

Implant Cards – Instructions for Healthcare Organizations

Foreword

Neo Medical as legal manufacturer of the Neo Pedicle Screw System™ and Neo Cage System™ has to provide Implant cards and product safety information to the patients. This leaflet provides indications on how to fill in implant cards and provide information to the patient.

In Europe, European Economic Area, Switzerland, USA and Australia the implants must be accompanied by an implant card. Neo Medical provides these cards inside the packages of the rods for Neo Pedicle Screw System™ and inside the packages of the cages for Neo Cage System™.

After implantation of a Neo Medical implant the surgeon or treating physician shall provide the implant card duly compiled to the patient and provide adequate information related to safety, the post-operative precautions and required regular and extraordinary follow-up visits.

Official patient brochures for the Neo Pedicle Screw System™ and the Neo Cage System™ are available for download from Neo Medical Website in the Patient Section (www.neo-medical.com/patient).

Implant Card

Neo Medical provides folded implant cards inside the packages of the rods for Neo Pedicle Screw System™ and inside the packages of the cages for Neo Cage System™. The following pictures shows an example of the unfolded two sides of the implant card.

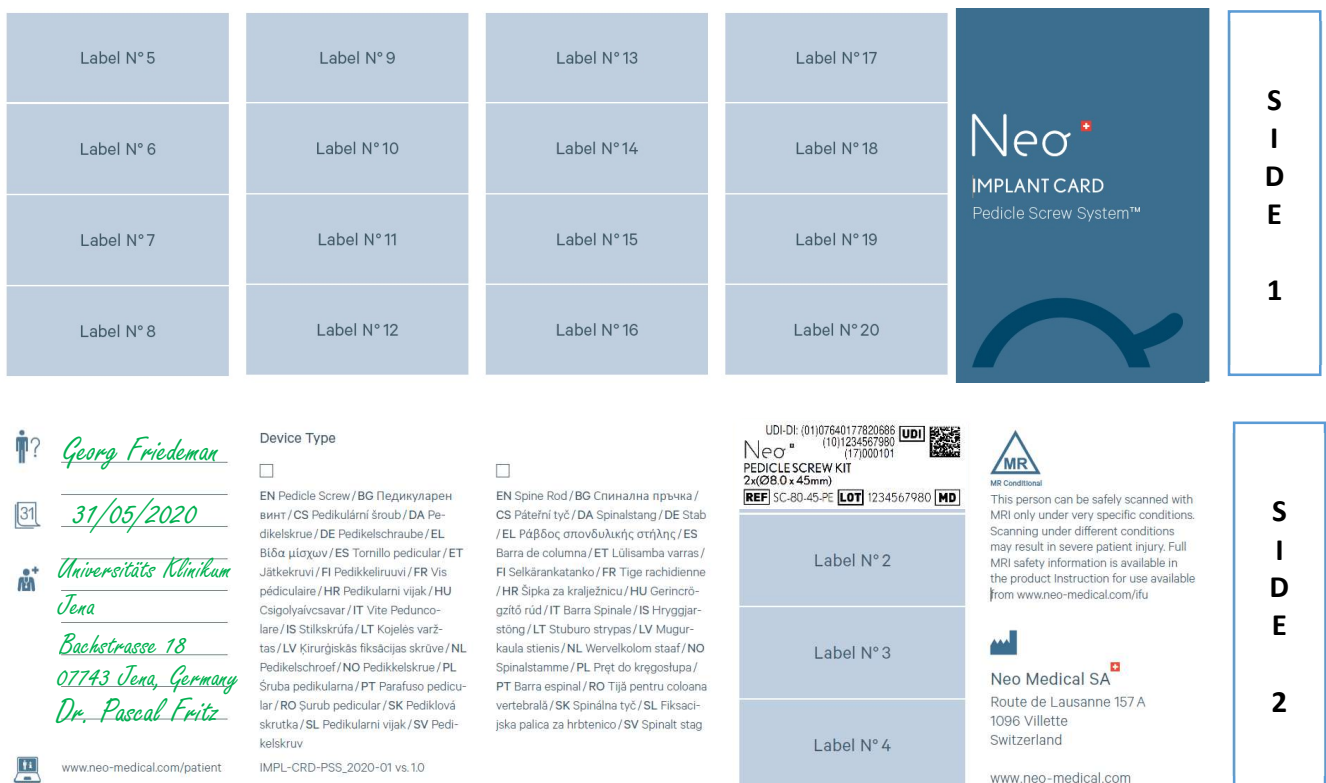


Figure 1 – unfolded implant card sides

First Surgery

After surgery the implant card must be filled in and labels of Neo Medical products implanted must be stuck in the appropriate places as shown in the following examples:

Figure 2 – example filled card

Figure 3 – example labels placement

The meaning of symbols is provided in the section at the end of this leaflet.

To fill in the implant card a standard pen can be used, however it is recommended to use permanent ink pens.

In principle only labels belonging to implants from Neo Medical should be attached on the implant card. Do not stick labels of instruments.

If label space is insufficient please provide a second implant card. We recommend you to have spare implant cards which can be ordered at Neo Medical and are delivered free of charge.

Explant / Revision Surgery











In case of explantation of one or more components and subsequent substitution of any component the implant card shall be updated by striking the components that are explanted and writing the date of explantation (see following example). A new implant card shall be completed for any new component that are implanted.


Figure 4 – example for explanted components



Please remind the patient to make a photocopy or a scan copy of the implant card and conserve this copy in a safe place away from sources that can deteriorate it.

Explanation of symbols on the Implant Card

	Manufacturer		Catalogue Number
	Unique Device Identification		Lot number
	Medical Device		MR Conditional
	Patient identification		Date of operation
	Health care centre and/or doctor		Patient information website

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