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Instructions for Use

JRI Thompson Hemiarthroplasty

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English

Important Information

Please read instructions for use and corresponding operative technique, prior to use in a clinical setting. The Surgeon should be familiar with the appropriate operative technique.

Material(s)

Material(s):	Standard(s):
CoCr	BS ISO 5832-4

Intended Use

The JRI Thompson Hemiarthroplasty Stem is a collared Cobalt Chrome femoral prosthesis, intended for use with cement in hip hemi-arthroplasty for the management of hip fractures**.**

Description

JRI Thompson Hemiarthroplasty Stem is a single use, Cobalt chrome, sterile implant intended for use with cement during hemi-hip arthroplasty. The primary design function is the restoration of biomechanics via replacement of the damaged femur and femoral head.

JRI Thompson Hemiarthroplasty Stems are supplied sterile via gamma irradiation, in a single pack, double-barrier packaging. Various sizes of the implant are available to accommodate anatomical variations of the acetabulum.

Indications

JRI Thompson Hemiarthroplasty Stem is indicated for the treatment of fractures of the femoral neck.

JRI Thompson Hemiarthroplasty Stem is intended for use in elderly patients with low mobility and potential comorbidities.

Contra-indications

The device should NOT be implanted where there is active infection, insufficient bonestock to support the prosthesis or provide adequate fixation. JRI Thompson Hemiarthroplasty Stem is not intended for use in revision surgery.

Further contra-indications may be, but are not limited to, the following conditions:

- Severe muscle, nerve or vascular diseases that endanger the extremity in question
- Severe deformations, tumours
- Severe osteoporosis or deficient bone substance that may endanger stable seating of the prosthesis
- Systematic and metabolic disorders
- Weakened or compromised immune system (HIV, tumours, infections)

Precautions

The following conditions require caution and due consideration during pre-operative planning by the surgeon:

- Obese or severely overweight patients
- Excessive loading through arduous activity
- Lack of mental faculties to understand post-operative recuperative regime
- Alcohol dependency or drug abuse
- History of falls or disabilities

In patients' with a high body mass index, where delayed surgery is feasible, it is advisable that a programme of weight reduction is undertaken prior to any joint replacement surgery.

Warning

This device should only be implanted by operating surgeons who are familiar with the general problems of prosthetic surgery and who are sufficiently trained to the product-specific operative technique. The surgeon is responsible for ensuring the surgery is carried out properly and in line with the instructions provided in the operative technique.

As a manufacturer, JRI Orthopaedics Ltd. Is not responsible for any complications arising from incorrect diagnosis, incorrect choice of implant, incorrect operative technique, treatment methods limitations or inadequate asepsis.

Pre-operative

Pre-operative planning allows the surgeon to assess 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. Consult operative technique and training materials provided by JRI Orthopaedics Ltd. before use.

Functionality of surgical instruments should be checked. Use of damaged instruments may lead to early failure of implant.

Transient bacteraemia can occur after surgical procedures. To prevent late infection at the implant site, many orthopaedic surgeons advise the use of antibiotic prophylaxis before and after such procedures for their patients.

Intra-operative

This implant is intended for use with cement. The surgeon must follow the cement manufacturer instructions concerning preparation and technique.

The posterior surgical approach has been shown in published literature to have a higher risk of dislocation with this style of prosthesis, therefore would not be recommended.

Avoid contact with materials that might damage the surface of the implant after removing from packaging. It is important to check the implant before it is inserted to ensure there is no damage. Packaging should only be removed immediately prior to implantation.

Prior to wound closure, the surgical site should be cleared from bone cement, particulate matter or other debris.

Implants MUST NOT be re-used under any circumstances as the functionality, integrity and/or sterility of that device may have been adversely affected and therefore cannot be guaranteed.

Post-Operative

Physicians should ensure patients are aware of implant loading limitations and ensure consistent post-operative care, from a suitably qualified professional, is made available.

Post-operative care should incorporate recognised procedures and take into account information from the operative technique and documented according to internal hospital procedures. Failure to do this may result in malalignment, delayed wound/bone healing, implant failure, infection or impaired joint function.

Side Effects

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

- Problems resulting from anaesthesia and patient positioning (pain, nausea etc.)
- Infection
- Aseptic loosening of implant
- Dislocation, subluxation, insufficient range of movement, leg length discrepancy
- Damage to soft tissue
- Fracture of implant, bone or cement
- Allergy/hypersensitivity reactions
- Cardiovascular/pulmonary embolism, respiratory infection, venous thrombosis, neuronal dysfunction, haematoma or delayed wound healing

Revision

In the event the JRI Thompson Hemiarthroplasty Stem requires revising; ensure all fragments or the primary prosthesis are removed. Clean and prepare the area for implantation in line with current Instructions for Use and Operative Technique of selected revision implant, prior to insertion of device.

Storage & Handling

Store implants in their original protective packaging in a clean and dry atmosphere.

Do not use if the packaging is damaged. Do not use this 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 handled implants and implants that have already been used must not be implanted under any circumstances as the functionality, integrity and/or sterility of that device may have been adversely affected and therefore cannot be guaranteed.

MRI Safety Information

Non-clinical testing has demonstrated that JRI Thompson Hemiarthroplasty Stemis 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 T
- Maximum spatial field gradient of 720 gauss/cm
- Maximum whole body averaged specific absorption rate (SAR) of 3.0W/kg

Under the scan conditions defined above, the JRI Thompson Hemiarthroplasty Stem is expected to produce a maximum temperature rise of 1.7°C after 15 minutes of continuous scanning.

The image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the medical device. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	42,763-mm^2	17,875-mm^2	56,249-mm^2	28,917-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Additional information regarding MRI safety is available upon request at JRI Orthopaedics Ltd.

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.

Products intended for single-use must not be re-used

Re-use or reprocessing (e.g. cleaning and re-sterilisation) may compromise the structural integrity of the device and / or lead to device failure which may result in patient injury or death.

Reuse or reprocessing of single-use devices may create a risk of contamination (e.g. transmission of infectious material) which may result in injury or death.

Further information

For product specific operative technique training or further information, please contact your JRI Orthopaedics Ltd. Sales Representative or JRI Orthopaedics Ltd. directly.

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