VESALIO™

CHANGING OUTCOMES
CHANGING LIVES

CHOOSE TO REMOVE

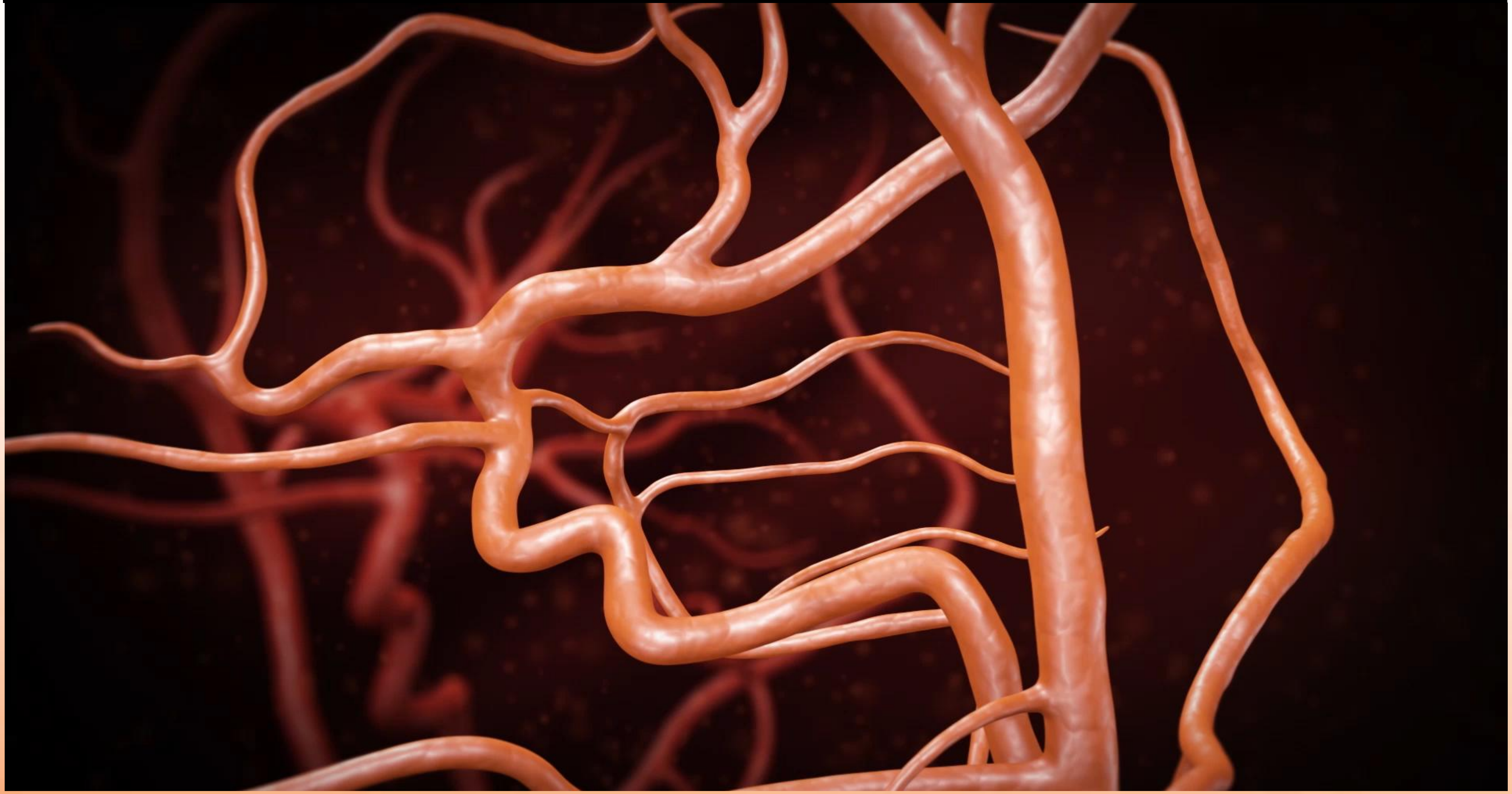
enVast™

PROCEDURE STEPS

LV-MKT-020 – REV C

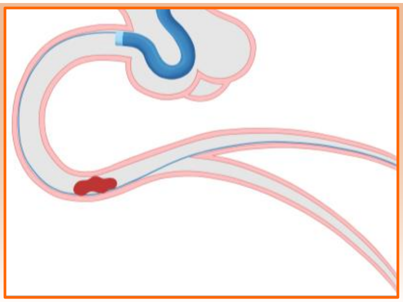
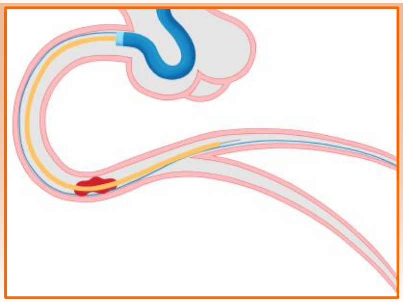
THE 1ST AND ONLY STENT RETRIEVER CE-APPROVED FOR CORONARY ANATOMY

This animation shows enVast in cerebro-vascular anatomy & intervention

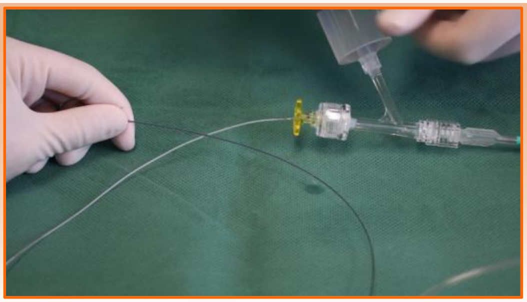


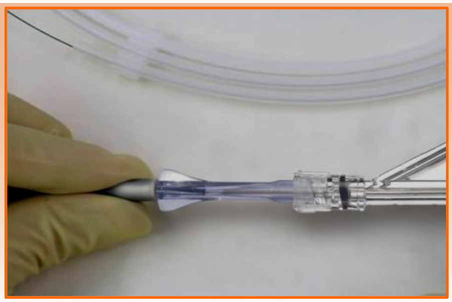
PROCEDURE OVERVIEW

1. Guidewire and Microcatheter Placement

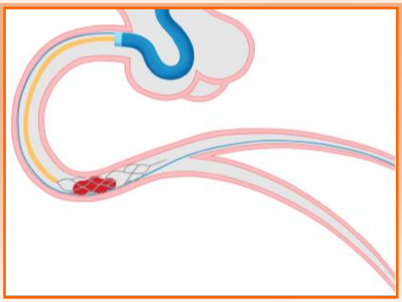



2. enVast Preparation

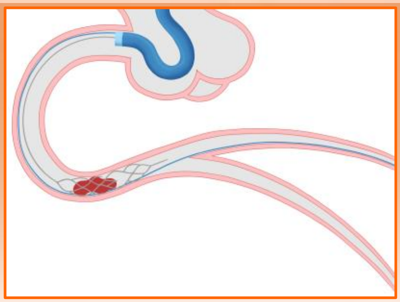


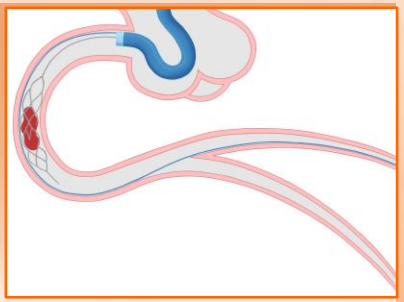



3. enVast Deployment




4. enVast Retrieval



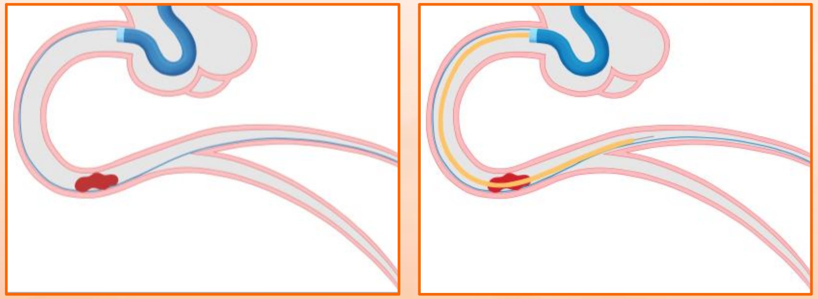


ANGIO

- TIMI 2/3 flow with large thrombus burden in mid LAD

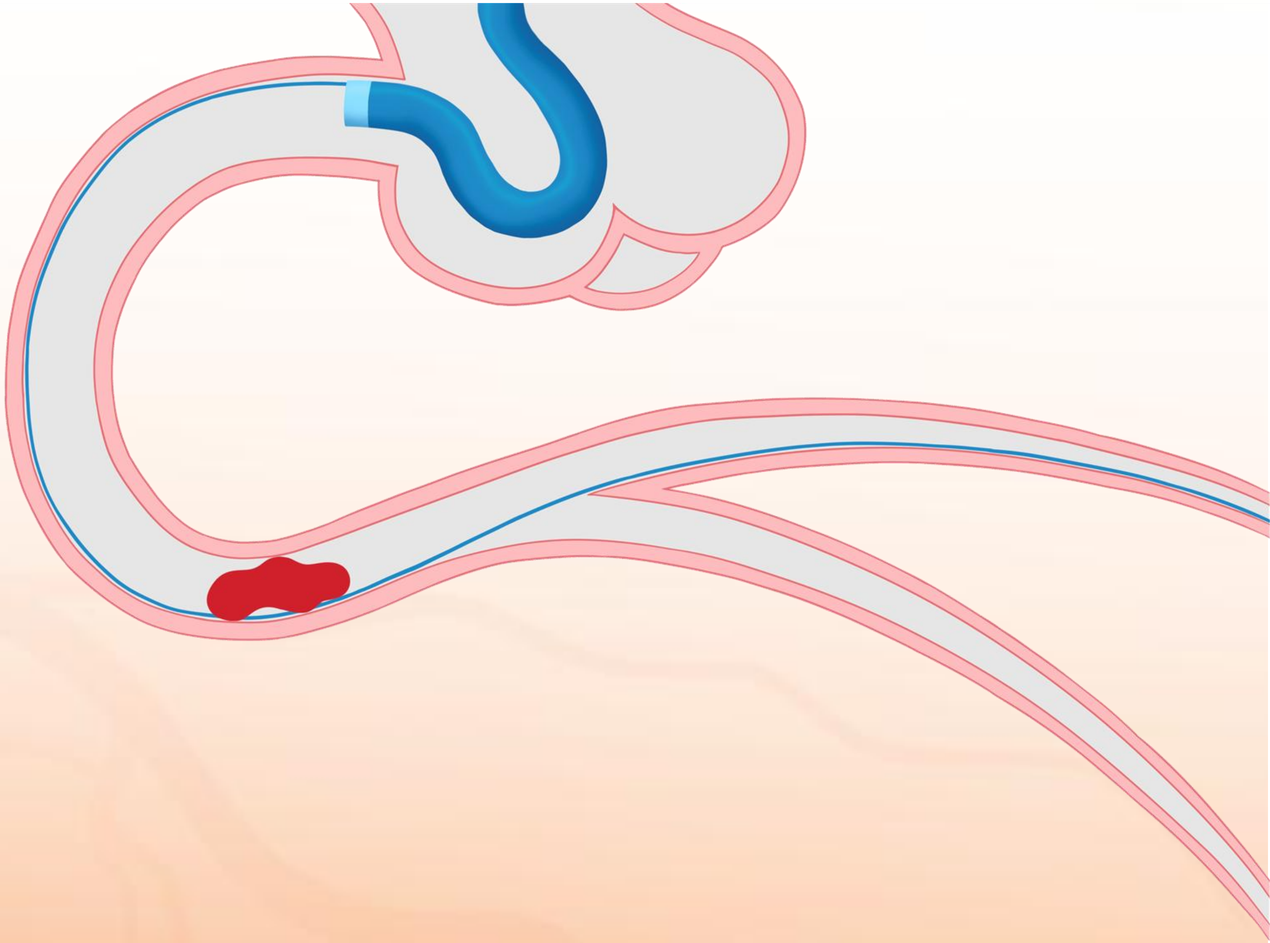
 Angio example courtesy of Dr Marco Valgimigli, Lugano, SWITZERLAND

STEP 1: GUIDEWIRE AND MICROCATHETER PLACEMENT



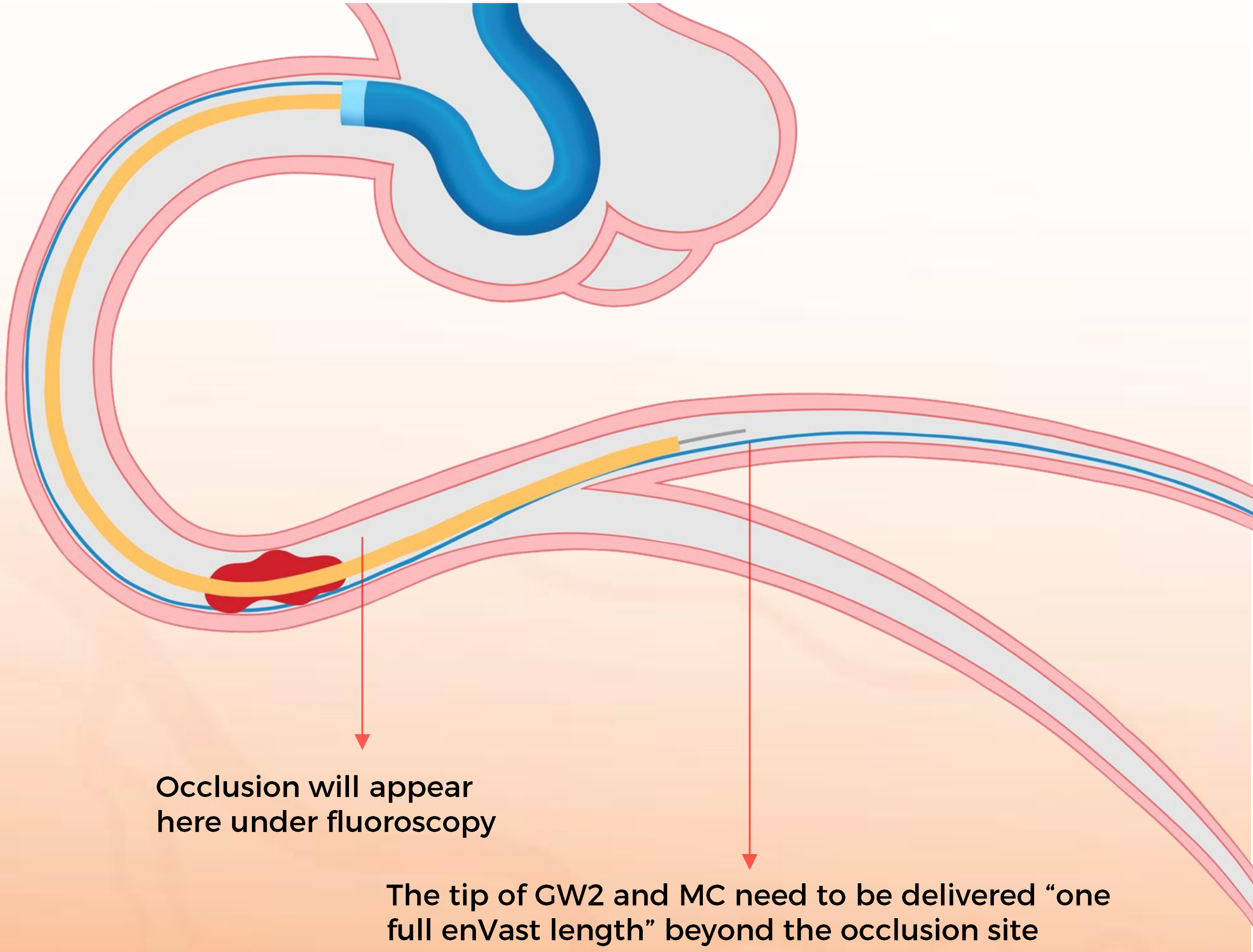
1st GUIDEWIRE PLACEMENT

- Cross the lesion with a standard 0.014” coronary wire (GW1) and go as distal as possible
- This wire will stay in place during the procedure and be used as a stabilizer for the Guide Catheter during thrombectomy, and for further intervention



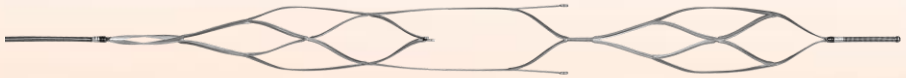
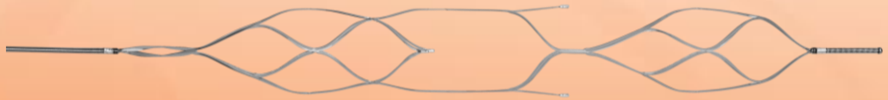
2ND GUIDEWIRE & MICROCATHETER PLACEMENT

- Backload the second wire (GW2) into the microcatheter (MC)
- Deliver MC with the GW2 leading (yellow)
  - Use an approved 0.021 or 0.027 ID MC
  - Flush the MC before use
  - **The MC distal tip needs to go sufficiently distal beyond the thrombus for correct enVast positioning (i.e. the full length of enVast needs to be deployed beyond the fluoroscopic site of occlusion)**
- Once the tip of the MC is at the desired position, remove GW2 from the MC for enVast insertion

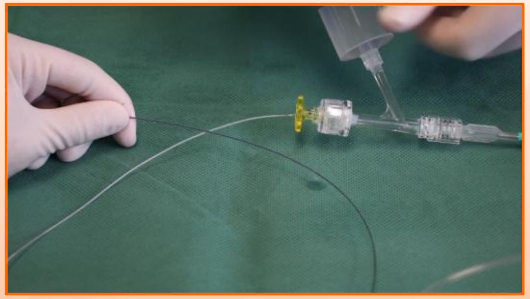


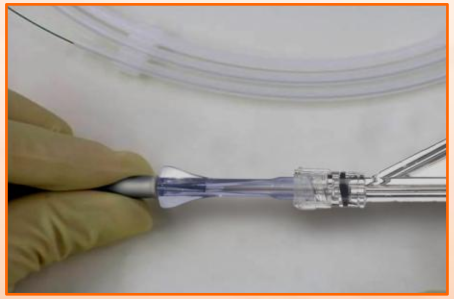
VESALIO

enVast™

Product Name	Code	Maximal diameter	Working Length	Full Length	Drop Zones	Pusher Wire	Recommended Vessel Diameter (mm)	Min MC inner diameter
enVast 4.0 x 30 	EV-4030-F2RR	4.0 mm	30 mm	48 mm	2	200 cm	≥ 2.0 & ≤ 3.5	.021”
enVast 4.5 x 37 	EV-4537-F2RR	4.5 mm	37 mm	57 mm	2	200 cm	≥ 2.0 & ≤ 4.5	.021”
enVast 4.5 x 46 	EV-4546-F3RR	4.5 mm	46 mm	66 mm	3	200 cm	≥ 2.0 & ≤ 4.5	.021”
enVast 6.0 x 35 	EV-6035-F2RR	6.0 mm	35 mm	55 mm	2	200 cm	≥ 3.5 & ≤ 6.0	.027”

STEP 2: ENVAST PREPARATION



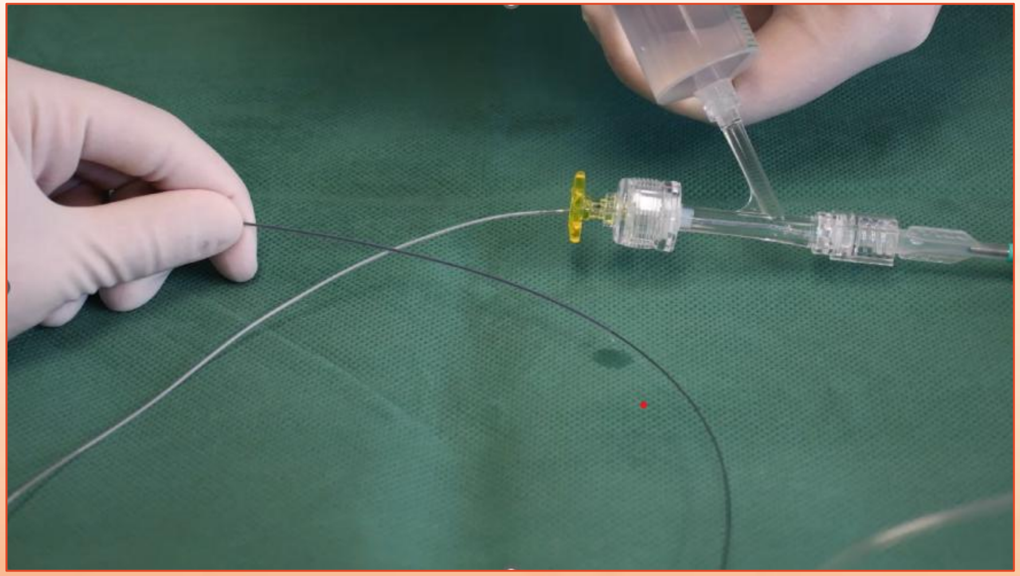


ENVAST PREPARATION - FLUSH

- Prepare the enVast by either:
  - De-airing under heparinized saline

  or

  - Placing the enVast with sleeve into a Y connector and back flushing



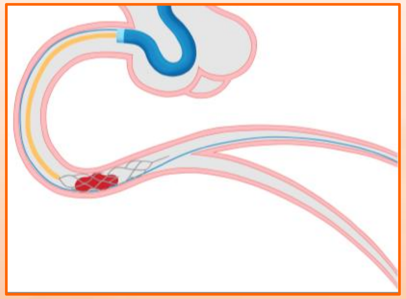
ENVAST LOADING INTO MICROCATHETER

- Loosen the RHV and visually confirm that the tip of the enVast introducer sheath is seated deeply in the hub of the MC
- Tighten the RHV around the introducer sheath to prevent back flow of blood, but not so tight as to damage the enVast device
- Push the enVast pusher wire such that the basket of the device is delivered into the MC
- Continue pushing until the proximal section of the pusher wire completely enters into the distal end of the introducer sheath

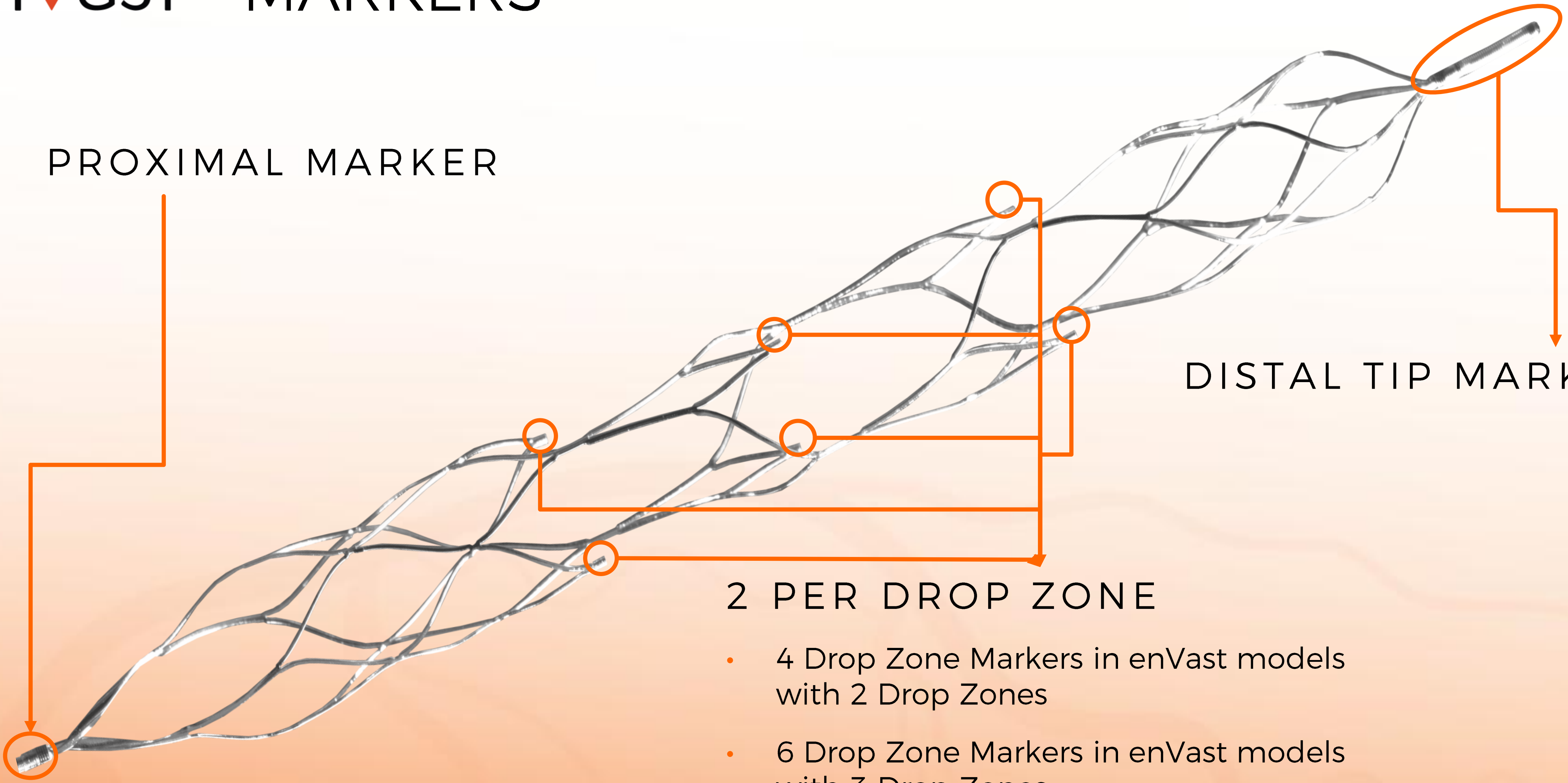
NAVIGATION TO SITE - DELIVER

- Gently remove the introducer sheath by pulling it back and out
- DO NOT THROW AWAY THE INTRODUCER SHEATH, keep it on the sterile table as it may be needed for a second pass
- Continue pushing the enVast pusher wire until the zebra markers enter the MC hub, start fluoroscopic visualization
- Continue pushing until the enVast tip aligns with the MC tip marker

STEP 3: ENVAST DEPLOYMENT



enVast™ MARKERS



- 4 Drop Zone Markers in enVast models with 2 Drop Zones
- 6 Drop Zone Markers in enVast models with 3 Drop Zones

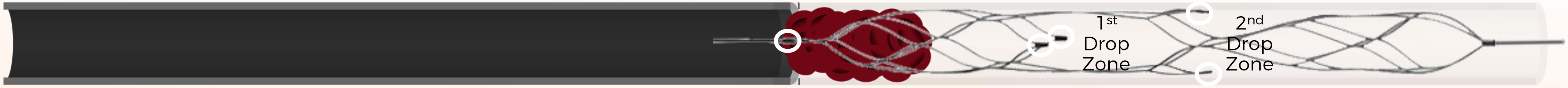
IDEAL ENVAST POSITIONING

Position enVast proximal marker at the proximal edge of clot where occlusion begins

fluoroscopic edge of the occlusion → *→ clot and the anatomy beyond the clot, invisible under fluoro due to the occlusion*

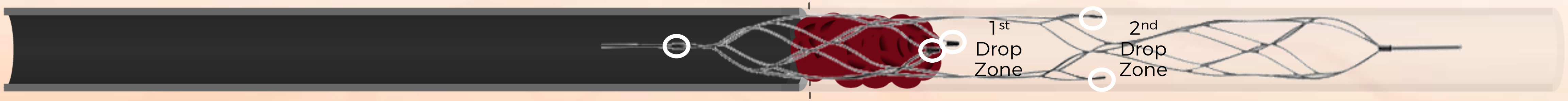
The Flow Restoration Zone and Drop Zones interacting with the clot:

GOOD POSITIONING



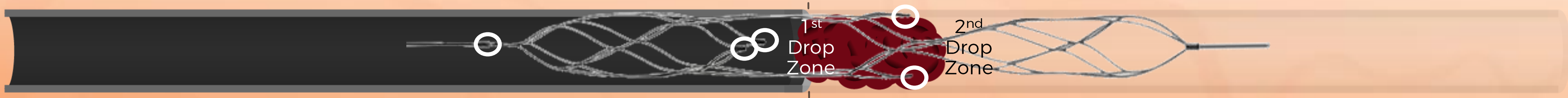
Most of the working length of the Flow Restoration Zone and the Drop Zones interacting with the clot:

GOOD POSITIONING



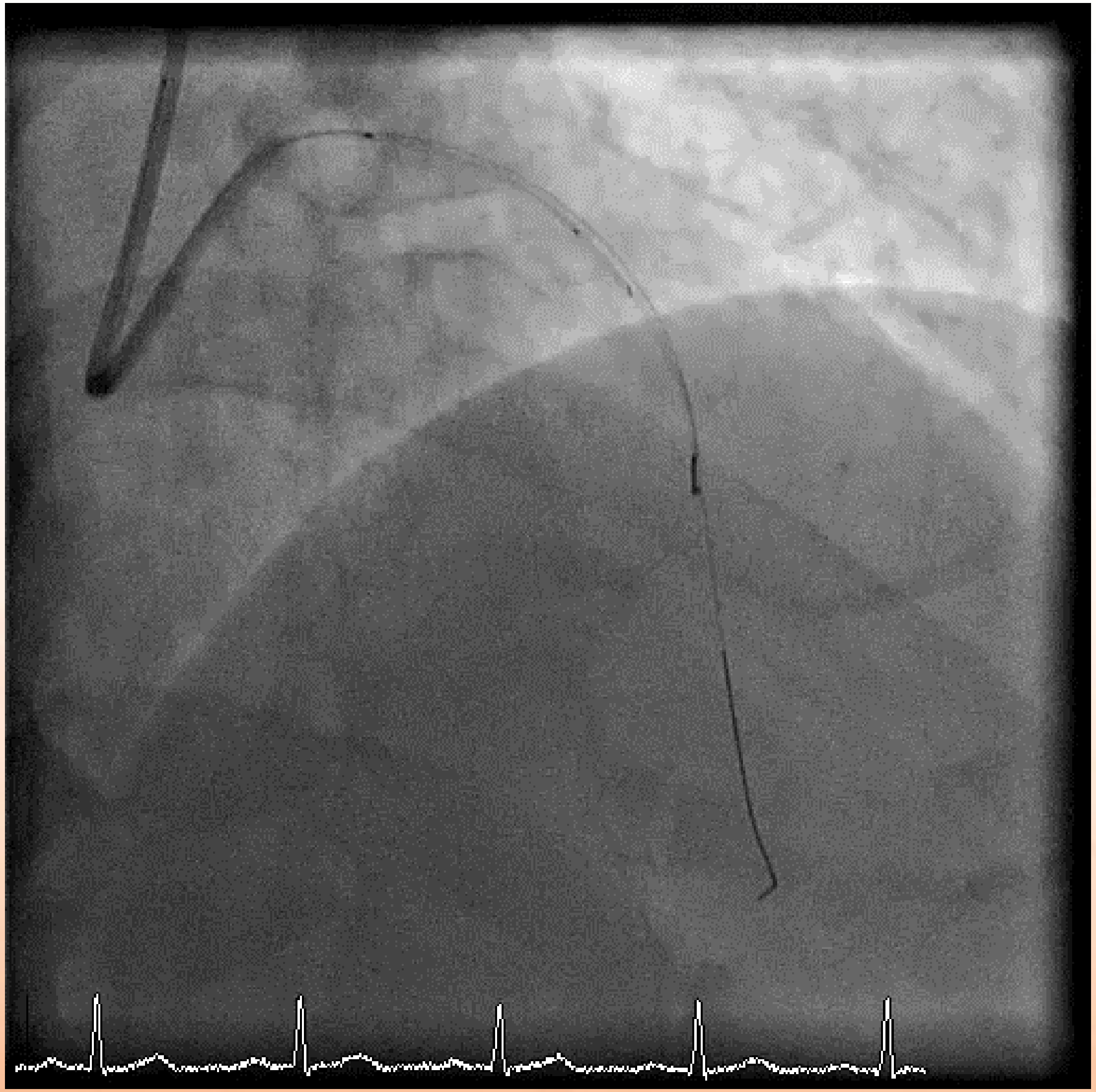
The Flow Restoration Zone and part of the first Drop Zone is not interacting with the clot:

POSITIONING NOT IDEAL



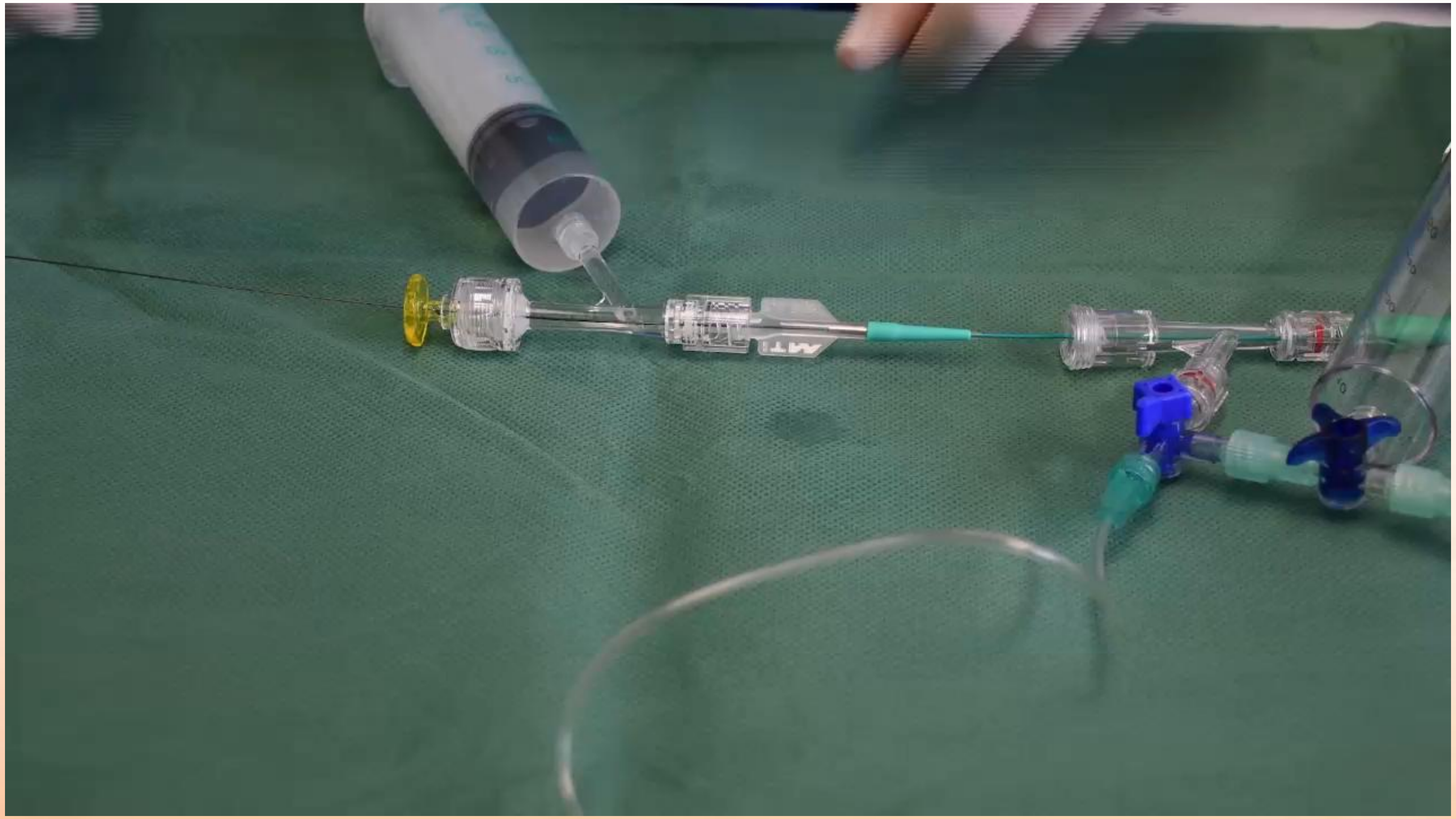
ENVAST DEPLOYMENT - UNSHEATHING

- Release the extra tension on the micro-catheter just before proceeding to enVast deployment
- To deploy, fix enVast pusher wire still and carefully remove (glide back) the microcatheter proximally to unsheath enVast
- Note that enVast will start anchoring in the artery after ~1cm of unsheathing



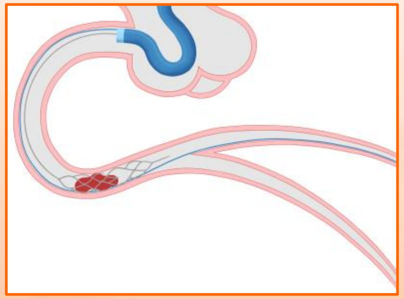
Angio example courtesy of Dr Marco Valgimigli, Lugano, SWITZERLAND

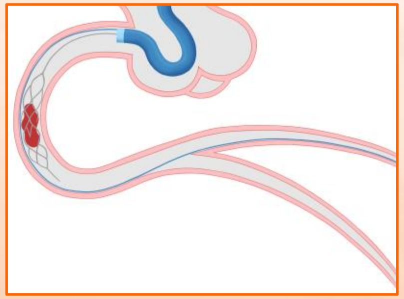
MICRO CATHETER REMOVAL



- Holding GW1 and enVast pusherwire, remove the MC at this point (Optional)
- Especially recommended if you are using a GC-Extension, for more efficient aspiration through the GC/ GC-extension)

STEP 4: ENVAST RETRIEVAL

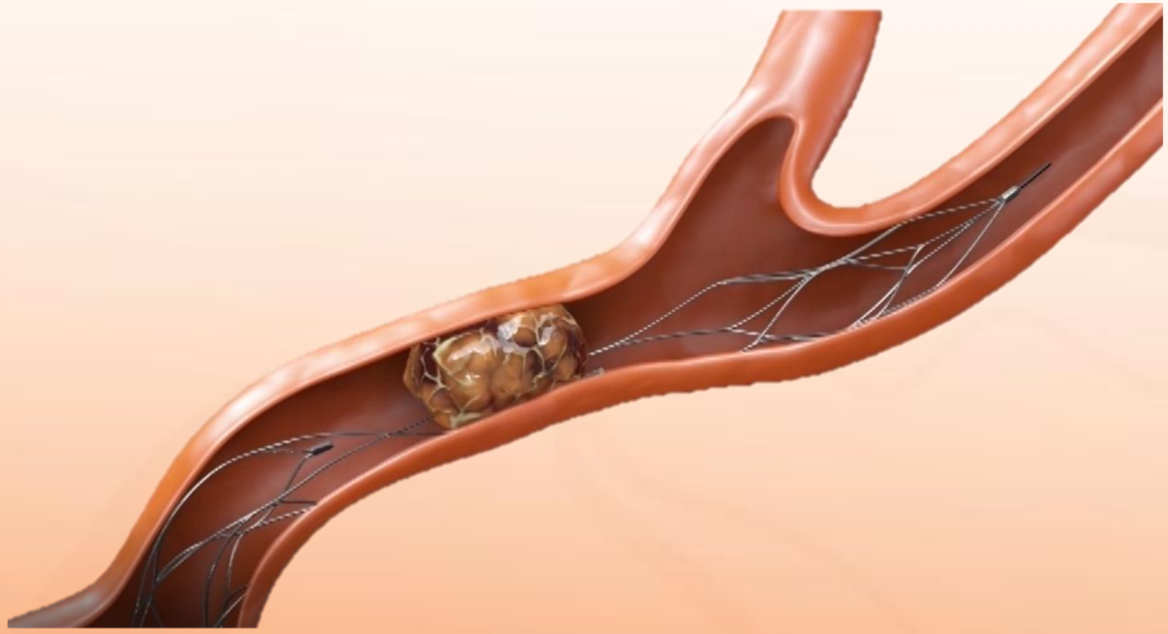




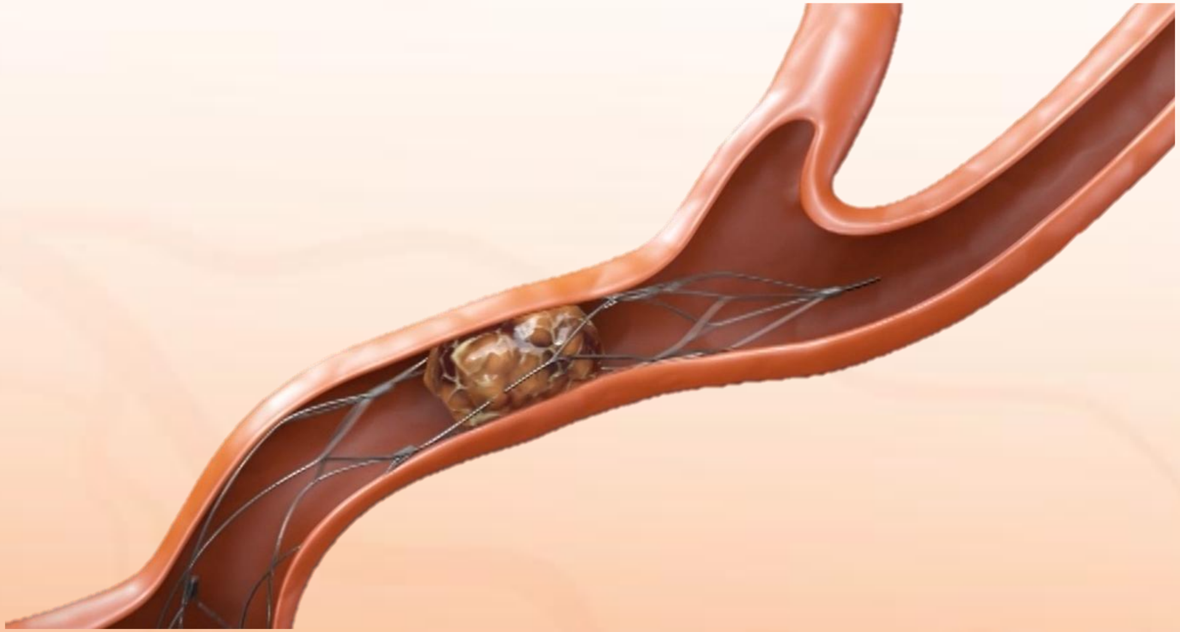
USING THE DROP ZONES

Drop Zone markers will get compressed when enVast is passing next to a hard, calcified clot

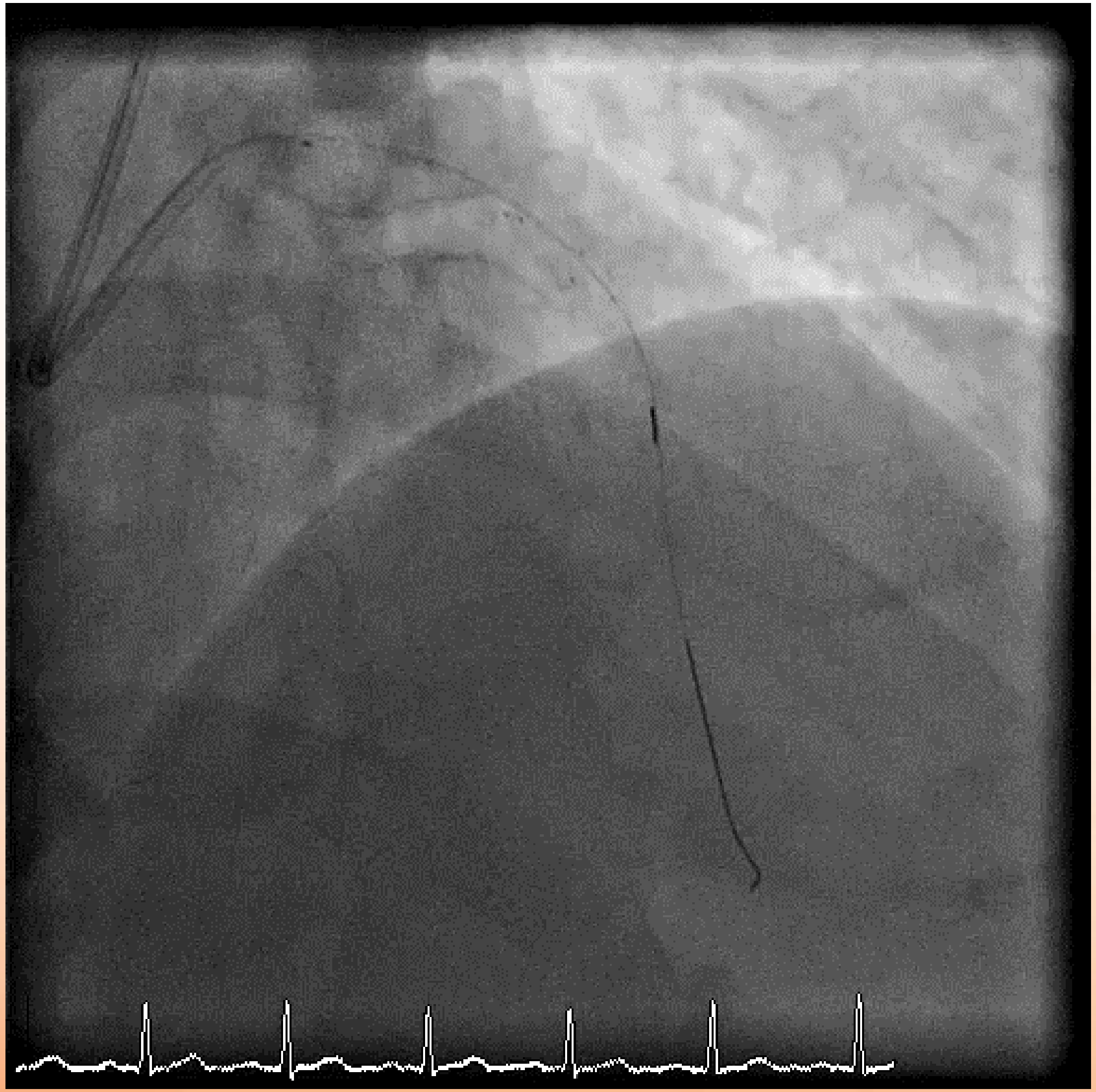
Markers compressed together:
You may be adjacent to a lesion or hard clot, slow down



Markers spring open:
You may be at the proximal edge of the lesion or hard clot, the DROP zone is on the clot



FLUORO TO ASSESS BLOOD FLOW RESTORATION



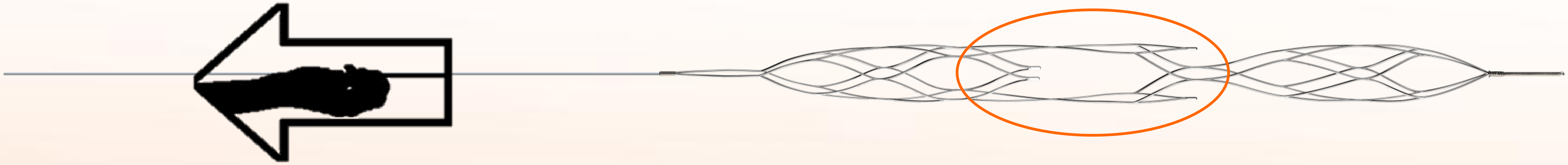
- Fluro acquisition to re-assess blood flow after enVast expansion (device in place)

Angio example courtesy of Dr Marco Valgimigli, Lugano, SWITZERLAND

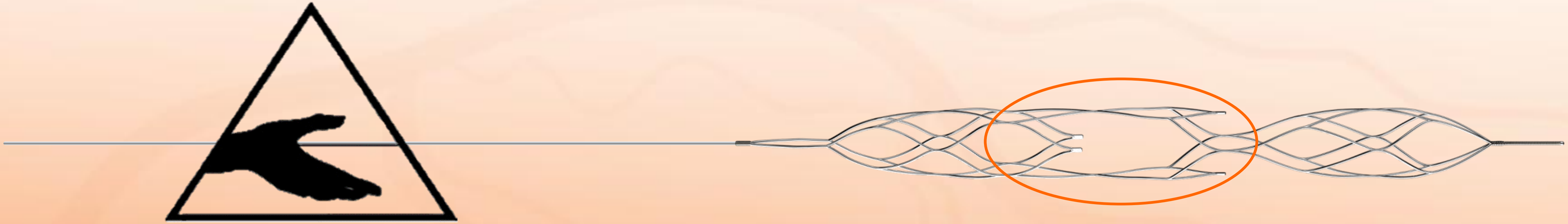
VESALIO

ENVAST WILL ELONGATE WHEN PULLING, LET THE PUSHER WIRE GO FOR IT TO RETURN TO SHAPE

- WHEN PULLING: enVast and the vessel will elongate

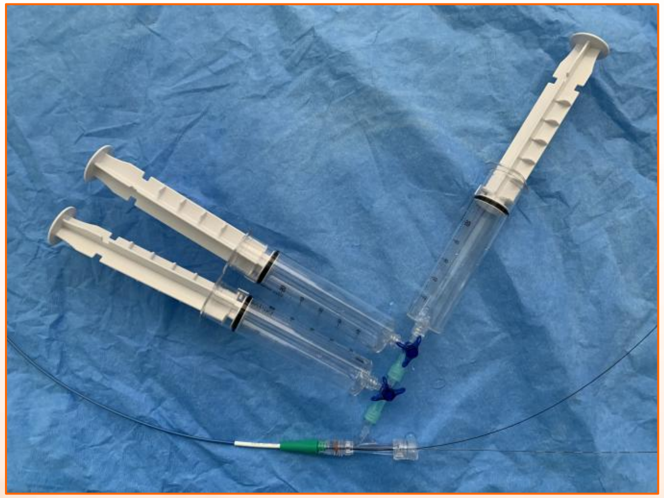


- LET IT GO: enVast and the vessel will relax…



ENVAST RETRIEVAL

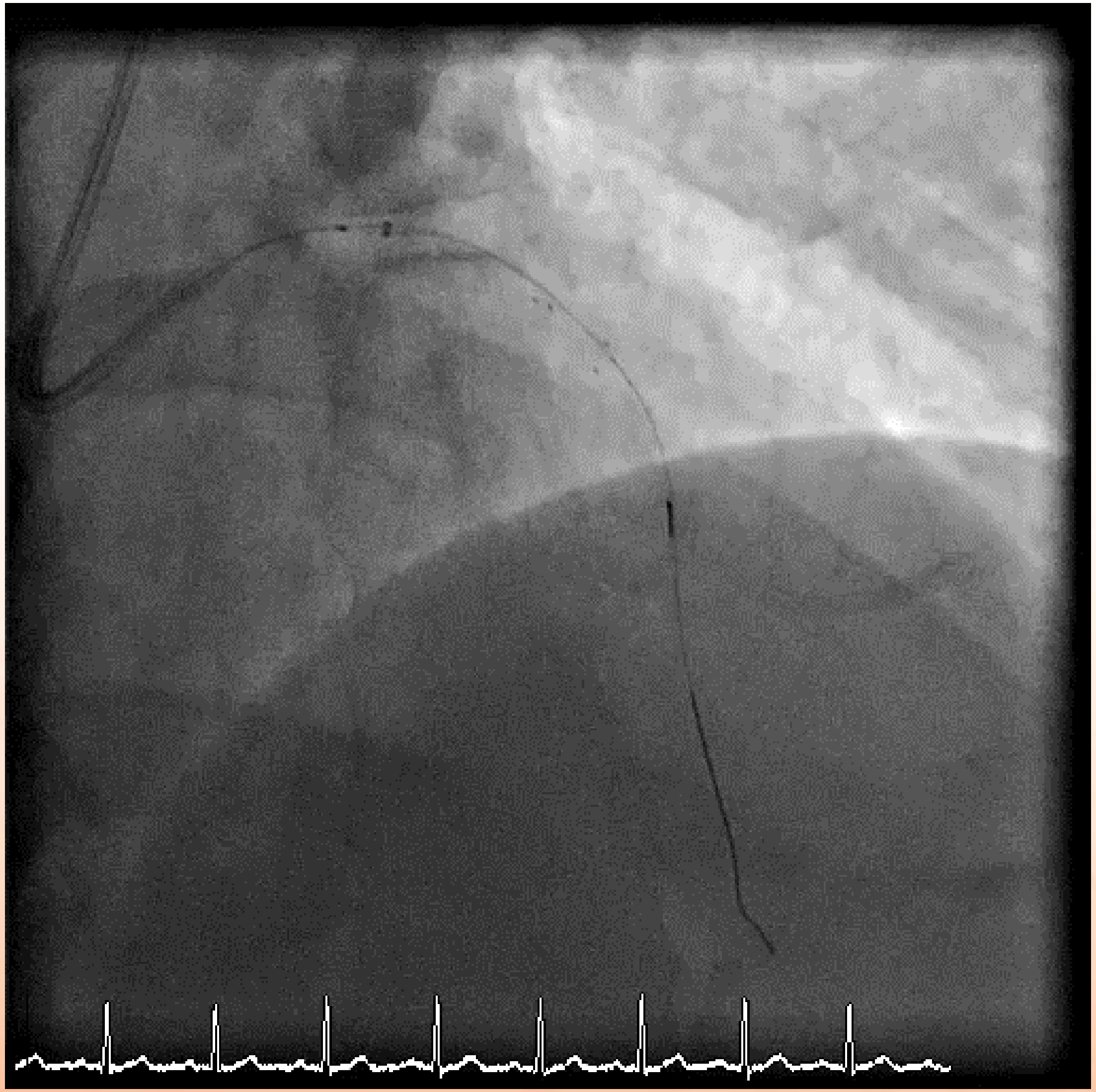
- Use 1 - 3 60ml VacLoc syringes



- Open stop cock to start continuous aspiration through the GC hub
- Start slow retrieval until enVast is removed from the GC-hub, leaving just the GW1 in place

ENVAST RETRIEVAL

- Withdraw enVast and GC-Extension under continuous aspiration

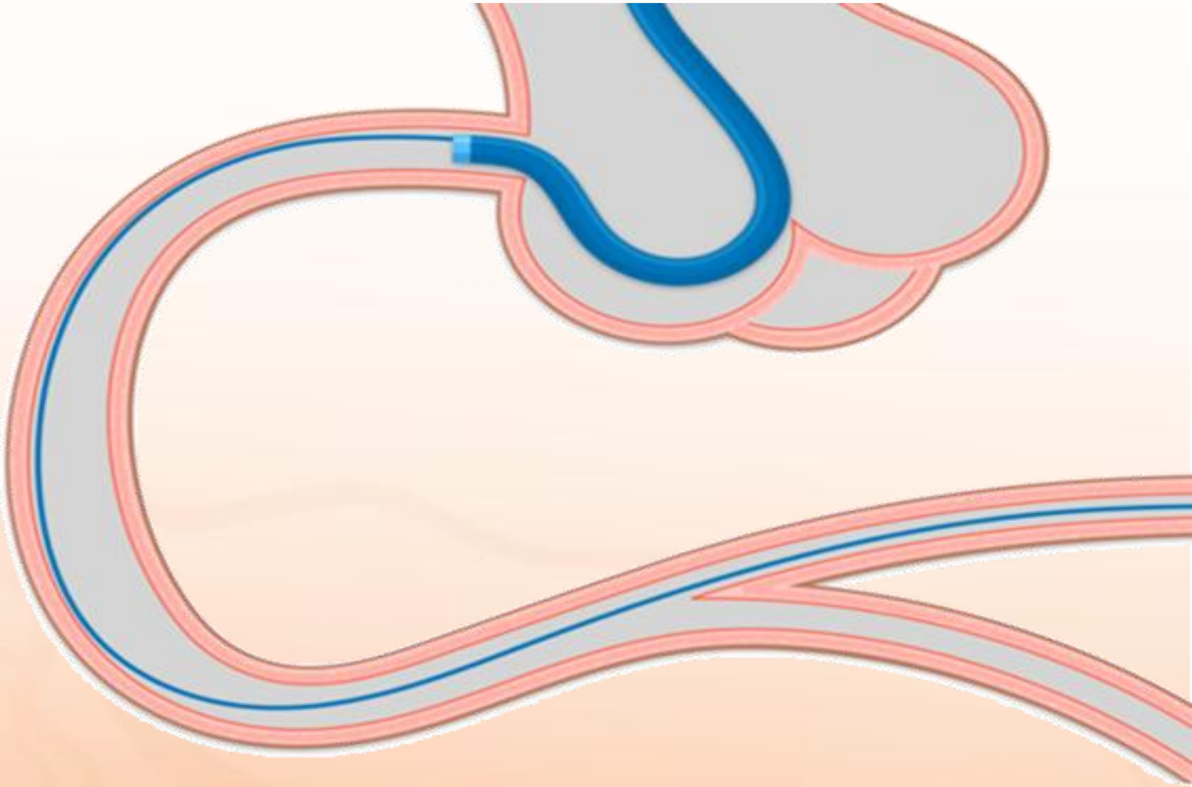


Angio example courtesy of Dr Marco Valgimigli, Lugano, SWITZERLAND

FINAL ASPIRATION

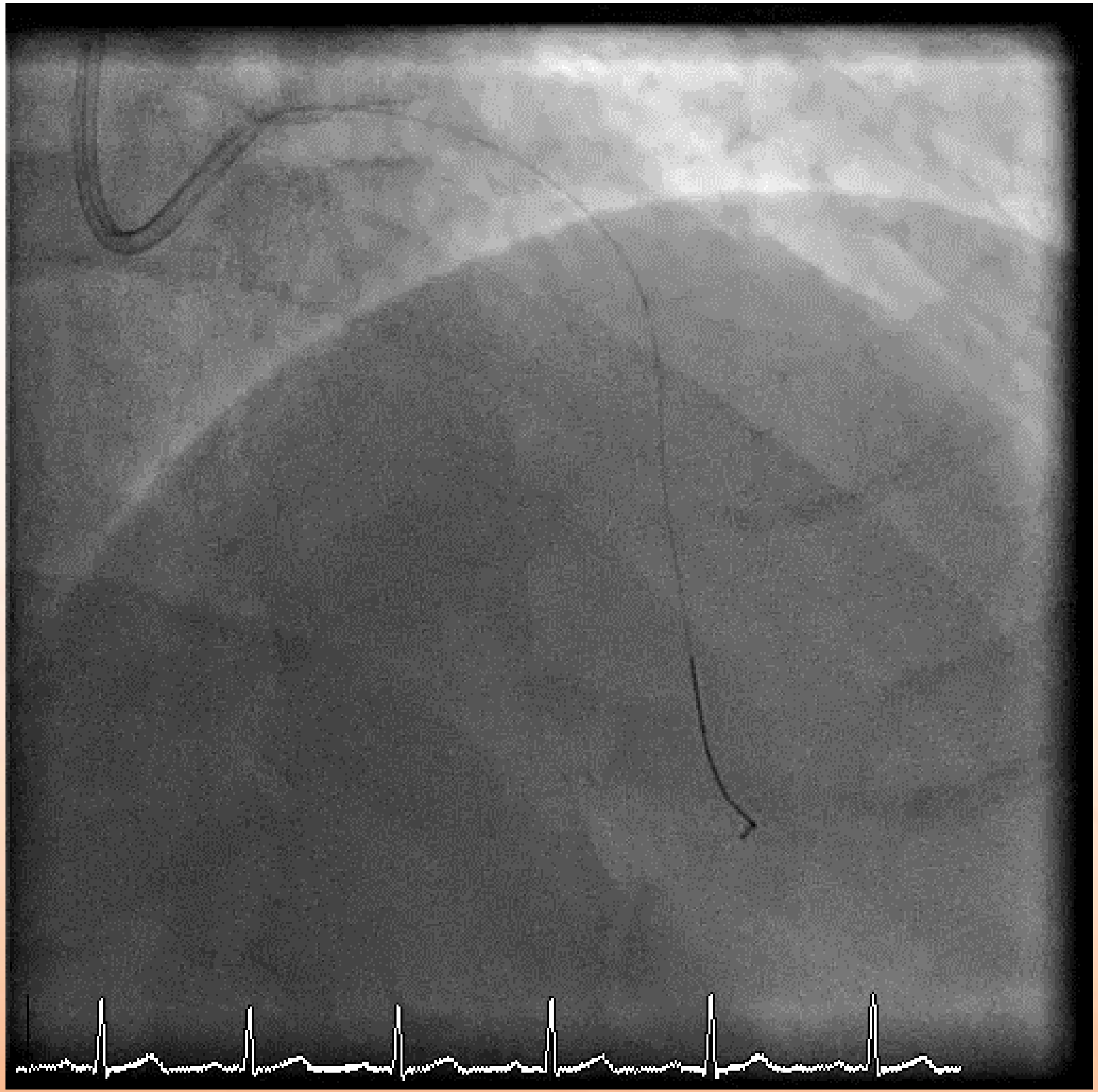
- After enVast retrieval, disconnect all syringes and perform strong aspiration to remove all thrombus from the guide catheter

- Leave the GW1 in place to continue PCI or repeat thrombectomy if needed (up to 3 passes in the same vascular territory)



FLUORO RUN

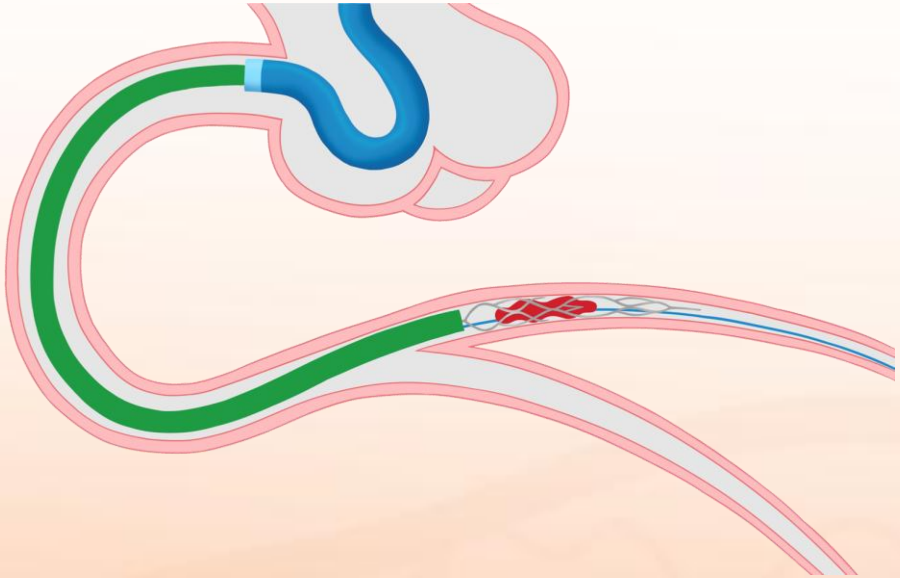
- Do final fluoro run to check recanalization status



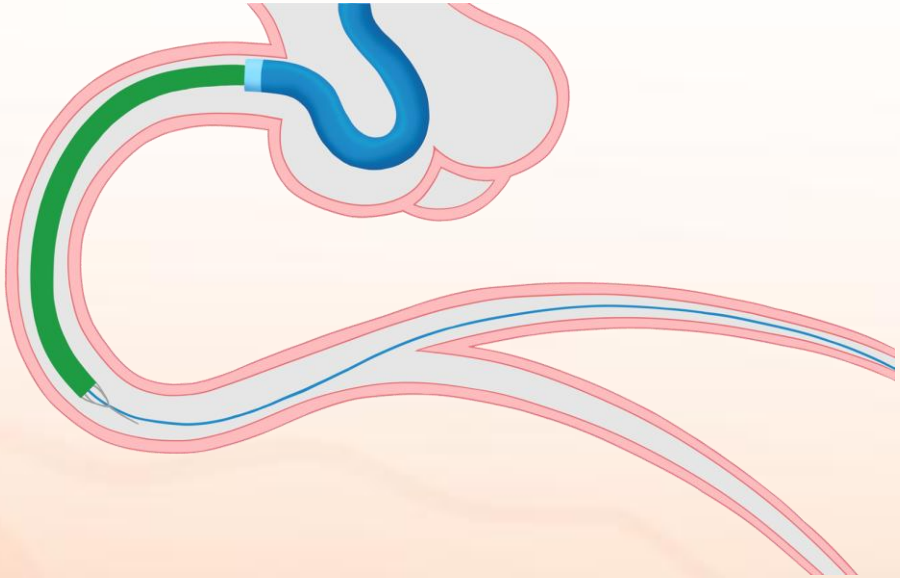
Angio example courtesy of Dr Marco Valgimigli, Lugano, SWITZERLAND

GUIDE CATHETER EXTENSION POSITIONING
FOR SIDE BRANCH PROTECTION

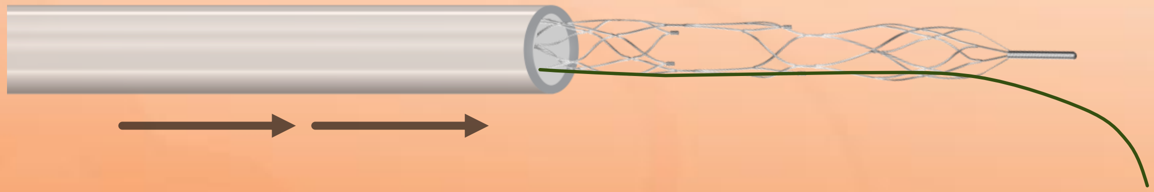
- Drive the GC-Extension (in green) beyond the side branch up to the proximal marker of enVast



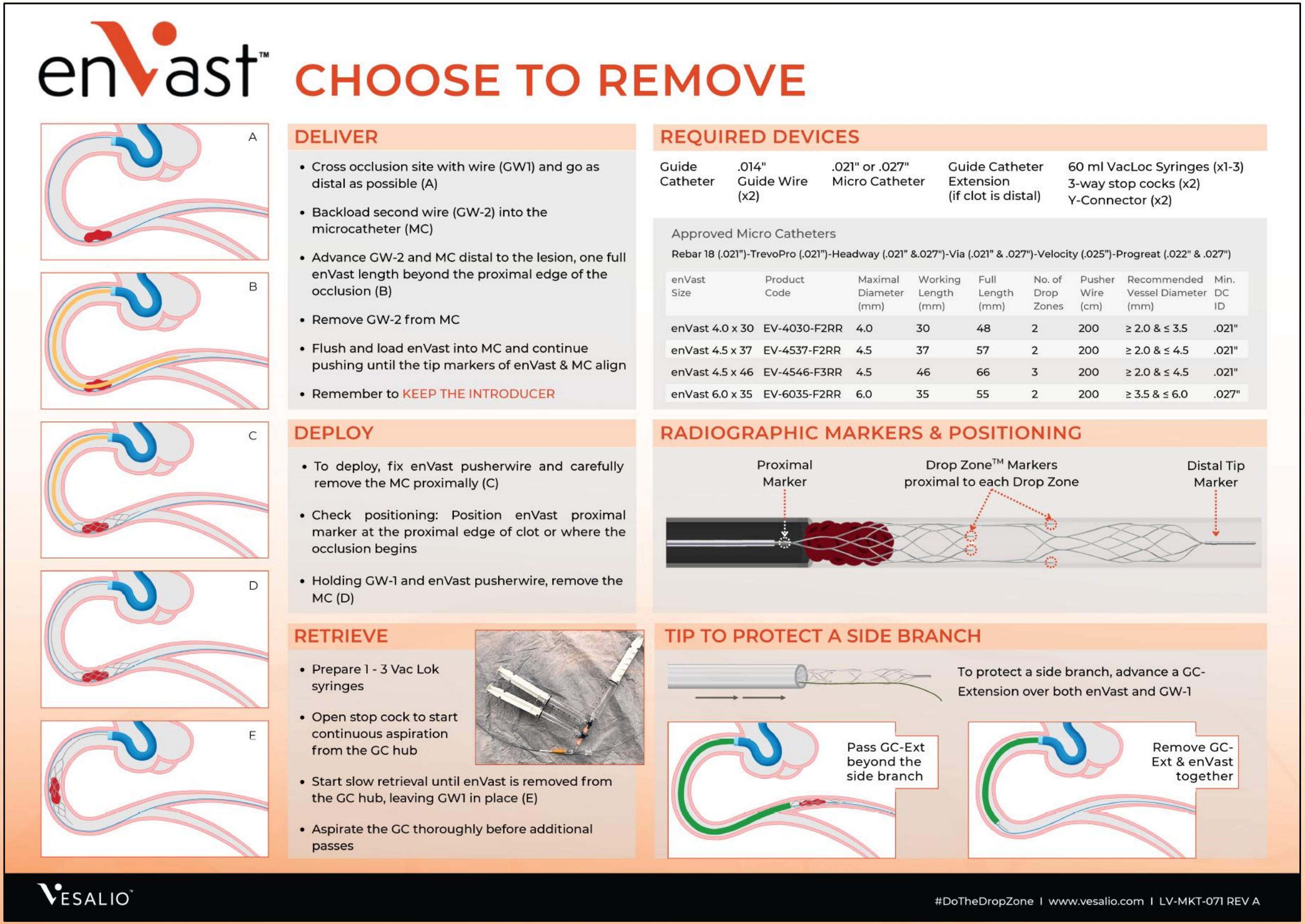
- Remove GC-Extension and enVast together



- Advance over both the enVast pusherwire and GW1



POSTER AVAILABLE UPON REQUEST



enVast™

CHOOSE TO REMOVE

DELIVER

- Cross occlusion site with wire (GW1) and go as distal as possible (A)
- Backload second wire (GW-2) into the microcatheter (MC)
- Advance GW-2 and MC distal to the lesion, one full enVast length beyond the proximal edge of the occlusion (B)
- Remove GW-2 from MC
- Flush and load enVast into MC and continue pushing until the tip markers of enVast & MC align
- Remember to KEEP THE INTRODUCER

DEPLOY

- To deploy, fix enVast pusherwire and carefully remove the MC proximally (C)
- Check positioning: Position enVast proximal marker at the proximal edge of clot or where the occlusion begins
- Holding GW-1 and enVast pusherwire, remove the MC (D)

RETRIEVE

- Prepare 1 - 3 Vac Lok syringes
- Open stop cock to start continuous aspiration from the GC hub
- Start slow retrieval until enVast is removed from the GC hub, leaving GW1 in place (E)
- Aspirate the GC thoroughly before additional passes

REQUIRED DEVICES

Guide Catheter | .014" Guide Wire (x2) | .021" or .027" Micro Catheter | Guide Catheter Extension (if clot is distal) | 60 ml VacLoc Syringes (x1-3), 3-way stop cocks (x2), Y-Connector (x2)

Approved Micro Catheters

Rebar 18 (.021")-TrevoPro (.021")-Headway (.021" &.027")-Via (.021" & .027")-Velocity (.025")-Prograet (.022" & .027")

enVast Size	Product Code	Maximal Diameter (mm)	Working Length (mm)	Full Length (mm)	No. of Drop Zones	Pusher Wire (cm)	Recommended Vessel Diameter (mm)	Min. DC ID
enVast 4.0 x 30	EV-4030-F2RR	4.0	30	48	2	200	≥ 2.0 & ≤ 3.5	.021"
enVast 4.5 x 37	EV-4537-F2RR	4.5	37	57	2	200	≥ 2.0 & ≤ 4.5	.021"
enVast 4.5 x 46	EV-4546-F3RR	4.5	46	66	3	200	≥ 2.0 & ≤ 4.5	.021"
enVast 6.0 x 35	EV-6035-F2RR	6.0	35	55	2	200	≥ 3.5 & ≤ 6.0	.027"

RADIOGRAPHIC MARKERS & POSITIONING

Proximal Marker

Drop Zone™ Markers proximal to each Drop Zone

Distal Tip Marker

TIP TO PROTECT A SIDE BRANCH

To protect a side branch, advance a GC-Extension over both enVast and GW-1

Pass GC-Ext beyond the side branch

Remove GC-Ext & enVast together

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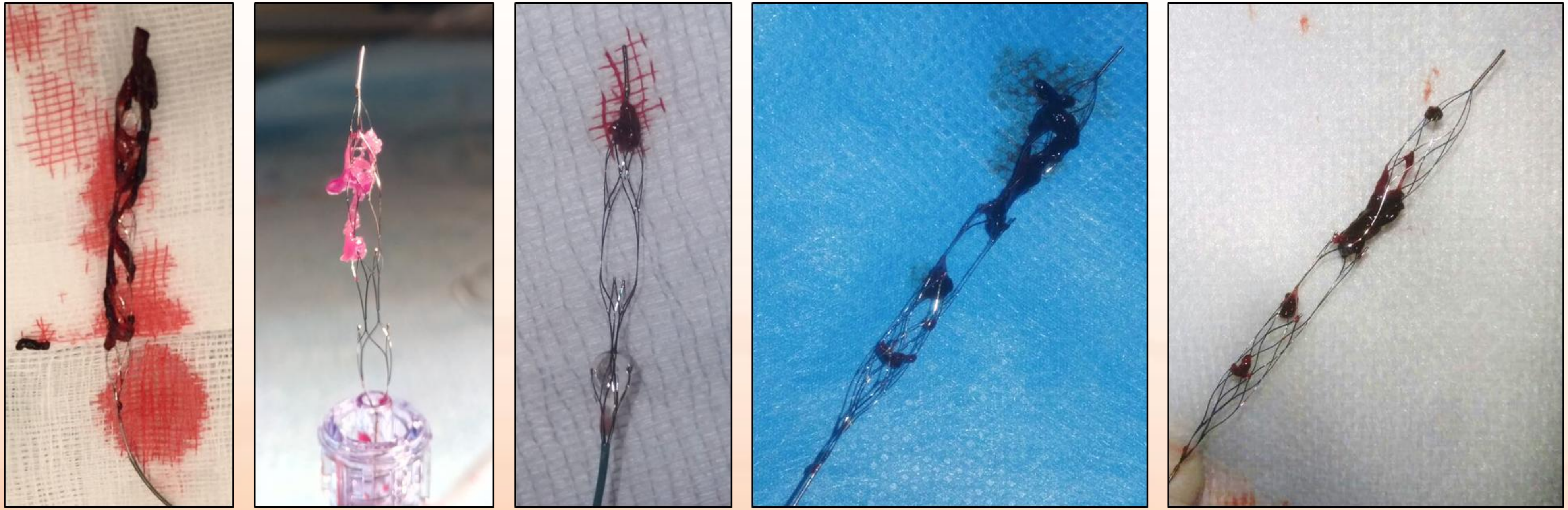
enVast™



CHOOSE TO REMOVE