VSD closure with Lifetech device

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Objective

To evaluate the safety, effect and complication in children with ventricular septal defect (VSD) closure using Lifetech device.

Methods

- To retrospectively study VSD patients successfully received transcatheter interventional closure with Lifetech device from May 2004 to April 2010 in Children's Hospital of Chongqing Medical University.
- Complications appeared immediately, 24 hours,1 months,3 months,6 months,1 year follow-up after the procedure were analyzed in all patients by TTE and ECG.

Results

- There were 431 VSD patients fited device closure by Echo, 408 cases closured,19 cases unsuited device closure by angiograhpy,4 cases had serious complications after planted device.
- age from 1 year 6 months to 16 years 3 months (average 5.14±3.22 years),
- weight from 8kg to 56kg (average 17.54±7.83kg).

Results

- The size of VSD from 3.5 mm to 12.1mm (average 5.27±3.04mm) measured by angiography before closure.
- The diameter of VSD occluders from 5mm to 16mm (average 6.50±2.20mm).

Results

The type of VSD by Echo and angiography

VSD type	number	percentage
Perimembranous	421	98.04%
Supracristal	8	1.47%
Muscular	1	0.25%
VSD after TOF	1	0.25%

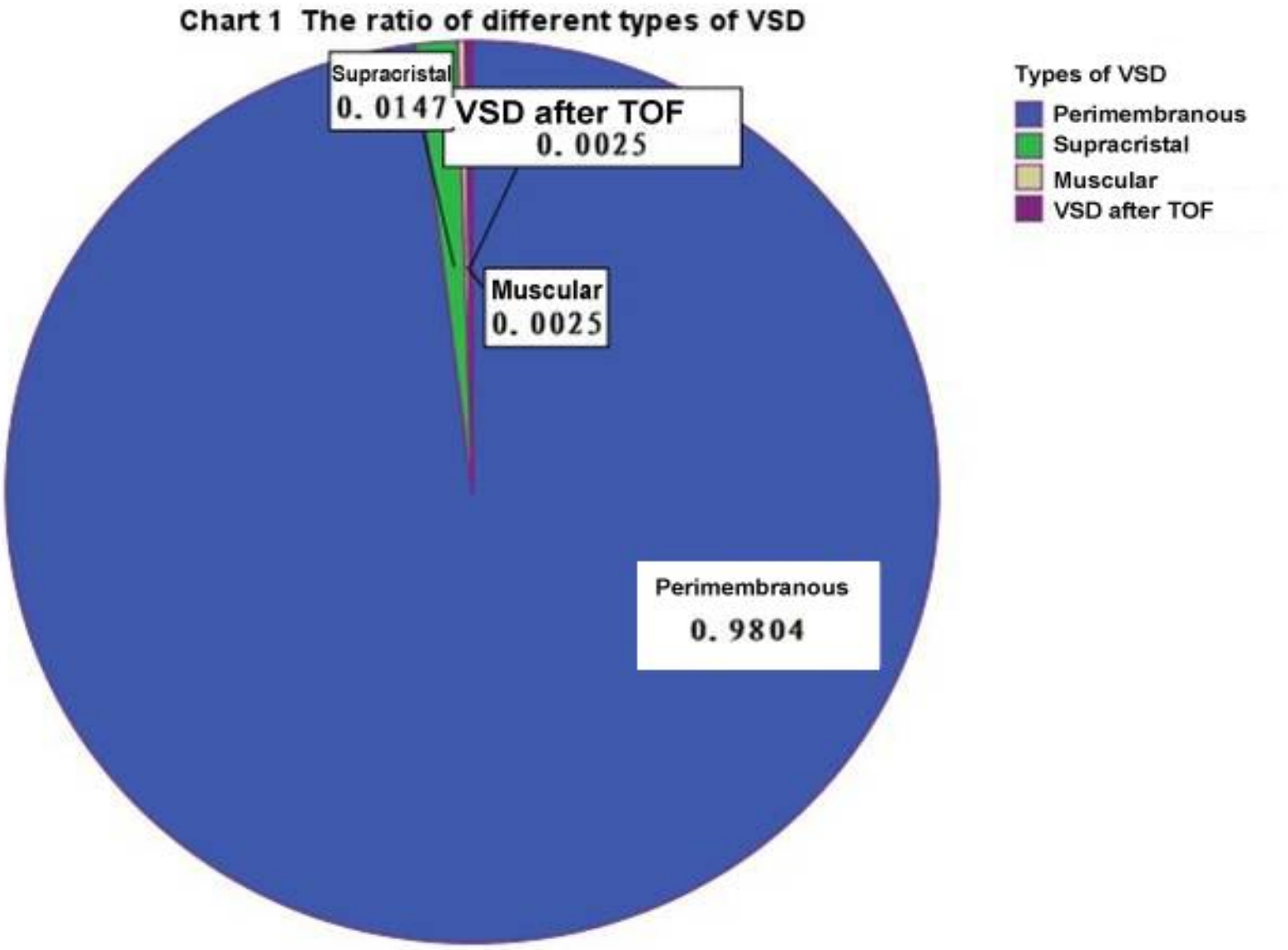


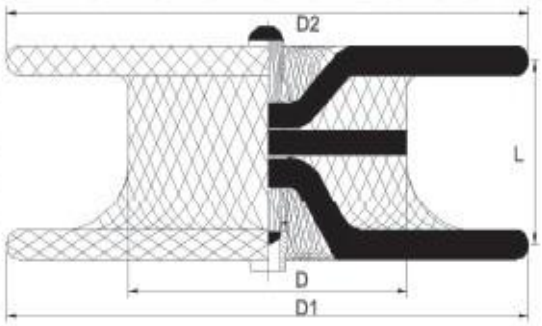
Chart 1 The ratio of different types of VSD
Supracristal
0. 0147
VSD after TOF
0. 0025
Muscular
0. 0025
Perimembranous
0. 9804
Types of VSD
Perimembranous
Supracristal
Muscular
VSD after TOF

Results

The type of VSD occluder

VSD occluder	number	percentage
Symmetric	362	88.73%
Eccentric	23	5.64%
Asymmetric	22	5.39%
Muscular	1	0.25%

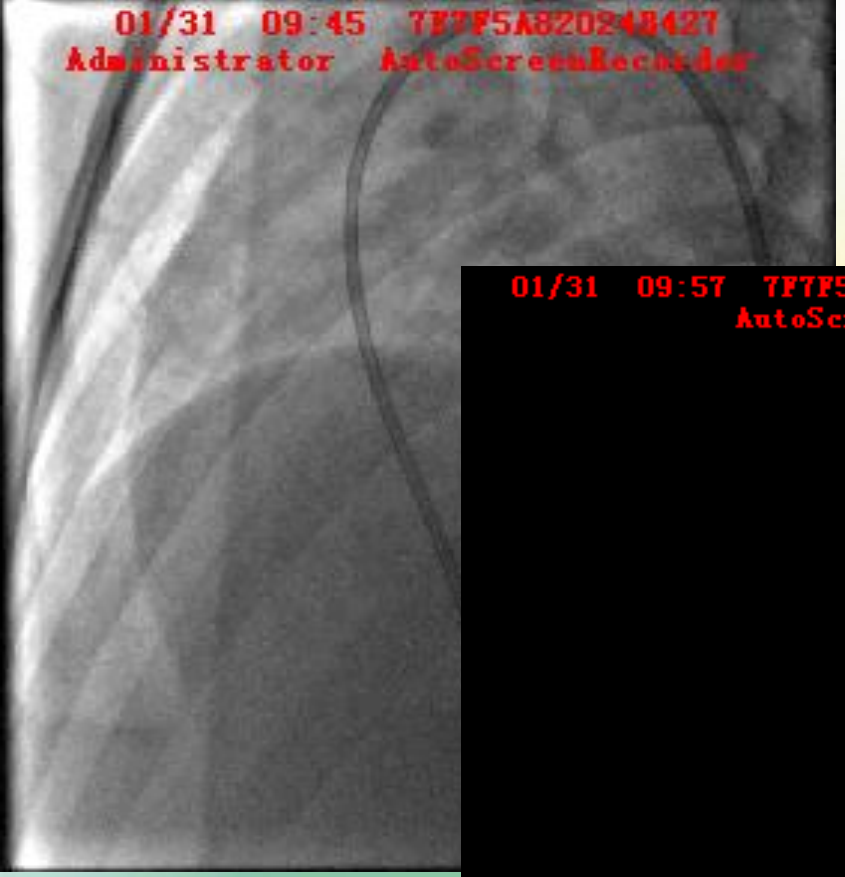
HeartR Membranous Symmetic VSD Occluder



HeartR™ Membranous VSD (Symmetric) Occluder Product Specification

CE 0344

Code	D Waist Diameter (mm)	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Recommended Sheath Size SteerEase™ (Fr.)
XJFVM04	4	8	8	3	SFP5F
XJFVM05	5	9	9	3	SFP5F
XJFVM06	6	10	10	3	SFP6F
XJFVM07	7	11	11	3	SFP6F
XJFVM08	8	12	12	3	SFP7F
XJFVM10	10	14	14	3	SFP7F
XJFVM12	12	16	16	3	SFP9F
XJFVM14	14	19	19	3	SFP9F
XJFVM16	16	21	21	3	SFP9F
XJFVM18	18	23	23	3	SFP10F
XJFVM20	20	25	25	3	SFP10F
XJFVM22	22	27	27	3	SFP12F
XJFVM24	24	29	29	3	SFP12F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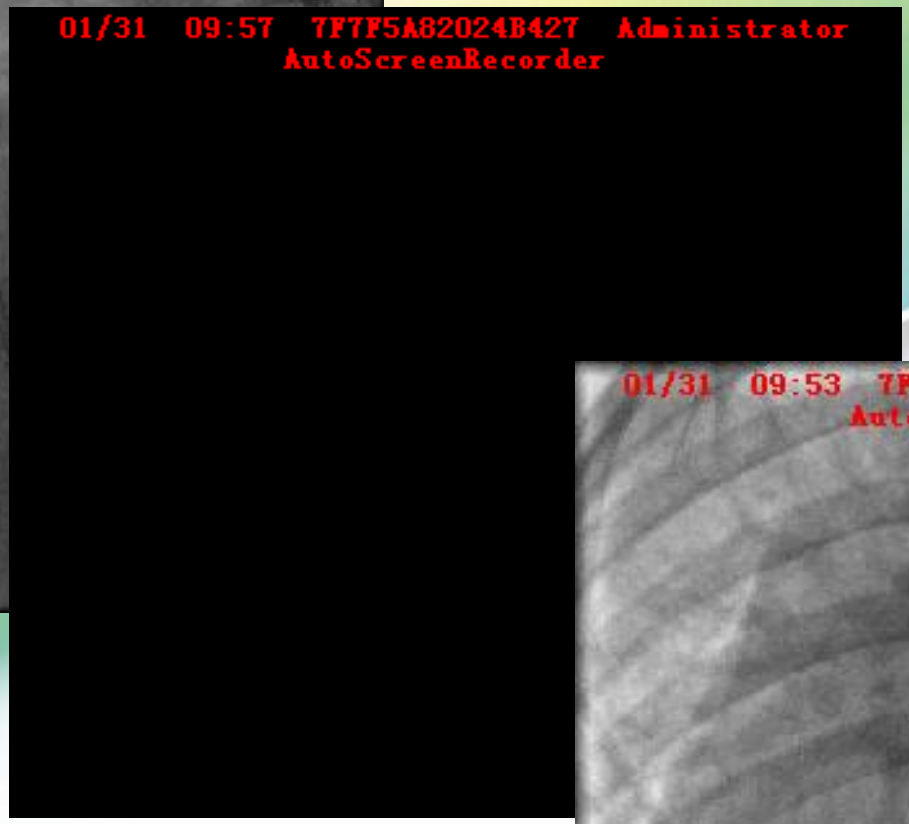
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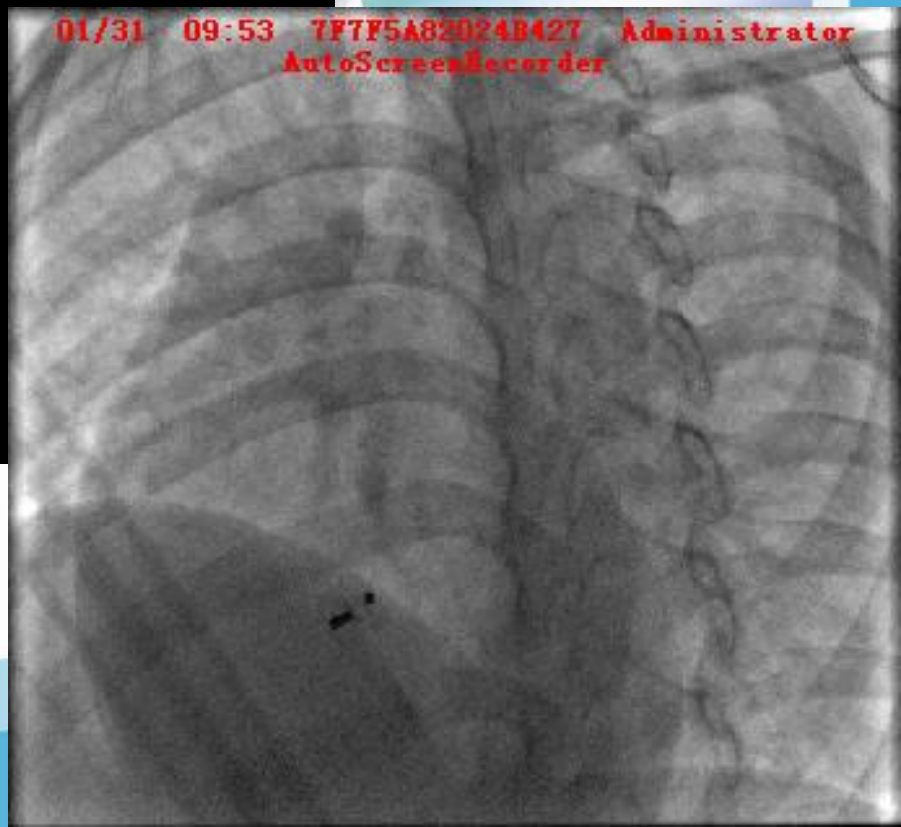
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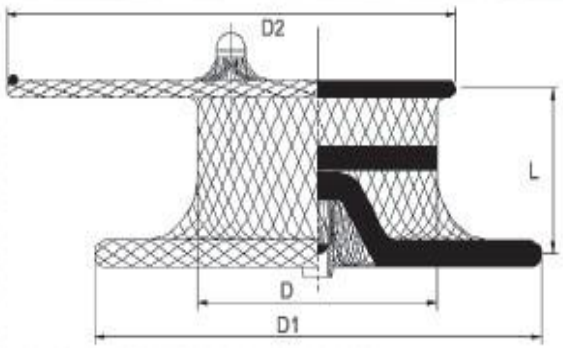
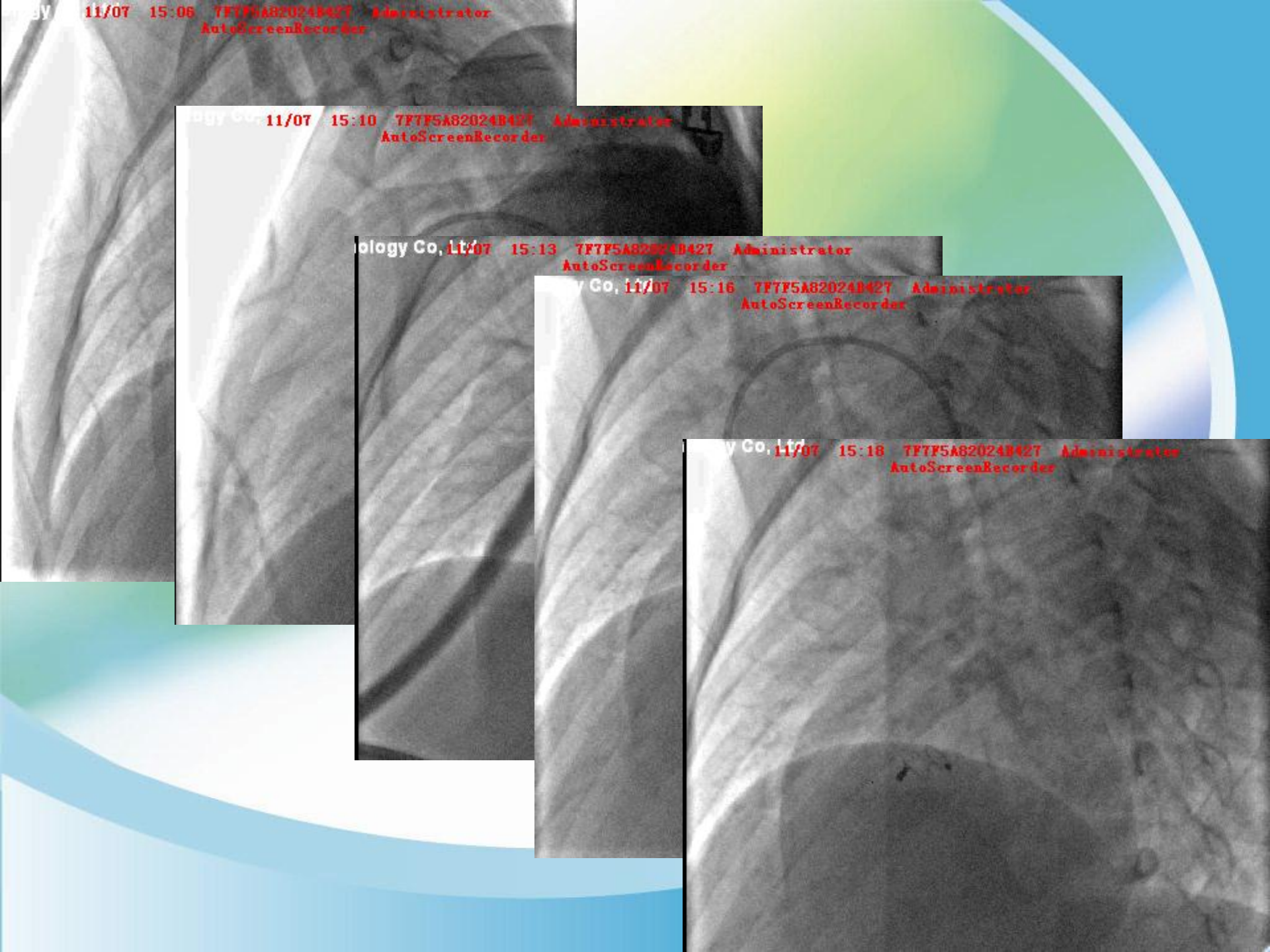
HeartR Membranous Eccentric VSD Occluder



HeartR™ Membranous VSD (Eccentric) Occluder Product Specification

CE 0344

Code	D Waist Diameter (mm)	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Recommended Sheath Size SteerEase™ (Fr.)
XJFVM04B	4	10	10	3	SFP5F
XJFVM05B	5	11	11	3	SFP5F
XJFVM06B	6	12	12	3	SFP6F
XJFVM07B	7	13	13	3	SFP6F
XJFVM08B	8	14	14	3	SFP7F
XJFVM10B	10	16	16	3	SFP7F
XJFVM12B	12	18	18	3	SFP9F
XJFVM14B	14	20	20	3	SFP9F
XJFVM16B	16	22	22	3	SFP9F
XJFVM18B	18	24	24	3	SFP10F
XJFVM20B	20	26	26	3	SFP10F
XJFVM22B	22	28	28	3	SFP12F
XJFVM24B	24	30	30	3	SFP12F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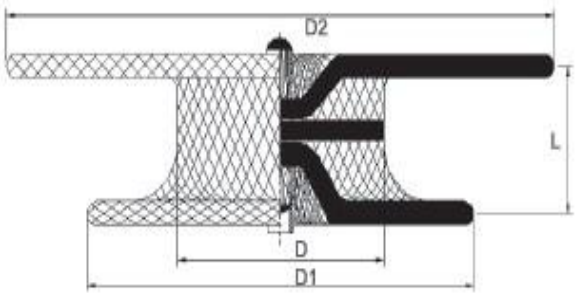
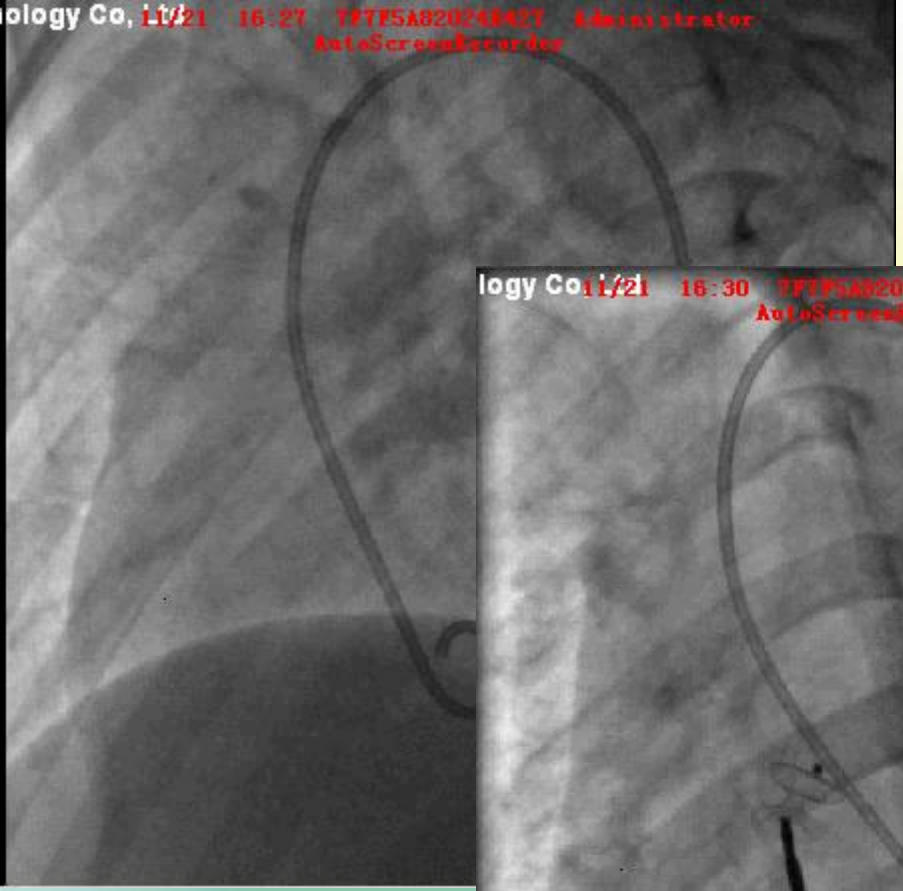
HeartR Membranous Asymmetic VSD Occluder



HeartR™ Membranous VSD (Asymmetric) Occluder Product Specification

CE 0344

Code	D Waist Diameter (mm)	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Recommended Sheath Size SteerEase™ (Fr.)
XJFVM04A Ⅱ	4	9	11.6	3	SFP5F
XJFVM05A Ⅱ	5	10	12.6	3	SFP5F
XJFVM06A Ⅱ	6	11	13.6	3	SFP6F
XJFVM07A Ⅱ	7	12	14.6	3	SFP6F
XJFVM08A Ⅱ	8	13	15.6	3	SFP7F
XJFVM10A Ⅱ	10	15	17.6	3	SFP7F
XJFVM12A Ⅱ	12	17	19.6	3	SFP9F
XJFVM14A Ⅱ	14	19	21.6	3	SFP9F
XJFVM16A Ⅱ	16	21	23.6	3	SFP9F
XJFVM18A Ⅱ	18	23	25.6	3	SFP10F
XJFVM20A Ⅱ	20	25	27.6	3	SFP10F
XJFVM22A Ⅱ	22	27	29.6	3	SFP12F
XJFVM24A Ⅱ	24	29	31.6	3	SFP12F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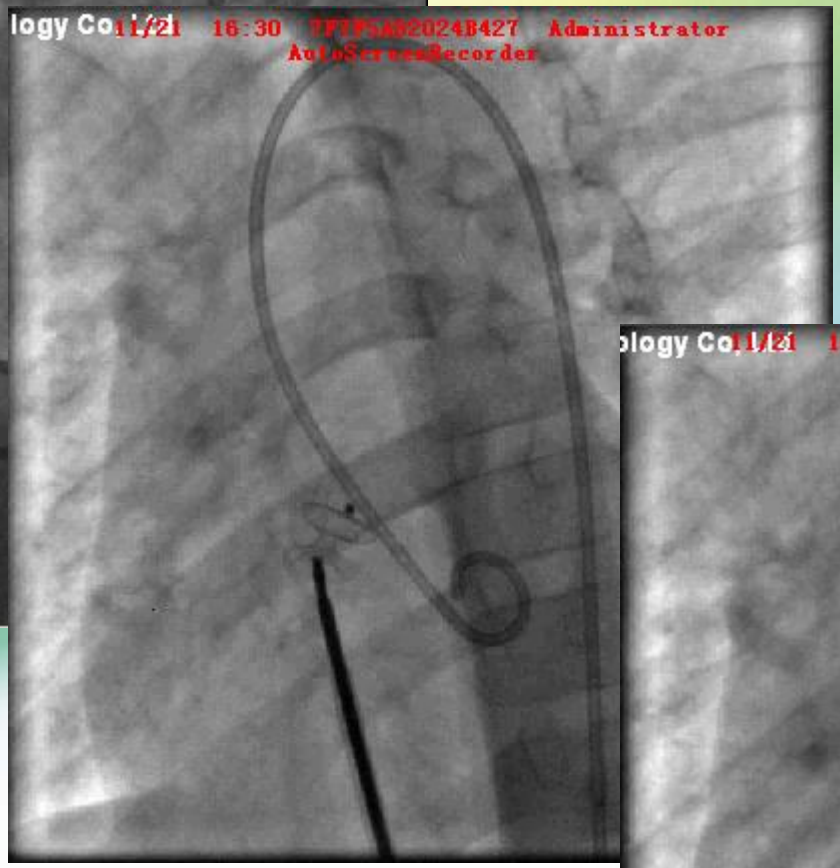
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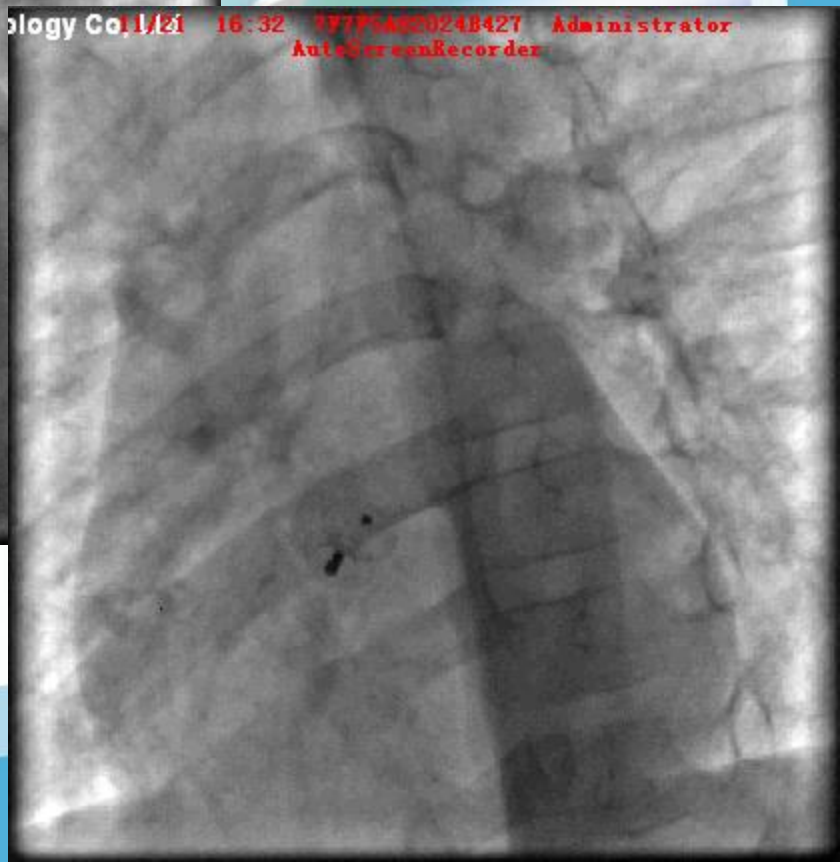
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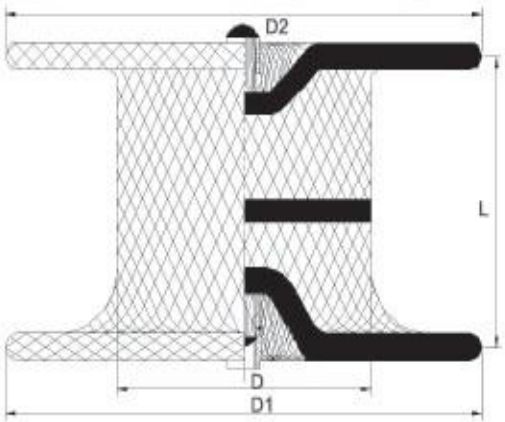
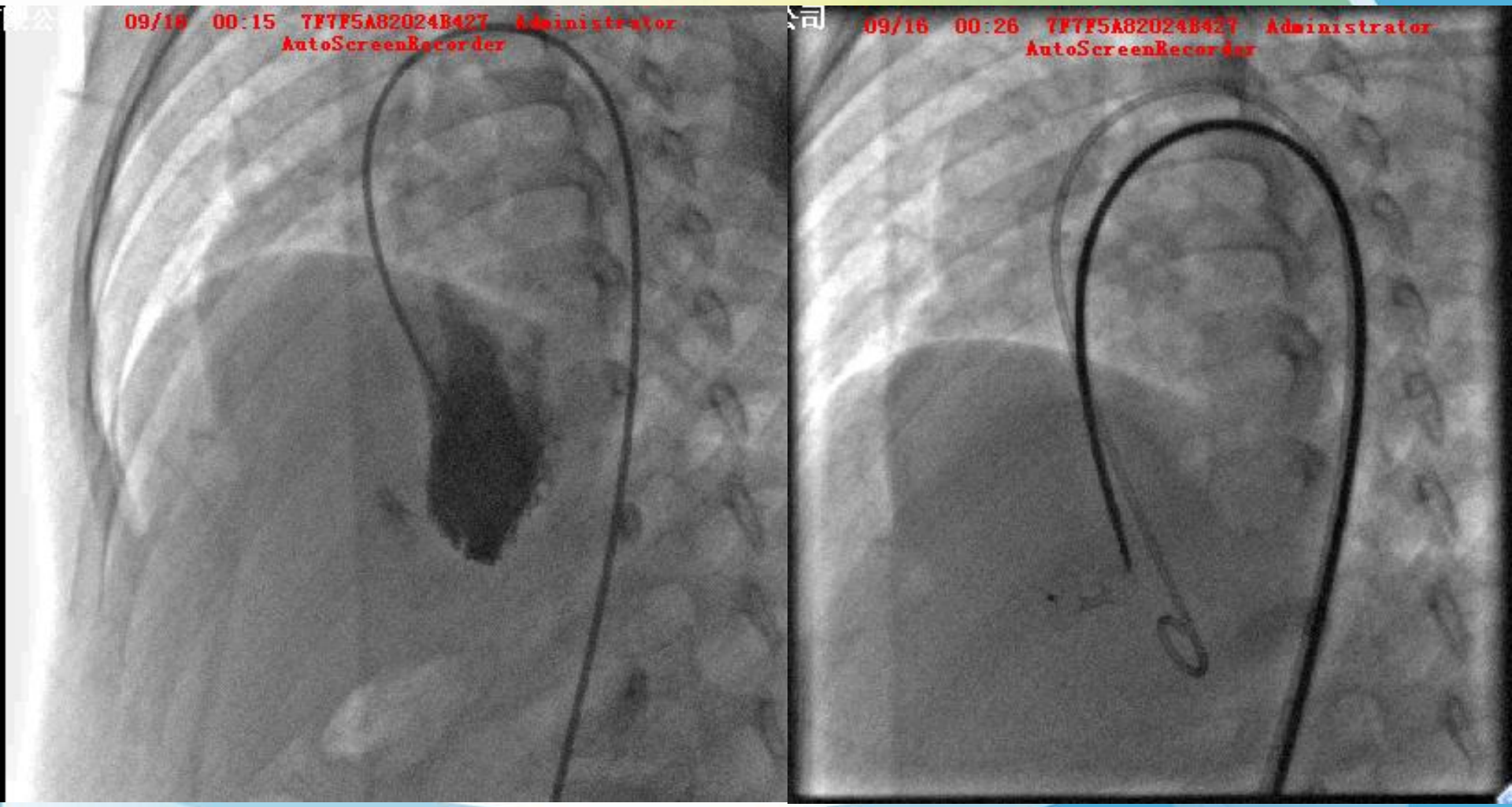
HeartR Muscular VSD Occluder



HeartR™ Muscular VSD Occluder Product Specification

CE 0344

Code	D Waist Diameter (mm)	D1 Right Disc Diameter (mm)	D2 Left Disc Diameter (mm)	L Waist Length (mm)	Minimum Recommended Sheath Size SteerEase™ (Fr.)
XJFVJ04	4	10	10	7	SFP5F
XJFVJ05	5	11	11	7	SFP5F
XJFVJ06	6	12	12	7	SFP5F
XJFVJ07	7	13	13	7	SFP6F
XJFVJ08	8	14	14	7	SFP7F
XJFVJ10	10	16	16	7	SFP7F
XJFVJ12	12	18	18	7	SFP9F
XJFVJ14	14	20	20	7	SFP9F
XJFVJ16	16	22	22	7	SFP9F
XJFVJ18	18	24	24	7	SFP10F
XJFVJ20	20	26	26	7	SFP10F
XJFVJ22	22	28	28	7	SFP12F
XJFVJ24	24	30	30	7	SFP12F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Results

Serious complications: 12 patients (2.94%)

- success rate 408/431(94%)
- 3 cases(0.74%) had Ⅲ° AVB after implanted VSD occluder and recovery by using temporary pacemaker and adrenal cortex hormone for 3~5 days
- 6 (1.47%) had hemolysis and recovery within 7 days
- 1 (0.25%) had aortic valve clampped by occluder device
- 3 cases(0,74%) happened occluder device displaced and closure by surgery
- no death

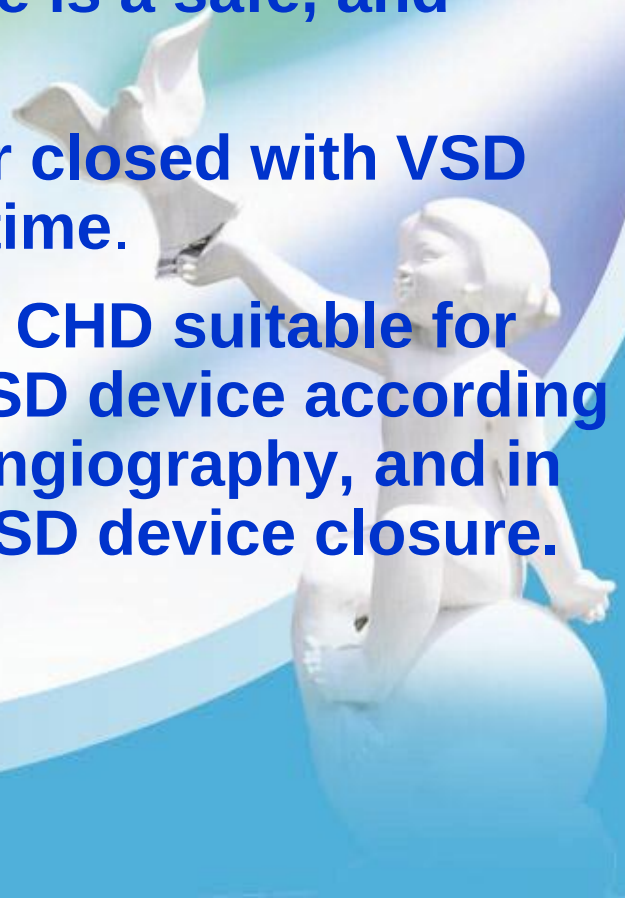
Results

Mild complications: 121(29.66%) within 24hrs

	24hrs	1month	3months	6months	1year
residual shunt	49(12.01%)	10(2.45%)	7(1.72%)	4(0.98%)	2(0.49%)
pulmonary regurgitation	25(6.13%)	16(3.92%)	9(2.21%)	6(1.47%)	2(0.49%)
aortic regurgitation	10(2.45%)	0	0	0	0
tricuspid regurgitation	13(3.19%)	3(0.74%)	1(0.25%)	0	0
mitral regurgitation	3(0.74%)	0	0	0	0
RBBB	49(12.01%)	16(3.92%)	10(2.45%)	5(1.23%)	3(0.74%)
LBBB	11(2.70%)	3(0.74%)	2(0.49%)	2(0.49%)	2(0.49%)
Ⅰ° AVB	5 (1.23%)	1(0.25%)	0	0	0
idionodal rhythm	4(0.98%)	0	0	0	0
Ventricularprematurebeat	7(1.72%)	0	0	0	0
nodal escape beat	8(1.96%)	0	0	0	0
ventricular escape beat	2(0.49%)	0	0	0	0
junctional escape beat	3(0.74%)	0	0	0	0
sinus bradycardia	1(0.25%)	0	0	0	0

Conclusion

- VSD closure with Lifetech device is a safe, and effective treatment method
- most of mild complications after closed with VSD occluder can be disappeared with time.
- We should strictly decide which CHD suitable for VSD device closure, and choose VSD device according to the shape of VSD by Echo and angiography, and in principle, as small as possible in VSD device closure.



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Thank you for your attention!