



Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

In respect of:

MemoPart[™] ASD, PDA, VSD, PFO Occluders and related Delivery Systems. MemoPart[™] Snares.

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

Gay C Stade

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 1 of 31

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ ASD Occluder

Intended purpose per IFU: The MemoPart[™] ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

Classification: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
FQFDQ-I06	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F		
FQFDQ-I07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F		
FQFDQ-I08	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F		
FQFDQ-I09	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F		
FQFDQ-I10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F		
FQFDQ-I11	11.0±0.6	5.5±0.75	25.0±1.25	21.0±1.25	9-10F		
FQFDQ-I12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F		
FQFDQ-I13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F		
FQFDQ-I14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F		
FQFDQ-I15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F		
FQFDQ-I16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F		
FQFDQ-I17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F		
FQFDQ-I18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F		
FQFDQ-I19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F		

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Page 2 of 31

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Supplementary Information to CE 650110

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Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ ASD Occluder

Intended purpose per IFU: The MemoPart[™] ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

Classification: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
FQFDQ-I20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F		
FQFDQ-I22	22.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F		
FQFDQ-I24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F		
FQFDQ-I26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F		
FQFDQ-I28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F		
FQFDQ-I30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F		
FQFDQ-I32	32.0±1.0	5.5±1.0	47.0±1.75	42.0±1.75	14F		
FQFDQ-I34	34.0±1.0	5.5±1.0	49.0±1.75	44.0±1.75	14F		
FQFDQ-I36	36.0±1.0	5.5±1.0	51.0±1.75	46.0±1.75	14F		
FQFDQ-I38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F		
FQFDQ-I40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F		
FQFDQ-I42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F		
FQFDQ-I44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F		
FQFDQ-I46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F		
FQFDQ-I48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F		
FQFDQ-I50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F		

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Page 3 of 31

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Device name: MemoPart™ ASD Occluder

Intended purpose per IFU: The MemoPart™ ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

Classification: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
WTFQFDQ-I06	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F		
WTFQFDQ-I07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F		
WTFQFDQ-I08	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F		
WTFQFDQ-I09	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F		
WTFQFDQ-I10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F		
WTFQFDQ-I11	11.0±0.6	5.5±0.75	25.0±1.5	21.0±1.25	9-10F		
WTFQFDQ-I12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F		
WTFQFDQ-I13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F		
WTFQFDQ-I14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F		
WTFQFDQ-I15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F		
WTFQFDQ-I16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F		
WTFQFDQ-I17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F		
WTFQFDQ-I18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F		
WTFQFDQ-I19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F		
WTFQFDQ-I20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F		

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Page 4 of 31

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Classification: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
WTFQFDQ-I22	20.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F		
WTFQFDQ-I24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F		
WTFQFDQ-I26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F		
WTFQFDQ-I28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F		
WTFQFDQ-I30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F		
WTFQFDQ-I32	32.0±1.0	5.5±1.0	48.0±1.75	42.0±1.75	14F		
WTFQFDQ-I34	34.0±1.0	5.5±1.0	50.0±1.75	44.0±1.75	14F		
WTFQFDQ-I36	36.0±1.0	5.5±1.0	52.0±1.75	46.0±1.75	14F		
WTFQFDQ-I38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F		
WTFQFDQ-I40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F		
WTFQFDQ-I42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F		
WTFQFDQ-I44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F		
WTFQFDQ-I46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F		
WTFQFDQ-I48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F		
WTFQFDQ-I50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F		

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Page 5 of 31

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Classification: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
FQFDQ-II06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F		
FQFDQ-II08	8±0.75	5.5±0.5	32±1.5	24±1.5	9-10F		
FQFDQ-II10	10±0.75	5.5±0.5	34±1.5	26±1.5	10-12F		
FQFDQ-II12	12±0.75	5.5±0.5	36±1.5	28±1.5	10-12F		
FQFDQ-II14	14±0.75	5.5±0.5	38±1.5	30±1.5	10-12F		
FQFDQ-II16	16±0.75	5.5±0.75	40±1.5	32±1.5	12-14F		
FQFDQ-II18	18±0.75	5.5±0.75	42±1.5	34±1.5	12-14F		
FQFDQ-II20	20±0.75	5.5±0.75	44±1.5	36±1.5	12-14F		

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Page 6 of 31

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Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ ASD Occluder

Intended purpose per IFU: The MemoPart[™] ASD Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload.

Classification: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
FQFDQ-II22	22±0.75	5.5±0.75	46±1.5	38±1.5	12-14F		
FQFDQ-II24	24±0.75	5.5±0.75	48±1.5	40±1.5	14F		
WTFQFDQ-II06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F		
WTFQFDQ-II08	8±0.75	5.5±0.5	32±1.5	24±1.5	9-10F		
WTFQFDQ-II10	10±0.75	5.5±0.5	34±1.5	26±1.5	10-12F		
WTFQFDQ-II12	12±0.75	5.5±0.5	36±1.5	28±1.5	10-12F		
WTFQFDQ-II14	14±0.75	5.5±0.5	38±1.5	30±1.5	10-12F		
WTFQFDQ-II16	16±0.75	5.5±0.75	40±1.5	32±1.5	12-14F		
WTFQFDQ-II18	18±0.75	5.5±0.75	42±1.5	34±1.5	12-14F		
WTFQFDQ-II20	20±0.75	5.5±0.75	44±1.5	36±1.5	12-14F		
WTFQFDQ-II22	22±0.75	5.5±0.75	46±1.5	38±1.5	12-14F		
WTFQFDQ-II24	24±0.75	5.5±0.75	48±1.5	40±1.5	14F		

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Page 7 of 31

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Issued To:

Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ-Ia04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F		
SQFDQ-Ia05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F		
SQFDQ-Ia06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F		
SQFDQ-Ia07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F		
SQFDQ-Ia08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F		
SQFDQ-Ia09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F		
SQFDQ-Ia10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F		
SQFDQ-Ia12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F		
SQFDQ-Ia14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F		
SQFDQ-Ia16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F		
SQFDQ-Ia18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F		
SQFDQ-Ib04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F		
SQFDQ-Ib05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F		
SQFDQ-Ib06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F		
SQFDQ-Ib07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F		
SQFDQ-Ib08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F		
SQFDQ-Ib09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F		

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Page 8 of 31

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Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart[™] Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ- Ib10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F		
SQFDQ-Ib12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F		
SQFDQ-Ib14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F		
SQFDQ-Ib16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F		
SQFDQ-Ib18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F		
SQFDQ-Ic04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F		
SQFDQ-Ic05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F		
SQFDQ-Ic06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F		
SQFDQ-Ic07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F		
SQFDQ-Ic08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F		
SQFDQ-Ic09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F		
SQFDQ-Ic10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F		
SQFDQ-Ic12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F		
SQFDQ-Ic14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F		

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Page 9 of 31

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Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart™ Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ-Ic16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F		
SQFDQ-Ic18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F		
SQFDQ-Id04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F		
SQFDQ-Id05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 10 of 31

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Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart[™] Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ-Id06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F		
SQFDQ-Id07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F		
SQFDQ-Id08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F		
SQFDQ-Id09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F		
SQFDQ-Id10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F		
SQFDQ-Id12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F		
SQFDQ-Id14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F		
SQFDQ-Id16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F		
SQFDQ-Id18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F		
WTSQFDQ-Ia04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F		
WTSQFDQ-Ia05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F		
WTSQFDQ-Ia06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F		
WTSQFDQ-Ia07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F		
WTSQFDQ-Ia08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F		

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Page 11 of 31

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Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
WTSQFDQ-Ia09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F		
WTSQFDQ-Ia10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F		
WTSQFDQ-Ia12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F		
WTSQFDQ-Ia14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F		
WTSQFDQ-Ia16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F		
WTSQFDQ-Ia18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F		
WTSQFDQ-Ib04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F		
WTSQFDQ-Ib05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F		
WTSQFDQ-Ib06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F		
WTSQFDQ-Ib07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F		
WTSQFDQ-Ib08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F		
WTSQFDQ-Ib09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F		
WTSQFDQ-Ib10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F		
WTSQFDQ-Ib12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F		
WTSQFDQ-Ib14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 12 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
WTSQFDQ-Ib16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F		
WTSQFDQ-Ib18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F		
WTSQFDQ-Ic04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F		
WTSQFDQ-Ic05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F		
WTSQFDQ-Ic06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F		
WTSQFDQ-Ic07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F		
WTSQFDQ-Ic08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F		

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Page 13 of 31

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Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart[™] Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

Catalogue No	Model, type						
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
WTSQFDQ-Ic09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F		
WTSQFDQ-Ic10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F		
WTSQFDQ-Ic12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F		
WTSQFDQ-Ic14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F		
WTSQFDQ-Ic16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F		
WTSQFDQ-Ic18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F		
WTSQFDQ-Id04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F		
WTSQFDQ-Id05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F		
WTSQFDQ-Id06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F		
WTSQFDQ-Id07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F		
WTSQFDQ-Id08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F		
WTSQFDQ-Id09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F		
WTSQFDQ-Id10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F		
WTSQFDQ-Id12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 14 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

Catalogue No	Model, type						
	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
WTSQFDQ-Id14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F		
WTSQFDQ-Id16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F		
WTSQFDQ-Id18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F		
SQFDQ-IIa04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 15 of 31

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Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ-IIa05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F		
SQFDQ-IIa06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F		
SQFDQ-IIa07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F		
SQFDQ-IIa08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F		
SQFDQ-IIa09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F		
SQFDQ-IIa10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F		
SQFDQ-IIa12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F		
SQFDQ-IIa14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F		
SQFDQ-IIa16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F		
SQFDQ-IIa18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F		
SQFDQ-IIa20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F		
SQFDQ-IIb04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F		
SQFDQ-IIb05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F		
SQFDQ-IIb06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 16 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District

Shanghai 201612 China

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Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

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Classification: Class III Implant

	Model, type							
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath			
SQFDQ-IIb07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F			
SQFDQI-IIb08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F			
SQFDQ-IIb09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F			
SQFDQ-IIb10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F			
SQFDQ-IIb12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F			
SQFDQ-IIb14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F			
SQFDQ-IIb16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F			
SQFDQ-IIb18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F			
SQFDQ-IIb20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F			
WTSQFDQ-IIa04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F			
WTSQFDQ-IIa05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F			
WTSQFDQ-IIa06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F			
WTSQFDQ-IIa07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F			
WTSQFDQ-IIa08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F			
WTSQFDQ-IIa09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F			

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 17 of 31

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Supplementary Information to CE 650110

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Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

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Classification: Class III Implant

	Model, type							
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath			
WTSQFDQ-IIa10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F			
WTSQFDQ-IIa12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F			
WTSQFDQ-IIa14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F			
WTSQFDQ-IIa16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F			
WTSQFDQ-IIa18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F			
WTSQFDQ-IIa20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F			
WTSQFDQ-IIb04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F			
WTSQFDQ-IIb05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F			
WTSQFDQ-IIb06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F			
WTSQFDQ-IIb07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F			
WTSQFDQ-IIb08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F			
WTSQFDQ-IIb09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F			
WTSQFDQ-IIb10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F			
WTSQFDQ-IIb12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F			
WTSQFDQ-IIb14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F			

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 18 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type							
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath			
WTSQFDQ-IIb16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F			
WTSQFDQ-IIb18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F			
WTSQFDQ-IIb20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F			
SQFDQ-III04	12.0±1.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F			
SQFDQ-III05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F			
SQFDQ-III06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F			
SQFDQ-III07	15.0±1.0	4.0±1.5	7.0±1.2	11.0±1.0	8-9F			
SQFDQ-II08	16.0±1.2	4.0±1.5	8.0±1.2	12.0±1.2	9-10F			
SQFDQ-III09	17.0±1.2	4.5±1.5	9.0±1.2	13.0±1.2	9-10F			
SQFDQ-III10	18.0±1.2	4.5±1.5	10.0±1.5	14.0±1.2	9-10F			
SQFDQ-III12	20.0±1.5	4.5±1.5	12.0±1.5	16.0±1.2	10-12F			
SQFDQ-III14	22.0±1.5	4.5±1.5	14.0±1.8	18.0±1.5	10-12F			
SQFDQ-III16	24.0±1.5	5.0±1.5	16.0±1.8	20.0±1.5	10-12F			

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 19 of 31

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Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart[™] Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ-III18	26.0±1.5	5.0±1.5	18.0±1.8	22.0±1.5	12-14F		
WTSQFDQ-III04	12.0±1.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F		
WTSQFDQ-III05	13.0±1.0	4.0±1.5	5.0±1.0	9.0±1.0	8-9F		
WTSQFDQ-III06	14.0±1.0	4.0±1.5	6.0±1.0	10.0±1.0	8-9F		
WTSQFDQ-III07	15.0±1.0	4.0±1.5	7.0±1.2	11.0±1.0	8-9F		
WTSQFDQ-III08	16.0±1.2	4.0±1.5	8.0±1.2	12.0±1.2	9-10F		
WTSQFDQ-III09	17.0±1.2	4.5±1.5	9.0±1.2	13.0±1.2	9-10F		
WTSQFDQ-III10	18.0±1.2	4.5±1.5	10.0±1.5	14.0±1.2	9-10F		
WTSQFDQ-III12	20.0±1.5	4.5±1.5	12.0±1.5	16.0±1.2	10-12F		
WTSQFDQ-III14	22.0±1.5	4.5±1.5	14.0±1.8	18.0±1.5	10-12F		
WTSQFDQ-III16	24.0±1.5	5.0±1.5	16.0±1.8	20.0±1.5	10-12F		
WTSQFDQ-III18	26.0±1.5	5.0±1.5	18.0±1.8	22.0±1.5	12-14F		
SQFDQ-IV04	9.0±2.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F		
SQFDQ-IV05	10.0±2.0	3.5±1.5	5.0±0.8	9.0±1.0	7-8F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 20 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart™ Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

			Model, type		
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath
SQFDQ-IV06	11.0±2.0	4.0±1.5	6.0±1.0	10.0±1.0	7-8F
SQFDQ-IV07	12.0±2.5	4.0±1.5	7.0±1.0	11.0±1.0	8-9F
SQFDQ-IV08	13.0±2.5	4.5±1.5	8.0±1.2	12.0±1.2	8-9F
SQFDQ-IV09	14.0±2.5	5.0±1.5	9.0±1.2	13.0±1.2	9-10F

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 21 of 31

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Supplementary Information to CE 650110

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Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ VSD Occluder

Intended purpose per IFU: The MemoPart[™] Membranous VSD Occluder is used for minimally invasive transcatheter closure of perimembranous ventricular septal defects.

The MemoPart[™] Muscular VSD Occluder is indicated for use in patients with a complex ventricular septal defect (VSD) of significant size to warrant closure (large volume left-to-right shunt, pulmonary hypertension, and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition.

Classification: Class III Implant

	Model, type						
Catalogue No	LV Disc OD (mm)	Connecting waist height (mm)	Connecting waist OD (mm)	RV Disc OD (mm)	Smallest recommended Sheath		
SQFDQ-IV10	17.0±2.5	5.0±1.5	10.0±1.7	15.0±1.2	9-10F		
SQFDQ-IV12	20.0±3.5	5.0±1.5	12.0±1.7	18.0±1.2	10-12F		
SQFDQ-IV14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F		
SQFDQ-IV16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F		
WTSQFDQ-IV04	9.0±2.0	3.5±1.5	4.0±0.8	8.0±1.0	7-8F		
WTSQFDQ-IV05	10.0±2.0	3.5±1.5	5.0±0.8	9.0±1.0	7-8F		
WTSQFDQ-IV06	11.0±2.0	4.0±1.5	6.0±1.0	10.0±1.0	7-8F		
WTSQFDQ-IV07	12.0±2.5	4.0±1.5	7.0±1.0	11.0±1.0	8-9F		
WTSQFDQ-IV08	13.0±2.5	4.5±1.5	8.0±1.2	12.0±1.2	8-9F		
WTSQFDQ-IV09	14.0±2.5	5.0±1.5	9.0±1.2	13.0±1.2	9-10F		
WTSQFDQ-IV10	17.0±2.5	5.0±1.5	10.0±1.7	15.0±1.2	9-10F		
WTSQFDQ-IV12	20.0±3.5	5.0±1.5	12.0±1.7	18.0±1.2	10-12F		
WTSQFDQ-IV14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F		
WTSQFDQ-IV16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 22 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ PDA Occluder

Intended purpose per IFU: The MemoPart™ PDA Occluder can be used for the nonsurgical closure of patent ductus arteriosus (PDA) in

the percutaneous, transcatheter therapy. **Classification:** Class III Implant

	Model, type							
Catalogue No	Aortic disc OD (mm)	Connecting waist height (mm)	Aortic waist OD (mm)	Pulmonic waist OD (mm)	Smallest recommended Sheath			
WBFDQ-I04	8.0±1.0	4.0±1.5	4.0±1.0	· (7) -	6-7F			
WBFDQ-I05	9.0±1.0	5.0±1.5	5.0±1.0	7-47/29	6-7F			
WBFDQ-I06	10.0±1.0	6.0±1.5	6.0±1.0) 	6-7F			
WBFDQ-I07	11.0±1.0	6.5±1.5	7.0±1.0	- 10	7-8F			
WBFDQ-I08	12.0±1.0	6.5±1.5	8.0±1.0	- 7	7-8F			
WBFDQ-I09	13.0±1.0	7.0±1.5	9.0±1.0	100	8-9F			
WBFDQ-I10	14.0±1.5	7.5±2.0	10.0±1.5	7	8-9F			
WBFDQ-I11	15.0±1.5	8.0±2.0	11.0±1.5	-	8-9F			
WBFDQ-I12	16.0±1.5	8.5±2.0	12.0±1.5	11.07 40	8-9F			
WBFDQ-I13	17.0±1.5	8.5±2.0	13.0±1.5	- 9	8-9F			
WBFDQ-I14	18.0±1.5	9.5±2.0	14.0±1.5	11/1/2 +	9-10F			
WBFDQ-I16	21.0±2.0	10.5±2.5	16.0±2.0	- WIII-	9-10F			
WBFDQ-I18	23.0±2.0	10.5±2.5	18.0±2.0	-	10-12F			
WBFDQ-I20	25.0±2.0	12±2.5	20.0±2.0	-	12-14F			
WBFDQ-I22	27.0±2.0	12±2.5	22.0±2.0	-	12-14F			
WBFDQ-II06	10.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F			

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 23 of 31

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Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ PDA Occluder

Intended purpose per IFU: The MemoPart™ PDA Occluder can be used for the nonsurgical closure of patent ductus arteriosus (PDA) in the

percutaneous, transcatheter therapy. **Classification:** Class III Implant

	Model, type							
Catalogue No	Aortic disc OD (mm)	Connecting waist height (mm)	Aortic waist OD (mm)	Pulmonic waist OD (mm)	Smallest recommended Sheath			
WBFDQ-II08	12.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F			
WBFDQ-II10	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F			
WBFDQ-II12	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F			
WBFDQ-II14	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F			
WBFDQ-II16	20.0±1.5	10.5+2.5	16.0±2.0	14.0±2.0	9-10F			
WBFDQ-II18	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F			
WBFDQ-II20	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F			
WBFDQ-II22	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F			
WTWBFDQ-I04	8.0±1.0	4.0±1.5	4.0±1.0	100	6-7F			
WTWBFDQ-I05	9.0±1.0	5.0±1.5	5.0±1.0	44 4	6-7F			
WTWBFDQ-I06	10.0±1.0	6.0±1.5	6.0±1.0	- 4	6-7F			
WTWBFDQ-I07	11.0±1.0	6.5±1.5	7.0±1.0	-11/10 -	7-8F			
WTWBFDQ-I08	12.0±1.0	6.5±1.5	8.0±1.0		7-8F			
WTWBFDQ-I09	13.0±1.0	7.0±1.5	9.0±1.0	- 1 H	8-9F			
WTWBFDQ-I10	14.0±1.5	7.5±2.0	10.0±1.5		8-9F			
WTWBFDQ-I11	15.0±1.5	8.0±2.0	11.0±1.5		8-9F			
WTWBFDQ-I12	16.0±1.5	8.5±2.0	12.0±1.5		8-9F			

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 24 of 31

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Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ PDA Occluder

Intended purpose per IFU: The MemoPart[™] PDA Occluder can be used for the nonsurgical closure of patent ductus arteriosus (PDA) in the percutaneous, transcatheter therapy.

Classification: Class III Implant

	Model, type						
Catalogue No	Aortic disc OD (mm)	Connecting waist height (mm)	Aortic waist OD (mm)	Pulmonic waist OD (mm)	Smallest recommended Sheath		
WTWBFDQ-I13	17.0±1.5	8.5±2.0	13.0±1.5		8-9F		
WTWBFDQ-I14	18.0±1.5	9.5±2.0	14.0±1.5	V(-100 a)	9-10F		
WTWBFDQ-I16	21.0±2.0	10.5±2.5	16.0±2.0	1	9-10F		
WTWBFDQ-I18	23.0±2.0	10.5±2.5	18.0±2.0	7 A-13	10-12F		
WTWBFDQ-I20	25.0±2.0	12±2.5	20.0±2.0	1-75	12-14F		
WTWBFDQ-I22	27.0±2.0	12±2.5	22.0±2.0	All St	12-14F		
WTWBFDQ-II06	9.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F		
WTWBFDQ-II08	11.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F		
WTWBFDQ-II10	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F		
WTWBFDQ-II12	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F		
WTWBFDQ-II14	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F		
WTWBFDQ-II16	20.0±1.5	10.5+2.5	16.0±2.0	14.0±2.0	9-10F		
WTWBFDQ-II18	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F		
WTWBFDQ-II20	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F		
WTWBFDQ-II22	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 25 of 31

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Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ PFO Occluder

Intended purpose per IFU: The MemoPart™ PFO Occluder is a percutaneous, transcatheter occlusion device intended to close all types PFOs (i.e. classical as well as those with aneurysm of the septum) in patients with a history of stroke or transient ischemic attacks (TIAs) diagnosed by echocardiography with right-to-left shunting during the Valsalva maneuver.

Classifications: Class III Implant

	Model, type						
Catalogue No	Connecting waist OD (mm)	Connecting waist height (mm)	LA Disc OD (mm)	RA Disc OD (mm)	Smallest recommended Sheath		
LYKFDQ-I1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F		
LYKFDQ-I1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F		
LYKFDQ-I2424	4.0±1.0	7.0±2.0	24.0±2.0	24.0±2.0	10-12F		
LYKFDQ-I2228	4.5±1.0	7.0±2.0	22.0±2.0	28.0±2.0	12-14F		
LYKFDQ-I2828	4.5±1.0	7.0±2.0	28.0±2.0	28.0±2.0	12-14F		
LYKFDQ-I2534	5.0±1.0	7.0±2.0	25.0±2.0	34.0±2.0	12-14F		
LYKFDQ-I3434	5.0±1.0	7.0±2.0	34.0±2.0	34.0±2.0	12-14F		
WTLYKFDQ-I1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F		
WTLYKFDQ-I1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F		
WTLYKFDQ-I2424	4.0±1.0	7.0±2.0	24.0±2.0	24.0±2.0	10-12F		
WTLYKFDQ-I2228	4.5±1.0	7.0±2.0	22.0±2.0	28.0±2.0	12-14F		
WTLYKFDQ-I2828	4.5±1.0	7.0±2.0	28.0±2.0	28.0±2.0	12-14F		
WTLYKFDQ-I2534	5.0±1.0	7.0±2.0	25.0±2.0	34.0±2.0	12-14F		
WTLYKFDQ-I3434	5.0±1.0	7.0±2.0	34.0±2.0	34.0±2.0	12-14F		

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 26 of 31

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Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy Co., Ltd. 1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District Shanghai 201612 China

Device name: MemoPart™ Occluder Delivery System

Intended purpose per IFU: MemoPart[™] Occluder Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Classification: Class III

	Model, type								
	Loader			Long sheath		Dilator		Pusher	4/1
Catalogue No	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	Effective Length (mm, ±60)	Effective Length (mm, ±50)	OD (mm, ±0.20)	Screw OD (mm, ±0.06)				
ODS-A-I-5F	(mm,±30)	130	1.85	800	45°	920	1200	1.4	0.80
ODS-A-I-6F	1.85	130	2.00	800	45°	920	1200	1.6	0.80
ODS-A-I-7F	2.00	130	2.33	800	45°	920	1200	1.8	0.80
ODS-A-I-8F	2.33	130	2.67	800	45°	920	1200	1.8	0.80
ODS-A-I-9F	2.67	130	3.00	800	45°	920	1200	1.8	0.80
ODS-A-I-10F	3.00	130	3.33	800	45°	920	1200	1.9	0.80
ODS-A-I-12F	3.33	160	4.00	800	45°	920	1200	2.0	0.80
ODS-A-I-14F	4.00	160	4.67	800	45°	920	1200	2.0	0.80
ODS-P/V-II-5F	4.67	130	1.85	800	180°	920	1200	1.4	0.80
ODS-P/V-II-6F	1.85	130	2.00	800	180°	920	1200	1.6	0.80
ODS-P/V-II-7F	2.00	130	2.33	800	180°	920	1200	1.8	0.80
ODS-P/V-II-8F	2.33	130	2.67	800	180°	920	1200	1.8	0.80
ODS-P/V-II-9F	2.67	130	3.00	800	180°	920	1200	1.8	0.80
ODS-P/V-II-10F	3.00	130	3.33	800	180°	920	1200	1.9	0.80
ODS-P/V-II-12F	3.33	160	4.00	800	180°	920	1200	2.0	0.80
ODS-P/V-II-14F	4.00	160	4.67	800	180°	920	1200	2.0	0.80
ODS-A-III-5F	4.67	130	1.85	600	45°	680	1200	1.4	0.80

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 27 of 31

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





Supplementary Information to CE 650110

Issued To:

Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612

20161 China

Device name: MemoPart™ Occluder Delivery System

Intended purpose per IFU: MemoPart[™] Occluder Delivery System is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Classification: Class III

	Model, type								
_	Loader			Long sheath		Dilator	Pusher		
Catalogue No	ID (mm, ±0.25)	Effective Length (mm, ±30)	ID (mm, ±0.25)	Effective Length (mm, ±60)	Angle (±20°)	Effective Length (mm, ±60)	Effective Length (mm, ±50)	OD (mm, ±0.20)	Screw OD (mm, ±0.06)
ODS-A-III-6F	2.00	130	2.00	600	45°	680	1200	1.6	0.80
ODS-A-III-7F	2.33	130	2.33	600	45°	680	1200	1.8	0.80
ODS-A-III-8F	2.67	130	2.67	600	45°	680	1200	1.8	0.80
ODS-A-III-9F	3.00	130	3.00	600	45°	680	1200	1.8	0.80
ODS-A-III-10F	3.33	130	3.33	600	45°	680	1200	1.9	0.80
ODS-A-III-12F	4.00	160	4.00	600	45°	680	1200	2.0	0.80
ODS-A-III-14F	4.67	160	4.67	600	45°	680	1200	2.0	0.80
ODS-P/V-IV-5F	1.85	130	1.85	600	180°	680	1200	1.4	0.80
ODS-P/V-IV-6F	2.00	130	2.00	600	180°	680	1200	1.6	0.80
ODS-P/V-IV-7F	2.33	130	2.33	600	180°	680	1200	1.8	0.80
ODS-P/V-IV-8F	2.67	130	2.67	600	180°	680	1200	1.8	0.80
ODS-P/V-IV-9F	3.00	130	3.00	600	180°	680	1200	1.8	0.80

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 28 of 31

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ Occluder Delivery System

Intended purpose per IFU: MemoPart™ Occluder Delivery System is intended to provide a pathway through which devices are introduced within the chambers and correspond to the heart or in the peripheral vasculature.

introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.

Classification: Class III

	Model, type								
	Lo	Loader		Long sheath		Dilator	Pusher		
Catalogue No	ID (mm, ±0.25)	Effective Length (mm, ±30)	ID (mm, ±0.25)	Effective Length (mm, ±60)	Angle (±20°)	Effective Length (mm, ±60)	Effective Length (mm, ±50)	OD (mm, ±0.20)	Screw OD (mm, ±0.06)
ODS-P/V-IV-10F	3.33	130	3.33	600	180°	680	1200	1.9	0.80
ODS-P/V-IV-12F	4.00	160	4.00	600	180°	680	1200	2.0	0.80
ODS-P/V-IV-14F	4.67	160	4.67	600	180°	680	1200	2.0	0.80

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 29 of 31

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Device name: MemoPart™ Snare

Intended purpose per IFU: The MemoPart™ Snare is used in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system.

Classification: Class III

Catalogue No	Model, type					
	Effective Length, mm	Circle diameter, mm	Angle			
Snare-15	1240±60	15±2	90°±20°			
Snare-20	1240±60	20±2	90°±20°			

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 30 of 31

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





Supplementary Information to CE 650110

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Certificate History

Date	Reference Number	Action
24 November 2016	10161708	First issue.
01 March 2019	8250592	Traceable to NB 0086.
20 November 2019	9771438	Change affecting Tyvek 1073B® packaging materials – all product codes are affected.
03 June 2020	8953253	Change of sterilization parameters. Administrative change on product table.
Current	3162825	Certificate renewal. Removal of MemoPart Plug from the scope and product table. Correction to typo in PDA Occluder intended use.

First Issued: **2016-11-24** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Page 31 of 31

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.





EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 650109

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

In respect of:

The design, development and manufacture of Occluders and related Delivery Systems, and Snares.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

Gay C Stade

This certificate was issued electronically and is bound by the conditions of the contract.

First Issued: **2016-11-24** Date: **2020-05-04** Expiry Date: **2024-05-26**

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Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.





EC Certificate - Full Quality Assurance System

Supplementary Information to CE 650109

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Number	Device Name	Intended purpose per IFU
Class III		
	MemoPart [™] ASD, PDA, VSD, PFO, Plug Occluders and related Delivery Systems. MemoPart [™] Snares	See CE 650110

First Issued: **2016-11-24** Date: **2020-05-04** Expiry Date: **2024-05-26**

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Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.





EC Certificate - Full Quality Assurance System

ETO Sterilization

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 650109**Date: **2020-05-04**

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District

Shanghai 201612 China

Subcontractor: Service(s) supplied

BQ Plus Medical Co., Ltd. No.18, Che Ye Road Che Dun Town, Songjiang 201611 Shanghai

China

Lepu Medical (Europe) Cooperatief U.A. **EU Representative**

Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36 8448 JB, Heerenveen The Netherlands

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 650109**Date: **2020-05-04**

Issued To: Shanghai Shape Memory Alloy

Co., Ltd.

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park CaoHeJing Development District

Shanghai 201612 China

Reference Number	Action
8486062	First issue.
8250592	Traceable to NB 0086.
3163693	Certificate renewal.
	Addition of product table.
	Correction of the ETO sterilization subcontractor from NELSON Techno Medical Co., Ltd. to BQ Plus Medical Co., Ltd.
_	Number 8486062 8250592

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.





Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name Issuer's address Shanghai Shape Memory Alloy Co., Ltd.

1F and 5F, Tower 41, No. 258 XinZhuan Road, Songjiang High-Tech Park, CaoHeJing Development District, 201612 Shanghai,

P.R. China

Tel.: +86-21-37013390 Fax: +86-21-37013391 Website: www.shsma.com/

EU Authorized Representative:

Address

Lepu Medical (Europe) Cooperatief U.A.

Abe Lenstra Boulevard 36, 8448 JB, Heerenveen, The

Netherlands

Tel: +31-515-573399 Fax: +31-515-760020

Object of the declaration

Relevant certificate(s)	Product group	Classification / rule
TBD	MemoPart™ Occluder System: o MemoPart™ Occluder (MemoPart™ VSD	Class III, Rule 8
	Occluder, MemoPart TM ASD Occluder, MemoPart TM PDA Occluder, MemoPart TM	
	PFO Occluder)	
	 o MemoPart™ Occluder Delivery System 	Class III, Rule 6
	 MemoPart™ Snare 	Class III, Rule 6

Conformity assessment: MDD Annex II

As delivered, the object of the declaration described above is on conformity with the requirements of the following documents:

Document number	Title	Edition/Date of issue			
MDD 93/42/EEC	Medical Device Directive: Council Directive 93/42/EEC concerning medical devices, including all amendments	Amended on 5 th , Sep. 2007			
All harmonized standards which are applicable to the object, as published in the Official Journal of the European Communities.					

Additional information

Notified Body:

BSI **CE 2797**

Say Building, John M.Keynesplein 9,1066 EP Amsterdam. The Netherlands

Tel: +31 20 346 0780

Page 1 of 20



Certificate	Initially issued	Last renewal	Valid until
EC Certificate-Full Quality Assurance System No.: CE 650109	24 November 2016	4 May 2020	26 May 2024
EC Certificate-Design Examination Certificate No.: CE 650110	24 November 2016	29 April 2021	26 May 2024

Signed for and on behalf of name: Yu Ting

Function (Company) : Management

Representative Signature:

Date: 2021. 12.1

Annex: CE-MPOS-002-01 Product List of MemoPart™ Occluder System



Product List of Memo PartTM Occluders

Medical device:

Product name: Memo PartTM Occluders

Group(s):

MemoPart™ Occluder (MemoPart™ ASD Occluder, MemoPart™ VSD Occluder, MemoPart™ PDAOccluder, MemoPart™ PFO Occluder

Product List:

Table 1 Specifications of MemoPartTM ASD Occluder

Smallest	Recommended	Sheath Size	,	1.0 8-9F	1.0 8-9F	1.0 8-9F	1.0 8-9F	1.0 9-10F	1.25 9-10F	1.25 9-10F	1.25 9-10F	1.25 9-10F	1.25 9-10F	1.25 10-12F	1.25 10-12F	1.5 10-12F	1.5 10-12F
O	RADiscDiameter	(mm)		14.0±1.0	17.0±1.0	16.0±1.0	19.0±1.0	18.0±1.0	21.0±1.25	20.0±1.25	23.0±1.25	22.0±1.25	25.0±1.25	26.0±1.25	27.0±1.25	28.0±1.5	29.0±1.5
В	I ADiscDiameter	(mm)	(mmn)	16.0±1.0	21.0±1.0	18.0±1.0	23.0±1.0	20.0±1.0	25.0±1.25	22.0±1.25	27.0±1.25	24.0±1.25	29.0±1.25	30.0±1.5	31.0±1.5	32.0±1.5	33.0+1.5
I	Height of	connecting waist	(mm)	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5 5+0 75
∢	Connecting	waist diameter	(mm)	6.0±0.5	7.0±0.5	8.0±0.5	9.0∓0.5	10.0±0.5	11.0±0.6	12.0±0.6	13.0±0.6	14.0±0.6	15.0±0.6	16.0±0.6	17.0±0.75	18.0±0.75	19 0+0 75
	Device	Size		90	20	80	60	10	τ	12	13	41	15	16	17	18	19
	old empolated	Catalogue NO		FQFDQ- I 06	FQFDQ- I 07	FQFDQ- I 08	FQFDQ- I 09	FQFDQ- I 10	FQFDQ- I 11	FQFDQ- I 12	FQFDQ- I 13	FQFDQ- I 14	FQFDQ- I 15	FQFDQ- I 16	FQFDQ- I 17	FQFDQ- I 18	FOFDO- I 19

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		4	H	17.2	C	Smallest
Ostalogia No	Device	Connecting	Height of	L'ADiscDiameter	RADiscDiameter	Recommended
Catalogue	Size	waist diameter (mm)	connecting waist (mm)	(mm)	(mm)	Sheath Size
FQFDQ- I 20	20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F
FQFDQ- I 22	22	22.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F
FQFDQ- I 24	24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F
FQFDQ- I 26	26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F
FQFDQ- I 28	28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F
FQFDQ- I 30	30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F
FQFDQ- I 32	32	32.0±1.0	5.5±1.0	47.0±1.75	42.0±1.75	14F
FQFDQ- I 34	8	34.0±1.0	5.5±1.0	49.0±1.75	44.0±1.75	14F
FQFDQ- I 36	36	36.0±1.0	5.5±1.0	51.0±1.75	46.0±1.75	14F
FQFDQ- I 38	38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F
FQFDQ- I 40	40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F
FQFDQ- I 42	42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F
FQFDQ- I 44	4	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F
FQFDQ- I 46	46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F
FQFDQ- I 48	48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F
FQFDQ- I 50	20	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F
WTFQFDQ- I 06	90	6.0±0.5	5.5±0.5	16.0±1.0	14.0±1.0	8-9F
WTFQFDQ- I 07	07	7.0±0.5	5.5±0.5	21.0±1.0	17.0±1.0	8-9F
WTFQFDQ- I 08	80	8.0±0.5	5.5±0.5	18.0±1.0	16.0±1.0	8-9F
WTFQFDQ- I 09	60	9.0±0.5	5.5±0.5	23.0±1.0	19.0±1.0	8-9F
WTFQFDQ- I 10	10	10.0±0.5	5.5±0.5	20.0±1.0	18.0±1.0	9-10F
WTFQFDQ- I 11	11	11.0±0.6	5.5±0.75	25.0±1.5	21.0±1.25	9-10F
WTFQFDQ- I 12	12	12.0±0.6	5.5±0.75	22.0±1.25	20.0±1.25	9-10F
WTFQFDQ- I 13	13	13.0±0.6	5.5±0.75	27.0±1.25	23.0±1.25	9-10F



Recommended Sheath Size

Smallest

	Ü	RADiscDiameter	(mm)	()	22.0±1.25	25.0±1.25	26.0±1.25	27.0±1.25	28.0±1.5	29.0±1.5	30.0±1.5	32.0±1.75	34.0±1.75	36.0±1.75	38.0±1.75	40.0±1.75	42.0±1.75	44.0±1.75	46.0±1.75	50.0±1.75	52.0±1.75	54.0±1.75	56.0±1.75	58.0±1.75	60.0±1.75	62.0±1.75	22±1.5	24±1.5
	В	I ADiscDiameter	(mm)	(,,,,,,)	24.0±1.25	29.0±1.25	30.0±1.5	31.0±1.5	32.0±1.5	33.0±1.5	34.0±1.5	36.0±1.75	38.0±1.75	40.0±1.75	42.0±1.75	44.0±1.75	48.0±1.75	50.0±1.75	52.0±1.75	54.0±1.75	56.0±1.75	58.0±1.75	60.0±1.75	62.0±1.75	64.0±1.75	66.0±1.75	30±1.5	32±1.5
11/		Height of	connecting waist	(mm)	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±1.0	5.5±0.5	5.5±0.5
	A	Connecting	waist diameter	(mm)	14.0±0.6	15.0±0.6	16.0±0.6	17.0±0.75	18.0±0.75	19.0±0.75	20.0±0.75	22.0±1.0	24.0±1.0	26.0±1.0	28.0±1.0	30.0±1.0	32.0±1.0	34.0±1.0	36.0±1.0	38.0±1.0	40.0±1.0	42.0±1.0	44.0±1.0	46.0±1.0	48.0±1.0	50.0±1.0	6±0.75	8±0.75
		Device	Size		14	15	16	17	18	19	20	22	24	26	28	30	32	8	36	38	40	42	4	46	48	50	90	80
			Catalogue No		WTFQFDQ- I 14	WTFQFDQ- I 15	WTFQFDQ- I 16	WTFQFDQ- I 17	WTFQFDQ- I 18	WTFQFDQ- I 19	WTFQFDQ- I 20	WTFQFDQ- I 22	WTFQFDQ- I 24	WTFQFDQ- I 26	WTFQFDQ- I 28	WTFQFDQ- I 30	WTFQFDQ- I 32	WTFQFDQ- I 34	WTFQFDQ- I 36	WTFQFDQ- I 38	WTFQFDQ- I 40	WTFQFDQ- I 42	WTFQFDQ- I 44	WTFQFDQ- I 46	WTFQFDQ- I 48	WTFQFDQ- I 50	FQFDQ-II 06	FQFDQ-II 08

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Smallest Recommended Sheath Size	10-12F	10-12F	10-12F	12-14F	12-14F	12-14F	12-14F	14F	9-10F	9-10F	10-12F	10-12F	10-12F	12-14F	12-14F	12-14F	12-14F	14F
C RADiscDiameter (mm)	26±1.5	28±1.5	30±1.5	32±1.5	34±1.5	36±1.5	38±1.5	40±1.5	22±1.5	24±1.5	26±1.5	28±1.5	30±1.5	32±1.5	34±1.5	36±1.5	38±1.5	40±1.5
B LADiscDiameter (mm)	34±1.5	36±1.5	38±1.5	40±1.5	42±1.5	44±1.5	46±1.5	48±1.5	30±1.5	32±1.5	34±1.5	36±1.5	38±1.5	40±1.5	42±1.5	44±1.5	46±1.5	48±1.5
H Height of connecting waist (mm)	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.5	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75	5.5±0.75
A Connecting waist diameter (mm)	10±0.75	12±0.75	14±0.75	16±0.75	18±0.75	20±0.75	22±0.75	24±0.75	6±0.75	8±0.75	10±0.75	12±0.75	14±0.75	16±0.75	18±0.75	20±0.75	22±0.75	24±0.75
Device	10	12	41	16	18	20	22	24	90	80	10	12	14	16	18	20	22	24
Catalogue No	FQFDQ-II 10	FQFDQ-II 12	FQFDQ-II 14	FQFDQ-II 16	FQFDQ-II 18	FQFDQ-II 20	FQFDQ-II 22	FQFDQ-II 24	WTFQFDQ-II 06	WTFQFDQ-II 08	WTFQFDQ-II 10	WTFQFDQ-II 12	WTFQFDQ-II 14	WTFQFDQ-II 16	WTFQFDQ-II 18	WTFQFDQ-II 20	WTFQFDQ-II 22	WTFQFDQ-II 24

Table 2 Specifications of MemoPart™ VSD Occluder

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Smallest Recommended	Sheath Size	7-8F	7-8F	8-9F	8-9F	8-9F	8-9F	9-10F	9-10F	10-12F	10-12F	10-12F	7-8F	7-8F	8-9F	8-9F	8-9F	8-9F	9-10F	9-10F	10-12F	10-12F	10-12F
υ <u>}</u>	DiscDiameter (mm)	8.0±1.0	9.0±1.0	10.0±1.0	11.0±1.0	12.0±1.0	13.0±1.0	14.0±1.0	16.0±1.0	18.0±1.0	20.0±1.0	22.0±1.0	8.0±1.0	9.0±1.0	10.0±1.0	11.0±1.0	12.0±1.0	13.0±1.0	14.0 ± 1.0	16.0 ± 1.0	18.0±1.0	20.0±1.0	22.0±1.0
B Connecting	Waist diameter (mm)	4.0±1.0	5.0±1.0	6.0±1.0	7.0±1.0	8.0±1.0	9.0±1.0	10.0±1.2	12.0±1.2	14.0±1.5	16.0±1.5	18.0±1.5	4.0±1.0	5.0±1.0	6.0±1.0	7.0±1.0	8.0±1.0	9.0±1.0	10.0±1.2	12.0±1.2	14.0±1.5	16.0±1.5	18.0±1.5
H Height of	connecting waist (mm)	5.0±1.5	5.0±1.5	5.0±1.5	5.0±1.5	5.0±1.5	5.0±1.8	5.0±1.8	5.0±1.8	5.0±1.8	5.0±1.8	5.0±1.8	7.0±1.5	7.0±1.5	7.0±1.5	7.0±1.5	7.0±1.5	7.0±1.8	7.0±1.8	7.0±1.8	7.0±1.8	7.0±1.8	7.0±1.8
A LV DiscDiamete	, (mm)	8.0±1.0	9.0±1.0	10.0±1.0	11.0±1.0	12.0±1.0	13.0±1.0	14.0±1.0	16.0±1.0	18.0±1.0	20.0±1.0	22.0±1.0	10.0±1.0	11.0±1.0	12.0±1.0	13.0±1.0	14.0±1.0	15.0±1.0	16.0±1.0	18.0±1.0	20.0±1.0	22.0±1.0	24.0±1.0
Devic	Size	40	05	90	07	80	60	10	12	14	16	18	40	02	98	20	80	60	9	12	14	16	18
Catalogue No		SQFDQ- I a04	SQFDQ- I a05	SQFDQ- I a06	SQFDQ- I a07	SQFDQ- I a08	SQFDQ- I a09	SQFDQ- I a10	SQFDQ- I a12	SQFDQ- I a14	SQFDQ- I a16	SQFDQ- I a18	SQFDQ- I b04	SQFDQ- I b05	SQFDQ- I b06	SQFDQ- I b07	SQFDQ- I b08	SQFDQ- I b09	SQFDQ- I b10	SQFDQ- I b12	SQFDQ- I b14	SQFDQ- I b16	SQFDQ- I b18



	THE REAL PROPERTY.	A	I	œ	O	
	Devic	K	Height of	Connecting	RV	Smallest
Catalogue No	e Size	DiscDiamete	connecting waist	Waist diameter	DiscDiameter	Recommended Sheath Size
		- (ww)	(mm)	(mm)	(mm)	
SQFDQ- I c04	8	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
SQFDQ- I c05	05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
SQFDQ- I c06	90	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
SQFDQ- I c07	20	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
SQFDQ- I c08	80	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
SQFDQ- I c09	60	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
SQFDQ- I c10	9	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
SQFDQ- I c12	12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
SQFDQ- I c14	4	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
SQFDQ- I c16	16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
SQFDQ- I c18	18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
SQFDQ- I d04	8	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
SQFDQ- I d05	02	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
SQFDQ- I d06	90	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
SQFDQ- I d07	07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
SQFDQ- I d08	88	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
SQFDQ- I d09	60	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
SQFDQ- I d10	9	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
SQFDQ- I d12	12	26.0±1.0	10.0±1.8	12.0±1.2	18.0土1.0	9-10F
SQFDQ- I d14	14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
SQFDQ- I d16	16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
SQFDQ- I d18	18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F



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	Devic	A L A A A A A A A A A A A A A A A A A A	Height of	Connecting	N N	Smallest
Catalogue No	e Size	DiscDiamete	connecting waist	Waist diameter	DiscDiameter	Recommended Sheath Size
		(mm)	(mm)	(mm)	(mm)	
WTSQFDQ- I a04	8	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F
WTSQFDQ- I a05	92	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F
WTSQFDQ- I a06	90	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F
WTSQFDQ- I a07	07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F
WTSQFDQ- I a08	88	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F
WTSQFDQ- I a09	60	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F
WTSQFDQ- I a10	9	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F
WTSQFDQ- I a12	12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F
WTSQFDQ- I a14	14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F
WTSQFDQ- I a16	16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F
WTSQFDQ- I a18	18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F
WTSQFDQ- I b04	8	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F
WTSQFDQ- I b05	02	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F
WTSQFDQ- I b06	90	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F
WTSQFDQ- I b07	20	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F
WTSQFDQ- I b08	80	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F
WTSQFDQ- I b09	60	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F
WTSQFDQ- I b10	10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F
WTSQFDQ- I b12	12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F
WTSQFDQ- I b14	14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F
WTSQFDQ- I b16	16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F
WTSQFDQ- I b18	18	24.0±1.0	7.0±1.8	18.0±1.5	22.0±1.0	10-12F



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	Devic	2			o à	Smallest
Catalogue No	ø	DiscDiamete	Height of	Connecting	Ž	Recommended
	Size	,	connecting waist	Waist diameter	DiscDiameter	Sheath Size
		- (ww)	(mm)	(mm)	(mm)	
WTSQFDQ- I c04	8	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
WTSQFDQ- I c05	92	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
WTSQFDQ- I c06	90	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
WTSQFDQ- I c07	07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
WTSQFDQ- I c08	80	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
WTSQFDQ- I c09	60	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
WTSQFDQ- I c10	9	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
WTSQFDQ- I c12	12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
WTSQFDQ- I c14	14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
WTSQFDQ- I c16	16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
WTSQFDQ- I c18	18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
WTSQFDQ- I d04	8	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
WTSQFDQ- I d05	92	19.0±1.0	10.0±1.5	5.0±1.0	11.0土1.0	7-8F
WTSQFDQ- I d06	98	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
WTSQFDQ- I d07	20	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
WTSQFDQ- I d08	88	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
WTSQFDQ- I d09	8	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
WTSQFDQ- I d10	9	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
WTSQFDQ- I d12	12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
WTSQFDQ- I d14	4	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
WTSQFDQ- I d16	16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
WTSQFDQ- I d18	18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F

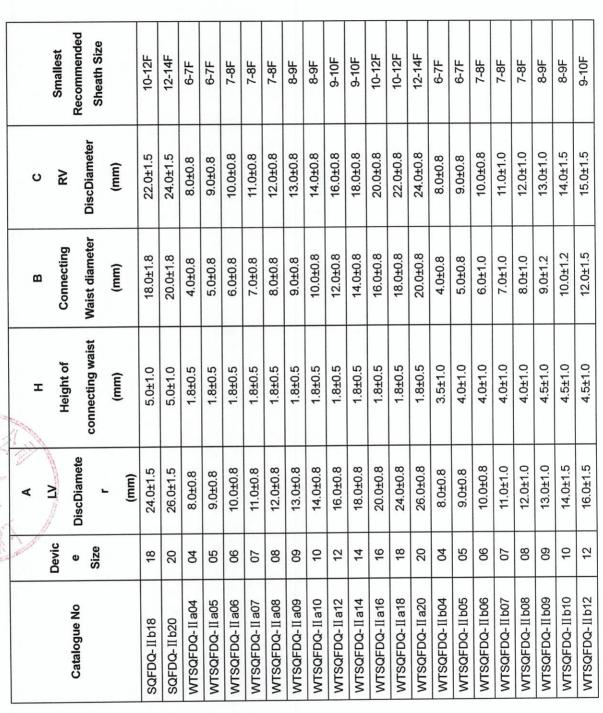


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Catalogue No	Devic	A LV DiscDiamete	Height of	B Connecting	o X	Smallest Recommended
	Size	r (mm)	connecung waist (mm)	waist diameter (mm)	(mm)	Sheath Size
SQFDQ-II a04	8	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F
SQFDQ-II a05	92	9.0±0.8	1.8±0.5	5.0±0.8	9.0∓0.8	6-7F
SQFDQ-II a06	90	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F
SQFDQ-II a07	20	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F
SQFDQ-II a08	80	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F
SQFDQ-II a09	60	13.0±0.8	1.8±0.5	9.0∓0.8	13.0±0.8	8-9F
SQFDQ-II a10	10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F
SQFDQ-II a12	12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F
SQFDQ-II a14	41	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F
SQFDQ-II a16	16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F
SQFDQ-II a18	18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F
SQFDQ-II a20	20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F
SQFDQ-II b04	4	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F
SQFDQ-II b05	90	9.0±0.8	4.0±1.0	5.0±0.8	9.0∓0.6	6-7F
SQFDQ-II b06	90	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F
SQFDQ-II b07	07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F
SQFDQ-II b08	80	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F
SQFDQ-II b09	60	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F
SQFDQ-II b10	10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F
SQFDQ-II b12	12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F
SQFDQ-II b14	14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F
SOFDO-II b16	16	22.0±1.5	5.0±1.0	16.0±1.5	20.0±1.5	10-12F

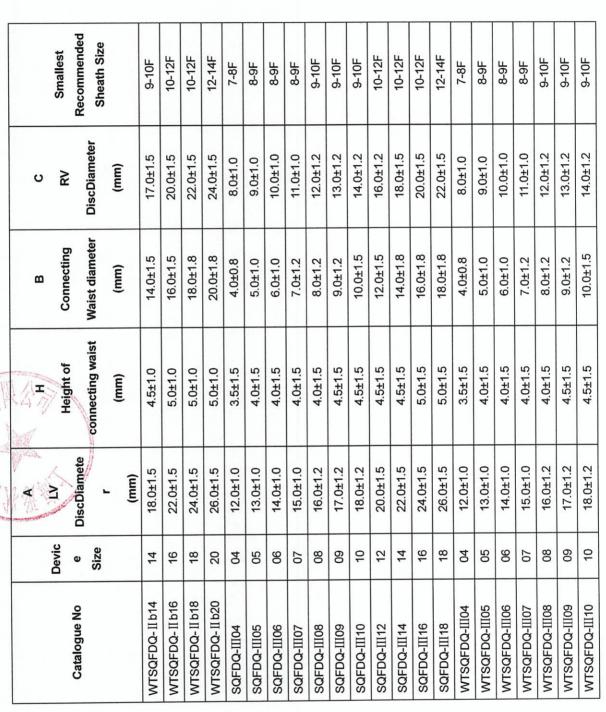


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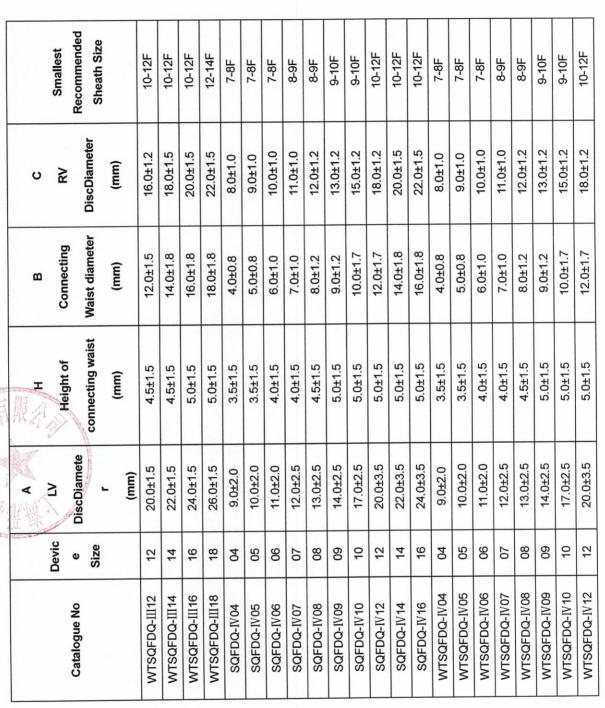


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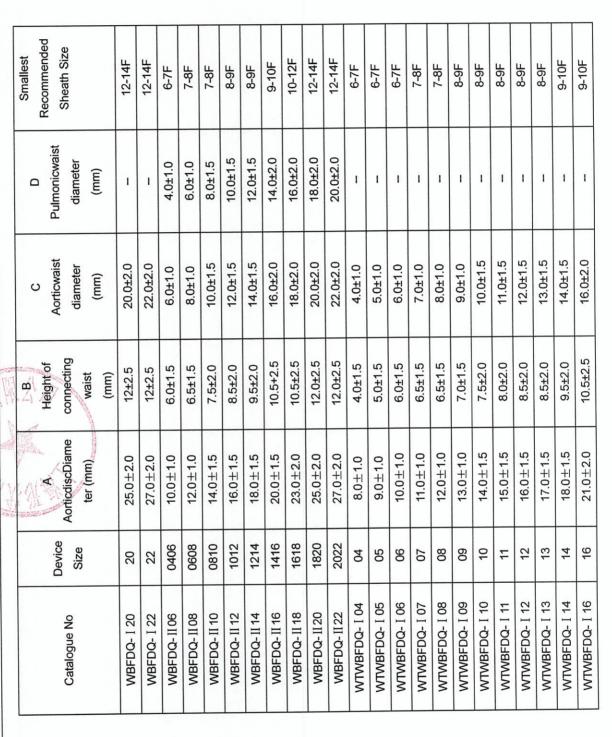
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Catalogue No	Devic e e Size	LV DiscDiamete (mm)	H Height of Connecting waist (mm)	B Connecting Waist diameter (mm)	C RV DiscDiameter (mm)	Smallest Recommended Sheath Size
WTSQFDQ-IV14	14	22.0±3.5	5.0±1.5	14.0±1.8	20.0±1.5	10-12F
WTSQFDQ-IV16	16	24.0±3.5	5.0±1.5	16.0±1.8	22.0±1.5	10-12F

Table 3 Specifications of Memo Part™ PDAOccluder

			В	(c	Smallest
Catalogue No	Device	A AorticdiscDiame	Height of connecting	Aorticwaist	Pulmonicwaist diameter	Recommended Sheath Size
	230	ter (mm)	waist (mm)	(mm)	(mm)	
WBFDQ- I 04	40	8.0±1.0	4.0±1.5	4.0±1.0	1	6-7F
WBFDQ- I 05	90	9.0±1.0	5.0±1.5	5.0±1.0	1	6-7F
WBFDQ- I 06	90	10.0±1.0	6.0±1.5	6.0±1.0	ı	6-7F
WBFDQ- I 07	70	11.0±1.0	6.5±1.5	7.0±1.0	1	7-8F
WBFDQ- I 08	80	12.0±1.0	6.5±1.5	8.0±1.0	ı	7-8F
WBFDQ- I 09	60	13.0±1.0	7.0±1.5	9.0±1.0	ı	8-9F
WBFDQ- I 10	10	14.0±1.5	7.5±2.0	10.0±1.5	1	8-9F
WBFDQ- I 11	#	15.0±1.5	8.0±2.0	11.0±1.5	ı	8-9F
WBFDQ- I 12	12	16.0±1.5	8.5±2.0	12.0±1.5	ı	8-9F
WBFDQ- I 13	13	17.0±1.5	8.5±2.0	13.0±1.5	1	8-9F
WBFDQ- I 14	14	18.0±1.5	9.5±2.0	14.0±1.5	ı	9-10F
WBFDQ- I 16	16	21.0±2.0	10.5±2.5	16.0±2.0	1	9-10F
WBFDQ- I 18	18	23.0±2.0	10.5±2.5	18.0±2.0	ı	10-12F

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Smallest Recommended Sheath Size	10-12F	12-14F	12-14F	6-7F	7-8F	7-8F	8-9F	8-9F	9-10F	10-12F	12-14F	12-14F
D Pulmonicwaist diameter (mm)	ı	1	1	4.0±1.0	6.0±1.0	8.0±1.5	10.0±1.5	12.0±1.5	14.0±2.0	16.0±2.0	18.0±2.0	20.0±2.0
C Aorticwaist diameter (mm)	18.0±2.0	20.0±2.0	22.0±2.0	6.0±1.0	8.0±1.0	10.0±1.5	12.0±1.5	14.0±1.5	16.0±2.0	18.0±2.0	20.0±2.0	22.0±2.0
B Height of connecting waist (mm)	10.5±2.5	12±2.5	12±2.5	6.0±1.5	6.5±1.5	7.5±2.0	8.5±2.0	9.5±2.0	10.5+2.5	10.5±2.5	12.0±2.5	12.0±2.5
A AorticdiscDiame ter (mm)	23.0±2.0	25.0±2.0	27.0±2.0	9.0±1.0	11.0±1.0	14.0±1.5	16.0±1.5	18.0±1.5	20.0±1.5	23.0±2.0	25.0±2.0	27.0±2.0
Device	18	20	22	0406	8090	0810	1012	1214	1416	1618	1820	2022
Catalogue No	WTWBFDQ- I 18	WTWBFDQ- I 20	WTWBFDQ- I 22	WTWBFDQ-II 06	WTWBFDQ-II 08	WTWBFDQ-II 10	WTWBFDQ-II 12	WTWBFDQ-II 14	WTWBFDQ-II 16	WTWBFDQ-II 18	WTWBFDQ-II 20	WTWBFDQ-II 22

Table 4 Specifications of MemoPart™ PFO Occluder

Smallest Recommended	Sheath Size	10-12F	10-12F	10-12F
C RADiscDiamete r	(mm)	18.0±2.0	24.0±2.0	24.0±2.0
B LADiscDiameter (mm)		18.0±2.0	18.0±2.0	24.0±2.0
H Height of connecting waist	(mm)	6.0±2.0	7.0±2.0	7.0±2.0
A Connecting waist diameter	(mm)	3.5±1.0	4.0±1.0	4.0±1.0
Devic e Size		1818	1824	2424
Catalogue No		LYKFDQ- I 1818 1818	LYKFDQ- I 1824 1824	LYKFDQ- I 2424



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	Smallest	Recommended	Sheath Size	12-14F	12-14F	12-14F	12-14F	10-12F	10-12F	10-12F	12-14F	12-14F	12-14F	12-14F
v	RADiscDiamete	_	(mm)	28.0±2.0	28.0±2.0	34.0±2.0	34.0±2.0	18.0±2.0	24.0±2.0	24.0±2.0	28.0±2.0	28.0±2.0	34.0±2.0	34.0±2.0
	B LADiscDiameter	1	(mm)	22.0±2.0	28.0±2.0	25.0±2.0	34.0±2.0	18.0±2.0	18.0±2.0	24.0±2.0	22.0±2.0	28.0±2.0	25.0±2.0	34.0±2.0
H	Height of	connecting waist	(mm)	7.0±2.0	7.0±2.0	7.0±2.0	7.0±2.0	6.0±2.0	7.0±2.0	7.0±2.0	7.0±2.0	7.0±2.0	7.0±2.0	7.0±2.0
A	Connecting	waist diameter	(mm)	4.5±1.0	4.5±1.0	5.0±1.0	5.0±1.0	3.5±1.0	4.0±1.0	4.0±1.0	4.5 ±1.0	4.5±1.0	5.0±1.0	5.0±1.0
San	Devic	e Size		2228	2828	2534	3434	1818	1824	2424	2228	2828	2534	3434
	Catalogue No			LYKFDQ- I 2228	LYKFDQ- I 2828	LYKFDQ- I 2534	LYKFDQ- I 3434	WTLYKFDQ- I 1818	WTLYKFDQ- I 1824	WTLYKFDQ- I 2424	WTLYKFDQ- I 2228	WTLYKFDQ- I 2828	WTLYKFDQ- I 2534	WTLYKFDQ- I 3434

Table 5 Specifications of MemoPart™ Occluder Delivery system

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	Screw	Diameter,	mm(±0.06)		0.80	08.0	0.80	08.0	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	0.80	08.0	0.80	0.80	08.0	08.0	0.80
pusher	Diameter,	mm	(D±0.20)		1.4	1.6	1.8	1.8	1.8	1.9	2.0	2.0	1.4	1.6	1.8	1.8	1.8	1.9	2.0	2.0	1.4	1.6	1.8	1.8	1.8	1.9	2.0	2.0
	Effective	Length,	mm	(L±50)	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200
Dilator	Effective	Length,	mm	(L±60)	920	920	920	920	920	920	920	920	920	920	920	920	920	920	920	920	089	089	089	089	089	089	089	089
171 171 171	Angle	(6)	(a±20°)	No. of Street,	45°	45°	45°	45°	45°	45°	45°	45°	180°	180°	180°	180°	180°	180°	180°	180°	45°	45°	45°	45°	45°	45°	45°	45°
Long sheath	Effective	Length,	mm	(L±60)	800	800	800	800	800	800	800	800	800	800	800	800	800	800	800	800	009	009	009	009	009	009	009	009
	Ď,	mm	(±0.25)		1.85	2.00	2.33	2.67	3.00	3.33	4.00	4.67	1.85	2.00	2.33	2.67	3.00	3.33	4.00	4.67	1.85	2.00	2.33	2.67	3.00	3.33	4.00	4.67
der	Effective	Length,	mm	(L±30)	130	130	130	130	130	130	160	160	130	130	130	130	130	130	160	160	130	130	130	130	130	130	160	160
Loader	D,	ш	(±0.25)		1.85	2.00	2.33	2.67	3.00	3.33	4.00	4.67	1.85	2.00	2.33	2.67	3.00	3.33	4.00	4.67	1.85	2.00	2.33	2.67	3.00	3.33	4.00	4 67
Catalogue No	,				ODS-A-I-5F	ODS-A-I-6F	ODS-A-I-7F	ODS-A-I-8F	ODS-A-I-9F	ODS-A-I-10F	ODS-A-I-12F	ODS-A-I-14F	ODS-PW-II-5F	ODS-P/V-II-6F	ODS-PA-II-7F	ODS-PN-II-8F	ODS-PIV-II-9F	ODS-P/V-II-10F	ODS-PW-II-12F	ODS-PW-II-14F	ODS-A-III-5F	ODS-A-III-6F	ODS-A-III-7F	ODS-A-III-8F	ODS-A-III-9F	ODS-A-III-10F	ODS-A-III-12F	ODS-A-III-14F



Catalogue No	Ļ	Loader	effe l L	Long sheath	混	Dilator		pusher	
,	D.	Effective	ľď.	Effective	Angle	Effective	Effective	Diameter,	Screw
2	E	Length,	mm	Length,	(6)	Length,	Length,	шш	Diameter,
	(± 0.25)	шш	(±0.25)	mm	(a±20°)	mm	шш	(D±0.20)	mm(±0.06)
		(L±30)		(C+60)		(L±60)	(L±50)		
ODS-P/V-IV-5F	1.85	130	1.85	009	180°	089	1200	1.4	0.80
ODS-P/V-IV-6F	2.00	130	2.00	009	180°	089	1200	1.6	0.80
ODS-PW-IV-7F	2.33	130	2.33	009	180°	089	1200	1.8	08.0
ODS-PW-IV-8F	2.67	130	2.67	009	180°	089	1200	1.8	0.80
95-VI-V-SE	3.00	130	3.00	009	180°	089	1200	1.8	0.80
ODS-P/V-IV-10F	3.33	130	3.33	009	180°	089	1200	1.9	0.80
ODS-P/V-IV-12F	4.00	160	4.00	009	180°	089	1200	2.0	0.80
ODS-P/V-IV-14F	4.67	160	4.67	009	180°	089	1200	2.0	08.0

Table 6 Specifications of MemoPart™ Snare

Snare-20	1240±60mm	20±2mm	90°±20°
Snare-15	1240±60mm	15±2mm	90°±20°
Туре	Effective Length, mm	Diameter of snare circle, mm	Angle
		Snare	

Accessories:

No accessories packaged with the device.





Certificate of Registration

OUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Shanghai Shape Memory Alloy

Co., Ltd

1F and 5F, Tower 41 No. 258 XinZhuan Road Songjiang High-Tech Park

CaoHeJing Development District

Shanghai 201612 China

上海形状记忆合金材料有限公司

中国 上海

漕河泾开发区 松江高科技园 莘砖公路258号 41幢一层, 五层 邮编: 201612

Holds Certificate No: MD 698501

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

> The design, development, manufacture and distribution of occluder systems, occluder delivery systems and snares.

封堵器系统、封堵器输送系统及圈套器的设计开发、制造及分销。

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-06-04

Latest Revision Date: 2022-08-12

Effective Date: 2022-06-04 Expiry Date: 2025-06-03

Page: 1 of 1





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