GENERAL INSTRUCTIONS FOR USE
SPINAL SYSTEM "DERO"

Manufacturer:
LfC Sp. z o.o.
Kożuchowska 41,
65-364 Zielona Góra, Poland

CE 1434

REALIZATION
The products meet the requirements of Directive 93/42 EEC concerning medical devices (including later amendments) for compliance with the European Union's safety requirements. Meeting the requirements of Directive 93/42/EEC has been confirmed by the Notified Body PCBC S.A. (Polish Centre for Testing and Certification), Identification Number of the Notified Body - 1434.
The quality management system is compliant with EN ISO 13485. The products are delivered in a sterile or non-sterile state.

MATERIAL
Implants are executed from special high-grade materials: stainless steel, titan, titanium alloy (form – solid, powder), polymers, which fulfil requirements contained in: ISO 5832 "Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy", ASTM F136 "Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications", ASTM F3001 „Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion", ASTM F2026 "Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications". Products made of the above materials allow use of typical diagnostic techniques.

DESTINATION AND INDICATIONS
Devices of Spinal System DERO, applied in orthopaedic and neuro-surgery, are designed for support of the human's musculo-skeletal system. Spinal System DERO includes multifunctional, compatible, universal surgical implants designed for biomechanical support and for reconstruction of anatomical structures, moreover the special instruments make possible the proper and safe performing of surgical procedures.

CONTRADICTIONS
- local or general infections;
- reduced endurance of bone caused e.g. osteoporosis, which make impossible the proper fixation of implant,
- allergy of patient onto implants material or onto chemical components contained in implants;
- bad general condition of patient carrying with itself great risk of health worsening or losses of life in result of surgical treatment;
- lack of patient's agreement for operating treatment or another medical prescriptions and recommendations;
- pregnancy, obesity;
- patient's mental disease;
- patient addiction to alcohol, drugs or others;
- other contradictions connected with surgical treatment of patient with implants, which can exclude potential advantages of operating treatment.

RECOMMENDATIONS
- device is sold on basis of catalogue offer, exclusively onto physician's order or entitled medical institution;
- devices not included in the catalogue (special orders, for scientific researches) are sold only on well signed, written customer`s order; responsibility for use of these devices passes on the customer;
- surgical operations with use of implants should be performed by the adequately prepared operative team, experienced and well trained surgeons, and in well prepared medical center;
- it courts that the operating use Spinal System DERO should be preceded with practical training in experienced medical center;
- surgeon should know the biomechanical properties of implants, material's limitations connected with the use of implants and technique and conditions of their installation;
- before operation patient should be warned and informed, that implant:
  - does not fully replace healthy bone and it cannot transfer excessive loads, it may undergo to loosening, deforming and even breaking;
  - may be damaged in consequence of lack of adoption of postoperative prescriptions;
  - may affect as an allergen as a consequence of unfavourable, bio-physics-chemical reactions and mechanical influence.
- patient should be warned about the necessity of informing the physician about possessing implants in his body by every next medical treatment;
- it courts to check the patient's sensibility onto chemical components contained in implants;
- proper choice of implants should be performed by surgeon every time, with consideration of the patient's clinical, biological, biomechanical and another data, which may influence the treatment process;
- implants should be inserted in the proper surgically prepared place and fixed one to another in accordance with biomechanical rules;
- it courts that implant should remain in body until fulfilling of its functions, but not longer than 2 years, unless other medical regards show differently or the implant is a prosthesis;
- patient must be aware, that longer remain of implant in body carries with itself high risk of complication including the normal mechanical and the bio-physics-chemical consumption;
- diagnostic and therapeutic techniques applied after the surgical treatment require special knowledge, including the knowledge about installed implants;
- special attention and physician's consultation is recommended, in case when patient is subject of energy influences e.g. vibrations, high frequency field emission, diadynamic energies and another external influences, which may affect the implant with negative consequences for the patient;
- in case of functioning changes of implant, patient should immediately contact his physician.

Note:
before operation patient or his legal guardian should be informed about benefits, potential limitations and threats resulting from implantation treatment, having implants in body during healing process and consequences of not removing or conscious leaving implant in the body after fulfilling of its supporting functions in the healing process.

USING
- implants of Spinal System DERO are designed exclusively for single use;
- date of expiry as well as general state of implant and package should be checked before the use. Any damage of implant and/or device eliminates its form further use;
- for sterile devices the date of expiry of sterilization process should be additionally checked;
- every implantation as well as removal of implant can be hold only by using special DERO instruments;
- every operation should be planned suitably; selection of type and quantities of implants should be accomplished by experienced surgeon on basis of suitable diagnostic data as well as individual patient's conditions;
- it is inadmissible to make any changes in geometry of implant before and during the operation unless the manufacturer indicates differently;
- it is inadmissible to apply DERO-implants together with implants of other manufacturers as well as mixing delivered sets;
- mechanical damage and other damage of implant's surface is forbidden;
- every efforts should be made to decrease load bearing by the implant and the points of applied forces were chosen according to biomechanical rules;
- manufacturer does not bear responsibility in case of inappropriate use of the devices.
- each implant delivered by manufacturer is placed in separate package with sticked label containing information concerning implant and manufacturer. Additionally each implant contains identification labels. This label should be removed from the package, sticked on the implantation card to secure it in the hospital records. In case of any complications the implants should be removed.

THREATS
- lack of osseous concrescence caused as a result of intolerance of implant in the body;
- allergy of patient onto chemical components included in the implant;
- irritation of skin e.g. allergic or mechanical;
- discomfort, abnormality or pain caused by the presence of foreign body in the organism;
- mechanical waste or degradation of physics-chemical processes, especially in points of join of implants,
- loosening or damage/brakeage or migration of implant, destabilization of the stabilizer resulting from inappropriate biomechanical selection, incorrect implantation, utilizable wear because of disregarding of postoperative prescriptions;
- solid paralysis resulting from inappropriate fixing or loosening of the implant or moving of implant caused by extreme life actions of patient;
- bleeding, scarring, infection, injury of vessels or another organs;
- another general surgical and hospital threats.

PROPERTIES AND TECHNIACAL FACTORS (KNOWN TO THE PRODUCER), THAT MAY INVOLVE RISK FACTORS IN CASE OF PRODUCT RE-USE
The insufficient role of the product in patient's body (e.g. loosening, migration, vulnerability, accelerated wearing, infection) caused by:
- infection caused by contamination, which was introduced to the product during its first usage;
- previous mechanical, chemical interference in the surface of product, causing the changes in physical and mechanical properties (including the loss of biotolerance);
- breakage/damage of the product (e.g. scratch, cracking, chipping, deformation, flexion, fracture);
- loss of compatibility with other elements of the system, which leads to the loss of its function, damage or defecting of other products of the system;
- incomplete number of the product`s elements (loss of junction/cooperation with other components) after first usage or after renewed preparation of the product;
- difficult or disabled cooperation of the product with surgical instruments;
- inability to identify the signature/trading mark due to the it`s damage (this also refers to the inappropriate selection of the product size, lack of cooperation with surgical instrument; inability to identify the origin/LOT number, usage of a product with unknown origin).

REMOVAL
- well-chosen fixator is designed to serve biomechanical function only in those cases, where after suitable surgical preparation it is followed by osseous concrescence and interception of this functions through the musculo-sceletal system;
- after fulfilling the healing function implant should be removed, unless there are important indications motivating implant leaving in organism, about what patient should be informed,
- implant removing should be performed in accordance with implant removing procedure recommended by manufacturer and resulting from general international standards; removal should be documented in enclosed "Card of use of implant".

STERILIZATION
Devices delivered by LfC are sterilized according to recommended standards: steam method according to EN ISO 17665-1 and irradiation method according to EN ISO 11137-1, -2:
- if the device is delivered into the special trays and sterilization cases or single foil-paper pouches, it should be washed and sterilized;
- if the device is delivered into the double foil-paper pouches with indicators of sterilization process (with or without the outer cardboard boxes) it should only be sterilized;
- sterility cannot be guaranteed if the packaging has been destroyed, damaged. Check carefully the packaging before use;
- expiry date of implant as well as expiry date for sterilization (in case of sterile devices) is situated at the brand label;
- check the expiration date of sterilization. Do not use device with expired sterilization date;
- devices originally steam sterilized according to EN ISO 17665-1 norm can be resterilized only in case when they have not been in contact with a patient and aren't damaged. Do not resterilized single use products which were in contact with a patient's blood, bone, tissue or body fluids.
  It is allowed to perform steam resterilization by end user of the product. In this case end user takes full responsibility for proper performance of the steam sterilization process. Devices can be steam sterilized only by the method complying with EN ISO 17665-1. Sterilizers differ in design and performance characteristics. Parameters of the sterilization cycle and load configuration have to be verified according to the instruction for use provided by the producer of sterilizer. Guidelines concerning resterilization can be found in ""Handling instruction for SURGICAL IMPLANTS intended for re-/multiple sterilization" and "Handling instruction for SURGICAL INSTRUMENTS intended for re-/multiple sterilization";
- devices should be repacked in packaging intended for steam sterilization that meet the requirements of EN-ISO 11607-1 and marked with CE mark;
- it must be strictly obeyed to do not resterilized devices which were first sterilized with irradiation method. These products must be returned to the manufacturer.

11. STORAGE
- Storeroom should be free of any insects, dust, available for authorized personnel only, located far away from major communications roads, in case of storage onto the shelves the distance from the floor should be equal at least 30cm;
- Devices should be stocked into undamaged packaging, in the separate dry room, at temperature approximately 23°C (15-25°C) and humidity approximately 50% (40-60%);
- Damaging of implant and/or package during the transport and storage eliminates it's from further use;
- It is acceptable to repacking devices in the specialist medical center only when all of the subject standards are restricted, including EN ISO 11607-1 "Packing for terminally sterilized medical devices"

Note:
The manufacturer does not bear any responsibility for devices in case of disregarding the Instruction for Use.

** devices are protected by patent law,*
*** LfC is exclusive owner of the project*

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INFORMATION CONCERNING THE CHANGE OF A NOTIFIED UNIT

LfC Sp. z o.o. informs that from 02/09/2018, the notified body certifying the company's products is the PCBC S.A. (Polish Centre for Testing and Certification), Identification Number of the Notified Body - 1434. PCBC S.A. completed the assessment of conformity of LfC Sp. z o.o. with a positive result and issued the CE certificate No. 1434-MDD-098/2018, 1434-MDD-291/2020. In connection with the above, LfC changed the labels for the products by entering the CE1434 mark. On the inner packaging and on the product, however, there may be different notifications of the notified body, ie CE 0434 DNV GL Business Assurance, CE 2460 DNV GL Nemko Presafe AS (these are the designations of the previous notified bodies of the LfC company). PCBC S.A. on the above circumstance issued a letter (available on the LfC website, www.lfc.com.pl,, tab "About the company", "Certificates"), informing that they have the full knowledge about the existing situation and taking over responsibility for the products manufactured by LfC so far.

Additional information is accessible (address for correspondence):

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CE 1434

The meaning of the symbols contained in the LfC Sp. z o. o. products label (symbols according to EN ISO 15223-1 standard).

	**„CAUTION”**		**„DO NOT RESTERILIZE”**
	**„DO NOT REUSE”**		**„DO NOT USE IF PACKAGE IS DAMAGED”**
	**„STORE IN TEMPERATURE 15 °C ÷ 25 °C”**		**„STORAGE IN HUMIDITY 40% ÷ 60%”**
	**„KEEP AWAY FROM SUNLIGHT”**		**„CONSULT INSTRUCTIONS FOR USE”**
	**„KEEP DRY”**		**„NON STERILE”**
	**„STERILIZED USING STEAM”**		**„STERILIZED USING IRRADIATION”**

Implant Use Card

Each implant sent by manufacturer is placed in separate packaging with fixed label containing information about device and its producer. Adhesive identification labels are also included. Label should be removed from packaging, attached to implant use card and secured in hospital documentation. In case of complications implant should be removed according to the rules of deposition.

Only fulfillment of manual's recommendations obliges manufacturer to consider any complaints.

Gender …….. Age …….. Name and Surname ……..……..……...

Recognition ……..……..……

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Medical documentation number ……

Physician's Name and Surname ……...

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Name and Surname of the person completing the document ……..……

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Documentation of used device – Label/Labels: