

Implant Card for MemoCarna ASD Occluder

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

Front:

SHSMA International Implant Card

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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
1F and 5F, Tower 41, No. 258 XinZhuan Road, Songjiang High-Tech Park,
CaoHeJing Development District, Shanghai 201612, China
<http://en.scientechmed.com>

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.


Shanghai Shape Memory Alloy Co.,Ltd.




ICIF-DMASD-001 Rev.01


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


For example:





International Implant Card



















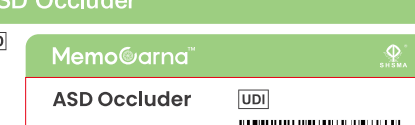
<http://en.scientechned.com/product/118.html>

IC-DMASD-001 Rev.01

SHSMA International Implant Card	
	<i>John Smith</i>
	<i>20/05/2022</i>
	<i>ABC Healthcare center</i>
	<i>123 Medical Parkway, Cork, Ireland</i>
	<i>Dr.H.C Professional</i>
	http://en.scienteched.com/product/118.html

	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.

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



The image shows the packaging for the ASD Occluder. The top section is green with the company name 'Shanghai Shape Memory Alloy Co., Ltd.' and the product name 'ASD Occluder' in white. Below this, the 'MemoCarna™' logo is visible. The main body of the box is white with a red border. It features the product name 'ASD Occluder' in large black letters, a 'UDI' (Unique Device Identifier) label, and two barcode areas. The first barcode is labeled 'REF DMFQFDQ- I 18' and the second is labeled 'SN F23041112'. Below the second barcode, the numbers '(17) 280421 (21) F23041112' are printed. The bottom of the box is green with the company name and address in white. A small 'MD' logo is in the bottom right corner.

ASD Occluder

MemoCarna™

UDI

REF DMFQFDQ- I 18







SN F23041112

(17) 280421 (21) F23041112

Shanghai Shape Memory Alloy Co., Ltd.
 1F and 5F, Tower 41, No. 258 Xinchuan Road, Songjiang High-Tech Park,
 CaoHeJing Development District, Shanghai 201612, China
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MD

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.
	<p>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:</p> <ul style="list-style-type: none"> · 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.