

# First-in-human results of the Omega left atrial appendage occluder for patients with non-valvular atrial fibrillation

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## Introduction

Several strategies have been devised to obliterate the left atrial appendage (LAA) space, which is the suspected origin of the majority of cardioembolic thrombi in patients with non-valvular atrial fibrillation (NVAf)-related stroke<sup>1</sup>. The Omega™ LAA occluder (Vascular Innovations Co., Ltd., Nonthaburi, Thailand) is a novel self-expanding, cup-and-disc device made from a continuous, platinum-coated nitinol wire mesh (**Figure 1**), designed to occlude the LAA. The cup and disc are linked together by a flexible connecting waist. The disc has a polypropylene fabric securely sewn inside it, adding to the occlusive aspect of the device. For stabilisation, the cup carries 6 to 10 anchoring hooks. This study reports on the first-in-human experience and procedural safety and efficacy of the Omega LAA occluder.

## Methods

### STUDY POPULATION

Patients were enrolled in an open-label, non-randomised trial at the King Chulalongkorn Memorial Hospital, Bangkok, Thailand, between February 2019 and October 2019. Eligible patients had confirmed NVAf with an indication for oral anticoagulation but

were ineligible for this medical therapy due to a high bleeding risk. Exclusion criteria comprised both clinical and cardiac imaging features (**Supplementary Table 1**). The study protocol obtained approval from the local ethics committee and all patients provided informed consent.

### PROCEDURE PLANNING

An ECG-gated, thin-sliced ( $\leq 1.0$  mm) and contrast-enhanced cardiac computed tomography (CT) was performed in all patients and was analysed to measure the dimensions of the LAA orifice and LAA landing zone at a depth of 9 to 15 mm distal to the orifice – corresponding to the planned landing zone of the Omega anchoring cup. To enhance accuracy of device size selection further, a CT-based 3D silicone LAA model was created and used to simulate and test device deployment. A patient selection committee reviewed cases to ensure anatomical suitability.

### DEVICE IMPLANTATION AND MEDICAL THERAPY

The Omega LAA occluder system consists of an occlusion device and a delivery system intended for transvenous femoral deployment with transseptal access to the left atrium (LA).

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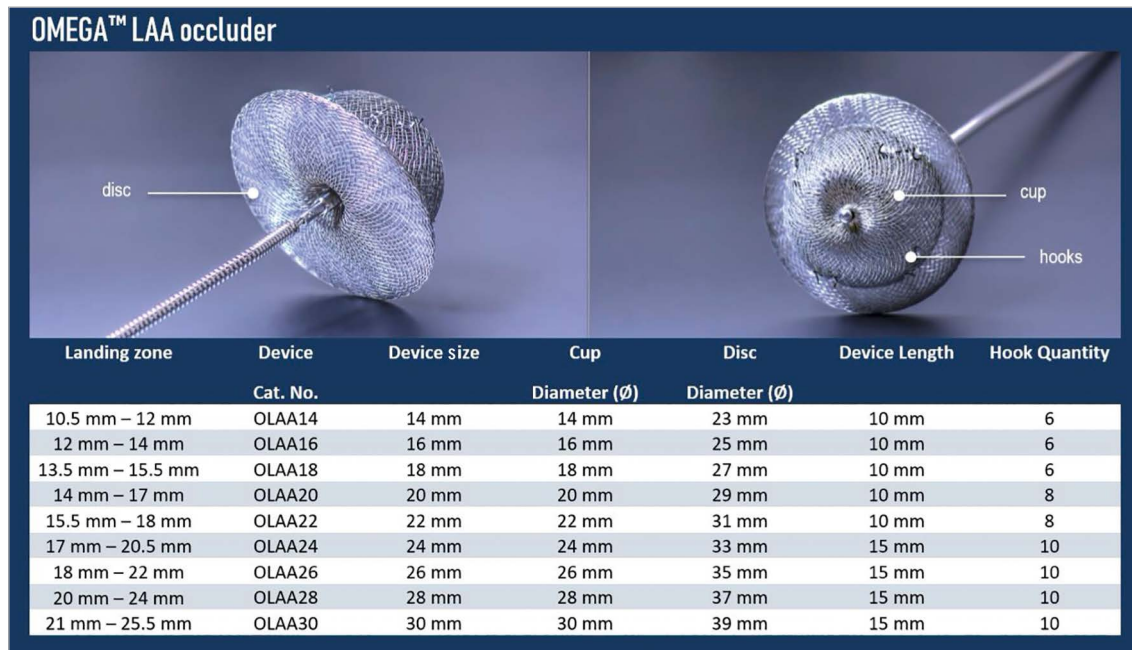


Figure 1. The Omega left atrial appendage occluder.

Nine device sizes ranging from 14 to 30 mm (with 2 mm increments) are available and referred to by the maximal diameter of the cup, allowing anchoring in LAAs with a landing zone diameter between 10.5 and 25.5 mm. A minimum LAA depth of 10 mm to 15 mm is required for the Omega size 14 to 22 mm devices and size 24 to 30 mm devices, respectively (Figure 1). The delivery system consists of a 14 Fr double curve catheter that is introduced into the LA after transseptal puncture and when an activated clotting time of >250 seconds is reached. All patients received dual antiplatelet therapy for three months post procedure, followed by single antiplatelet therapy for a minimum of six months.

#### PRIMARY ENDPOINTS

The primary efficacy endpoint of the study was LAA closure (defined as either complete LAA seal or efficient seal with a peri-device leak <5 mm) at 30 to 90 days, as documented by transoesophageal echocardiography (TEE) with colour flow Doppler. The primary safety endpoint was device-related complications (adverse events) between 7 and 90 days post procedure. All study endpoints conform to the Munich consensus document on LAA closure research<sup>2</sup>.

#### Results

Among 18 patients screened, 13 patients were eligible to receive the Omega LAA occluder. Five patients were excluded due to one patient withdrawal, one LAA with insufficient depth, two LAA landing zones outside the intended size range, and one LAA with pre-existing thrombus. The baseline characteristics of the 13 enrolled patients are reported in Table 1.

Table 1. Summary of baseline characteristics.

Characteristic	n/N (%) or mean±SD
Age, years	74.4±9.4
Male	8/13 (62)
BMI, kg/m <sup>2</sup>	24.5±4.3
Prior stroke	4/13 (31)
Prior stroke or TIA	5/13 (38)
Stroke within 90 days	2/13 (15)
Carotid stenosis	0
Aortic disease	1/13 (8)
Peripheral vascular disease	2/13 (15)
eGFR, ml/min/1.73 m <sup>2</sup>	65.2±10.5
COPD	1/13 (8)
Coronary artery disease	5/13 (38)
PCI	3/13 (23)
Coronary artery bypass	3/13 (23)
Permanent pacemaker	0
Diabetes mellitus type 2	6/13 (46)
Hypertension	11/13 (85)
Dyslipidaemia	7/13 (54)
Myocardial infarct	0
Congestive heart failure	0
LVEF, %	54±14
Pulmonary arterial hypertension	0
CHADS <sub>2</sub> score	3.3±1.3
CHA <sub>2</sub> DS <sub>2</sub> -VASc score	4.3±1.4
HAS-BLED score	3.0±0.7

BMI: body mass index; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; LVEF: left ventricular ejection fraction; PCI: percutaneous coronary intervention; TIA: transient ischaemic attack

Percutaneous LAA closure was successful in all patients with a total mean procedure time of 59±16 minutes – including 21±8 minutes from introduction to removal of the delivery system, 6±3 minutes fluoroscopy time and the use of 101±31 ml of contrast dye (**Table 2**). Only one device per procedure was used in all procedures, requiring a mean of 1.7±0.9 deployment attempts before the final position was accepted. In seven patients (54%), a single initial deployment was accepted.

The primary efficacy endpoint of LAA closure at 30 to 90 days was obtained in all Omega recipients, with complete LAA closure in 11 patients (85%) and a small residual peri-device leak <3 mm in 2 patients (15%). The primary safety endpoint was noted in one patient who developed a periprocedural pericardial effusion, which was initially managed conservatively but drained percutaneously six weeks later. One patient had a local venous access haematoma, managed conservatively.

During follow-up, there was no device embolisation, major bleeding, device-related thrombosis, ischaemic stroke or systemic embolism. Thus, technical success was noted in 12/13 patients (92%) and procedural success in 11/13 patients (85%) (**Table 2**).

**Table 2. Procedural characteristics and study endpoints.**

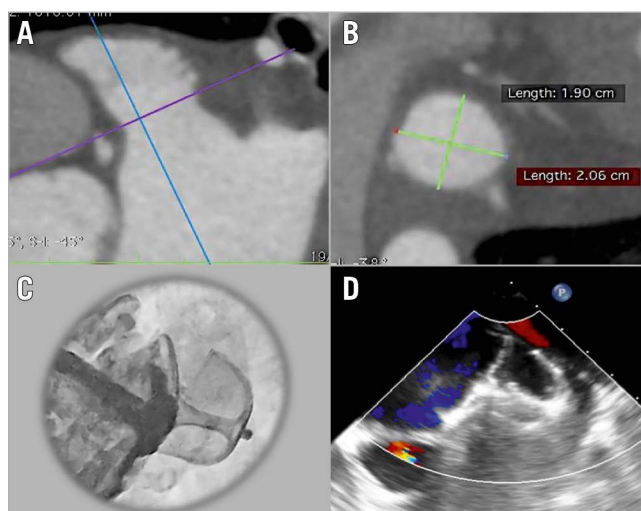
Procedural characteristics	n/N (%) or mean±SD
Local anaesthesia with sedation	13/13 (100)
Successful implantation	13/13 (100)
Device deficiency	0
Number of deployments	1.7±0.9
Total procedure time, min	59.0±16.1
Delivery sheath in-out time, min	21.4±7.6
Contrast use, ml	101±31
Fluoroscopy time, min	6.1±3.3
Number of devices used per procedure	1.0±0
<b>30- to 90-day outcomes</b>	
Complete LAA occlusion	11/13 (85)
Efficient LAA occlusion with leak <5 mm	13/13 (100)
Device-related complications	1/13 (8)
Procedure-related complications <7 days post procedure	1/13 (8)
Major bleeding	0
Ischaemic stroke	0
Systemic embolism	0
Device-related thrombus	0
Pericardial effusion	1/13 (8)
Technical success of implant *	12/13 (92)
Procedural success **	11/13 (85)

\* No device-related complications and occlusion of the left atrial appendage (LAA) with no leak >5 mm on colour Doppler transoesophageal echocardiography (TEE). \*\* Technical success and no procedure-related complications except uncomplicated (minor) device embolisation resolved by percutaneous retrieval during the procedure without surgical intervention or damage to surrounding cardiovascular structures. LAA: left atrial appendage

## Discussion

First-in-human experience with the Omega LAA occluder shows a favourable safety and efficacy profile with successful device implantation, effective LAA closure and no device deficiencies in all cases. In the majority of procedures, the first device deployment was accepted.

The design features of the Omega LAA occluder provide a conformable device, targeting close wall apposition and effective LAA seal (**Figure 2**). A unique feature of the Omega device is the very flexible waist between the cup and disc, permitting use in a wide range of LAA anatomies, including sharply angulated LAAs/landing zones. This may provide an alternative to currently available LAA closure devices – such as the WATCHMAN™ (Boston Scientific, Marlborough, MA, USA), AMPLATZER™ Amulet™ (Abbott Vascular, Santa Clara, CA, USA) and LAmbré™ (Lifetech Scientific [Shenzhen] Co., Ltd., Shenzhen, China) – and provide effective LAA seal in a broader range of patients than currently treatable. Additional 32 mm and 34 mm Omega device sizes are planned.



**Figure 2.** Procedural planning and implantation of the Omega left atrial appendage (LAA) occluder. A) Cardiac CT identification and assessment of LAA anatomy. B) Measurement of the LAA landing zone. C) In vivo deployment of the Omega device showing occlusion of the LAA with contrast injection. D) Procedural transoesophageal echocardiography showing the deployed Omega device and no residual flow into the LAA.

## Limitations

This study is limited by the small number of patients and single-centre experience, as is often the case for first-in-human studies. The presence of a selection committee to select appropriate LAA anatomies to receive the Omega device may limit the generalisability of these study outcomes. Larger studies investigating long-term clinical efficacy and ongoing safety monitoring are planned.

## Conclusion

Initial human experience with the Omega LAA occluder is favourable with all patients meeting the pre-specified primary efficacy endpoint of LAA closure immediately post procedure and at 30- to 90-day echocardiographic evaluation.

## Impact on daily practice

As experience with LAA closure increases, it is hoped that additional technologies, including the Omega LAA occluder, will increase procedural safety and improve patient outcomes.

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## Conflict of interest statement

L. Søndergaard is a shareholder in Eclipse Medical. The other authors have no conflicts of interest to declare.

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## Supplementary data

**Supplementary Table 1.** Exclusion criteria.

The supplementary data are published online at:  
[https://eurointervention.pcronline.com/  
doi/10.4244/EIJ-D-20-00552](https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-20-00552)



**Supplementary Table 1. Exclusion criteria.**

<b>Clinical exclusion criteria</b>
1. Requires long-term oral anticoagulation therapy for any indication other than atrial fibrillation
2. Contraindicated for or allergic to aspirin, clopidogrel, warfarin or novel oral anticoagulant (NOAC) use
3. History of surgical atrial septal defect (ASD) repair or has an ASD closure device implanted
4. History of surgical patent foramen ovale (PFO) repair or has a PFO closure device implanted
5. Implanted with a mechanical heart valve prosthesis requiring long-term oral anticoagulation
6. Has any contraindications for a percutaneous catheterisation procedure (e.g., unable to accommodate transoesophageal echocardiogram [TEE/TOE] probe or required catheters, or subject has active infection or bleeding disorder)
7. Stroke or transient ischaemic attack (TIA) within 90 days prior to implant procedure
8. Underwent any cardiac or non-cardiac intervention or surgery within 30 days prior to implant, or intervention or surgery is planned within 60 days after implant procedure
9. Myocardial infarction (MI) within 90 days prior to implant
10. New York Heart Association Class IV congestive heart failure
11. Left ventricular ejection fraction (LVEF) <30%
12. Symptomatic carotid artery disease (defined as >50% reduced diameter with symptoms of ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral stroke); if subject has a history of carotid stent or endarterectomy the subject is eligible if there is >50% reduced diameter
13. Reversible cause of AF (i.e., secondary thyroid disorders, acute alcohol intoxication, trauma, recent major surgical procedures)
14. History of idiopathic or recurrent venous thromboembolism requiring long-term oral anticoagulation
15. Left atrial appendage is obliterated or surgically ligated
16. Resting heart rate >110 bpm
17. Thrombocytopenia (defined as <70,000 platelets/mm <sup>3</sup> ) or anaemia with haemoglobin concentration of <10 g/dl (i.e., anaemia as determined by the investigator which would require transfusion)

18. Actively enrolled or plans to enrol in a concurrent clinical study in which the active treatment arm may confound the results of this trial
19. Active endocarditis or other infection producing bacteraemia
20. Subject has a known malignancy or other illness where life expectancy is less than 2 years
21. Impaired renal function with eGFR <40 ml/min/1.73 m <sup>2</sup>
22. Patient with more than mild hepatic failure as per Munich consensus document
<b>Cardiac imaging exclusion criteria</b>
1. Intracardiac thrombus – including LAA - visualised by echocardiographic imaging
2. Existing circumferential pericardial effusion >2 mm
3. Significant mitral valve stenosis (i.e., mitral valve area <1.5 cm <sup>2</sup> )
4. High-risk patent foramen ovale (PFO), defined as an atrial septal aneurysm (atrial septal excursion >15 mm; excursion defined as maximal protrusion of the ASA beyond the plane of the atrial septum during cardiac cycle) or large shunt (substantial passage of bubbles, i.e., >20, within 3 cardiac cycles from appearing in the right atrium)
5. Complex atheroma with mobile plaque of the descending aorta and/or aortic arch
6. Cardiac tumour
7. LAA anatomy cannot accommodate an Omega device (as per IFU)
8. Placement of the device would interfere with any intracardiac or intravascular structure