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Rx only

Instructions for Use
Implants and Instruments
LINK Embrace Shoulder System - Anatomical Configuration

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

www.ifu-us.link-ortho.com

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Legend of label symbols and descriptions

	Manufacturer
US DIST	U.S. Distributor
	Caution
	Consult instructions for use or consult electronic instructions for use
eifu.link-ortho.com	Consult instructions for use or consult electronic instructions for use
	Do not re-use
STERILE R	Sterilized using irradiation
STERILE EO	Sterilized using Ethylene Oxide
STERILE	Sterilized using steam or dry heat
NON STERILE	Non-sterile
	Keep away from sunlight
Qty.	Number of units in the package
REF	Article number
SN	Serial number
LOT	Batch number
ONR	Order number
	Date of manufacture (YYYY-MM-DD)
	Use-by date (YYYY-MM-DD)
	Fragile, handle with care
	Keep dry
	Do not use if package is damaged and consult instructions for use
UDI	Unique device identifier
	Contains hazardous substances
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
MAT	Material Number
MD	Medical Device

Further information on the symbols glossary and a list of Class 1 instrument article numbers and their associated UDI-DIs can be found on our website.

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. Components made of polyethylene are sterilized with ethylene oxide (ETO) and are supplied 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.

2.1 Warnings / Precautions

- 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.
- 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 Alloy, ultra-high molecular weight polyethylene, highly cross-linked polyethylene with vitamin E are used as basic materials.

- Titanium Aluminum Vanadium Alloy (Ti6Al4V) according to ISO 5832-3/ASTM F136
- Cobalt-based alloy (CoCrMo) according to ISO 5832-4/ASTM F75
- Ultra-high molecular weight polyethylene (UHMWPE) according to ISO 5834-2/ASTM F648
- Highly cross-linked UHMWPE with Vitamin E (E-Dur) according to ISO 5834-2/ASTM F648/ASTM F2565/ASTM F2695
- Calcium phosphate coating (HX) according to ASTM F1609

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 Anchoring of the implants:

Implant components are labeled as to whether they are intended for cemented and/or cementless fixation.

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

5. Indications and contraindications

General indications:

The LINK Embrace Shoulder System - Anatomic Configuration is intended for anatomic total or hemi shoulder arthroplasty.

Indications:

- A severely painful and/or disabled shoulder joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
- Avascular necrosis of the humeral head
- Deformity and/or limited motion
- Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory
- Revision of a failed primary component
- Ununited humeral head fractures
- Cuff tear arthropathy (CTA Heads only)

The All Poly Glenoid Components are intended for cemented use.

The Humeral Stems Standard with CaP (HX) and Short with CaP (HX) are intended for cementless fixation.

The Humeral Stems Standard without CaP (HX) are intended for cemented or cementless fixation.

The Humeral Fracture Stems are intended for cemented or cementless fixation.

Contraindications:

- Acute or chronic infections, local and systemic, insofar as they compromise the successful implantation of a total shoulder endoprosthesis
- Inadequate bone stock in the proximal humerus or glenoid fossa for supporting the components (for example caused by persistent acute or chronic osteomyelitis, or Paget's disease)
- Absent, irreparable or nonfunctional rotator cuff or other essential muscles in cases of anatomic reconstruction
- Axillary nerve lesions in cases of rotator cuff tear
- Deltoid muscle insufficiency
- Any mental, neurological, or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, complications in postoperative care or patient compliance
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of fixation of the device or to failure of the device itself
- Local bone tumors

Relative contraindications:

- Vascular or nerve diseases affecting the concerned limb
- Poor bone quality, such as osteoporosis, where there could be considerable migration of the prosthesis and/ or a chance of fracture of the humerus or glenoid
- Metabolic disorders which may impair fixation and stability of the implant
- Any concomitant disease and dependence that might affect the implanted prosthesis
- Allergies or sensitivity to implant materials
- Foreseeable patient non-compliance

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 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

- Implant damage, implant fracture
- Infection
- Instability, Dislocation
- Malalignment
- Migration
- Noises (e.g. cracking, popping, snapping, squeaking or grinding)
- Periprosthetic fracture
- Residual complaints
- Scapular Notching
- Septic, aseptic loosening
- Soft tissue problems
- Stress shielding
- Wear
- Implant protrusion/erosion

8. Reprocessing

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

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.

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

- Severe osteoporosis
- Severe deformities
- Local bone tumours
- 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, special attention must be paid to carefully instructing the patient during the postoperative phase. Physician-supervised postoperative monitoring of healing progress is recommended. Where applicable, patients should also be advised on how to avoid overstraining themselves.

12. MRI Safety Information

The Link Embrace Shoulder 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 Embrace Shoulder 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 that the patient be informed about measures that he or she can take to reduce the effects of such complications. All information provided to the patient should be documented in writing by the operating surgeon.
- The patients should be instructed 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. They should be encouraged to adjust their activities accordingly.
- Proper selection, placement and fixation of the devices are decisive factors, which will determine the life of the implant.
- Enquiries of any kind should be directed 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:

- initial use
- performance test
- maintenance
- manual cleaning
- reprocessing
- sterilization
- servicing
- transport

15. Complaints about our products

Complaints of whatever kind must be filed with Waldemar Link at: complaint@link-ortho.com

When filing a complaint, always quote the name or REF number of the relevant component along with the LOT and SN number, your name and your contact address.

16. Servicing

Medical devices and instruments that are sent in for servicing must be processed beforehand in such a way that they cannot constitute 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.