Supplementary material

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I. Transesophageal echocardiography of ASD

Standard evaluation of the septum begins with midesophageal four chamber view at 0º and should be performed with increments of 15°-30° to obtain the complete view of the septum. Apart from 2D imaging, it's important to applied also color Doppler with velocity reduction to 35–40 cm/sec. This adjustment enables visualization of small defects and fenestrations or flow through the PFO.

With the use of 2D imaging defect diameter should be obtained at least at 0°, 45°, 90°, 135° to approximate the shape as well as the size and morphology of the rims - *Figure S1 A, B, C, F.* Round defect is recognized when its minimal and maximal dimension differ by max. 1 mm. Lack of aortic rim or tissue deficiency in surrounding of the vena cava superior carries a risk of erosion and tamponade or intracardiac fistula after device closure.. In case of absent aortic rim it is advisable not to oversize the occluder more than 2mm to diameter measured during balloon sizing.

Recommended views during ASD II assessment

Lower esophageal view:

- the most important issue is the assessment of the distance between the defect and the coronary sinus - *Figure S1D*

Midesophageal view:

- 0°-30° which is the midesophageal four chamber view enables to obtain the distance between ASD and anterior mitral valve leaflet defined as mitral rim - *Figure S1A*
- 30°-70°- short-axis view demonstrates aortic rim (anterior–superior), visibility of the posterior rim is usually of worse quality. Facilitates imaging of spatial relations when ASD and PFO are both present - *Figure S1B*

- 70°-120°- bicaval view demonstrates drainage of vena cava superior (superior – posterior rim) and vena cava inferior (inferior – posterior rim) as well as the roof of right atrium and drainage of right superior pulmonary vein - Figure S1C. This view is used for detection of superior sinus venosus defects - *Figure S3 B,C*

- 120°-150°- long-axis view - is important for evaluating the extent of the defect and occluder location on the septum during percutaneous procedure.

The upper esophageal view:

- 0°- 45°- upper esophageal short-axis view – used to image upper part the septum, drainage of right pulmonary veins to right atrium, aorta - *Figure S1 E*

II. 3D imaging

It is advisable to obtain 3D data in several acquisitions of different views with comprehensive presentation of the defect and surrounding structures. Apart from images focused on the defect, wide-angled acquisition of septum surrounding structures is recommended. As the septum (except in special cases of excessively mobile aneurysm) is a stable structure, the frame rate does not have to be high, usually FPS about 8-12 is sufficient.

Multi-D (X-plane)- visualization using two perpendicular views is also very useful and quick methods for verification of ASD morphology - Figure S2 A, B.

Additional imaging with color Doppler is necessary especially in case of thin septum. That enables to differentiate the presence of second defect with the presence of flow in the color doppler from only apparent lack of continuity of the septum in 2D and 3D, without flow. 3D imaging is extremely useful in assessing the size of oval defects – Figure 2 E, F. It is pivotal in case of multifenestrated ASD as provides the spatial relationships of the defects and enables to assess the feasibility of percutaneous procedure and its planning - *Figure S4 A, B, C.* Recorded images can be evaluated in postprocessing. This allows to shorten the examination and subsequent assessment of dimensions, shape, dynamics with the use of available software. Comprehensive analysis of defect should include the shape (round, oval, irregular, etc.), minimal and maximal size, orifice area. The measurements should be taken in end-systole of the atrium. Due to the dynamics of the defect size, the systolic dimension and percentage of its change in size should also be provided – Figure S2 C, D. Figure S3 demonstrates examples of different defects not suitable for percutaneous closure.

III. TEE assessment during procedure of percutaneous ASD closure

The most frequent modality used for monitoring of ASD closure is TEE. During the procedure, the patient should be sedated with good TEE probe tolerance. In rare cases of difficult and long procedures, to increase comfort and reduce the risk of aspiration, general anesthesia may be considered. Measurement of the defect is the crucial part of the procedure conditioning selection of occluder size. It may be performed in TEE and with the use of sizing balloon. Nevertheless it is also guided with a color doppler TEE, the so-called stop flow method - *Figure S5 E, F*. This particular technique reduces the risk of floppy septum stretching. The measurement should be taken both in TEE and fluoroscopy and the final dimension of the occluder is recommended to be maximally 2 mm larger than the obtained dimension. Greater oversizing increases the risk of erosion. During the procedure, TEE provides visualization of guidewires, catheters and occluder and their spatial relation to the surrounding structures – Figure S4 D, E, F. Just at the first stage of the procedure, TEE is dedicated to verify the level of passage through the septum - Figure S*5 A, B, C, D* - especially important in the case of multifenestrated defects. After crossing the septum the guidewire should be preferably located in the left upper pulmonary vein (LUPV) and not in thin-walled LAA, what should be ruled out.

The left atrial occluder disc is usually opened deeply in the left atrium, usually close to the LUPV and than slowly withdraw to the septum. As it reaches the septum the right atrial disc of the occluder is opened - *Figure S6 A, B, C, D, E, F*. Before releasing the occluder, it is crucial to verify its position and appropriate capture of all the rims with the discs - *Figure S7 A, B, C, D*. It may be challenging in case of thin, floppy and excessively mobile septum. Presentation of posterior rims may be difficult in TEE, however 3D imaging might be helpful (Figure S7 F) as well as Minnesota maneuver (push-pull maneuver; the "Minnesota wiggle") enables to verify the stability of the occluder's position. It is obligatory to assess the presence of residual shunt before releasing the occluder. Usually tension of the delivery system causes deflection of right atrial disc with trivial shunt through the device disappearing after occluder release (Figure S7 E), whereas flow at the edge of the device may indicate that the occluder is undersized. It is necessary to re-verify the position of the occluder and its relation to the surrounding structures including especially atrioventricular valves and residual shunt after device release. Pericardium should be verified, trivial effusion may occur generally after long procedures, nevertheless it should be monitored due to the risk of tamponade.

IV. Short review of the devices for ASD closure available in Poland

The Amplatzer Septal Occluder (ASO) (Abbott - USA)

The ASO is currently the most widely used ASD device on the market with excellent safety and sustained efficacy results in pediatric and adult patients alike. It is both FDA and CE approved. The ASO consists of two nitinol woven discs connected by a waist designed to occlude the ASD. The inner parts of the device are covered with an ePTFE membrane. The device is self-expandable and self-centering, and fully recapturable and repositionable if necessary. The size of device is determined by dimensions of the central waist. The available sizes range from 4 to 40 mm., with 1.0 mm increments from 4 to 20 mm and 2.0 mm increments from 20 to 40 mm. The Amplatzer device is available in twenty-six sizes. The device is connected with the delivery system by a micro thread. The delivery systems range from 6 to 12F [71]. The ASO "cribriform" is a specially designed non-self-centering device for multi-fenestrated defects with 4 available sizes from 18 to 40 mm. Nonetheless, the serious complication of cardiac perforation/erosion has been reported with the estimated incidence of 0.19% [72].

ASO is regarded as a "gold-standard" device for many newer devices. All Amplatzer-like occluders are very similar in shape, dimensions, delivery system structure and implantation technique [73,74]. To minimize serum nickel release, the occluders have different protective layers: titanium oxide (Occlutech), titanium nitride (Cera), pre-oxidized nitinol (Hyperion) and platinum (Cocoon). Some devices (Amplatzer-like occluders) require larger delivery sheaths. This may increase the risk of vascular complications, especially in pediatric patients.

Figulla Flex II ASD Occluder (FSO) (Occlutech GmbH – Germany)

The device has a couple of important structural innovations. There is no stainless steel hub on the left atrial disc. This modification makes the tip of the device soft and atraumatic which reduced trauma risk and risk of clot formation, it also changes the geometry of the left disc [75]. The delivery system is completely different. The unique ball-connection between the pusher and the occluder increases the flexibility of the device and its adaptability to the septal anatomy. The titanium oxide-coated nitinol wires provide superior biocompatibility and reduce nitinol release. The device is available in twenty different sizes from 4 to 40 mm. The delivery systems range from 7 to 12F, they are slightly larger than in ASO devices. A fenestrated device for closure of ASD with pulmonary hypertension is available on an order-

made basis. The largest study with FSO, the IRFACODE study, showed a 98% success rate in 1395 patients and a 97.3% complete closure rate at 1 year [76].

Cera, CeraFlex (CSO) (Lifetech Scientific Co – China)

They are the different generation of the devices made by Liftech Co. Same in design as the ASO, this occluder is made from titanium nitride-coated nitinol wire. In contrast to the ASO, the two discs of the CSO consist of less metal, and the bioceramic titanium nitride coating on the disc surface potentially minimizes the risk of thrombus formation, causes less nickel ion elution, and facilitates endothelial tissue growth [77]. The last generation CeraFlex device is preloaded as a package. This device has couple of shared features with FSO; a coated surface of nitinol-wire, flexible connection between the device and delivery cable, and no hub on left atrial disk. The Cera is available in nineteen sizes ranging from 6 to 42 mm. The delivery system ranges from 7 to 14F. The CeraFlex is available with limited number of sizes.

Cocoon Septal Occluder (Vascular Innovations Co - Thailand)

The device is similar in design to the Amplatzer device. It is made from nitinol wire mesh nanocoated with platinum to prevent the release of nickel. The platinum coating also provides superior biocompatibility and prevents corrosion. The device is available in seventeen sizes from 8 to 40 mm (in 2.0 mm increments) and requires a 6 to 14F delivery system. European multicenter study reported an excellent results with procedural success rate of 100% and no complication in 92 patients. This device has been described as softest and lightest currently available device with less metal-to-septum ratio than other devices [78].

Hyperion (Lepu Medical Co - China)

Amplatzer-like device with pre-oxidized nitinol wires. The device is available in sizes ranging from 6 to 42 mm in 2 mm increments (nineteen different sizes). Delivery sheaths range from 8 to 14F.

MemoPart Atrial Septal Defect Occlusion Device (Shanghai Shape Memory Alloy Co, Shanghai - China)

The device is available in twenty-six different sizes from 6 to 42 mm. Delivery sheaths range from 8 to 14F.

Nit-Occlud ASD-R (NOA-R) (PFM Medical – Germany)

This is a double-disc, self-expandable, self-centering device; however, the device characteristics are quite different from other nitrol-mesh devices. The device was made of one piece of nitinol wire without any connecting elements. NOA-R has reduced amount of metal on the left atrial disc without clamping or screwing hub on either side of the atrial discs and has a "reverse configuration" of the single-nitinol-layer on the left atrial disc. Device retrieval could be more difficult because of the no-hub design. The release mechanism is unique as it is "snare-like", which includes a central locking wire and a pusher with a distal wire noose [79]. A total of 12 sizes are available from 8 to 30 mm. with 2.0 mm increments, and the delivery sheath sizes range from 8 to 14F. This is a preloaded device. The device is dedicated to closure ASD smaller than 18 mm. The device is no longer available on the market.

Ultrasept II ASD Occluder (Cardia Mineapolis – USA)

The device has a unique design. The nitinol wire frame forms two sails with a self-centering mechanism. There is a reduced amount of nitinol in the device. The dual articulating sails along with the patented self-centering mechanism allow for a super-low profile of the device. Fractures of the nitinol wire frame have been reported in previous-generation devices, where the nitinol wire frame was covered by a polyvinyl alcohol (PVA) membrane. Because of perforation incidence, this membrane was replaced with a Gore-tex patch in the last generation of the devices [80]. The device is available in fifteen sizes ranging from 6 to 34 mm in 2.0 mm increments. Delivery sheaths range from 9 to 11F.

Helex Septal Occluder (HSO), Gore Cardioform Septal Occluder (GSO) (W.L. Gore and Associates Inc.- USA)

HSO – the previous generation of the device was composed of single nitinol wire helical frame covered with expanded polytetrafluoroethylene (ePTFE) membrane. The GSO – next generation of the device is a non-self-centering double disk device composed of single platinum filled nitinol wire framework covered with ePTFE membrane. The GSO is preloaded as a package of the device and whole delivery system. There are 4 device sizes from 15 to 30 mm with 5.0 mm increments. It is not suitable for defects over 18 mm due to the non-self-centering feature. Currently the device is not available on the Polish market.

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VI. FIGURES:

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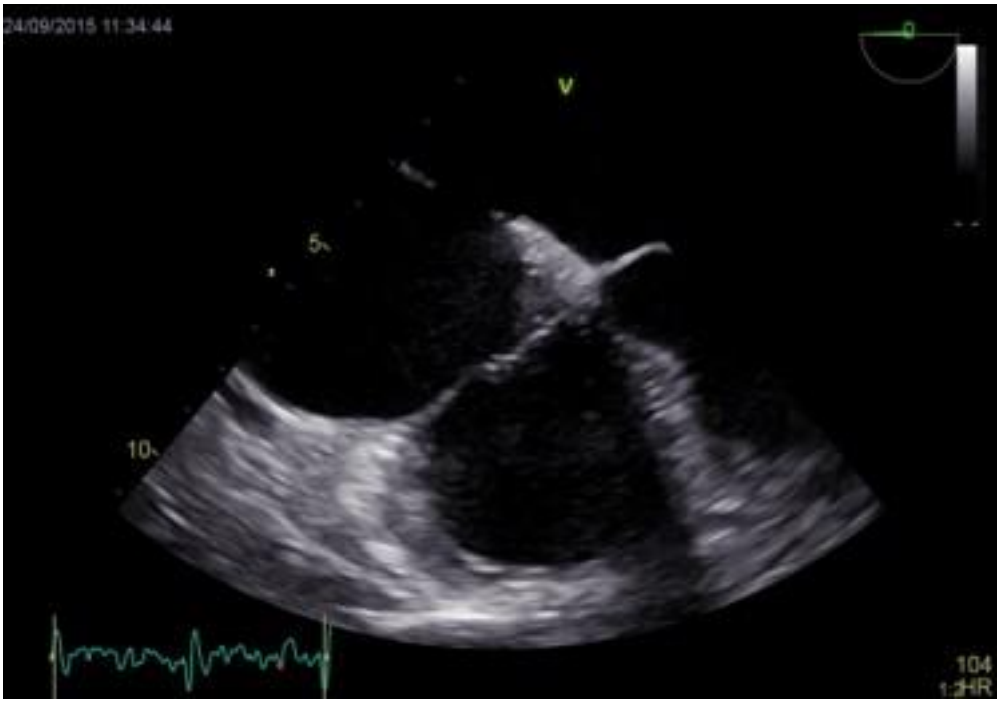


Figure S1B

Figure S1C

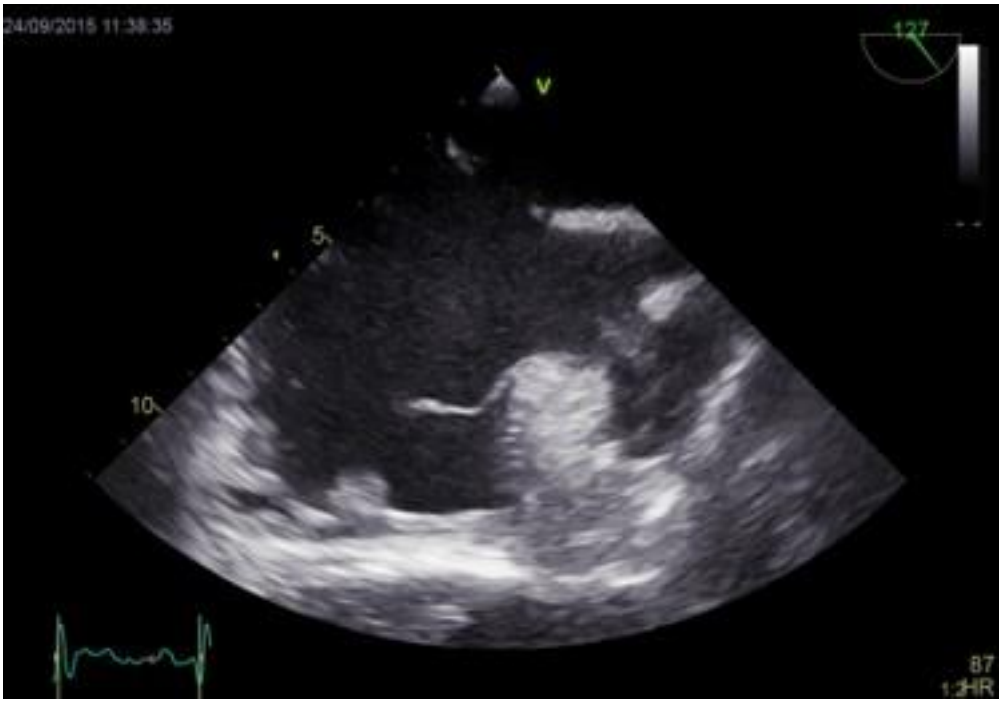
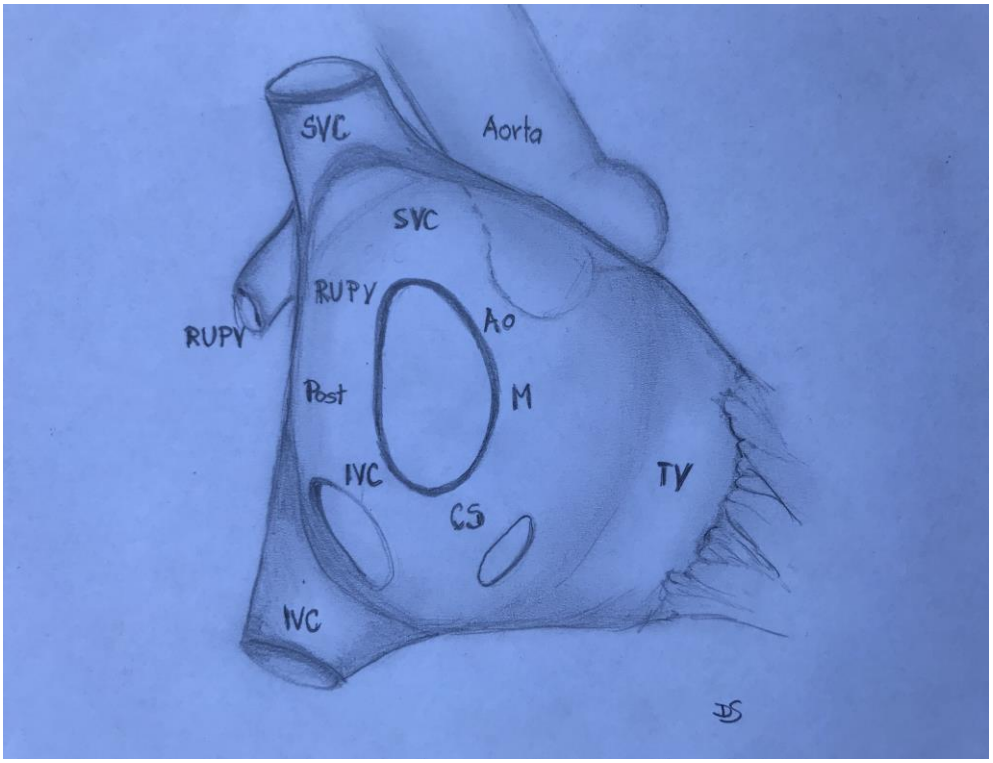


Figure S1D

Figure S1E

Figure S1F



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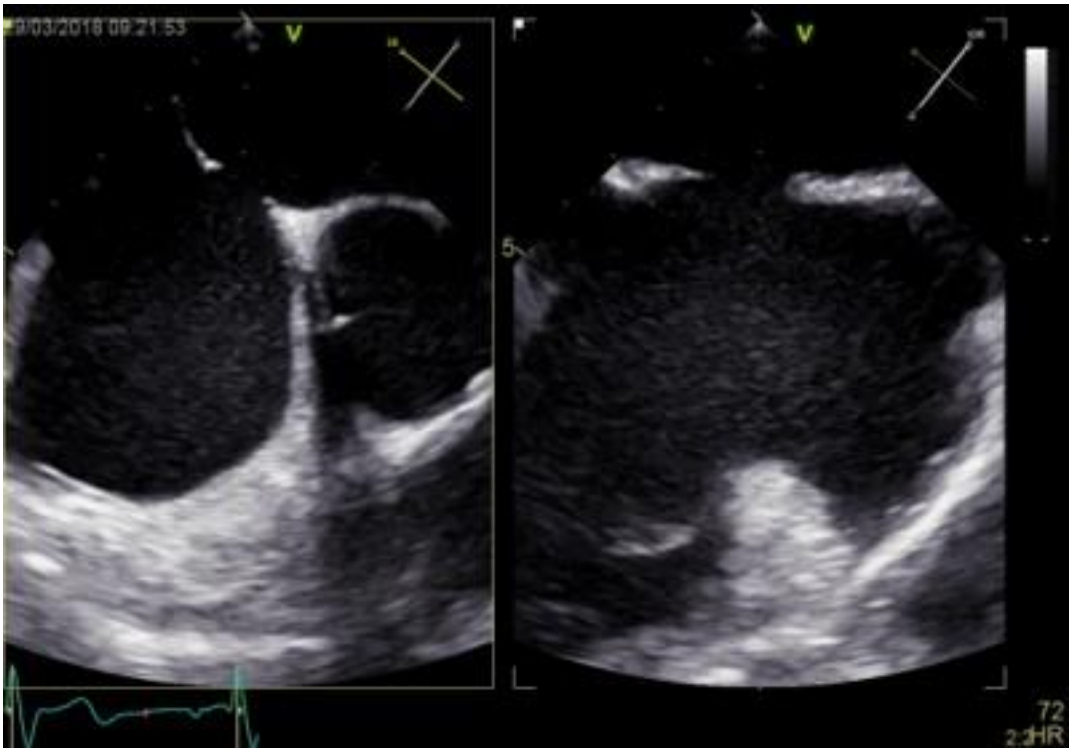

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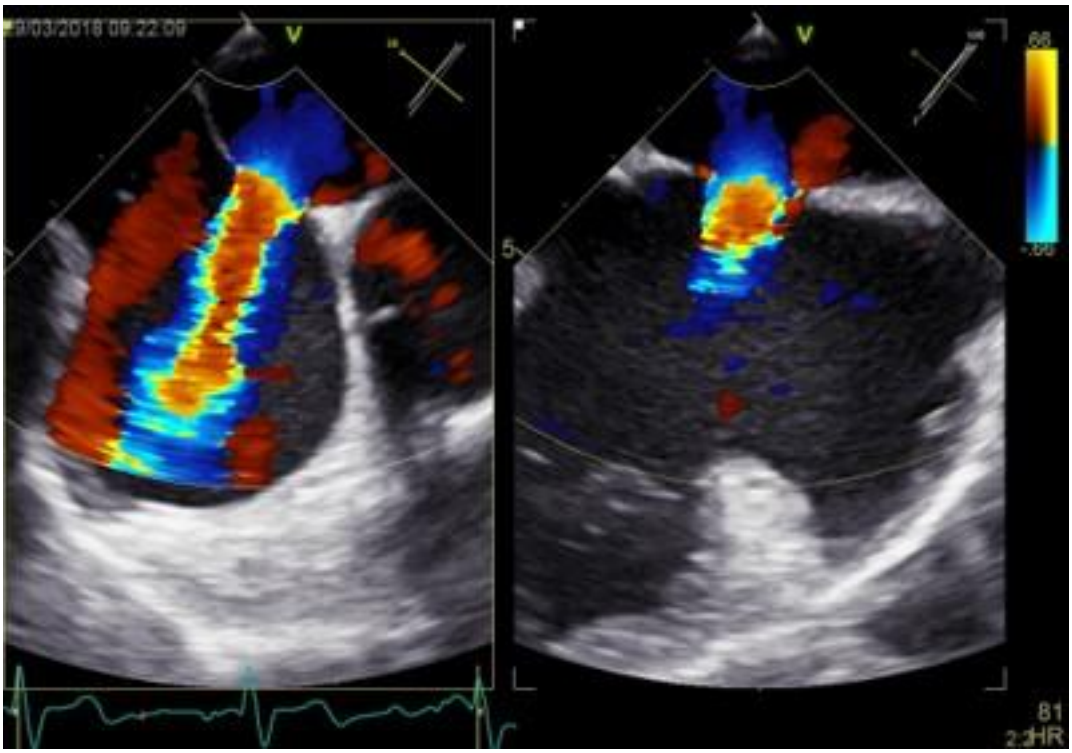

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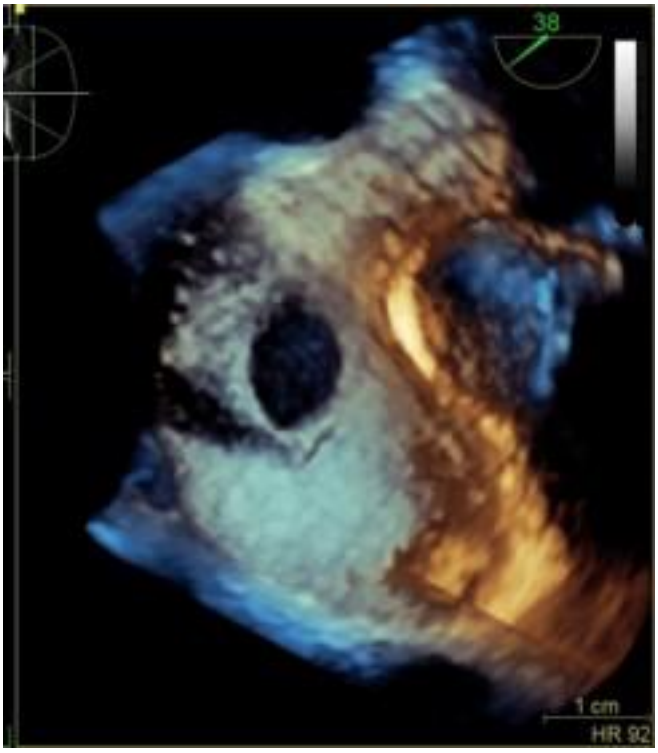

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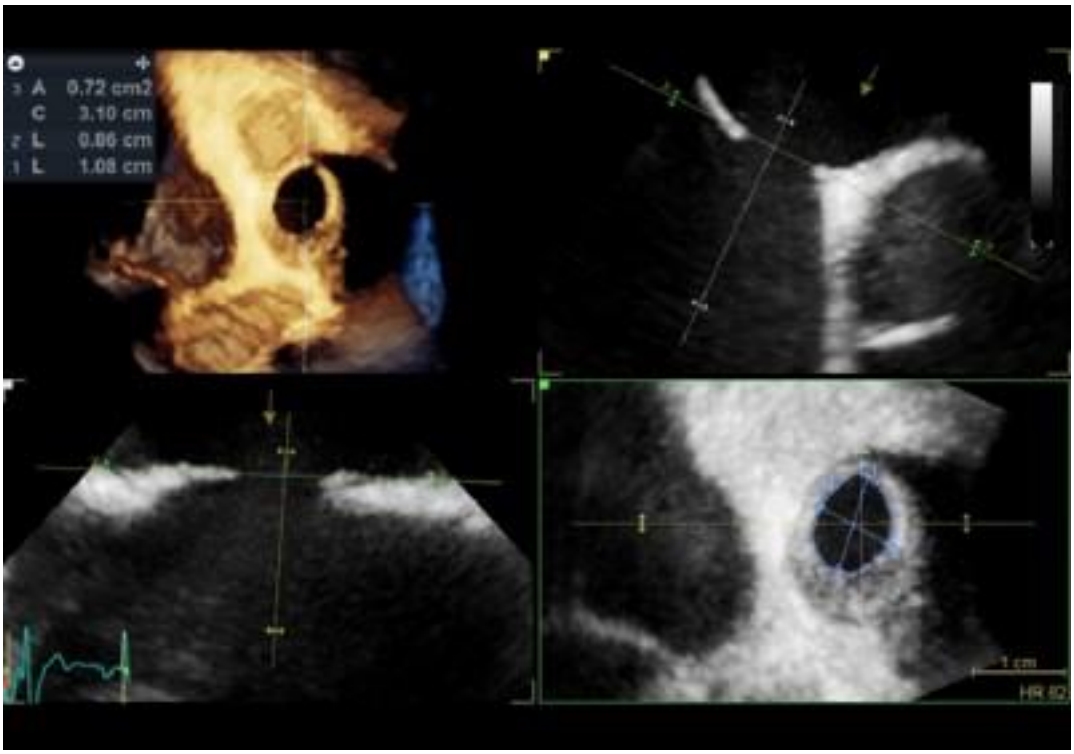

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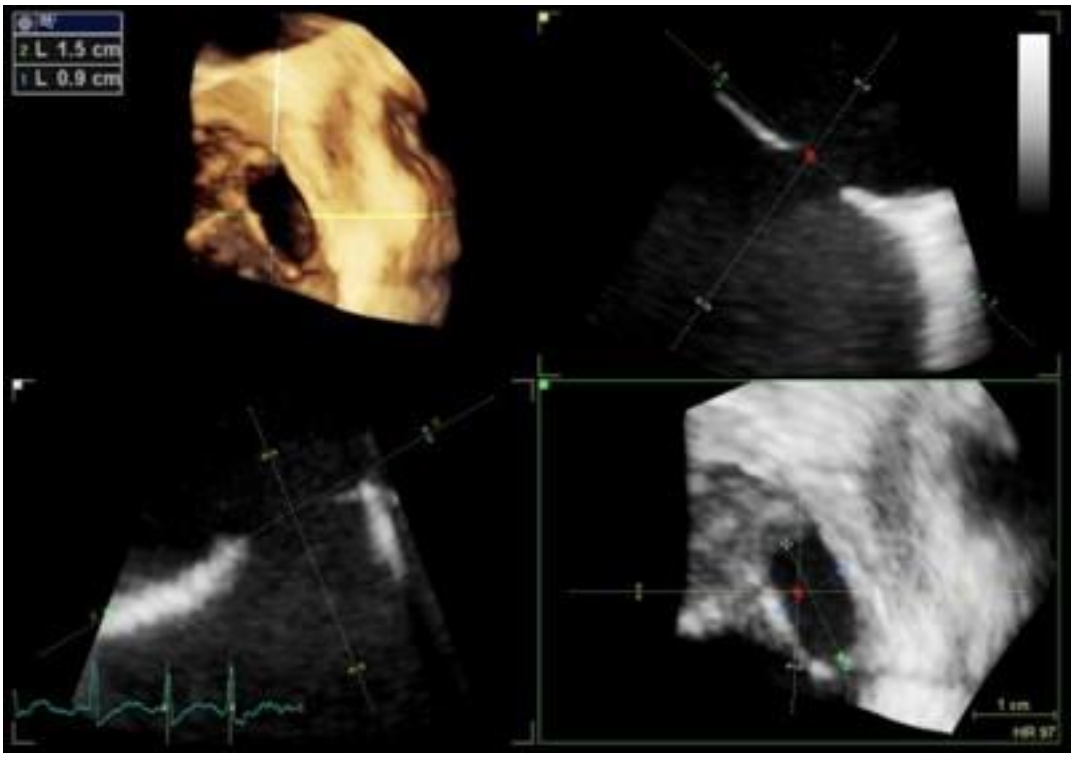

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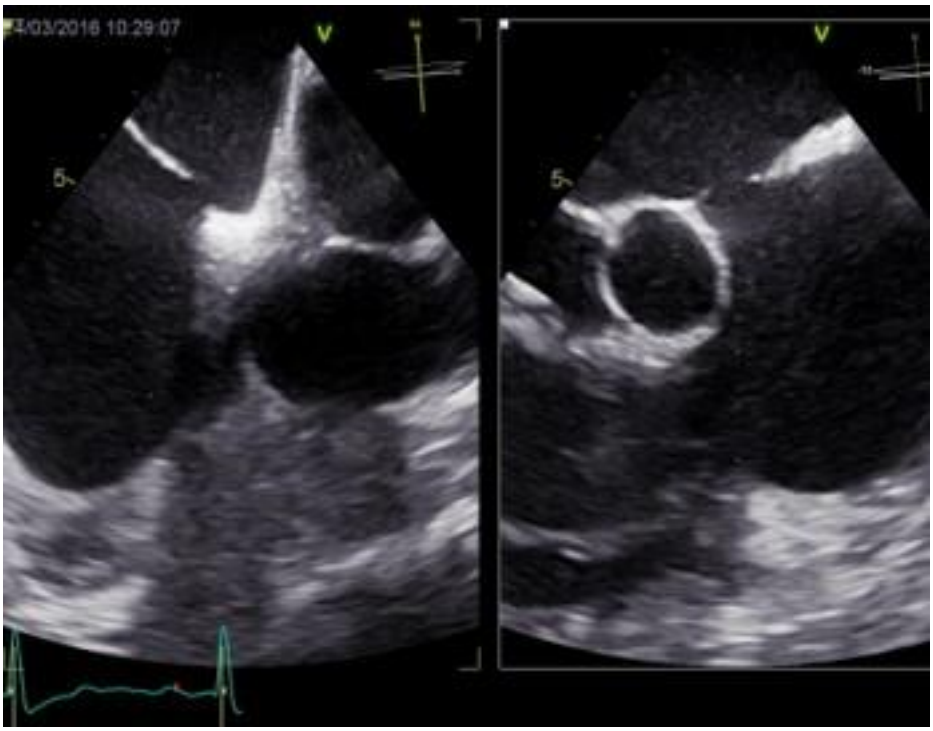

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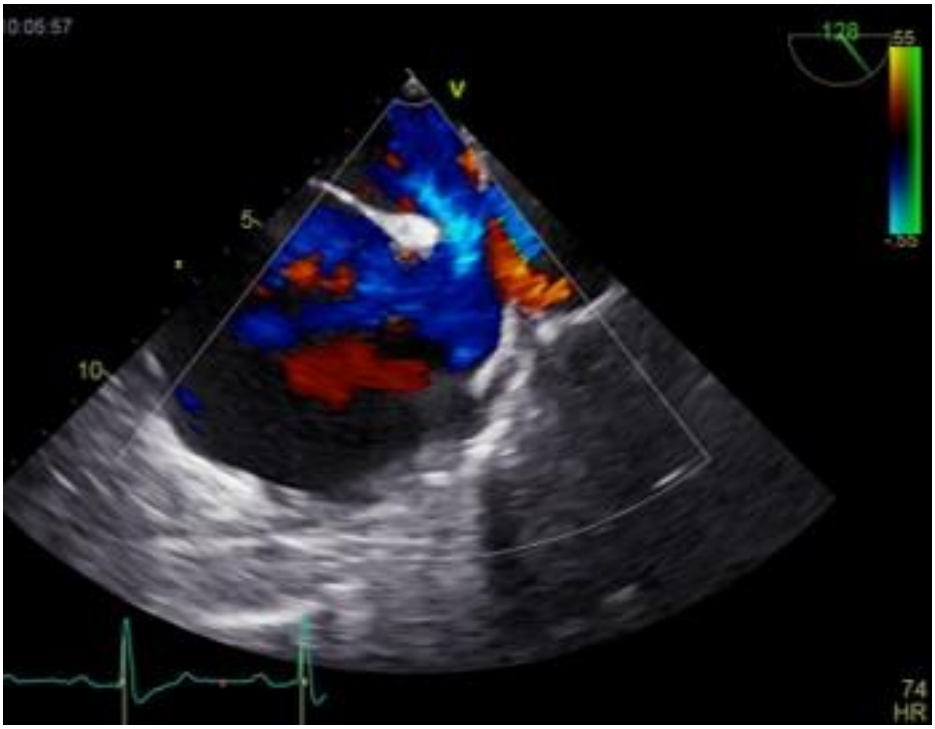

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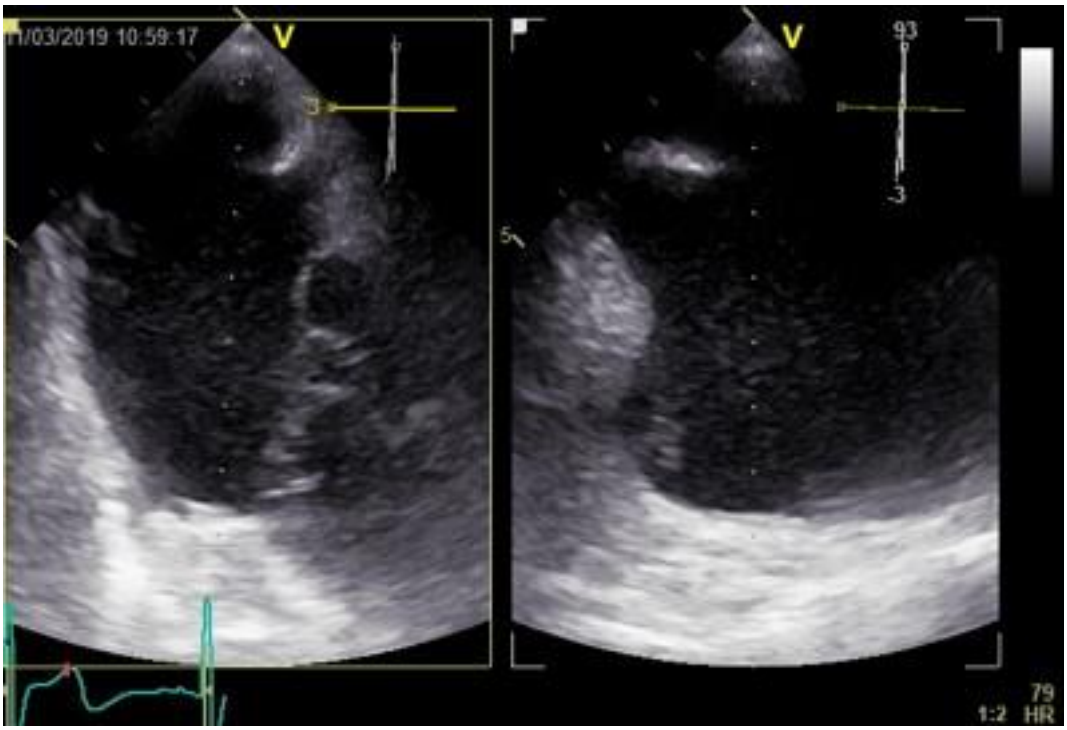

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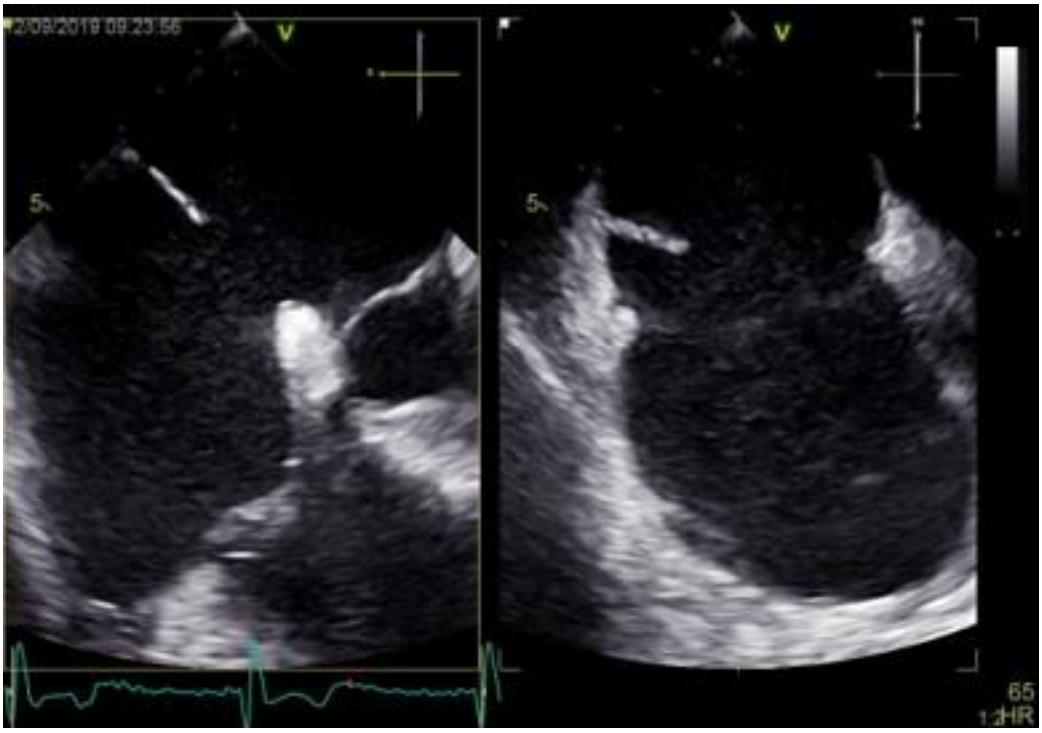

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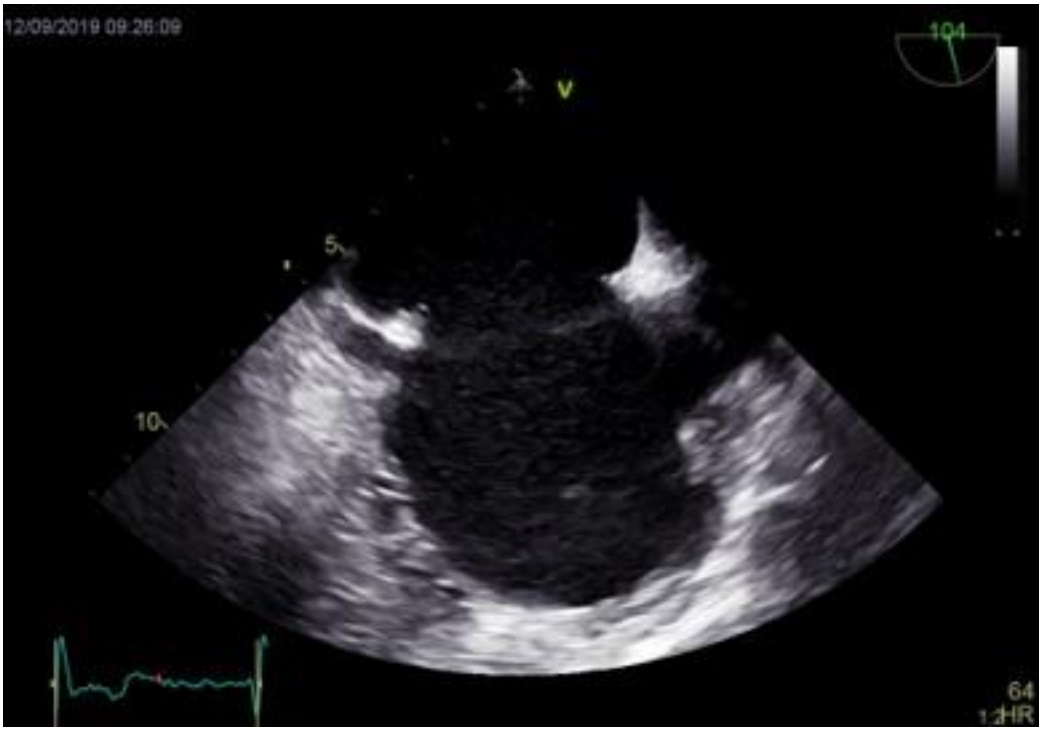

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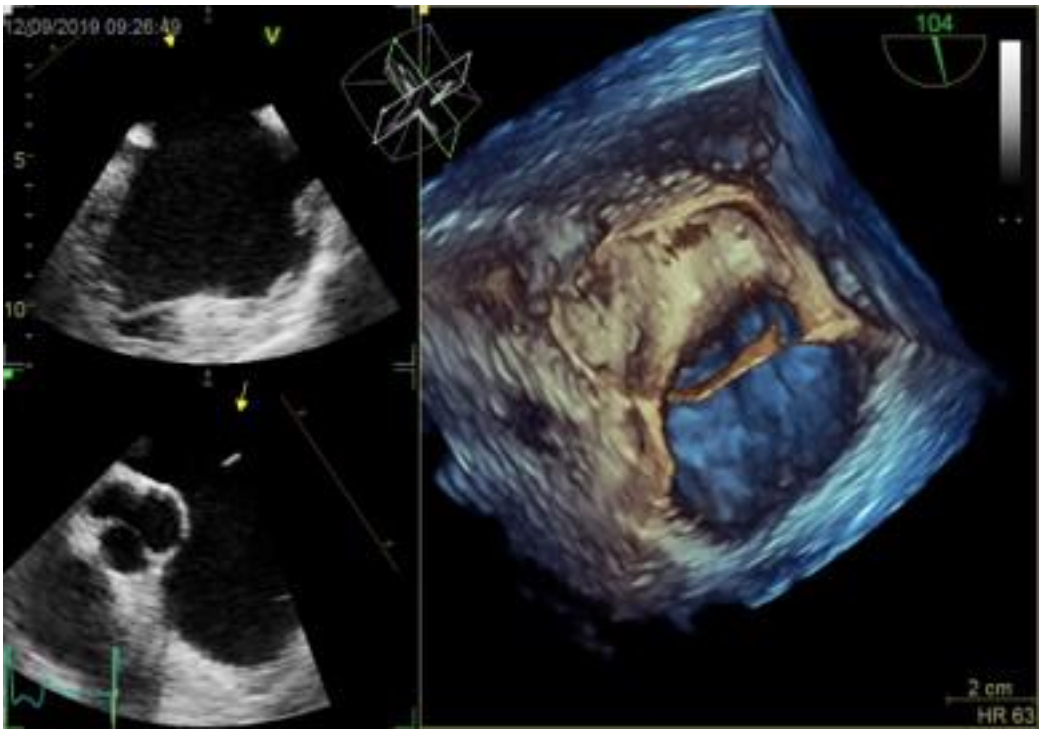

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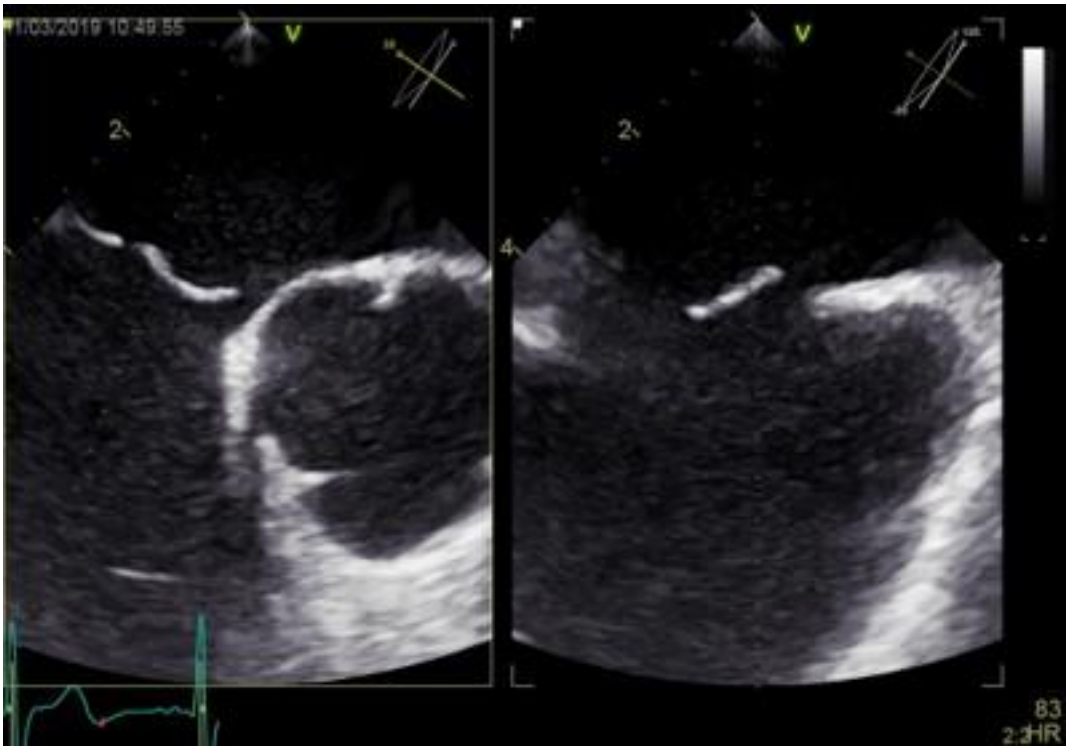

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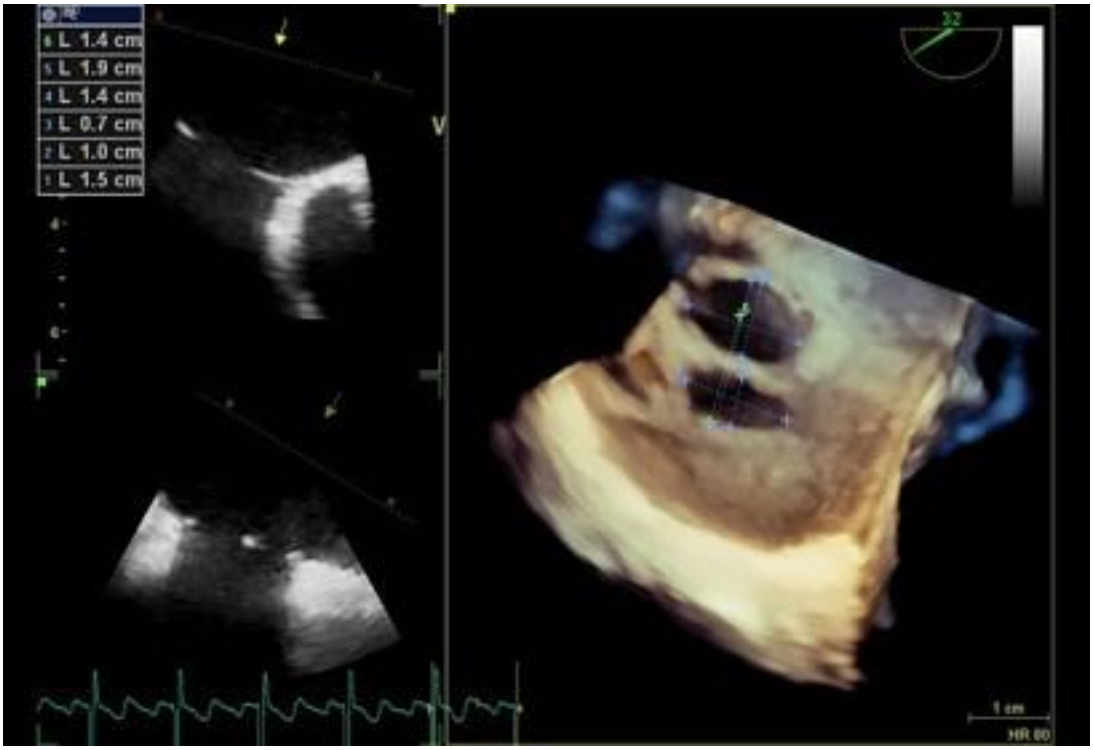

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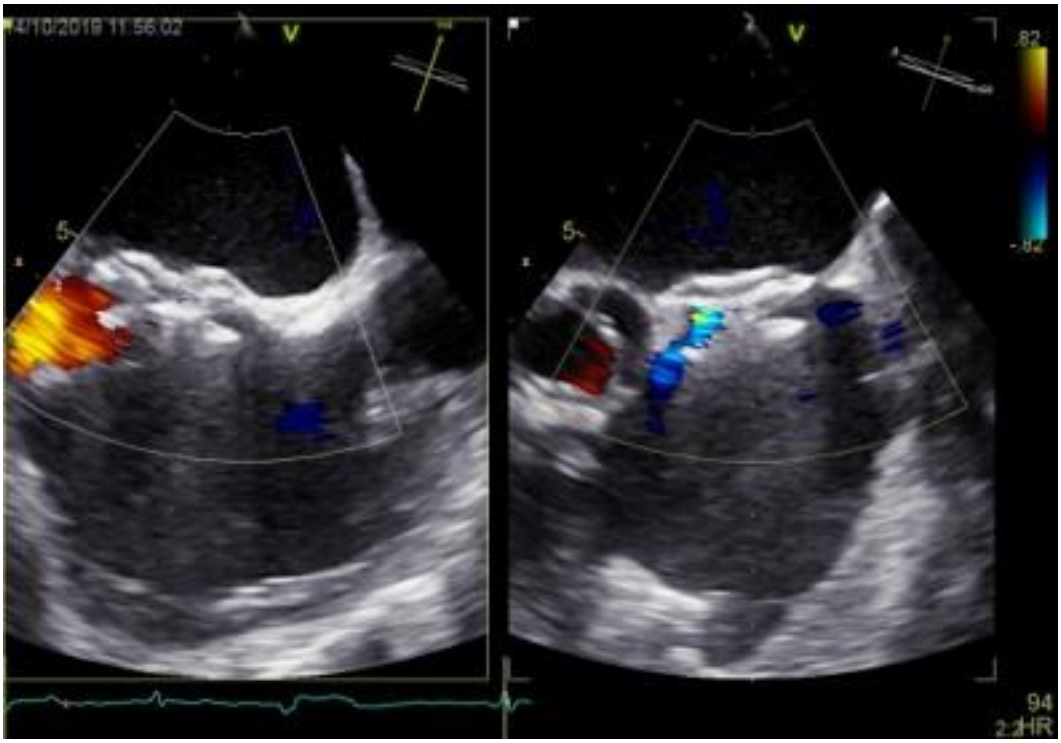

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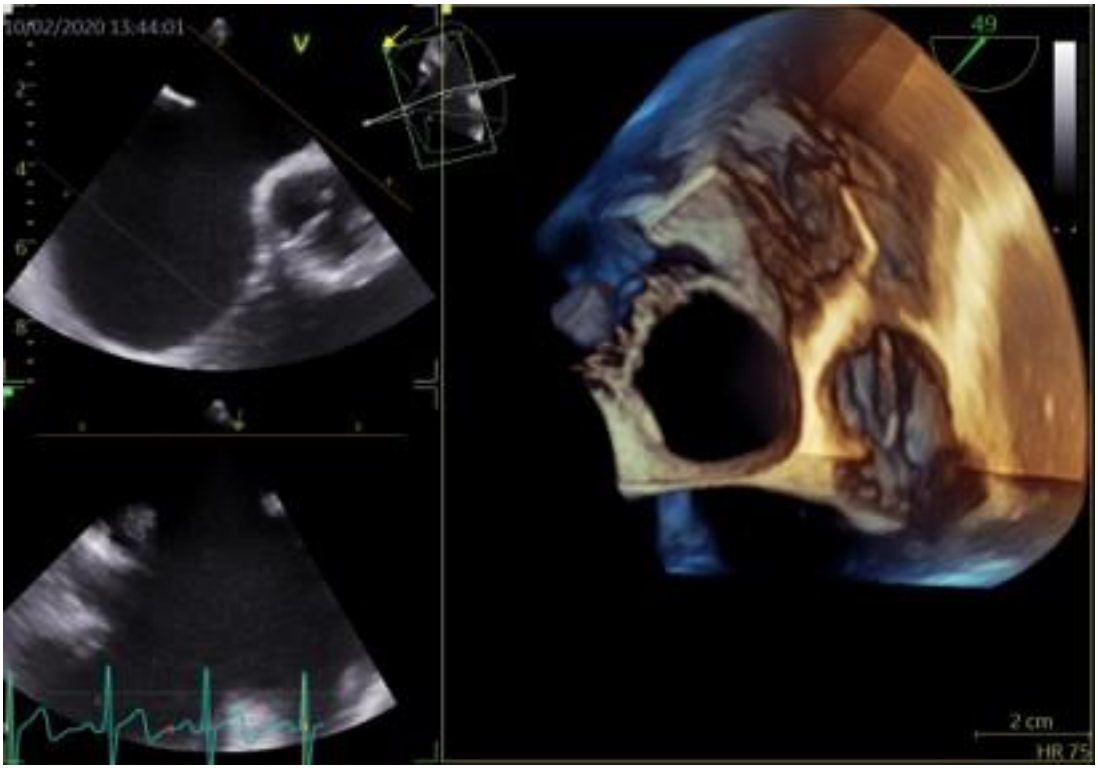

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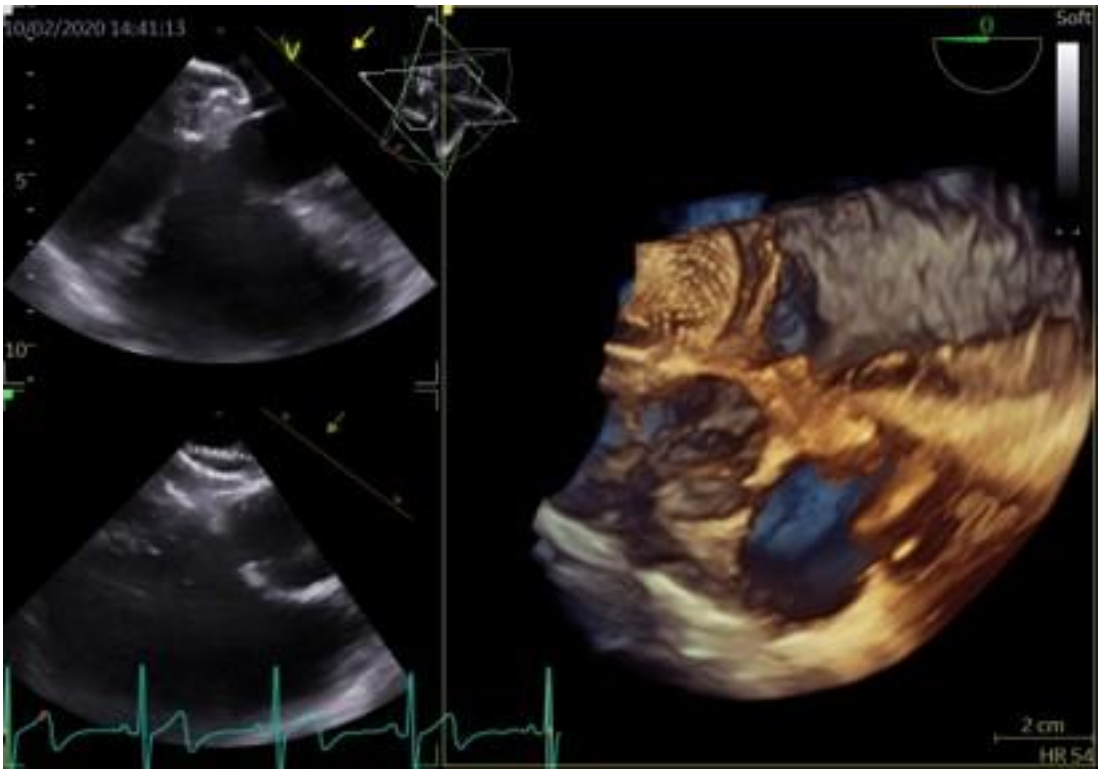

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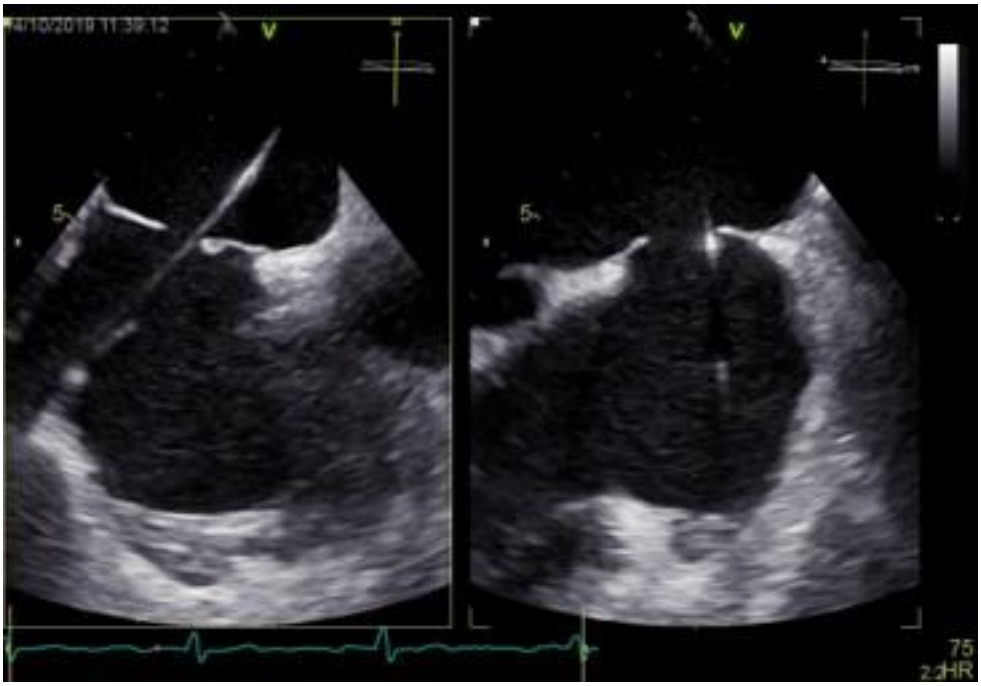

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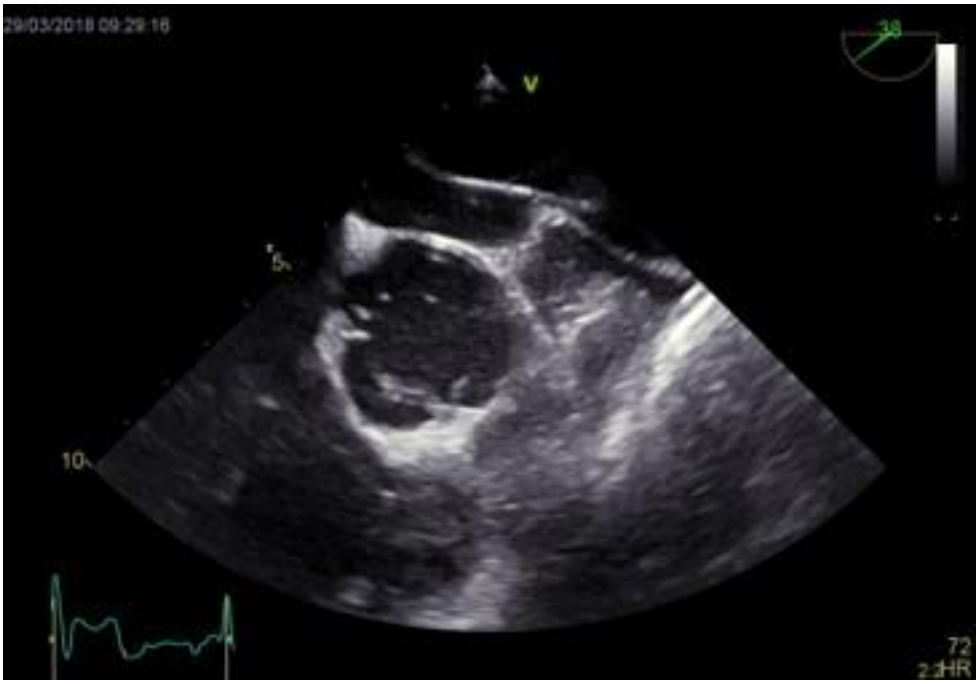

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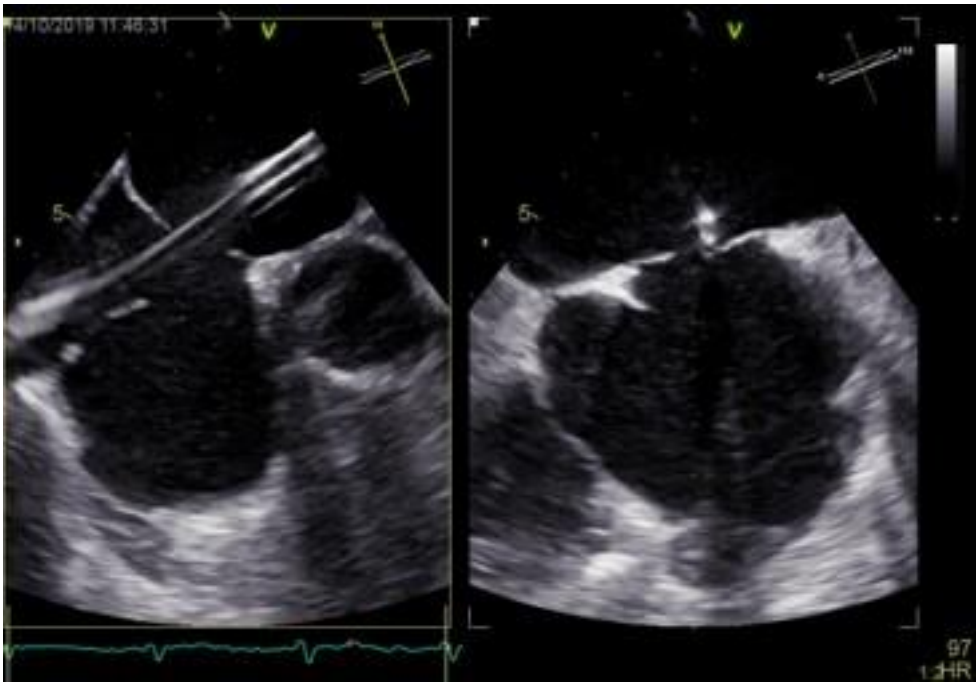

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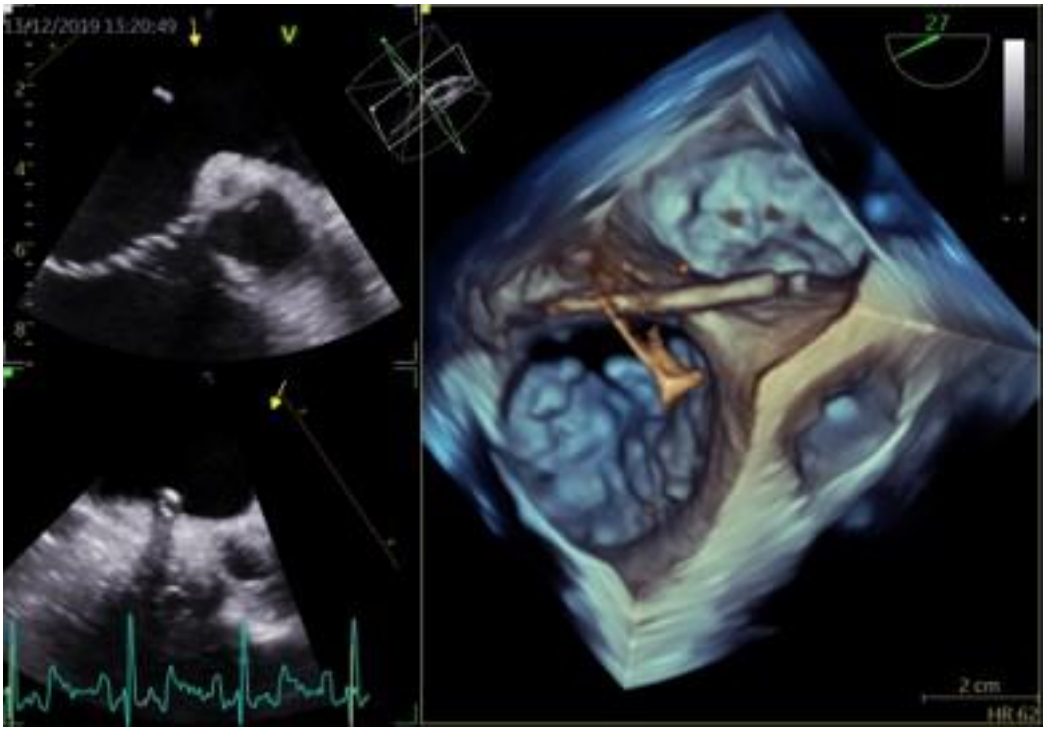

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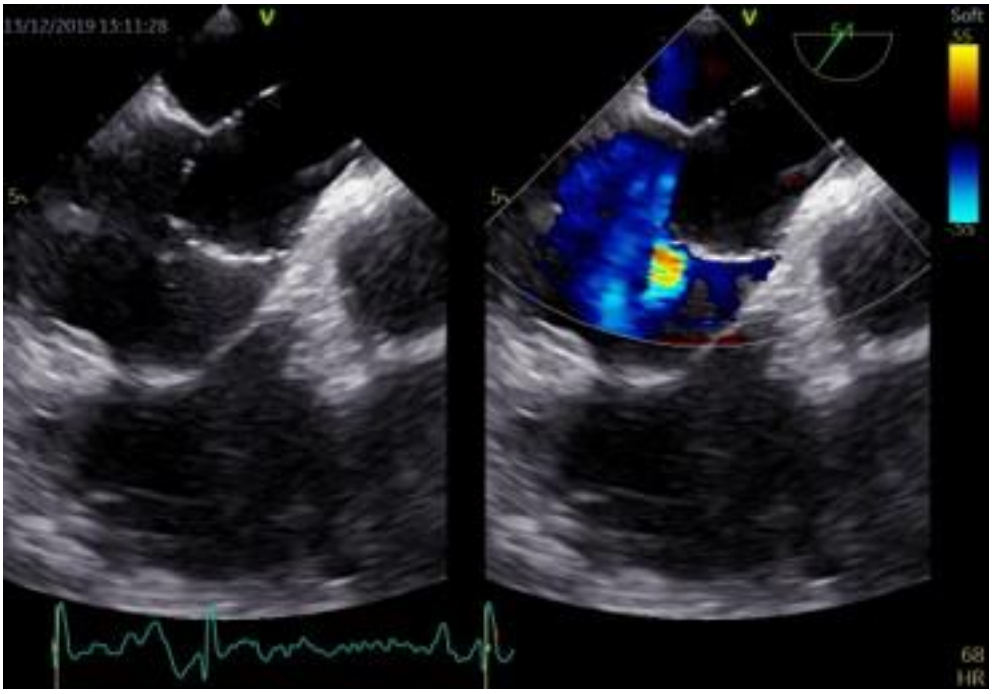

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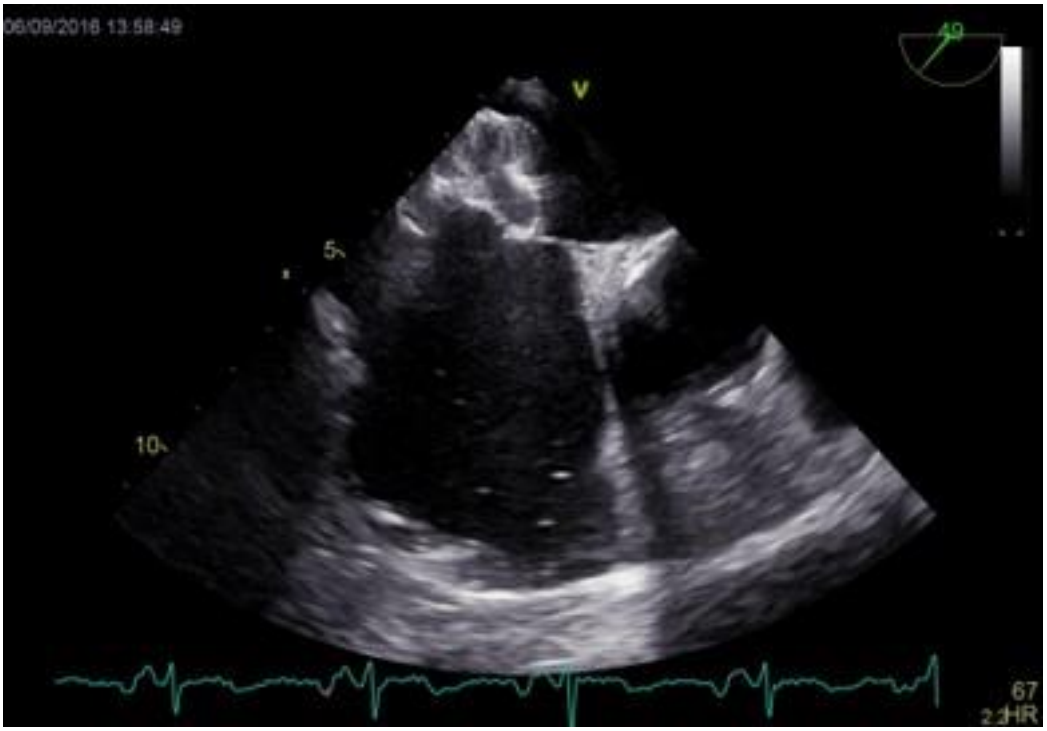

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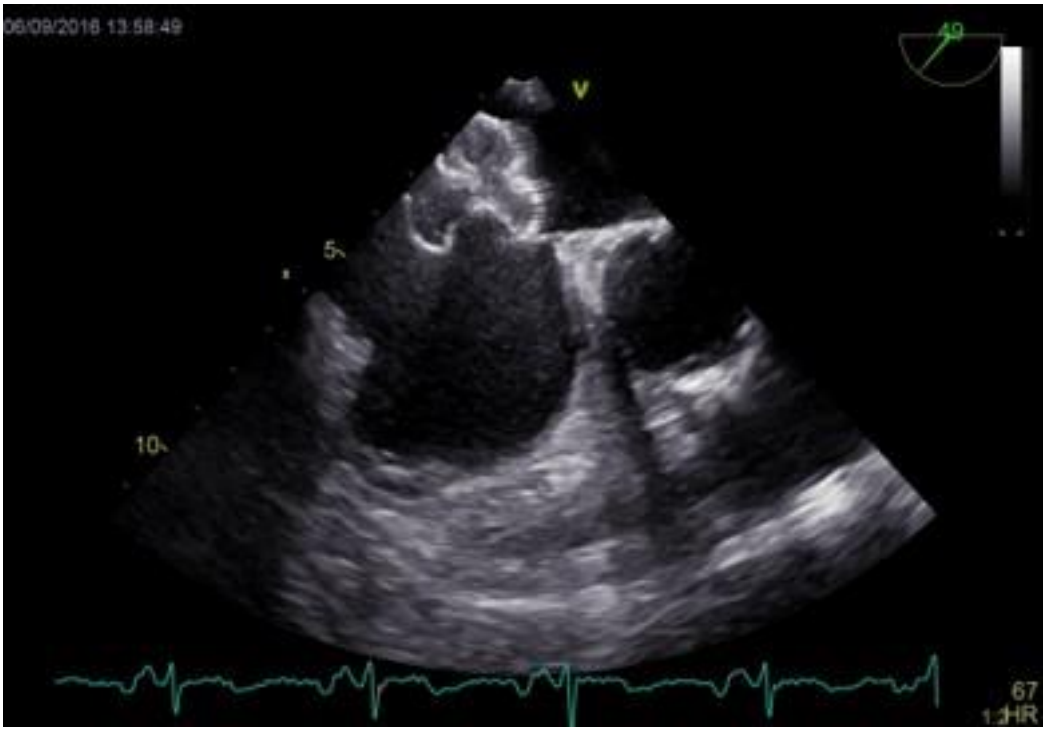

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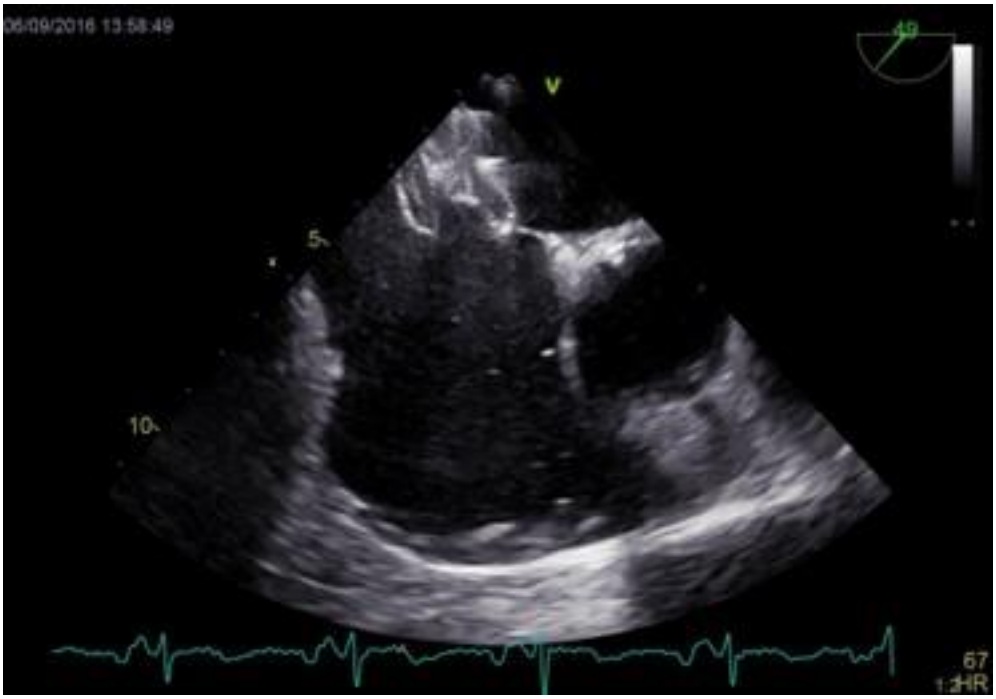

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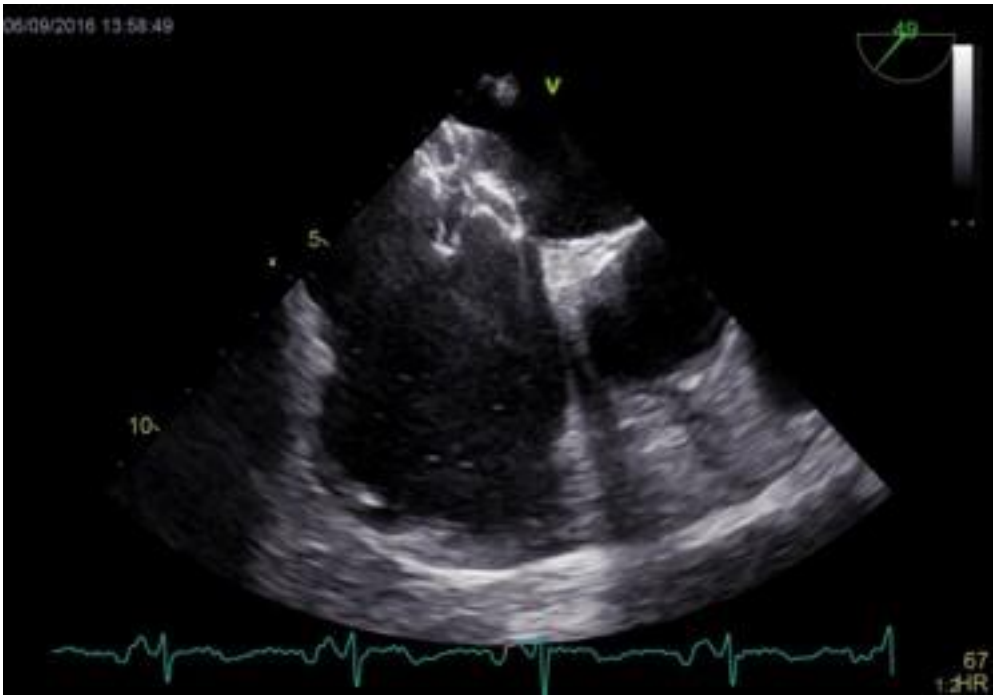
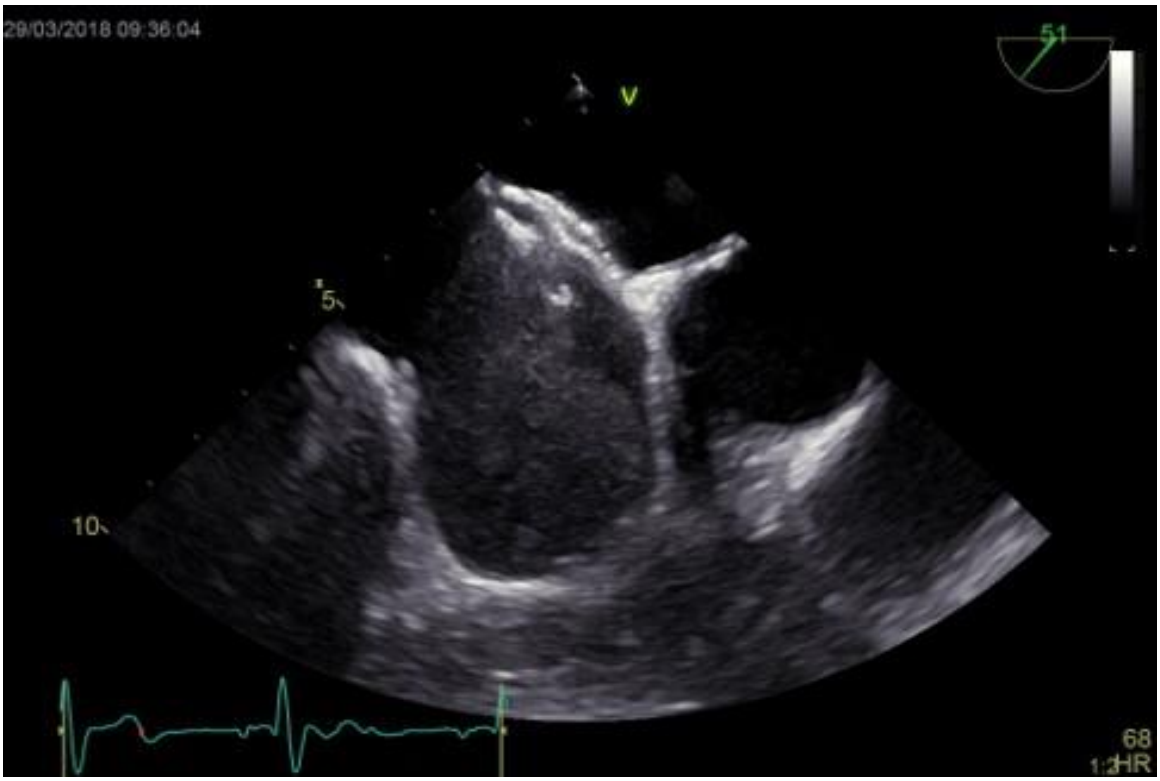


Figure S6F

Figure S6G

Figure S7A

Figure S7B



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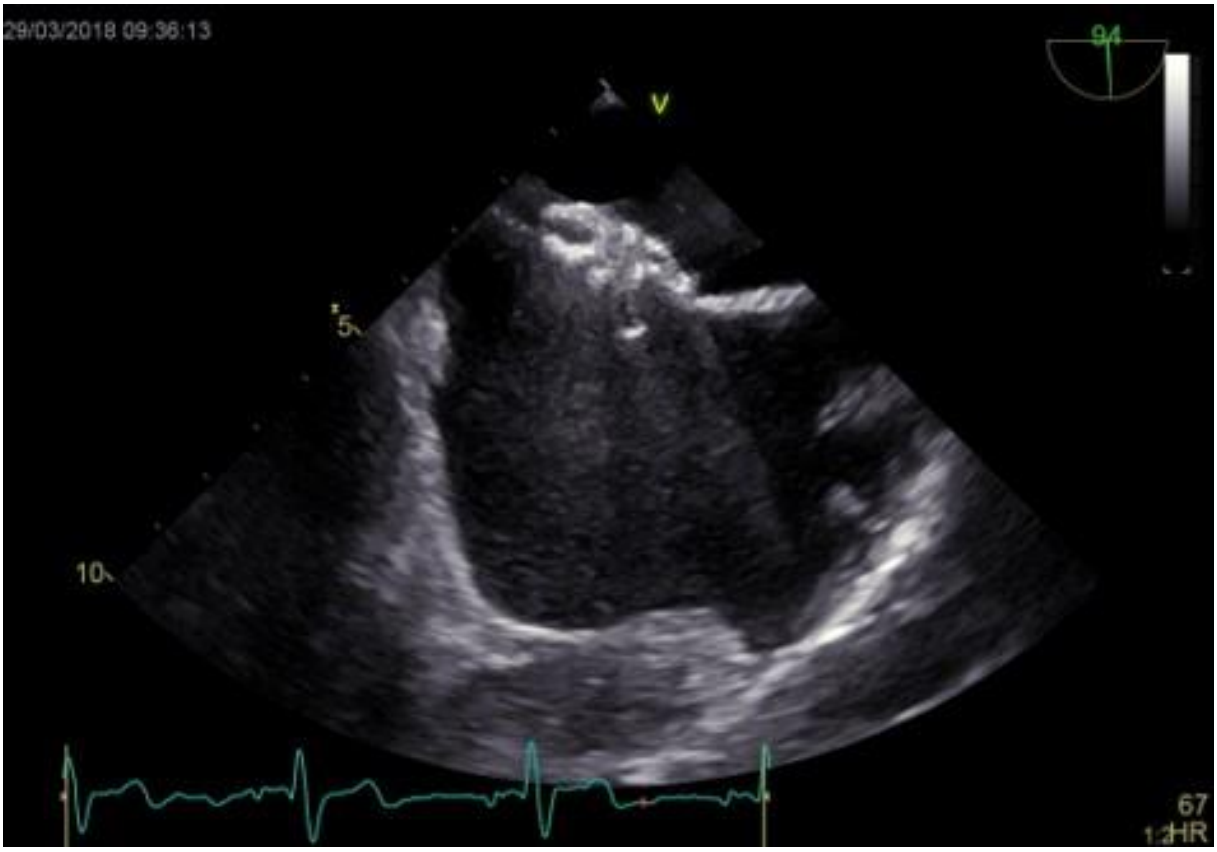

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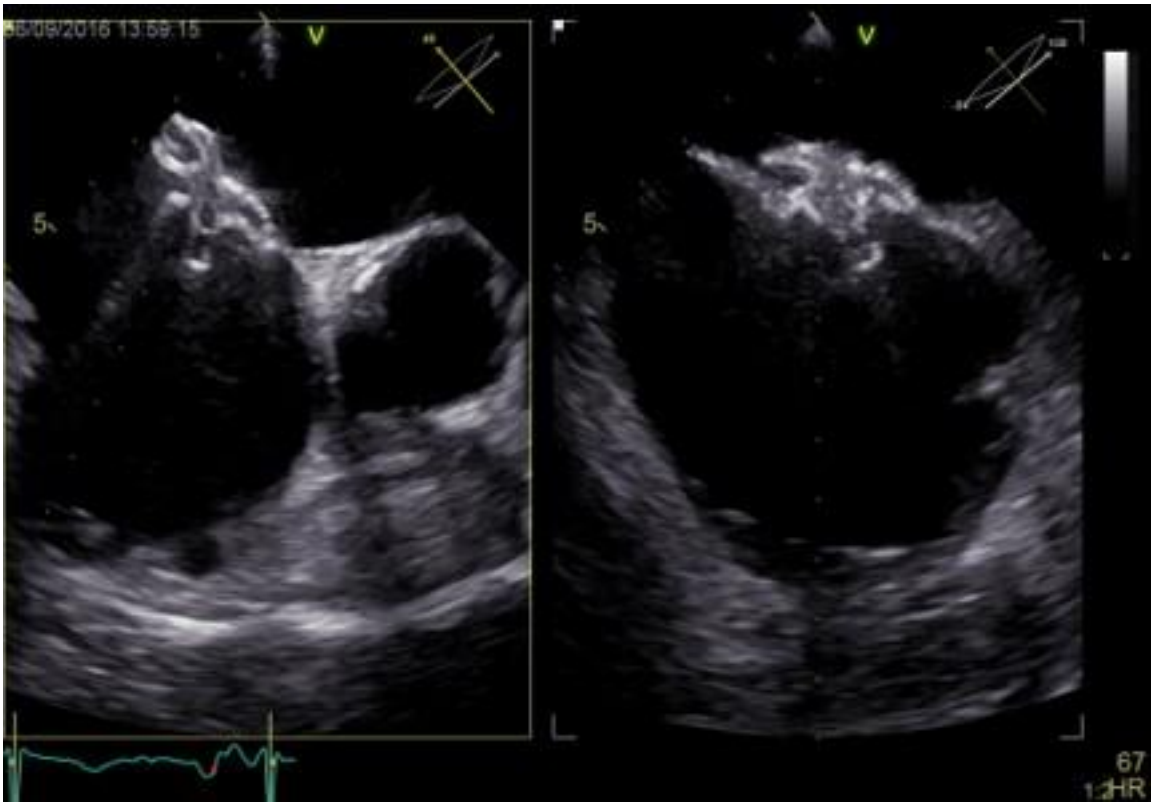

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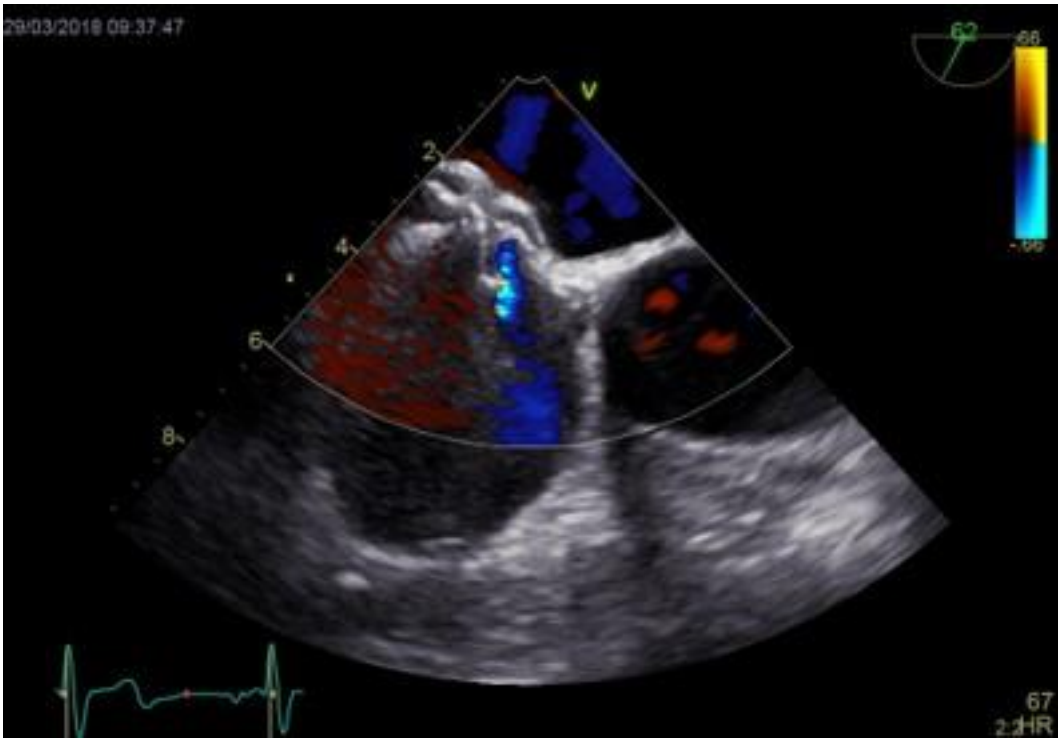

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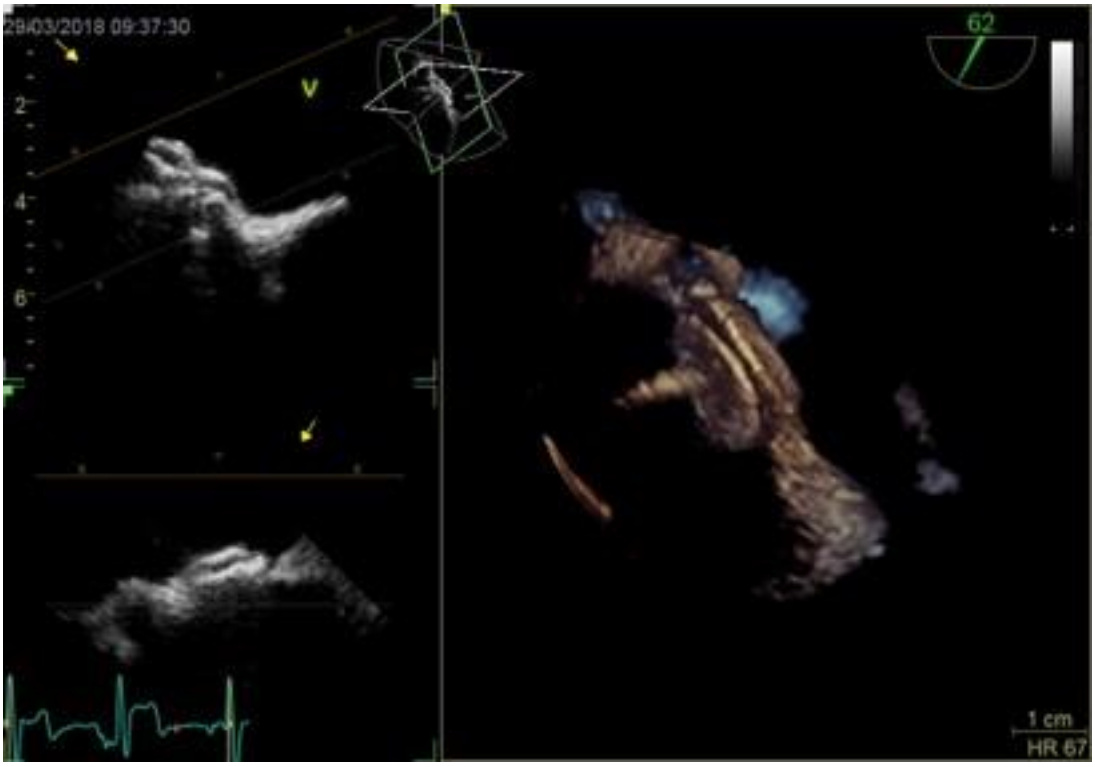

FIGURES – LEGEND

Fig. S1. TEE Assessment of ASD rims. A, B, C- midesophagus- rotation should be continuous with recording every 15°-30° D- deep position at 0°- coronary sinus ostium is visible E- high position at 0°- aorta and LA roof is visible. Red arrow- ASD II

Fig. S2. 3D TEE A- multi-D (X-plane) modality: two perpendicular simultaneous plane through the hole of the defect; B- color doppler- flow through the single defect; C- dynamic change of ASD size during cardiac cycle; D- measurement of defect: maximal, minimal diameter and area; E- 3D of very oval defect 2F- measurement of oval ASD

Fig. S3 ASD not suitable for percutaneous closure: A,B,C: sinus venosus defect with concomitant ASD II; D- another case: TEE deep position of the probe at 0° , multi-D: large defect very close to sinus venosus ostium; E, F, G another case: huge defect with residual thin and floppy band of septum. Red arrow- ASD II, yellow arrow sinus venosus defect, green arrow- residual band of septum

Fig. S4. Importance of 3D imaging in special cases: A, B, C: two defects: 3D allow to assesse the spatial relations of the hols and surrounding structures and planning the ASD closure procedure; D,E,F: Another patient: large ASD II, close to the mitral valve. 3D allow to plan the procedure and after deployment to verify the contact with mitral valve anterior leaflet. Red arrow- ASD II, yellow arrow- mitral valve anterior leaflet, green arrow- distans between occluder and mitral valve, blue arrow- occluder

Fig. S5. ASD closure procedure. A- wire passes through the defect; B- the optimal position of wire in LUPV; C- catheter passes through the defect; D- 3D helps to verify wire passage through the selected defect especially in the case of a thin septum;
E- classic balloon sizing - measurement performed on the level of waist - yellow arrow; F- balloon sizing with „color flow stop" method- inflation up to stop of flow in color doppler through the defect. Red arrow- ASD II, yellow arrow- wire, blue arrow- catheter, green arrow- balloon

Fig. S6. Step by step implantation of occluder: A- opening of left disc in LA; B- left disc on the left side of the septum; C,D,E,- opening of the right disc; G - final shape of the occluder

Fig. S7. Assessment before final release of the occluder: A, B, C- it is mandatory to verify the presence of septum between two discs of occluder (yellow arrow); D- the same using multi-d imaging; E- verification of residual shunt: the tension of the system can be a reason of small shunts through the occluder (red arrow); F- 3D imaging may helps in assessing position of the device on the septum