INSTRUCTION FOR USE (IFU) OF IMPLANT CARD

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How does this work?

This factsheet explains implant card requirements, how Ortonom Medical is fulfilling those requirements, and the responsibilities of manufacturers, HCPs, and patients.

What is the Implant Card?

The Implant Card is required by the EU/MDR to be shipped with the device and given to the patient. The Implant Card contains device specific information with a link to the eIFU website for patients to obtain the Implant Leaflet and view additional device information.

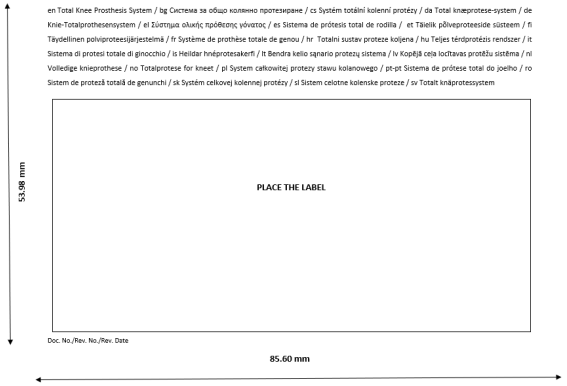
Implant Card

A. The healthcare institution or provider completes the following information:
1. Name of the patient or patient ID.
2. Name and address of the healthcare institution or provider.
3. Date of implantation.

B. The sticker shows the following information:
4.1. Device name.
4.2. Device type (provided in the accepted language).
4.3. Unique device identification (UDI).
4.3.1 UDI-DI: Device Identification Number.
4.4. REF Number
4.5. LOT Number
4.6. Name and address of the manufacturer of the medical device.

FRONT

BACK



Instructions

1. Use the language spoken by the patient to fill out the Patient Implant Card.
2. Fill in the name and surname of the patient (or patient ID).
3. Fill in the date of implantation.
4. Fill in the name and address of the healthcare institution / provider which performed the implantation.
5. Remove one of the patient labels that includes the data matrix code from the sterile packaging and stick it on the designated field.
6. Once the Patient Implant Card has been filled out completely, it must be handed over to the patient. The purpose of the Patient Implant Card and the information contained

therein must be explained to patients in a language that they understand.

Explanations of the symbols use

	Patient name or patient ID
	Name and address of the implanting healthcare institution or provider
31	Date of implantation
MD	Device name
	Manufacturer
	Information website for patients
LOT	LOT Number
REF	Reference number
UDI-DI	UDI-DI: Device identification number
UDI	Unique device identifier

Examples for how to fill out the patient implant card completely

To help you fill out the card, see the following examples with explanations. These examples should help you check the content of the patient implant card for completeness and accuracy prior to giving it to the patient.

A fully completed patient implant card contains:

> the patient's name in full or patient ID

> date of implantation

> full name and address of the healthcare facility performing the implantation

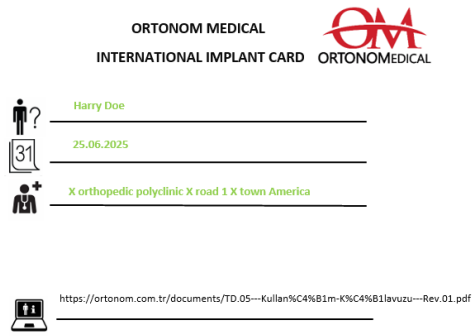
An incompletely filled out patient implant card, for example, contains:

> illegible and partial details

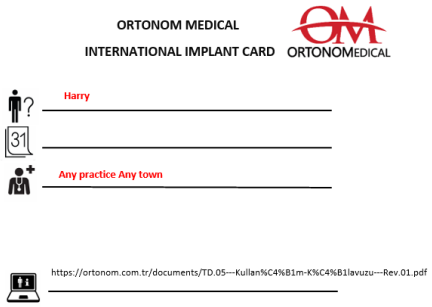
> abbreviations which are not customary

> incomplete name and address of the healthcare facility performing the implantation

A fully completed patient implant card example



An incompletely filled out patient implant card example



e-IFU

HCP directs patient to visit the Ortonom Medikal eIFU website to view and download the device specific Patient Implant Leaflet Implant device information is available to patients via the eIFU website https://ortonom.com.tr/qrdirected-010 the folder.