# Ceramic Femoral Heads and Acetabular Cup Liners

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English

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## 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:

Ceramic products for hip joint replacements are made of high purity alumina ceramic ($Al_2O_3$) or Biolox delta. They display practically 100% theoretical density; are pore free having been manufactured by the HIP process and machined to the highest precision with respect to the surface roughness, sphericity, diameter and observation of dimensional tolerances. As a consequence, ceramic products, if correctly handled and implanted, display minimum abrasive wear, minimum debris and long life expectancy.

**Ceramic Femoral heads** in various diameters and neck lengths are available for use with Acetabular cups fitted with either a ceramic or UHMWPE liner. However due to strength constraints, a 22.25mm diameter head is unavailable. A range of Revision heads made from Biolox delta and used with the appropriate titanium adaptor are available for Revision purposes. Titanium adaptors are used to provide a new taper for the ceramic head and are available in various neck length options.

**Ceramic 5 degree liners** are available to suit the correct size of Furlong® H-AC CSF, Threaded, Acetabular cup.

A range of Biolox delta ceramic **18 Degree liners** in are available for use with the Furlong® H-AC CSF *Plus* Acetabular Cup.

5 Degree liners and 18 degree liners are not interchangeable and must be used with their correct acetabular cups.

Metallic heads must not be used with Biolox delta inserts

NOTE: CERAMIC LINERS, BIOLOX delta or REVISION CERAMIC HEADS ARE NOT FOR SALE IN THE U.S.A.

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

## Note:

This is a component of the Furlong® Modular Total Hip Replacement System or the Furlong® HAC Total Hip Replacement System. It should only be used with other compatible components of the Furlong® System, with the corresponding taper connection and should not be used in conjunction with those of another manufacturer, other than those specifically identified below, since compatibility of mating parts cannot be assured.

In addition to JRI femoral components, JRI ceramic heads are approved for use with AEON stems.

## Symbols:

S = short neck, M = medium neck, L = long neck, 28 = 28mm spherical diameter

## Indications:

A ceramic head is indicated for implantation in conjunction with a femoral stem whilst ceramic liners are indicated for implantation in conjunction with an acetabular cup. Both in the replacement of the hip joint.



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## Note:

his 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:

This device should not be used if the corresponding femoral stem taper or Acetabular cup taper is damaged, deformed or of a differing size configuration. If a femoral head is being revised, and the stem is not also revised, only a dedicated revision head should be used. Do not implant a ceramic liner during hip replacement revision if the acetabular cup shell is not being revised. Further contraindications are active infections of the joint and obesity.

## Pre-operative:

The following conditions require precaution: - obese or severely overweight patients, excessive loading through strenuous activity, poor, or deficient bone stock or bone density (osteoporosis),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. 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 detailed in our brochure, video or CD (which are available on request) are used, with JRI Orthopaedics Ltd 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. The use of components other than JRI approved devices, in combination with ceramic JRI heads and liners, is not recommended.

Points of note when using a ceramic head: -

1) Ensure that the femoral stem taper and the ceramic femoral head taper or the liner and cup taper remain clean and dry prior to implantation and that foreign bodies of any kind including bone fragments, soft tissue, cement or other material are totally removed from the interface. This can be achieved by thorough lavage and subsequent drying of the tapers. The protective plastic cap, protecting the taper of the head, should not be removed until just before it is to be implanted.



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2) Inspect the head and stem tapers or the liner and cup tapers thoroughly for damage, deformation or contamination before positioning the ceramic implant on the taper.
3) Do not use excessive force particularly an impact during attachment of a ceramic femoral head to a stem. Place the head on the taper using slight axial pressure with a slight rotational force. Check that it sits correctly and can no longer be removed. Apply a slight blow axially using a JRI head impactor on the pole of the femoral head. Never use a metallic hammer to hit or impact the ceramic head on the taper.
4) Do not use the ceramic head or the ceramic liner if it has been used previously, dropped on a hard surface or been damaged.
5) Cup Inclination, this should not be significantly greater or less than a value of 40-45$^0$. If the inclination angle is greater than 50$^0$, ceramic cup inserts MUST NOT be used.
6) Cup Anteversion, this should not be significantly greater or less than a value of 10-20$^0$. If the cup is retroverted, ceramic cup liners MUST NOT be used.
7) Trial devices must be used, prior to placement of the definitive implant, to ensure correct tissue tensioning. The joint should not luxate during movement, or subluxate due to impingement of the implant components or of soft tissue.
8) If screw fixation of the acetabular cup is to be used, these screws should be fully seated in the countersunk recesses of the implant, with no part protruding, as this might interfere with the final placement and fixation of the corresponding liner.
9) For 18 Degree 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 fit of the liner by feeling the rim of the liner/cup interface, which should be flush and on the same plane, to ensure it is correctly seated in the cup shell. Impact the liner using the supplied liner impactor and light axial hammer stroke(s). Metal hammers should never be applied directly to ceramic inserts
10) Failure to observe the surgical technique requirements with regards to cup position may lead to an increased risk of product failure.

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 Orthopaedics Ltd instructions. Failure to use the optimum size of implant or to ensure the component is stable, may result in dislocation, subsidence, or loosening of the components. Implants MUST NOT be re-used because the mechanical properties of the implant may be impaired from previous actions.

### Post-operative:

Patients should be advised by the physician about the post-operative recuperative regime and be given suitable directions or warnings. In particular, competitive, and contact sports involving jerking and jolting movements of the affected joint, may lead to excessive strains and are therefore contra-indicated for this procedure. 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

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occur. Brief, extreme overloading of the joint, such as in trauma, accident or excessive strain, can lead to fracturing, sometimes long after the event

### Revision:

If revision of a ceramic femoral head is required and the prosthetic stem remains in-situ, always replace with a revision ceramic or a metallic head. Never reuse a ceramic femoral head on a different stem once the femoral head has been placed on a stem and has then been removed. Never use the ceramic femoral head on a damaged taper or on a taper that does not fit the femoral head, i.e. on a stem from another manufacturer, or use with a stem taper adaptor. If re-operation is required in case of fracture of the ceramic femoral head make sure that the ceramic femoral head is substituted by a revision ceramic or a metallic femoral head, never use another ceramic head on an existing stem, make sure all ceramic particles have been removed and replace the polyethylene cup/liner, even if it seems to be in good condition and well fixed. If Revision ceramic heads are to be used, the titanium adaptor must be chosen to provide the correct neck length. The revision ceramic head should be assembled to the adaptor whilst still in its protective packaging, the tightly attached ceramic head and adaptor can then be placed on the clean and dry stem taper.

Ceramic liners should always be replaced with a UHMWPE liner unless the Acetabular cup is replaced. Never re-use a ceramic liner or fit a ceramic liner to a damaged Acetabular cup or an Acetabular cup from another manufacturer. When removing 5 Degree ceramic liners using JRI instrumentation always irrigate with clean, sterile water and ensure that replacement cutters are available for use if necessary. When removing 18 Degree ceramic liners use the appropriate ceramic liner extraction head. For CSF Plus Cups-Ceramic either the cup must be revised or the use of a taper adaptor must be employed. These taper adaptors enable use of a UHMWPE insert but the range of head sizes are restricted. 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:

Furlong® Total Hip Replacement 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 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. Unnecessary touching of the articular surfaces or the taper of the head or 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 or scratched implants, 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.

### 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.



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## 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 Orthopaedics Ltd Sales Representative or JRI Orthopaedics Ltd directly.