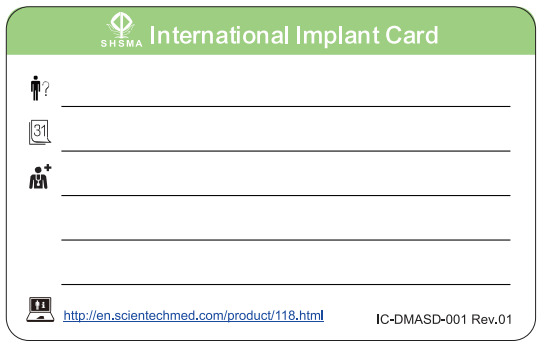
Implant Card Information Leaflet

Shanghai Shape Memory Alloy Co.,Ltd.

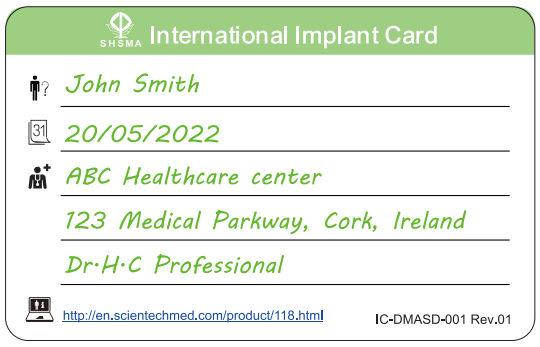
ICIF-DMASD-001 Rev.01

This device is a permanent cardiac implant. An implant card is provided by the manufacturer together with the device. Please complete this card as the following instructions and give it to the patient.

The front of the implant card, the design is as below figure:



For example:

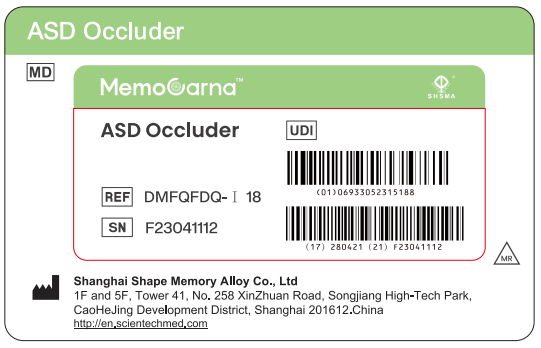


	Means patient identification. This column shall be filled with patient name or patient ID by healthcare institution/provider.
	Date of implantation, to be filled by healthcare institution/provider.
	Name and Address of the implanting healthcare institution/provider, to be filled by healthcare institution/provider.
	Information website for patients, where patients can obtain additional information on this medical device.

The back of the implant card:

Please tear off one peelable part of the device label on the package and attach it on the back of the implant card. The information on the sticker to be placed including device name, serial number, catalogue number and UDI.

For example: (the sticker provided is only for illustration, please be subject to the actual)



MD	Device name
REF	Catalogue number, by which can identify the medical device.
UDI	Unique device identifier, which contains device identifier information of UDI-DI, expiration date and serial number.
SN	Serial number, which is unique, we can trace the production batch by this number.
MR	MR Conditional, means the device has been shown in non-clinical testing to be MRI conditional. That's to say, when patients are under the following magnetic resonance environment, will be safe: · Static magnetic field of 1.5T and 3.0T. · 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 2.0 W/Kg for 15 minutes of scanning in Normal Operating Mode. · The presence of this implant may produce an image artifact.
	Manufacturer of the device.

Implant Card for MemoCarna ASD Occluder

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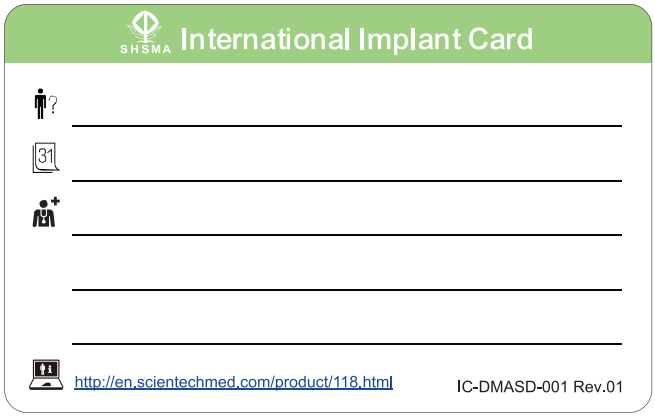
Front:



Back:

Note: the contents in rectangular frame are printed on the peelable parts of the device labelplease healthcare institution/provider tear off one of them and attach it on the back of thisimplant card. The information on the sticker to be placed including device name, serial numbercatalogue number and UDI.