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Important Information

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

Caution

Federal (U.S.A) law restricts this device to sale by or on the order of a physician. For use in the U.S.A. please read Physician for Orthopaedic Surgeon or Surgeon and 'Adequate Directions for Use' (ADU) for instructions for use in the following text:

Description

JRI Instrumentation consists of medical devices and their accessories for use in orthopaedic surgical procedures using JRI products. The range includes manual surgical instruments from Class I and surgical instruments that can be used under power or as trial components from Class IIa (93/42/EEC). Stainless Steel is used for most metallic instruments (Titanium alloy Ti-6Al-4V and CoCr are also used for some trial components) and all non-metallic materials are of medical grade.

Note

JRI Instrumentation is part of the Furlong® Joint Replacement System. It should only be used with other compatible components of the Furlong® System. Instrument assemblies should only contain compatible components with corresponding connections. Instrumentation components from one manufacturer should not be used together with those of another manufacturer, since compatibility of mating parts cannot be assured.

Symbols

12/14 = 12mm Small taper diameter, 14mm Large taper diameter

LS = Long Spigot. < = Angle AF = Across Flats

For Trial Stems: XXS = Extra Extra Small. XS = Extra Small. S = Small. M = Medium. L = Large XL = Extra Large

For Trial Heads Neck lengths: S = Short M = Medium L = Long XL = Extra Long
XL+4 = Extra Long plus 4mm, XL+8 = Extra Long plus 8mm.

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 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.

Contra-indications

This instrumentation should not be used where there is active infection.

Pre-operative

Before clinical use the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. The surgeon should discuss all aspects of the surgery

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with the patient. Allergies and other reactions to instrument 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 instrumentation should be thoroughly inspected for possible damage prior to surgery. The surgeon should ensure that all instrumentation has been sterilised adequately, reassembled correctly prior to use and is fit for purpose. For more complicated instrumentation, specific Assembly Instructions may be provided.

Intra-operative

Care should be taken not to cut through surgical gloves when handling any sharp-edged instruments and to take into account the risk of infection if a cut appears. The recommended operative technique and use of the JRI instrumentation is described in a brochure, Video or CD (which are available on request). This demonstrates how the instrument is to be used in combination with other instruments, devices or equipment restrictions. The surgeon is responsible for ensuring optimum implantation of the prosthetic device using this JRI Instrumentation and should also refer to the relevant implant Instruction For Use. Reasonable but NOT excessive force may be required in the use of this instrumentation. Extra care and cautions should be applied when using Class IIa instruments. 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.

Post-operative

If the instrumentation is not fully intact or complete after the operation then the surgeon should be adequately convinced that no parts are left in vivo. Fragments of instruments may be located by means of an image intensifier and/or X-ray radiography.

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. Cleaning / decontamination instructions apply. Patients identified as risk patients with regard to Creutzfeldt-Jakob disease (CJD), related infections or other unusual transmissible diseases should be treated with single use instruments, which are disposed after surgery. Because of insufficient scientific evidence available today, a general efficient cleaning and decontamination procedure cannot be recommended. Current national recommendations should be considered.

Revision

A range of JRI specific revision instruments are available.

Sterilisation

JRI Instrumentation is supplied non-sterile. Remove all packaging prior to decontamination and sterilisation. These instruments are to be decontaminated by soaking/scrubbing/ultrasonic clean and auto-wash/disinfect before being sterilised to an approved method for medical devices; (BS EN 554 - by moist heat (136^{0}C for a minimum of 3 minutes) is recommended) and shall be maintained in a sterile state until used. Prolonged immersion in a disinfecting solution can damage surgical instruments and should not be soaked for a long period of time. Immediately after cleaning/rinsing, the instruments should be dried. After autoclaving, all instruments must be allowed to cool and dry thoroughly. The amount of dry-time required is dependant upon the load

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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.

Decontamination

These instruments should be decontaminated immediately after use. At point of use, remove foreign debris with a disposable cloth or paperwipe. If instruments have been exposed to blood, tissue, saline or other foreign matter they must be rinsed in warm (not hot) water before these substances are allowed to dry. Both physical and chemical processes are necessary to minimize the bioburden on all soiled items. Chemical (detergent) alone cannot remove all debris and a careful manual cleaning of each item is essential for maximum decontamination. JRI recommend the use of a mild detergent. Once items have been cleaned and decontaminated they should be thoroughly rinsed with distilled water to remove any detergent before sterilisation. Placing instruments on top of one another and the mixing of dissimilar metals should be avoided. Any instrument that can be dismantled should have the various components cleaned separately. Attention should be paid to any cannulated instrument and any screw holes where debris may enter before being re-assembled. Recesses and hidden areas within an instrument should be inspected regularly to ensure that entrapped or other residual materials are completely removed. If the instrument requires a complicated assembly technique then a separate Instruction for Use will be provided for assembly/dis-assembly. Lubrication oil is not required and should not be used on these instruments. Where these instruments are to be returned to JRI, the appropriate decontamination certificate shall be completed by the Theatre Manager or their authorised Deputy

Storage & Handling

Surgical instruments are sensitive to damage. Even small scratches can increase wear and the risk of corrosion. Instruments should be handled with care at all times. Surgical instruments are susceptible to wear and tear and therefore should be checked for defects in any way. If they are damaged in any way they should not be used but returned to JRI Orthopaedics Ltd for inspection. Surgical instrumentation must be neither treated mechanically nor modified unless this is required by the design. Storage zones for surgical instrumentation should be kept dry. This recommendation is equally valid for the transport and packaging of surgical instruments. Care should be taken when lifting complete instrument sets or transit cases. Instruments may be loaded into instrument trays or general purpose sterilization trays and should be wrapped using a double wrap method. The acceptable storage period depends to a very great extent on the storage conditions, which must be determined by the Hospital.

Device Lifetime

The lifetime of instrumentation is dependant amongst other things upon the surgeons' level and degree of use. The cutting edges of sharp instruments should be maintained and replaced at the surgeons' discretion. Repeated processing has minimal effect on these instruments. All instruments should be visually inspected for damage and wear prior to use.

Further information

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