

# 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:

SHSMA

International Implant Card

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<http://en.scientechmed.com/product/118.html>

IC-DMASD-001 Rev.01

SHSMA

International Implant Card

John Smith

20/05/2022

ABC Healthcare center

123 Medical Parkway, Cork, Ireland

Dr.H.C Professional

<http://en.scientechmed.com/product/118.html>

IC-DMASD-001 Rev.01

	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:

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

ASD Occluder

MD

Place attach the sticker here

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  
<http://en.scientechmed.com>

ASD Occluder

MD

MemoCarna™

SHSMA

ASD Occluder

UDI

REF

DMFQFDQ- I 18

SN

F23041112

(01) 06933052315188

(17) 280421 (21) F23041112

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

	Device name
	Catalogue number, by which can identify the medical device.
	Unique device identifier, which contains device identifier information of UDI-DI, expiration date and serial number.
	Serial number, which is unique, we can trace the production batch by this number.
	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: <ul style="list-style-type: none"><li>· Static magnetic field of 1.5T and 3.0T.</li><li>· Maximum spatial gradient field is 20T/m in 3T and 40T/m in 1.5T MR system.</li><li>· Maximum whole-body specific absorption rate (SAR) of 2.0 W/Kg for 15 minutes of scanning in Normal Operating Mode.</li><li>· The presence of this implant may produce an image artifact.</li></ul>
	Manufacturer of the device.

# Implant Card for MemoCarna ASD Occluder

File Number and Version :IC-DMASD-001 Rev.01

Front:

SHSMA International Implant Card

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31

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<http://en.scientechmed.com/product/118.html> IC-DMASD-001 Rev.01

Back:

ASD Occluder

MD

Place attach the sticker here

MR

**Shanghai Shape Memory Alloy Co., Ltd**  
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CaoHeJing Development District, Shanghai 201612, China  
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Note: the contents in rectangular frame are printed on the peelable parts of the device label please healthcare institution/provider tear off one of them and attach it on the back of this implant card. The information on the sticker to be placed including device name, serial number catalogue number and UDI.