INSTRUCTIONS FOR USE – SAMO IMPLANT CARD

Introduction

The Implant Card is provided by the Company to the Health Institutions both in paper format, delivered with the device, and in electronic format, by downloading it directly from the company website www.samobiomedica.com in the section "Implant Card".

The information contained in the card and in these instructions are made available to the patient and the Health institution through the company website, or upon request by sending an e-mail to the address info@samobiomedica.com.

Figure 1: Example of Implant Card

Instructions for filling

The Implant Card (example in figure 1) is provided in a pre-printed version, but it's also possible to download it directly from the Company website.

Pre-printed paper format

To fill in the pre-printed format, proceed as follow:

- Fill in fields 1,2 and 3 (*figure 2*)

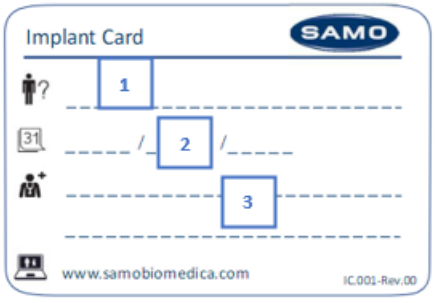


Figure 2

1 Patient name or patient ID

2 Date of the surgery

3 Name and address of the Health Institution

- Apply the specific label delivered with the device in the dedicated space (4) (*figure 3*)

Figure 3

4 Device-specific label

- Provide the Implant Card to the patient

! **ATTENTION: If several components are implanted, provide and fill in an Implant Card for each components**

Digital format

To fill in the digital format, proceed as follow:

- Access the following website: www.samobiomedica.com
- Access the section “Implant Card” reported in the website
- Download, print and cut the card
- Fill in fields 1,2 and 3 (*figure 2*)
- Apply the specific label delivered with the device in the dedicated space (4) (*figure 3*)
- Provide the Implant Card to the patient

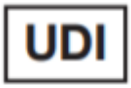
> ! **ATTENTION: If several components are implanted, provide and fill in an Implant Card for each components**

The Health institution are require to make available to all patients to whom the device (or devices) certified according to the EC Regulation 2017/745 has been implanted, the following information:

- Warnings, precautions, or measures to be taken by the patient or a healthcare professional about the reciprocal interference with other devices (example Magnetic resonance), medical examinations, or environmental conditions; for such information refer to the device instructions for use.
- Information about the expected lifetime of the device; for such information refer to the device instructions for use.
- Information about the necessary follow up.
- Any other information to ensure the safe use of the device by the patient; for such information refer to the device instructions for use.

All the above-mentioned information are available also for devices certified according to the EC Regulation 2017/745. The Health institutions are responsible for monitoring the Company website for any updates to the above-mentioned additional information and they must be made available to all patients with the implanted device.

SYMBOLOGY

	Name or ID of the patient
	Date of the surgery
	Name and address of the Health Institution
	Use by
	Lot number
	Reference number
	Patient information website
	Manufacturer
	Sterilized using irradiation
	Sterilized using ethylene oxide
	Medical device
	Unique Device Identifier