An AK MEDICAL Company

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Instructions for Use

ICOS Custom-made Instruments

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ICOS Custom-made Instruments

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Important Information

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

Material(s)		Standards
Polyamide	PA	ISO 16396-1:2015

Intended Use

ICOS Custom-made Instrumentation is intended for use during joint replacement surgery to facilitate the implantation of custom-made implants. These devices are provided to the user non-sterile and require sterilising before use. These devices are designated as single-use only.

Treatment Population

ICOS Custom-made Instrumentation are designed for use in skeletally mature individuals undergoing total primary or revision joint replacement surgery using a custom-made implant component. These instruments are for transient use during surgically invasive procedures.

Description

Non-Sterile, Single-use Patient Specific Instrumentation (PSI)

The range includes:

- Cutting/Tissue Resection Guides
- Trial Implants
- Anatomical models

Note

ICOS Custom-made Instrumentation has been designed and manufactured for use with specific ICOS Custom-made devices which are intended for the exclusive clinical use with individual patients on the written prescription of a qualified healthcare professional.

Indications

This instrumentation is to be used only 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 these surgical instruments and the relevant surgical procedures. The medical team have a duty of care towards their patient which includes the correct use of this instrumentation. 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

This instrumentation should **not** be used:

- Where there is active infection
- By untrained, or inexperienced persons, or persons who are not clinically qualified to carry out the procedure for which the instruments are intended
- For clinical procedures for which they are not intended.
- If they are visibly broken, or damaged intra-operatively, or fail to function as intended due to incorrect assembly
- In patients who are not the intended recipient of the corresponding custom-made implantable components.

Pre-operative
Clinicians should familiarise themselves with the instrumentation, prior to clinical use, particularly where that instrumentation requires intra-operatively assembly.

The surgeon should discuss all aspects of the surgery with the patient. Allergies and other reactions to instrument materials, although rare, should be considered and ruled out pre-operatively.

Pre-operative Preparation of Instruments

For non-sterile, single-use instrumentation, all packaging should be removed prior to sterilisation. ICOS Custom-made Instruments are provided clean and are to be sterilised by the end user to an approved, validated, method for medical devices; (BS EN ISO 17665-1 - by moist heat (134^0C - 137^0C for a minimum of 3 minutes) is recommended) and shall be maintained in a sterile state until used (see JRI Instructions for Use *F403O* for sterilisation information).

After autoclaving, all instruments must be allowed to cool and dry thoroughly. The amount of dry-time required is dependent upon the load size and its mass. The instruments should be placed on a shelf with a linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.

Sterilisation by chemical means or higher temperatures should not be used as these could adversely affect the materials used. The adequacy of any sterilisation procedure should be developed and tested only by trained personnel.

All instrumentation should be thoroughly inspected for possible damage prior to surgery.

The surgical staff should ensure that all instrumentation has been adequately sterilised, using an approved and validated process. It should be ensured that instruments have been correctly assembled prior to use and are fit for purpose. For more complicated instrumentation, specific assembly instructions are provided within the 'Case Report' and should be consulted.

Intra-operative
Care should be taken not to cut through surgical gloves when handling any sharp-edged instruments and the risk of infection should be considered if a cut appears. The recommended operative technique for a specific procedure, and the use of the corresponding instrumentation, is provided by JRI Orthopaedics Ltd. and is available on request.

The operative technique (included in the provided 'Case Report') describes the correct use of the instrumentation and its use in combination with other instruments and implantable devices, and if applicable, restrictions in the use of the instrumentation. Competitor instruments should not be used in direct combination with JRI Orthopaedics Ltd. instrumentation where they might influence the positioning, alignment, or placement of the respective JRI implants.

The surgeon is responsible for ensuring optimum implantation of the prosthetic device using ICOS Custom-made Instrumentation and should refer to the relevant implant Instruction for Use.

Reasonable, but NOT excessive, force may be required in the use of this instrumentation. Where a specific force or torque is required, this is indicated in the operative technique.

Post-operative
If the instrumentation is not fully intact or complete after the operation, the surgeon should ensure that no parts are left *in vivo*.

It is the responsibility of the surgical staff to ensure that all instrumentation is disposed of in accordance with the corresponding hospital procedure for such components, following the completion of the surgical procedure.

Adverse Effects
Bone fractures may result from one-sided overloading or weakening of the bone substance. There may also be a risk of cardiovascular disorders, tissue reactions and haematoma. The surgeon is responsible for any complications that may result from erroneous indication, incorrect operative technique or inadequate aseptic precautions.

Surgical instrumentation must not be treated mechanically, nor modified, unless this is required by the design.

Storage & Handling
Instrumentation should be stored in the original protective packaging in a clean and dry atmosphere. This recommendation is equally valid for the transport and packaging of surgical instruments.
Surgical instruments are sensitive to damage. Small scratches may increase wear and the risk of corrosion. Instruments should be handled with care at all times.

Instrument Shelf-life
ICOS Custom-made Instruments 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.

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.

Re-use 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.

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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.
	Non-sterile device.
	Medical Device
	Product reference code
	Batch number, batch code or lot number.
	Manufacturer.
	Date of manufacture.

	Use by date.

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