets: for lateral integration of clot inside the device structure



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!

#DoTheDropZone

1. Choosing the correct NeVa size
2. Positioning NeVa
3. Retrieving NeVa

CHOOSING THE CORRECT NEVA SIZE

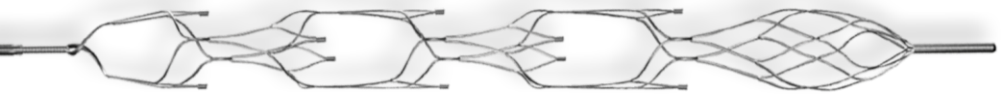
NeVa 4.0 x 22 mm, 2 Drop Zones

Vessel diameters 2.0 – 3.5 mm
Ideal for MCA, ACA, PCA
Compatible with: 0.021” MC
Full length: 39 mm

NeVa 4.5 x 29 mm, 3 Drop Zones

Vessel diameters 2.0 – 4.5 mm
Ideal for ICA Tip, Proximal MCA, Basilar
Compatible with: 0.021” MC
Full length: 46 mm

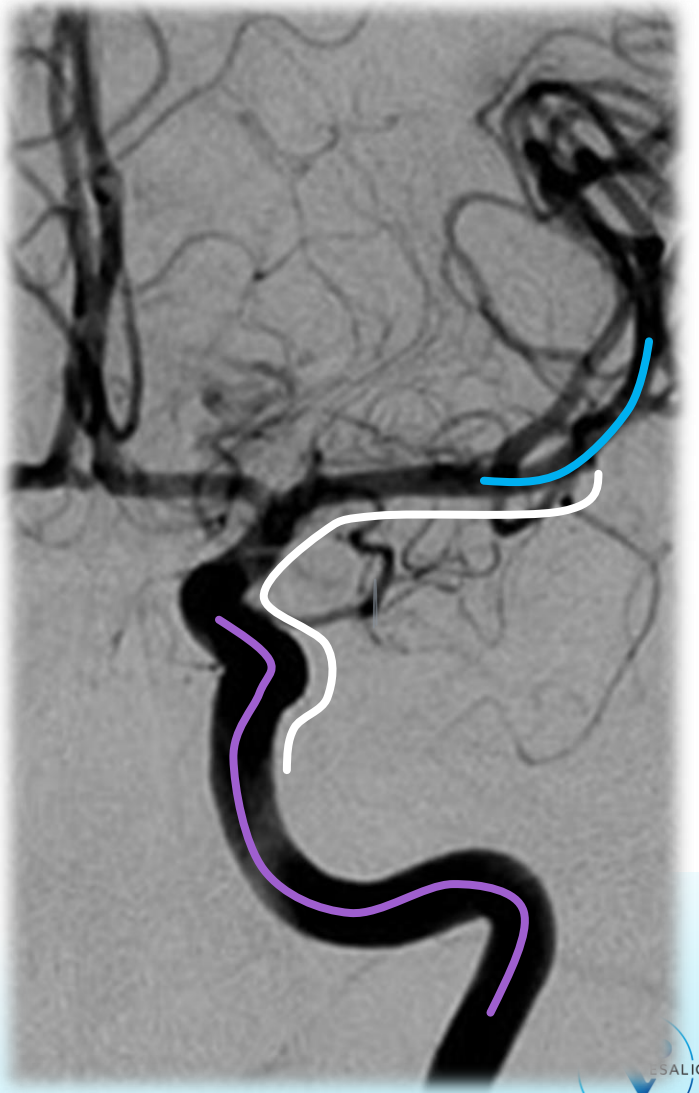
NeVa 4.5 x 44 mm, 5 Drop Zones



Vessel diameters 2.0 – 4.5 mm
Ideal for ICA Tip, Proximal MCA
Ideal for long occlusions, high clot burden
Compatible with: 0.021” MC
Full length: 61 mm

NeVa 6.0 x 44 mm, 3 Drop Zones, Flow Restoration Zone

Vessel diameters 3.5 – 6.0 mm
Ideal for Proximal Carotid Artery
Ideal for large, proximal arteries
Compatible with: 0.027” MC
Full length: 63 mm



IDEAL POSITIONING

Ideally we want: **Multiple Drop Zones to interact with clot**

And we need to: **Balance the benefit and risk of distal placement**

To achieve this: **Deploy NeVa with the 1st or 2nd marker at the edge of the occlusion**

IDEAL POSITIONING
EXAMPLE WITH NEVA 4.5 X 29 MM

Ideally we want: **Multiple Drop Zones to interact with clot**

And we need to: **Balance the benefit and risk of distal placement**

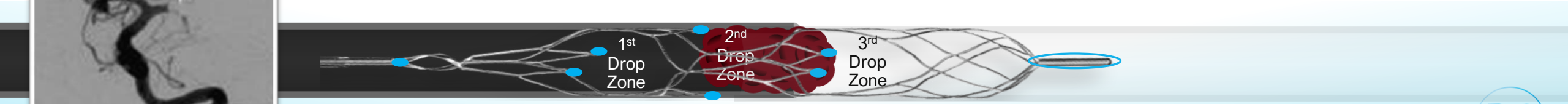
To achieve this: **Deploy NeVa with the 1st or 2nd marker at the edge of the occlusion**

Example:
4.3 mm vessel,
1 cm clot

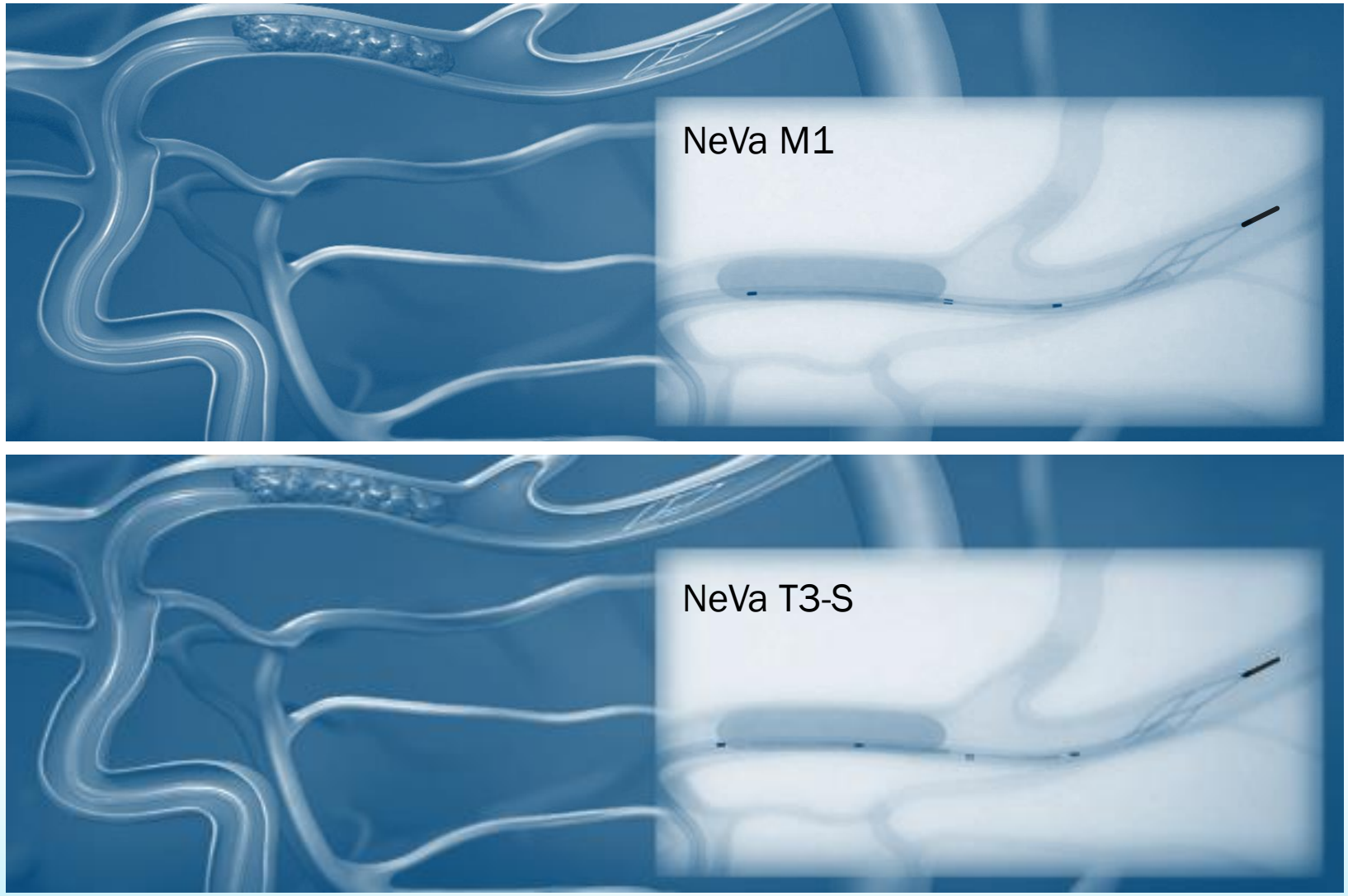
The first or second marker at the edge of the occlusion

Minimum 2 Drop Zones interacting with clot

A Drop Zone deployed proximal to clot: **LESS THAN IDEAL**



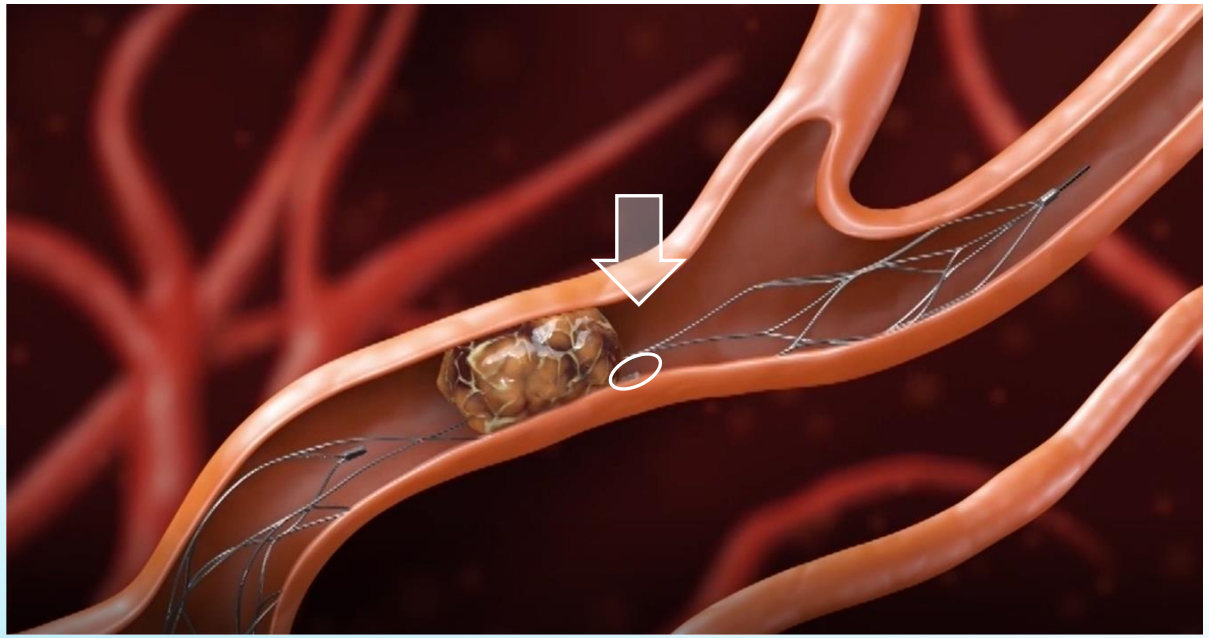
EXPECT INITIAL ANCHORING AFTER 1CM OF UNSHEATHING



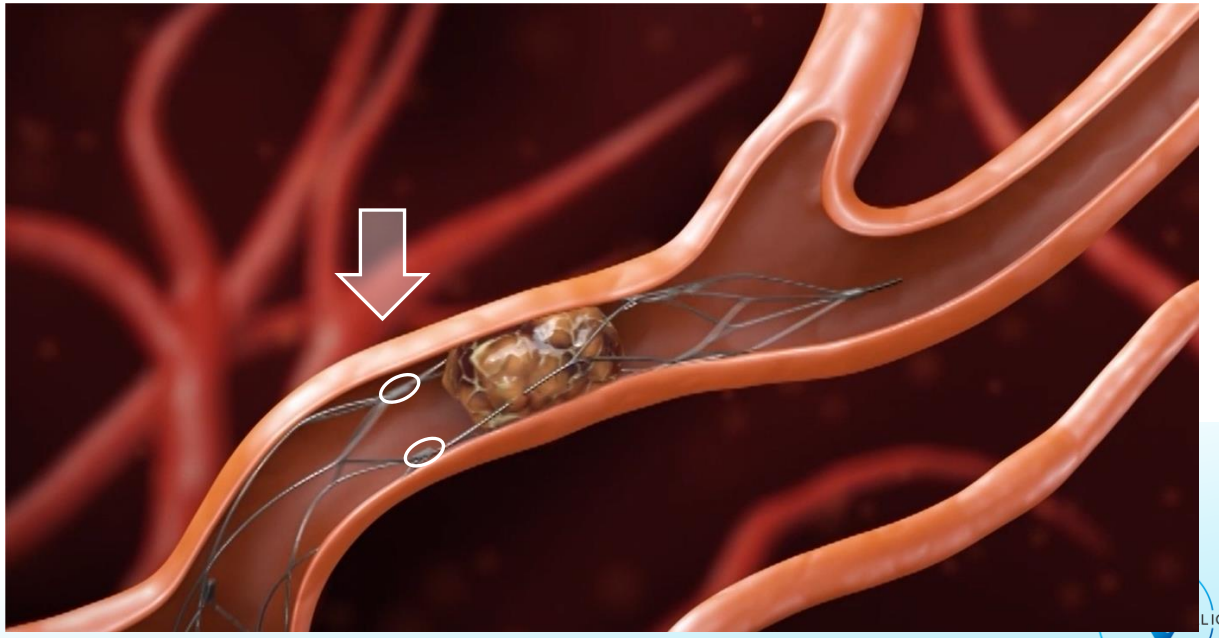
USING THE DROP ZONES TO INCORPORATE CLOTS

Drop Zone markers will get compressed when NeVa is passing next to a hard, calcified clot in the vascular system

Markers compressed together:
YOU MAY BE ADJACENT TO A HARD CLOT:
SLOW DOWN!



Markers spring open:
YOU MAY NOW BE AT THE PROXIMAL EDGE OF THE HARD CLOT:
THE DROP ZONE IS ON THE CLOT



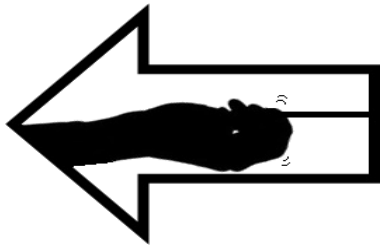
USING THE DROP ZONES TO INCORPORATE CLOTS

Slow and alert retrieval is recommended

POSITION CORRECTLY

Deploy the device with the 1st or 2nd marker at the occlusion

You do not need wait



START SLOW PULL

Apply slow & gentle vessel straightening traction

WATCH THE SMART MARKERS

Watch Drop Zone markers, observe if one of the pairs is compressing on one another

GENERAL RECOMMENDATIONS

The following recommendations are not specific to NeVa

MICROCATHETER CONSIDERATIONS

Choose

micro-catheters with

sufficient distal support,

especially in tortuous cases

Flush

NeVa

before insertion

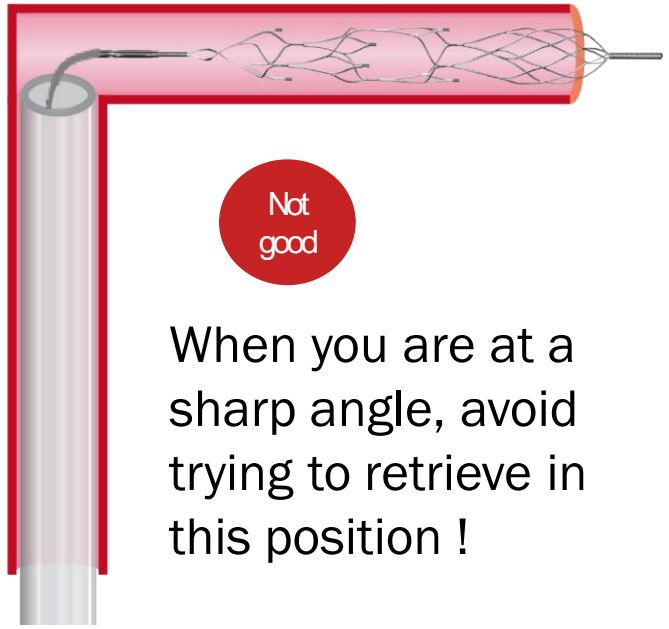
Release tension

on the micro-catheter

just before starting the

deployment (unsheathing)

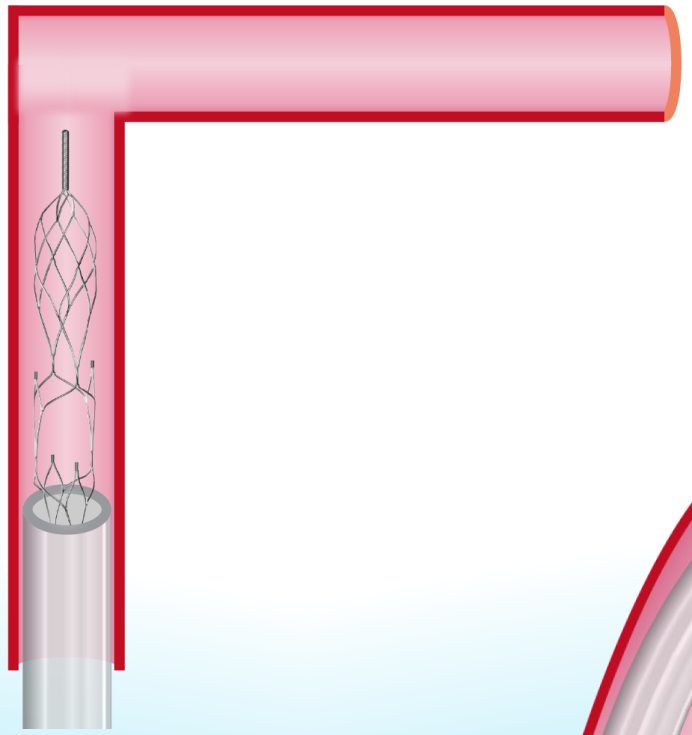
AT SHARP ANGLES



When you are at a sharp angle, avoid trying to retrieve in this position !

OPTION 1:

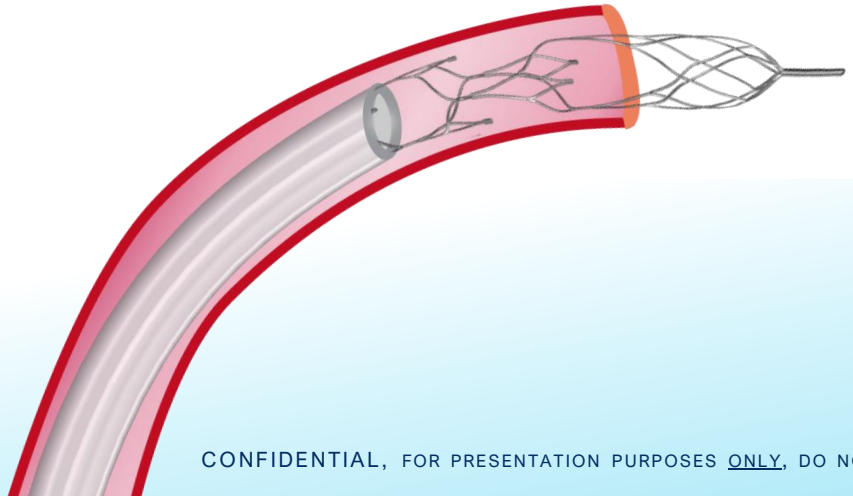
Bring NeVa proximally towards the DAC and align NeVa with the tip of your DAC



OPTION 2:

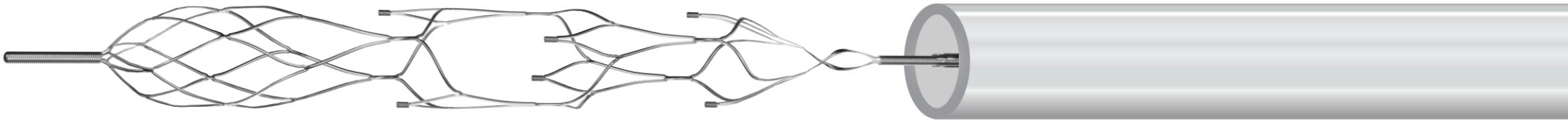
Use NeVa as an anchor, and drive up your DAC

1. Straightening the anatomy eases retrieval
2. Avoids clot fragmentation
3. Aspiration via DAC will be more efficient

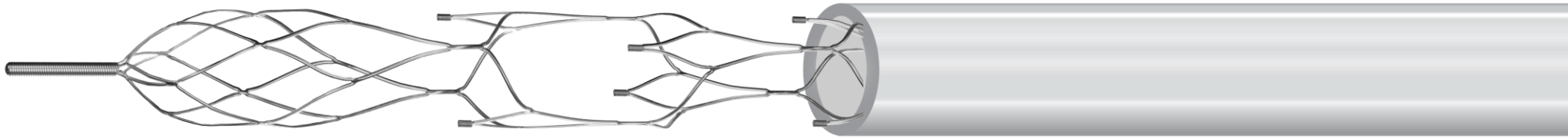


WHEN LARGE CLOT BURDEN IS SUSPECTED: PARTIAL RETRIEVAL TECHNIQUE

After deploying NeVa, bring the DAC tip up to the proximal marker



Remove excess tension from the DAC and slowly retrieve NeVa. If significant resistance is encountered, stop retrieval. Clot is likely partially incorporated and trapped between stent and DAC.



- Tighten the RHV of DAC around the MC and retrieve the whole system together (DAC+MC+NeVa) while gently aspirating

RECAP

1. Choose correct NeVa size
2. Flush before use
3. Position NeVa as recommended
4. Release tension on the microcatheter before unsheathing
5. Apply slight forward pressure on the pusher wire during unsheathing until NeVa anchors in the vessel
6. Take your time in deploying Neva to take advantage of the Drop Zones
7. Retrieval should be slow and gently: Watch the Drop Zone markers
8. At sharp angles: use NeVa as anchor and drive up your DAC to straighten the anatomy or pull NeVa down to the DAC
9. When combined with aspiration: If you feel a resistance, take the whole system out together to avoid clot shearing/ tooth paste effect

Question & Answer Session

THANK YOU