Cerenovus Embotrap Devices Evaluated in EXCELLENT Registry of Mechanical Thrombectomy for Acute Ischemic Stroke

Cerenovus Revascularization Device, Embotrap의 real-world Excellent Registry Primary outcomes가 2022년 11월에 미국 캘리포니아에서 개최한 SVIN(Society of Vascular and Interventional Neurology)을 통하여 발표되었습니다.

EXCELLENT registry는 2018년부터 2021년까지 34개(27 US, 5 EU, 1 UK, 1 Israel) 병원에서 약 1,000명의 환자들을 대상으로 진행되었습니다. 최근까지 진행된Registry 중 가장 큰 규모로, international, multi-cohort(all-comer) 형식으로 진행되었으며, 다수 병원에서 사용되고 있는 술기에 Embotrap을 특성화시키고 회수된 혈전을 연구하여 다양한 혈전의 구성이 임상결과에 미치는 영향에 대해 확인하고자 디자인되었습니다.

EXCELLENT registry는 변동성(variability)과 편향(bias)를 최소화하기 위하여 Core Imaging Lab Assessment (including per pass reperfusion), Independent 90-day mRS Assessment, Clinical Events Committee (CEC), Central Clot Labs 기준으로 진행되었습니다.

Excellent Registry Result

- Final successful reperfusion of 94.5% achieved with mixed techniques
- >50% of completed procedures performed with a single pass of Embotrap
- First pass substantial reperfusion of 63% and near-complete reperfusion of 38.1%
- Good to ideal clinical outcomes in 46.8% of patients
- Symptomatic complications of 1.6% and 0.6% in cases with a single pass of Embotrap

STUDY POPULATION - ALL COMERS

997
SUBJECTS

34
STUDY SITES
(27 US, 5 EU, 1 UK, 1 Israel)

KEY INCLUSION CRITERION:
Use of the EMBOTRAP™ Device in first mechanical thrombectomy pass
NOTE: All other techniques and devices were operator's choice

PATIENT CHARACTERISTICS
Age, mean: 70.0 years
Female: 51.8%
Pre-stroke mRS 3-5: 9.5%
ASPECT 0-5: 9.9%
NIHSS, mean: 15.6

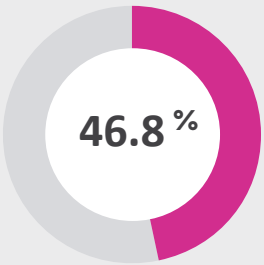
EXCLUSION CRITERIA:
- Pregnancy
- Participation in another is chemic stroke trial which could confound results

NOTE: There were no other exclusion criteria: all patients, stroke types and techniques were allowed

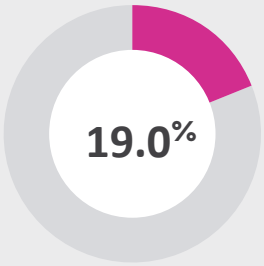
PROCEDURAL DATA

Use of IV-tPA38.1%	
Procedure Time (min), puncture to mTICI ≥2b	37.8 min
Median No. of Passes	1
Subjects with ≤3 passes	85.1%

Clinical Outcome

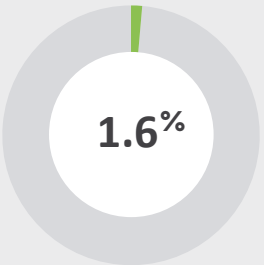


mRS 0-2 or no worsening from baseline at 90 days

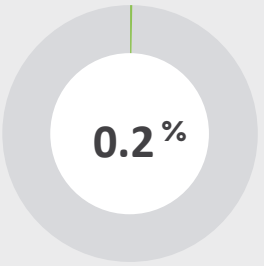


90-day all-cause mortality

Safety Outcome

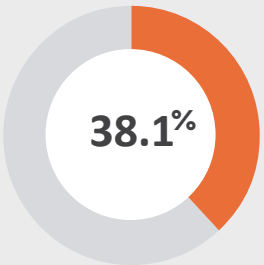


24-h sICH [a]

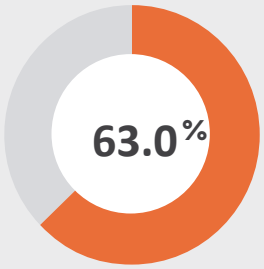


Embolization to new territory

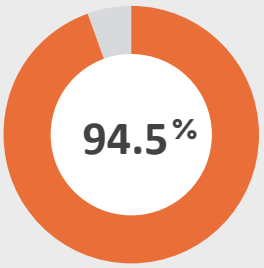
Procedural Outcome



First pass mTICI ≥ 2c



First pass mTICI ≥ 2b



Final mTICI ≥ 2b

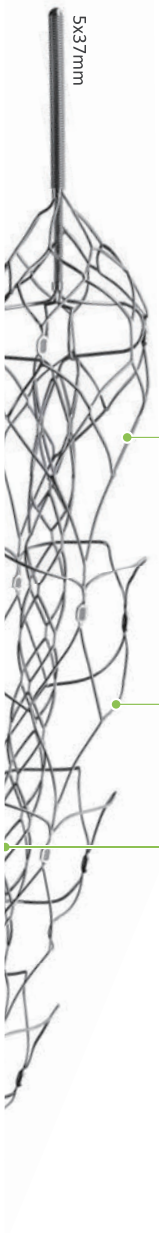
These results of EXCELLENT showed:

- **Nearly half (46.8%)** of the EMBOTRAP™ Device treated patients achieved **good to ideal functional outcome** (mRS 0-2 or no worsening from baseline at 90 days).
- Good safety outcomes were achieved with **low rates of sICH at 24-hours (1.6%)** and **embolization to new territory (0.2%).**
- A **high first pass rate of 38.1%** (first pass mTICI ≥2c) with **over 50% of subjects only needing 1 pass.**

mRS, modfied Ranking Scale; mTICI, modified Thrombolysis in Cerbrovascular Infarction; sICH, symptomatic intracerebral hemorrhage
According to the Heidelberg Bleeding Classification

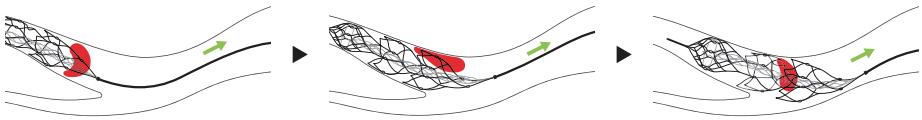
Designed to engage and grip differently

The EMBOTRAP® III Revascularization Device design is based on a foundation of clot science research[1]



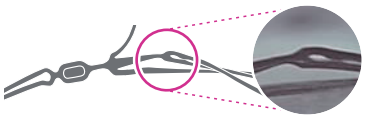
OUTER CAGE

The open and articulated outer cage is designed to engage and integrate the clot and to maintain wall apposition during retrieval, including around bends.[5,6,7]



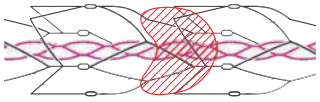
UPDATE

Tapered connector struts minimize contact area with vessel wall in tortuous anatomy and potentially reduce withdrawal force.[7]



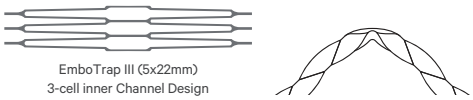
INNER CHANNEL

Designed to have high expansion power, to pinch and stabilize blood clots taken from the outer cage, and to reduce spillage.



UPDATE

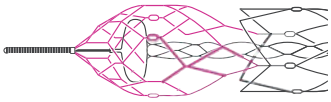
The flexible, 3-cell inner channel is designed for clot stabilization during retrieval. The 3-cell inner channel design has improved kink resistance and flexibility.[4,5]



EmboTrap III (5x22mm)
3-cell inner Channel Design

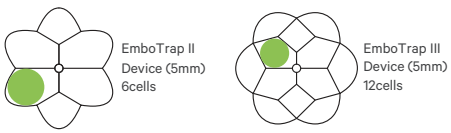
DISTAL CLOSED MESH

The enhanced dense distal mesh on the outer cage maintains control of the clot during retrieval.[7]



UPDATE

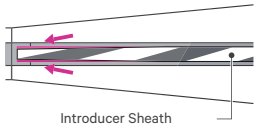
The smallest cell in the distal mesh is decreased from a 1.61 mm diameter in the EMBOTRAP® II Device to 1.20 mm in the EMBOTRAP® III Device.[5]



INTRODUCER SHEATH

UPDATE

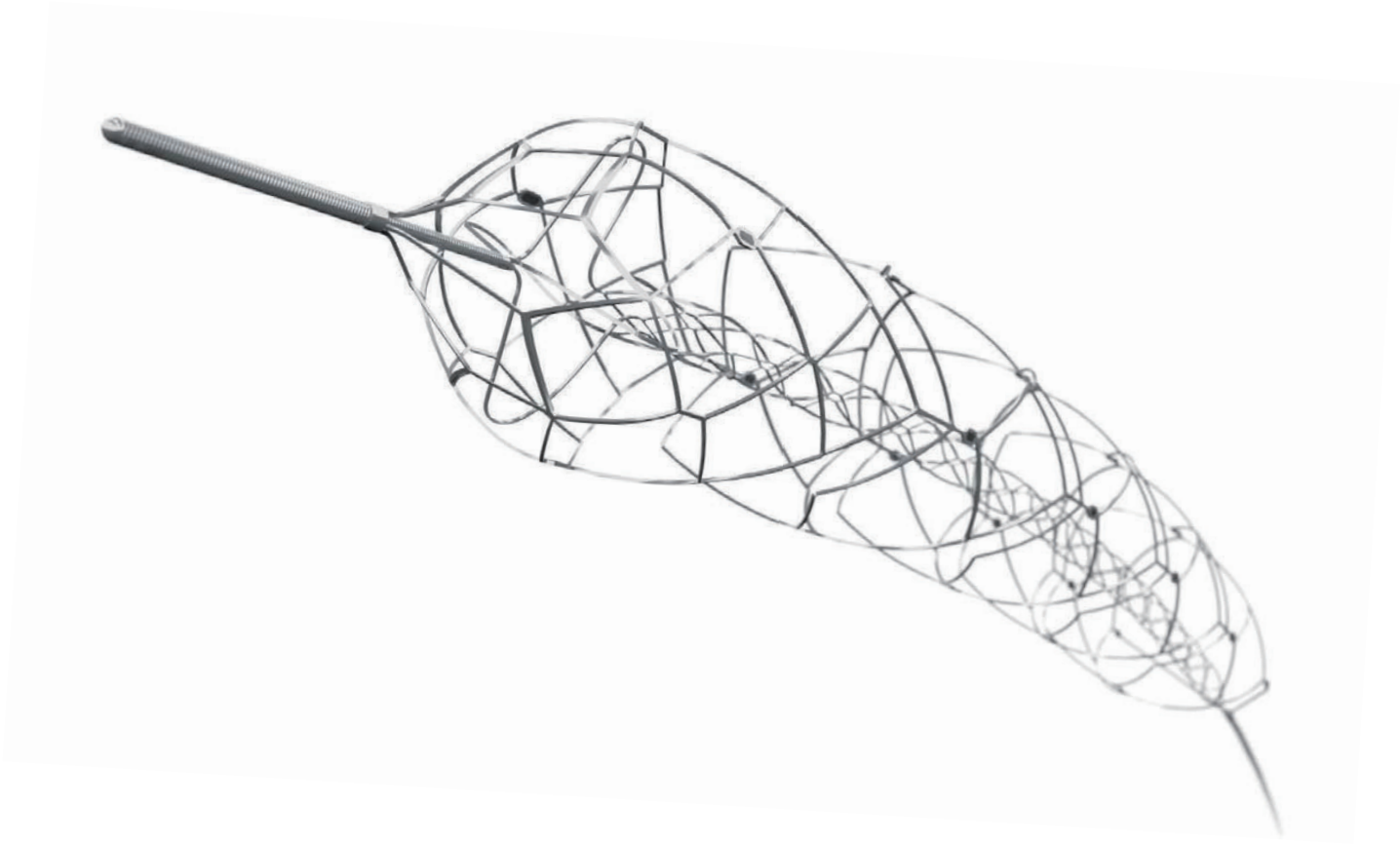
Tapered insertion tool to improved ease of use loading into a microcatheter.



Introducer Sheath

EMBOTRAP®III

revascularization device



EMBOTRAP™ III Revascularization Device

Product Code	Outer Cage Diameter	Recommended Vessel Diameter	Working Length	Overall Length	Microcatheter compatibility	Radiopaque Tip Length	Proximal coil length	Number of Radiopaque Markers		
								Proximal	Body	Distal
ET307522	5mm	1.5-5.0mm	22mm	194cm	0.021"	4mm	20mm	2	8	3
ET307537	5mm	1.5-5.0mm	37mm	195cm	0.021"	4mm	20mm	2	16	3
ET307645	6.5mm	1.5-6.5mm	45mm	196cm	0.021"	4mm	20mm	2	16	3

Reference

1. CERENOVUS. 137218-200416. Claim 2 20200601.
3. EMBOTRAP® III Revascularization Device [instructions for use]. CERENOVUS; 2020.
4. CERENOVUS. 137258-200416. Claim 3 20200602.
5. CERENOVUS. CERENOVUS Dimensional and Geometric Features ET3 Evidence Generation. TR374.
6. CERENOVUS. 137259-200416. Claim 2 20200528.
7. CERENOVUS. CERENOVUS EMBOTRAP III Clinical Evaluation Report Rev03. TR027-01.

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Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, warnings and precautions.

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166364-210203 / 189184-210914 / 145272-200701 EMEA /
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