Radifocus® Guide wire M Non-Vascular type – Guide wires

Enlarge image

Radifocus® Guide wire M Non-Vascular type are standard and stiff Nitinol hydrophilic guide wires covered with polyurethane and hydrophilic coating for non-vascular procedures (endourology).

Indicated for use for non-vascular procedures such as Endoscopic and Urologic applications (drainage, endoprothesis placement, and embolization), catheterization and exchange procedures in normal, tortuous and narrow, and tight and stenotic ducts (bile and pancreatic ducts).

Product Characteristics

- Extra flexible & non traumatic tapered tip: increased flexibility, smooth and safe navigation through ducts.
- Extra hydrophilic (“M” polymer coating): smooth navigation through both catheters and ducts, providing time savings to user.
- Polyurethane radiopaque jacket: smooth surface to minimize adhesion to the wire, soft and atraumatic navigation. Includes tungsten for higher visibility.
- Super elastic Nitinol alloy core: excellent shape memory, greater flexibility, increased control in difficult cases. Prevents kinking for an easier and faster catheter placement.
- One-piece construction: improved steering control, true one-to-one torque transmission, easier, faster and safer navigation through both catheter and ducts.
- Rounded end: decreased likelihood of duct trauma, smoother wire insertion.

General Specifications

Core material	Standard or stiff Nitinol
Radiopaque jacket	Polyurethane layer containing tungsten
Hydrophilic coating	“M” polymer
Guide wire diameters	0.020” (0.51 mm) / 0.025” (0.64 mm) / 0.032” (0.81 mm) / 0.035” (0.89 mm)
Guide wire lengths	150 cm / 260 cm / 400 cm / 450 cm
Distal flexible length	30 mm
Distal curves	Straight / 45° angled
Units per box	5

Item Specifications

Shaft	Outer diameter	Length	Flexible length	Distal curve	Item reference
Standard	0.035” / 0.89 mm	150 cm	30 mm	Angled	NV-GA35153M
Standard	0.035” / 0.89 mm	150 cm	30 mm	Straight	NV-GS35153M
Stiff	0.035” / 0.89 mm	150 cm	30 mm	Angled	NV-PA35153M
Stiff	0.035” / 0.89 mm	150 cm	30 mm	Straight	NV-PS35153M
Standard	0.032” / 0.81 mm	260 cm	30 mm	Angled	NV-GA32263M
Standard	0.035” / 0.89 mm	400 cm	30 mm	Angled	NV-GA35403M
Standard	0.032” / 0.81 mm	400 cm	30 mm	Angled	NV-GA32403M
Standard	0.035” / 0.89 mm	260 cm	30 mm	Angled	NV-GA35263M
Standard	0.035” / 0.89 mm	450 cm	30 mm	Angled	NV-GA35453M
Standard	0.032” / 0.81 mm	260 cm	30 mm	Straight	NV-GS32263M
Standard	0.032” / 0.81 mm	400 cm	30 mm	Straight	NV-GS32403M
Standard	0.035” / 0.89 mm	260 cm	30 mm	Straight	NV-GS35263M
Standard	0.035” / 0.89 mm	400 cm	30 mm	Straight	NV-GS35403M
Standard	0.035” / 0.89 mm	450 cm	30 mm	Straight	NV-GS35453M
Stiff	0.020” / 0.51 mm	450 cm	30 mm	Angled	NV-PA18453M
Stiff	0.025” / 0.64 mm	450 cm	30 mm	Angled	NV-PA25453M
Stiff	0.035” / 0.89 mm	260 cm	30 mm	Angled	NV-PA35263M
Stiff	0.035” / 0.89 mm	400 cm	30 mm	Angled	NV-PA35403M
Stiff	0.020” / 0.51 mm	450 cm	30 mm	Straight	NV-PS18453M
Stiff	0.025” / 0.64 mm	450 cm	30 mm	Straight	NV-PS25453M
Stiff	0.035” / 0.89 mm	260 cm	30 mm	Straight	NV-PS35263M
Stiff	0.035” / 0.89 mm	400 cm	30 mm	Straight	NV-PS35403M

Please quote above item reference codes when placing an order.
Other code numbers are available on special demand. For any further information, please contact your local Terumo representative.

EC Design-Examination Certificate

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

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

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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

Catalogue No	Model, type				
	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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Classification: Class III Implant

Catalogue No	Model, type				
	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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Classification: Class III Implant

Catalogue No	Model, type				
	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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Classification: Class III Implant

Catalogue No	Model, type				
	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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Classification: Class III Implant

Catalogue No	Model, type				
	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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Classification: Class III Implant

Catalogue No	Model, type				
	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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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
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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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
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

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

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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
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

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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
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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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-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

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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-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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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

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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

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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
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

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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
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

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Catalogue No	Model, type				
	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

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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-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

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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

Catalogue No	Model, type				
	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

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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

Catalogue No	Model, type				
	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

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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
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

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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

Catalogue No	Model, type				
	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	--	6-7F
WBFDQ-I05	9.0±1.0	5.0±1.5	5.0±1.0	--	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	--	7-8F
WBFDQ-I08	12.0±1.0	6.5±1.5	8.0±1.0	--	7-8F
WBFDQ-I09	13.0±1.0	7.0±1.5	9.0±1.0	--	8-9F
WBFDQ-I10	14.0±1.5	7.5±2.0	10.0±1.5	--	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	--	8-9F
WBFDQ-I13	17.0±1.5	8.5±2.0	13.0±1.5	--	8-9F
WBFDQ-I14	18.0±1.5	9.5±2.0	14.0±1.5	--	9-10F
WBFDQ-I16	21.0±2.0	10.5±2.5	16.0±2.0	--	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

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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

Catalogue No	Model, type				
	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	--	6-7F
WTWBFDQ-I05	9.0±1.0	5.0±1.5	5.0±1.0	--	6-7F
WTWBFDQ-I06	10.0±1.0	6.0±1.5	6.0±1.0	--	6-7F
WTWBFDQ-I07	11.0±1.0	6.5±1.5	7.0±1.0	--	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	--	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

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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

Catalogue No	Model, type				
	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	--	9-10F
WTWBFDQ-I16	21.0±2.0	10.5±2.5	16.0±2.0	--	9-10F
WTWBFDQ-I18	23.0±2.0	10.5±2.5	18.0±2.0	--	10-12F
WTWBFDQ-I20	25.0±2.0	12±2.5	20.0±2.0	--	12-14F
WTWBFDQ-I22	27.0±2.0	12±2.5	22.0±2.0	--	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

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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

Catalogue No	Model, type				
	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

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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

Catalogue No	Model, type								
	Loader		Long sheath			Dilator	Pusher		
	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-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**

EC Design-Examination Certificate

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

Catalogue No	Model, type								
	Loader		Long sheath			Dilator	Pusher		
	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

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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

Catalogue No	Model, type								
	Loader		Long sheath			Dilator	Pusher		
	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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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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Issued To:

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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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By Royal Charter

Certificate of Registration

QUALITY 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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-06-04
Effective Date: 2019-06-04
Latest Revision Date: 2019-06-04
Expiry Date: 2022-06-03

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