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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

The Furlong® Modular THR consists of the following components:

A **Femoral stem** which is a straight double tapered, collarless prosthesis, made of stainless steel and for use with cement. **Femoral heads** with a taper connection and of various diameters and neck lengths are available for use with this system. Special Instructions For Use are required for ceramic heads: Refer to JRI Instructions for Use 155-020 A cemented **type Acetabular Cup** is available in a variety of sizes for use with cement and is made of UHMWPE with an integral radiopaque stainless steel X-ray wire.

An **Acetabular Support Ring** (ASR) for use with cemented acetabular cups is available where there is a deficient acetabulum. This is made of unalloyed titanium and should be used with JRI Acetabular bone screws made of titanium alloy Ti-6Al-4V. In this application the X-ray wire MUST be removed from the Muller type acetabular cup prior to use.

Cement plugs made of UHMWPE with an integral radiopaque stainless steel X-ray wire are available to contain the pressurised cement in the femoral canal at the correct depth.

Extensive clinical use of this design since 1979 has proven its biomechanical stability and biocompatibility. Various sizes of implant are available 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

Components of the Furlong® Modular Total Hip Replacement System 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.

Symbol

Heads: S = Short neck M = Medium neck L = Long neck XL = Extra Long neck
Stems: LS = Long Spigot 5 = 5mm lateral offset XXS = Extra Extra Small. XS = Extra Small. S = Small. M = Medium L = Large

Indications

The Furlong® Modular Total Hip Replacement System is indicated by, but not limited to the following conditions:

1. Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

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

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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.

Contra-indications

The device should not be implanted where there is active infection, insufficient bone stock to either support the prosthesis or provide adequate fixation. Further contra-indications may be, but are not limited to the following conditions:

1. Severe deformities.
2. Severe Osteoporosis.
3. Tumours.
4. Systematic and metabolic disorders.
5. Obesity.
6. Drug addiction.

Pre-operative

The following conditions require precaution: - obese or severely overweight patients, 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. In patients' with a High Body Mass Index of 25 or more, when delayed surgery is feasible, it is advisable that a programme of weight reduction is undertaken prior to any Total Hip Replacement. 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. JRI recommend the use of bone cements that do not contain zirconia and pressurisation of the bone cement. 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 are available on request), with JRI specific instrumentation. Always use a trial for any test fit and to check the range of motion. 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 within the cement mantle or to ensure the component is supported in the metaphysis and is stable, may result in dislocation, subsidence, fracture or loosening of the components. Care should be taken not to over tighten bone screws. The optimum number of bone screws (with a minimum of three) should be used in Acetabular support rings so as to provide adequate stability whilst minimising any fretting effects or the potential of screw failure. Ensure the appropriate selection of bone screw length and location to avoid damage to underlying soft tissue areas. 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.

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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.

Adverse effects

All joint prostheses are subject to wear. JRI Ltd recommends the use of specific materials to minimise wear, i.e. ceramic femoral heads. 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 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.

Revision

A range of revision implants based on this system, are available. In general a larger stem and acetabular cup must be used. A longer distal length is provided for additional stability. When ceramic femoral heads are to be replaced a range of Revision Ceramic heads are available otherwise a metal femoral head MUST be used. 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® Modular Total Hip Prosthesis system is supplied sterile having been sterilised by Gamma irradiation. The components should be stored in their original boxes in a clean and dry atmosphere at room temperature, 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 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 JRI Orthopaedics 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

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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.