

Patient Implant Card










Purpose

The purpose of the Patient Implant Card is to inform patients about implantable products they have received, providing an easy access to all relevant information related to the device which the patients have been implanted with. In case of emergencies, it enables patients to inform the clinical staffs or first responders about any specific special cares they might need.

Background

In accordance with regulations, SigmaGraft, Inc. as the legal manufacturer provides the Patient Implant Card together with its implantable devices. The card must be filled with the required information by the healthcare institution or provider and handed to the patient. The card includes name of the patient, date of implantation, name and address of the implanting healthcare institution or provider, the information of the manufacturer of the medical device, and the information of the implanted device.

Below is a list of symbols used on the Patient Implant Card:

SYMBOL	DESCRIPTION
	Patient Name and Surname or Patient ID
	Date of implantation
	Name and address of implanting healthcare institution
	Patient information website
	Medical device
	Manufacturer's name, address and website
	Model of the device
	Indicates the manufacturer's lot code for identification purposes
	Indicates the date after which the medical device is not to be used

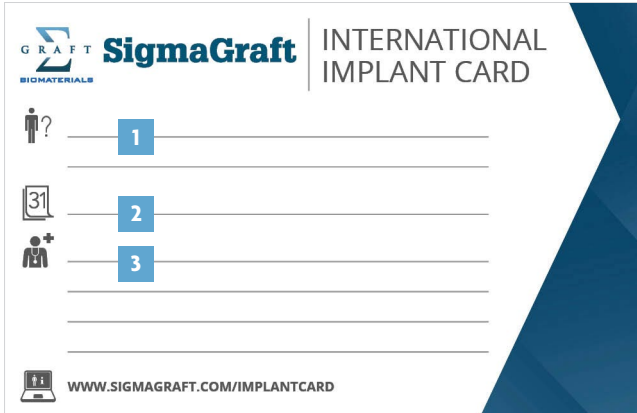
Instructions

The following items on the Patient Implant Card must be filled by the healthcare institution/provider:

- 1 The name and surname of the patient or patient ID
- 2 Date of implantation
- 3 The name and address of implanting healthcare institution/provider that performed the implantation
- 4 Information about the medical device
(This information is indicated on the labels adhered to the device's sterile packaging. Detach one and place it onto the designated field on the Patient Implant Card.)

Once the Patient Implant Card has been filled out completely, it must be provided to the patient.

Front of the card



The front of the card features the SigmaGraft logo and the text "INTERNATIONAL IMPLANT CARD". It contains three numbered fields for patient information: 1. Patient Name and Surname or Patient ID, 2. Date of implantation, and 3. Name and address of implanting healthcare institution. At the bottom, there is a field for the patient information website (WWW.SIGMAGRAFT.COM/IMPLANTCARD).

Back of the card



The back of the card contains a list of translations for "regenerative biomaterial" in various languages. Below this is a field for the "Product Name" (MD icon) with a dashed box labeled "4 PLACE STICKER HERE". At the bottom, there is contact information for SigmaGraft, Inc. (575 Sally Place, Fullerton, CA 92831, USA) and a reference number (SG-QSP-1700-12(Rev02)).

Medical device sterile packaging labels



Three examples of sterile packaging labels are shown. Each label includes the "Product Name", "Product Tagline", and "Product Specifications". The first label shows the full company name and address for both SigmaGraft, Inc. (USA) and mdi Europa GmbH (Germany). The second and third labels show abbreviated information with "LOT" and "REF" codes and an expiration date. Each label also features a QR code and a "STERILE" icon.