



CE-SHSMA-002

Manufacturer's Declaration of Conformity

(in accordance with ISO/IEC 17050-1)

Issuer's name : Shanghai Shape Memory Alloy Co., Ltd.
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Object of the declaration :

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

Conformity assessment: MDD Annex II

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

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

Additional information

Notified Body : BSI **CE 2797**
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. The Netherlands
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Certificate	Initially issued	Last renewal	Valid until
EC Certificate-Full Quality Assurance System No.: CE 650109	24 November 2016	4 May 2020	26 May 2024
EC Certificate-Design Examination Certificate No.: CE 650110	24 November 2016	29 April 2021	26 May 2024

Signed for and on behalf of name: Yu Ting

Function (Company) : Management

Representative Signature:

Date: 2021.12.1



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

Product List of Memo 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- I 14	14	14.0±0.6	5.5±0.75	24.0±1.25	22.0±1.25	9-10F
WTFQFDQ- I 15	15	15.0±0.6	5.5±0.75	29.0±1.25	25.0±1.25	9-10F
WTFQFDQ- I 16	16	16.0±0.6	5.5±0.75	30.0±1.5	26.0±1.25	10-12F
WTFQFDQ- I 17	17	17.0±0.75	5.5±0.75	31.0±1.5	27.0±1.25	10-12F
WTFQFDQ- I 18	18	18.0±0.75	5.5±0.75	32.0±1.5	28.0±1.5	10-12F
WTFQFDQ- I 19	19	19.0±0.75	5.5±0.75	33.0±1.5	29.0±1.5	10-12F
WTFQFDQ- I 20	20	20.0±0.75	5.5±0.75	34.0±1.5	30.0±1.5	10-12F
WTFQFDQ- I 22	22	22.0±1.0	5.5±1.0	36.0±1.75	32.0±1.75	10-12F
WTFQFDQ- I 24	24	24.0±1.0	5.5±1.0	38.0±1.75	34.0±1.75	12-14F
WTFQFDQ- I 26	26	26.0±1.0	5.5±1.0	40.0±1.75	36.0±1.75	12-14F
WTFQFDQ- I 28	28	28.0±1.0	5.5±1.0	42.0±1.75	38.0±1.75	12-14F
WTFQFDQ- I 30	30	30.0±1.0	5.5±1.0	44.0±1.75	40.0±1.75	14F
WTFQFDQ- I 32	32	32.0±1.0	5.5±1.0	48.0±1.75	42.0±1.75	14F
WTFQFDQ- I 34	34	34.0±1.0	5.5±1.0	50.0±1.75	44.0±1.75	14F
WTFQFDQ- I 36	36	36.0±1.0	5.5±1.0	52.0±1.75	46.0±1.75	14F
WTFQFDQ- I 38	38	38.0±1.0	5.5±1.0	54.0±1.75	50.0±1.75	14F
WTFQFDQ- I 40	40	40.0±1.0	5.5±1.0	56.0±1.75	52.0±1.75	14F
WTFQFDQ- I 42	42	42.0±1.0	5.5±1.0	58.0±1.75	54.0±1.75	14F
WTFQFDQ- I 44	44	44.0±1.0	5.5±1.0	60.0±1.75	56.0±1.75	14F
WTFQFDQ- I 46	46	46.0±1.0	5.5±1.0	62.0±1.75	58.0±1.75	14F
WTFQFDQ- I 48	48	48.0±1.0	5.5±1.0	64.0±1.75	60.0±1.75	14F
WTFQFDQ- I 50	50	50.0±1.0	5.5±1.0	66.0±1.75	62.0±1.75	14F
FQFDQ- II 06	06	6±0.75	5.5±0.5	30±1.5	22±1.5	9-10F
FQFDQ- II 08	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 r (mm)	H Height of connecting waist (mm)	B Connecting Waist diameter (mm)	C RV DiscDiameter (mm)	Smallest Recommended Sheath Size
SQFDQ- I a04	04	8.0±1.0	5.0±1.5	4.0±1.0	8.0±1.0	7-8F
SQFDQ- I a05	05	9.0±1.0	5.0±1.5	5.0±1.0	9.0±1.0	7-8F
SQFDQ- I a06	06	10.0±1.0	5.0±1.5	6.0±1.0	10.0±1.0	8-9F
SQFDQ- I a07	07	11.0±1.0	5.0±1.5	7.0±1.0	11.0±1.0	8-9F
SQFDQ- I a08	08	12.0±1.0	5.0±1.5	8.0±1.0	12.0±1.0	8-9F
SQFDQ- I a09	09	13.0±1.0	5.0±1.8	9.0±1.0	13.0±1.0	8-9F
SQFDQ- I a10	10	14.0±1.0	5.0±1.8	10.0±1.2	14.0±1.0	9-10F
SQFDQ- I a12	12	16.0±1.0	5.0±1.8	12.0±1.2	16.0±1.0	9-10F
SQFDQ- I a14	14	18.0±1.0	5.0±1.8	14.0±1.5	18.0±1.0	10-12F
SQFDQ- I a16	16	20.0±1.0	5.0±1.8	16.0±1.5	20.0±1.0	10-12F
SQFDQ- I a18	18	22.0±1.0	5.0±1.8	18.0±1.5	22.0±1.0	10-12F
SQFDQ- I b04	04	10.0±1.0	7.0±1.5	4.0±1.0	8.0±1.0	7-8F
SQFDQ- I b05	05	11.0±1.0	7.0±1.5	5.0±1.0	9.0±1.0	7-8F
SQFDQ- I b06	06	12.0±1.0	7.0±1.5	6.0±1.0	10.0±1.0	8-9F
SQFDQ- I b07	07	13.0±1.0	7.0±1.5	7.0±1.0	11.0±1.0	8-9F
SQFDQ- I b08	08	14.0±1.0	7.0±1.5	8.0±1.0	12.0±1.0	8-9F
SQFDQ- I b09	09	15.0±1.0	7.0±1.8	9.0±1.0	13.0±1.0	8-9F
SQFDQ- I b10	10	16.0±1.0	7.0±1.8	10.0±1.2	14.0±1.0	9-10F
SQFDQ- I b12	12	18.0±1.0	7.0±1.8	12.0±1.2	16.0±1.0	9-10F
SQFDQ- I b14	14	20.0±1.0	7.0±1.8	14.0±1.5	18.0±1.0	10-12F
SQFDQ- I b16	16	22.0±1.0	7.0±1.8	16.0±1.5	20.0±1.0	10-12F
SQFDQ- I b18	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 r (mm)	H Height of connecting waist (mm)	B Connecting Waist diameter (mm)	C RV DiscDiameter (mm)	Smallest Recommended Sheath Size
SQFDQ- I c04	04	14.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
SQFDQ- I c05	05	15.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
SQFDQ- I c06	06	16.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
SQFDQ- I c07	07	17.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
SQFDQ- I c08	08	18.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
SQFDQ- I c09	09	19.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
SQFDQ- I c10	10	20.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
SQFDQ- I c12	12	22.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
SQFDQ- I c14	14	24.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
SQFDQ- I c16	16	26.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
SQFDQ- I c18	18	28.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F
SQFDQ- I d04	04	18.0±1.0	10.0±1.5	4.0±1.0	10.0±1.0	7-8F
SQFDQ- I d05	05	19.0±1.0	10.0±1.5	5.0±1.0	11.0±1.0	7-8F
SQFDQ- I d06	06	20.0±1.0	10.0±1.5	6.0±1.0	12.0±1.0	8-9F
SQFDQ- I d07	07	21.0±1.0	10.0±1.5	7.0±1.0	13.0±1.0	8-9F
SQFDQ- I d08	08	22.0±1.0	10.0±1.5	8.0±1.0	14.0±1.0	8-9F
SQFDQ- I d09	09	23.0±1.0	10.0±1.8	9.0±1.0	15.0±1.0	8-9F
SQFDQ- I d10	10	24.0±1.0	10.0±1.8	10.0±1.2	16.0±1.0	9-10F
SQFDQ- I d12	12	26.0±1.0	10.0±1.8	12.0±1.2	18.0±1.0	9-10F
SQFDQ- I d14	14	28.0±1.0	10.0±1.8	14.0±1.5	20.0±1.0	10-12F
SQFDQ- I d16	16	30.0±1.0	10.0±1.8	16.0±1.5	22.0±1.0	10-12F
SQFDQ- I d18	18	32.0±1.0	10.0±1.8	18.0±1.5	24.0±1.0	10-12F

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

Catalogue No	Device Size	A LV DiscDiameter r (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 r (mm)	H Height of connecting waist (mm)	B Connecting Waist diameter (mm)	C RV DiscDiameter (mm)	Smallest Recommended Sheath Size
SQFDQ-II a04	04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F
SQFDQ-II a05	05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F
SQFDQ-II a06	06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F
SQFDQ-II a07	07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F
SQFDQ-II a08	08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F
SQFDQ-II a09	09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F
SQFDQ-II a10	10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F
SQFDQ-II a12	12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F
SQFDQ-II a14	14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F
SQFDQ-II a16	16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F
SQFDQ-II a18	18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F
SQFDQ-II a20	20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F
SQFDQ-II b04	04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F
SQFDQ-II b05	05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F
SQFDQ-II b06	06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F
SQFDQ-II b07	07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F
SQFDQ-II b08	08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F
SQFDQ-II b09	09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F
SQFDQ-II b10	10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F
SQFDQ-II b12	12	16.0±1.5	4.5±1.0	12.0±1.5	15.0±1.5	9-10F
SQFDQ-II b14	14	18.0±1.5	4.5±1.0	14.0±1.5	17.0±1.5	9-10F
SQFDQ-II b16	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 r (mm)	H Height of connecting waist (mm)	B Connecting Waist diameter (mm)	C RV DiscDiameter (mm)	Smallest Recommended Sheath Size
SQFDQ- II b18	18	24.0±1.5	5.0±1.0	18.0±1.8	22.0±1.5	10-12F
SQFDQ- II b20	20	26.0±1.5	5.0±1.0	20.0±1.8	24.0±1.5	12-14F
WTSQFDQ- II a04	04	8.0±0.8	1.8±0.5	4.0±0.8	8.0±0.8	6-7F
WTSQFDQ- II a05	05	9.0±0.8	1.8±0.5	5.0±0.8	9.0±0.8	6-7F
WTSQFDQ- II a06	06	10.0±0.8	1.8±0.5	6.0±0.8	10.0±0.8	7-8F
WTSQFDQ- II a07	07	11.0±0.8	1.8±0.5	7.0±0.8	11.0±0.8	7-8F
WTSQFDQ- II a08	08	12.0±0.8	1.8±0.5	8.0±0.8	12.0±0.8	7-8F
WTSQFDQ- II a09	09	13.0±0.8	1.8±0.5	9.0±0.8	13.0±0.8	8-9F
WTSQFDQ- II a10	10	14.0±0.8	1.8±0.5	10.0±0.8	14.0±0.8	8-9F
WTSQFDQ- II a12	12	16.0±0.8	1.8±0.5	12.0±0.8	16.0±0.8	9-10F
WTSQFDQ- II a14	14	18.0±0.8	1.8±0.5	14.0±0.8	18.0±0.8	9-10F
WTSQFDQ- II a16	16	20.0±0.8	1.8±0.5	16.0±0.8	20.0±0.8	10-12F
WTSQFDQ- II a18	18	24.0±0.8	1.8±0.5	18.0±0.8	22.0±0.8	10-12F
WTSQFDQ- II a20	20	26.0±0.8	1.8±0.5	20.0±0.8	24.0±0.8	12-14F
WTSQFDQ- II b04	04	8.0±0.8	3.5±1.0	4.0±0.8	8.0±0.8	6-7F
WTSQFDQ- II b05	05	9.0±0.8	4.0±1.0	5.0±0.8	9.0±0.8	6-7F
WTSQFDQ- II b06	06	10.0±0.8	4.0±1.0	6.0±1.0	10.0±0.8	7-8F
WTSQFDQ- II b07	07	11.0±1.0	4.0±1.0	7.0±1.0	11.0±1.0	7-8F
WTSQFDQ- II b08	08	12.0±1.0	4.0±1.0	8.0±1.0	12.0±1.0	7-8F
WTSQFDQ- II b09	09	13.0±1.0	4.5±1.0	9.0±1.2	13.0±1.0	8-9F
WTSQFDQ- II b10	10	14.0±1.5	4.5±1.0	10.0±1.2	14.0±1.5	8-9F
WTSQFDQ- II b12	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 r (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 r (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- I 04	04	8.0±1.0	4.0±1.5	4.0±1.0	—	6-7F
WBFDQ- I 05	05	9.0±1.0	5.0±1.5	5.0±1.0	—	6-7F
WBFDQ- I 06	06	10.0±1.0	6.0±1.5	6.0±1.0	—	6-7F
WBFDQ- I 07	07	11.0±1.0	6.5±1.5	7.0±1.0	—	7-8F
WBFDQ- I 08	08	12.0±1.0	6.5±1.5	8.0±1.0	—	7-8F
WBFDQ- I 09	09	13.0±1.0	7.0±1.5	9.0±1.0	—	8-9F
WBFDQ- I 10	10	14.0±1.5	7.5±2.0	10.0±1.5	—	8-9F
WBFDQ- I 11	11	15.0±1.5	8.0±2.0	11.0±1.5	—	8-9F
WBFDQ- I 12	12	16.0±1.5	8.5±2.0	12.0±1.5	—	8-9F
WBFDQ- I 13	13	17.0±1.5	8.5±2.0	13.0±1.5	—	8-9F
WBFDQ- I 14	14	18.0±1.5	9.5±2.0	14.0±1.5	—	9-10F
WBFDQ- I 16	16	21.0±2.0	10.5±2.5	16.0±2.0	—	9-10F
WBFDQ- I 18	18	23.0±2.0	10.5±2.5	18.0±2.0	—	10-12F

Catalogue No	Device Size	A Aortic disc diameter (mm)	B Height of connecting waist (mm)	C Aortic waist diameter (mm)	D Pulmonic waist diameter (mm)	Smallest Recommended Sheath Size
WBFDDQ- I 20	20	25.0±2.0	12±2.5	20.0±2.0	—	12-14F
WBFDDQ- I 22	22	27.0±2.0	12±2.5	22.0±2.0	—	12-14F
WBFDDQ- II 06	0406	10.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F
WBFDDQ- II 08	0608	12.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F
WBFDDQ- II 10	0810	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F
WBFDDQ- II 12	1012	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F
WBFDDQ- II 14	1214	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F
WBFDDQ- II 16	1416	20.0±1.5	10.5±2.5	16.0±2.0	14.0±2.0	9-10F
WBFDDQ- II 18	1618	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F
WBFDDQ- II 20	1820	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F
WBFDDQ- II 22	2022	27.0±2.0	12.0±2.5	22.0±2.0	20.0±2.0	12-14F
WTWBFDDQ- I 04	04	8.0±1.0	4.0±1.5	4.0±1.0	—	6-7F
WTWBFDDQ- I 05	05	9.0±1.0	5.0±1.5	5.0±1.0	—	6-7F
WTWBFDDQ- I 06	06	10.0±1.0	6.0±1.5	6.0±1.0	—	6-7F
WTWBFDDQ- I 07	07	11.0±1.0	6.5±1.5	7.0±1.0	—	7-8F
WTWBFDDQ- I 08	08	12.0±1.0	6.5±1.5	8.0±1.0	—	7-8F
WTWBFDDQ- I 09	09	13.0±1.0	7.0±1.5	9.0±1.0	—	8-9F
WTWBFDDQ- I 10	10	14.0±1.5	7.5±2.0	10.0±1.5	—	8-9F
WTWBFDDQ- I 11	11	15.0±1.5	8.0±2.0	11.0±1.5	—	8-9F
WTWBFDDQ- I 12	12	16.0±1.5	8.5±2.0	12.0±1.5	—	8-9F
WTWBFDDQ- I 13	13	17.0±1.5	8.5±2.0	13.0±1.5	—	8-9F
WTWBFDDQ- I 14	14	18.0±1.5	9.5±2.0	14.0±1.5	—	9-10F
WTWBFDDQ- I 16	16	21.0±2.0	10.5±2.5	16.0±2.0	—	9-10F

Catalogue No	Device Size	A Aortic Disc Diameter (mm)	B Height of connecting waist (mm)	C Aortic waist diameter (mm)	D Pulmonic waist diameter (mm)	Smallest Recommended Sheath Size
WTWBFDDQ- I 18	18	23.0±2.0	10.5±2.5	18.0±2.0	—	10-12F
WTWBFDDQ- I 20	20	25.0±2.0	12±2.5	20.0±2.0	—	12-14F
WTWBFDDQ- I 22	22	27.0±2.0	12±2.5	22.0±2.0	—	12-14F
WTWBFDDQ- II 06	0406	9.0±1.0	6.0±1.5	6.0±1.0	4.0±1.0	6-7F
WTWBFDDQ- II 08	0608	11.0±1.0	6.5±1.5	8.0±1.0	6.0±1.0	7-8F
WTWBFDDQ- II 10	0810	14.0±1.5	7.5±2.0	10.0±1.5	8.0±1.5	7-8F
WTWBFDDQ- II 12	1012	16.0±1.5	8.5±2.0	12.0±1.5	10.0±1.5	8-9F
WTWBFDDQ- II 14	1214	18.0±1.5	9.5±2.0	14.0±1.5	12.0±1.5	8-9F
WTWBFDDQ- II 16	1416	20.0±1.5	10.5±2.5	16.0±2.0	14.0±2.0	9-10F
WTWBFDDQ- II 18	1618	23.0±2.0	10.5±2.5	18.0±2.0	16.0±2.0	10-12F
WTWBFDDQ- II 20	1820	25.0±2.0	12.0±2.5	20.0±2.0	18.0±2.0	12-14F
WTWBFDDQ- II 22	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 LADisc Diameter (mm)	C RADisc Diameter (mm)	Smallest Recommended Sheath Size
LYKFDQ- I 1818	1818	3.5±1.0	6.0±2.0	18.0±2.0	18.0±2.0	10-12F
LYKFDQ- I 1824	1824	4.0±1.0	7.0±2.0	18.0±2.0	24.0±2.0	10-12F
LYKFDQ- I 2424	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±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-PV-II-5F	1.85	130	1.85	800	180°	920	1200	1.4	0.80
ODS-PV-II-6F	2.00	130	2.00	800	180°	920	1200	1.6	0.80
ODS-PV-II-7F	2.33	130	2.33	800	180°	920	1200	1.8	0.80
ODS-PV-II-8F	2.67	130	2.67	800	180°	920	1200	1.8	0.80
ODS-PV-II-9F	3.00	130	3.00	800	180°	920	1200	1.8	0.80
ODS-PV-II-10F	3.33	130	3.33	800	180°	920	1200	1.9	0.80
ODS-PV-II-12F	4.00	160	4.00	800	180°	920	1200	2.0	0.80
ODS-PV-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 ($L \pm 30$)	ID, mm (± 0.25)	Effective Length, mm ($L \pm 60$)		Effective Length, mm ($L \pm 50$)	Diameter, mm ($D \pm 0.20$)	Screw Diameter, mm (± 0.06)
ODS-P/V-IV-5F	1.85	130	1.85	600	680	1200	1.4	0.80
ODS-P/V-IV-6F	2.00	130	2.00	600	680	1200	1.6	0.80
ODS-P/V-IV-7F	2.33	130	2.33	600	680	1200	1.8	0.80
ODS-P/V-IV-8F	2.67	130	2.67	600	680	1200	1.8	0.80
ODS-P/V-IV-9F	3.00	130	3.00	600	680	1200	1.8	0.80
ODS-P/V-IV-10F	3.33	130	3.33	600	680	1200	1.9	0.80
ODS-P/V-IV-12F	4.00	160	4.00	600	680	1200	2.0	0.80
ODS-P/V-IV-14F	4.67	160	4.67	600	680	1200	2.0	0.80

Table 6 Specifications of MemoPart™ Snare

Snare	Type	Snare-15	Snare-20
	Effective Length, mm	1240 $\pm$ 60mm	1240 $\pm$ 60mm
	Diameter of snare circle, mm	15 $\pm$ 2mm	20 $\pm$ 2mm
	Angle	90° $\pm$ 20°	90° $\pm$ 20°

Accessories:

No accessories packaged with the device.