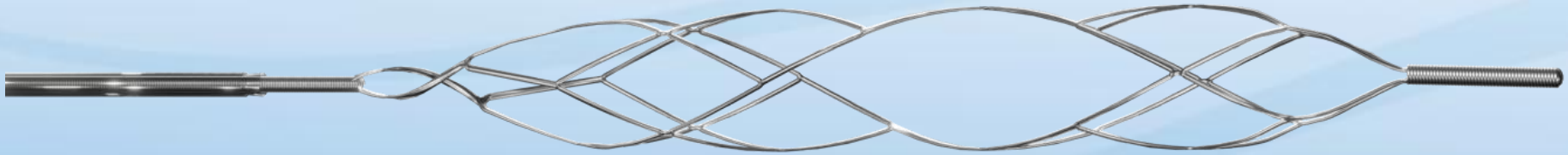
Neva™ VS

A DEFINITIVE SOLUTION

for post aSAH cerebral vasospasm



INDICATION FOR USE – CE

Endovascular temporary use to restore blood flow in patients who are experiencing:

- symptoms of an **acute ischemic stroke caused by an embolus** in a cerebral vessel
- reduced blood flow in cerebral vessels due to **acute phase of vasospasm**

- The intended population of patients for the NeVa System consists of persons that have been diagnosed with an acute ischemic stroke from a thromboembolic event and patients who are experiencing symptoms of thrombosis in the coronary vasculature.
- The intended population of patients for the NeVa VS variant also consists of persons who have aSAH and who develop delayed symptomatic cerebral vasospasm. **Endovascular embolization or surgical clipping of the aneurysm should be performed prior to the use of NeVa VS.**

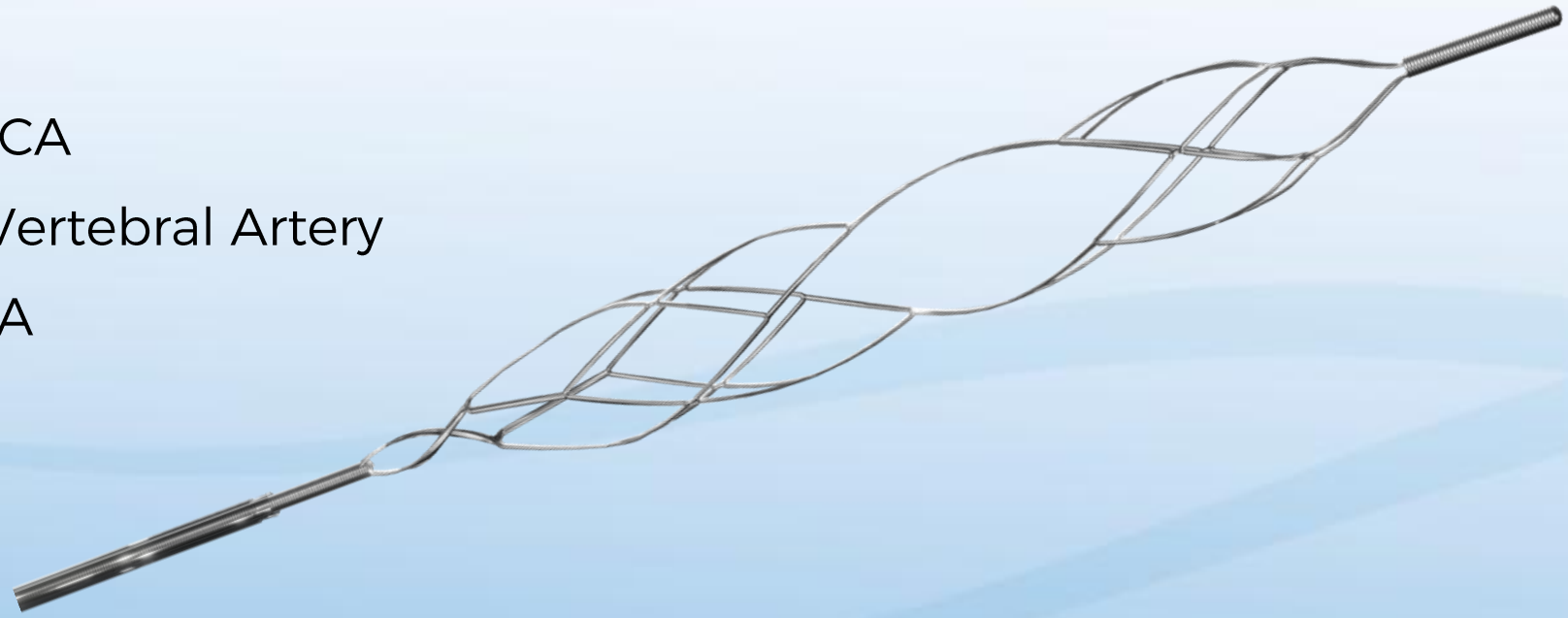
CONTRAINDICATIONS – CE

- Coma
- CT/MRI scan reveals significant mass effect with midline shift (ischemic stroke
- only)
- Delivery of pharmacological agents not routinely used to treat ischemic stroke or
- thrombosis in the coronary vasculature
- Do not use the device in calcified lesions
- Evidence of rapidly improving neurological signs of stroke (for ischemic stroke interventions)
- Excessive vessel tortuosity that prevents the placement of the device
- Glucose <50mg/dl
- Known hemorrhagic diathesis, coagulation factor deficiency or oral anticoagulant therapy with INR>3.0
- Patient has baseline platelets <30,000
- Patient has severe sustained hypertension
- Patient presents with nickel allergy
- Patient received heparin within 48 hours with a PTT greater than 2 times the lab normal
- Patients with suspected or known allergies to contrast media
- Patient's angiogram shows an arterial stenosis >50% proximal to the embolus
- Pre-existing neurological or psychiatric disease
- Pregnancy
- An unsecured, ruptured intracranial aneurysm.
- Large territory completed cerebral infarction, edema with mass effect and intra-parenchymal hemorrhage in vascular territory to be treated.
- Patients 18 years of age or younger

TARGET VESSELS

Vessels with pre-vasospasm diameter ≥ 2.0 mm and ≤ 4.0 mm:

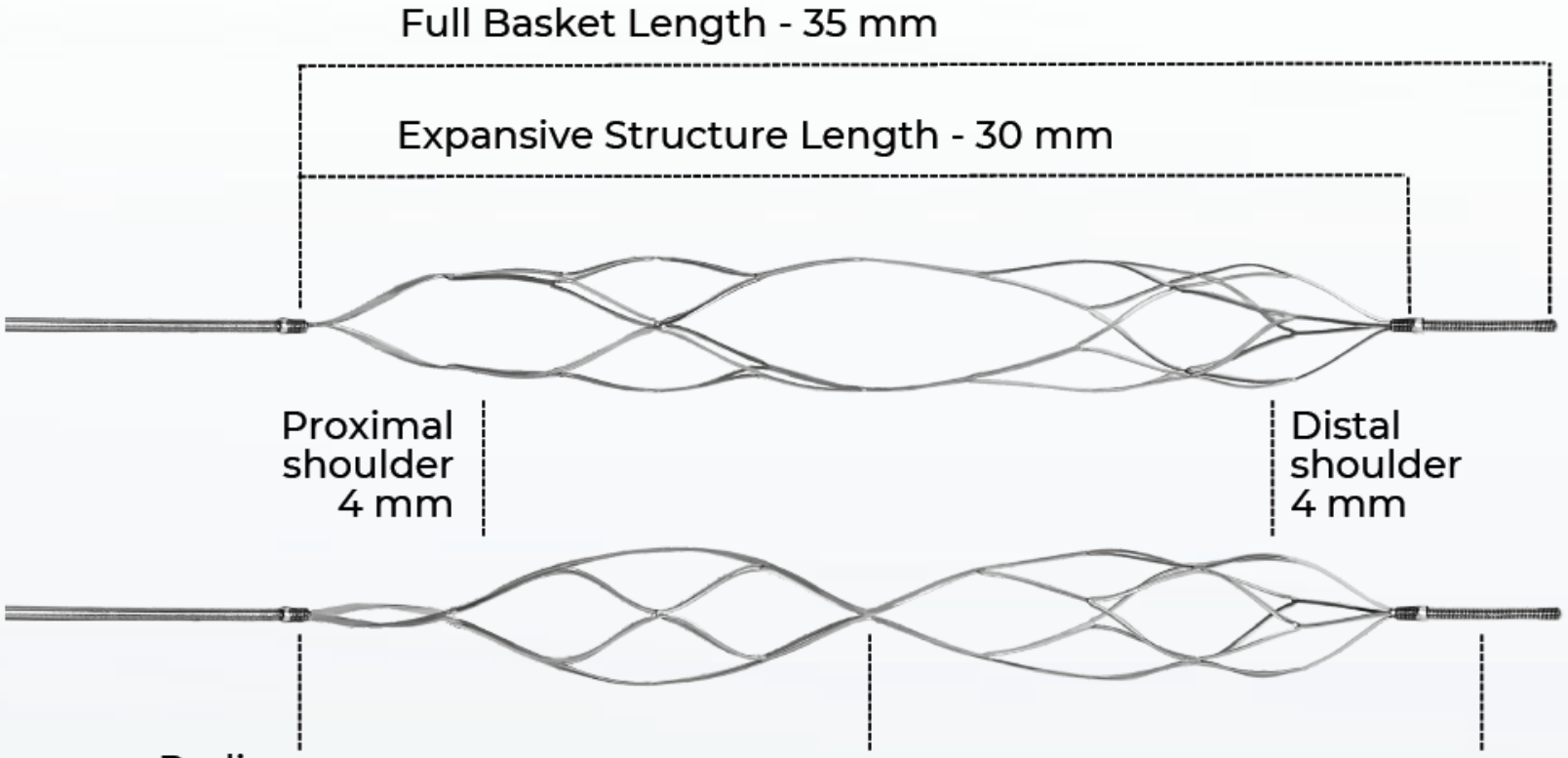
- M1 and M2 branches of the MCA
- ACA
- Intracranial ICA
- Intracranial Vertebral Artery
- P1 of the PCA
- Basilar



NEVA VS: DEVICE DESCRIPTION

- Leveraged from stent-retriever technology and specifically designed as a retrievable stent to treat aneurysmal SAH induced vasospasm
- Comprised of :
  - Nitinol self-expanding stent structure
  - Nitinol pusher wire
- Presented in an introducer sheath
  - When firmly seated in hub of MC, the introducer allows for smooth delivery of the NeVa VS into the micro-catheter

NEVA VS: SELF EXPANDING STENT STRUCTURE

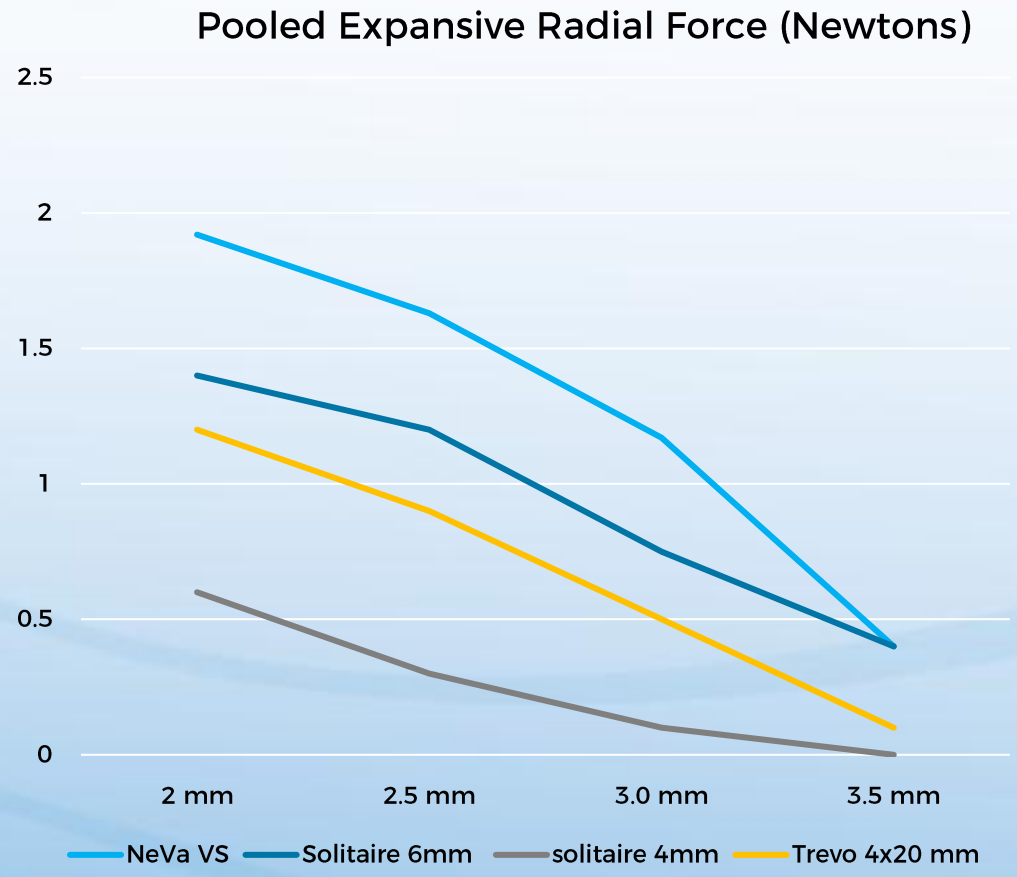


Maximal Diameter	Pusherwire		Microcatheter Compatibility	Indicated for
	Size	Length		
4.0 mm	0.018"	200 cm	0.021"	Vessel sizes of 2 - 4 mm

NEVA VS: USER INSTRUCTIONS

- The self expanding nitinol structure is deployed across the vessel segment experiencing vasospasm
- Central flex zone provides enhanced flexibility & maneuverability especially if the vasospasm is occurring in a branched segment
- Radiopaque markers at proximal & distal ends provide enhanced fluoroscopic visibility and safety
  - Hyper-flexible, a-traumatic distal tip (5mm)
  - Proximal marker (1mm)

NEVA VS: RADIAL FORCE



Greater expansive radial force at every diameter of expansion across the indicated range

NEVA VS: MATERIAL

Description	Material	OD	Length
NeVa VS Expandable Tip	Nitinol	4 mm	35 mm
Distal Radiopaque Tip	92% platinum/ 8% tungsten	≤ .020”	5 mm
Proximal Radiopaque Marker	92% platinum/ 8% tungsten	≤ .020”	1 mm
Body coil with	304V stainless steel	≤ .020”	23 cm
PET heat shrink over the coil	Polyethylene terephtahalate		
Wire inside coil to strengthen distal marker	Nitinol		
Introducer Sheath	HDPE	ID = .0265” OD = .040”	40” (101.6 cm)
Pusher Wire	Nitinol	Proximal OD = .018” Distal OD = .005”	200 cm
Solders	Light cure epoxy over gold solder joints for support and smooth surface		

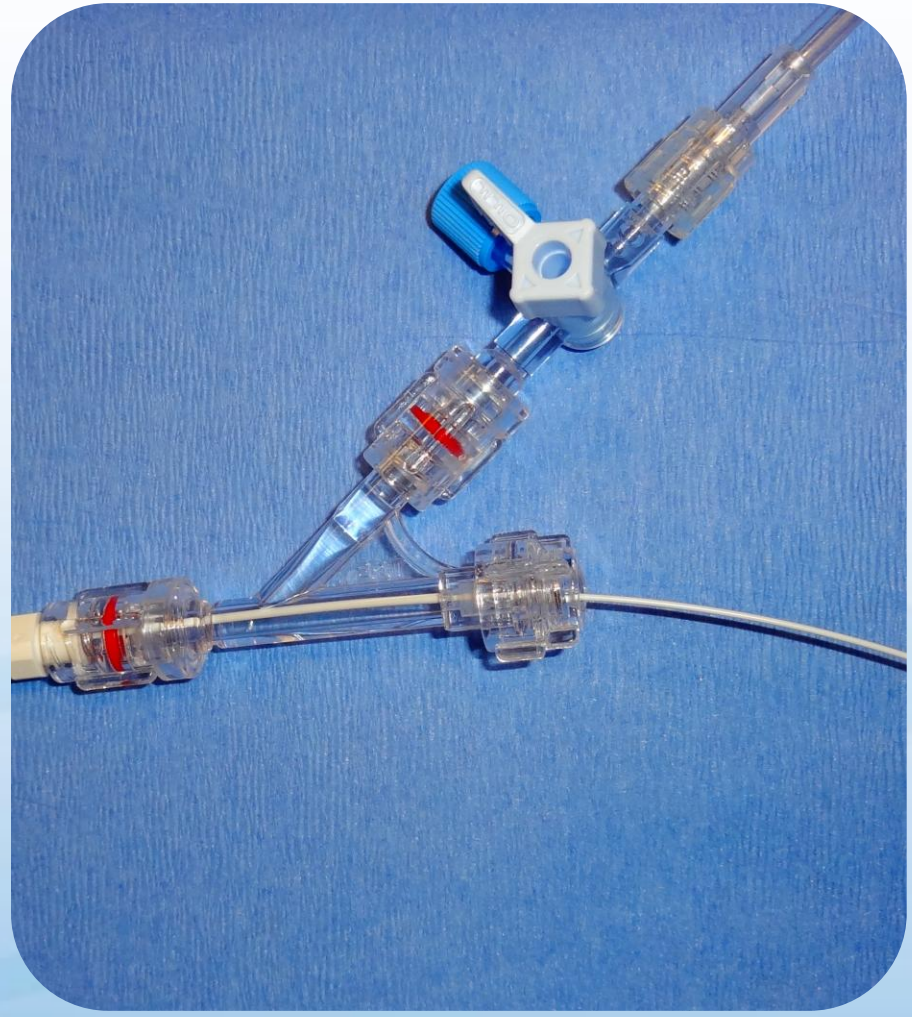
PROCEDURE STEPS

STEP 1: ACCESS & POSITIONING OF THE MICRO-CATHETER

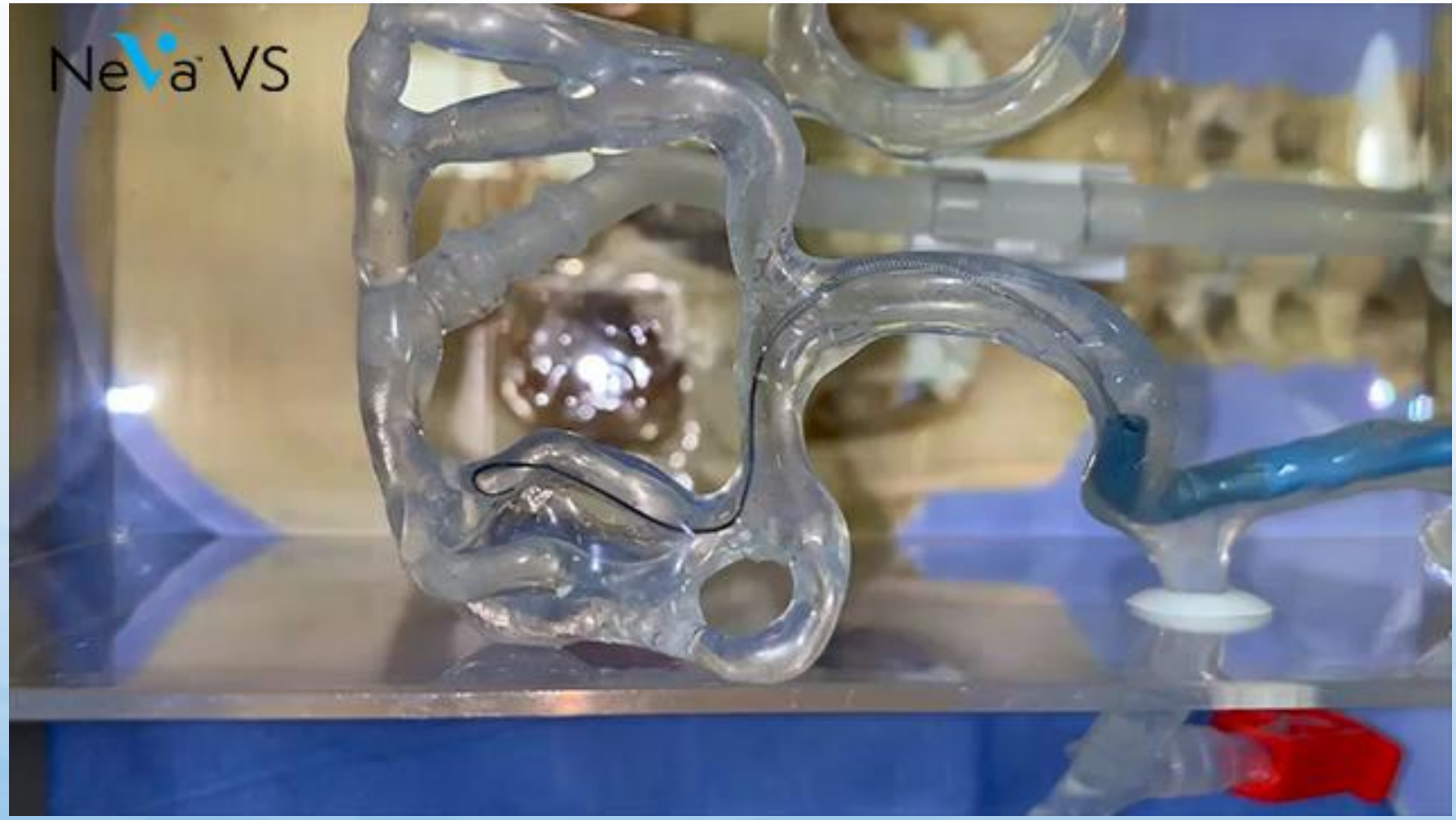
1. Position a suitable guide catheter as per standard practice

2. With guidewire, navigate the micro-catheter 10 mm past the most distal vessel segment treatable per indication

3. If there is a need to treat more distal vasospasm, use standard practice



STEP 1: ACCESS & POSITIONING OF THE MICRO-CATHETER

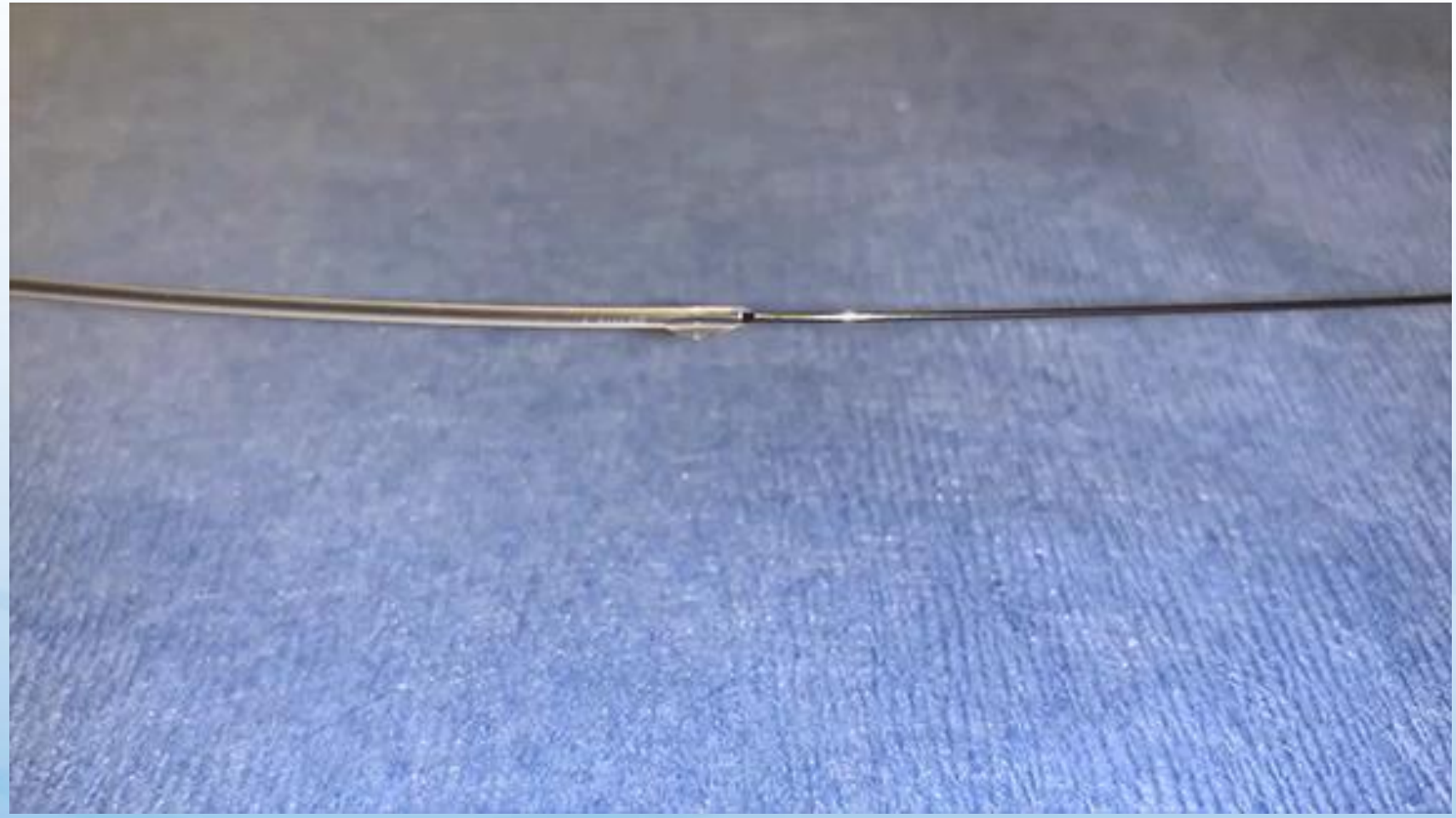


STEP 2: DELIVERY OF THE NEVA VS TO THE LESION

1. Insert the distal end of the introducer sheath partially into the RHV connected to MC,

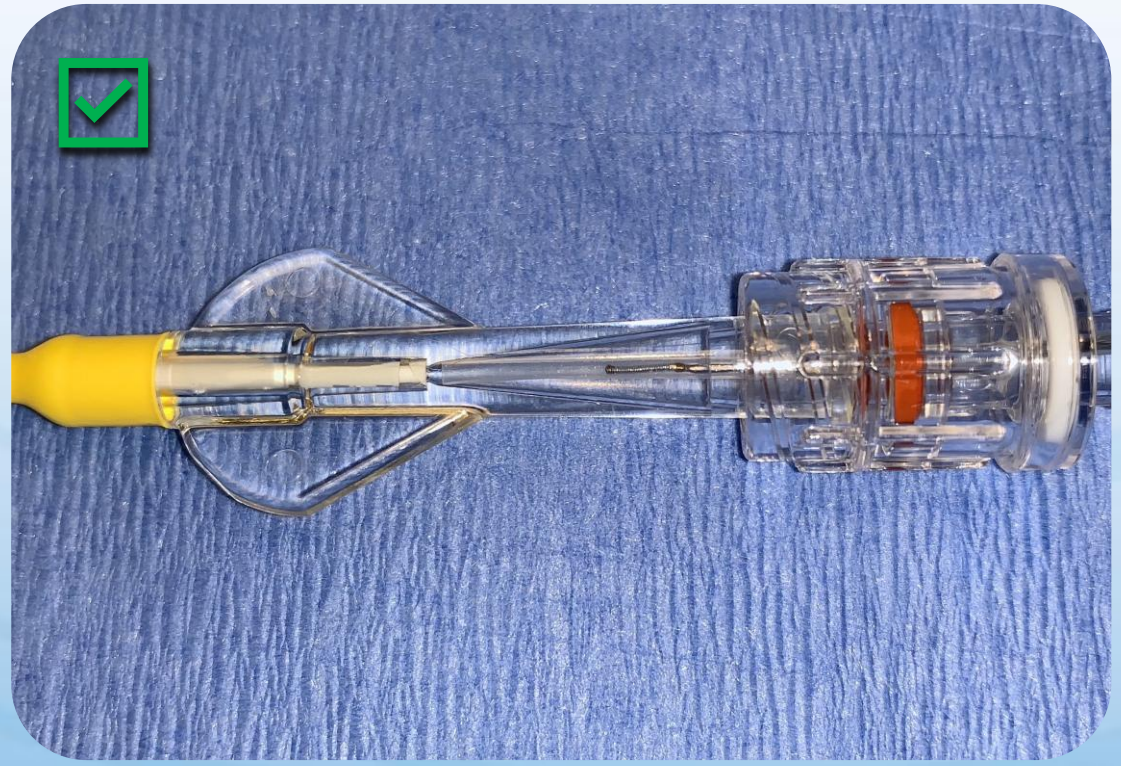
2. Tighten the RHV and verify that fluid exits the proximal end of the introducer sheath (flush)

STEP 2: DELIVERY OF THE NEVA VS TO THE LESION

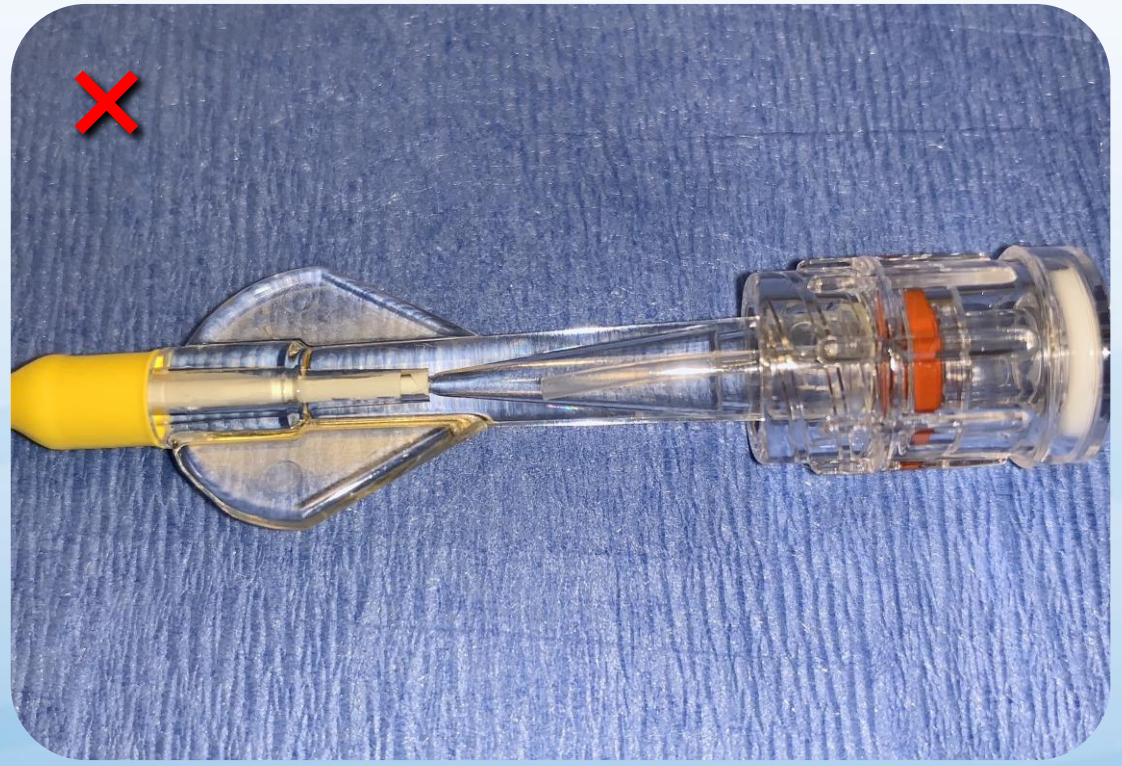


STEP 2: DELIVERY OF THE NEVA VS TO THE LESION

Loosen RHV & advance the introducer sheath until it is firmly seated in the hub of the MC, tighten RHV (not so tight as to damage the NeVA™ VS system)



Right

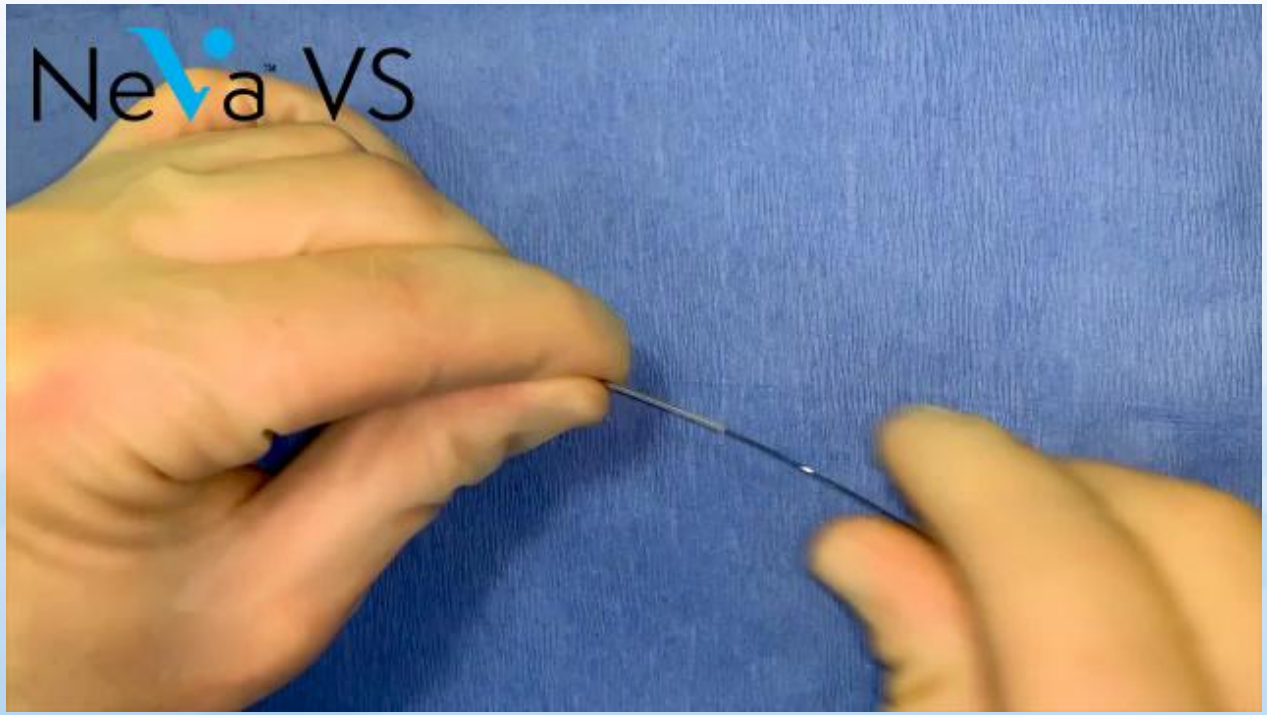


Wrong

STEP 2: DELIVERY OF THE NEVA VS TO THE LESION

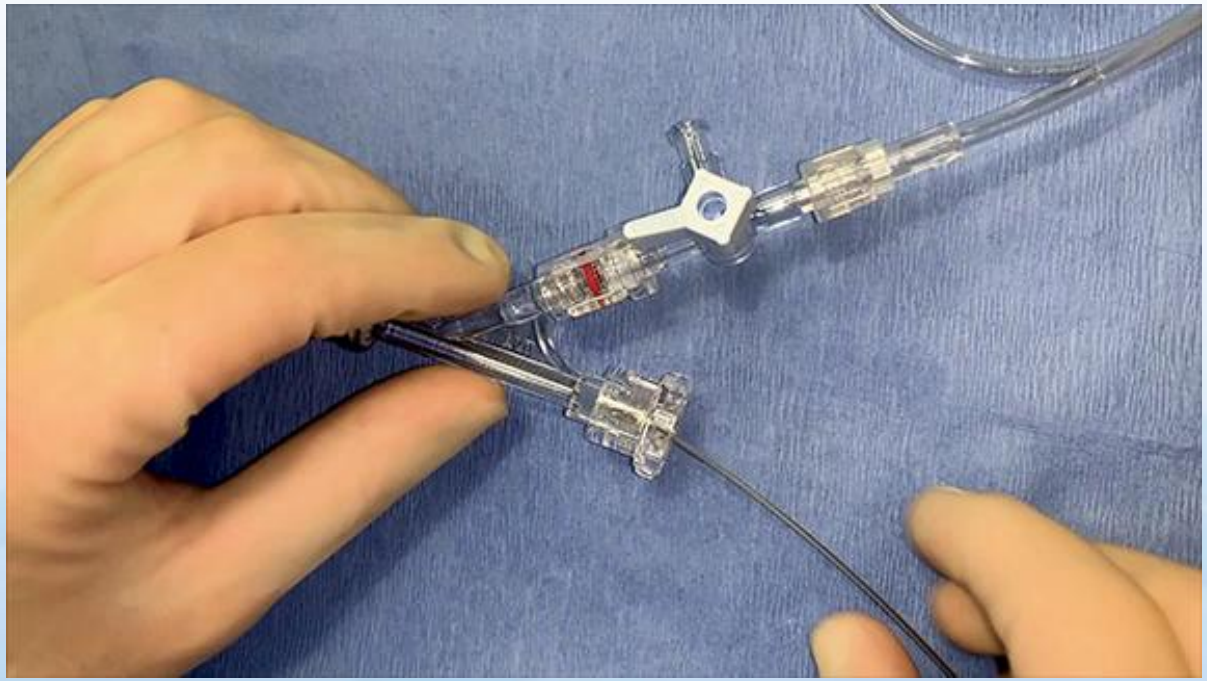
1. Transfer the NeVa VS system into the MC by advancing the pusher wire. May feel a little stiffer than SR due to the increased expansion radial force

2. Once the flexible portion of wire has entered MC shaft, loosen RHV and remove sheath & tighten RHV



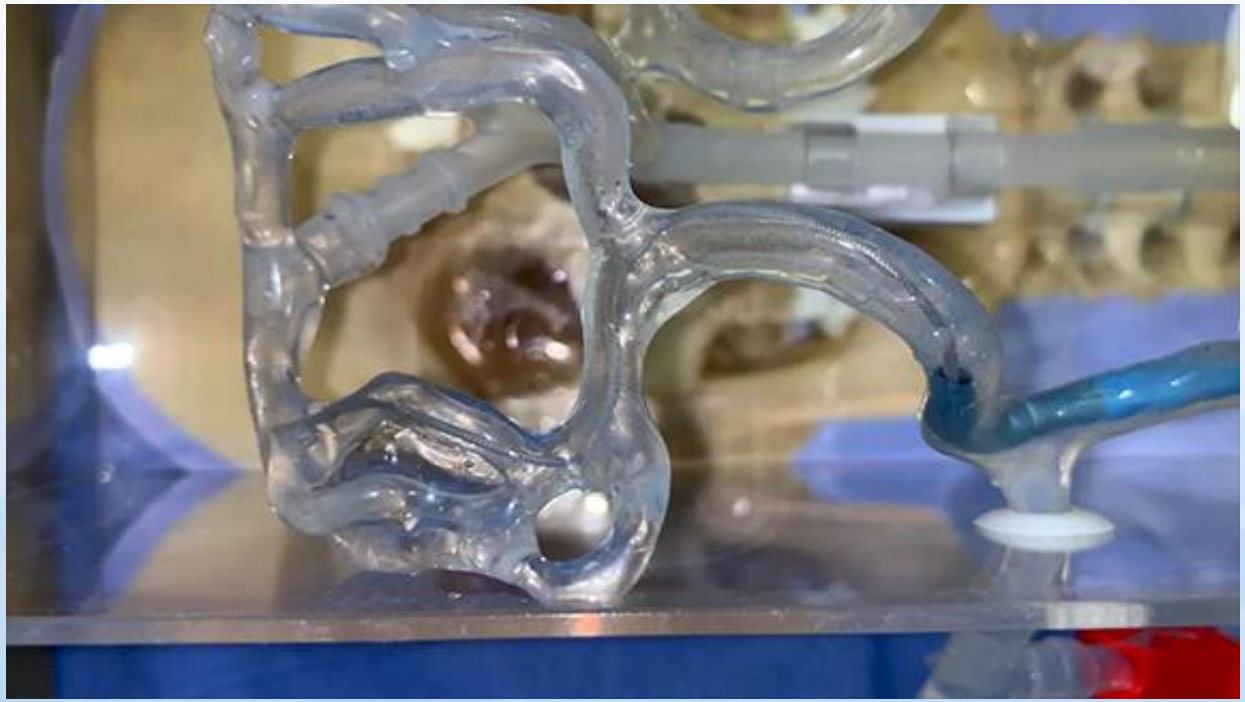
STEP 2: DELIVERY OF THE NEVA VS TO THE LESION

With the aid of fluoroscopic monitoring, align device distal tip marker with MC tip marker.



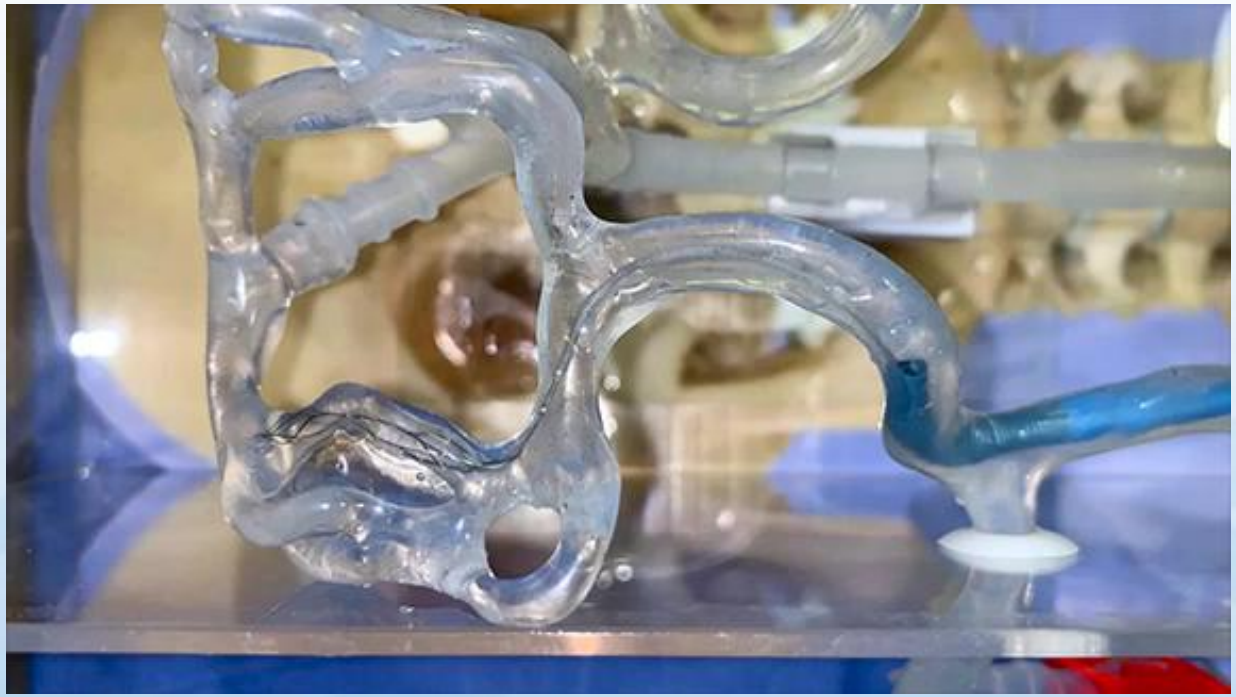
STEP 3: DEPLOYING THE NEVA™ VS

1. Remove forward tension from the MC
2. Unsheathe by holding the pusher wire steady while withdrawing the MC in the proximal direction
3. Retract the MC until its tip marker is proximal to the proximal marker of the NeVa VS system
4. Tighten the RHV to prevent any movement of the pusher wire
5. Allow to remain in place for 7 minutes



STEP 4: RE-CAPTURING THE NEVA™ VS

1. Loosen RHV around MC & pusher wire, hold wire firmly in position to prevent the NeVa VS system from moving
2. Re-sheath by advancing the MC over the NeVa VS system until the distal markers line up at the end of the MC
3. Once re-captured in the MC, the catheter can be withdrawn to a more proximal segment and the device re-deployed
4. Do not drag self-expanding stent segment



STEP 5: RE-CAPTURING THE NEVA™ VS

1. When moving to a new branch & using same device
   - Re-capture NeVa VS, when visible in MC hub, disconnect RHV and pull device through RHV (do not pull through diaphragm)
   - Inspect device to ensure no blood or clots
   - Inspect distal wire, if stretched use new NeVa VS device
     - Stretch strength low, breakoff strength high
   - Re-sheath device into its introducer sheath for re-introduction
2. Repeat deployment steps
3. After final deployment, re-sheath into MC and remove through guide catheter
4. It is possible to re-deploy NeVa VS up to six times
   - No more than 6 device interventions per vessel