JRI ORTHOPAEDICS LTD
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Important Information

Please read prior to use in a clinical setting. The Surgeon should be familiar with the operative technique.

Description

JRI offers 2 Hemi-Arthoplasty systems, one for use with cement and the other cementless.

The Furlong® Hemi-Arthroplasty system is for use WITH cement and consists of a Femoral stem which is a straight stem, double tapered, collarless prosthesis, made of stainless steel.

Extensive clinical use of this design has proven its biomechanical stability and biocompatibility.

The Furlong® H-A.C. Hemi-Arthroplasty is for use WITHOUT cement and consists of a Femoral stem which is straight stemmed, collared Hemi-Arthroplasty made of stainless steel and fully coated with Hydroxy-apatite Ceramic $CA_5OH(PO_4)_3$. Fixation being achieved through bone ingrowth and union of the coating and the host bone. Supravit granules are available to supplement this system where required.

Both types of stem can be used with EITHER a **Solid Physiological size head** or a **Bi-polar Physiological size head** made up of an outer physiological size head, a UHMWPE inlay and an inner head of 22.25mm diameter.

These implants are available in a range of sizes to accommodate anatomical variations. Smaller sized implants are intended for patients with small bone and normally slight weight and could be inappropriate for other patients.

Note

This is a component of the Furlong® Hemi-Arthroplasty System. It should only be used with other compatible components of the Furlong® System, with the corresponding taper connection. Implant components from one manufacturer should not be used together with those of another manufacturer, since compatibility of mating parts cannot be assured.

JRI offer a range of **Bone substitute** materials primarily for implantation in rebuilding bonestock in cementless implant operations.

Symbol

LS = Long Spigot. XXS = Extra Extra Small. XS = Extra Small. S = Small. M = Medium. L = Large

Indications

The Furlong® Hemi-Arthroplasty systems are indicated by, but not limited to the following conditions:

1. Acute traumatic fracture of the femoral head or neck.
2. Irreparable fracture of the femoral neck

Note

This device is to be used only under the control and supervision of an accredited Orthopaedic Surgeon. The medical team have a duty of care towards their patient which includes the following: A responsibility to diagnose appropriately the necessity for the implantation of this device, bearing in mind any indications and contra-indications present in any particular patient; to carry out a full and adequate consultation with the patient before surgery, explaining the risks and consequences of the surgical procedure and the longevity of the implant and any factors affecting the same; to use an appropriate operative technique, and implement a suitable post-operative regime with appropriate follow up and monitoring for any adverse effects of surgery. As a manufacturer of the product, JRI take no responsibility for any damage, breakage or adverse affects caused as a result of any failure in the medical team to discharge such duty. Patients receiving hip joint replacements should be advised before surgery that the longevity of the implant might depend on their weight and level of activity.

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Contra-indications

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

Pre-operative

The following conditions require precaution: - Patients' with a Body Mass Index of 25 or more, excessive loading through arduous activity, lack of mental faculties to understand post-operative recuperative regime, alcohol or drug abuse, a history of falls or disabilities. The surgeon should discuss all aspects of the surgery and the implant with the patient and allow the patient to read these Instructions For Use, with the surgeon explaining them, before surgery takes place. Allergies and other reactions to implant materials although rare should be considered and ruled out pre-operatively. X-ray templates should be used to estimate implant sizes, placement and joint alignment. All packages and implants should be thoroughly inspected for possible damage prior to surgery. The patient should be advised of all surgical risks including the risk of cardiovascular disorders, tissue reactions, haematoma and infection.

Intra-operative

The surgeon is responsible for the operative technique used for implanting the product, however JRI recommend that to ensure optimum implantation of this device the recommended operative technique is used (and is available on request), with JRI specific instrumentation. Always use a trial for any test fit and to check the range of motion. As large a stem size as possible should always be used allowing for the reaming of the diaphysis one size up on the definitive sized stem to be implanted. No responsibility can be taken for complications due to improper implantation technique or non-specific instrumentation. Failure to use the optimum size of implant, to adequately seat the component adjacent to adequate bone and For Furlong® H-AC Hemi-Arthroplasty Systems only, to ream out the diaphysis to create a gap around the distal stem of the prosthesis and to ensure the component is supported in the metaphysis and is stable, may result in dislocation, subsidence, fracture or loosening of the components. Implants MUST NOT be re-used because the fatigue strength and mechanical properties of the implant may be impaired from previous actions. As the manufacturer, JRI Ltd can take no responsibility for damage, breakage or other adverse effects caused as a result of the failure of any person to follow these instructions or any other relevant applicable JRI instructions.

Post-operative

Patients should be advised by the surgeon about the post-operative recuperative regime and be given suitable directions or warnings. Accepted surgical practices should be followed with regard to patient handling, post-operative therapy, unassisted physical activity and trauma. The incidence and severity of complications are usually greater in surgical revisions than primary operations.

JRI considers the Furlong® and the Furlong® HAC Hemi-Arthroplasty stems to be substantially equivalent to those tested by US Institute for Magnetic Resonance Safety, Education and Research. Following this, JRI considers the Furlong® and the Furlong® HAC Hemi-Arthroplasty stems to be MRI safe under an MRI machine rating of up to 3.0 Tesla.

Adverse effects

All joint prostheses are subject to wear. JRI Ltd recommends the use of specific materials to minimise wear. JRI Ltd can take no responsibility for the effects of wear debris, dislocations, subluxation, rotation problems, decreased range of motion, lengthening/shortening of the leg or from erroneous indication, incorrect operative technique, or inadequate aseptic precautions. A decreased range of motion may be caused through improper positioning or looseness of components. Loosening may also occur due to inadequate fixation or improper positioning. Bone fractures may result from one-sided overloading or weakening of the bone substance. Early or late infection may require the removal of the implant. Allergic reactions to the implant materials can sometimes occur.

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Revision

A range of long stem implants based on this system, are available for the Furlong Hemi-Arthroplasty stems. In general a larger stem must be used. A longer distal length is provided for additional stability. For revision operations the notes in this Instruction For Use apply. Ensure that all fragments of the primary prosthesis and any bone cement (if applicable) are removed, the area cleansed and prepared in accordance with the operative technique instructions.

Storage & Handling

The Furlong® and the Furlong® HAC Hemi-Arthroplasty systems are supplied sterile having been sterilised by Gamma irradiation. The components should be stored in their original boxes in a clean and dry atmosphere, protected from direct sunlight. If the inner packaging becomes wet, is damaged or opened, do not use. JRI do not recommend the resterilisation of medical devices and the device. Do not use this product after the expiry date (year-month) shown on the product packaging. Exposed articular surfaces must be neither marked nor come into contact with metallic or hard objects. Touching the articular surfaces or the taper for the head must be avoided. If they are damaged in any way the device should not be implanted, but returned to Joint Replacement Instrumentation Ltd for inspection. Protective caps fitted to the stem taper should be removed just prior to use. Joint prostheses must be neither treated mechanically nor modified. 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. NOTE: UHMWPE cannot be re-sterilised.

Post-operative follow up

The patient should be instructed to inform his surgeon without delay of the slightest change in his operated joint. Early detection of an impending complication allows the surgeon to initiate timely and effective countermeasures. A revision performed at the right time has a much better chance of success. It is advisable that the surgeon systematically monitors every patient and if annual checks are not possible the surgeon should be sent a control radiograph of the joint. This will enable the surgeon to detect any complications at an early stage.

MRI safety

Non-clinical testing has demonstrated that JRI Hip Systems are MR Conditional. A patient with this device can be scanned safely under the following conditions: - Static magnetic field of 3-Tesla or less and a maximum spatial gradient magnetic field of 720-Gauss/cm or less. Non-clinical testing has indicated that MRI-related heating is negligible at 3-Tesla.Image quality may be compromised if the area of interest is in the vicinity of, or relatively close to, the implanted device. Additional information is available upon request.

Device Lifetime

The lifetime of this device is dependant amongst other things upon the patients' weight / level of activity and on the operational technique. 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 use.

Further information

For further information, please contact your JRI Ltd Sales Representative or JRI Ltd directly.