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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

Description:

The VAIOS® shoulder system is a modular system, available for use as a total anatomic shoulder system, a partial joint arthroplasty or a reverse shoulder system. It also has cemented or cementless options.

In the anatomical arrangement the shoulder prosthesis is a minimally constrained prosthesis for resurfacing the humeral head and glenoid. The humeral component is modular in form, with a number of distal stem diameters available in both cemented (CoCr) and uncemented (titanium alloy Ti6Al4V) forms. The cementless stem is fully coated with Hydroxyapatite Ceramic $Ca_5OH(PO_4)_3$.

Longer stems are available for bridging fractures. IMPORTANT: Adjunctive proximal fixation / support is ***required*** for 220mm long stems. 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.

The humeral neck component is manufactured from titanium alloy (Ti6Al4V) and is fully coated with Hydroxyapatite Ceramic $Ca_5OH(PO_4)_3$, It features fixation holes to facilitate attachment of the tuberosities by means of heavy non-absorbable sutures. Humeral head components (CoCr) fit into the humeral neck component via a locking taper connection. A variety of sizes are available to suit normal anatomies and a range of offsets provide the flexibility to adequately cover the resected humeral head and recreate the humeral centre of rotation (COR).

There are two glenoid types: the metal backed glenoid has a UHMWPE bearing insert that is clipped into the metal back (titanium alloy Ti6Al4V) and that is HAC coated; Included in the bottom of the taper bore is a screw plug (Ti6Al4V). The metal backed glenoid utilizes four spherical headed bone screws for primary fixation that are angularly adjustable. The superior and inferior screws can be locked in angular position with a titanium alloy (Ti6Al4V) locking screw cap, that because of the small nature of these components, is machined from a handle with an attachment interface designed to fail, in torque, on assembly. VAIOS® system bone screws are available for use in a variety of lengths and all are manufactured from Titanium alloy (Ti6Al4V). The cemented glenoid is an all UHMWPE component stabilised in the cement bed via pegs. Various sizes of glenoid are available to suit normal anatomies. Different articular radii are available for each type and size of glenoid, providing the option for a conforming or a 4mm radially mismatched joint. Glenoid preparation is initiated using a short guide wire manufactured from non-implant grade stainless steel and that provides a positional and angular reference for a cannulated reamer. The guidewire is supplied sterile and is intended for single use. DO NOT resterilise and/or reuse.

In the reverse arrangement the humeral and metal backed glenoid components are common to those used in the anatomic shoulder. A reverse cup component (titanium alloy Ti6Al4V) fits into the humeral neck component using a locking taper connection and with the additional security of a taper retaining screw (Ti6Al4V), which is then fitted with an all UHMWPE reverse bearing that clips into the reverse cup. The reverse bearing is available in a range of sizes to adjust deltoid tension. Concomitantly a reverse dome (CoCr) is available to insert into the metal glenoid backing, once the screw plug is removed, using a locking tapered connection and with the additional security of a taper retaining screw (Ti6Al4V) and offering the ability to offset the COR position laterally.

The VAIOS® resurfacing prostheses are available for use as partial, or, in conjunction with a VAIOS glenoid component, a total joint arthroplasty. VAIOS® humeral resurfacing heads are manufactured from Cobalt Chrome and are available in a range of sizes for use as a partial 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

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various sizes to accommodate anatomical variations of the humeral head. The resurfacing heads can be used with a range of glenoid components.

Smaller sized implants should be restricted to patients with smaller bone and regular body mass index and could be inappropriate for other patients. All HAC Coated components are for use WITHOUT cement, fixation being achieved through bone ingrowth and union of the coating and the host bone.

Bone Substitute granules and blocks are also available for cementless systems, please refer to 155-028.

Note:

Components should only be used with other compatible components of the 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:

48 = 48mm spherical diameter etc

Indications:

An anatomic shoulder system is indicated for the following conditions where the humerus is of sufficient bonestock and there is presence of an intact or reconstructable rotator cuff which is necessary for proper functioning and dislocation resistance. Similarly resurfacing heads are indicated 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, the reverse shoulder system is 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.

The general principles of patient selection and sound surgical judgment apply to proximal humeral replacement and shoulder procedures. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft tissue condition and component placement are critical to minimise a variety of postoperative complications.

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 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.

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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.

A total anatomic shoulder system and resurfacing heads are contraindicated where there is not an intact or reconstructable rotator cuff.

Pre-operative:

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.

It is important to have adequate and continuous bone support of the HA components, particularly the glenoid. When preparing the bed for the glenoid component, use particular care to preserve a portion of the subchondral bone plate.

All modular junctions must be firmly impacted together to prevent dissociation. Taper joints should be clean and dry prior to impaction. Repeated assembly and disassembly of modular components could compromise the locking action of the taper joint. Wherever possible, modular junctions should be assembled prior to implantation.

With the VAIOS® system it is essential that the components are assembled to the correct technique as specified in the operational technique and that any connection bolts are tightened to the correct torque values. It is also essential that the locking caps on the glenoid screws are securely tightened to the correct torque and that care is taken during placement. Care should also be taken when fitting the UHMWPE inserts into the metal glenoid backing or the reverse cup. These components cannot be reused.

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Care should be taken not to overtighten bone screws. Ensure the appropriate selection of bone screw length and location to avoid damage to underlying soft tissue areas.

When using the reverse anatomy configuration, care should be taken to ensure that the retaining screw is not cross-threaded or over tightened, and is fully located within the axial recess of the corresponding reverse anatomy dome. If the screw cannot be fully located in the recess, or fails to engage in the glenoid, the location of the dome should be checked before attempting to reapply the screw.

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. The Surgeon is responsible for ensuring optimum implantation of the prosthetic device using JRI Instrumentation.

During the assessment of the range of motion, it is important to check the stability of the joint. For the anatomic total shoulder, insufficient tension in the rotator cuff mechanism can lead to subluxation of the humeral component increasing the risk of glenoid loosening and lead to higher wear rates due to edge loading.

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 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. Sudden drops in blood pressure intra-operatively may occur due to the use of bone cements.

Revision:

In cases of revision, a total or anatomic shoulder prosthesis can be revised to a reverse shoulder prosthesis. Larger sizes of implants are also available for revision purposes. 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:

VAIOS® shoulder system prostheses including guidewires 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 Joint Replacement Instrumentation Ltd for inspection. Joint prostheses must be neither treated mechanically nor modified. Visibly damaged, scratched, improperly handled implants and implants that have already been

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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. Discard single use guidewires 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 :

The 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

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. Guidewires are for single use only.

Further information:

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