LINK®

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MAR-03291, Vers.2

Instructions for use Rx only

Custom-made Device

For U.S. Distribution Only

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

www.ifu-us.link-ortho.com

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

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

Legend of label symbols and descriptions

	Observe the enclosed instructions for use
	Single-use device, not for reuse
STERILE R	Sterilisation by radiation
STERILE EO	Sterilized using Ethylene Oxide
STERILE	Sterilized using steam or dry heat
REF	Article number
LOT	Batch number
SN	Serial number
	Manufacturer
Qty.	Number of units in the package

NON STERILE	Non-sterile
	Consult instructions for use
MD	Medical Device
	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
	Store in a place protected from sunlight
	Do not use if packaging is damaged
	Contains hazardous substances
	Health care centre or doctor
31	Date of implantation
	Patient information website
?	Patient identification
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Sterile barrier system with additional inner covering
STERILE	Do not use if the packaging (Sterile Barrier System) is damaged and check the instructions for use
MAT	Material Number
UDI	UDI Number
ONR	Order number
eifu.link-ortho.com	Consult instructions for use or consult electronic instructions for use

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.

MAT	Legend of Materials
M1	Cobalt-based alloy, CoCrMo, ISO 5832-12; ASTM F1537, (EndoDur-S)
M2	Titanium-aluminum alloy, Ti6Al4V, DIN EN ISO 5832-3 ; ASTM F136, (Tilastan-S)
M3	Ultra-high molecular weight polyethylene, UHMWPE, ISO 5834-1, ISO 5834-2 / ASTM F-648
M4	Highly cross-linked polyethylene based on ultra-high molecular weight polyethylene, UHMWPE, ISO 5834-2 / ASTM F-648 / ASTM F-2565, (X-Linked PE)
M5	Highly cross-linked polyethylene based on ultra-high molecular weight polyethylene, UHMWPE, with vitamin E, ISO 5834-2 / ASTM F-648 / ASTM F-2565 / ASTM F-2695, (E-DUR)
M6	Calcium phosphate coating, CaP, ASTM F-1609, (HX)
M7	Titan-Niob-Nitrid, Titanium nitride coating, TiNbN, titanium niobium nitride, ISO 5832-7, (LINK PorEx)
M8	Polyphenylsulfone, PPSU
M9	Neodmyium, Nickel-plated, NdFeB
M10	Stainless steel, X5CrNi18-10, DIN EN 10088-1
M11	Stainless steel, X8CrNiS 18-9, DIN EN 10088-1
M12	Stainless steel, X20Cr13, DIN EN 10088-1
M13	Stainless steel, X10CrNi 18-8, DIN EN 10270-3
M14	Stainless steel, X90CrMoV18, DIN EN 10088-3
M15	Stainless steel, X5CrNiCuNb 16-4 / X5CrNiCuNb 17-4, ISO 7153-1, AISI 630
M16	Stainless steel, X2CrNiTiMo12-11-2-1
M17	Stainless Steel, X17CrNi16-2, DIN EN 10088-3, AISI 431
M18	Stainless steel, XM-16, ASTM F 899-12
M19	Cobalt-based alloy, CoCrNiMoFe, ISO 5832-7 ASTM F1058
M20	Aluminum alloy, Al99,5, EN AW-1050A, DIN EN 573-3
M21	Sillicone, BGA XV
M22	Polyamide, PA6 SA, DIN EN 15860
M23	Polypropylene homopolymer, PP-H, DIN EN 15860, ASTM D4101
M24	Polyvinyl chloride, PVC
M25	Polytetrafluoroethylene. PTFE
M26	X5CrNiMo17-12-2, DIN EN 10088-3, AISI 316
M27	X6CrNiMoTi17-12-2, DIN EN 10088-2
M28	X46 Cr-13, ISO 7153-1
M29	X2CrNiMo 18-15-3, DIN ISO 5832-1:97, ASTM F138-00, ASTM F139-00
M30	Cobalt-based alloy, CoCrMo, DIN ISO 5832-4, ASTM F75 (EndoDur)
M31	Titanium-aluminum alloy, Ti6Al4V, ASTM F1108, (Tilastan)
M32	Titanium-aluminum alloy, Ti6Al4V, DIN EN ISO 5832-3, (Tilastan-E)
M33	Stainless Steel, X2CrNiMo 17-12-2, ISO 7153-1
M34	Stainless Steel, X2CrNiMo18-14-3, DIN EN 10088-3
M35	Aluminum alloy, AlMg1, EN EN5005/H14, DIN EN 573-3
M36	Thermoplastic elastomer, TPE
M37	Sillicone Rubber, FDA§ 177.2600
M38	Cobalt-based alloy, CoNi35Cr20Mo10, ISO 5832-6
M39	Titanium-aluminum alloy, Ti6Al4V, ASTM F2924
M40	Commercially Pure Titanium coating, CPTi, ASTM F1580
M41	Aluminum alloy, AlSi1MgMn, DIN EN 573-3
M42	Stainless Steel, X105CrMo17, DIN EN 10088-3; EN 10278
M43	Zirconia Toughened Alumina, ZTA, ISO 6474-2
M44	Polyetheretherketone, XL 515 CF, PEEK
M45	Silicone Rubber
M46	Stainless Steel, FeCrNiMnMoNbN, ISO 5832-9, ASTM F1586-13
M47	Titanium-aluminum alloy, Ti6Al4V, DIN EN ISO 5832-3
M48	Highly cross-linked polyethylene based on ultra-high molecular weight polyethylene, UHMWPE, ISO 5834-1/2 / ASTM F-648
M49	Highly cross-linked polyethylene based on ultra-high molecular weight polyethylene, UHMWPE, with vitamin E, ISO 5834-1/2 / ASTM F-648 / ASTM F-2695
M50	Cobalt-based alloy, CoCrMo, ISO 5832-12; ASTM F799
M51	X20CrNiMoS13-1, ISO 7153-1
M52	Polysulfone, PSU
M53	Stainless Steel, X40CrMoVN16.2, ASTM F 899
M54	EPDM rubber, ethylene propylene diene monomer rubber
M55	Polyamide, PA12, DIN EN 15860
M56	Cast steel, GX5CrNiMoNb19-11-2, DIN EN 10283mod
M57	Cast steel, GX5CrNiMoNb19-11-2, DIN EN 10283
M58	Stainless steel, X2CrNi18-9, DIN EN 10088-1
M59	Silicone Rubber, RTV-4136-M
M60	Stainless steel, X2CrNiMo 18-15-3, DIN ISO 5832-1:97, ASTM F138-00, ASTM F139-00
M61	Stainless steel, X38CrMoV15, DIN EN ISO7153-1
M62	Stainless steel, X30Cr13, DIN EN ISO7153-1
M63	Polyoxymethylene, POM-C
M64	Stainless steel, S21800, ASTM F899-12b
M65	Commercially Pure Titanium coating, CpTi, DIN ISO 5832-2, ASTM F1580
M66	Stainless steel, X40 CoorVN 16-2, DIN EN 10088-3, AISI 420 MOD, EN 10278-h8
M67	Silicone Rubber (VMQ)
M68	Polyamide, PA2200
M69	Stainless Steel, X15Cr13, AISI 410D, ISO 7153-1
M70	Aluminium Oxide, Al2O3, ISO 6474-1
M71	Polytehylene HDPE
M72	Polymethyl methacrylate PMMA
M73	Polyoxymethylene POM-AC

M79	Stainless Steel, X40 CrMoVN 16-2, DIN EN 10088-3, AISI 420 MOD, EN 10278-h8
M80	Stainless Steel, X4CrNi 18 12, ISO 7153-1
M81	Stainless Steel, X10Cr15, AISI 429
M82	Stainless Steel, X90CrMoV17, DIN EN 10088-3
M83	Aluminium Alloy, AlMg3
M84	Stainless Steel, X3CrNiCu18-9-4, AISI 304 Cu
M85	Stainless Steel, X39CrMo17-1, DIN EN 10088-3; EN 17440; ISO7153-1

EN ENGLISH

1. General

Please read this document carefully before using the system and keep it for future consultation!
This document does not contain all of the information necessary for the selection and application of the system. For safe and proper handling, refer to further product-related instructions, such as the design description, the related surgical technique and the device labels on the packaging.

2. User Group and Environment

The products may only be used and operated in an aseptic medical environment by persons who have the appropriate training, knowledge or experience in the orthopaedic and surgical field.
The intended users of this system are experienced and trained
- surgeons,
- theatre nurses,
- CSSD staff (CSSD = Central Sterile Supply Department)

3. Patient Group

The custom-made device(s) is/are intended for exclusive use for the patient named in the accompanying documents.

4. System Description

For the description of the custom-made device(s) please refer to the accompanying design description.

5. Intended Use

For the intended use of the custom-made device(s) please refer to the accompanying documents.

6. Indications

The patient cannot be treated solely with standard implants.

7. Contraindications

Implants
– Acute and chronic infections, local and systemic, insofar as they may compromise the successful implantation
– Allergies to (implant) materials
– insufficient / inadequate bone mass- or quality, which prevents a stable anchorage of the prosthesis.

Instruments
– The instruments in the present combination are not intended for the application and implantation of another Medical Device aside from the custom-made device.
– Material intolerance to the instrument material

Instruments are not allowed to be implanted.

8. Possible Risks and Side Effects

Surgery-related Risks and Side Effects:
– Swelling / hematoma
– Thrombosis / embolism / Cardio-vascular complications
– Wound healing disorders
– Increased bleeding
– Infections
– Muscle and nerve damage
– Vascular injuries
– Postoperative pain
– Heterotopic ossification
– Bursitis
– Laceration
– Tendonitis
– Urinary Tract Disorders
– Ileus

Implant-related Risks and Side Effects:
– Aseptic loosening
– Dislocation
– Malpositioning
– Heterotopic ossification
– Pain
– Periprosthetic / Stress fracture
– Implant wear / osteolysis
– Implant fractures
– Deep infection
– Periprosthetic joint infection
– Sepsis
– Leg length discrepancy
– Device-device incompatibility
– Failure of primary fixation
– Missing pressfit
– Acetabular floor perforation
– Heterotopic ossification
– Squeaking

9. Clinical Benefit

This custom-made product is explicitly manufactured for the patient documented under the mentioned case number and the documented individual defect and anatomy situation and is specially adapted to the indication described by the attending physician. Alternative treatments using e.g. standard products are associated with a higher probability of complications or loss of extremities and thus a poorer quality of life to be expected. Thus, the benefit of this custom-made product outweighs the risk.

10. Implant Materials

Please refer to the accompanying design description and the identification on the packaging for further information on implant materials.
Further information on the material compositions is available from the manufacturer upon request.

11. Instrument Materials

Please refer to the accompanying design description and the identification on the packaging for further information on instrument materials.
Further information on the material compositions is available from the manufacturer upon request.

12. CMR Substances

Some 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

- Repr. 1B

For identification of the affected components and further material specification, please refer to the accompanying design description and the legend of materials in this document.

13. Implant Selection, permissible Combinations

Please refer to the accompanying surgical technique for implant selection and permissible combinations.

14. Permissible materials for tribological pairings of implants

Please refer to the accompanying surgical technique and the design description for information about permissible materials for tribological pairings.

15. Implant Size

Please refer to the accompanying design description for further information on implant size.

16. Implant Anchoring

Please refer to the accompanying design description for further information on implant anchoring.

17. 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.
The expected life time of instruments depends on material, design, application and processing. The expected life time of instruments by Waldemar Link GmbH & Co. KG is limited by restrictions in their usability and / or functionality.

18. Reprocessing / Reuse

Note: Custom-made implants are usually delivered sterile. A non-sterile delivery is only made at the express request of the physician. Since in such a case there is no documentation from the manufacturer, the manufacturer does not assume any guarantee for sterilization.
The implants are supplied as sterile single-use devices. Implants whose protective packaging is opened or damaged, or implants which have already been implanted are not permitted to be reprocessed or reused.
The following risks may occur if implants are re-used:

– Infections
– Reduced implant lifetime
– Increased wear and wear debris complications
– Disease transmission
– Inadequate implant fixation
– Limited implant function
– Implant response and / or rejection

Instruments must be disinfected and sterilized prior to use. For more information please refer to the related chapters in this document and to the description in the reprocessing instructions H50.
Custom-made instruments made of polyamide are supplied unsterile as single-use devices in individual packages.
Additionally, observe our separate packaging and cleaning instructions for instruments.
Single-use products may not be reused.

19. Resterilization

The Implants are designed for single-use only. Resterilization 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 H50. Resterilization of single-use instruments is not permitted

20. Storage and Transportation

Sterile-packaged implants and instruments 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.
For Storage and Transport of the non-sterile Instruments, please refer to the description in the reprocessing instructions H50.

21. Information for Patient Advisory

If the implantation of this system is considered to be the best solution for the patient and one of the circumstances described in section 22 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 to take to reduce the effects of such complications. All information provided to the patient should be documented in writing by the operating surgeon. An implant ID for the patient must be handed over by the surgeon or hospital and the patient must be informed about the availability of a special patient information.
The patient should also be instructed:

– iin detail about the surgery-related risks.
– 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.
– about possible postoperative complications.
– about the material composition of the implant.
– that implants may respond to metal detectors during security checks (e.g. at airports) and carrying an implant ID as a proof is recommended.
– that implants may interact with medical imaging technique (e. g. MRI))

22. 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

23. Warnings / Precautions

– Custom-made implants that are produced patient-specific, based on imaging procedures, e.g. CT images. The period of 4 weeks after delivery up to use of the implant should not be exceeded. In case of implantation of custom-made implants after this time, the suitability of the custom-made implant cannot be guaranteed due to a possible change in the patient-specific situation. 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.
– The reuse of LINK single-use products is not permissible.
– 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.
– 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.
– Do not manipulate or misuse instruments. We do not accept liability for products that have been modified, subjected to unintended use, or used improperly.
– For the processing of LINK instruments, it is presumed that the personnel have technical knowledge level I (Germany) and in other countries technical knowledge and expertise.
– Medical devices that are sent in for servicing must be processed beforehand in such a way that they cannot constitute a hazard to third parties.
– Products made of plastic (e.g. polyamide (PA), polyethylene (PE), polyoxymethylene (POM), ultra-high molecular weight polyethylene (UHMWPE)) may not be localizable using external imaging procedures..

24. 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. Trial implants 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, sterilized and intact.
If prosthesis implantation is indicated, then it must be taken into consideration, along with the overall circumstances 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 proper selection, placement and fixation of the devices are decisive factors, which will determine the life of the implant.
– 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 the patient consents to undergo the operation and accepts the risks involved
– that if load-transferring 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
– that acute and chronic infections, local and systemic, may compromise the successful implantation, so pre-operative microbiological analysis is recommended

Generally, the mechanical failure or fracture of an implant 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 of the implants are required 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.
For definitive identification information on the product such as system compatibility, article number, material and shelf life, refer to the identification on the implant and / or the packaging. 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.

25. Handling

Note: Custom-made implants are usually delivered sterile. A non-sterile delivery is only made at the express request of the physician. Since in such a case there is no documentation from the manufacturer, the manufacturer does not assume any guarantee for sterilization.
All implant components are supplied sterile as single-use devices in individual packages. The implant components are sterilized by gamma sterilization, at least 25 kGy. By contrast, components made of highly cross-linked polyethylene or highly cross-linked polyethylene with vitamin E are sterilized with ethylene oxide (ETO).
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!
– After opening the package, check that model and size of the implant are matching with the information printed on the package labelling.
– 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.

Instruments must always be treated with care, this particularly applies during transport, cleaning, maintenance, sterilization, and storage. The sterile status of the instruments depends, inter alia, on the sterile items packaging and the prevailing storage conditions and must be established together with the operator's hygiene officer on a case-by-case basis. Direct sunlight must be avoided. Improper handling and care, as well as unintended use, can lead to premature wear or damage.
Custom-made instruments made of polyamide are supplied unsterile as single-use devices in individual packages.
Devices made of plastics (e.g. PP-H) may not be located by means of an external imaging device.

26. Intraoperative Use

Please refer to the relevant surgical technique associated with the system for information about the intraoperative use of the system.

27. Postoperative

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.
Follow-up examinations should be carried out regularly or immediately if symptoms occur.

28. 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.

29. Explantation of Implants / Revision Surgery

Information about explantation of the custom-made device and revision surgery is available from the manufacturer upon request.

30. Disposal

Packaging and system components to be discarded must be handled in compliance with your national and local regulations for hospital disposal.

31. Non-sterile Instruments

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

– initial use
– performance test
– maintenance
– manual cleaning
– cleaning in a washer-disinfector
– reprocessing
– sterilization
– servicing
– transport

32. Link to Summary of Safety and Clinical Performance

At the time of creation of this document, the EUDAMED database was not yet active. Therefore, no link to the summary of safety and clinical performance can be given here.

33. Requests

Requests of any kind should be directed to Waldemar Link GmbH& Co. KG (see contact information in this document).

34. Complaints about our Products

All complaints must be addressed to Waldemar Link GmbH & Co. KG at: complaint@link-ortho.com.
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.

35. Report of serious incidents

Any serious incident that occurs in relation to the device must be reported to the manufacturer and the authority responsible for your location.