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

ACE HAC 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. Screw holes permit the use of low profile 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. A coated plug, which can be fitted in the M7 threaded polar hole, is supplied separately. The ACE cup is a true hemispherical cup. If the bone quality is felt to be insufficient to ensure good primary stability then cancellous bone screws should be used for the ACE cup. The ACE cup accept two types of liners; ceramic and UHMWPE. The ACE cup has been designed to maximise the UHMWPE liner life/thickness and for easier revision of the ceramic liner. Various sizes of acetabular cup 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.

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 or a UHMWPE.

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 and ACE liners are not interchangeable. They must be used with the correct corresponding acetabular cup/shell.

A range of hooded liners are available where there are concerns of dislocation. It should be noted that use of these liners slightly decreases the range of motion. ACE hooded liners are available in 10 and 20 degrees only. Ceramic liners are available only in Biolox delta Zero. Metal femoral heads should NOT be used with ceramic liners.

JRI bone screws comprise of cancellous bone screws for use with ACE 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 materials used for the manufacture of JRI Acetabular components.

ACE Dual Mobility Acetabular cups are made of Cobalt Chrome alloy. They are to be used with cement only. The cup is designed with grooves which hold the cup in the cement and let the excess cement escape when inserted under pressure to leave a uniform 3mm cement mantle.

Cemented ACE Dual Mobility UHMWPE liners should be used with the ACE Dual Mobility Acetabular cup in conjunction with either a cobalt chrome or a ceramic head. Standard ACE Acetabular UHMWPE liners should not be used.

A cobalt chrome sleeve and an ACE Dual Mobility UHMWPE liner can also be used in conjunction with the **ACE HAC Acetabular cups** to offer an uncemented Dual Mobility option. Standard ACE Acetabular UHMWPE liners should not be used.

Note

The ACE Acetabular cup system is a part of the Furlong® HAC Total Hip Replacement System. However only ACE acetabular components should be used in conjunction with each other and are not compatible with other Furlong® acetabular components.

Stainless Steel screws should not be used with this device.

Implant components from one manufacturer should not be used in combination with those of the ACE Acetabular Cup System, since compatibility of mating parts cannot be assured.

Symbols

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

Indications for the ACE Acetabular Cup System

The ACE Systems are indicated by, but not limited to the following conditions:

- Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
- Avascular necrosis of the femoral head.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement.
- Certain cases of ankylosis.
- Inflammatory joint disease.
- Slipped capital epiphysis.
- Pelvic fracture.
- Traumatic arthritis.
- Increased risk of dislocation (for dual mobility inserts only)

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 effects 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 for the ACE Acetabular Cup System

The device should NOT be implanted where there is:

- Active infection
- Insufficient bonestock to support the prosthesis or provide adequate fixation
- Severe deformities.
- Severe Osteoporosis.
- Active or suspected infection in or about the hip joint.
- Skeletal immaturity.
- Neuromuscular disorder which could compromise joint stability.
- Tumours.
- Systematic and metabolic disorders.
- Obesity.
- Drug addiction.

Nickel Sensitivity

Where the use of the dual mobility system is planned, patients should be assessed with respect to sensitivity to elemental nickel, as the raw material used for the manufacture of some of the components (cobalt chrome alloy) may leach nickel in concentrations sufficient to elicit an allergic response in sensitive people. Where nickel sensitivity is known or suspected, it is advisable to use a procedure that does not involve components with a known capacity to leach elemental nickel.

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 for the ACE HAC Acetabular cups

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 (which is available on request) is used, with JRI specific instrumentation.

No responsibility can be taken for complications due to improper implantation technique or the use of non-specific instrumentation.

A trial device should be used to test component fit, range of motion, and joint tensioning.

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.

The acetabular cup should be seated at 45° inclination and 10° anteversion for proper positioning, and to decrease the chance of dislocation.

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 with the ACE 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. Failure to use the drill guide correctly may result in drill breakage and/or screw misalignment. The appropriate bone screw length, and location, should be gauged, to avoid damage to underlying soft tissue. Care should be taken not to overtighten the screws. Following screw insertion, the screw heads should be inspected, to ensure that they are properly seated below the inner surface of the cup.

Surgical debris should be cleaned from the interior of the cup, prior to seating the liner, to ensure an adequate liner/cup interlock. Failure to properly seat the liner into the cup can lead to liner separation. Proper alignment and seating of the acetabular liner should be ensured, before impaction, to prevent damage. For the 18° liners in particular; the cup bore should be clean and dry, prior to fitting the liner by sliding the taper along the cup taper. The liner circumference should be inspected, to ensure it is correctly seated in the cup, followed by impaction with a soft faced instrument.

Damage to the hydroxyapatite coating should be avoided, as this could lead to debris particles. Implants MUST NOT be re-used because the fatigue strength and mechanical properties of the implant may be impaired as a result of previous actions.

Intra-operative considerations for the ACE Dual Mobility Acetabular Cup (in addition to the above)

The Dual Mobility head assembling tool must be used when assembling both the trial, and definitive, implant dual-mobility (DM) bearings and corresponding femoral heads (FH) by press-fitting the FH into the DM bearing.

When dual mobility components are to be used in conjunction with the HAC Acetabular Cup, an intermediary cobalt chrome sleeve must first be fitted in the cup, to provide the necessary secondary bearing with the liner bearing.

The bearing surfaces on both the cobalt chrome ACE Dual Mobility Acetabular cup, and the sleeve, when used in conjunction with the cementless acetabular acetabular cup, must be free of any debris, so as not to restrict movement between the liners and the bearing surfaces.

When using cement – An appropriate mix (according to acetabular size) of high viscosity cement should be prepared according to the manufacturer's instructions.

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 arise as a result of improper positioning or looseness of components. Component loosening may also occur, post-operatively, 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 as a result of 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.

All fragments of the primary prosthesis, and any bone cement (if applicable), should be removed, and the area cleansed and prepared in accordance with the operative technique instructions.

NOTE: If a ceramic liner is to be replaced, the acetabular cup will also need to be removed, as ceramic fragments may have damaged the inner surface/taper of the cup. If a UHMWPE liner is to be replaced, the acetabular cup can remain *in situ*, provided that there is still adequate fixation to the acetabulum. The larger ACE acetabular cups can be used where bonestock may be compromised: they offer a greater range of holes, providing 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

The ACE Acetabular Cup system includes gamma-sterilised, single use, drills.

The components should be stored in their original boxes in a clean and dry atmosphere, protected from direct sunlight. They should not be used if the inner packaging becomes wet, is damaged, or is found to be open.

JRI Orthopaedics Ltd do not recommend the resterilisation of medical devices by the user.

The product should not be used after the expiry date (year-month) shown on the product packaging.

Exposed articular surfaces, including the inner bore of the dual mobility cups and cobalt chrome bearing insert and the bearing surfaces of the dual mobility liners 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 should be avoided.

If the device is seen to be damaged, in any way, it 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.

Single use drills should be discarded responsibly after use, and should not be resterilised or reused.

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, allowing a more comprehensive evaluation, and the early detection of potential complications.

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. However, 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.

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