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Rx only

# Instructions for Use
# Implants and Instruments

## MP Reconstruction System

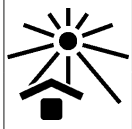
**For U.S. Distribution Only**
For further information please refer to the U.S. section of our website:

ifu-us.linkorthopaedics.com

US | DIST **LinkBio Corp.**
69 King Street | Dover NJ 07801, USA
info@linkbio.com | www.linkorthopaedics.com/us
Phone number: +1 973-625-1333

**Waldemar Link GmbH & Co. KG**
Barkhausenweg 10
22339 Hamburg
Germany
info@linkhh.de
www.linkorthopaedics.com
Tel.: +49 (0) 40 5 39 95 – 0
Fax: +49 (0) 40 5 38 69 29

## Legend of label symbols and descriptions

| SYMBOL | STANDARD REFERENCE | STANDARD TITLE | SYMBOL TITLE | EXPLANATORY TEXT |
|---|---|---|---|---|
|  | ISO 15223-1, Clause 5.1.1 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Manufacturer | Indicates the medical device manufacturer. |
| | ISO 7000-3082 | Graphical symbols for use on equipment. | | |
| US DIST | — | — | U.S. Distributor | Indicates the medical device distributor. |
|  | ISO 15223-1, Clause 5.4.4 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Caution: Read all warnings and precautions in instructions for use | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
| | ISO 7000-0434 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.4.3 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Consult instructions for use | Indicates the need for the user to consult the instructions for use. |
| | ISO 7000-1641 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.4.2 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Do not reuse | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
| | ISO 7000-1051 | Graphical symbols for use on equipment. | | |
| Qty. | — | — | Number of units in the package | Quantity of devices. |
|  | ISO 15223-1, Clause 5.3.2 | Medical devices — Symbols to be used with information to be supplied by the manufacturer. | Keep away from sunlight | Indicates a medical device that needs protection from light sources. |
| | ISO 7000-0624 | Graphical symbols for use on equipment. | | |
| REF | ISO 15223-1, Clause 5.1.6 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Catalogue or model number | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
| | ISO 7000- 2493 | Graphical symbols for use on equipment. | | |
| SN | ISO 15223-1, Clause 5.1.7 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Serial number | Indicates the manufacturer's serial number so that a specific medical device can be identified. |
| | ISO 7000-2498 | Graphical symbols for use on equipment. | | |
| LOT | ISO 15223-1, Clause 5.1.5 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
| | ISO 7000-2492 | Graphical symbols for use on equipment. | | |
| ONR | — | — | Order number | Indicates the manufacturer's order number so that the medical device can be identified. |
| Rx only | 21 CFR 801.15(c)(1)(i)F | Labeling-Medical devices; prominence of required label statements. | Prescription only | Requires prescription in the United States. |
| | 21 CFR 801.109 | Labeling-Prescription devices. | | |
|  | ISO 15223-1, Clause 5.1.3 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Date of manufacture | Indicates the date when the medical device was manufactured. |
| | ISO 7000-2497 | Graphical symbols for use on equipment. | | |

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|---|---|---|---|---|
|  | ISO 15223-1, Clause 5.1.4 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Use by | Indicates the date after which the medical device is not to be used. |
| | ISO 7000-2607 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.3.1 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Fragile, handle with care | Indicates a medical device that can be broken or damaged if not handled carefully. |
| | ISO 7000-0621 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.3.4 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Keep dry | Indicates a medical device that needs to be protected from moisture. |
| | ISO 7000-0626 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.2.8 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied . | Do not use if package is damaged | Indicates a medical device that should not be used if the package has been damaged or opened. |
| | ISO 7000-2606 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.4.10 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied . | Contains hazardous substances | Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties. |
| | ISO 7000-3723 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.2.4 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Sterilized using irradiation | Indicates a medical device that has been sterilized using irradiation. |
| | ISO 7000-2502 | Graphical symbols for use on equipment. | | |
|  | ISO 15223-1, Clause 5.2.7 | Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. | Non sterile | Indicates a medical device that has not been subjected to a sterilization process. |
| | ISO 7000-2609 | Graphical symbols for use on equipment. | | |
|  | — | — | Material | Indicates all material used in the medical device. |
|  | ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.7.7 | Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements. | Medical device | Indicates the item is a medical device. |

## Instructions for Use Implants

### 1. Brief description

The implant systems, cementless and cemented by Waldemar Link GmbH & Co. KG are intended for the partial or complete replacement of a diseased joint or a diseased bone region. They consist of defined components that can be combined with each other in accordance with their approved uses.

The selection and application of the devices presuppose standard training for orthopaedic and surgical specialists and suitable experience with orthopaedic and surgical procedures.

The package inserts provided with the devices do not contain all of the information necessary for the selection and application of the devices. For proper handling, refer to other device-related instructions, such as the instructions on the surgical technique associated with the relevant system, as well as the special handling recommendations and device labels, where applicable. Refer to the identification tag on the implant and/or the packaging label for the definitive identification information on the device, such as system compatibility, article number, materials and shelf life. You should also take advantage of the training courses and printed materials provided for your information. To learn more, please contact the Waldemar Link GmbH & Co. KG sales office or your field representative.

### 2. Handling

The metal components are supplied sterile (gamma sterilization, at least 25 kGy) as single-use devices in individual packages. The packaging may contain protective components for the implants. These components are not intended for implantation.

Implants should always be stored in their unopened protective packaging. Examine the packaging for damage before using the implant. Damaged packaging can have an adverse effect on both the sterility of the device as well as the proper performance of the implant, such that the device may no longer be used. Check the use by date on the implants. Implants with expired use by dates are no longer permitted to be used for implantation!

Observe the pertinent standards for the aseptic handling of devices during and after removal of the implant from the packaging. When removing the packaging, make a record of the batch or serial numbers on the label, since this information is decisive for batch tracing. Self-adhesive labels with this information are enclosed with every package for your convenience.

### Caution!

- Implants must be handled with great care and should not be modified or changed, even the smallest scratches and damages can considerably impair their stability or performance. Damaged implants are not permitted to be used.
- Manipulations, such as vigorous bending, kinking or bending backward are not permitted to be performed on implants that have fastening elements (e.g. straps) for intraoperative adjustment.
- Surfaces provided for the connection of modular prosthetic components (cone, pins, screws) must not be damaged and may need to be cleaned with sterile liquid and dried before being joined together, so that neither blood nor any other coating impairs any of the connections, which could compromise the reliability of the connection.
- Ceramic implants may only be used in combination with brand new, unused implants.
- In the case of broken ceramic components, the ceramic particles must be removed completely, since otherwise increased abrasion can be expected.
- Packaging and implants to be discarded must be handled in compliance with national and local regulations for hospital disposal.

### 3. Storage

Sterile-packaged implants must be stored in the undamaged original packaging in buildings with adequate protection against damage due to impacts, frost, humidity, excessive heat, and direct sunlight. Further information is available from the manufacturer upon request.

### 4. Materials, implant selection, permissible combinations

Cobalt chromium molybdenum as well as titanium aluminium alloys are the basic materials.

- Cobalt-based alloy (CoCrMo) according to ISO 5832-4/ASTM F-75 and ISO 5832-12/ASTM F-1537
- Titanium aluminium alloy, Ti6Al4V, DIN EN ISO 5832-3; ASTM F136, (Tilastan-S) and ASTM F-1108

Further information on the material compositions is available from the manufacturer upon request.

Please refer to the relevant surgical technique associated with the system and the identification on the packaging for further information on implant selection, permissible combination options and implant materials. Also, refer to the relevant surgical technique for information on allocating and handling the instruments to be used for the implantation.

Combinations with implants from other manufacturers and/or combinations with LINK implants that deviate from the surgical technique specifications have not been tested and are not permitted.

### 4.1 Range of motion of the implants

The range of motion rises as the head diameter of the prosthesis increases. Waldemar Link GmbH & Co. KG offers specialized components that reduce the risk of dislocation in patients with an increased tendency to luxation. These include, for example, XL 28-size prosthesis head made of CoCrMo, acetabular cups and cup inserts with shoulders (raising the cup edge). There is less range of motion than with a standard combination because the neck of the head and the cup shoulder reduce the range of motion. Acetabular cup components with 22 mm inside diameter have less range of motion than standard components.

### 4.2 Cones

The male and female cones of modular stem connections, such as a hip prosthesis stem with a hip prosthesis head, must match. Special attention must be paid to correct cone coupling. The cones have been optimally matched to each other and are not permitted to be combined with devices by other manufacturers.

### 4.3 Diameters

The diameters of articulating bearing surface components must match; e.g. the diameter of the femoral head used must fit the inside diameter of the articulating opposite bearing surface (e.g. of the acetabular cup).

### 4.4 Anchoring of the implants

Implant components are labelled as to whether they are to be cemented or not.

When cemented implant components are selected, use of bone cement with a high viscosity is recommended.

## 5. Indications and contraindications

**Indications:**

The MP Reconstruction System is intended for revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. The MP Reconstruction System is indicated for the following conditions:

- Revision arthroplasty due to juxta-articular bone defects.
- Revision of loosened femoral prosthesis components involving extensive bone resorption of the proximal femur and widening of the medullary cavity or marked thinning of proximal femoral cortical bone.
- Revision of loosened femoral prosthesis components by peri-/subprosthetic fracture.
- Deformed proximal femur due to fractures or osteotomies.
- Correction of bone deficiencies, e.g. due to tumors.
- Large post-revision and post-trauma segmental bone defects.

The MP Reconstruction System is for cementless use. Only cemented labeled modular stems are indicated for cemented use.

**Contraindications:**

- Acute or chronic infections, local and systemic
- Allergies due to (implant) materials
- Revision in septic environment
- For preparation of the prosthesis bearing insufficient length of intact diaphysis (less than 80 mm)
- Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk
- Insufficient bone integrity which prevents a stable anchorage of the prosthesis

**Relative Contraindications:**

- Obesity
- Lacking or foreseeable not assured compliance
- Foreseeable overload/overstressing of joint prosthesis

## 6. Preoperative planning

Preoperative planning provides important information to identify the appropriate implant system and select the components of a system. Make sure that all components required for the operation are laid out and ready in the operating room. Test prostheses to verify proper fit (where applicable) and additional implants should be kept at the ready, in case other sizes are needed or the intended implant cannot be used. All LINK instruments necessary for the implantation must be on-hand and intact. If endoprosthetic joint replacement is indicated, then it must be taken into consideration, along with the overall picture of the patient:

- that all non-surgical and surgical treatment alternatives for the joint disease have been considered
- that artificial joint replacement performance is categorically inferior to natural joint performance, and an indication-related improvement in the preoperative condition is the only aim here
- that an artificial joint may loosen due to stress, wear and tear, and infection, or luxation or dislocation may occur
- that revision surgery, which under certain circumstances may exclude the possibility of restoring joint function, may be necessary due to loosening of the implant
- that if the selection of cementless implants is indicated, the biological age of the patient, among other things, must be considered
- that the patient consents to undergo the operation and accepts the risks involved
- that if load-transferring bone cement and/or bone structures are damaged, then the loosening of the components, bone and implant fractures, as well as other serious complications cannot be ruled out
- that if the patient is suspected of having allergies and tests positive on the applicable tests, then the patient's foreign body sensitivities (material tolerances) must be examined

Generally, the mechanical failure or fracture of joint replacement prosthesis is a rare exception. However, this cannot be excluded with absolute certainty despite the sound structure of the implant. This may be due to stress on the implant and prosthesis as the result of a fall or accident, among other things. If the bone area where the implant is anchored is altered in such a way, that the prosthesis is no longer able to withstand normal stress and an area of the prosthesis becomes subject to a stress imbalance, then a mechanical failure of the implant system may result. Such stress imbalances may also occur if the anchoring elements for the joint replacement implant are obliged to form a bridge over larger bone deficiencies without optimal reinforcement of the bone.

It is recommended that the implant with the largest possible anchoring elements will be used.

Proper preparation for surgical procedures also includes the functional testing of implants and instruments prior to use.

## 7. Possible risks and side effects

**Surgery-related risks and side effects:**

- Blood loss, allogeneic/autologous blood transfusions
- Swelling/hematomas
- Thrombosis/embolism/heart attack
- Impaired wound healing
- Infections
- Muscle and nerve damage
- Damage to blood vessels
- Postoperative pain
- Complications associated with the anesthesia applied
- Postoperative calcification

**Implant-related risks and side effects:**

- Intraoperative fractures
- Periprosthetic infection
- Allergic reactions to implant components and 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
- Protrusion/Erosion

## 8. Reprocessing/Reuse

The implants are supplied as sterile single-use devices. Implants that have already been implanted are not permitted to be reprocessed.

Instruments must be disinfected and sterilized prior to use. For more information please refer to the description in the reprocessing instructions US-H50.

Additionally observe our separate packaging and cleaning instructions for instruments.

Single-use products may not be reused.

## 9. Resterilization

Our implants are designed for single-use only. Resterilization by the user is not permitted. Implants, as well as their materials are not suitable to be resterilized. Unpredictable degradations may occur in these implants during resterilization.

For sterilization of the instruments, please refer to the description in the reprocessing instructions US-H50.

## 10. Circumstances that can interfere with the success of an operation

- Severe osteoporosis
- Severe deformities
- Local bone tumors
- Systemic diseases
- Metabolic disorders
- Case history of infections and falls
- Drug dependency or abuse, including excessive alcohol and nicotine consumption
- Obesity
- Mental disorders or neuromuscular diseases
- Heavy physical activities associated with strong vibrations
- Hypersensitivities

## 11. Postoperative phase

In addition to movement and muscle training, pay special attention to carefully instructing the patient during the postoperative phase. Physician-supervised postoperative monitoring of healing progress is recommended. Where applicable, advise patients on how to avoid overstraining themselves.

## 12. MRI information

The MP Reconstruction System components have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the MP Reconstruction System components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## 13. Important

- If the implantation of a LINK implant system is considered to be the best solution for the patient and one of the circumstances described in section 10 is applicable to the patient, it is necessary to advise the patient with regard to the anticipated effects that these circumstances could have on the success of the operation. It is further recommended to inform the patient about measures that he or she can take to reduce the effects of such complications. The operating surgeon should document all information provided to the patient in writing.
- Instruct the patients in detail about the limitations of the implants, especially about the effects of excessive stress caused by body weight and physical activity, among other things. Encourage the patients to adjust their activities accordingly.
- Proper selection, placement and fixation of the devices are decisive factors, which will determine the life of the implant.
- Address all kinds of inquiries to Waldemar Link GmbH & Co. KG (see contact information on the cover sheet). The same applies for requests for further information on the devices.

## 14. Instruments

Please refer to the description in the reprocessing instructions US-H50 for the:

- first use
- performance test
- handling
- cleaning
- reprocessing
- sterilization
- maintenance
- servicing
- storage

## 15. Complaints about our products

Send complaints of any kind to Waldemar Link at: complaint@linkhh.de. When filing a complaint, always quote the name or REF number of the relevant component along with the LOT number, your name and your contact address. Describe the reason for the complaint in brief.

## 16. Servicing

Prepare medical devices and instruments that are sent in for servicing beforehand in such a way that they are not a hazard to third parties.

We will be pleased to provide you with further information about special instrument sets, their applications, disassembly, cleaning, and care.