Neo Pedicle Screw System™ – Patient brochure

General information

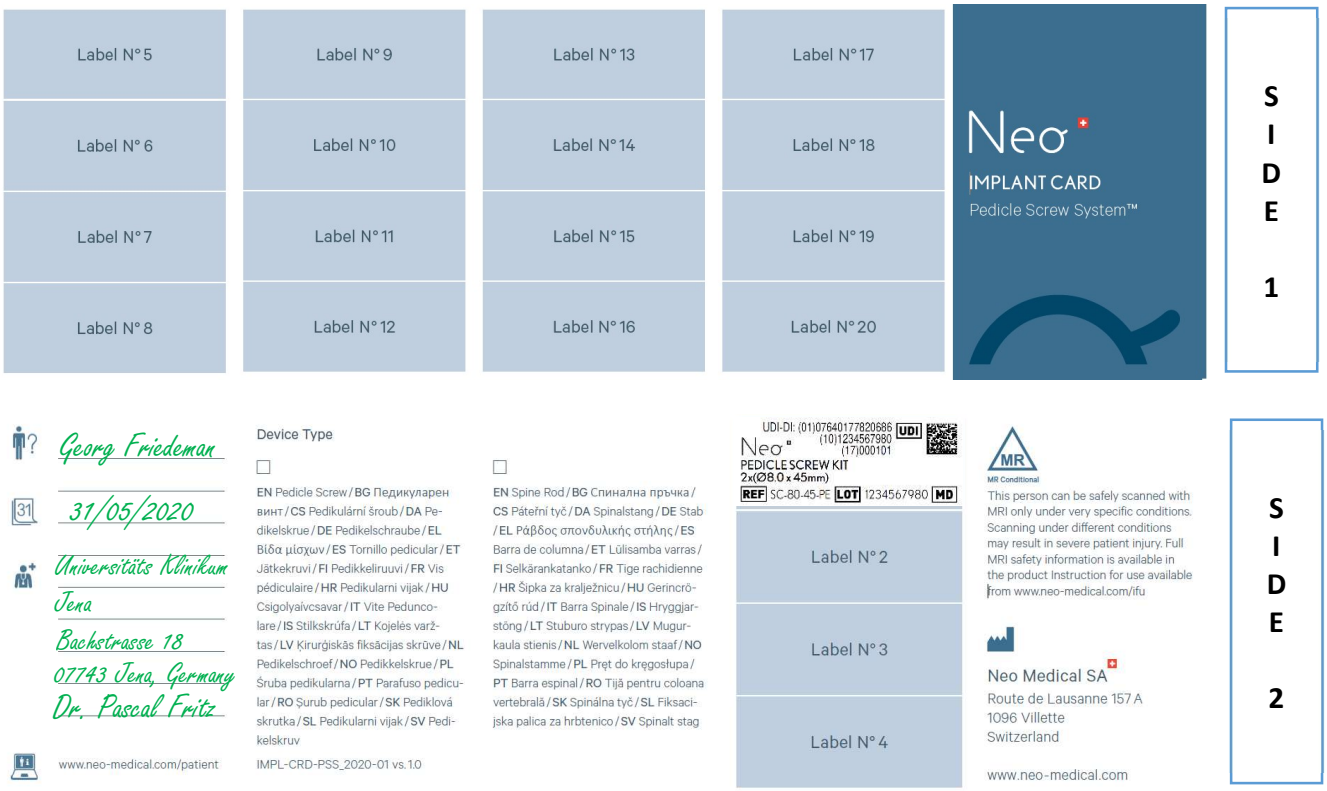
If you have been implanted a NEO Pedicle Screw System™ please read the following information. If you have any question or need further detail you can contact Neo Medical (www.neo-medical.com/contact) or your treating physician.

Neo Medical as legal manufacturer of the NEO Pedicle Screw System™ has to provide the following information to the patients. The information below is sourced from the Instructions for Use and general best practices in spine surgery.

The aim of spine surgery is to immobilize either temporarily (in some trauma cases) or permanently two or more levels of the spine. The effect of this treatment is necessary to treat your medical condition but also results in the inability to bend or rotate at the level of the spinal fusion. In any case there are ways to compensate this limitation in body motion, please ask your treating physician or physiotherapist.

Details on the implants you received are included in the Implant Card you should have received after surgery. On the Implant card there are all labels of the implants which include the device name, lot number, the Unique Device Identification (UDI), the device model as well as the name, address and the website of the manufacturer.

The following pictures provides an example on how the foldable implant card has to be filled in.



Please keep your implant card with you and make a photocopy or a scan copy to be kept in a safe place away from sources that can deteriorate it.

Safe Use and necessary follow-up

Before undergoing surgery and upon discharge you should have received clear indication from your treating physician on precautions and measures you should follow to ensure the best outcome of the treatment. Please follow always the indications of your treating physician.

Your treating physician shall advice you on any activity and weight-bearing limitation, especially for the healing time after surgery. Please stick on the follow-up schedule required by your treating physician and report any strange feelings and events which in your view could have affected the implant, for example: back pain, redness of skin on the area of the surgery, recurrent fever, any fall, hits or strange movements that you experienced.

If you fall in one of these conditions, there are higher chances to experience an adverse effect after surgery. Please consider taking adequate measures if you fall in one of these cases:

- Obesity
- Malnourishment
- Alcohol abuse
- Smoking, use of nicotine products
- Poor muscle and bone quality
- Nerve paralysis

During the healing process it is strongly recommended not to smoke tobacco, utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin which could affect the fusion and therefore result in failure of the surgery.

In many trauma cases the NEO Pedicle Screw System™ may be removed after healing, especially in young patients. In trauma and in all the other cases the decision whether to remove or leave the implants in the body lies within the responsibility of the treating physician and depend highly on patient conditions (e.g. ability to withstand another surgery). Please be aware that in both cases there are risks, ask your treating physician what is the best follow-up during and after the healing process.

As a precaution, before receiving any subsequent surgery (such as dental procedures), ask your treating physician if prophylactic antibiotics may be considered, especially for high-risk patients.

Expected lifetime

Lifetime of implants depends on many factors, such as the overall state of health of the patient, the level of activity, the exposure to mechanical stress, bad health habits (smoking, alcohol consumption). Your treating physician shall also regularly follow-up the status of the implants. Without following the precautions provided within this leaflet the product lifetime can be strongly reduced. Data available on similar implants show that pedicle screw systems, if not explanted, can be left in the body for an indefinite time.

Material and substance

NEO Pedicle Screw System™ implants are made from materials that are in use for implantation since many years in humans and show excellent properties for use in spinal systems. The rods, the connectors and the screws are made out of Titanium alloy is conforming to the international standards ISO 5832-3 and ASTM F136. The 500 mm rods are available also in CoCr alloy conforming to international standards ISO 5832-12 and ASTM F1537. All materials were tested according to the biocompatibility standard ISO 10993-1 which confirmed that these materials are suitable for long term implantation. Based on the biocompatibility tests required by the international standard ISO 10993-1, there is no indication that the long term implantation of device can cause adverse health effects.

It is common practice, especially in case of known allergies, to undergo allergy testing before implantation to test material compatibility and rule out potential adverse reactions. Although, given the multiplicity of materials and products used during and after surgery, inflammatory processes, infections or adverse reactions are to be considered as part of possible adverse effects.

Warning related to possible Interference

In case you need to undergo a Magnetic Resonance Imaging (MRI) exam with the NEO Pedicle Screw System™ please inform the clinician about the following.

 MR Conditional	MRI Safety Information Non-clinical testing and MRI simulations and human body model for *in vivo* modeling were performed to evaluate the entire family of the Neo Pedicle Screw System™. Non-clinical testing demonstrated that the entire family of the Neo Pedicle Screw System™ is MR Conditional. A patient with an implant from this family may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5-T and 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

When travelling have always the Implant Card with you and inform the security check personnel about your implant before entering the scanner. The implants you have are not affected by security check scanners.

Product Complaints

In case you are dissatisfied with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, you can notify Neo Medical via the contact information available on the webpage. We take care of every feedback, nevertheless we will need to know from you detailed information about the complaint and receive adequate objective evidence (e.g., complete pre-operative, surgery and post-operative reports and examinations), have contact information of your treating physician to confirm and get necessary information.
For data protection laws we cannot have access to the above mentioned information without receiving your written consent, therefore we will need you to sign our forms. Without receiving your consent, it might not be possible for us to process your complaint.
Reporting of Australian adverse events: www.tga.gov.au

Explanation of symbols on the Implant Card

	Manufacturer		Catalogue Number

UDI	Unique Device Identification	LOT	Lot number
MD	Medical Device	MR Conditional	MR Conditional
	Patient identification	31	Date of operation
	Health care centre and/or doctor		Patient information website

Neo Medical S.A.
Route de Lausanne 157A
1096 Villette
Switzerland

CE 0476