

Implant Card: Informative Instruction Leaflet

Description

An Implant Card (IC) is given to patients who receive any JRI Orthopaedics Ltd. implantable device. The implant card is provided within the box of each device. A Patient Label (sticker) is also provided with each device; this outlines all relevant information for the patient that is specific to the medical device.

The IC intends to:

- Enable the patient to identify the implanted devices and to get access to other information related to the implanted device (e.g. via EUDAMED, and other websites).
- Enable patients to identify themselves as persons requiring special care in relevant situations e.g. security checks.
- Enable e.g. emergency clinical staff or first responder to be informed about special care/needs for relevant patients in case of emergency situations.

Instruction for Completion

The healthcare institution/provider should stick the appropriate Patient Label (sticker) onto the spaces specified on the patients Implant Card.

Lines **1**, **2** and **3** of the Implant Card should be completed by hand, by the healthcare institution/provider (see Figure 1):

1. Name of the patient or patient ID.
2. Date of implantation.
3. Name and address of the healthcare institution/provider.

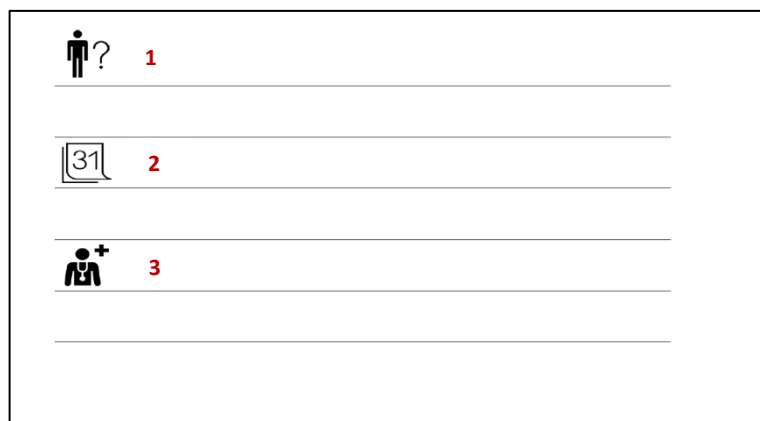
















Figure 1 shows a section of the Implant Card with three numbered fields for completion:

- 1**: Name of the patient or patient ID. (Icon: person with question mark)
- 2**: Date of implantation. (Icon: calendar)
- 3**: Name and address of the healthcare institution/provider. (Icon: person with plus sign)


Figure 1. Implant Card section to be completed by the healthcare institution/provider.

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Symbols that may be included on the Implant Card and/or Patient Labels are defined within the table below:

Symbols	Description
	eIFU Indicator. Electronic Instructions for Use is available on the manufacturer's website. Read the instructions for use.
	Batch number, batch code or lot number.
	Catalogue Number
	Read the instructions for use/ electronic instructions for use.
	Use by date.
	Manufacturer – JRI Orthopaedics Ltd.
	Medical Device
	MRI Conditional
	The device meets the essential requirement of the European Medical Device Regulations
	The device meets the essential requirement of the UK Medical Device Regulations
	Contains hazardous substances
	Patient Name or patient ID (see Implant Card)
	Name and Address of the implanting healthcare institution/provider (see Implant Card)
	Date of Implantation (see Implant Card)

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	Information website for patients (see Patient Label)
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