

封堵器产品植入卡

文件及版本号：IC-2022-01 Rev. 01

Front:

SHSMA International Implant Card

Person icon: _____

Calendar icon: _____

Person icon: _____

Laptop icon: _____

<http://en.scientechmed.com> IC-2022-01 Rev.01

85.6mm 54mm R: 3mm

Back:

Cardiac occluder

MD

Please attach sticker here

Shanghai Shape Memory Alloy Co., Ltd.
1F and 5F, Tower 41, No.258 Xinzhuang Rd., Songjiang High-Tech
Park, CaoHeJing Development District, Shanghai, P.R. China
<https://en.scientechmed.com>

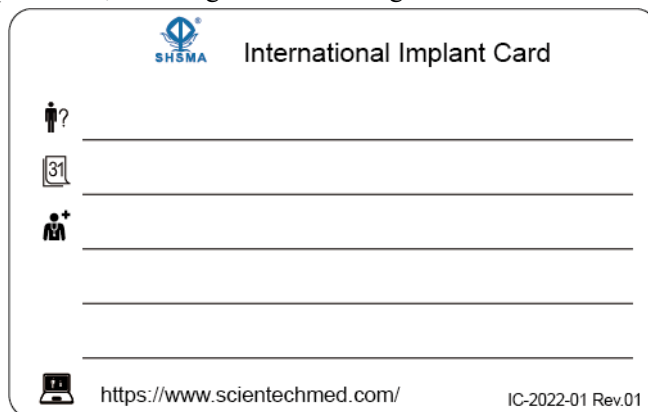
MR

注：在“Please attach sticker here”所示区域，由临床医生从产品包装上撕下可撕小标签贴到植入卡上，随ASD、VSD、PFO和PDA不同封堵器而异。





Implant Card Information Leaflet

This device is a permanent cardiac implant. Please complete this card as the following instructions and give it to the patient.

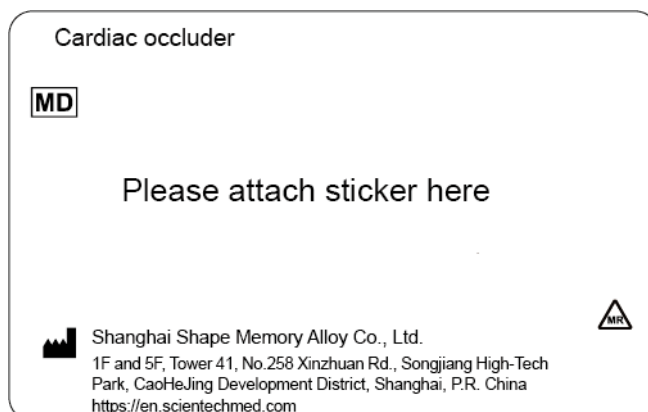
The front of the implant card, the design is as below figure:



The front of the implant card is a rectangular card with a rounded top. It features the SHSMA logo at the top left, followed by the title "International Implant Card". Below the title, there are four horizontal lines for text entry, each preceded by a small icon: a person with a question mark, a calendar, a person with a plus sign, and a computer monitor. At the bottom left, there is a small computer monitor icon next to the website URL "https://www.scientechmed.com/". At the bottom right, the text "IC-2022-01 Rev.01" is printed.

	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:

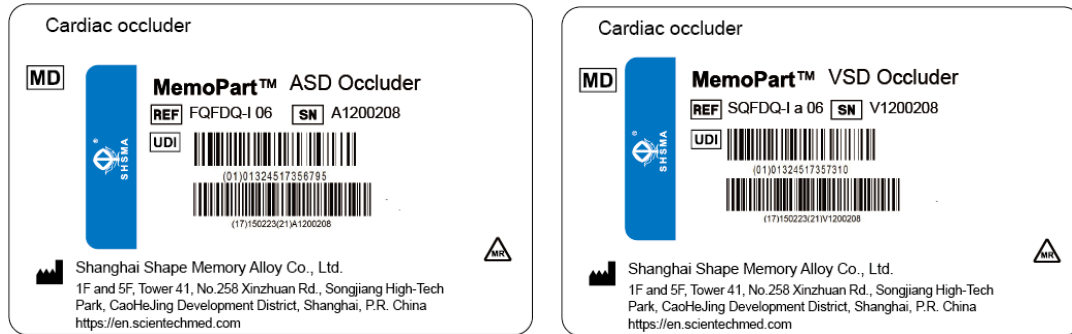



The back of the implant card is a rectangular card with a rounded top. It features the text "Cardiac occluder" at the top. Below this, there is a small box containing the letters "MD". In the center, the text "Please attach sticker here" is printed. At the bottom left, there is a small factory icon next to the company name "Shanghai Shape Memory Alloy Co., Ltd." and its address: "1F and 5F, Tower 41, No.258 Xinzhuang Rd., Songjiang High-Tech Park, CaoHeJing Development District, Shanghai, P.R. China". Below the address is the website URL "https://en.scientechmed.com". At the bottom right, there is a small triangle icon containing the letters "MIL".

Please tear off one peelable part of the device label on the package and attach it to the area of 'Please attach sticker here' on the back of the implant card and cover these words. 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	<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.