Neo Cage System™ – Patient brochure

General information

If you are going to receive or you have been implanted a NEO Cage 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.

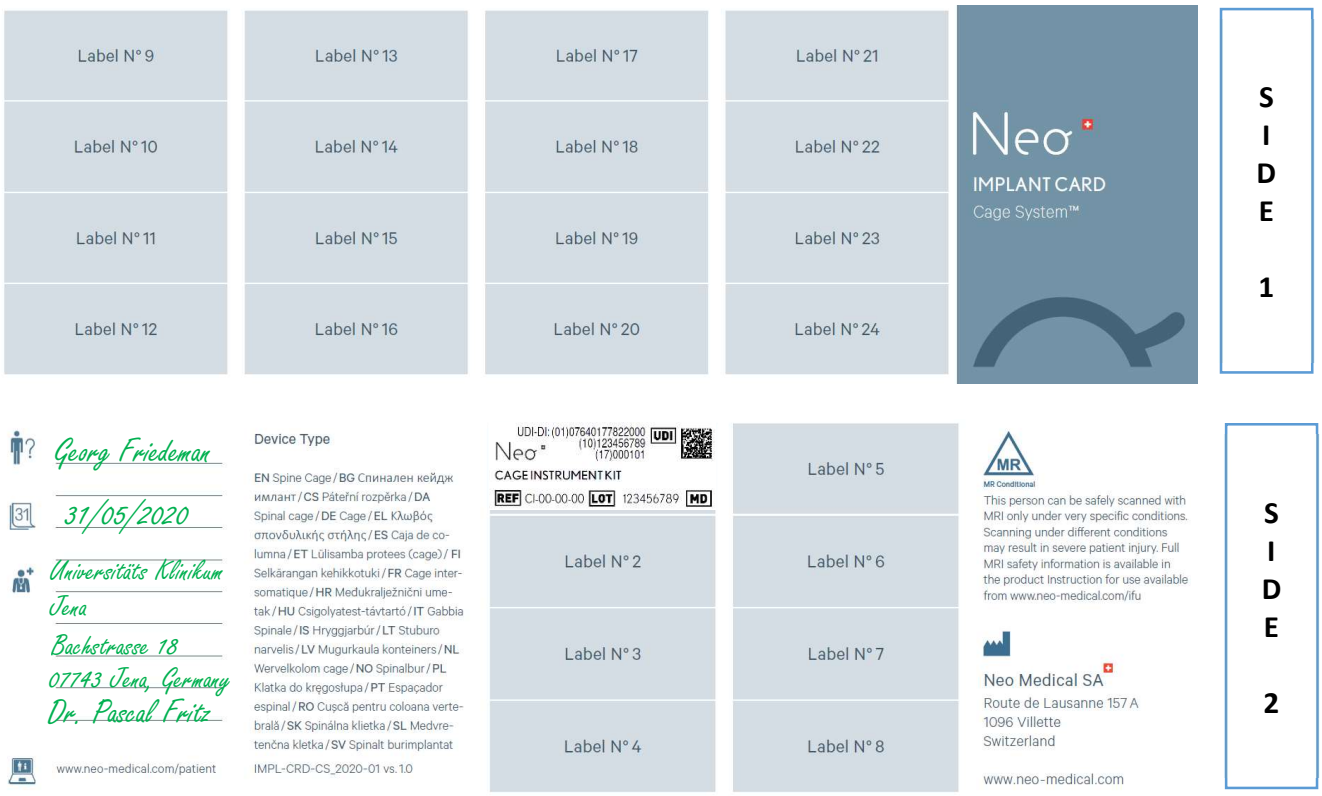
Pease also check from time to time for any updates of the information contained in the present brochure that will be made available to you via the www.neo-medical.com website.

Neo Medical as legal manufacturer of the NEO Cage 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 using cages is to immobilize two or more levels of the spine. This procedure is necessary to treat your medical condition, however it 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 always follow 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. Before resuming full weight bearing the fusion of the levels treated Neo Cage System™ shall be confirmed by radiological examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.

Please stick to 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-steroidal or anti-inflammatory medications such as aspirin which could affect the fusion and therefore result in failure of the surgery.

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 cage systems, if stable fusion is achieved, can be left in the body for an indefinite time.

Material and substance

Neo Cage System™ implants are made from materials that are in use for implantation since many years and in humans and show excellent properties for use in spinal systems. The cages are made from Titanium alloy is conforming to the international standards ISO 5832-3 and ASTM F136. 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 Cage 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 Cage System™. Non-clinical testing demonstrated that the entire family of the Neo Cage 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 undergoing security check with portable or walk-through detectors have always the Implant Card with you and inform the security check personnel about your implant before any screening or 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
	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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