JRI ORTHOPAEDICS LTD
18 CHURCHILL WAY
35A BUSINESS PARK
CHAPELTOWN
SHEFFIELD, UK
S35 2PY
TEL: +44 (0) 114 345 0000
FAX +44 (0) 114 345 0004

## 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

**Furlong® H-A.C. Acetabular cups** are made of Titanium alloy Ti-6Al-4V coated with Hydroxyapatite Ceramic $CA_5OH(PO_4)_3$. They are intended for use without cement where there is adequate bonestock to support the device in skeletally mature individuals. JRI Threaded Acetabular cups are directly fixated through their own peripheral thread. For CSF and CSF Plus cups, the screw holes permit the use of titanium alloy screws for additional fixation and security, particularly in those cases where the acetabular bonestock is deficient. Bone in-growth with union of the HAC coating and the host bone will result in complete fixation. CSF Plus UHMWPE cups are supplied with a coated plug fitted in the M7 threaded polar hole. This plug should be removed to use the associated introducer and replaced after impaction. DO NOT fit a plug to CSF or Threaded Cups.

CSF and CSF Plus acetabular cup shells are designed to have pressfit properties in that their equatorial diameter is slightly larger than the nominal diameter. This causes a compressive force around the mouth of the acetabulum. If the bone quality is felt to be insufficient to ensure good primary stability then cancellous bone screws should be used for the CSF and CSF Plus Cup shells.

CSF Plus cup shells have 2 variants. One for use with Ceramic liners ONLY and one for use with UHMWPE liners ONLY. CSF Plus UHMWPE cup shells have been designed to minimize affects of osteolysis by utilizing screwholes that can be plugged. All cups will be supplied with plugs fitted. These should be removed if a screw is to be used. CSF Plus UHMWPE cup shells have also been designed to maximize the liner life/thickness. CSF Plus CERAMIC cup shells have been designed for easier revision of the ceramic liner. Various sizes of acetabular shells are available to accommodate anatomical variations of the acetabulum. Smaller sized implants are intended for patients with small bone and normally slight weight and could be inappropriate for other patients.

CSF Plus multi-hole revision cups are a version of CSF Plus acetabular cups for use with ceramic liners only.

They are based on the larger sizes and have more screw holes to provide greater flexibility in the choice of screw position.

IMPORTANT: Ensure that the heads of cancellous bone screws used with Acetabular Cups DO NOT PROTRUDE above the bore tapered surface when using a Ceramic liner.

NOTE: CSF Plus Cups are not for sale in the USA.

Acetabular Cup liners of either UHMWPE or ceramic must be used with these components to provide an articulation surface. A ceramic liner MUST only be used with a ceramic head. Special Instructions For Use are required for ceramic implants refer to JRI Instructions For Use 155-020.

NOTE: Threaded CSF, CSF Plus UHMWPE and CSF Plus CERAMIC liners are not interchangeable. They must be used with the correct corresponding acetabular cup shell. CSF Plus UHMWPE liners are also available in highly crosslinked UHMWPE for further reduction in wear. Metal heads larger than 32mm must only be used with Highly crosslinked UHMWPE liners. Ceramic Femoral heads can be used with either standard, highly crosslinked UHMWPE or ceramic liners.

A range of hooded liners are available where there are concerns of dislocation. It should be noted that use



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of these liners slightly decreases the range of motion. CSF hooded liners are available in 10 degrees only. Ceramic liners are available only in Biolox Forte for CSF Cups whereas they are available in both Biolox Forte and Biolox delta for CSF Plus Ceramic Cups and CSF Plus multi-hole revision cups. Biolox delta has an improved strength and can be used with either Biolox Forte or Biolox delta Femoral heads. Metal femoral heads should not be used with ceramic liners.

JRI bone screws comprise of acetabular bone screws for use with JRI Acetabular Support Rings and cancellous bone screws for use with CSF and CSF Plus Acetabular Cups. They are available in a variety of lengths and are manufactured from Titanium alloy Ti-6Al-4V.

The screws require use of a pre-drill manufactured of a non implant grade stainless steel. This drill is supplied sterile and is intended for single use. DO NOT resterilise and/or reuse.

Extensive clinical use has proven the biomechanical stability and biocompatibility of the aforementioned JRI Acetabular components.

### Note

HAC Acetabular cups are a component part of the Furlong® H-A.C. Total Hip Replacement System and can also be used with the Furlong® Modular Total Hip Replacement System. They should only be used with other compatible components of the Furlong® Systems. Stainless Steel screws should not be used with this device. Implant components from one manufacturer should not be used together with those of another manufacturer, since compatibility of mating parts cannot be assured.

### Symbols

48 = 48mm spherical diameter, M7 = 7mm threaded hole.

### Indications

The Furlong® Total Hip Replacement Systems are 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 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 Orthopaedics Ltd 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 bonestock to support the prosthesis or provide adequate fixation. Further contra-indications may be, but are not limited to the following conditions:

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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 by the surgeon 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. Transient bacteremia 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 with total joint implants.

### Intra-operative

The surgeon is responsible for the operative technique used for implanting the product, however JRI Orthopaedics Ltd recommend that to ensure optimum implantation of this device the recommended operative technique detailed in our brochure, video or CD (which are available on request) is used, 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 the use of non-specific instrumentation. Failure to use the optimum size of implant, to adequately seat the component adjacent to adequate bone or to ensure the component is supported in the acetabulum and is stable, may result in dislocation, subsidence, fracture or loosening of the components. Seat the cup at 45° inclination and 10° anteversion for proper positioning to decrease the chance of dislocation. Note: Threaded cups require a greater accuracy since they cannot be repositioned intra-operatively. For CSF and CSF Plus cups: Ensuring that the cup is seated without the use of screws requires a greater level of surgical experience and it is recommended that experience is first gained using screws. The optimum number of bone screws should be used in CSF and CSF Plus Cups so as to provide adequate stability whilst minimising any fretting effects or the potential of screw failure. It is advisable to pre-drill holes for screws using the provided Single Use drills and drill guide, and care should be taken not to over tighten bone screws. Failure to use the drill guide correctly has resulted in broken drills. Ensure the appropriate selection of bone screw length and location to avoid damage to underlying soft tissue. Following screw insertion ensure that the screwheads are properly seated below the tapered surface. Clean surgical debris from the interior of the shell prior to seating the liner to prevent inadequate liner/shell interlock. Failure to properly seat the liner into the cup can lead to liner separation. Always ensure proper alignment and seating of the acetabular liner before impaction to prevent damage. For 18° Liners in particular; ensure the cup bore is clean and dry, fit the liner by sliding the liner taper along the cup taper, check the circumference of the liner to ensure it is correctly seated in the cup shell, impact the liner with a soft faced instrument.

Avoid damage to the HA coating which could lead to debris particles. Implants MUST NOT be re-used because the fatigue strength and mechanical properties of the implant may be impaired from previous actions.



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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.

## 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. While formation of wear debris may be an inevitable consequence of motion at the articulating implant surface, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis interface. JRI Orthopaedics Ltd can take no responsibility for the effects of wear debris, dislocations, subluxation, rotation problems, a 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. Care must be taken when determining and selecting the proper length of screws, many complications including internal bleeding and damage to vital organs have been reported from transacetabular pelvic penetration. The risk of injury to vascular or neuralgic structures may be reduced by placing screws in the posterior inferior and posterior superior quadrants of the acetabulum.

## Revision

Various sizes of acetabular cups are available to accommodate anatomical variations of the acetabulum. Larger sizes are offered for revision applications. 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. NOTE: For CSF and CSF Plus Ceramic cups a new ceramic liner should NOT be fitted into a used cup taper. For CSF cups a replacement UHMWPE liner can be used whilst for CSF Plus cup- Ceramic the cup must be revised. CSF Plus multi-hole revision cups are for use where bonestock may be compromised and feature a greater range of holes to provide the optimum position of the screw in the best bonestock. Fixation and pressfit of the cup should be considered to provide adequate fixation in the poorer quality bone.

## Storage & Handling

Furlong® Total Hip Replacement systems including single use drills 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 Orthopaedics Ltd 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 tapered interface for the liner must be avoided. If they are damaged in any way the device should not be implanted, but returned to JRI Orthopaedics Ltd for inspection. 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.

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Discard single use drills after use. DO NOT resterilise.

### 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. Sterile pre-drills are for single use only.

### Further information

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