VESALIO

DRIVEN TO ADVANCE PATIENT CARE IN VASCULAR OCCLUSION BY PROVIDING PHYSICIANS SUPERIOR TECHNOLOGY DESIGNED TO IMPROVE CLINICAL OUTCOMES

CHOOSE TO REMOVE

VESALIO™

enVast™

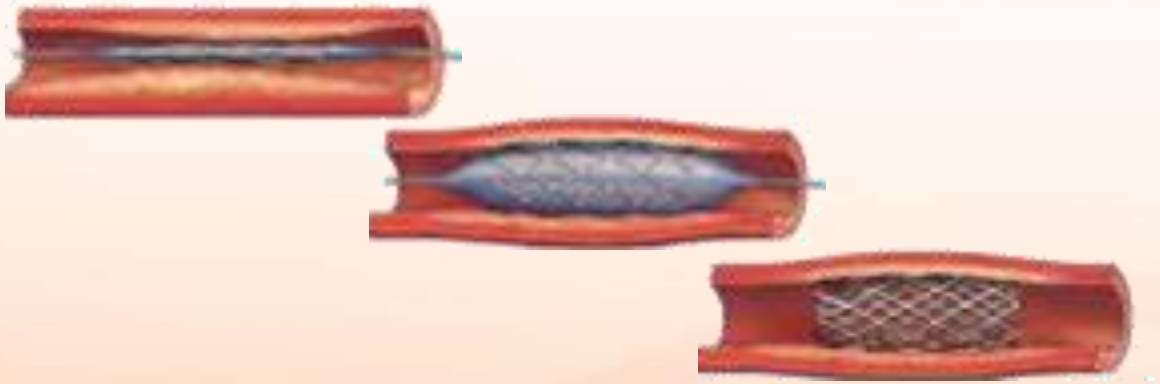
CATH-LAB STAFF PRESENTATION

LV-MKT-028

ENDOVASCULAR TREATMENT MODALITIES FOR STEMI

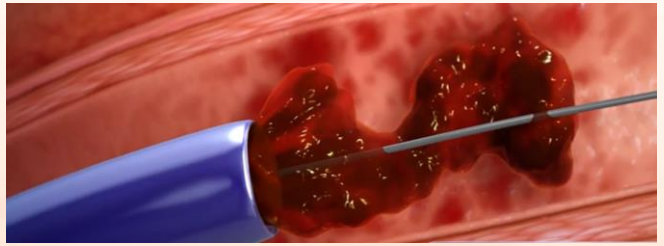
Standard endovascular treatment involves opening the artery with balloon & stent

- Outcomes remain poor in ~50% due to residual thrombus in the vessel



Endovascular aspiration continues to be debated

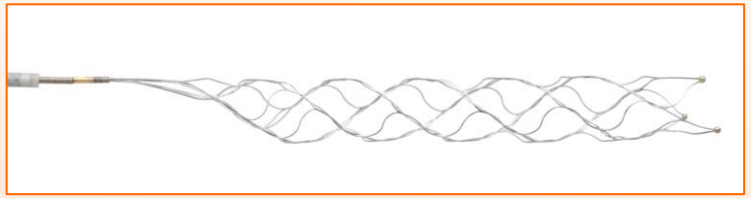
- CHEETAH, TOTAL, TASTE, TAPAS studies showed success in clot removal but also increased risk of AIS and variable outcomes

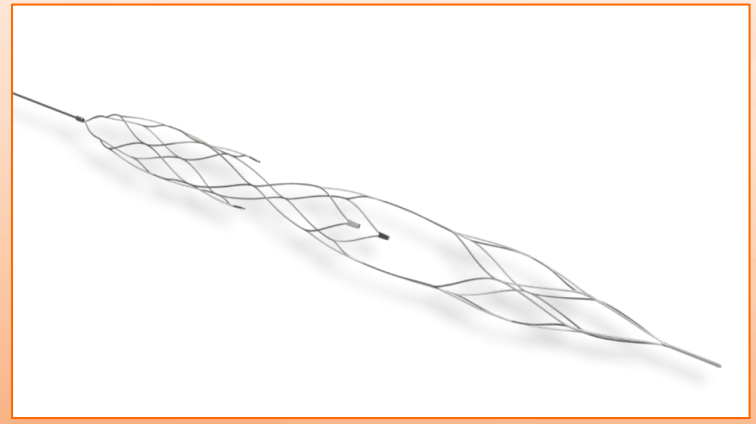


Studies show thrombus aspiration alone does not improve reperfusion or outcomes and bears higher potential for stroke

Neumann FJ, Sousa-Uva M, Ahlsson A, Alfonso F, Banning AP, Benedetto U, Byrne RA, Collet JP, Falk V, Head SJ, Juni P, Kastrati A, Koller A, Kristensen SD, Niebauer J, Richter DJ, Seferovic PM, Sibbing D, Stefanini GG, Windecker S, Yadav R, Zembala MO, Group ESCSD. 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J 2019;40(2):87-165.

WHAT IS A STENT RETRIEVER

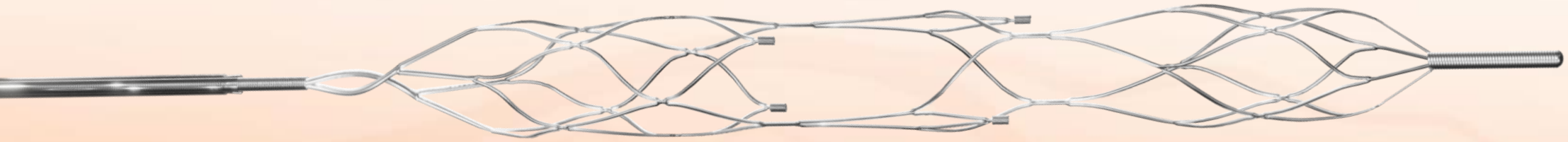




- A stent-retriever is a medical device
  - with a cylindrical mesh structure made of self-expanding nitinol
  - mounted on a wire
  - deployed within a micro-catheter
- Once at the site of the blood clot, the stent is released from within the catheter and self-expands within the thrombus
- This immediately pushes the clot against the wall of the artery, instantaneously reestablishing blood flow to the brain in most cases
- Standard of care for Ischemic Stroke

enVast™

THE FIRST AND ONLY CE-APPROVED STENT-RETRIEVER FOR CORONARY THROMBECTOMY



CHOOSE TO REMOVE

enVast™ THE RATIONALE

1. TREAT ALL LTB LESIONS

FROM SOFT CLOTS
THAT EASILY FRAGMENT
TO HARD, FIBRIN-RICH CLOTS
THAT CANNOT BE REMOVED

2. IMPROVE PROCEDURAL PERFORMANCE

A REAL SOLUTION FOR HIGH
CLOT BURDEN SITUATIONS

3. PROVIDE EASE OF USE

SYNERGISTIC WITH
ASPIRATION

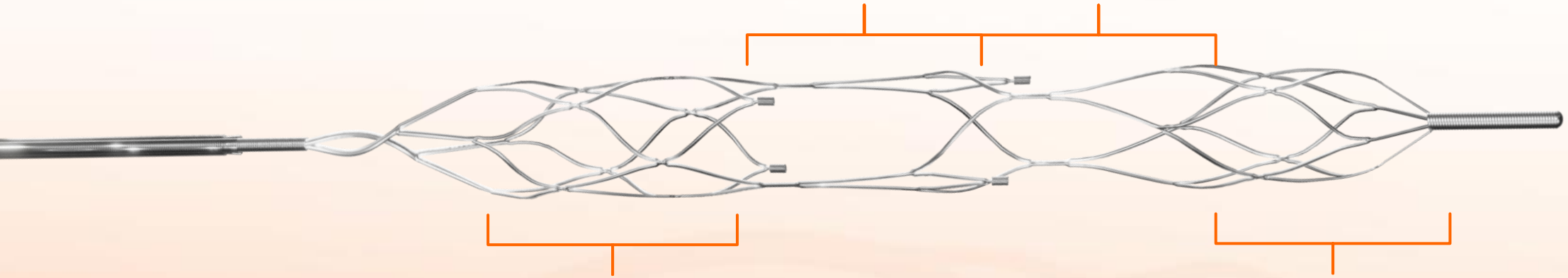
Strive to achieve better patient outcomes

DROP ZONE™ TECHNOLOGY

A BALANCED DESIGN FOR SMOOTH TRACKING AND SAFE RETRIEVAL

DROP ZONES

entry points for large, organized thrombi



FLOW RESTORATION ZONE

radial force optimized for artery apposition

CLOSED DISTAL BASKET

clot retention inside structure

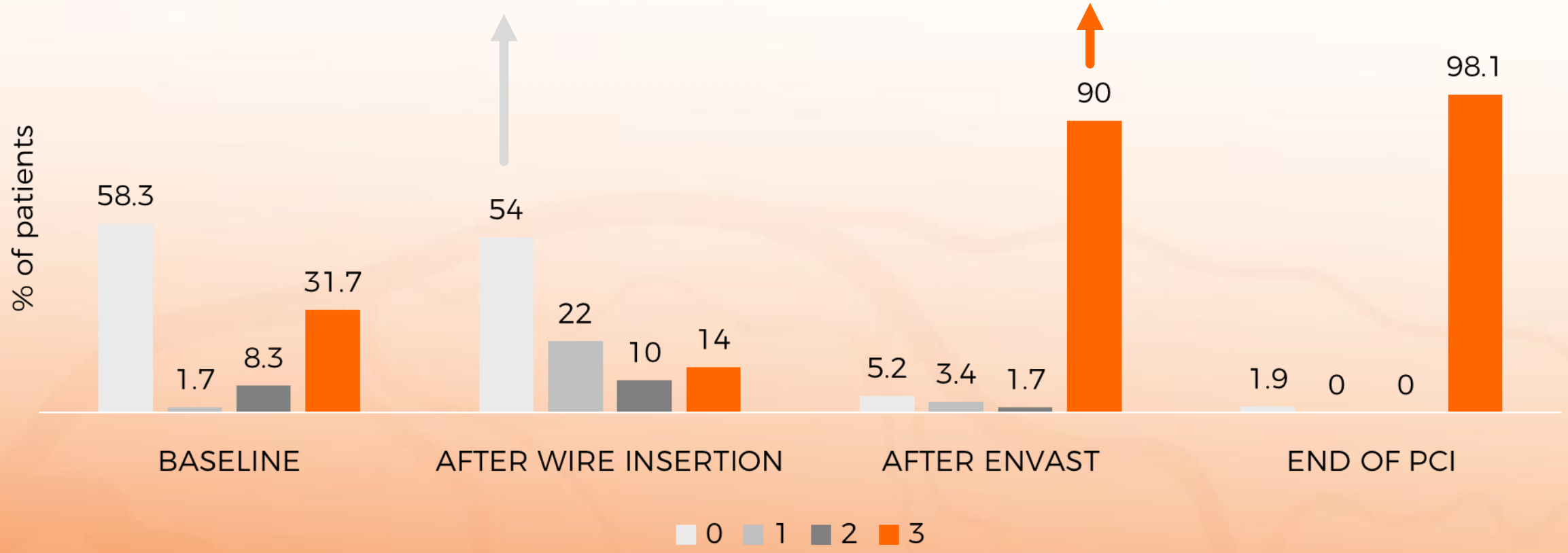
DESIGNED FOR

RAPID, HI-FLOW REPERFUSION

EFFICACY OUTCOMES – TIMI FLOW

enVast stent deployment was associated with immediate reperfusion in **85%** and TIMI-3 flow in **74%** of the patients with TIMI 0 after wire insertion

TIMI-3 increase from **31.7%** to **90%** after enVast (*p <.001*)

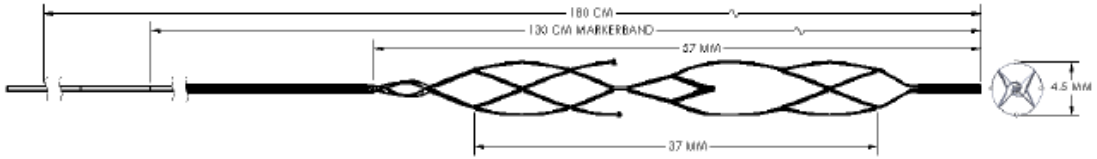


EuroIntervention. 2021 Feb 5;16(15):e1245-e1253. doi: 10.4244/EIJ-D-20-00221.

NeVa Mechanical Thrombectomy System

enVast™

Diameter	Working Length	Drop Zones	Wire Length
4.5 mm	37 mm	2	180 cm



Contents: (1) enVast 4.5 x 37 mm - Flow Restoration, 2 Drop Zones - 180 cm wire System
Contenido: (1) Sistema enVast de 4,5 x 37 mm – restauración del flujo, 2 zonas de captura – guía portadora de 180 cm
Conteúdo: (1) Sistema enVast de 4,5 x 37 mm – restabelecimento de fluxo, 2 zonas de captura – guia portadora de 180 cm

CATALOG NUMBER

REF EV-4537-F2RR LOT 050621X

Vesalio LLC
105 North Pointe Drive
Lake Forest, CA 92630
+615-206-7788

EC REP MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

2023-05-06 Use By Date

Rx Only Prescription

Consult Instructions for Use
STERILE EO Sterilized Using EO
Latex Free
Do Not Reuse
Do Not Use Device if Packaging Damaged
CE 0297 CE Mark
Keep Dry
Attention, Consult Accompanying Documents

REF EV-4537-F2RR
LOT 050621X
enVast 4.5 mm / 37 mm

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LOT 050621X
enVast 4.5 mm / 37 mm

Patents www.vesalio.com/patents

LV-LB-0102 REV B

enVast™ Diameter 4.5 mm Working Length 37 mm Drop Zones 2 Wire Length 180 cm

REF EV-4537-F2RR LOT 050621X 2023-05-06

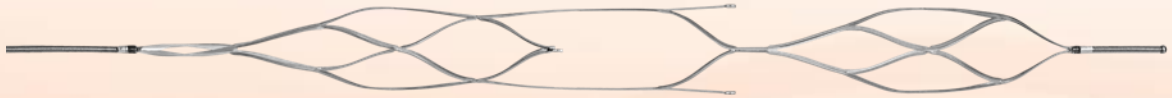
(01)00851279008712(17)230506(10)050621X

PROCEDURE STEPS

CHOOSE TO REMOVE

enVast™ CHOOSE TO REMOVE

- Choose an enVast size with labelled diameter that approximates the target vessel diameter

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	39 mm	2	180 cm	≥ 2.0 & ≤ 3.5	.021”
								
enVast 4.5 x 37	EV-4537-F2RR	4.5 mm	37 mm	57 mm	2	180 cm	≥ 2.0 & ≤ 4.5	.021”
								
enVast 4.5 x 46	EV-4546-F3RR	4.5 mm	46 mm	66 mm	3	180 cm	≥ 2.0 & ≤ 4.5	.021”
								
enVast 6.0 x 35	EV-6035-F2RR	6.0 mm	35 mm	55 mm	2	180 cm	≥ 3.5 & ≤ 6.0	.027”
								

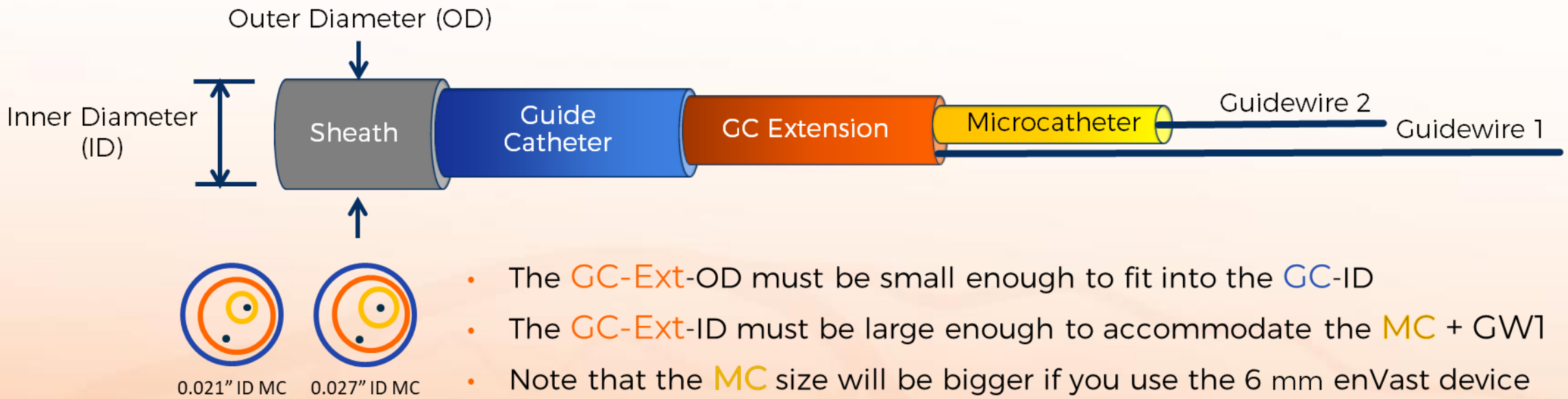
MICROCATHETER CONSIDERATIONS

- Choose a microcatheter size compatible with the enVast size chosen for the procedure

4.0 & 4.5 mm enVast sizes are compatible with microcatheters with min ID of 0.021”	6.0 mm enVast size is compatible with microcatheters with min ID of 0.027”
Via – 0.021”	Marksman – 0.027”
Headway – 0.021”	Via – 0.027”
TrevoPro – 0.021”	Phenom – 0.027”
Phenom – 0.021”	
Rebar 18 – 0.021”	
Velocity – 0.025”	
Marksman – 0.027”	
Via – 0.027”	
Phenom – 0.027”	

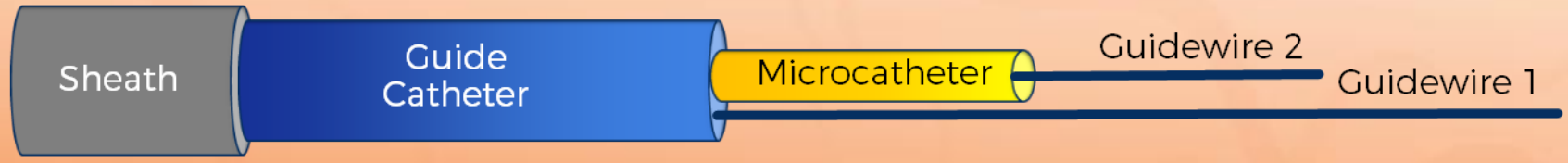
OTHER ACCESS CONSIDERATIONS

- Depending on the location of the lesion, you may choose to use:
  - A Guide Catheter + A Guide Catheter Extension: If clot is distal

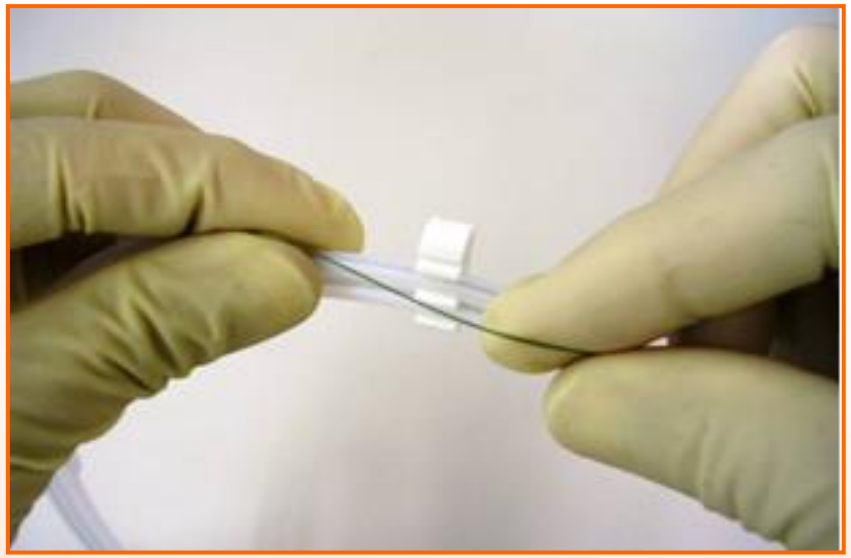


- The GC-Ext-OD must be small enough to fit into the GC-ID
- The GC-Ext-ID must be large enough to accommodate the MC + GW1
- Note that the MC size will be bigger if you use the 6 mm enVast device

  - A Guide Catheter only: If clot is sufficiently proximal



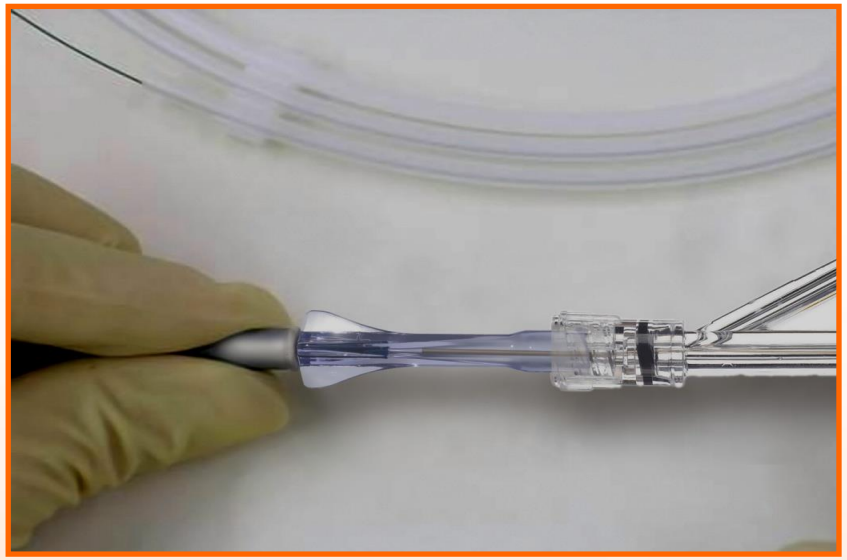
ENVAST PREPARATION & FLUSHING



- Remove packaging hoop from the pouch and detach wire from the white rubber wire-holder
- Carefully remove delivery wire and introducer sheath out of the packaging hoop

- Flush enVast by inserting the distal end of the introducer sheath partially into the RHV connected to the microcatheter
- Tighten the RHV and verify that fluid exits the proximal end of the introducer sheath

LOADING ENVAST INTO THE MICROCATHETER



- Loosen the RHV and visually confirm that the tip of the sheath is seated deeply in the hub of the micro catheter

- Tighten the RHV around the introducer sheath to prevent back flow of blood, but not so tight as to damage the enVast device

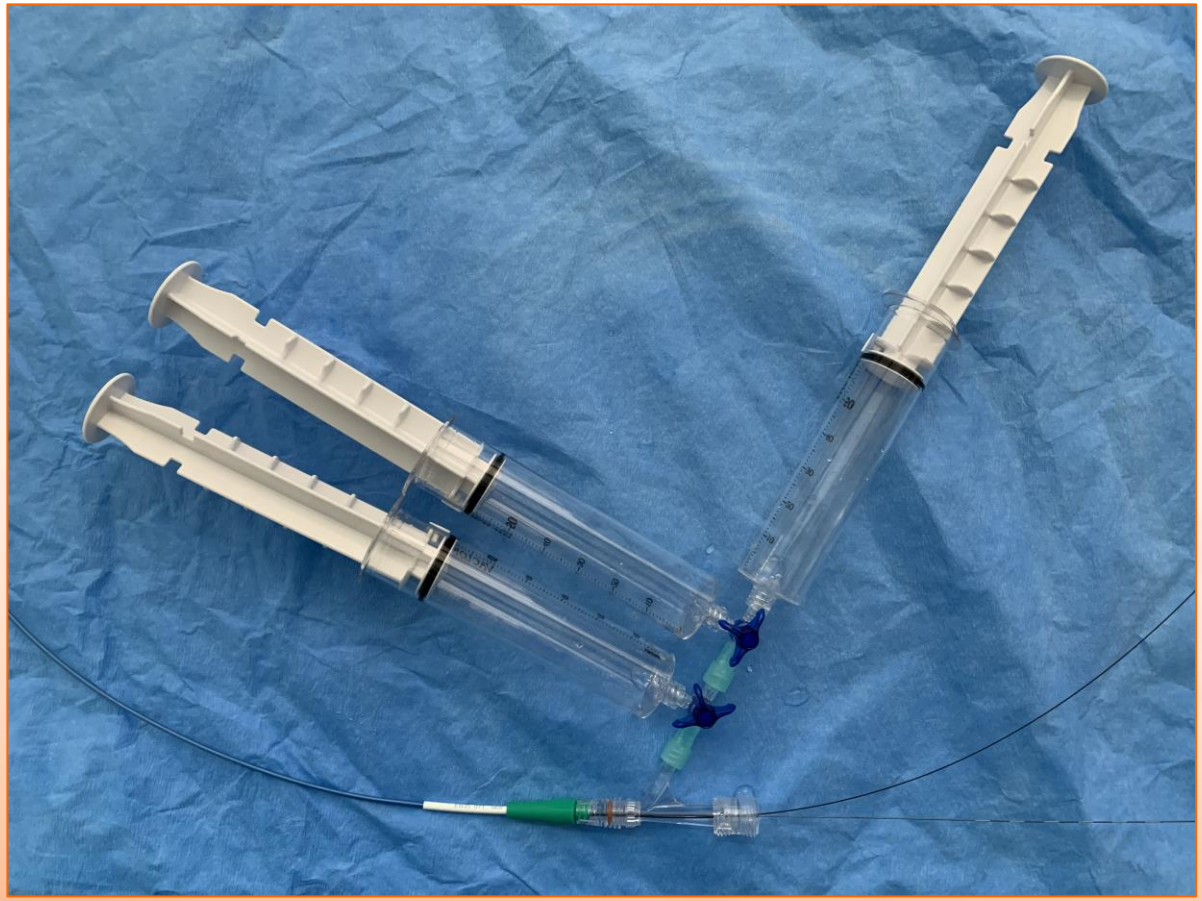
NAVIGATING ENVAST TO THE OCCLUSION SITE

- Once the flexible portion of the pusher wire has entered the microcatheter shaft, loosen the RHV and remove the introducer sheath
- DO NOT THROW AWAY THE INTRODUCER SHEATH: Keep it on the sterile table as it may be needed for a second pass

NAVIGATING ENVAST TO THE OCCLUSION SITE

- Advance the enVast device in the microcatheter until the tip of the enVast basket aligns with the tip of the micro catheter under fluoro
- You can use the zebra markers on the enVast pusher wire to decide when to start visualizing the procedure under fluoroscopy
- If excessive resistance felt, discontinue delivery of enVast and identify the cause of resistance

ENVAST RETRIEVAL



- Use 3- 60ml VacLoc syringes.
- Check enVast position, take your time and start retrieval slowly
- Withdraw enVast and the GC-Extension simultaneously under continuous aspiration from the GC hub
- Aspirate GC, contrast run
- enVast can be used up to 3 times

WHAT DO YOU NEED TO HAVE AVAILABLE FOR STEMI THROMBECTOMY

ENVAST Thrombectomy Device

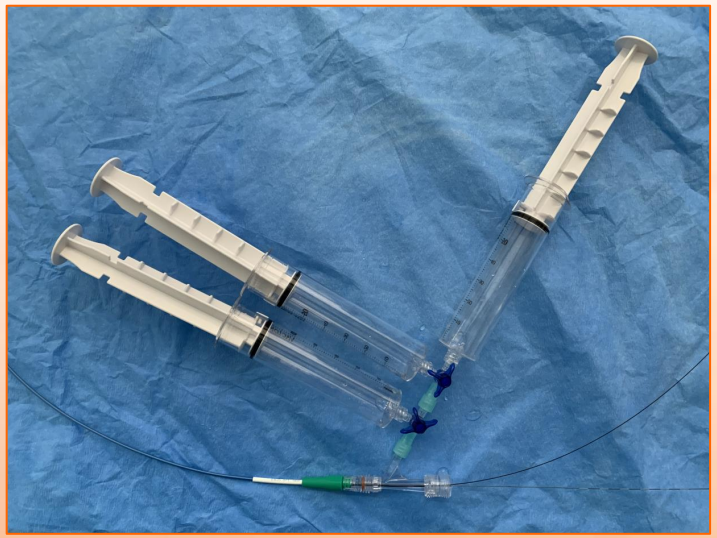
Remember to KEEP the INTRODUCER SHEATH!

2 x .014 Workhorse wires

Approved .021" or .027" ID Microcatheter

Guide Catheter and Guide Catheter Extension

3 -60 ml VacLoc Syringe
with 3-way stop cocks



enVast™ STEMI thrombectomy cheat sheet

ENVAST THROMBECTOMY DEVICE

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	39 mm	2	180 cm	≥ 2.0 & ≤ 3.5	.021”
enVast 4.5 x 37	EV-4537-F2RR	4.5 mm	37 mm	57 mm	2	180 cm	≥ 2.0 & ≤ 4.5	.021”
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enVast 6.0 x 35	EV-6035-F2RR	6.0 mm	35 mm	55 mm	2	180 cm	≥ 3.5 & ≤ 6.0	.027”

LIST OF PRODUCTS REQUIRED

- enVast
- Approved .021 or .027 Microcatheter
- 3-60 ml VacLoc Syringe
- 3-way stop cocks
- Guide Catheter
- Guide Catheter Extension
- 2 x .014 Workhorse wires

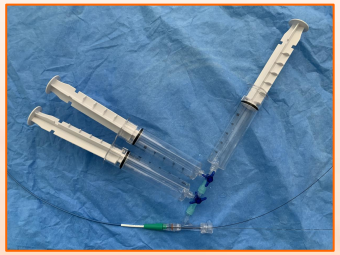
MICROCATHETER CONSIDERATIONS

4.0 & 4.5 mm enVast sizes are compatible with MCs with min ID of 0.021”		6.0 mm enVast size is compatible with MCs with min ID of 0.027”
Rebar 18 – 0.021”	TrevoPro – 0.021”	Marksman – 0.027”
Headway – 0.021”	Via – 0.021”	Via – 0.027”
Phenom – 0.021”	Velocity – 0.025”	Phenom – 0.027”
Marksman – 0.027”	Via – 0.027”	
Phenom – 0.027”		

enVast™ STEMI thrombectomy cheat sheet

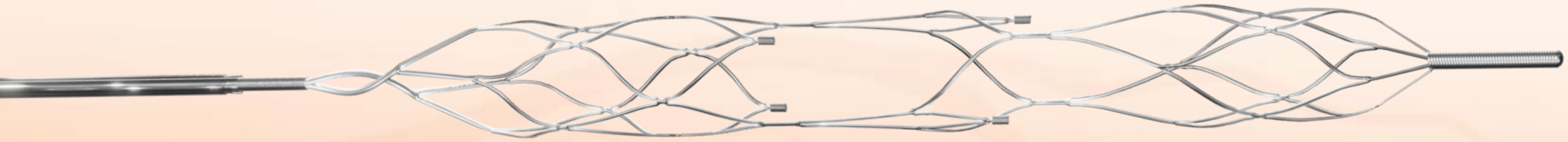
PROCEDURE STEPS

1. Cross occlusion site with .014” wire (GW-1) and go as distal as possible
2. Backload second .014 wire (GW-2) into .021” or .027” microcatheter (MC)
3. Advance MC and GW-2 to position MC tip past thrombus
4. Remove GW-2 from MC
5. Prep enVast device and advance into MC, drive to distal tip of MC
6. Unsheath enVast and remove the MC - Remember to KEEP the INTRODUCER SHEATH
7. If using a Guide Catheter Extension, advance over both enVast and GW-1
8. Attach 3 x 60 ml VacLoc Syringe with 3-way stop cocks to Guide Catheter (GC)
9. Check positioning and start slow retrieval
10. Withdraw enVast and GC-Extension simultaneously under continuous aspiration from the GC hub
11. Aspirate GC, perform fluro run
12. If needed, repeat up to three enVast passes



enVast™

QUESTIONS?



CHOOSE TO REMOVE