

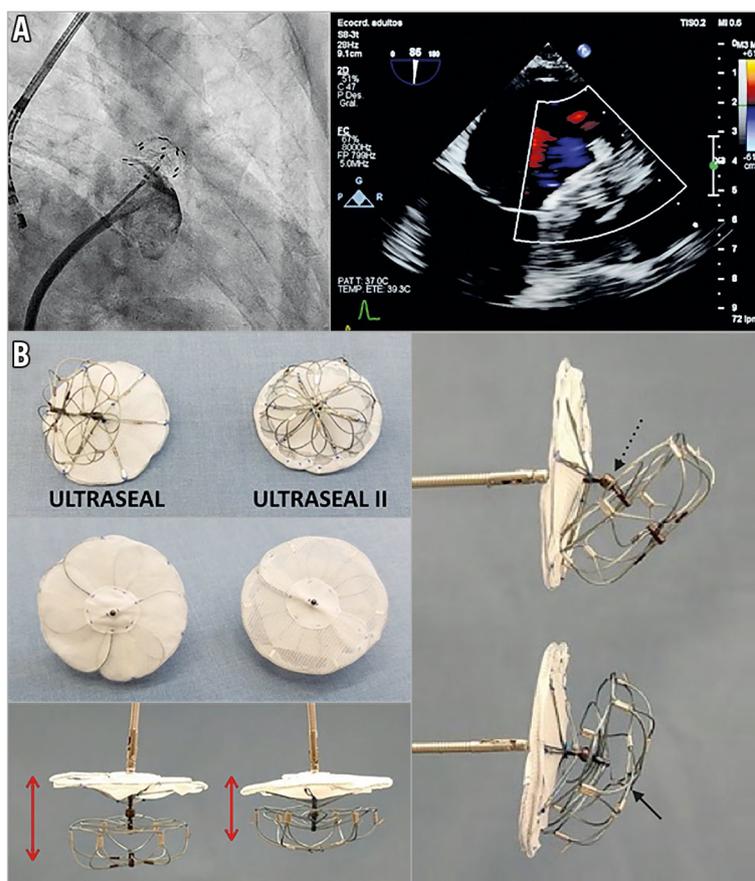
# First-in-man percutaneous closure of left atrial appendage using the Ultraseal II device



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This paper also includes supplementary data published online at: <https://eurointervention.pconline.com/doi/10.4244/EIJ-D-18-01084>



**Figure 1.** First-in-human experience with the Ultraseal II. A) LAA occlusion with the Ultraseal II device and (B) comparison between the first Ultraseal device and the new Ultraseal II.

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A 74-year-old man with atrial fibrillation and spontaneous intracerebral haemorrhage was admitted for percutaneous closure of the left atrial appendage (LAA). We present the first-in-man experience with the Ultraseal II device (Cardia, Inc., Eagan, MN, USA).

Under conscious sedation, the procedure was carried out using transoesophageal echocardiography (TEE) with an S8-3t microprobe (Philips Medical Systems, Andover, MA, USA) and fluoroscopic guidance. A 22 mm Ultraseal II was selected. The sheath was positioned at the intended landing zone, then the bulb was deployed. Next, the sheath was retracted until the sail was deployed, achieving a complete sealing of the LAA (**Figure 1A**, **Moving image 1-Moving image 3**). Follow-up TEE showed no device-related thrombus and no residual leak.

The initial experience with this device has already been reported, with a high success rate and a low complication rate. However, modifications were warranted in order to facilitate deployment and retrieval and potentially to reduce the rate of device thrombosis (see **Supplementary Table 1** for additional information). The Ultraseal II is a self-expanding nitinol device composed of two parts – the bulb, which secures the device position but does not seal the appendage, and the sail. These are connected by an articulating joint (**Figure 1B**, dashed arrow) that allows the sail to conform naturally to the LAA ostium. The new device is shorter, so the minimum required depth is smaller (**Figure 1B**, red arrows). The distal centre post has been removed (**Figure 1B**, black arrow), so the new device is more flexible. The joint is less articulated to enhance the anchoring of the bulb, without allowing the device to roll over easily, but being able to adapt to different LAA anatomies. The sail covering has been

moved, the polyester coating is placed outside and the polyvinyl alcohol (PVA) inside, which makes it easier to load and retrieve the device. It will be necessary to evaluate whether this improvement could have an impact on the rate of thrombosis related to the device. The main distinctive features of the Ultraseal II compared to other disc-lobe devices are: the articulating joint that allows the sail to conform naturally to the LAA anatomy, the soft and flexible bulb, with low radial force, which allows a safe deep implant in the case of limited usable length and permitted oversizing if required, and the option of partial or total recapture up to five times.

In conclusion, the new device has the potential to adapt to different LAA morphologies and could be very useful in difficult anatomies.

### Conflict of interest statement

The authors have no conflicts of interest to declare.

### Supplementary data

**Supplementary Table 1.** Ultraseal II vs Ultraseal features.

**Moving image 1.** Angiography evaluating the left atrial appendage morphology.

**Moving image 2.** Complete deployment of the Ultraseal II device.

**Moving image 3.** Angiography showing the final position of the Ultraseal II device and successful sealing of the LAA.

*The supplementary data are published online at:*

*<https://eurointervention.pronline.com/>*

*[doi/10.4244/EIJ-D-18-01084](https://doi.org/10.4244/EIJ-D-18-01084)*



## Supplementary data

**Supplementary Table 1. Ultraseal II vs Ultraseal features.**

Device feature	Ultraseal II	Ultraseal
Design	Self-expanding nitinol frame	
Articulation	Reduced on distal section to enhance the anchoring of the bulb	Complete, proximal and distal sections
Distal centre post	No	Yes
Distal radiopaque markers	Yes	No
Stabilising hooks (n)	12	
Sail covering	Proximal polyester layer and distal polyvinyl alcohol foam	Distal polyester, and proximal polyvinyl alcohol
Compression reaction	Slight decrease in overall device length	Slight increase in overall device length
Bulb sizes	16 to 32 mm	
Sail sizes	22 to 38 mm	
Device height	10 to 18 mm	15 to 21 mm
Minimum LAA depth	12 mm	16 mm

### Moving image legends

**Moving image 1.** Angiography evaluating the left atrial appendage morphology.

**Moving image 2.** Complete deployment of the Ultraseal II device.

**Moving image 3.** Angiography showing the final position of the Ultraseal II device and successful sealing of the LAA.