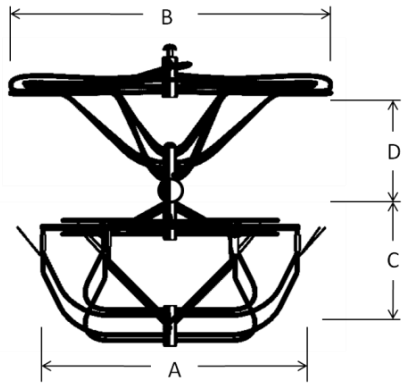


Device Dimensions



REF	A	B	C	D	C+D
LAA-16	16 mm	22 mm	8 mm	7 mm	15 mm
LAA-18	18 mm	24 mm	8 mm	7 mm	15 mm
LAA-20	20 mm	26 mm	8 mm	7 mm	15 mm
LAA-22	22 mm	28 mm	8.5 mm	7.5 mm	16 mm
LAA-24	24 mm	30 mm	9 mm	8 mm	17 mm
LAA-26	26 mm	32 mm	9.5 mm	8.5 mm	18 mm
LAA-28	28 mm	34 mm	10 mm	9 mm	19 mm
LAA-30	30 mm	36 mm	10.5 mm	9.5 mm	20 mm
LAA-32	32 mm	38 mm	11 mm	10 mm	21 mm

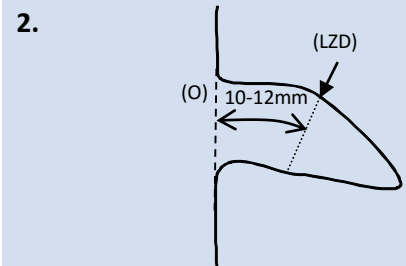
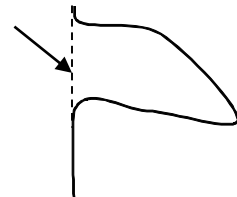
Sizing the LAA

Maximum Measured Landing Zone Diameter	Ultraseal LAA Device	Minimum LAA Depth (mm)	Cardia Delivery System	Depth of Sheath
11 mm – 12 mm	LAA-16	16 mm	10 Fr	10 mm
12 mm – 13.5 mm	LAA-18	16 mm	11 Fr	10 mm
13.5 mm – 15 mm	LAA-20	16 mm	11 Fr	10 mm
15 mm – 16.5 mm	LAA-22	17 mm	11 Fr	10 mm
16.5 mm – 18 mm	LAA-24	18 mm	11 Fr	10 mm
18 mm – 19.5 mm	LAA-26	19 mm	11 Fr	12 mm
19.5 mm – 21 mm	LAA-28	20 mm	12 Fr	12 mm
21 mm – 22.5 mm	LAA-30	21 mm	12 Fr	12 mm
22.5 mm – 24 mm	LAA-32	22 mm	12 Fr	12 mm

Procedure

- Using 3 TEE views (45°, 90° and 135°) determine the intended location of the sail of the device on the orifice of the LAA. (O) See Figure 1.
- Measure the diameter of the LAA (using the same TEE views) at a depth of 10/12 mm from the intended sail location. This distance should be determined by following the contour of the LAA to the intended location of the bulb. This is the landing zone for the anchors of the device. Record the largest diameter. (LZD) See Figure 2.
- Choose the appropriate Ultraseal LAA device based on the chart above. The selected device should have a bulb diameter at least 25% greater than the largest diameter of the landing zone. Measure the entire depth of the LAA along its contour. Ensure the LAA depth is above the minimum listed in the chart above.
- Verify the sail diameter: For the selected device, ensure that the distance between the perimeters of the sail at its intended location (O) are at least 5mm from other cardiac structures including the mitral valve and pulmonary veins.
- Position the sheath in the appendage such that the distal end of its marker band is located at the intended landing zone of the anchors. (LZD) See Figure 3.

1. Intended location of the sail of the device (O)



6. While holding the sheath in place, advance the forceps until the entire bulb section of the device is deployed. See Figure 4.
7. Assess the compression of the bulb. The anchor markers of the bulb should appear to have a non-symmetric shape. This indicates that the bulb is under compression.
8. While holding the forceps in place, retract the sheath until the entire sail section of the device is deployed. See Figure 5.
9. Assess the shape and position of the sail. Once closure is confirmed, release the device. See Figure 6.

To Retrieve the Bulb section: Advance the sheath up to the bulb of the device; hold the sheath in place and retract the forceps until the bulb is contained within the sheath.

To Retrieve the Sail section: Advance the sheath up to the sail of the device; hold the sheath in place and retract the forceps until the sail is retrieved up to the sail collars; hold the forceps in place and advance the sheath until the sail is fully retrieved.

