Instructions for Use

Hip Joint Prostheses Systems

Version 1.5

Beijing Lidakang Technology Co., Ltd.

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Effective date: 05-February-2025

Caution:
Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. Additional warnings and precautions may be included in the surgical technique or on the label. This product must only be used by trained, qualified persons, aware of the directions for use. EU law restricts this device to sale, distribution, and use by or on the order of a physician.

1.Device Descriptions

The Hip Joint Prostheses Systems is comprised of sterile, single-use implantable devices for use in primary and revision total or Hemi hip arthroplasty, with or without bone cement.

The Hip Joint Prostheses Systems consists of Acetabular Cups, Acetabular liners, femoral heads, femoral stems and accessories. All devices described herein are available in a range of sizes to allow implant selection to match the patient's anatomy.

All cemented acetabular cups and femoral stems require cement, but cementless acetabular cups and femoral stems don't need cement. Cementless cups include LAC-TCⅠ Cementless Acetabular Cup, LAC-TCIV Cementless Acetabular Cup, LAC-TCⅡ Cementless Acetabular Cup, LAC-Ⅰ Cementless Acetabular Cup, LAC-Ⅱ Cementless Acetabular Cup, LAC-Ⅲ Cementless Acetabular Cup, LAC-IV Cementless Acetabular Cup, TAC-Ⅰ Acetabular Cup, TAC-Ⅱ Acetabular Cup, TAC-Ⅲ Acetabular Cup. Cemented cups include Cemented Acetabular Cup. The cemented femoral stems are RCH Cemented Femoral Stem, RCH Long Cemented Femoral Stem, RCL Cemented Femoral Stem and RRH Cemented Femoral Stem which could match with Restrictor and Centralizer. The cementless femoral stems contain STH-Ⅰ Cementless Femoral Stem, STH-Ⅱ Cementless Femoral Stem, STH-Ⅲ Cementless Femoral Stem, RSH Cementless Femoral Stem, RLH Cementless Femoral Stem, RWH Cementless Femoral Stem, RAH Cementless Femoral Stem, RML Cementless Femoral Stem, RWH Cone Cementless Femoral Stem.
Bipolar Head can be used in hemiarthroplasty replacement, the other implants are used in total hip replacement.

Materials

The components of Hip Joint Prostheses Systems are made of the following materials:

Component	Material
STH-Ⅰ Cementless Femoral Stem, STH-Ⅱ Cementless Femoral Stem, STH-Ⅲ Cementless Femoral Stem	Ti6Al4V as per EN ISO 5832-3
RSH Cementless Femoral Stem, RLH Cementless Femoral Stem, RWH Cementless Femoral Stem, RWH Cone Cementless Femoral Stem, RAH Cementless Femoral Stem, RML Cementless Femoral Stem	Ti6Al4V as per EN ISO 5832-3
RMH Proximal Femoral Stem, RMH Distal Femoral Stem, Tumor Extension Stem, Cementless Tumor Extension Stem, Tumor Extension Stem (curved), Extension Piece	Ti6Al4V as per EN ISO 5832-3
Proximal Femur, RCH Cemented Femoral Stem, RCH Long Cemented Femoral Stem, RRH Cemented Femoral Stem, RCL Cemented Femoral Stem	CoCrMo Alloy as per ISO 5832-4
LAC-TCⅠ Cementless Acetabular Cup, LAC-TCIV Cementless Acetabular Cup, LAC-TCⅡ Cementless Acetabular Cup	TC4 as per EN ISO 5832-3
LAC-Ⅰ Cementless Acetabular Cup, LAC-Ⅱ Cementless Acetabular Cup, LAC-Ⅲ Cementless Acetabular Cup, LAC-IV Cementless Acetabular Cup	TA2G as per EN ISO 5832-3
TAC-Ⅰ Acetabular Cup, TAC-Ⅱ Acetabular Cup, TAC-Ⅲ Acetabular Cup	TC4 as per EN ISO 5832-3
Trabecular Augment	TC4 as per EN ISO 5832-3
Acetabular Cage	Ti6Al4V as per EN ISO 5832-3
VE Liner, Dual Mobility Cup System VE Liner	VE-XLPE as per ASTM F2565
XLPE Liner, LAC-Ⅱ XLPE Liner, Dual Mobility Cup System XLPE Liner	XLPE as per ASTM F2565
LAC-Ⅰ PE Liner, LAC-Ⅱ PE Liner, LAC-IV PE Liner	UHMWPE as per ISO 5834-2
Cemented Acetabular Cup	UHMWPE as per ISO 5834-2
Bipolar Head	CoCrMo Alloy as per ISO 5832-4 UHMWPE as per ISO 5834-2
Ceramic Head	Ceramic Delta as per ISO 6474-2
Ceramic Liner	Ceramic Delta as per ISO 6474-2
Dual Mobility Cup System CoCrMo Liner	CoCrMo Alloy as per ISO 5832-4
Metal Head	CoCrMo Alloy as per ISO 5832-4
Centralizer	UHMWPE as per ISO 5834-2
Restrictor	UHMWPE as per ISO 5834-2
RMH Locking Screw	Ti6Al4V as per EN ISO 5832-3
RMH Trochanter Claw	TA2G as per EN ISO 5832-3
Screw, RMH Screw	Ti6Al4V as per EN ISO 5832-3
Distal Sleeve	Ti6Al4V as per EN ISO 5832-3
Titanium Cable	Ti6Al4V as per EN ISO 5832-3

Caution:

1.Devices should only be used with compatible components and should not be used in conjunction with those of another manufacturer since compatibility of mating parts cannot be assured.

2.Femoral components for revision surgery include: RMH Proximal Femoral Stem, RMH Distal Femoral Stem, RMH Screw, RMH Locking Screw, RMH Trochanter Claw.

2.Indications

It's intended for use as a hip joint prosthesis together with components of our company under the same system, including the following indications:

1. High level hip injury caused by osteoarthritis or rheumatoid arthritis;
2. Congenital hip dysplasia and joint destruction due to pathological reasons;
3. Joint destruction due to traumatic reasons or ischemic femoral head necrosis requiring total hip, partial hip arthroplasty and previous surgery Joint revision surgery is required;
4. Hip bone tumor.

3.Contraindications

The device should not be implanted where there is active infection or insufficient bone-stock to support the prosthesis or provide adequate fixation.

Some contraindications are relative to the extent and severity of conditions and the benefits of prosthetic arthroplasty should be considered based on the patient's overall evaluation and the possibility of alternative treatment. Examples of such conditions include; osteoporosis, osteomalacia, osteogenesis imperfecta, or hypophosphatemia.

Further contraindications may be, but are not limited to the following conditions:

- Conditions limiting blood supply to the bone or joint
- Systemic or local infection or previous intra-articular infection
- Preoperative radiological examination with excessive dose
- Psychological or neurological conditions which would restrict the patient's ability or compliance in restricting physical activity
- Skeletal immaturity
- Conditions or activity which may place excessive load on the components such as obesity, muscle deficiencies, tendon & ligament deficiencies, multiple joint disabilities, and Charcot joints.
- Circumstances that lead to excessive loads on implants, such as body weight and range of motion.
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. Please take caution that CoCrMo Alloy and HNSS contains nickel. If sensitivity is suspected. Preoperative test should be conducted
- Distant foci of infection which may spread to the implant site

4.Patient Selection Pre-Cautions

The following conditions require cautions and due considerations during pre-operative planning by the surgeon:

- Body mass; an obese patient may place increased loads on the prosthesis which can lead to failure of the device or loosening in the bone. The risk increases with smaller size implants and increasing patient weight.

- Excessive loading through arduous activity; if the patient's occupation or activity includes significant impact loads, the increased forces can cause failure of the implant or failure of the fixation of the device to bone. High levels of physical activity over time can accelerate the normal wear process that occurs with the bearing surface of prosthetic joints.
- Mental illness, or substance dependence which may tend to reduce the patients compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications.
- Material sensitivity; patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, pre-operative tests should be conducted

Caution: A higher incidence of sciatic nerve palsy is associated with arthroplasty in the treatment of congenitally dislocated hips. Also, in such patients, a pseudo acetabulum should not be utilized as a placement site for the acetabular cup.

5. Pre-operative

Pre-operative planning allows assessment for implant size and restoration of biomechanics. Failure to carry out proper planning may lead to incorrect choice of implant type/size. Ensure all implant sizes and required instrumentation are available prior to surgery.

As with all surgical procedures, the patient should be made aware of the risks and possible adverse effects. In particular the patient should be warned of limitations of the prosthetic device components being implanted, including the limited expected service life of the device and the possible requirement for revision surgery to replace worn or damaged prostheses.

Care should be taken when handling the prosthetic components to avoid damage to the surface of the device. Denting, notching or scratching can greatly reduce the tensile strength, fatigue resistance or wear properties of the component potentially leading to fracture or failure of the device. The porous or coated surfaces of the device should be protected from contact with gauze, cloth or other fibre-releasing materials.

Surgical technique information is available for each device component. The surgeon should familiarise themselves thoroughly with the technique prior to consideration of the use of the device for any specific patient.

Implants are only to be used with approved LDK Medical instrumentation and/or devices. Implants have been designed and tested for use with one another, and use with third party devices is untested and strictly prohibited. The surgical instrumentation prescribed within the technique for the implantation of the prosthesis should not be used for any other device or in a manner contrary to its intended use.

Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear, damage or corrosion and replaced prior to surgery if required. Instrumentation should be sterilized according to the manufacturer's protocols. Do not re-sterilize component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

6. Intra-operative

Check device prior to implantation. Do not use any device that shows signs of damage, contamination or previous use.

The correct selection and positioning of the acetabular component and the choice of the appropriate neck length and/ or offset of the stem is important to prevent complications. Malposition of the components can result in loosening, or joint dislocation.

Penetration of the inner cortex of the pelvis should be avoided when drilling for or placing screws for fixation of the acetabular component as damage to neurovascular structures may occur from the drill or screws of excessive length. Similarly, drilling and/or placing screws in the acetabular prosthesis when oriented in an anterior or medial direction, is associated with a high risk of serious vascular injury. Screws must be completely seated in the shell to allow proper seating for the acetabular liner.

The stem taper and femoral head bore must be clean and dry prior to assembly or postoperative separation of the head from the stem may occur. Assemble the stem and head by gentle placing the head on the stem while maintaining alignment, then sharply hitting the ball with the soft plastic hammer instrument to firmly connect the components.

Before assembly of components, surgical debris must be cleaned from the surfaces. Debris may inhibit the component coupling mechanism. When inserting acetabular liners, ensure soft tissue does not impinge between the shell and liner. Modular components such as femoral heads must be assembled securely to prevent disassociation. Incorrectly seated acetabular liners may loosen and disassociate from the shell.

If assembled modular components must be disassembled then those components must be disposed of and new components used. Disassembly can damage the components and cause a reduction in assembly strength. If a liner is disassembled from a cup then the liner must be disposed of. If a femoral head is disassembled from a stem, both the stem and head must be disposed of.

Where removal of the prosthetic femoral head is required in revision surgery, a ceramic head should not be placed on a previously used taper connection. Irregularities in the femoral taper may induce stress concentrations in the ceramic head which could result in fracture of the ceramic head.

Implants removed from **the patient at revision surgery should never be re-implanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the country's waste regulations where the implant is removed.**

The wound site should be thoroughly cleaned of bone and other debris before closure. Range of motion should also be assessed before closure. Osteophytes, ectopic bone or old scar tissue causing impingement should be removed to reduce the possibility of reduced range of motion or dislocation.

7. Post-operative

It is extremely important that patients are provided with clear directions regarding the extent, type and progression of post-operative physical activity. The level of weight bearing should be determined for the individual patient depending on the type of procedure and components used. In the event of bone grafting or extensive revision surgery a non-weight bearing period should be considered.

Patients should be warned against unassisted activity, particularly the use of bathing and toilet facilities and other activities requiring significant non-gait motion of the hip.

When manual patient handling is required, care should be taken to support the operative leg and pelvis to minimize the risk of dislocation.

The use of post-operative physiotherapy is recommended to rehabilitate the muscles affecting hip function as physical activity is increased.

Staged follow up with x-ray comparison to the immediate postoperative imaging is recommended to detect evidence of detrimental change in the implant. Any indication of structural failure of the implant, radiolucencies, or osteolysis should be monitored carefully for the potential need of early revision surgery.

The patient should be advised that prophylactic antibiotics therapy may be required for subsequent treatments, procedures, or situations which may result in bacteremia.

8. Retrieval and Analysis of Removed Implants

Take into account the need for patient safety, the surgical implant shall be retrieved in a manner which cause as little damage as possible to both the surgical implant and the surrounding tissues. As far as possible, functional surfaces, e.g. bearing surfaces of joint prostheses, mechanical connections, e.g. hinges, joints, screws, and fracture surfaces of broken surgical implants, shall be protected during and after explanation. Fragments and debris, which can provide valuable information, shall also be retrieved.

<u>Warnings and Precautions</u>

9. Possible Adverse Effects

As with all major surgical procedures, side effects and adverse events can occur. Some of the more common complications include:

- Decreased range of motion, dislocation, subluxation, leg length discrepancies.
- Heterotopic bone formation, penetration of the femoral prosthesis through the femoral cortex, acetabular fracture, intra-pelvic protrusion of the prosthesis.
- myositis ossificans or femoral impingement.
- Vascular injury and/or delayed wound healing.
- Excess femoral medialisation or lateralisation, causing gait change or pain in the joints of the affected or contralateral extremity nerve damage, with consequential pain or numbness of the affected limb.
- Patients who are overweight or have high activity levels are also at risk of implanting a small size femoral stem. Younger patients have high activity levels and body weight is prone to change. In addition, if the patient has other disabilities, abnormal gait results. The stress on the femoral component will increase.
- The small femoral stem is suitable for patients with small medullary cavity and / or small femoral epiphyseal plate. The reduced cross-section of the femoral stem can better meet this special structural requirement. As the size decreases, the fatigue strength of the implant decreases accordingly. Such patients should be carefully screened. The small femoral stem is only suitable for patients with low to medium activity levels, and young, overweight and high activity patients are not suitable for implantation of small femoral stem.
- Femoral heads with big offset are at greater risk, such as possible fracture of the femoral stem or early loosening. The smaller the femoral stem size, the greater the risk. Therefore, the +8 femoral head cannot be matched with the small-sized femoral stem.

Wear

The bearing surfaces of components may wear with use over time. The presence of third body particles of metal, bone or other materials which can develop as a result of the surgical procedure may cause abrasion of the articulating surfaces and

lead to accelerated wear. Higher rates of wear may reduce the functional life of the hip replacement and result in the need for early revision surgery to replace the worn components.

Osteolysis

Progressive bone resorption or osteolysis may occur around the prosthetic components as a consequence of the body's immune reaction to particulate wear debris. Particles are generated by interaction between the prosthetic components, as well as between the components and bone interface. Particles may also be generated by third-body debris between the articulating surfaces. Osteolysis can lead to failure of the fixation between the implant and bone requiring the removal or replacement of the prosthetic components.

Structural Failure

Fracture

Pelvic or femoral: May occur intraoperatively, due to reaming, broaching or implant insertion. May occur postoperatively, due to prosthesis stress transfer caused by inappropriate early weight bearing or trauma.

Nerve Injury

Femoral, sciatic, peroneal nerve, and lateral femoral cutaneous nerve injury resulting in temporary or permanent Infection. Local or systemic, acute post-operative wound infection and late onset prosthetic infection.

Hematoma

Deep and superficial wound hematoma. Thromboembolic incidents including venous thrombosis, pulmonary embolus, cerebrovascular events or myocardial infarction, may lead to death.

Material Sensitivity

Metal sensitivity reactions and/or allergic reactions to foreign materials may occur.

10. Storage and Handling

Implants are supplied sterile and have been double sterile packaged. The method of sterilization is noted on the package label.

Ethylene oxide sterilization only used for VE Liner and XLPE Liner, is valid for 5 years as shelf life; cobalt 60 irradiation sterilization used for all other components is valid for 5 years as shelf life. Sterilization is invalid if product package is damaged. Refer to the package label for the sterilization indicator. The Ceramic femoral head should not be sterilized by steam.

Store implants in original protective packaging in a clean and dry atmosphere with temperature from 0 °C to 30 °C and less than 80% of relative humidity. Keep away from sunlight. Do not use when the packaging is damaged.

Do not use the product after the expiry date (year-month) shown on the product packaging. Avoid removing from packaging until immediately prior to use.

Inspect device prior to use. Visibly damaged, scratched, improperly handed implants or previously used implants, must not be implanted under any circumstances as the functionality, integrity and/or sterility of the device may be compromised. Used devices should be disposed of according to local hospital procedures or returned to the manufacturer for investigational purposes.

Instruments specified for Hip Joint Prostheses Systems can be successfully sterilized by moist heat sterilization processes and dried when using FDA-cleared sterilization wrap as the sterile barrier system with the following parameters:

Prevacuum (4-pulse) conditioning; 4-minute, 132 °C exposure; 30-minute dry time

Instruments specified for Hip Joint Prostheses Systems can be effectively cleaned by following recommended automated cleaning process:

R1. Point-of-Use
   a. Decontamination of reusable instruments should occur immediately after completion of the surgical procedure.
   b. Do not allow soiled instruments to dry prior to cleaning / reprocessing.
   c. Excess blood and/or debris should be wiped off to prevent it from drying onto the surface.

R2. Initial Rinse
   a. Remove devices from tray and rinse devices under flowing, cool (20-25 °C) Utility Water for a minimum of 1 minute, using a soft-bristled nylon brush and gloved hand to aid in the removal of visible residual soil. While rinsing, actuate each of the devices' components through their full range of motion.
   b. Rinse complex devices for an additional minimum of 1 minute using a water jet, paying special attention to the challenging areas.
   c. Visually inspect devices for soil and/or damage, using ambient light and paying special attention to challenging areas.
   d. Repeat steps b. and c. until there is no visible gross soil

R3. Load Washer
   a. Place devices in Washer basket.
   b. Cover devices with a mesh lid.

R4. Program/Select Washer Cycle
   a. Pre-wash Cold Utility Water 2 minutes
   b. Wash Heated Utility Water, minimum 65.5 °C 4 minutes Enzymatic detergent: per manufacturer's instructions
   c. Rinse Heated Utility Water, 43.3 – 82.2 °C 2 minutes
   d. Thermal Rinse Heated Utility Water, 82.2 – 95.0 °C 1 minute NO lubricant
   e. Dry Maximum 100 °C for 10 minutes

11. MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated the "Hip Joint Prostheses Systems" are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

-Static magnetic field of 3.0-Tesla (3.0T)

-Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 0.90W/kg for 1200s scanning.

-The effects of using MR conditions above these levels have not been determined.

3.0T MR System

MR System: 128MHz, Philips Medical Systems, Software Versions 3.2.7, 3.2.7.1.

A temperature rises of 0.5 °C or less was measured when scaled to a phantom average SAR of 2.6W/kg for 1200s of RF power application.

Image Artifacts

MR image quality may be compromised if the area of interest is in the same area of relatively close to the position of the device. Distortion extended as much as 8 cm from the implant in image distortion tests performed according to ASTM F2119 in a 3.0T MR system. Therefore, it may be necessary to optimize MR image parameters for the presence of theses implants.

12. Functional Device Lifespan

The functional lifespan of an implant may be impacted by surgeon and selected operative technique, patient physiology and activity levels. Whilst it is normally expected that the lifetime of this implant will exceed a minimum of 10 years, it will be subject to wear and tear through normal everyday use.

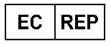
13. Limited Warranty / Liability

As a manufacturer, Beijing Lidakang Technology Co., Ltd. is not responsible for complications arising from incorrect diagnosis, choice of implant, incorrect operative technique, treatment method limitations or inadequate asepsis.

Beijing Lidakang Technology Co., Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. These instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

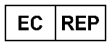
14. Symbols on Label

Symbols	Titles	Symbols	Titles
	Catalogue Number		Caution
	Batch Code		Do not re-use
	Date of Manufacture		Consult instruction for use
	Use by date		Do not use if package is damaged
	Keep away from sunlight		Do not resterilize
	Keep dry	STERILE R	Sterilized using irradiation

	Manufacturer		Sterilized using ethylene oxide
	Authorized representative in the European Community		Medical device
	Double sterile barrier system		Unique device identifier
	Temperature limit		Humidity limitation

15. Further Information

For product specific training or further information, please contact your supplier or Beijing Lidakang Technology Co., Ltd. directly.



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