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

JRI VAIOS® Humeral Resurfacing Replacement Prostheses

155-031 Issue 3 - June 2012
English

Important Information

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

Description

The **VAIOS® HUMERAL RESURFACING PROSTHESES** are available for use as partial or total joint arthroplasty.

The **VAIOS®** humeral resurfacing heads and Cuff Tear Arthroplasty (CTA) resurfacing heads are manufactured from Cobalt Chrome and are available in a range of sizes for use as a partial joint arthroplasty. Cuff Tear arthroplasty (CTA) resurfacing heads are not preferred for use in a total joint arthroplasty. The internal bore of both heads are fully coated with Hydroxyapatite Ceramic $CA_5OH(PO_4)_3$ and are for use WITHOUT cement, fixation being achieved through bone ingrowth and union of the coating and the host bone. They are available in various sizes to accommodate anatomical variations of the humeral head.

The resurfacing heads can be used with a range of Glenoid components (refer to instruction for use 155-032)

Note

Components should only be used with other compatible components of the JRI VAIOS® shoulder system, 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

42 = 42mm spherical diameter

Indications

Resurfacing heads are indicated for the following conditions where the humeral head and neck are of sufficient bonestock and there is presence of an intact or reconstructable rotator cuff which is necessary for proper functioning and dislocation resistance:

1. Severely painful and/or disabled shoulder joint from osteoarthritis or rheumatoid arthritis.
2. Acute traumatic fracture of the humeral head.
3. Correction of a painful and disabling functional deformity
4. A painful and disabling arthritis with a reconstructable rotator cuff
5. A painful and disabling post -traumatic arthritis

Where painful and disabling arthritis of the shoulder with a massive, irreparable rotator cuff tear is indicated, a range of cuff tear arthroplasty (CTA) resurfacing heads are available. Specific indications include:

1. Cuff tear arthroplasty
2. Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate.

Note

This prosthesis 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 prosthesis, 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

CE 0473 STERILE R

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

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 shoulder 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, sepsis, osteomyelitis, 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, painful disabling deformities.
2. Severe Osteoporosis.
3. Neuropathic joints
4. Paralytic disorders
5. Tumours.
6. Systematic and metabolic disorders.
7. Obesity.
8. Drug addiction.
9. Revision procedures where other devices have failed
10. Absence of effective shoulder cuff or Deltoid

CTA Resurfacing heads are contraindicated where there is an intact or reconstructable rotator cuff.

Pre-operative

Cuff Tear arthroplasty (CTA) resurfacing heads are not preferred for use in a total joint arthroplasty.

It is advisable that conventional stemmed implants are available when resurfacing hemiarthroplasty is performed

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 are available on request), 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 non-specific instrumentation. Failure to use the optimum size of implant, to adequately seat the component adjacent to endosteal bone or to ensure the component is supported and 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.

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.

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

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 can take no responsibility for the effects of wear debris, dislocations, subluxation, rotation problems, decreased range of motion, lengthening/shortening of the limb 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 cases of revision, total or reverse shoulder prostheses are available in the VAIOS® Shoulder system. 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

JRI VAIOS® humeral resurfacing prostheses 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 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 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.

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

The JRI VAIOS® shoulder 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

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

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 Ltd Sales Representative or JRI Ltd directly.