By Royal Charter

# 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.**

Digitally signed by Jighili Tatiana
Date: 2023.07.11 17:09:52 EEST
Reason: MoldSign Signature
Location: Moldova

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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**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

| 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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**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

| 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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**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

| 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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**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

| 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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**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-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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# 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™ 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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**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-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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**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-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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**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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**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 |

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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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**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-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**

# 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™ 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 |

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

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# EC Design-Examination Certificate

**Supplementary Information to CE 650110**

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**1F and 5F, Tower 41**
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**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-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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**No. 258 XinZhuan Road**
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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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**Device name: MemoPart™ VSD Occluder**
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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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**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 |

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

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**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-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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**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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**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

| 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 |

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

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# 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-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 |

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

# EC Design-Examination Certificate

**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™ 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**

# 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™ 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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# 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**

# 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.<br>Administrative change on product table. |
| Current | 3162825 | Certificate renewal.<br>Removal of MemoPart Plug from the scope and product table.<br>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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# 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

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

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# 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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# EC Certificate - Full Quality Assurance System

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.**<br>**1F and 5F, Tower 41**<br>**No. 258 XinZhuan Road**<br>**Songjiang High-Tech Park**<br>**CaoHeJing Development District**<br>**Shanghai**<br>**201612**<br>**China** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| BQ Plus Medical Co., Ltd.<br>No.18, Che Ye Road<br>Che Dun Town, Songjiang<br>201611 Shanghai<br>China | **ETO Sterilization** |
| Lepu Medical (Europe) Cooperatief U.A.<br>Abe Lenstra Boulevard 36<br>8448 JB, Heerenveen<br>The Netherlands | **EU Representative** |

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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**

| Date | Reference Number | Action |
|---|---|---|
| 24 November 2016 | 8486062 | First issue. |
| 01 March 2019 | 8250592 | Traceable to NB 0086. |
| Current | 3163693 | Certificate renewal.<br>Addition of product table.<br>Correction of the ETO sterilization subcontractor from NELSON Techno Medical Co., Ltd. to BQ Plus Medical Co., Ltd. |

SHSMA

CE-SHSMA-002

# Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)


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

**Issuer's address** :

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**: **Lepu Medical (Europe) Cooperatief U.A.**

**Address** : 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: | Class III, Rule 8 |
| | ○ MemoPart™ Occluder (MemoPart™ VSD Occluder, MemoPart™ ASD Occluder, MemoPart™ PDA Occluder, MemoPart™ PFO Occluder) | |
| | ○ 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 5th, 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

| 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: Yu Ting

Date: 2021.12.1

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

# Product List of Memo Part™ Occluders

## Medical device:

Product name: Memo Part™ Occluders

Group(s):

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

## Product List:

**Table 1 Specifications of MemoPart™ ASD Occluder**

| Catalogue No | Device Size | A Connecting waist diameter (mm) | H Height of connecting waist (mm) | B LADiscDiameter (mm) | C RADiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| FQFDQ- I 06 | 06 | 6.0±0.5 | 5.5±0.5 | 16.0±1.0 | 14.0±1.0 | 8-9F |
| FQFDQ- I 07 | 07 | 7.0±0.5 | 5.5±0.5 | 21.0±1.0 | 17.0±1.0 | 8-9F |
| FQFDQ- I 08 | 08 | 8.0±0.5 | 5.5±0.5 | 18.0±1.0 | 16.0±1.0 | 8-9F |
| FQFDQ- I 09 | 09 | 9.0±0.5 | 5.5±0.5 | 23.0±1.0 | 19.0±1.0 | 8-9F |
| FQFDQ- I 10 | 10 | 10.0±0.5 | 5.5±0.5 | 20.0±1.0 | 18.0±1.0 | 9-10F |
| FQFDQ- I 11 | 11 | 11.0±0.6 | 5.5±0.75 | 25.0±1.25 | 21.0±1.25 | 9-10F |
| FQFDQ- I 12 | 12 | 12.0±0.6 | 5.5±0.75 | 22.0±1.25 | 20.0±1.25 | 9-10F |
| FQFDQ- I 13 | 13 | 13.0±0.6 | 5.5±0.75 | 27.0±1.25 | 23.0±1.25 | 9-10F |
| FQFDQ- I 14 | 14 | 14.0±0.6 | 5.5±0.75 | 24.0±1.25 | 22.0±1.25 | 9-10F |
| FQFDQ- I 15 | 15 | 15.0±0.6 | 5.5±0.75 | 29.0±1.25 | 25.0±1.25 | 9-10F |
| FQFDQ- I 16 | 16 | 16.0±0.6 | 5.5±0.75 | 30.0±1.5 | 26.0±1.25 | 10-12F |
| FQFDQ- I 17 | 17 | 17.0±0.75 | 5.5±0.75 | 31.0±1.5 | 27.0±1.25 | 10-12F |
| FQFDQ- I 18 | 18 | 18.0±0.75 | 5.5±0.75 | 32.0±1.5 | 28.0±1.5 | 10-12F |
| FQFDQ- I 19 | 19 | 19.0±0.75 | 5.5±0.75 | 33.0±1.5 | 29.0±1.5 | 10-12F |

| Catalogue No | Device Size | A Connecting waist diameter (mm) | H Height of connecting waist (mm) | B LADiscDiameter (mm) | C RADiscDiameter (mm) | Smallest Recommended 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 | 34 | 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 | 44 | 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 | 50 | 50.0±1.0 | 5.5±1.0 | 66.0±1.75 | 62.0±1.75 | 14F |
| WTFQFDQ- I 06 | 06 | 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 | 08 | 8.0±0.5 | 5.5±0.5 | 18.0±1.0 | 16.0±1.0 | 8-9F |
| WTFQFDQ- I 09 | 09 | 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 |

| Catalogue No | Device Size | A Connecting waist diameter (mm) | H Height of connecting waist (mm) | B LADiscDiameter (mm) | C RADiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WTFQFDQ-Ⅰ14 | 14 | 14.0±0.6 | 5.5±0.75 | 24.0±1.25 | 22.0±1.25 | 9-10F |
| WTFQFDQ-Ⅰ15 | 15 | 15.0±0.6 | 5.5±0.75 | 29.0±1.25 | 25.0±1.25 | 9-10F |
| WTFQFDQ-Ⅰ16 | 16 | 16.0±0.6 | 5.5±0.75 | 30.0±1.5 | 26.0±1.25 | 10-12F |
| WTFQFDQ-Ⅰ17 | 17 | 17.0±0.75 | 5.5±0.75 | 31.0±1.5 | 27.0±1.25 | 10-12F |
| WTFQFDQ-Ⅰ18 | 18 | 18.0±0.75 | 5.5±0.75 | 32.0±1.5 | 28.0±1.5 | 10-12F |
| WTFQFDQ-Ⅰ19 | 19 | 19.0±0.75 | 5.5±0.75 | 33.0±1.5 | 29.0±1.5 | 10-12F |
| WTFQFDQ-Ⅰ20 | 20 | 20.0±0.75 | 5.5±0.75 | 34.0±1.5 | 30.0±1.5 | 10-12F |
| WTFQFDQ-Ⅰ22 | 22 | 22.0±1.0 | 5.5±1.0 | 36.0±1.75 | 32.0±1.75 | 10-12F |
| WTFQFDQ-Ⅰ24 | 24 | 24.0±1.0 | 5.5±1.0 | 38.0±1.75 | 34.0±1.75 | 12-14F |
| WTFQFDQ-Ⅰ26 | 26 | 26.0±1.0 | 5.5±1.0 | 40.0±1.75 | 36.0±1.75 | 12-14F |
| WTFQFDQ-Ⅰ28 | 28 | 28.0±1.0 | 5.5±1.0 | 42.0±1.75 | 38.0±1.75 | 12-14F |
| WTFQFDQ-Ⅰ30 | 30 | 30.0±1.0 | 5.5±1.0 | 44.0±1.75 | 40.0±1.75 | 14F |
| WTFQFDQ-Ⅰ32 | 32 | 32.0±1.0 | 5.5±1.0 | 48.0±1.75 | 42.0±1.75 | 14F |
| WTFQFDQ-Ⅰ34 | 34 | 34.0±1.0 | 5.5±1.0 | 50.0±1.75 | 44.0±1.75 | 14F |
| WTFQFDQ-Ⅰ36 | 36 | 36.0±1.0 | 5.5±1.0 | 52.0±1.75 | 46.0±1.75 | 14F |
| WTFQFDQ-Ⅰ38 | 38 | 38.0±1.0 | 5.5±1.0 | 54.0±1.75 | 50.0±1.75 | 14F |
| WTFQFDQ-Ⅰ40 | 40 | 40.0±1.0 | 5.5±1.0 | 56.0±1.75 | 52.0±1.75 | 14F |
| WTFQFDQ-Ⅰ42 | 42 | 42.0±1.0 | 5.5±1.0 | 58.0±1.75 | 54.0±1.75 | 14F |
| WTFQFDQ-Ⅰ44 | 44 | 44.0±1.0 | 5.5±1.0 | 60.0±1.75 | 56.0±1.75 | 14F |
| WTFQFDQ-Ⅰ46 | 46 | 46.0±1.0 | 5.5±1.0 | 62.0±1.75 | 58.0±1.75 | 14F |
| WTFQFDQ-Ⅰ48 | 48 | 48.0±1.0 | 5.5±1.0 | 64.0±1.75 | 60.0±1.75 | 14F |
| WTFQFDQ-Ⅰ50 | 50 | 50.0±1.0 | 5.5±1.0 | 66.0±1.75 | 62.0±1.75 | 14F |
| FQFDQ-Ⅱ06 | 06 | 6±0.75 | 5.5±0.5 | 30±1.5 | 22±1.5 | 9-10F |
| FQFDQ-Ⅱ08 | 08 | 8±0.75 | 5.5±0.5 | 32±1.5 | 24±1.5 | 9-10F |

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

**Table 2 Specifications of MemoPart™ VSD Occluder**

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| SQFDQ-Ⅰa04 | 04 | 8.0±1.0 | 5.0±1.5 | 4.0±1.0 | 8.0±1.0 | 7-8F |
| SQFDQ-Ⅰa05 | 05 | 9.0±1.0 | 5.0±1.5 | 5.0±1.0 | 9.0±1.0 | 7-8F |
| SQFDQ-Ⅰa06 | 06 | 10.0±1.0 | 5.0±1.5 | 6.0±1.0 | 10.0±1.0 | 8-9F |
| SQFDQ-Ⅰa07 | 07 | 11.0±1.0 | 5.0±1.5 | 7.0±1.0 | 11.0±1.0 | 8-9F |
| SQFDQ-Ⅰa08 | 08 | 12.0±1.0 | 5.0±1.5 | 8.0±1.0 | 12.0±1.0 | 8-9F |
| SQFDQ-Ⅰa09 | 09 | 13.0±1.0 | 5.0±1.8 | 9.0±1.0 | 13.0±1.0 | 8-9F |
| SQFDQ-Ⅰa10 | 10 | 14.0±1.0 | 5.0±1.8 | 10.0±1.2 | 14.0±1.0 | 9-10F |
| SQFDQ-Ⅰa12 | 12 | 16.0±1.0 | 5.0±1.8 | 12.0±1.2 | 16.0±1.0 | 9-10F |
| SQFDQ-Ⅰa14 | 14 | 18.0±1.0 | 5.0±1.8 | 14.0±1.5 | 18.0±1.0 | 10-12F |
| SQFDQ-Ⅰa16 | 16 | 20.0±1.0 | 5.0±1.8 | 16.0±1.5 | 20.0±1.0 | 10-12F |
| SQFDQ-Ⅰa18 | 18 | 22.0±1.0 | 5.0±1.8 | 18.0±1.5 | 22.0±1.0 | 10-12F |
| SQFDQ-Ⅰb04 | 04 | 10.0±1.0 | 7.0±1.5 | 4.0±1.0 | 8.0±1.0 | 7-8F |
| SQFDQ-Ⅰb05 | 05 | 11.0±1.0 | 7.0±1.5 | 5.0±1.0 | 9.0±1.0 | 7-8F |
| SQFDQ-Ⅰb06 | 06 | 12.0±1.0 | 7.0±1.5 | 6.0±1.0 | 10.0±1.0 | 8-9F |
| SQFDQ-Ⅰb07 | 07 | 13.0±1.0 | 7.0±1.5 | 7.0±1.0 | 11.0±1.0 | 8-9F |
| SQFDQ-Ⅰb08 | 08 | 14.0±1.0 | 7.0±1.5 | 8.0±1.0 | 12.0±1.0 | 8-9F |
| SQFDQ-Ⅰb09 | 09 | 15.0±1.0 | 7.0±1.8 | 9.0±1.0 | 13.0±1.0 | 8-9F |
| SQFDQ-Ⅰb10 | 10 | 16.0±1.0 | 7.0±1.8 | 10.0±1.2 | 14.0±1.0 | 9-10F |
| SQFDQ-Ⅰb12 | 12 | 18.0±1.0 | 7.0±1.8 | 12.0±1.2 | 16.0±1.0 | 9-10F |
| SQFDQ-Ⅰb14 | 14 | 20.0±1.0 | 7.0±1.8 | 14.0±1.5 | 18.0±1.0 | 10-12F |
| SQFDQ-Ⅰb16 | 16 | 22.0±1.0 | 7.0±1.8 | 16.0±1.5 | 20.0±1.0 | 10-12F |
| SQFDQ-Ⅰb18 | 18 | 24.0±1.0 | 7.0±1.8 | 18.0±1.5 | 22.0±1.0 | 10-12F |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| SQFDQ-Ⅰc04 | 04 | 14.0±1.0 | 10.0±1.5 | 4.0±1.0 | 10.0±1.0 | 7-8F |
| SQFDQ-Ⅰc05 | 05 | 15.0±1.0 | 10.0±1.5 | 5.0±1.0 | 11.0±1.0 | 7-8F |
| SQFDQ-Ⅰc06 | 06 | 16.0±1.0 | 10.0±1.5 | 6.0±1.0 | 12.0±1.0 | 8-9F |
| SQFDQ-Ⅰc07 | 07 | 17.0±1.0 | 10.0±1.5 | 7.0±1.0 | 13.0±1.0 | 8-9F |
| SQFDQ-Ⅰc08 | 08 | 18.0±1.0 | 10.0±1.5 | 8.0±1.0 | 14.0±1.0 | 8-9F |
| SQFDQ-Ⅰc09 | 09 | 19.0±1.0 | 10.0±1.8 | 9.0±1.0 | 15.0±1.0 | 8-9F |
| SQFDQ-Ⅰc10 | 10 | 20.0±1.0 | 10.0±1.8 | 10.0±1.2 | 16.0±1.0 | 9-10F |
| SQFDQ-Ⅰc12 | 12 | 22.0±1.0 | 10.0±1.8 | 12.0±1.2 | 18.0±1.0 | 9-10F |
| SQFDQ-Ⅰc14 | 14 | 24.0±1.0 | 10.0±1.8 | 14.0±1.5 | 20.0±1.0 | 10-12F |
| SQFDQ-Ⅰc16 | 16 | 26.0±1.0 | 10.0±1.8 | 16.0±1.5 | 22.0±1.0 | 10-12F |
| SQFDQ-Ⅰc18 | 18 | 28.0±1.0 | 10.0±1.8 | 18.0±1.5 | 24.0±1.0 | 10-12F |
| SQFDQ-Ⅰd04 | 04 | 18.0±1.0 | 10.0±1.5 | 4.0±1.0 | 10.0±1.0 | 7-8F |
| SQFDQ-Ⅰd05 | 05 | 19.0±1.0 | 10.0±1.5 | 5.0±1.0 | 11.0±1.0 | 7-8F |
| SQFDQ-Ⅰd06 | 06 | 20.0±1.0 | 10.0±1.5 | 6.0±1.0 | 12.0±1.0 | 8-9F |
| SQFDQ-Ⅰd07 | 07 | 21.0±1.0 | 10.0±1.5 | 7.0±1.0 | 13.0±1.0 | 8-9F |
| SQFDQ-Ⅰd08 | 08 | 22.0±1.0 | 10.0±1.5 | 8.0±1.0 | 14.0±1.0 | 8-9F |
| SQFDQ-Ⅰd09 | 09 | 23.0±1.0 | 10.0±1.8 | 9.0±1.0 | 15.0±1.0 | 8-9F |
| SQFDQ-Ⅰd10 | 10 | 24.0±1.0 | 10.0±1.8 | 10.0±1.2 | 16.0±1.0 | 9-10F |
| SQFDQ-Ⅰd12 | 12 | 26.0±1.0 | 10.0±1.8 | 12.0±1.2 | 18.0±1.0 | 9-10F |
| SQFDQ-Ⅰd14 | 14 | 28.0±1.0 | 10.0±1.8 | 14.0±1.5 | 20.0±1.0 | 10-12F |
| SQFDQ-Ⅰd16 | 16 | 30.0±1.0 | 10.0±1.8 | 16.0±1.5 | 22.0±1.0 | 10-12F |
| SQFDQ-Ⅰd18 | 18 | 32.0±1.0 | 10.0±1.8 | 18.0±1.5 | 24.0±1.0 | 10-12F |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WTSQFDQ-Ⅰa04 | 04 | 8.0±1.0 | 5.0±1.5 | 4.0±1.0 | 8.0±1.0 | 7-8F |
| WTSQFDQ-Ⅰa05 | 05 | 9.0±1.0 | 5.0±1.5 | 5.0±1.0 | 9.0±1.0 | 7-8F |
| WTSQFDQ-Ⅰa06 | 06 | 10.0±1.0 | 5.0±1.5 | 6.0±1.0 | 10.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰa07 | 07 | 11.0±1.0 | 5.0±1.5 | 7.0±1.0 | 11.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰa08 | 08 | 12.0±1.0 | 5.0±1.5 | 8.0±1.0 | 12.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰa09 | 09 | 13.0±1.0 | 5.0±1.8 | 9.0±1.0 | 13.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰa10 | 10 | 14.0±1.0 | 5.0±1.8 | 10.0±1.2 | 14.0±1.0 | 9-10F |
| WTSQFDQ-Ⅰa12 | 12 | 16.0±1.0 | 5.0±1.8 | 12.0±1.2 | 16.0±1.0 | 9-10F |
| WTSQFDQ-Ⅰa14 | 14 | 18.0±1.0 | 5.0±1.8 | 14.0±1.5 | 18.0±1.0 | 10-12F |
| WTSQFDQ-Ⅰa16 | 16 | 20.0±1.0 | 5.0±1.8 | 16.0±1.5 | 20.0±1.0 | 10-12F |
| WTSQFDQ-Ⅰa18 | 18 | 22.0±1.0 | 5.0±1.8 | 18.0±1.5 | 22.0±1.0 | 10-12F |
| WTSQFDQ-Ⅰb04 | 04 | 10.0±1.0 | 7.0±1.5 | 4.0±1.0 | 8.0±1.0 | 7-8F |
| WTSQFDQ-Ⅰb05 | 05 | 11.0±1.0 | 7.0±1.5 | 5.0±1.0 | 9.0±1.0 | 7-8F |
| WTSQFDQ-Ⅰb06 | 06 | 12.0±1.0 | 7.0±1.5 | 6.0±1.0 | 10.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰb07 | 07 | 13.0±1.0 | 7.0±1.5 | 7.0±1.0 | 11.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰb08 | 08 | 14.0±1.0 | 7.0±1.5 | 8.0±1.0 | 12.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰb09 | 09 | 15.0±1.0 | 7.0±1.8 | 9.0±1.0 | 13.0±1.0 | 8-9F |
| WTSQFDQ-Ⅰb10 | 10 | 16.0±1.0 | 7.0±1.8 | 10.0±1.2 | 14.0±1.0 | 9-10F |
| WTSQFDQ-Ⅰb12 | 12 | 18.0±1.0 | 7.0±1.8 | 12.0±1.2 | 16.0±1.0 | 9-10F |
| WTSQFDQ-Ⅰb14 | 14 | 20.0±1.0 | 7.0±1.8 | 14.0±1.5 | 18.0±1.0 | 10-12F |
| WTSQFDQ-Ⅰb16 | 16 | 22.0±1.0 | 7.0±1.8 | 16.0±1.5 | 20.0±1.0 | 10-12F |
| WTSQFDQ-Ⅰb18 | 18 | 24.0±1.0 | 7.0±1.8 | 18.0±1.5 | 22.0±1.0 | 10-12F |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WTSQFDQ- I c04 | 04 | 14.0±1.0 | 10.0±1.5 | 4.0±1.0 | 10.0±1.0 | 7-8F |
| WTSQFDQ- I c05 | 05 | 15.0±1.0 | 10.0±1.5 | 5.0±1.0 | 11.0±1.0 | 7-8F |
| WTSQFDQ- I c06 | 06 | 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 | 08 | 18.0±1.0 | 10.0±1.5 | 8.0±1.0 | 14.0±1.0 | 8-9F |
| WTSQFDQ- I c09 | 09 | 19.0±1.0 | 10.0±1.8 | 9.0±1.0 | 15.0±1.0 | 8-9F |
| WTSQFDQ- I c10 | 10 | 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 | 04 | 18.0±1.0 | 10.0±1.5 | 4.0±1.0 | 10.0±1.0 | 7-8F |
| WTSQFDQ- I d05 | 05 | 19.0±1.0 | 10.0±1.5 | 5.0±1.0 | 11.0±1.0 | 7-8F |
| WTSQFDQ- I d06 | 06 | 20.0±1.0 | 10.0±1.5 | 6.0±1.0 | 12.0±1.0 | 8-9F |
| WTSQFDQ- I d07 | 07 | 21.0±1.0 | 10.0±1.5 | 7.0±1.0 | 13.0±1.0 | 8-9F |
| WTSQFDQ- I d08 | 08 | 22.0±1.0 | 10.0±1.5 | 8.0±1.0 | 14.0±1.0 | 8-9F |
| WTSQFDQ- I d09 | 09 | 23.0±1.0 | 10.0±1.8 | 9.0±1.0 | 15.0±1.0 | 8-9F |
| WTSQFDQ- I d10 | 10 | 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 | 14 | 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 |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| SQFDQ-Ⅱa04 | 04 | 8.0±0.8 | 1.8±0.5 | 4.0±0.8 | 8.0±0.8 | 6-7F |
| SQFDQ-Ⅱa05 | 05 | 9.0±0.8 | 1.8±0.5 | 5.0±0.8 | 9.0±0.8 | 6-7F |
| SQFDQ-Ⅱa06 | 06 | 10.0±0.8 | 1.8±0.5 | 6.0±0.8 | 10.0±0.8 | 7-8F |
| SQFDQ-Ⅱa07 | 07 | 11.0±0.8 | 1.8±0.5 | 7.0±0.8 | 11.0±0.8 | 7-8F |
| SQFDQ-Ⅱa08 | 08 | 12.0±0.8 | 1.8±0.5 | 8.0±0.8 | 12.0±0.8 | 7-8F |
| SQFDQ-Ⅱa09 | 09 | 13.0±0.8 | 1.8±0.5 | 9.0±0.8 | 13.0±0.8 | 8-9F |
| SQFDQ-Ⅱa10 | 10 | 14.0±0.8 | 1.8±0.5 | 10.0±0.8 | 14.0±0.8 | 8-9F |
| SQFDQ-Ⅱa12 | 12 | 16.0±0.8 | 1.8±0.5 | 12.0±0.8 | 16.0±0.8 | 9-10F |
| SQFDQ-Ⅱa14 | 14 | 18.0±0.8 | 1.8±0.5 | 14.0±0.8 | 18.0±0.8 | 9-10F |
| SQFDQ-Ⅱa16 | 16 | 20.0±0.8 | 1.8±0.5 | 16.0±0.8 | 20.0±0.8 | 10-12F |
| SQFDQ-Ⅱa18 | 18 | 24.0±0.8 | 1.8±0.5 | 18.0±0.8 | 22.0±0.8 | 10-12F |
| SQFDQ-Ⅱa20 | 20 | 26.0±0.8 | 1.8±0.5 | 20.0±0.8 | 24.0±0.8 | 12-14F |
| SQFDQ-Ⅱb04 | 04 | 8.0±0.8 | 3.5±1.0 | 4.0±0.8 | 8.0±0.8 | 6-7F |
| SQFDQ-Ⅱb05 | 05 | 9.0±0.8 | 4.0±1.0 | 5.0±0.8 | 9.0±0.8 | 6-7F |
| SQFDQ-Ⅱb06 | 06 | 10.0±0.8 | 4.0±1.0 | 6.0±1.0 | 10.0±0.8 | 7-8F |
| SQFDQ-Ⅱb07 | 07 | 11.0±1.0 | 4.0±1.0 | 7.0±1.0 | 11.0±1.0 | 7-8F |
| SQFDQ-Ⅱb08 | 08 | 12.0±1.0 | 4.0±1.0 | 8.0±1.0 | 12.0±1.0 | 7-8F |
| SQFDQ-Ⅱb09 | 09 | 13.0±1.0 | 4.5±1.0 | 9.0±1.2 | 13.0±1.0 | 8-9F |
| SQFDQ-Ⅱb10 | 10 | 14.0±1.5 | 4.5±1.0 | 10.0±1.2 | 14.0±1.5 | 8-9F |
| SQFDQ-Ⅱb12 | 12 | 16.0±1.5 | 4.5±1.0 | 12.0±1.5 | 15.0±1.5 | 9-10F |
| SQFDQ-Ⅱb14 | 14 | 18.0±1.5 | 4.5±1.0 | 14.0±1.5 | 17.0±1.5 | 9-10F |
| SQFDQ-Ⅱb16 | 16 | 22.0±1.5 | 5.0±1.0 | 16.0±1.5 | 20.0±1.5 | 10-12F |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| SQFDQ-Ⅱb18 | 18 | 24.0±1.5 | 5.0±1.0 | 18.0±1.8 | 22.0±1.5 | 10-12F |
| SQFDQ-Ⅱb20 | 20 | 26.0±1.5 | 5.0±1.0 | 20.0±1.8 | 24.0±1.5 | 12-14F |
| WTSQFDQ-Ⅱa04 | 04 | 8.0±0.8 | 1.8±0.5 | 4.0±0.8 | 8.0±0.8 | 6-7F |
| WTSQFDQ-Ⅱa05 | 05 | 9.0±0.8 | 1.8±0.5 | 5.0±0.8 | 9.0±0.8 | 6-7F |
| WTSQFDQ-Ⅱa06 | 06 | 10.0±0.8 | 1.8±0.5 | 6.0±0.8 | 10.0±0.8 | 7-8F |
| WTSQFDQ-Ⅱa07 | 07 | 11.0±0.8 | 1.8±0.5 | 7.0±0.8 | 11.0±0.8 | 7-8F |
| WTSQFDQ-Ⅱa08 | 08 | 12.0±0.8 | 1.8±0.5 | 8.0±0.8 | 12.0±0.8 | 7-8F |
| WTSQFDQ-Ⅱa09 | 09 | 13.0±0.8 | 1.8±0.5 | 9.0±0.8 | 13.0±0.8 | 8-9F |
| WTSQFDQ-Ⅱa10 | 10 | 14.0±0.8 | 1.8±0.5 | 10.0±0.8 | 14.0±0.8 | 8-9F |
| WTSQFDQ-Ⅱa12 | 12 | 16.0±0.8 | 1.8±0.5 | 12.0±0.8 | 16.0±0.8 | 9-10F |
| WTSQFDQ-Ⅱa14 | 14 | 18.0±0.8 | 1.8±0.5 | 14.0±0.8 | 18.0±0.8 | 9-10F |
| WTSQFDQ-Ⅱa16 | 16 | 20.0±0.8 | 1.8±0.5 | 16.0±0.8 | 20.0±0.8 | 10-12F |
| WTSQFDQ-Ⅱa18 | 18 | 24.0±0.8 | 1.8±0.5 | 18.0±0.8 | 22.0±0.8 | 10-12F |
| WTSQFDQ-Ⅱa20 | 20 | 26.0±0.8 | 1.8±0.5 | 20.0±0.8 | 24.0±0.8 | 12-14F |
| WTSQFDQ-Ⅱb04 | 04 | 8.0±0.8 | 3.5±1.0 | 4.0±0.8 | 8.0±0.8 | 6-7F |
| WTSQFDQ-Ⅱb05 | 05 | 9.0±0.8 | 4.0±1.0 | 5.0±0.8 | 9.0±0.8 | 6-7F |
| WTSQFDQ-Ⅱb06 | 06 | 10.0±0.8 | 4.0±1.0 | 6.0±1.0 | 10.0±0.8 | 7-8F |
| WTSQFDQ-Ⅱb07 | 07 | 11.0±1.0 | 4.0±1.0 | 7.0±1.0 | 11.0±1.0 | 7-8F |
| WTSQFDQ-Ⅱb08 | 08 | 12.0±1.0 | 4.0±1.0 | 8.0±1.0 | 12.0±1.0 | 7-8F |
| WTSQFDQ-Ⅱb09 | 09 | 13.0±1.0 | 4.5±1.0 | 9.0±1.2 | 13.0±1.0 | 8-9F |
| WTSQFDQ-Ⅱb10 | 10 | 14.0±1.5 | 4.5±1.0 | 10.0±1.2 | 14.0±1.5 | 8-9F |
| WTSQFDQ-Ⅱb12 | 12 | 16.0±1.5 | 4.5±1.0 | 12.0±1.5 | 15.0±1.5 | 9-10F |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WTSQFDQ-Ⅱb14 | 14 | 18.0±1.5 | 4.5±1.0 | 14.0±1.5 | 17.0±1.5 | 9-10F |
| WTSQFDQ-Ⅱb16 | 16 | 22.0±1.5 | 5.0±1.0 | 16.0±1.5 | 20.0±1.5 | 10-12F |
| WTSQFDQ-Ⅱb18 | 18 | 24.0±1.5 | 5.0±1.0 | 18.0±1.8 | 22.0±1.5 | 10-12F |
| WTSQFDQ-Ⅱb20 | 20 | 26.0±1.5 | 5.0±1.0 | 20.0±1.8 | 24.0±1.5 | 12-14F |
| SQFDQ-III04 | 04 | 12.0±1.0 | 3.5±1.5 | 4.0±0.8 | 8.0±1.0 | 7-8F |
| SQFDQ-III05 | 05 | 13.0±1.0 | 4.0±1.5 | 5.0±1.0 | 9.0±1.0 | 8-9F |
| SQFDQ-III06 | 06 | 14.0±1.0 | 4.0±1.5 | 6.0±1.0 | 10.0±1.0 | 8-9F |
| SQFDQ-III07 | 07 | 15.0±1.0 | 4.0±1.5 | 7.0±1.2 | 11.0±1.0 | 8-9F |
| SQFDQ-III08 | 08 | 16.0±1.2 | 4.0±1.5 | 8.0±1.2 | 12.0±1.2 | 9-10F |
| SQFDQ-III09 | 09 | 17.0±1.2 | 4.5±1.5 | 9.0±1.2 | 13.0±1.2 | 9-10F |
| SQFDQ-III10 | 10 | 18.0±1.2 | 4.5±1.5 | 10.0±1.5 | 14.0±1.2 | 9-10F |
| SQFDQ-III12 | 12 | 20.0±1.5 | 4.5±1.5 | 12.0±1.5 | 16.0±1.2 | 10-12F |
| SQFDQ-III14 | 14 | 22.0±1.5 | 4.5±1.5 | 14.0±1.8 | 18.0±1.5 | 10-12F |
| SQFDQ-III16 | 16 | 24.0±1.5 | 5.0±1.5 | 16.0±1.8 | 20.0±1.5 | 10-12F |
| SQFDQ-III18 | 18 | 26.0±1.5 | 5.0±1.5 | 18.0±1.8 | 22.0±1.5 | 12-14F |
| WTSQFDQ-III04 | 04 | 12.0±1.0 | 3.5±1.5 | 4.0±0.8 | 8.0±1.0 | 7-8F |
| WTSQFDQ-III05 | 05 | 13.0±1.0 | 4.0±1.5 | 5.0±1.0 | 9.0±1.0 | 8-9F |
| WTSQFDQ-III06 | 06 | 14.0±1.0 | 4.0±1.5 | 6.0±1.0 | 10.0±1.0 | 8-9F |
| WTSQFDQ-III07 | 07 | 15.0±1.0 | 4.0±1.5 | 7.0±1.2 | 11.0±1.0 | 8-9F |
| WTSQFDQ-III08 | 08 | 16.0±1.2 | 4.0±1.5 | 8.0±1.2 | 12.0±1.2 | 9-10F |
| WTSQFDQ-III09 | 09 | 17.0±1.2 | 4.5±1.5 | 9.0±1.2 | 13.0±1.2 | 9-10F |
| WTSQFDQ-III10 | 10 | 18.0±1.2 | 4.5±1.5 | 10.0±1.5 | 14.0±1.2 | 9-10F |

| Catalogue No | Device Size | A LV DiscDiameter (mm) | H Height of connecting waist (mm) | B Connecting Waist diameter (mm) | C RV DiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WTSQFDQ-III12 | 12 | 20.0±1.5 | 4.5±1.5 | 12.0±1.5 | 16.0±1.2 | 10-12F |
| WTSQFDQ-III14 | 14 | 22.0±1.5 | 4.5±1.5 | 14.0±1.8 | 18.0±1.5 | 10-12F |
| WTSQFDQ-III16 | 16 | 24.0±1.5 | 5.0±1.5 | 16.0±1.8 | 20.0±1.5 | 10-12F |
| WTSQFDQ-III18 | 18 | 26.0±1.5 | 5.0±1.5 | 18.0±1.8 | 22.0±1.5 | 12-14F |
| SQFDQ-IV04 | 04 | 9.0±2.0 | 3.5±1.5 | 4.0±0.8 | 8.0±1.0 | 7-8F |
| SQFDQ-IV05 | 05 | 10.0±2.0 | 3.5±1.5 | 5.0±0.8 | 9.0±1.0 | 7-8F |
| SQFDQ-IV06 | 06 | 11.0±2.0 | 4.0±1.5 | 6.0±1.0 | 10.0±1.0 | 7-8F |
| SQFDQ-IV07 | 07 | 12.0±2.5 | 4.0±1.5 | 7.0±1.0 | 11.0±1.0 | 8-9F |
| SQFDQ-IV08 | 08 | 13.0±2.5 | 4.5±1.5 | 8.0±1.2 | 12.0±1.2 | 8-9F |
| SQFDQ-IV09 | 09 | 14.0±2.5 | 5.0±1.5 | 9.0±1.2 | 13.0±1.2 | 9-10F |
| SQFDQ-IV10 | 10 | 17.0±2.5 | 5.0±1.5 | 10.0±1.7 | 15.0±1.2 | 9-10F |
| SQFDQ-IV12 | 12 | 20.0±3.5 | 5.0±1.5 | 12.0±1.7 | 18.0±1.2 | 10-12F |
| SQFDQ-IV14 | 14 | 22.0±3.5 | 5.0±1.5 | 14.0±1.8 | 20.0±1.5 | 10-12F |
| SQFDQ-IV16 | 16 | 24.0±3.5 | 5.0±1.5 | 16.0±1.8 | 22.0±1.5 | 10-12F |
| WTSQFDQ-IV04 | 04 | 9.0±2.0 | 3.5±1.5 | 4.0±0.8 | 8.0±1.0 | 7-8F |
| WTSQFDQ-IV05 | 05 | 10.0±2.0 | 3.5±1.5 | 5.0±0.8 | 9.0±1.0 | 7-8F |
| WTSQFDQ-IV06 | 06 | 11.0±2.0 | 4.0±1.5 | 6.0±1.0 | 10.0±1.0 | 7-8F |
| WTSQFDQ-IV07 | 07 | 12.0±2.5 | 4.0±1.5 | 7.0±1.0 | 11.0±1.0 | 8-9F |
| WTSQFDQ-IV08 | 08 | 13.0±2.5 | 4.5±1.5 | 8.0±1.2 | 12.0±1.2 | 8-9F |
| WTSQFDQ-IV09 | 09 | 14.0±2.5 | 5.0±1.5 | 9.0±1.2 | 13.0±1.2 | 9-10F |
| WTSQFDQ-IV10 | 10 | 17.0±2.5 | 5.0±1.5 | 10.0±1.7 | 15.0±1.2 | 9-10F |
| WTSQFDQ-IV12 | 12 | 20.0±3.5 | 5.0±1.5 | 12.0±1.7 | 18.0±1.2 | 10-12F |

| Catalogue No | Device Size | A LV DiscDiameter (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**

| Catalogue No | Device Size | A AorticdiscDiameter (mm) | B Height of connecting waist (mm) | C Aorticwaist diameter (mm) | D Pulmonicwaist diameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WBFDQ-Ⅰ04 | 04 | 8.0±1.0 | 4.0±1.5 | 4.0±1.0 | -- | 6-7F |
| WBFDQ-Ⅰ05 | 05 | 9.0±1.0 | 5.0±1.5 | 5.0±1.0 | -- | 6-7F |
| WBFDQ-Ⅰ06 | 06 | 10.0±1.0 | 6.0±1.5 | 6.0±1.0 | -- | 6-7F |
| WBFDQ-Ⅰ07 | 07 | 11.0±1.0 | 6.5±1.5 | 7.0±1.0 | -- | 7-8F |
| WBFDQ-Ⅰ08 | 08 | 12.0±1.0 | 6.5±1.5 | 8.0±1.0 | -- | 7-8F |
| WBFDQ-Ⅰ09 | 09 | 13.0±1.0 | 7.0±1.5 | 9.0±1.0 | -- | 8-9F |
| WBFDQ-Ⅰ10 | 10 | 14.0±1.5 | 7.5±2.0 | 10.0±1.5 | -- | 8-9F |
| WBFDQ-Ⅰ11 | 11 | 15.0±1.5 | 8.0±2.0 | 11.0±1.5 | -- | 8-9F |
| WBFDQ-Ⅰ12 | 12 | 16.0±1.5 | 8.5±2.0 | 12.0±1.5 | -- | 8-9F |
| WBFDQ-Ⅰ13 | 13 | 17.0±1.5 | 8.5±2.0 | 13.0±1.5 | -- | 8-9F |
| WBFDQ-Ⅰ14 | 14 | 18.0±1.5 | 9.5±2.0 | 14.0±1.5 | -- | 9-10F |
| WBFDQ-Ⅰ16 | 16 | 21.0±2.0 | 10.5±2.5 | 16.0±2.0 | -- | 9-10F |
| WBFDQ-Ⅰ18 | 18 | 23.0±2.0 | 10.5±2.5 | 18.0±2.0 | -- | 10-12F |

| Catalogue No | Device Size | A AorticdiscDiameter (mm) | B Height of connecting waist (mm) | C Aorticwaist diameter (mm) | D Pulmonicwaist diameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WBFDQ-Ⅰ20 | 20 | 25.0±2.0 | 12±2.5 | 20.0±2.0 | – | 12-14F |
| WBFDQ-Ⅰ22 | 22 | 27.0±2.0 | 12±2.5 | 22.0±2.0 | – | 12-14F |
| WBFDQ-Ⅱ06 | 0406 | 10.0±1.0 | 6.0±1.5 | 6.0±1.0 | 4.0±1.0 | 6-7F |
| WBFDQ-Ⅱ08 | 0608 | 12.0±1.0 | 6.5±1.5 | 8.0±1.0 | 6.0±1.0 | 7-8F |
| WBFDQ-Ⅱ10 | 0810 | 14.0±1.5 | 7.5±2.0 | 10.0±1.5 | 8.0±1.5 | 7-8F |
| WBFDQ-Ⅱ12 | 1012 | 16.0±1.5 | 8.5±2.0 | 12.0±1.5 | 10.0±1.5 | 8-9F |
| WBFDQ-Ⅱ14 | 1214 | 18.0±1.5 | 9.5±2.0 | 14.0±1.5 | 12.0±1.5 | 8-9F |
| WBFDQ-Ⅱ16 | 1416 | 20.0±1.5 | 10.5+2.5 | 16.0±2.0 | 14.0±2.0 | 9-10F |
| WBFDQ-Ⅱ18 | 1618 | 23.0±2.0 | 10.5±2.5 | 18.0±2.0 | 16.0±2.0 | 10-12F |
| WBFDQ-Ⅱ20 | 1820 | 25.0±2.0 | 12.0±2.5 | 20.0±2.0 | 18.0±2.0 | 12-14F |
| WBFDQ-Ⅱ22 | 2022 | 27.0±2.0 | 12.0±2.5 | 22.0±2.0 | 20.0±2.0 | 12-14F |
| WTWBFDQ-Ⅰ04 | 04 | 8.0±1.0 | 4.0±1.5 | 4.0±1.0 | – | 6-7F |
| WTWBFDQ-Ⅰ05 | 05 | 9.0±1.0 | 5.0±1.5 | 5.0±1.0 | – | 6-7F |
| WTWBFDQ-Ⅰ06 | 06 | 10.0±1.0 | 6.0±1.5 | 6.0±1.0 | – | 6-7F |
| WTWBFDQ-Ⅰ07 | 07 | 11.0±1.0 | 6.5±1.5 | 7.0±1.0 | – | 7-8F |
| WTWBFDQ-Ⅰ08 | 08 | 12.0±1.0 | 6.5±1.5 | 8.0±1.0 | – | 7-8F |
| WTWBFDQ-Ⅰ09 | 09 | 13.0±1.0 | 7.0±1.5 | 9.0±1.0 | – | 8-9F |
| WTWBFDQ-Ⅰ10 | 10 | 14.0±1.5 | 7.5±2.0 | 10.0±1.5 | – | 8-9F |
| WTWBFDQ-Ⅰ11 | 11 | 15.0±1.5 | 8.0±2.0 | 11.0±1.5 | – | 8-9F |
| WTWBFDQ-Ⅰ12 | 12 | 16.0±1.5 | 8.5±2.0 | 12.0±1.5 | – | 8-9F |
| WTWBFDQ-Ⅰ13 | 13 | 17.0±1.5 | 8.5±2.0 | 13.0±1.5 | – | 8-9F |
| WTWBFDQ-Ⅰ14 | 14 | 18.0±1.5 | 9.5±2.0 | 14.0±1.5 | – | 9-10F |
| WTWBFDQ-Ⅰ16 | 16 | 21.0±2.0 | 10.5±2.5 | 16.0±2.0 | – | 9-10F |

| Catalogue No | Device Size | A AorticdiscDiameter (mm) | B Height of connecting waist (mm) | C Aorticwaist diameter (mm) | D Pulmonicwaist diameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| WTWBFDQ-Ⅰ18 | 18 | 23.0±2.0 | 10.5±2.5 | 18.0±2.0 | – | 10-12F |
| WTWBFDQ-Ⅰ20 | 20 | 25.0±2.0 | 12±2.5 | 20.0±2.0 | – | 12-14F |
| WTWBFDQ-Ⅰ22 | 22 | 27.0±2.0 | 12±2.5 | 22.0±2.0 | – | 12-14F |
| WTWBFDQ-Ⅱ06 | 0406 | 9.0±1.0 | 6.0±1.5 | 6.0±1.0 | 4.0±1.0 | 6-7F |
| WTWBFDQ-Ⅱ08 | 0608 | 11.0±1.0 | 6.5±1.5 | 8.0±1.0 | 6.0±1.0 | 7-8F |
| WTWBFDQ-Ⅱ10 | 0810 | 14.0±1.5 | 7.5±2.0 | 10.0±1.5 | 8.0±1.5 | 7-8F |
| WTWBFDQ-Ⅱ12 | 1012 | 16.0±1.5 | 8.5±2.0 | 12.0±1.5 | 10.0±1.5 | 8-9F |
| WTWBFDQ-Ⅱ14 | 1214 | 18.0±1.5 | 9.5±2.0 | 14.0±1.5 | 12.0±1.5 | 8-9F |
| WTWBFDQ-Ⅱ16 | 1416 | 20.0±1.5 | 10.5+2.5 | 16.0±2.0 | 14.0±2.0 | 9-10F |
| WTWBFDQ-Ⅱ18 | 1618 | 23.0±2.0 | 10.5±2.5 | 18.0±2.0 | 16.0±2.0 | 10-12F |
| WTWBFDQ-Ⅱ20 | 1820 | 25.0±2.0 | 12.0±2.5 | 20.0±2.0 | 18.0±2.0 | 12-14F |
| WTWBFDQ-Ⅱ22 | 2022 | 27.0±2.0 | 12.0±2.5 | 22.0±2.0 | 20.0±2.0 | 12-14F |

**Table 4 Specifications of MemoPart™ PFO Occluder**

| Catalogue No | Device Size | A Connecting waist diameter (mm) | H Height of connecting waist (mm) | B LADiscDiameter (mm) | C RADiscDiameter (mm) | Smallest Recommended Sheath Size |
|---|---|---|---|---|---|---|
| LYKFDQ-Ⅰ1818 | 1818 | 3.5±1.0 | 6.0±2.0 | 18.0±2.0 | 18.0±2.0 | 10-12F |
| LYKFDQ-Ⅰ1824 | 1824 | 4.0±1.0 | 7.0±2.0 | 18.0±2.0 | 24.0±2.0 | 10-12F |
| LYKFDQ-Ⅰ2424 | 2424 | 4.0±1.0 | 7.0±2.0 | 24.0±2.0 | 24.0±2.0 | 10-12F |

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

**Table 5 Specifications of MemoPart™ Occluder Delivery system**

| Catalogue No | Loader | | Long sheath | | | Dilator | pusher | | |
|---|---|---|---|---|---|---|---|---|---|
| | ID, mm (±0.25) | Effective Length, mm (L±30) | ID, mm (±0.25) | Effective Length, mm (L±60) | Angle (°) (α±20°) | Effective Length, mm (L±60) | Effective Length, mm (L±50) | Diameter, mm (D±0.20) | Screw Diameter, mm(±0.06) |
| ODS-A-I-5F | 1.85 | 130 | 1.85 | 800 | 45° | 920 | 1200 | 1.4 | 0.80 |
| ODS-A-I-6F | 2.00 | 130 | 2.00 | 800 | 45° | 920 | 1200 | 1.6 | 0.80 |
| ODS-A-I-7F | 2.33 | 130 | 2.33 | 800 | 45° | 920 | 1200 | 1.8 | 0.80 |
| ODS-A-I-8F | 2.67 | 130 | 2.67 | 800 | 45° | 920 | 1200 | 1.8 | 0.80 |
| ODS-A-I-9F | 3.00 | 130 | 3.00 | 800 | 45° | 920 | 1200 | 1.8 | 0.80 |
| ODS-A-I-10F | 3.33 | 130 | 3.33 | 800 | 45° | 920 | 1200 | 1.9 | 0.80 |
| ODS-A-I-12F | 4.00 | 160 | 4.00 | 800 | 45° | 920 | 1200 | 2.0 | 0.80 |
| ODS-A-I-14F | 4.67 | 160 | 4.67 | 800 | 45° | 920 | 1200 | 2.0 | 0.80 |
| ODS-P/V-II-5F | 1.85 | 130 | 1.85 | 800 | 180° | 920 | 1200 | 1.4 | 0.80 |
| ODS-P/V-II-6F | 2.00 | 130 | 2.00 | 800 | 180° | 920 | 1200 | 1.6 | 0.80 |
| ODS-P/V-II-7F | 2.33 | 130 | 2.33 | 800 | 180° | 920 | 1200 | 1.8 | 0.80 |
| ODS-P/V-II-8F | 2.67 | 130 | 2.67 | 800 | 180° | 920 | 1200 | 1.8 | 0.80 |
| ODS-P/V-II-9F | 3.00 | 130 | 3.00 | 800 | 180° | 920 | 1200 | 1.8 | 0.80 |
| ODS-P/V-II-10F | 3.33 | 130 | 3.33 | 800 | 180° | 920 | 1200 | 1.9 | 0.80 |
| ODS-P/V-II-12F | 4.00 | 160 | 4.00 | 800 | 180° | 920 | 1200 | 2.0 | 0.80 |
| ODS-P/V-II-14F | 4.67 | 160 | 4.67 | 800 | 180° | 920 | 1200 | 2.0 | 0.80 |
| ODS-A-III-5F | 1.85 | 130 | 1.85 | 600 | 45° | 680 | 1200 | 1.4 | 0.80 |
| 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 |

| Catalogue No | Loader | | Long sheath | | | Dilator | pusher | | |
|---|---|---|---|---|---|---|---|---|---|
| | ID, mm (±0.25) | Effective Length, mm (L±30) | ID, mm (±0.25) | Effective Length, mm (L±60) | Angle (°) (α±20°) | Effective Length, mm (L±60) | Effective Length, mm (L±50) | Diameter, mm (D±0.20) | Screw Diameter, mm(±0.06) |
| 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 |
| 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 |

**Table 6 Specifications of MemoPart™ Snare**

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

## Accessories:

No accessories packaged with the device.

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:

**Graeme Tunbridge, Senior Vice President Medical Devices**

Original Registration Date: 2019-06-04
Effective Date: 2022-06-04
Latest Revision Date: 2022-08-12
Expiry Date: 2025-06-03



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