Information for Patient

Please read the following information carefully. If you have any questions or are not sure about the information provided below, ask your doctor.

You will receive an implant card that holds important information about your implant. If you need medical assistance, show your card to the doctor at your health facility.

Further information can be found in the European database on medical devices (Eudamed) by searching the Basic UDI-DI "69330523XZ0001JZ" at: https://ec.europa.eu/tools/eudamed (When Eudamed is available)

Device description

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. The occluders are composed of Nitinol compliant with ASTM F2063 standard, 00Cr18Ni14Mo3 Stainless steel compliant with ISO 5832-1 standard, Polyethylene terephthalate (PET, CAS No.: 25038-59-9) and Polyamide 6 (commonly known as nylon 6 (PA6), CAS No.: 25038-54-4). The material used for each individual device is listed in the table below. They do not contain medicinal substances, animal or human tissue; they are no blood products and are not radioactive.

Catalogue No	Device Weight (g)	Material Quantity (g)			
		Nitinol	00Cr18Ni14Mo3 Stainless steel	Polyethylene terephthalate (PET)	Polyamide 6 (PA6)
FQFDQ-I 06	0.21~0.26	0.10~0.15	0.078~0.130	0.006~0.013	Balance
FQFDQ-I 07	0.35~0.42	0.22~0.33	0.071~0.118	0.008~0.019	Balance
FQFDQ-I 08	0.26~0.32	0.14~0.21	0.075~0.125	0.007~0.016	Balance
FQFDQ-I 09	0.36~0.45	0.23~0.35	0.073~0.122	0.011~0.025	Balance
FQFDQ-I 10	0.32~0.39	0.19~0.29	0.073~0.122	0.009~0.022	Balance
FQFDQ-I 11	0.40~0.48	0.26~0.39	0.073~0.122	0.012~0.028	Balance
FQFDQ-I 12	0.36~0.44	0.22~0.34	0.073~0.122	0.012~0.028	Balance
FQFDQ-I 13	0.48~0.58	0.31~0.46	0.087~0.146	0.017~0.039	Balance
FQFDQ-I 14	0.38~0.46	0.24~0.36	0.073~0.122	0.015~0.036	Balance
FQFDQ-I 15	0.50~0.61	0.32~0.48	0.087~0.146	0.020~0.047	Balance
FQFDQ-I 16	0.64~0.78	0.43~0.65	0.105~0.175	0.019~0.045	Balance
FQFDQ-I 17	0.66~0.81	0.45~0.68	0.105~0.175	0.021~0.050	Balance
FQFDQ-I 18	0.66~0.81	0.45~0.67	0.105~0.175	0.024~0.057	Balance
FQFDQ-I 19	0.76~0.93	0.53~0.80	0.102~0.170	0.025~0.058	Balance
FQFDQ-I 20	0.80~0.97	0.56~0.84	0.102~0.170	0.027~0.062	Balance
FQFDQ-I 22	0.83~1.02	0.59~0.88	0.102~0.170	0.031~0.073	Balance
FQFDQ-I 24	0.94~1.15	0.69~1.03	0.097~0.161	0.033~0.078	Balance
FQFDQ-I 26	1.02~1.24	0.75~1.12	0.097~0.161	0.040~0.094	Balance
FQFDQ-I 28	1.23~1.50	0.89~1.33	0.137~0.228	0.043~0.099	Balance
FQFDQ-I 30	1.38~1.68	1.03~1.54	0.127~0.212	0.046~0.108	Balance

FQFDQ-I 32	1.46~1.79	1.09~1.64	0.127~0.212	0.051~0.119	Balance
FQFDQ-I 34	1.68~2.05	1.28~1.91	0.121~0.202	0.064~0.150	Balance
FQFDQ-I 36	1.91~2.33	1.43~2.15	0.155~0.259	0.073~0.169	Balance
FQFDQ-I 38	2.14~2.62	1.64~2.46	0.155~0.259	0.074~0.172	Balance
FQFDQ-I 40	2.33~2.85	1.80~2.70	0.142~0.236	0.090~0.209	Balance
FQFDQ-I 42	2.48~3.04	1.93~2.90	0.142~0.236	0.091~0.213	Balance
FQFDQ-I 44	2.84~3.47	2.20~3.31	0.168~0.280	0.104~0.242	Balance
FQFDQ-I 46	2.88~3.52	2.26~3.39	0.168~0.280	0.087~0.203	Balance
FQFDQ-I 48	2.74~3.34	2.11~3.16	0.168~0.280	0.109~0.255	Balance
FQFDQ-I 50	2.86~3.49	2.20~3.30	0.168~0.280	0.118~0.276	Balance
WTFQFDQ-I 06	0.19~0.24	0.11~0.17	0.049~0.081	0.006~0.013	Balance
WTFQFDQ-I 07	0.31~0.38	0.22~0.33	0.046~0.077	0.008~0.019	Balance
WTFQFDQ-I 08	0.25~0.30	0.16~0.24	0.046~0.077	0.007~0.016	Balance
WTFQFDQ-I 09	0.35~0.42	0.24~0.37	0.046~0.077	0.011~0.025	Balance
WTFQFDQ-I 10	0.31~0.37	0.21~0.32	0.046~0.077	0.009~0.022	Balance
WTFQFDQ-I 11	0.36~0.45	0.26~0.39	0.046~0.077	0.012~0.028	Balance
WTFQFDQ-I 12	0.32~0.39	0.22~0.33	0.046~0.077	0.012~0.028	Balance
WTFQFDQ-I 13	0.51~0.62	0.37~0.56	0.055~0.092	0.017~0.039	Balance
WTFQFDQ-I 14	0.42~0.52	0.31~0.46	0.046~0.077	0.015~0.036	Balance
WTFQFDQ-I 15	0.51~0.62	0.37~0.55	0.055~0.092	0.020~0.047	Balance
WTFQFDQ-I 16	0.59~0.72	0.43~0.64	0.066~0.110	0.019~0.045	Balance
WTFQFDQ-I 17	0.60~0.74	0.44~0.65	0.066~0.110	0.021~0.050	Balance
WTFQFDQ-I 18	0.67~0.81	0.49~0.73	0.066~0.110	0.024~0.057	Balance
WTFQFDQ-I 19	0.73~0.90	0.55~0.82	0.067~0.111	0.025~0.058	Balance
WTFQFDQ-I 20	0.75~0.91	0.56~0.84	0.067~0.111	0.027~0.062	Balance
WTFQFDQ-I 22	0.80~0.98	0.60~0.90	0.067~0.111	0.031~0.073	Balance
WTFQFDQ-I 24	0.90~1.09	0.68~1.02	0.065~0.108	0.033~0.078	Balance
WTFQFDQ-I 26	0.97~1.18	0.74~1.11	0.065~0.108	0.040~0.094	Balance
WTFQFDQ-I 28	1.13~1.38	0.84~1.27	0.093~0.154	0.043~0.099	Balance
WTFQFDQ-I 30	1.32~1.62	1.02~1.53	0.088~0.147	0.046~0.108	Balance
WTFQFDQ-I 32	1.37~1.67	1.05~1.58	0.088~0.147	0.051~0.119	Balance
WTFQFDQ-I 34	1.68~2.05	1.31~1.97	0.084~0.141	0.064~0.150	Balance
WTFQFDQ-I 36	1.90~2.32	1.47~2.21	0.113~0.188	0.073~0.169	Balance
WTFQFDQ-I 38	2.07~2.53	1.62~2.43	0.113~0.188	0.074~0.172	Balance
WTFQFDQ-I 40	2.32~2.83	1.83~2.75	0.101~0.168	0.090~0.209	Balance
WTFQFDQ-I 42	2.44~2.98	1.93~2.90	0.101~0.168	0.091~0.213	Balance
WTFQFDQ-I 44	2.82~3.44	2.24~3.36	0.118~0.197	0.104~0.242	Balance
WTFQFDQ-I 46	2.81~3.44	2.26~3.39	0.118~0.197	0.087~0.203	Balance
WTFQFDQ-I 48	2.95~3.60	2.35~3.52	0.118~0.197	0.109~0.255	Balance
WTFQFDQ-I 50	2.87~3.51	2.27~3.40	0.118~0.197	0.118~0.276	Balance
FQFDQ-II 06	0.63~0.76	0.42~0.63	0.175~0.016	0.016~0.037	Balance
FQFDQ-II 08	0.64~0.79	0.44~0.65	0.175~0.018	0.018~0.042	Balance
FQFDQ-II 10	0.78~0.95	0.55~0.83	0.170~0.024	0.024~0.055	Balance

FQFDQ-II 12	0.85~1.03	0.61~0.92	0.170~0.025	0.025~0.057	Balance
FQFDQ-II 14	0.90~1.10	0.66~0.99	0.161~0.029	0.029~0.068	Balance
FQFDQ-II 16	1.03~1.26	0.77~1.16	0.161~0.031	0.031~0.073	Balance
FQFDQ-II 18	1.17~1.43	0.85~1.27	0.228~0.033	0.033~0.078	Balance
FQFDQ-II 20	1.35~1.65	1.01~1.52	0.212~0.037	0.037~0.086	Balance
FQFDQ-II 22	1.40~1.71	1.05~1.58	0.212~0.043	0.043~0.100	Balance
FQFDQ-II 24	1.63~1.99	1.25~1.88	0.202~0.047	0.047~0.109	Balance
WTFQFDQ-II 06	0.59~0.72	0.43~0.64	0.066~0.110	0.016~0.037	Balance
WTFQFDQ-II 08	0.60~0.73	0.44~0.66	0.066~0.110	0.018~0.042	Balance
WTFQFDQ-II 10	0.75~0.91	0.56~0.84	0.067~0.111	0.024~0.055	Balance
WTFQFDQ-II 12	0.79~0.96	0.60~0.89	0.067~0.111	0.025~0.057	Balance
WTFQFDQ-II 14	0.90~1.10	0.69~1.04	0.065~0.108	0.029~0.068	Balance
WTFQFDQ-II 16	0.96~1.17	0.74~1.11	0.065~0.108	0.031~0.073	Balance
WTFQFDQ-II 18	1.13~1.38	0.86~1.29	0.093~0.154	0.033~0.078	Balance
WTFQFDQ-II 20	1.31~1.61	1.02~1.54	0.088~0.147	0.037~0.086	Balance
WTFQFDQ-II 22	1.35~1.64	1.04~1.57	0.088~0.147	0.043~0.100	Balance
WTFQFDQ-II 24	1.38~1.69	1.07~1.61	0.084~0.141	0.047~0.109	Balance

Note: If you are allergic to nickel or have a history of metal allergies, you should ask your doctor. Your doctor will help you decide whether it is appropriate for you to get an occluder.

Information for safe use

Make sure you follow your doctor's recommendations after the treatment. Not following your doctor's advice may result in complications and the need for additional medical procedures.

Discuss any questions, concerns, or potential side effects with your doctor.

Note: If you experience any symptoms of shortness of breath or chest pain at any time, seek medical care immediately.

Adverse Events

Potential adverse events that may occur during or after a procedure for implanting this device may include, but are not limited to:
Death, residual shunt, arrhythmia, heart blocks, cerebrovascular events (Stroke/TIA), thrombosis, pericardial effusion, occluder migration/malposition/dislocation, occluder embolization, cardiac tamponade, AV fistula, fever, cardiac perforation, air embolism, false aneurysm, hemolysis, dissection, neurologic complication, pulmonary edema, valve damage, cardiac arrest, vessel damage, pulmonary hypertension, valvular insufficiency/regurgitation, hematoma, device erosion, infective complications, shortness of breath, myocardial infarction/transient myocardial ischemia, pleural effusion, device fracture, heart failure/cardiac dysfunction, allergic reaction, hypertension/hypotension, chest pain, headache/migraine/dizziness, bleeding.

Magnetic Resonance Imaging (MRI)

An MRI scan of 1.5 and 3 Tesla is tested conditionally safe under specific settings and is possible to perform

immediately after the procedure. Please tell your radiologist prior to an MRI scan that you carry an implant, and show your implant card.

A patient after being implanted with this device can be safely scanned immediately after implantation under the following conditions:

- Static magnetic field of 3.0 Tesla and 1.5T
- Maximum spatial gradient field is 20T/m in 3T and 40T/m in 1.5T MR system
- Maximum whole-body specific absorption rate (SAR) of 2.0W/Kg for 15 minutes of scanning in Normal Operating Mode

Expected lifetime of the device

The MemoPart™ ASD Occluder is a permanent implant. Under normal conditions, the implanted device will remain in your body for life, unless it is required to be removed by the physician's professional judgment. The vitro bench testing has demonstrated that the device's minimum design life is 10 years.

Follow-up

It is important to schedule regular follow-up visits with your doctor. Follow-up visit will help the doctor to check your heart on a regular basis. The follow up visit should be performed at 24 hours, pre-discharge, 1 week, 1 month, 6 months, and 12 months after the procedure, and can be adjusted by the doctor depending on your individual condition. Routine clinical follow-ups with a cardiologist annually thereafter are also advised.

Travelling

The device will not set-off any metal detectors alarms. If your implant causes an alarm at a security scanner, show your implant card to security staff.

Symbols on Implant Card

SYMBOL	DESCRIPTION OF SYMBOL
	Patient Name or patient ID
	Date of implantation
	Name and Address of the implanting healthcare institution/provider
	Information website for patients, where patients can obtain additional information on the implant.
MD	Device name
REF	Catalogue number of the implant
UDI	Unique device identifier of the implant
SN	Serial number of the implant

	MR Conditional, indicates that non-clinical testing has demonstrated that the implant can safely be scanned under specific MR conditions.
	Name and Address of the manufacturer

In case of loss or degradation of the implant card, please contact your healthcare professional or the healthcare institution where your procedure took place to obtain information about a replacement. In line with data protection and patient confidentiality laws, SHSMA will not collect any information about patients or procedures where our devices are used.