An AK MEDICAL Company

JRI ORTHOPAEDICS LTD
18 Churchill Way,
35a Business Park,
Chapeltown,
Sheffield,
S35 2PY, UK

Instructions for Use

ICOS Custom-made Shoulder Implants

155-043_Issue 1
June 2021

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Important Information

Please read instructions for use and the corresponding operative technique, prior to use in a clinical setting. The Surgeon should be familiar with the appropriate operative technique.

Material	Standards
Titanium Alloy (Ti6Al4V)	ISO 5832-3 ASTM F136

Intended Use

ICOS Custom-made Shoulder Implants are intended for use during pre-planned cemented or uncemented primary or revision shoulder arthroplasty in conjunction with the corresponding JRI Orthopaedics Ltd. Shoulder System. The devices are provided to the end user sterile and are designated as single-use only.

Treatment Population

ICOS Custom-made Shoulder Implants are designed for the exclusive clinical use of an individual patient in accordance with a written prescription made by a qualified person due to the patients' unique and complex anatomy, physiology, or pathology. ICOS Custom-made Shoulder Implants are designed for use in skeletally mature individuals with sufficient bonestock to support implantation and fixation of the device. These devices are not suitable for use by any other patients.

Description

Sterile, Single-use Custom-Made Shoulder Implants

ICOS Custom-made Shoulder Implants are designed in accordance with the written prescription of a qualified healthcare professional, giving design specifications for the implant. ICOS custom-made implants are manufactured from Titanium Alloy (Ti6AL4V) by additive manufacturing and conventional machining. ICOS Custom-made Shoulder Implants are designed to be implanted at the shoulder without the use of bone cement, with fixation being achieved through bone ingrowth into the lattice structure at the bone-implant interface. Screw holes permit the use of compatible JRI titanium alloy bone screws, from the VAIOS® Shoulder System, for additional primary fixation (see the 'Case Report' for more details).

Compatibility

ICOS Custom-made Shoulder Implants are only compatible for use with the JRI **VAIOS® Shoulder System**, namely the **Reverse Glenoid Dome** component.

The **VAIOS® Shoulder System** has its own instructions for use, IFU-155-032, which can be accessed via the JRI Orthopaedics Ltd. website. A hard copy is also provided with each ICOS Custom-made Shoulder Implant.

JRI Orthopaedics Ltd. has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Indications

Indications may include the following conditions:

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

- A painful and disabling post -traumatic arthritis
- Cuff tear arthroplasty
- Difficult clinical management problems where other methods of treatment may not be suitable or may be inadequate

ICOS Custom-made Shoulder Implants are only to be used under the control and supervision of an accredited Orthopaedic Surgeon or Physician, whose responsibility it is to ensure that any user is qualified and trained in the use of the implants and the relevant surgical procedures. The medical team have a duty of care towards their patient which includes the correct use of ICOS Custom-made Shoulder Implants. As a manufacturer of the product, JRI Orthopaedics Ltd. take no responsibility for any damage, breakage or adverse effects as a result of any failure in the medical team to discharge such duty.

Contra-indications
Custom-made acetabular implants MUST NOT be used for any patients other than the individual patient for which the design is intended.

The device should NOT be implanted where there is active infection, insufficient bonestock to support the prosthesis or provide adequate fixation.

Further contra-indications may include the following conditions:

- Severe muscle, nerve or vascular diseases that endanger the extremity in question
- Severe deformations, tumours
- Severe osteoporosis or deficient bone substance that may endanger stable seating of the prosthesis
- Systematic and metabolic disorders
- Weakened or compromised immune system (HIV, tumours, infections)

Precautions
The following conditions require caution and due consideration during pre-operative planning by the surgeon:

- Obese or severely overweight patients
- Excessive loading through arduous activity
- Lack of mental facilities to understand post-operative the recuperative regime
- Alcohol dependency or drug abuse
- History of falls or disabilities
- Out of range movement of the joint

In patients' with a high body mass index, where delayed surgery is feasible, it is advisable that a programme of weight reduction is undertaken prior to any joint replacement surgery.

Warning
This device should only be implanted by operating surgeons who are familiar with the general problems of prosthetic surgery and who are sufficiently trained to the product-specific operative techniques. The surgeon is responsible for ensuring the surgery is carried out properly and in line with the instructions provided in the operative technique provided in the 'Case Report'.

As a manufacturer, JRI Orthopaedics Ltd. is not responsible for any complications arising from incorrect diagnosis, incorrect choice of implant, incorrect operative technique, treatment methods limitations or inadequate asepsis.

Pre-operative
Pre-operative planning allows the surgeon to assess for implant size and restoration of biomechanics. Failure to carry out proper planning may lead to incorrect choice of implant type/size. Ensure all implant sizes and required

instrumentation are available prior to surgery. Consult the 'Case Report' including operative technique and training materials provided by JRI Orthopaedics Ltd. before use.

Functionality of surgical instruments should be checked. Use of damaged instruments may lead to early failure of implant.

Transient bacteraemia 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.

Intra-operative
Always use a trial for any test fit and to check the range of motion. Failure to use the optimum size of implant for ensuring sufficient fixation may result in early revision surgery**.**

Refer to the 'Case Report' supplied with each Custom-made Shoulder implant for details of the operative technique. Implants MUST NOT be re-used under any circumstances as the functionality, integrity and/or sterility of that device may have been adversely affected and therefore cannot be guaranteed. Implant components from JRI Orthopaedics Ltd. should not be used together with those of another manufacturer, since compatibility of mating parts cannot be assured.

Post-operative
Physicians should ensure patients are aware of implant loading limitations and ensure that consistent post-operative care, from a suitably qualified healthcare professional, is made available. The incidence and severity of complications are usually greater in surgical revisions than primary operations. Early detection of an impending complication allows for timely and effective countermeasures.

Post-operative care should incorporate recognised procedures, considering information from the operative technique and should be documented according to internal hospital procedures. Failure to do this may result in malalignment, delayed wound/bone healing, implant failure, infection or impaired joint function.

Side Effects
As with all major surgical procedures, side effects and adverse events can occur. Some of the more common complications include:

- Problems resulting from anaesthesia and patient positioning (pain, nausea etc.)
- Infection
- Aseptic loosening of implant
- Dislocation, subluxation, insufficient range of movement
- Damage to soft tissue
- Fracture of implant or bone
- Allergy/hypersensitivity reactions
- Cardiovascular/pulmonary embolism, respiratory infection, venous thrombosis, neuronal dysfunction, haematoma or delayed wound healing

Revision
Ensure all fragments of the primary prosthesis and any bone cement (if applicable) are removed. Clean and prepare the area for implantation in line with current Instructions for Use and Operative Technique of selected revision implant, prior to insertion of device.

Storage & Handling
Store implants in their original protective packaging in a clean and dry atmosphere.

Do not use if the packaging is damaged. Do not use this product after the expiry date (year-month) shown on the product packaging.
Avoid removing from packaging until immediately prior to use. Inspect device prior to use. Visibly damaged, scratched, improperly handled instruments and implants must not be used under any circumstances as the functionality, integrity and/or sterility of that device may have been adversely affected and therefore cannot be guaranteed. Exposed articular surfaces must not be marked or come into contact with metallic or hard objects. Touching the articular surfaces and the tapered interface for the liner must be avoided.

Implant Shelf-life
ICOS Custom-made Implants are manufactured from materials that do not deteriorate over time when under ambient storage conditions. A 6 month shelf-life (from the date of manufacture) is given to all ICOS Custom-made devices in order to mitigate the risk of the patient bony anatomy changing over time.

MRI Safety Information
Non-clinical testing has demonstrated that the VAIOS® Shoulder System is MRI Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3.0 T
- Maximum spatial field gradient of 720 gauss/cm
- Maximum whole body averaged specific absorption rate (SAR) of 3.0W/kg

Under the scan conditions defined above, the **Custom-made Shoulder Implant** is expected to produce a maximum temperature rise of 1.7°C after 15 minutes of continuous scanning.

The image quality may be compromised if the area of interest is in the exact same area, or relatively close to, the position of the medical device. Therefore, optimisation of MR imaging parameters to compensate for the presence of this device may be necessary:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	42,763-mm^2	17,875-mm^2	56,249-mm^2	28,917-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Additional information regarding MRI safety is available upon request at JRI Orthopaedics Ltd.

Functional Device Lifespan

The functional lifespan of an implant may be impacted by surgeon and selected operative technique, patient physiology and activity levels. 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 everyday use.

Products Intended for Single-use Must Not be Re-used
Re-use or reprocessing (e.g. cleaning and re-sterilisation) may compromise the structural integrity of the device and /or lead to device failure which may result in patient injury or death.

Reuse or reprocessing of single-use devices may create a risk of contamination (e.g. transmission of infectious material) which may result in injury or death.

Further information

For product specific operative technique training or further information, please contact your JRI Orthopaedics Ltd. Sales Representative or JRI Orthopaedics Ltd. directly.

JRI ORTHOPAEDICS LTD
18 Churchill Way,
35A Business Park,
Chapeltown,
Sheffield,
S35 2PY, UK
Tel: +44(0)114 345 0000
Fax: +44(0)114 345 0004
www.jri-ltd.co.uk

Applicable Symbols	Description
	Read the instructions for use/ electronic instructions for use.
	Caution – check for specific warnings or precautions.
	Protect from sunlight.
	Keep dry.
	Do not use if packaging is damaged.
	Single-use device. Do not reuse.

	MRI Conditional
	Sterilised using Irradiation
	Double Sterile Barrier System
	Medical Device
	Product reference code
	Batch number, batch code or lot number.
	Manufacturer.
	Date of manufacture.
	Use by date.
	Person Identification (see Implant Card)
	Health care centre or Doctor (see Implant Card)
	Date of Implantation (see Implant Card)

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Issue	Date	Revision History
1	11 Jun 2021	First Issue for Instructions for Use