VESALIO™

is dedicated to

CHANGING OUTCOMES, CHANGING LIVES

by advancing the care of patients suffering from vascular occlusion by providing physicians superior technology designed to improve clinical outcomes

enVast

THE ART OF CAPTURING ALL CLOT TYPES[2]

THE NEED

Large thrombus burden (LTB) is a common and critical occurrence in Acute Coronary Syndrome (ACS)

60%
of patients with ACS[1]

75%
of patients presenting with STEMI
(ST-elevation myocardial infarction)

x2
higher risk of mortality

x2 - x4
higher risk of major adverse events[2]

Studies show thrombus aspiration alone may increase stroke re-occurrence[3]

There is no established technique for managing LTB in ACS

1. Napodano M, Dariol G, Al Mamary AH, Marra MP, Tarantini G, D'Amico G, Frigo AC, Buja P, Razzolini R, Iliceto S. Thrombus burden and myocardial damage during primary percutaneous coronary intervention. Am J Cardiol 2014;**113**(9):1449-56.
2. Singh M, Berger PB, Ting HH, Rihal CS, Wilson SH, Lennon RJ, Reeder GS, Bresnahan JF, Holmes DR, Jr. 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
3. 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.

WHY enVast

1. TREAT ALL LTB OCCLUSIONS

FROM SOFT CLOTS THAT EASILY DISINTEGRATE

TO HARD, FIBRIN-RICH CLOTS THAT CANNOT BE INGESTED

2. IMPROVE PROCEDURAL PERFORMANCE

HIGHER 1ST PASS SUCCESS

BETTER TIME TO RECANALIZATION

3. PROVIDE EASE OF USE

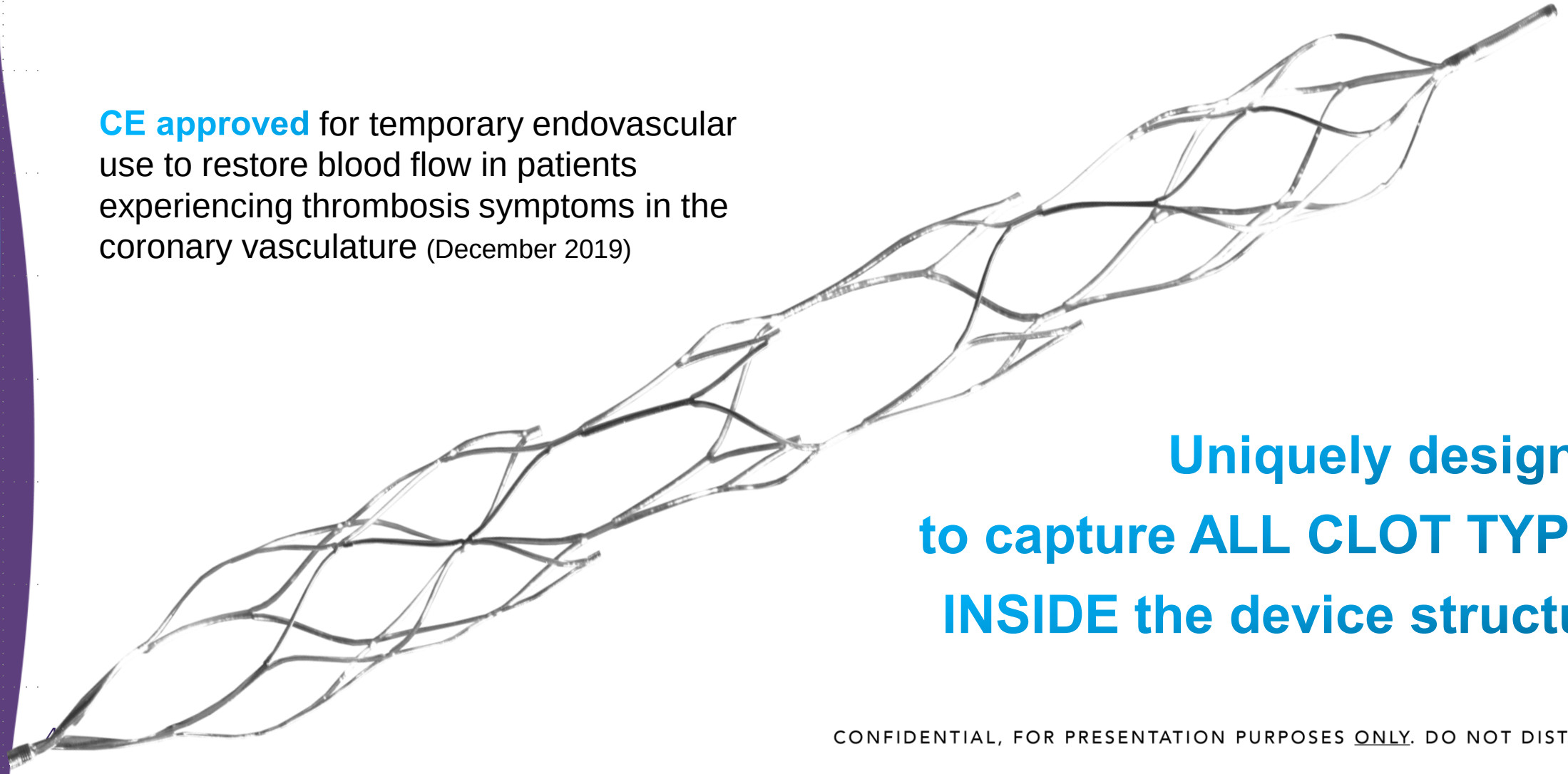
REAL TIME FEEDBACK DURING RETRIEVAL

SYNERGISTIC WITH ASPIRATION

To achieve better patient outcomes

DROP ZONE™
THE CLOT INSIDE

CE approved for temporary endovascular use to restore blood flow in patients experiencing thrombosis symptoms in the coronary vasculature (December 2019)



Uniquely designed
to capture ALL CLOT TYPES
INSIDE the device structure

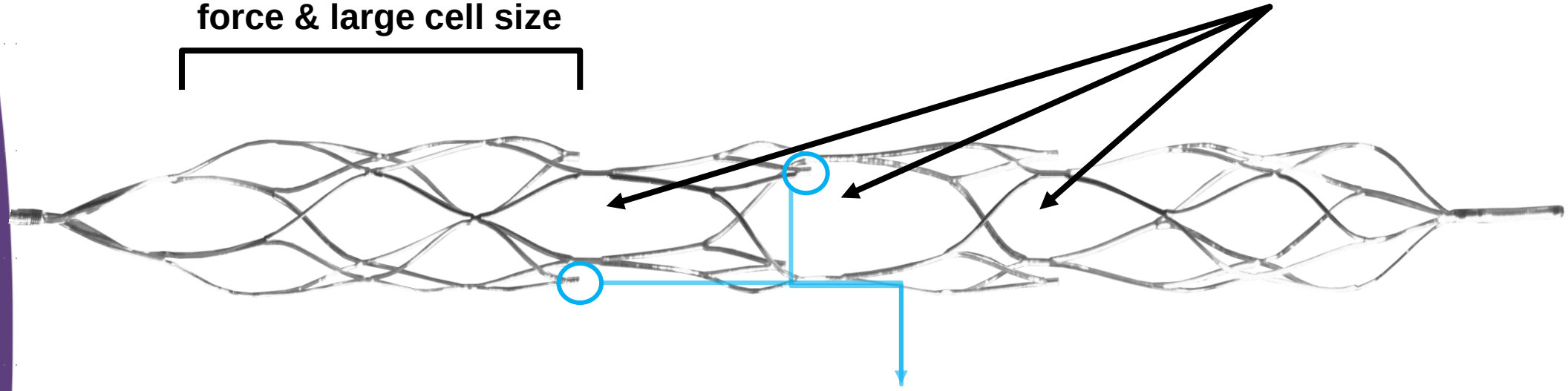
DROP ZONE™ TECHNOLOGY

FLOW RESTORATION ZONE

Clot initiation zone with optimized radial force & large cell size

DROP ZONES

Entry points for organized/ hard thrombi



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!

CE approved

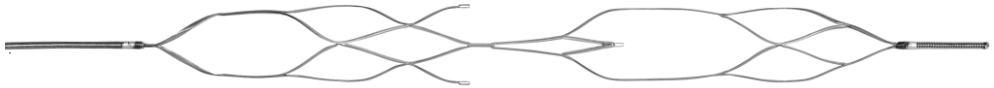
The Vesalio enVast Mechanical Thrombectomy System is indicated for endovascular temporary use to restore blood flow in patients who are experiencing symptoms of thrombosis in the coronary vasculature.

PORTFOLIO

Product Number	Product Name	Labeled Device Diameter (mm)	Labeled Device Length (mm)	Self Expanded Device Diameter (mm)	Recommended Vessel Diameter (mm)	Pusher Length	Introducer Microcatheter Minimum Inner Diameter
EV-4537-F2RR	enVast 4.5 x 37 mm	4.5	37	4.5	≥ 2.0 and ≤ 4.5	180cm	.021"
EV-4546-F3RR	enVast 4.5 x 46 mm	4.5	46	4.5	≥ 2.0 and ≤ 4.5	180cm	.021"
EV-4030-F2RR	enVast 4.0 x 30 mm	4.0	30	4.0	≥ 2.0 and ≤ 3.5	180cm	.021"
EV-4038-F3RR	enVast 4.0 x 38 mm	4.0	38	4.0	≥ 2.0 and ≤ 3.5	180cm	.021"
EV-6035-F2RR	enVast 6.0 x 35 mm	6.0	35	6.0	≥ 3.5 and ≤ 6.0	180cm	.027"
EV-6044-F3RR	enVast 6.0 x 44 mm	6.0	44	6.0	≥ 3.5 and ≤ 6.0	180cm	.027"

PORTFOLIO

enVast 4.0 x 30 mm, 2 Drop Zones, Full length: 39 mm

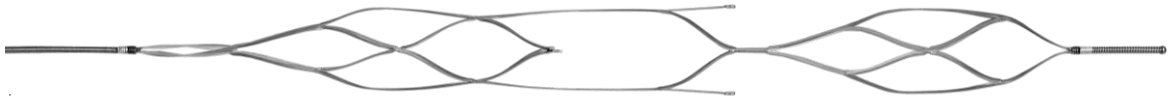


Vessel diameters 2.0 – 3.0 mm

Ideal for side branches or distal tracts of main vessels

Compatible with: 0.021” MC

enVast 4.5 x 37 mm, 2 Drop Zones, Full length: 57 mm

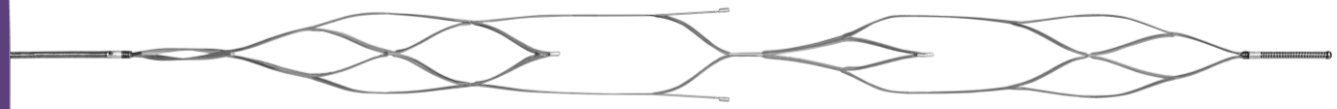


Vessel diameters 2.0 – 4.5 mm

Ideal for proximal to mid tracts of main branches

Compatible with: 0.021” MC

enVast 4.5 x 46 mm, 3 Drop Zones, Full length: 66 mm



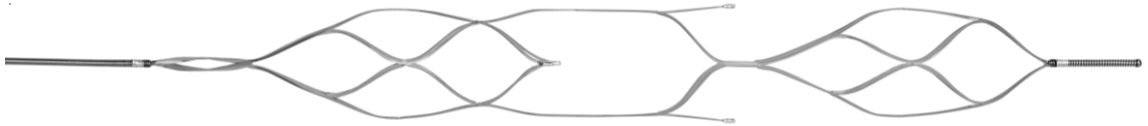
Vessel diameters 2.0 – 4.5 mm

Ideal for proximal to mid tracts of main branches

if thrombus burden is very large or difficult to quantify

Compatible with: 0.021” MC

enVast 6.0 x 35 mm, 2 Drop Zones, Full length: 55 mm



Vessel diameters 3.5 – 6.0 mm

Ideal for large RCA, left main or ectatic vessels

or every time the vessel RVs is greater than 4.00

Compatible with: 0.027” MC

CURRENT STATUS

First in man (FIM) completed

- 61-patient case series submitted for publication

FIM presented

- at the Transcatheter Cardiovascular Therapeutics (TCT) Meeting in November

Next Step: Starting European Registry

FIRST-IN-MAN

- Two tertiary centers in Switzerland (Bern, Lugano)
- 61 consecutive ACS patients with LTB (TTG ≥ 3)

EFFICACY ENDPOINTS

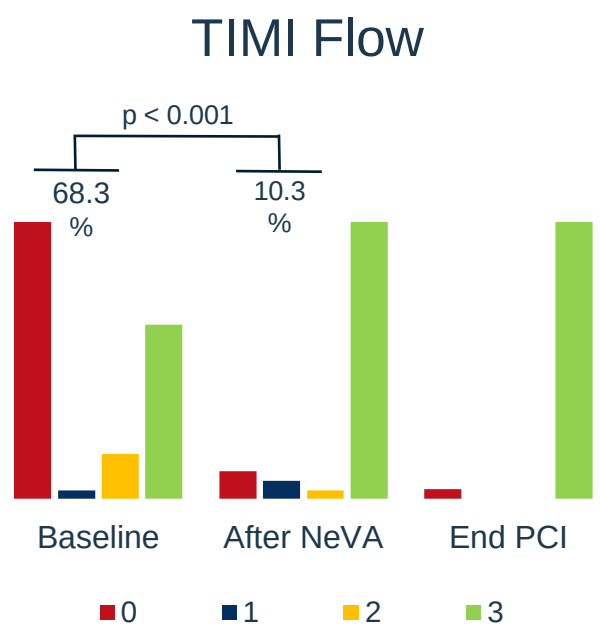
- ST-segment elevation resolution and TIMI flow
- TIMI Thrombus Grade and Myocardial Blush Grade by an independent core laboratory (MedsStar Washington Hospital Centre, Washington DC, USA)

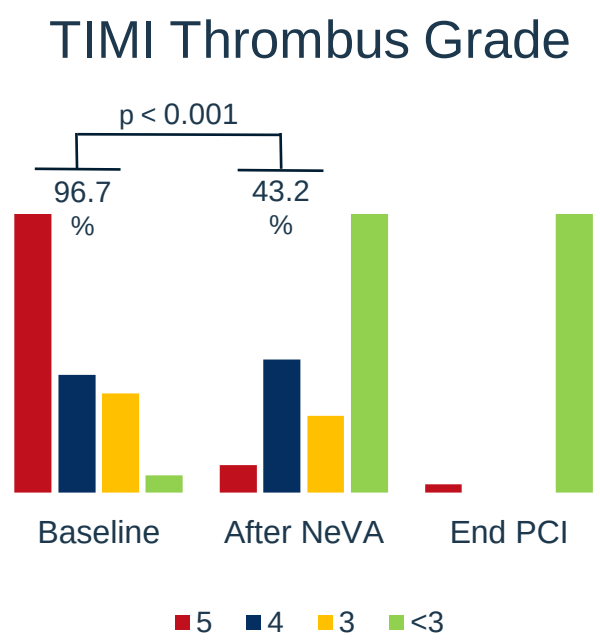
SAFETY ENDPOINTS

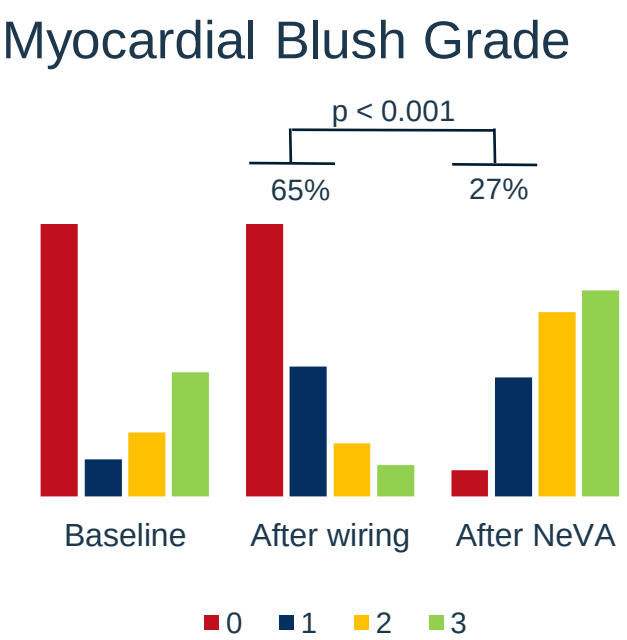
- device and procedure-related adverse events
- MACCE and bleedings at 30 days

FIRST-IN-MAN EFFICACY OUTCOMES

enVast deployment → immediate reperfusion in 85% of cases

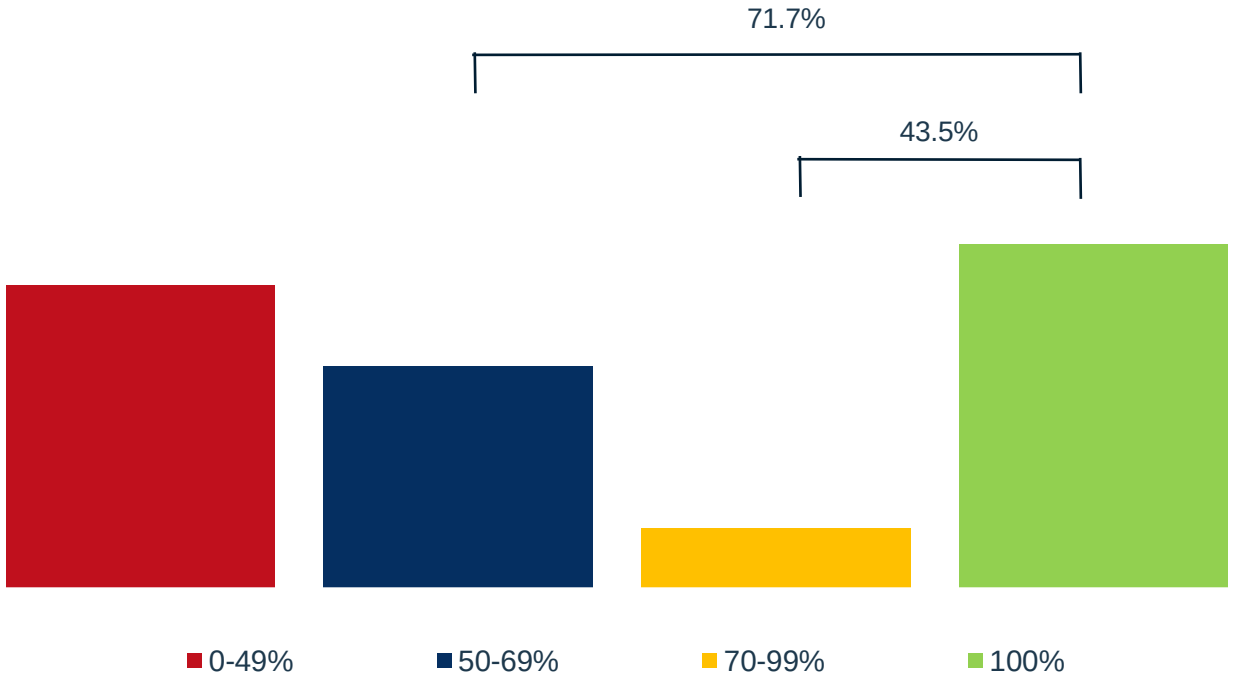






FIRST-IN-MAN EFFICACY OUTCOMES

ST resolution **> 50% in 71.7% of cases**
> 70% in 43.5% of cases



FIRST-IN-MAN 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

Procedural outcomes	n=61
Coronary dissection	0
Coronary perforation	0
Coronary occlusion	0
Coronary spasm	14 (23.0)
Flow limiting spasm	n=14, 0 (0)
Spasm resolution	n=14, 14 (100)
Embolization	1 (1.6)
Embolization resolution	n=1, 1 (100)
Cardiac tamponade	0
Life-threatening arrhythmias needing treatment	0

Clinical Outcomes	n=61
Death	2 (3.3)
Cardiovascular death	2 (3.3)
Non-cardiovascular death	0
Myocardial infarction	0
Unplanned revascularisation (any)	1 (1.6)
Definite Stent thrombosis	0
Cerebrovascular events	1 (1.6)
Stroke (any)	0 (0)
Transient ischemic attack	1 (1.6)
Bleeding BARC 3 or 5	0
Bleeding BARC 2	3 (4.9)
access site	3 (4.9)
non-access site	0

Data are presented as absolute numbers (percentage).

REGISTRY CONSIDERATIONS

enVast THROMBECTOMY DEVICE REGISTRY STUDY IN ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

A retrospective, multi-center registry study designed to assess the safety and effectiveness of the enVast coronary thrombectomy system as an adjunctive measure to conventional intervention in subjects presenting with ST-segment elevation myocardial infarction (STEMI)

Up to 200 subjects at up to 15 sites

enVast will be deployed as the first measure to obtain reperfusion at the occlusion site up to 3 times

± Conventional Treatment (ballooning, manual aspiration thrombectomy, stenting)

REGISTRY CONSIDERATIONS

enVast THROMBECTOMY DEVICE REGISTRY STUDY IN ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

Identification of Candidate Sites

- Hospital name & address
- Physician Name & contact information (principal investigator)
- Number of interventionalists that would contribute to the study at site
- STEMI case load/ year
- How do they currently treat large clot burden STEMI cases?
- Why should we consider this site?

Clinical Team to Present Protocol to the Site PI & Team

- Can they work with the protocol?
- Can they get informed patient consent within 72hrs from case?
- Documents needed for approval?
- Estimated timeline to approval?
- Buying enVast: any hurdles to consider?

Training / Evaluation

- Expect 3-5 cases/ physician to overcome the learning curve
- Cases can be done while the site is awaiting approval of the protocol

DISCUSSION OF NEXT STEPS

Selling – what needs to be considered?

Identification of sites: please come back with list (excel file will be provided after the call)

NATURE STUDY SITES TO EXCLUDE FROM OPTIONS FOR THE REGISTRY

Country	City	Hospital	PI
Switzerland	Bern	University Hospital Inselspital of Bern	Jonas Häener
	Lugano	Cardiocentro Ticino	Marco Valgamigili
	Genève	Hôpitaux Universitaires de Genève (HUG)	Juan Fernando Iglesias
	Luzern	Lucerne Cantonal Hospital	Florim Cuculi
Italy	Genova	IRCCS Ospedale Policlinico San Martino (referred to as "Policlinico")	Crimi
	Milan	Niguarda Hospital	Jacopo Oreglia
	Milan	Humanitas Hospital	Antonio Colombo
	CONA (FE)	Azienda Ospedaliero Universitaria di Ferrara	Matteo Tebaldi

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