Furlong® H-A.C. THR System

155-029 Issue 17 - August 2017

English

Important Information

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

Caution

Federal (U.S.A) law restricts this device to sale by or on the order of a physician. For use in the U.S.A. please read Physician for Orthopaedic Surgeon or Surgeon and 'Adequate Directions for Use' (ADU) for instructions for use in the following text:

Description

The Furlong® H-A.C.THR System is comprised of a Furlong® H-A.C or Furlong® Active Femoral Stem or Furlong Evolution® Femoral Stem , a Furlong® H-A.C Acetabular Cup (CSF, *CSF Plus* or Threaded), an acetabular cup liner (UHMWPE, Highly crosslinked UHMWPE (CLP-75), alumina ceramic or Biolox delta) and a femoral head (alumina ceramic, Biolox delta, High Nitrogen Stainless Steel (HNSS) or Cobalt Chrome). A high nitrogen stainless steel Bipolar Head is available for use in Hemi-Arthroplasty applications. Bone Substitute granules are available to supplement this system where required. Cancellous bone screws are available for use with CSF or CSF *Plus* cups The **Furlong® H-A.C. Stem** is a straight stemmed, collared prosthesis made of Titanium alloy Ti-6Al-4V and fully coated with Hydroxyapatite Ceramic $Ca_5OH(PO_4)_3$. The **Furlong® Active Stem** is a straight stemmed, double tapered, collarless prosthesis made of Titanium alloy Ti-6Al-4V and fully coated with Hydroxyapatite Ceramic $Ca_5OH(PO_4)_3$. The **Furlong Evolution® Femoral Stem** is a straight short stemmed, collared or collarless prosthesis made of Titanium alloy Ti-6Al-4V and fully coated with Hydroxyapatite Ceramic $Ca_5OH(PO_4)_3$. Smaller size 6 and 7 **Furlong Evolution® Femoral stems** are available for DDH and smaller patients or patients with small femoral canals. All stems are for use WITHOUT cement, fixation being achieved through bone ingrowth and union of the coating and the host bone. It is available in various sizes to accommodate anatomical variations of the femur.

A range of Furlong® H-A.C. Acetabular Cups are available in this system, refer to 155-019.

Special Instructions for Use are required for ceramic heads refer to 155-020.

JRI recommend the use of highly crosslinked UHMWPE (CLP-75) with larger metal head diameters because of reduced volumetric wear.

Bipolar Heads are a physiological size head made from a shell, a UHMWPE inlay and an inner 22.25mm diameter head. They are available for use with this stem in Hemi-Arthroplasties.

Bone Substitute granules and blocks (JRI Branded product CE 0086) are available for use with this system, please refer to 155-028. **Cancellous bone screws** are available for use with Furlong® H-A.C. CSF and CSF *Plus* acetabular cups in a variety of lengths and are manufactured from Titanium alloy Ti-6Al-4V.

NOTE: Some JRI products are not for sale in the U.S.A.

NOTE: All implants are single use.

NOTE: All implants constitute a biohazard once removed hence established procedures should be followed for its disposal.

Extensive clinical use has proven the biomechanical stability and biocompatibility of these components.

Smaller sized implants are intended for patients with smaller bone and regular Body Mass Index and could be inappropriate for other patients, as this may result in fracture of the neck or stem.

Note

MR ≤3 Tesla ≤720 gauss/cm CE 0473 STERILE R

Components should only be used with other compatible JRI Modular Femoral Head components with a corresponding taper connections, including hemiarthroplasty heads (155-027), if indicated by the clinical condition.

Implant components from one manufacturer MUST NOT be used together with those of another manufacturer, since compatibility of mating parts cannot be assured **except for product combinations specifically approved for use with JRI devices**.

JRI's HNSS, Cobalt Chrome, HNSS Bipolar & HNSS Physiological Femoral Heads are approved for use with **AEON stems.**

Symbols

LS = Long Spigot, 5 = 5mm lateral offset, 48 = 48mm spherical diameter

Indications

The Furlong® H-A.C. Total Hip Replacement System is indicated for, but not limited to the following conditions:

1. Severely painful and/or disabled hip 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 ankyloses*.

N.B Bipolar Heads should only be used for acute fracture of the femoral head or neck in the absence of other pathology.

* Furlong Evolution® Femoral Stems are not indicated for certain cases of ankyloses.

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.

Contra-indications

The device should not be implanted where there is active infection, insufficient bone stock to 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. The surgeon should discuss all aspects of the surgery and the implant with the patient and allow the patient to read this **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. The closer the angle between the hip stem and its neck is to 90 degrees the higher the loads on the implant. Similarly, increasing the offset for the same stem to neck angle will also increase implant loading. Lower neck-angled implants and those with higher offsets should be used with caution, particularly in patients with high body mass.

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. As large a stem size as possible should always be used, allowing for over-reaming of the diaphysis by 1 mm compared to the distal stem diameter of the definitive femoral prosthesis to be implanted (e.g. ream the diaphysis to 12 mm if a prosthesis with an 11 mm distal stem is 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 seat the component adjacent to adequate bone proximally, to ream out the diaphysis to create a circumferential gap around the distal stem of the prosthesis or 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. Please take care when rasping the stem cavity and on impaction of the stem. Heavy rasping and impaction may result in increased risk of peri-prosthetic fractures. Care should be taken not to over tighten bone screws. The optimum number of bone screws is to be chosen to provide adequate stability whilst minimizing any fretting or the potential of screw failure. Ensure the appropriate selection of bone screw length and location to avoid damage to underlying soft tissue areas. As the manufacturer, JRI Orthopaedics 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. The Surgeon is responsible for ensuring optimum implantation of the prosthetic device using JRI Instrumentation.

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 Orthopaedics Ltd recommends the use of specific materials to minimise wear, i.e. ceramic femoral heads. JRI Orthopaedics 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.

Revision

A range of revision implants based on this system, are available. In general a larger stem and acetabular cup should be used. A longer distal length is provided for additional stability. Caution must be taken to ensure that proximal stability is provided with these stems. A range of Revision plus stems are available where a different proximal body / distal diameter ratio is required. If revision of Furlong® Active Stems is necessary then the Furlong® HAC Revision stem can be used. When ceramic femoral heads are to be replaced a range of Revision Ceramic heads are available otherwise femoral head MUST be used with a PE cup liner. 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.

REVISION CERAMIC HEADS ARE NOT FOR SALE IN THE USA

Storage & Handling

Components of the Furlong® H-A.C. Total Hip Replacement system are 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, the Hydroxyapatite coating or the spigot taper on the stem must be avoided. If they are damaged in any way the device should not be implanted, but returned to JRI Orthopaedics Ltd for inspection. A femoral head should be fitted immediately after removing the protective cap on the stem taper. 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 (standard or highly crosslinked) 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 information

Non-clinical testing has demonstrated the HAC Hip System is 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 HAC Hip System is expected to produce a maximum temperature rise of 1.7ºC 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 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 Orthopaedics Ltd Sales Representative or JRI Orthopaedics Ltd directly.

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