JRI ORTHOPAEDICS LTD
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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

Furlong® H-A.C. revision stems are monobloc and comprise the following range in different distal diameters and with different neck angles and offsets: Straight monobloc stems, in standard and Plus proximal body sizes.

Securus revision stems are either monobloc or modular and comprise the following range in different distal diameters and with different neck angles and offsets: A-P bowed monobloc stems with anteversion and holes in the distal stem for anti-rotation screw fixation and a range of modular components.

The modular range consists of various sizes of proximal body and distal stems, in various lengths and a range of diameters, which are all interchangeable. The proximal body is locked to the distal diameter by a tapered interface and the use of a through locking bolt. The assembled stems all have distal screw fixation capability.

All revision stems with distal screw fixation capability have a screw connection in the proximal body superiorly for attachment of a distal targeting jig. The range incorporates a cap to seal off this screw connection after the stem has been implanted.

A range of lengths of Cortical Anti-Rotation Screws are available for use for distal screw fixation.

Bone Substitute materials are available to supplement this system where required.

The **Furlong® H-A.C. and Securus Revision Stems** are collared prostheses made of Titanium alloy Ti-6Al-4V and fully coated with Hydroxyapatite Ceramic $CA_5OH(PO_4)_3$.

The Securus modular revision stems are comprised of proximal body and distal stem sections. All proximal body and distal stem components of the modular revision system are made of Titanium alloy Ti-6Al-4V and fully coated with Hydroxyapatite Ceramic $CA_5OH(PO_4)_3$ apart from the interfaces which are free from coating.

All stems are for use WITHOUT cement, long term fixation being achieved through bone ingrowth and union of the coating and the host bone. Stems are available in various sizes to accommodate anatomical variations of the femur.

IMPORTANT: Adjunctive proximal fixation / support is ***required*** for Size 10, 11 and 12 monobloc, 11mm and 12mm diameter modular 250mm length stems and 13mm diameter 300 length modular stems and is ***recommended*** for all the Securus and Furlong® H-A.C. revision stems, both monobloc and modular. Where there is loss of proximal bone stock, or poor proximal bone quality, bone grafting or other adjunctive proximal fixation / support is advised for implant stability. It is important that the prosthesis is not distally fixed without proximal support.

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

Femoral Heads of various diameters and neck lengths are available for use with this system in Cobalt Chrome alloy or ceramic. Ceramic heads are made from alumina ceramic or Biolox delta. 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.

Bone Substitute granules, blocks and pastes are available for use with this system, please refer to 155-028.

All types of bone screw are available in a variety of lengths and are manufactured from Titanium alloy Ti-6Al-4V, as are the modular revision connection screw and blanking plug.

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Smaller sized implants are intended for patients with smaller bone and regular Body Mass Index and could be inappropriate for other patients.

Note

Components should only be used with other compatible components of the Securus and Furlong® H-A.C THR Systems, with the corresponding taper connections. 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 tested and approved by JRI**.

Symbols

5 = 5mm lateral offset, 133 = 133^0 Neck angle

Indications

The Securus and Furlong® H-A.C. Revision hip stems are indicated for, but not limited to the following conditions:

Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemi-arthroplasty, surface replacement arthroplasty, or total hip replacement. Distal locking screws are indicated for implants where a greater degree of torsional stability is required.

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. Patients with high-activity level and/or higher weight patients are at greater risk for implant complications or failures.

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.

Important notice

Important notice for the implantation of the Securus, Furlong® H-A.C. Coated or Furlong® Active Femoral Stems. Please read this notice which was issued by Mr.Ronald Furlong FRCS, designer and innovator of the concept of osteo-integration in joint replacement fixation. "*It is continually being brought to my attention when I view the numerous X-rays sent to me for my opinion, of the 'improper use' of smaller sizes of stem in the Furlong® H-A.C. total hip replacement range. Surgeons find it easier and quicker to implant a smaller*

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size to achieve the all round gap necessary in the diaphysis. By so doing, the support vital to the metaphysis is often compromised. ***This is not only wrong but is potentially dangerous to the stability of the implant and could lead to failures.*** *With care and time given to rasping and reaming, it is my own experience that the correct size of implant can always be accommodated.* ***This phase of the surgical procedure is important to the success of the fixation of all the Furlong® H-A.C. THR prostheses***". Ronald Furlong FRCS.

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. 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 is 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. 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 adjacent to adequate bone 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.

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With Securus modular revision stems it is essential that the stems are assembled to the correct technique as specified in the operational technique and that the through bolt is tightened to the correct torque value. It is also essential that the cap sealing off the screw connection is securely tightened to the correct torque and that care is taken during placement.

When using distal screw fixation, it is imperative that the screws do not see an axial load. The screws are intended to provide torsional rigidity for fracture cases and not to support the stem. If the latter does occur they may be liable to fracture. They must be used with caution for distal stems less than 13mm.

Curved stems are provided to follow the natural bow of the femur.

Care should be taken not to over tighten bone screws. Ensure the appropriate selection of bone screw length and location to avoid damage to underlying soft tissue areas. 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. The Surgeon is responsible for ensuring optimum implantation of the prosthetic device using JRI Instrumentation.

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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 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

In general for revision a larger stem and acetabular cup must be used. A longer distal length is provided for additional stability. Proximal stability is advised for all stems where applicable. Distal fixation should be used with caution (see intra-operative note). When ceramic femoral heads are to be replaced a range of Revision Ceramic heads are available otherwise a metal 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.

Storage & Handling

Components of the Securus and Furlong® H-A.C. Revision stem ranges 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 is 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.

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.