GENERAL INSTRUCTIONS FOR USE OF SPINAL SYSTEM "DERO"

Manufacturer:
LfC Sp. z o.o.
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CE 1434

DESCRIPTION

"DERO" Spinal System is a complete set of interconnected, compatible implants, surgical instruments, and surgical techniques. The system comes in multiple variants thanks to a combination of different implants, taking into account biomechanical needs of stabilization in the following sections of the spine: occipital, cervical, thoracic, lumbar, and ilio-scaral. Different types of implants, fixed to/in the bone create suitable for the disease, stabilizing, and load-bearing construction.
The selection of the type of the elements forming the stabilizer, their quantity, and size is made by the doctor-surgeon, depending on the disease, section of the spine, patient's individual data, age, mass, dimensions, and quality of the bone, also taking into account the anatomical, physiological, and biomechanical requirements of the stabilization.

PURPOSE AND INDICATIONS

Devices of the "DERO" System are intended for support of the skeletal, musculoskeletal and locomotor system in orthopedic and neural surgeries.
"DERO" System includes multifunctional, mutually compatible, and universal surgical implants, intended for biomechanical support and reconstruction of anatomical structures, with specialized surgical instruments to ensure correct and safe performance during surgical procedures.
Implants are designed to take on biomechanical functions, in cases in which during the treatment surgically provoked bone fusion occurs, and temporary stabilization functions are overtaken by the musculoskeletal system, or due to other treatment needs, to temporarily support the spine.

Indications:

Screw, screw-hook stabilizers: screws, hooks, anchors, rods, connectors	
– deformities, curvatures (i.e. scoliosis, kyphosis and/or lordosis),	– spondylolisthesis,
– DDD Degenerative Disc Disease,	– infectious changes,
– trauma (i.e., fracture or dislocation),	– rheumatoid changes,
– iatrogenic segmental instability,	– neoplastic changes.

Ilio-lumbo-sacral screw stabilizers:	
– sacroiliac joint degeneration,	– sacroiliac joint injury,
– trauma (fractures) to the sacrum of the spine,	– postpartum sacral pain.

Vertebral stabilizers: plates	
– DDD Degenerative Disc Disease,	– trauma,
– disc herniation.	– spondylosis,
– neoplastic changes,	– infectious changes,
– stabilization after corpectomy,	– stabilization after discectomy.

Intervertebral stabilizers: cages	
– DDD Degenerative Disc Disease,	– instability, trauma,
– spondylolisthesis,	– stenosis,
– neoplastic changes,	– disc herniation.

Vertebral body stabilizers: spacers, vertebral brackets	
– stabilization after corpectomy,	– neoplastic changes,
– multilevel spondylosis,	– infectious changes,
– vertebral body fractures (traumatic, explosive, osteoporotic),	– stenosis.

Interspinous stabilizers:	
– degenerative joint disease,	– intervertebral disc protrusion,
– central stenosis, stenosis of the intervertebral foramina,	– neurogenic claudication.
– DDD Degenerative Disc Disease,	

Target patient group

Implants should be used accordingly to the purpose, indications, contraindications, and with consideration of individual anatomy and health conditions of the patient.

Target user

The devices are intended to be used only by qualified, professional medical personnel (a professional user), e.g. surgeons, doctors, operating room staff, and persons involved in the preparation of the device for the surgery. Personnel using the device should be fully familiar with the instructions for use, surgical procedures, and if applicable, with instructions provided in the Sterilization section (available at www.lfc.com.pl, Devices - IFU tab).
Implantation of the device should be performed following instructions for use, under the recommended surgical technique. The surgeon should ensure, that the device is suitable for the patient and that the installation is carried out correctly.

MATERIALS

Devices are made with special, biocompatible materials:

Material	Standard	Chemical composition [values% max%]
Implant steel	ISO 5832-1, ASTM F138	Mo3.0, Mn2.0, Cr19.0, Si0.75, Ni15.0, S0.01, C0.03, N0.1, P0.03, Cu0.05
Titan	ISO 5832-2, ASTM F 67	Ti≥98.9, Fe≤0.30, O≤0.25, C≤0.080
Titanium alloy	ISO 5832-3, ASTM F136	Al6.75, V4.5, Fe0.3, O0.2, C0.08, N0.05, H0.009, Ti rest
	ASTM F3001	Al6.75, V4.5, Fe0.25, O0.13, C0.08, N0.05, H0.012, Ti rest
Polymer	ASTM F2026	100% ASTM F2026

Compatibility with MRI

MR conditional

Safety of device defined as MR conditional.
Devices made of implant steel. Non-ferromagnetic material. However, residual magnetism is present, which may result in a residual magnetic interaction in the MR environment. Having an implant made of implantable steel is considered as a relative contraindication to the MRI examination.
Devices made of titanium, titanium alloy. Non-ferromagnetic material. The literature on the subject and scientific research have shown the safety of the titanium alloy implants inside magnetic fields between 1.5 Tesla and 3 Tesla. This applies to passive, non-ferromagnetic implants.
These materials have a potential risk of heating or migration in the MR environment, as well as the formation of artifacts in the vicinity of the implant, interfering with the diagnosis.
Devices made of polymer materials. Non-metallic and non-ferromagnetic material does not pose threat when exposed to the MR environment.
Before the examination, read the guidelines from the manufacturer of the device included in "The possibility of using the MRI in the case of presence of spinal implants" (available at www.lfc.com.pl, Devices – IFU tab).

The decision to conduct an MRI examination is made by specialists based on the patient's medical records. The decision to conduct MRI should be made after considering the patient's benefits and risks.

CONTRAINDICATIONS

- local or general active infections;
- reduced bone strength caused by e.g. osteoporosis, which makes the proper fixation of implant impossible,
- the patient's allergy to the implant material or to the elements contained in it,
- bad general condition of the patient posing great threat of health or life loss as a result of surgical treatment,
- lack of patient's consent for surgical treatment or adherence to medical recommendations,
- pregnancy, obesity,
- patient's mental disease,
- patient's addiction to alcohol, drugs, or other,
- and other general contradictions associated with surgical treatment of the patient with implants, which can exclude the potential advantage of operating treatment.

RECOMMENDATIONS

- surgical operations with the use of implants should be performed by the properly prepared operative team, experienced and well-trained surgeons, and in well prepared medical center,
- it is recommended that the surgical use should be preceded with training and practice in an experienced medical center,
- surgeon should know the biomechanical properties of the implants, material's limitations associated with the use of implants and technique and conditions of their installation,
- patient should be warned and fully aware, that implant:
  - does not fully replace healthy bone (or other structures), and it cannot sustain excessive loads, it may undergo loosening, deformation, and even fracture,
  - may be damaged as a result of not respecting the postoperative recommendations,
  - may be allergenic as a consequence of local, unfavorable, bio-physics-chemical surface reactions and mechanical interaction.
- it is recommended to verify the patient's allergy to elements contained in implant material;
- proper selection of the implants should be performed by the surgeon each time, with consideration of the patient's clinical, biological, biomechanical, and individual data, which may influence the treatment,
- the implants should be inserted in the suitable, surgically prepared location and fixed together in accordance with biomechanical principles,
- it is recommended that implant-stabilizer remains in body until fulfilling its treatment functions, but not longer than 2 years, unless treatment requirements and other medical considerations indicate otherwise, or the implant is used as prosthesis,
- the patient must be aware, that longer presence of the implant in the patient's body carries a high risk of complications, also associated with the normal mechanical and bio-physics-chemical wear;
- diagnostic and therapeutic techniques applied after the surgery require specialized knowledge, also considering the installed implant,
- recommended is extreme caution and prior consultation with the physician about possible influence of exposure to external energy sources e.g. vibrations, high-frequency field emission, diadynamic currents, and other, which may affect the implant exposing patient to possible side effects,
- in the event of noticing changes in the functionality of the implant, the patient should immediately contact his physician.

USAGE

General rules

- both the implantation and removal of the DERO system implants can be only performed with specialized DERO instruments,
- every operation should be planned suitably; selection of type and quantities of implants should be done 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 types of damage to the implant's surface is forbidden,
- every effort should be made to decrease load-bearing of the implant, as well as for the contact points to be appropriate with their purpose and biomechanical principles,
- the manufacturer does not bear responsibility for the inappropriate use of the devices.

Direct use

- Implants of the DERO System are intended for single use only. The devices are delivered in both sterile and nonsterile conditions,
- the device is placed in a separate packaging with an adhered label containing device and manufacturer details. Besides, self-adhesive identification labels for hospital documentation are delivered with the implant,
- the device surgical technique is available upon request. This technique is not a substitute for the training and is intended for informational purposes only,
- before the use, check device's expiration date and/or the expiration date of the sterilization, and visually assess the condition of the packaging and the device (including the tightness of the sterile barrier system),
- for a device sterilized with radiation – check the color of the radiation sterilization indicator – i.e., located on the packaging round sticker with RED IS EXPOSED inscription. The sticker should be red,
- for device sterilized with steam – check the steam sterilization indicator – i.e., located inside the packaging indicator in a form of a strip. Check if the indication substance inside the window passed the acceptance threshold: between REJECT and ACCEPT. If the indication substance has not reached the ACCEPT window, it should be assumed that the sterilization process was incorrect and it is necessary to repeat it,
- separate all identified irregularities (e.g. packages that are crushed, torn, punctured, wet, stained, contaminated, etc.). Destruction or damage to the packaging eliminates the device from further use,
- the device should be removed from the package following the aseptic principles, immediately before use. In the event of unintentional opening of the sterile packaging before the actual use, follow the instructions given in the "Sterilization" section,
- after removing the packaging, compare the description on the package with its actual contents (LOT, device size).

THREATS

- lack of bone fusion due to rejection of the implant by the body,
- patient's allergy to chemical elements included in the implant material;
- skin irritation e.g. allergic or mechanical,
- feeling discomfort, abnormality, or pain caused by the presence of the foreign body in the organism;
- mechanical ware, degradative physicochemical processes, especially in implants joining points,
- loosening, fracture, shift or migration of the implant, destabilization of the system resulting from inappropriate biomechanical selection, incorrect implantation, mechanical wear, not respecting the postoperative recommendations,
- temporary or permanent paralysis resulting from inappropriate implantation, loosening of the implant or its movement caused by extreme activities of patient's everyday life,
- bleeding, scarring, infection, injury of vessels or other organs,

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- other, general surgical and hospital threats.

PROPERTIES AND TECHNICAL FACTORS (KNOWN TO THE MANUFACTURER), THAT MAY POSE RISK IN CASE OF DEVICE RE-USE

Failure to fulfill the roles foreseen for the device in the patient's body (e.g. loosening, migration, vulnerability, accelerated wearing, infection) caused by:

- infection caused by contamination, which was introduced to the device during its first use,
- previous mechanical, chemical interference in the surface of the device, causing the changes to physical and mechanical properties (including the loss of biotolerance),
- device damage or destruction (e.g. scratch, cracking, chipping, deformation, bending, fracture),
- loss of compatibility with other elements of the system, which leads to the loss of its function, damage or destruction of other devices of the system,
- incomplete set consisting of few elements (loss of junction/compatibility with other elements) after first use or re-preparation of the device,
- difficulty or lack of collaboration of the device with other surgical instruments,
- inability to identify due to the damage to the identification markings (what also means: an inappropriate selection of the device size, inability to cooperate with a surgical instrument, inability to identify the origin/LOT number, use of a device of unknown origin).

PRECAUTIONS

Before the surgery (correct diagnosis, patient and implant selection):

- before the surgery patient or legal guardian must be informed about benefits, potential limitations, and risks of the implantation, the use of the implant in the body during the treatment, and about consequences of not removing or deliberately leaving the implant after fulfilling its supportive functions,
- the patient should be mentally prepared to understand and follow safety precautions associated with the surgery using implants,
- obtain consent from the patient (or legal guardians) for the surgery with the implants. The patient should be warned about operational risks and possible side effects. The patient should accept these risks,
- the surgeon should be familiar with the rules of using implants, instruments, and implantation technique. The device's surgical technique is available upon request. This technique is not a substitute for the training and is intended for informational purposes only,
- the sterility of the device cannot be guaranteed, if the packaging was destroyed, or damaged, also the quality of the device cannot be guaranteed in this case.
- The implant should not come into contact with other objects, which could damage its surface or have any negative effect on it. Damage to the device during transit or storage eliminates it from further use,
- moreover, in case of any doubts regarding the packaging, sterile barrier, or contained device, the device should not be used,
- verify the accessibility to the implants in required sizes, the configuration necessary for the implantation procedure,
- verify the accessibility to complete and fully functional instruments indicated by the manufacturer, necessary for implantation of the device,
- the decision on the use of the specific implants should be made by the surgeon after careful consideration, taking into account risks and benefits.

During the surgery:

- use the instruments indicated by the manufacturer, following the instructions for use and surgical technique of the device,
- avoid damaging the implant during the surgery,
- implants and their components should not be bent, reshaped, or modified, unless the instructions for use, or surgical technique state otherwise,
- fracture, slipping, or improper use of instruments or implant elements may injure the patient or operating personnel,
- special care should be taken when working in the close vicinity of the spinal cord and nerve roots, to avoid violation or nerve damage,
- verify if the installation of the implant is correct.

After the surgery:

- inform the patient about appropriate postoperative procedure, including precautions to be taken in everyday life, and about limiting the physical activity for at least 3 months, as well as avoiding heavy lifting for at least 6 months after the surgery,
- the patient should lead a more sparing for the spine type of life with an emphasis on conscious movement. Avoid bending in or over, and sudden twisting movements. It is not recommended to drive a car for 6-12 weeks after the surgery. Inadvisable at this time, is also lifting and carrying of greater loads,
- the course of the physiotherapy, the start date, frequency, and duration are defined by the attending physician and physiotherapist,
- inform the patient about the necessity of regular postoperative control and follow-up appointments, and in case of inconvenience, or pain associated with the presence of the implant, to contact their appointed physician, as soon as possible,
- use orthopedic stabilization of the operated section of the spine (if necessary and/or recommended by the doctor),
- inform the patient about the necessity to report the presence of the implants in the body to the doctor in case of other forms of treatment,
- explain to the patient the necessity to follow all of the medical recommendations,
- the doctor-surgeon is responsible for the implementation of all safety measures.

REMOVAL

- well-chosen implant is designed to serve biomechanical function only in those cases, where during the treatment process bone fusion occurs, and the temporary functions of the implants are taken over by the musculoskeletal system
- after fulfilling its healing functions implant should be removed, unless present are important for patients life and health indications motivating the leaving of the implant in the body, what patient should be informed about,
- the removal of implants should be documented and follow general principles regulated by law, including the removal procedure of implants.

STERILIZATION

The devices delivered by LfC are sterilized following recommended standards: steam method under EN ISO 17665-1 and radiation method under EN ISO 11137-1, -2:

- if the device is delivered in trays and transport boxes, or single foil-paper pouches, it should be cleaned and sterilized,
- if the device is delivered in double foil-paper pouches with sterilization process indicators (with or without the outer cardboard boxes) it should only be steam-sterilized,
- implants originally sterilized by the steam method under EN ISO 17665-1 can only be re-sterilized by the same method if they have had no contact with the patient and are intact. If an implant that is a single-use device has come into contact with blood, bone, tissue, or body fluids it cannot be re-sterilized,
- resterilization by the end-user is allowed for steam-sterilized implants and instruments. The user assumes full responsibility for the resterilization. These devices can only be re-sterilized by steam sterilization method under EN ISO 17665-1. Parameters of the cycle and load configuration must always be verified with the instructions from the sterilizer manufacturer. Guidelines for re-sterilization are given in the: "Instructions for use of the SURGICAL IMPLANTS intended for re/multiple sterilizations" and "Instructions for use of the SURGICAL INSTRUMENTS intended for re/multiple sterilizations" (www.lfc.com.pl, IFU tab),
- devices originally sterilized by radiation method cannot be re-sterilized.

STORAGE

- store the devices in a separated and ventilated room, away from the main communication routes,
- limit the personnel access to the storeroom (room entrance, access to shelves, cabinets, drawers etc.),
- devices ought to be stored in the so-called room temperature, in a clean and dry place,
- in storage rooms, protection against sudden temperature and humidity changes, against contamination with, e.g. dust, pests, solar radiation, mechanical damage, and any other factors threatening the secondary contamination of the device must be assured,
- devices have to be stored in the original, and undamaged protective packaging,
- damage to the packaging and/or the device in transit and/or in storage eliminates it from further use.

Note: *Manufacturer is not responsible for the device in the event of non-compliance with the Instructions for Use.*

* device protected by patent
** the sole owner is LfC company

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 devices 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 devices by entering the CE1434 mark. On the inner packaging and on the device, however, there may be different notifications of the notified body, i.e. 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 devices manufactured by LfC so far.

Additional information is available at (address for correspondence):

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The meaning of the symbols included on the labels of the LfC Sp. z o. o. devices (symbols according to EN ISO 15223-1 standard).

MD	**„MEDICAL DEVICE"**
UDI	**„UNIQUE DEVICE IDENTIFIER"**
	„CAUTION"
	„DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE"
2	**„SINGLE USE ONLY"**
2 STERILIZE	**„DO NOT RESTERILIZE"**
	„DOUBLE STERILE BARRIER SYSTEM"
	„KEEP AWAY FROM SUNLIGHT"
	„KEEP DRY"
NON STERILE	**„NON STERILE"**
STERILE	**„STERILIZED USING STEAM"**
STERILE R	**„STERILIZED USING IRRADIATION"**
	„PATIENT INFORMATION WEBSITE"
	„CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE"

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