CHANGING OUTCOMES
CHANGING LIVES

CHOOSE TO REMOVE

VESALIO™

enVast™

VESALIO CHANGING OUTCOMES CHANGING LIVES

IN THE REARVIEW
Founded by Stroke Physicians

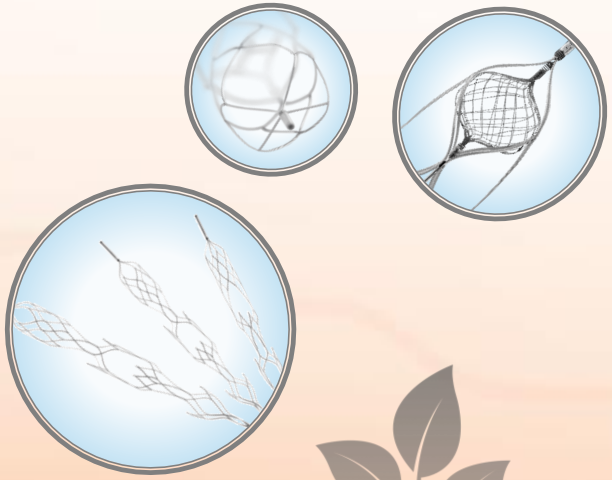
- Stroke: 12,000+ cases
- 50 Issued & 65 Filed Patents
- 8 CE Approvals, MDR certification
- U.S. FDA Approvals for vasospasm & peripheral

CURRENT COURSE
Growth & Diversification

- Growing adoption in neurovascular:
  - Launching unique NeVa NET – the 1st device with integrated distal filter
- Portfolio expansion into cardio and peripheral vascular:
  - enVast - the 1st device of its kind approved in cardio-thrombectomy
  - pVasc – in the U.S.

ON THE HORIZON
A Thrombectomy Company

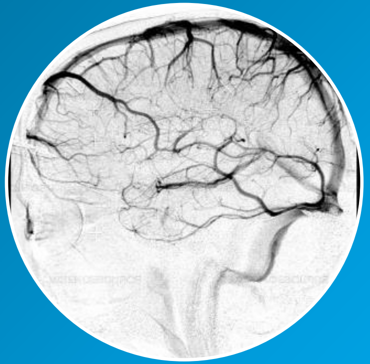
- New opportunities with stroke aspiration and pulmonary embolism



Vesalio is advancing patient care in vascular occlusion by providing physicians innovative technology designed to improve clinical outcomes

THE CLOT BURDEN: A BROAD ANATOMICAL CONCERN

Clots create vascular occlusions in the brain, heart, lungs, & limbs



Neurovascular

Clots block circulation to an artery in the brain causing damage and loss of neurological function

Cardiovascular

Clots restrict blood flow to a major artery in the heart, causing a heart attack and muscle damage

Peripheral Vascular

Clots can block flow anywhere in the body resulting in additional acute conditions

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CORONARY ARTERY DISEASE: #1 CAUSE OF DEATH WW

Myocardial Infarction (MI) ≈ **17 mio.** annual incidence WW

38%
of MIs[1]

ST-elevation myocardial infarction (STEMI)

The most severe type of CAD, occurs when a major artery is completely blocked

≈6.5 mio.
annual incidence

28%
of STEMIs[2]

STEMI with large thrombus burden

≈1.8 mio.
annual incidence

x2 - x4
higher risk of major adverse events[3]

x2
higher risk of mortality

91%
angiographic presence of thrombus[4]

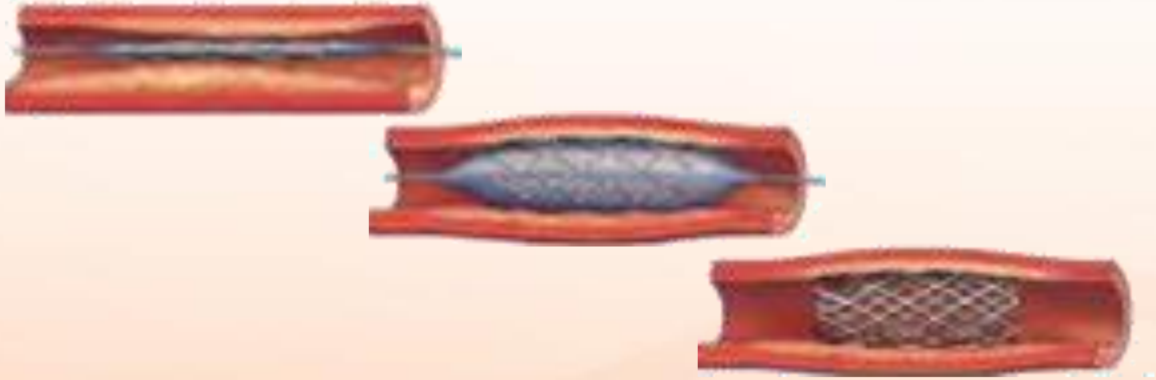
There is no established technique for managing LTB in acute coronary syndrome

1. https://my.clevelandclinic.org/health/diseases/22068-stemi-heart-attack
2. Scarparo P. et al., Impact of Large Thrombus Burden on Very Long-Term Clinical Outcomes in Patients Presenting With ST-Segment Elevation Myocardial Infarction. J Invasive Cardiol. 2021 Nov;33(11):E900-E909
3. Singh M, et al... Influence of coronary thrombus on outcome of percutaneous coronary angioplasty in the current era (the Mayo Clinic experience). Am J Cardiol 2001;88(10):1091-6
4. Kumar V. et al., Large intracoronary thrombus and its management during primary PCI. j.ihj.2020.11.009

ENDOVASCULAR TREATMENT MODALITIES FOR STEMI

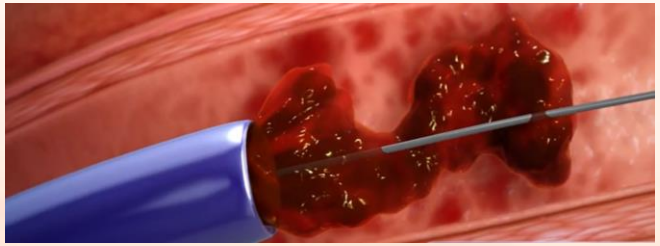
Standard endovascular treatment involves opening the artery with balloon & stent

- 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



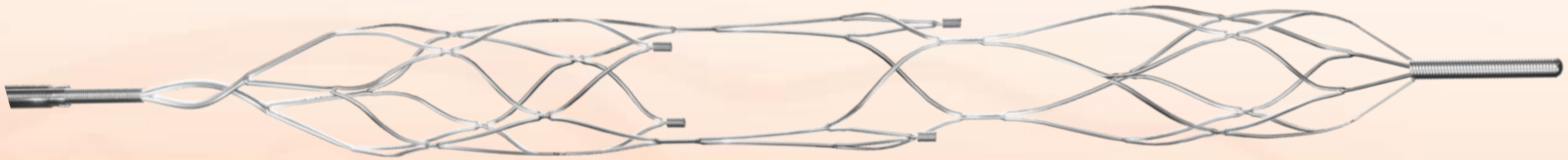
Studies show thrombus aspiration alone does not improve reperfusion or outcomes and bears higher potential for stroke

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 made of self-expanding nitinol
- It is delivered beyond the occlusion site via a delivery catheter
- Once at the occlusion site, it is deployed by retracting the delivery catheter proximally
- As soon as it is deployed, it immediately self-expands within the artery, pushing the clot against the artery wall, instantaneously reestablishing blood flow
- Standard of care for Ischemic Stroke

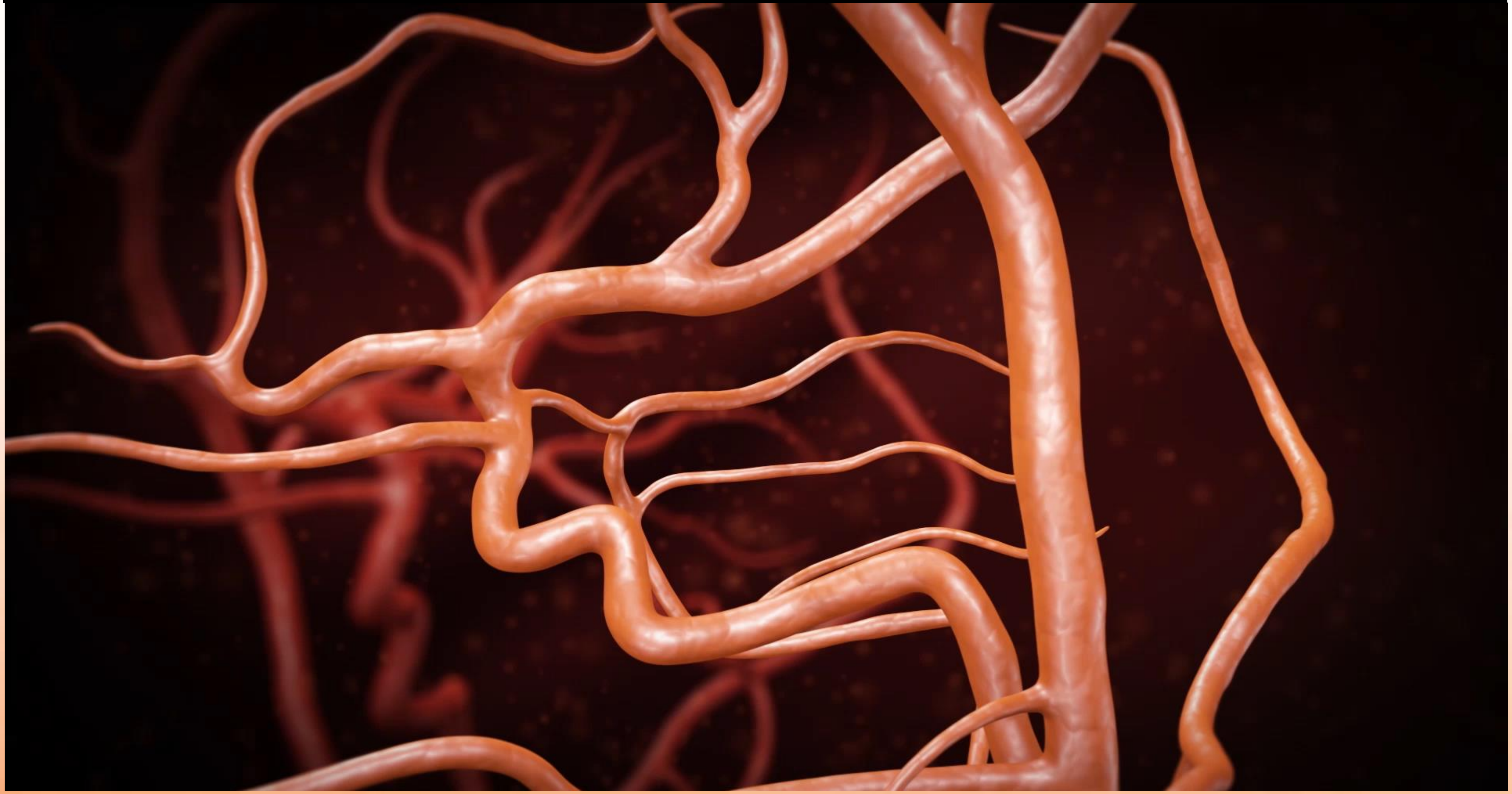
enVast™



The first and only ce-approved stent-retriever for coronary thrombectomy

CONCEPT OF ACTION

This animation shows enVast in cerebro-vascular anatomy & intervention



enVast™ THE RATIONALE

TREAT ALL LTB LESIONS

From soft clots that easily fragment to hard, fibrin-rich clots that cannot be removed by existing technologies

IMPROVE PROCEDURAL PERFORMANCE

A real solution for high clot burden situations

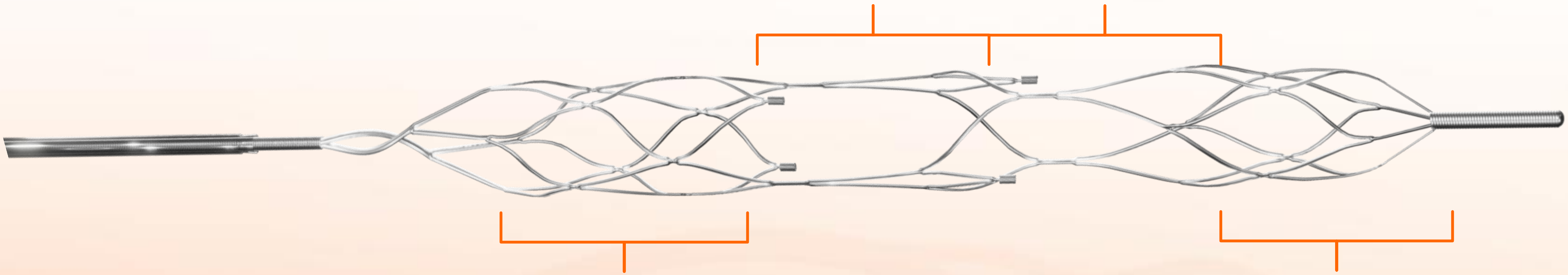
PROVIDE EASE OF USE

Synergistic with aspiration

Strive to achieve better patient outcomes

DROP ZONE™ TECHNOLOGY

A BALANCED DESIGN FOR SMOOTH TRACKING AND SAFE RETRIEVAL

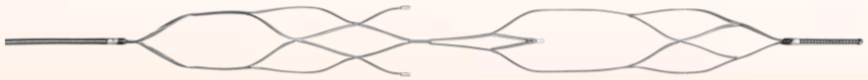
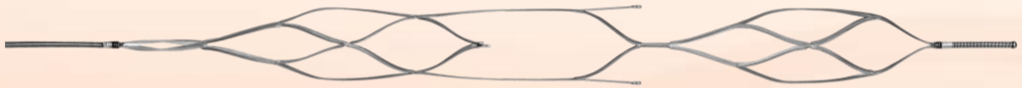
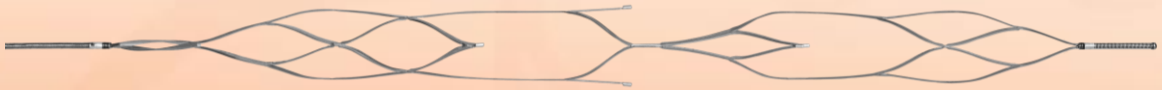
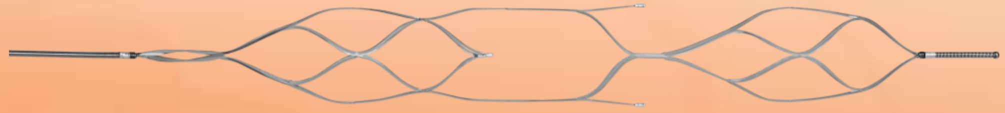


DESIGNED FOR

RAPID, HI-FLOW REPERFUSION

enVast™ PORTFOLIO

- 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 Length	Recommended Vessel Diameter (mm)	Min delivery catheter ID
enVast 4.0 x 30	EV-4030-F2RR	4.0 mm	30 mm	39 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”
								

CLINICAL STUDIES

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enVast™ FIRST IN MAN

- Two tertiary centers in Switzerland (Bern, Lugano)
- 61 consecutive ACS patients with LTB (TTG ≥ 3)
- All efficacy data core-lab abjugated by an independent center

Efficacy Outcomes

- 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
- IMI-3 increase from 31.7% to 90% after enVast (*p <.001*)
- STE Resolution (≥50%) in 71.7% of patients
- Complete STE Resolution (≥70%) in 43.5% of patients
- enVast retrieved macroscopic thrombotic material in 53% of the cases
- enVast use decreased the angiographic thrombus burden to ≤2 in 57% of the patients.
- MBG 0-1 was detected in 65% of patients at baseline and in 27% after enVast use (*p<.001*)

Safety Outcomes

- Cardiovascular death in two patients (3.3%) - in cardiogenic shock at admission;
- No major procedure-related adverse events (coronary dissection, coronary perforation, cardiac tamponade, coronary occlusion, life threatening arrhythmias)
- 14 *(23%)* non-flow-limiting coronary spasms, resolved with intracoronary nitrates
- 1 *(1.6%)* unplanned revascularization at 30 days (stent under-expanded);
- 1 *(1.6%)* case (without continuous aspiration) of side-branch embolization requiring additional stent retrieval with complete vessel reperfusion;
- 1 *(1.6%)* transient ischemic attack at day 29, after a conventional staged PCI

enVast in combination with aspiration proved safe and effective in removing coronary thrombus and allowed immediate prompt restoration of flow in a high proportion of patients with ACS and LTB

enVast™ ONGOING CLINICAL PROJECTS BY VESALIO

NATURE TRIAL - enrolling

- A prospective, multi-center, randomized trial
- Up to 150 subjects at 12 sites (CH, IT, NE)
- Comparing enVast + conventional tX to conventional tX alone

- enVast to be deployed as the first measure to obtain reperfusion at the occlusion site up to 3 times
- Conventional Treatment defined as: (ballooning, manual aspiration thrombectomy, stenting)

ENVAST REGISTRY – in planning

- A prospective, multi-center registry
- Up to 200 subjects at up to 15 sites
- Assessing the efficacy and safety of enVast + conventional tX

CURRENT PRACTICE

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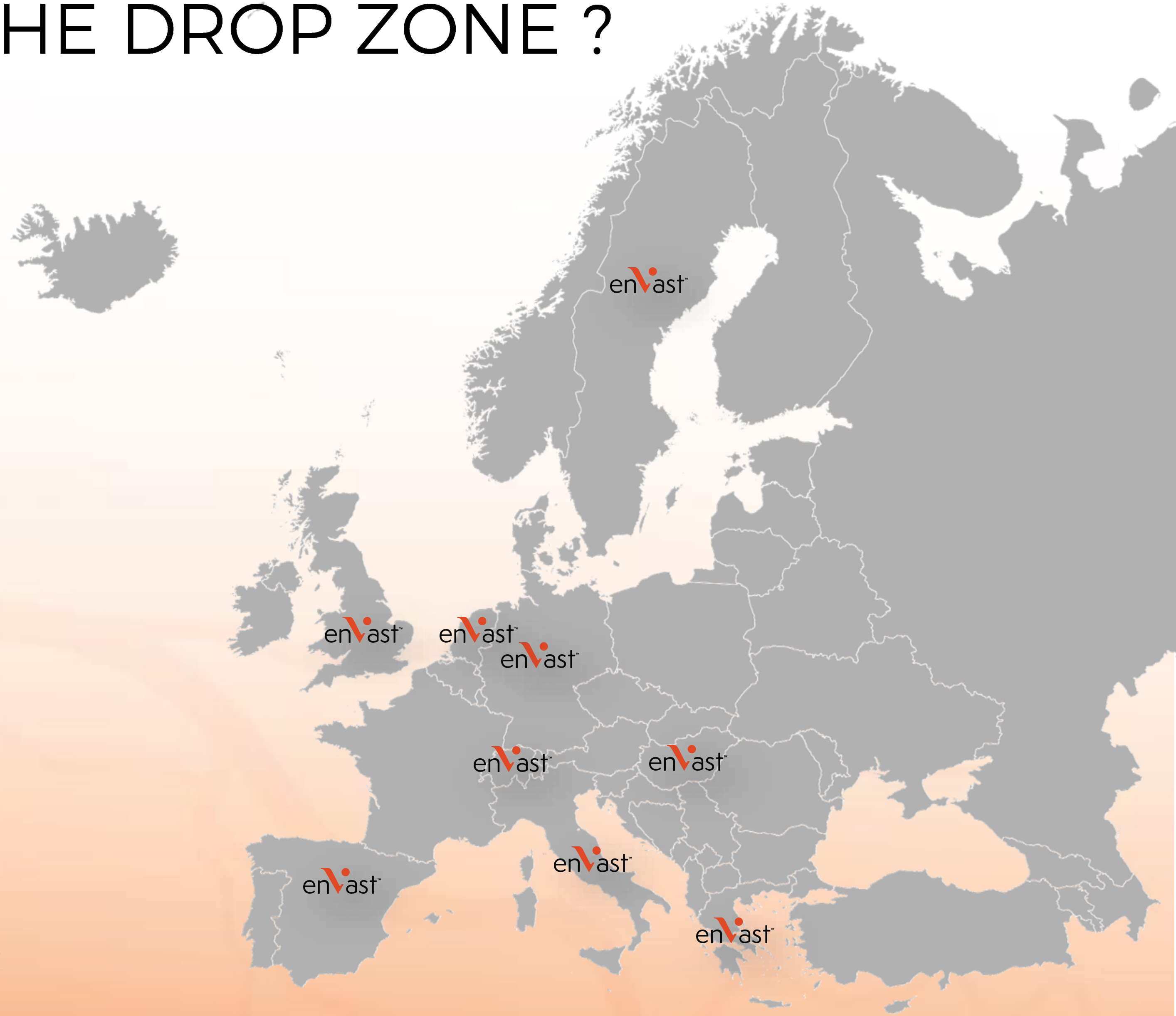
WHO’S DOING THE DROP ZONE ?

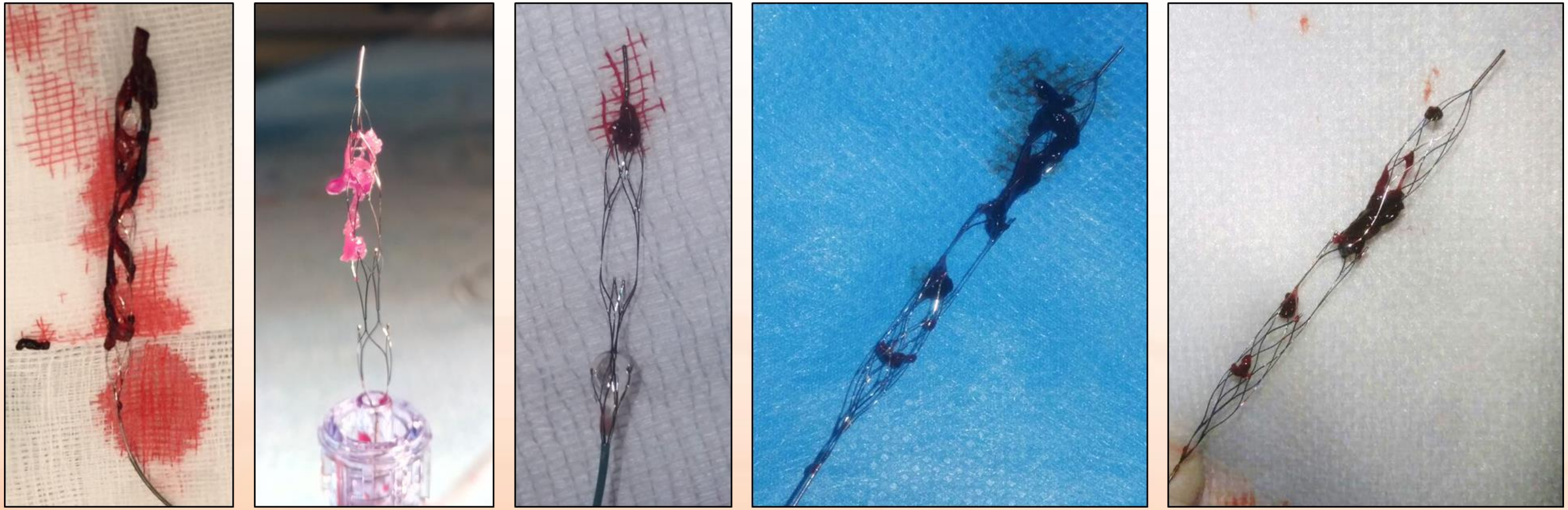
- Established users in 9 countries
  - Across 21 hospitals

- 5 expert proctors
  - Dr Marco Valgimigli, SWITZERLAND
  - Dr Dario Bongiovanni, GERMANY
  - Dr Andras Katona, SWEDEN
  - Dr Carlo Penzo, ITALY
  - Dr Mohammad Alkhalil, UK



map from freevectormaps.com

enVast™



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