# Information for Patient

Shanghai Shape Memory Alloy Co.,Ltd.

IFP-DMASD-001 Rev.01/2024.12.18

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 "69330523XZ0008KF" at:
*https://ec.europa.eu/tools/eudamed* (When Eudamed is available)

## Device description

The MemoCarna™ 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 erephthalate (PET) | Polyamide 6 (PA6) |
| DMFQFDQ-I 06 | 0.22~0.27 | 0.13~0.20 | 0.048~0.080 | 0.007~0.017 | Balance |
| DMFQFDQ-I 07 | 0.25~0.31 | 0.16~0.24 | 0.045~0.076 | 0.008~0.019 | Balance |
| DMFQFDQ-I 08 | 0.27~0.33 | 0.18~0.26 | 0.045~0.076 | 0.010~0.024 | Balance |
| DMFQFDQ-I 09 | 0.28~0.34 | 0.18~0.28 | 0.045~0.076 | 0.012~0.028 | Balance |
| DMFQFDQ-I 10 | 0.28~0.34 | 0.18~0.28 | 0.045~0.076 | 0.012~0.028 | Balance |
| DMFQFDQ-I 11 | 0.35~0.43 | 0.25~0.37 | 0.045~0.075 | 0.014~0.033 | Balance |
| DMFQFDQ-I 12 | 0.36~0.45 | 0.26~0.38 | 0.045~0.075 | 0.015~0.036 | Balance |
| DMFQFDQ-I 13 | 0.36~0.44 | 0.25~0.37 | 0.045~0.075 | 0.016~0.036 | Balance |
| DMFQFDQ-I 14 | 0.34~0.42 | 0.23~0.34 | 0.045 ~0.075 | 0.021~0.049 | Balance |
| DMFQFDQ-I 15 | 0.48~0.58 | 0.34~0.51 | 0.055~0.092 | 0.020~0.046 | Balance |
| DMFQFDQ-I 16 | 0.42~0.51 | 0.28~0.42 | 0.055~0.092 | 0.022~0.051 | Balance |
| DMFQFDQ-I 17 | 0.50~0.61 | 0.35~0.52 | 0.055~0.092 | 0.025~0.059 | Balance |
| DMFQFDQ-I 18 | 0.57~0.70 | 0.40~0.61 | 0.068~0.113 | 0.026~0.060 | Balance |
| DMFQFDQ-I 19 | 0.61~0.74 | 0.43~0.65 | 0.068~0.113 | 0.029~0.067 | Balance |
| DMFQFDQ-I 20 | 0.63~0.77 | 0.45~0.67 | 0.068~0.113 | 0.030~0.070 | Balance |
| DMFQFDQ-I 22 | 0.65~0.79 | 0.45~0.68 | 0.068~0.113 | 0.036~0.084 | Balance |
| DMFQFDQ-I 24 | 0.75~0.92 | 0.54~0.81 | 0.065~0.108 | 0.044~0.103 | Balance |
| DMFQFDQ-I 26 | 0.78~0.95 | 0.56~0.84 | 0.065~0.108 | 0.047~0.109 | Balance |
| DMFQFDQ-I 28 | 0.89~1.09 | 0.66~0.99 | 0.064~0.107 | 0.047~0.110 | Balance |
| DMFQFDQ-I 30 | 0.91~1.11 | 0.66~1.00 | 0.064~0.107 | 0.056~0.130 | Balance |
| DMFQFDQ-I 32 | 1.00~1.22 | 0.74~1.11 | 0.064~0.107 | 0.063~0.146 | Balance |
| DMFQFDQ-I 34 | 1.20~1.46 | 0.90~1.35 | 0.093~0.154 | 0.049~0.115 | Balance |
| DMFQFDQ-I 36 | 1.32~1.61 | 0.98~1.47 | 0.088~0.147 | 0.071~0.166 | Balance |
| DMFQFDQ-I 38 | 1.57~1.92 | 1.22~1.82 | 0.083~0.138 | 0.069~0.162 | Balance |
| DMFQFDQ-I 40 | 1.80~2.20 | 1.40~2.10 | 0.083~0.138 | 0.085~0.198 | Balance |

| Catalogue No | Device Weight (g) | Material Quantity (g) | | | |
|---|---|---|---|---|---|
| | | Nitinol | 00Cr18Ni14Mo3 Stainless steel | Polyethylene erephthalate (PET) | Polyamide 6 (PA6) |
| DMFQFDQ-I 42 | 1.86~2.27 | 1.42~2.13 | 0.106~0.177 | 0.090~0.209 | Balance |
| DMFQFDQ-I 44 | 1.97~2.41 | 1.51~2.27 | 0.106~0.177 | 0.095~0.221 | Balance |
| DMFQFDQ-I 46 | 2.18~2.67 | 1.69~2.54 | 0.106~0.177 | 0.099~0.230 | 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.

## 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 MemoCarna™ 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. In-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.

## 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 | 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.