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Only for distribution in the Commonwealth of Australia

Patient information SPII Model Lubinus

Dear Patient,

this document contains important information about your implant(s).
Please, keep this document together with the implant card for future reference.

1. Implant Identification

For information about implant identification, e. g. implant name, implant model, batch and serial number, please refer to the attached label(s) in this document. If no label(s) is (are) attached to this document, ask your physician for completion.

2. Implant Material

For information about the implant materials please refer to the attached label(s) in this document. If no label(s) is (are) attached to this document, ask your physician for completion.

3. CMR Substances

Some system components may contain cobalt as an alloy ingredient in a concentration above 0.1 % weight by weight.
Cobalt is listed as a CMR (carcinogenic, mutagenic and toxic to reproduction) substance.
The Hazard Class and Category Code(s) for cobalt are:
– Carc. 1B
For identification of the affected components please refer to the attached label(s) in this document.

4. Patient Group

The patient group for our medical device is made up of adult, anesthetized patients of any ethnic origin and of any gender, in whom one or more of the described indications are present and who are not considered unsuitable on the grounds of the listed contraindications.

Waldemar Link GmbH & Co. KG
Barkhausenweg 10 · 22339 Hamburg, Germany
www.linkorthopaedics.com

5. Intended Use

The non-active, surgically-invasive implantable SPII Model Lubinus system manufactured by Waldemar Link GmbH & Co. KG is intended for long-term replacement of the femoral side of a diseased and / or defective hip joint in the human body. The hip stem system forms a total replacement of the hip joint when combined with the prosthesis head and if applicable the acetabular cup. The SPII Model Lubinus system can be used with full-grown, anesthetized patients of any ethnic origin and sex. The SPII Model Lubinus system is implanted with cement.
The implants may only be used and operated in an aseptic medical environment by persons who have the required training, knowledge and experience in the orthopedic and surgical field. The implants are supplied in sterile condition individually packed as single-use products.

6. System Description

The SPII Model Lubinus is a hip stem that is to be implanted in the femoral bone.

7. Implant-related risks and side effects

- Intraoperative fractures
- Periprosthetic infection
- Allergic reactions to implant components and / or abraded particles
- Drop in blood pressure following application of bone cement
- Implant fractures / ceramic material fractures
- Implant loosening or subsidence
- Implant malpositioning / misalignment
- Reduced range of motion
- Luxation of joint components
- Discrepancies in the lengths of the extremities
- Premature wear and tear – reoperation
- Postoperative pain, e.g. thigh pain
- Implant protrusion / erosion (e.g. in the case of the acetabular components)

8. Implant Lifetime

The lifetime of our implants is limited in principle and is determined by individual factors such as, for example, body weight and the level of activity of the patient, as well as by the quality and professional execution of the implantation. Based on these individual influencing factors, Waldemar Link defines the overall average lifetime of an implant based on its survival rate (i.e. the proportion of functional implants after a certain period of time starting from the time of implantation). According to the results of the tests performed, the survival rate of our implants corresponds to the general state of the art at the time of approval of the implants.

Loosening is the main reason for having to replace an endoprosthesis or part of it with a revision endoprosthesis. Only rarely does a severe bacterial infection of the tissue around the endoprosthesis lead to the need for a revision surgery.
In particular, age-related bone loss and physical overload can be the cause of loosening of the endoprosthesis. Excessive body weight can also reduce the lifetime of an endoprosthesis.
If necessary, the complete knee joint can be replaced in a second operation.

Immediately contact your physican if the following symptoms occure:

- **Pain and unsteadiness when walking and standing**
- **Changes in bow-leg or x-leg position**

9. Precautions and measures before surgery

- You and your physician decide upon the date of surgery. You also discuss which clinic you wish to go to and where rehabilitation is to take place.
- Tell your physician about any medication you are taking, including over-the-counter products.
- Your physician should also be informed about any other illnesses, e.g., allergies.
- Tell your physician about any infections, particularly in the mouth, nose and throat, and also any problems with your teeth, skin and nails.
- Ask your physician for a schedule for periodically check-ups after the surgery.
- Build up your muscles, go to gait training to improve your walking ability and, if necessary, lose weight prior to the operation. This will create the optimal conditions for your new joint prosthesis.
- Remove any trip hazards from your home, for example, carpet edges.

10. Precautions and measures after surgery

- Attend all your check-ups and consult your physician immediately in the event of any problems.
- Avoid heavy physical work.
- Use a rucksack to go shopping as this is an easier way to carry heavy loads.
- Do appropriate exercise regularly to keep your muscles strong. Suitable sports include cycling, gymnastics, hiking and swimming. Ideally, you should choose a sport at which you are already good. Low-impact exercise involving steady and rhythmic movements is ideal. As a rule, competitive sports are not recommended with an artificial knee joint. Avoid all high-impact sports which involve abrupt changes in direction, e.g., jogging, football, tennis and horse riding. To be on the safe side, talk to your physician if you are in any doubt about a sport.
- Consult a physician immediately if you experience any problems.

11. Interaction of the implants with other equipment

11.1 Notes on MRI and CT Examination Procedures

Our implants were not evaluated for safety and compatibility for MRI and CT examination procedures.
In the case of our metallic implants and implant components, MRI examinations pose potential risks to the patient due to possible heating and migration of the implants or implant components.
Likewise, there is a potential risk of artifact formation in MRI and CT examinations of our metallic implants and implant components.
The probability of occurrence and the extent of the potential risks mentioned depend on the type of device used, its device parameters and the sequences used.
Always follow the instructions in the operating instructions of the manufacturer of the device used for the imaging.
The selection of the imaging examination procedure and the assessment of possible side effects is the responsibility of the examining physician.
The examining physician must take into account the individual condition of the patient and other diagnostic methods.

11.2 Interaction with metal detectors

Metal detectors at the security check (e.g. at the airport) may detect implants made of metal. To avoid possible inconvenience and waiting times, we recommend that you carry your implant card with you.

12. Complaints about our products

All complaints must be addressed to Waldemar Link GmbH & Co. KG at:
complaint@linkhh.de.
In the event of a complaint, the name or reference number of the corresponding component should be specified with the serial number (SN) or the lot number (LOT), your name, and your contact address. The reason for the complaint should be given in brief.

13. Report of serious incidents

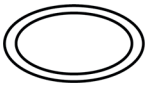
Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration.

Waldemar Link GmbH & Co. KG
complaint@linkhh.de

and

Therapeutic Goods Administration.
https://www.tga.gov.au

Legend of label symbols and descriptions

	Manufacturer
	Observe the enclosed instructions for use
	Consult instructions for use
	Single-use device, not for reuse
	Sterilisation by radiation
	Sterilized using Ethylene Oxide
	Sterilized using steam or dry heat
	Number of units in the package
	Non-sterile
	Store in a place protected from sunlight
	Article number
	Serial or batch number
	Medical Device
	Order number
	Date of manufacture/sterilisation (YYYY-MM or YYYY-MM-DD)
	Use by date (YYYY-MM or YYYY-MM-DD)
	Caution, fragile
	Store in a dry place
	Do not use if packaging is damaged
	Contains hazardous substances
	Health care centre or doctor
	Date of implantation
	Patient information website
	UDI Number
	Material Number
	Person identification
	Sterile barrier system with additional inner covering
	Do not use if the packaging (Sterile Barrier System) is damaged and check the instructions for use
	Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking

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Implant Labels

If no label(s) is (are) attached here, ask your physician for completion.
The number of labels depends on the number of implants.

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