

FOR DISTRIBUTION IN THE US

HUMELOCK II® SHOULDER PROSTHESIS

FX SOLUTIONS®

Sterile implants for shoulder surgery

Important information for the surgeon



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1) General information

Before using the FX SOLUTIONS® HUMELOCK II® shoulder prosthesis, the surgeon should familiarize himself with the contents of this instruction leaflet and with the surgical technique. This information is available from the distributor or the manufacturer (surgical techniques, brochures, etc.).

The devices may only be implanted in public or private orthopaedic surgery departments, and solely by orthopaedic and/or trauma surgeons who have had appropriate training and experience in the field of shoulder arthroplasty and traumatology.

This is a single-use device. Re-use of an explanted or modified device is prohibited because of the risk of infection.

Some components must be implanted with cement.

The device must not be allowed to come into contact with chlorinated or fluorinated derivatives.

In normal conditions of use, the devices can come into contact with any other substance and/or with gas.

FX Solutions® Ti+HA coated implants are intended for uncemented use only. These implants must never be implanted using cement or medicinal substances.

FX Solutions® un-coated implants are intended for cemented use only. These implants must be implanted with cement.

2) Combining prosthetic elements

The HUMELOCK II® Shoulder Systems consist of humeral stems, cortical screws, humeral heads, connectors, protector and screw, glenoid components, adapter, humeral cups, glenospheres, glenoid baseplates, screws and post extensions. Only the devices described in the surgical techniques are permitted for combined use. Any combination of prosthetic components and/or instruments, other than those delivered by the manufacturer and/or distributor, is strictly prohibited.

In a revision procedure, it is essential to replace the head. It is the surgeon's responsibility to ensure that the stem can be conserved in optimal conditions.

3) Indications

The HUMELOCK II® Cemented Shoulder System is indicated for use in total and hemi-shoulder replacement to treat :

- proximal humeral fractures.
- a severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.

- other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a previously implanted primary component, a humeral plate or a humeral nail).

The humeral stem and glenoid components of the HUMELOCK II® Cemented Shoulder System are intended for cemented use only.

The HUMELOCK II® Cementless Shoulder System is indicated for use in hemi shoulder replacement for fractures of the proximal humerus. The HUMELOCK II® Cementless Humeral Stem is intended for use with two cortical bone screws and is intended for cementless use only.

The HUMELOCK II® Reversible Shoulder is indicated for primary, fracture or revision total shoulder arthroplasty for the relief of pain and to improve function in patients with a massive and non-repairable rotator cuff tear.

The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The humeral stems are intended for cemented or cementless use. The metaglene baseplate is intended for cementless use with the addition of screws for fixation. For the augmented baseplate, minimum peripheral screw length is 20 mm on augment side.

TiN coated Heads are not intended for hemi-shoulder arthroplasty.

4) Contraindications

- Non-displaced or slightly displaced fractures.
- Dislocation fractures in elderly subjects.
- Acute, chronic, local or systemic infections.
- Severe muscular, neurological or vascular impairment affecting the joint in question.
- Bone destruction or poor bone quality that could compromise the stability of the device.
- Excessive alcohol consumption or other dependency disorders.
- Allergy to the material.
- Any concomitant illness that could compromise the function of the device.

5) Factors which may compromise the success of the implant

- severe osteoporosis
- significant deformity or congenital luxation
- localized bone tumors
- systemic or metabolic disorders
- infectious diseases
- drug addiction and/or a tendency towards drug or medicine abuse
- obesity

Important :

The surgeon must inform the patient that the safety and durability of the implant depends on the patient's weight and behavior, particularly the level of physical activity.

In cases where the surgeon considers that the patient needs this device, and the latter has one or more of the factors mentioned above, the surgeon must inform the patient of the effect that this factor(s) can have on the success of the procedure. The surgeon must tell the patient how he can reduce these factors and/or their effects, and inform him that it will not be possible to undergo nuclear magnetic resonance examinations.

An implanted patient must always indicate that he has had an implant before embarking on any new treatment at a later date.

6) Adverse effects

Adverse effects considered to be the most characteristic and most common:

- migration of the device if it was not possible to cement it
- luxation
- infection
- venous thrombosis and pulmonary embolism
- cardiovascular disorders
- haematoma
- deterioration of the ligaments or of the rotator cuff
- absence of active external shoulder rotation
- less range of motion for reverse shoulder arthroplasty than anatomic shoulder arthroplasty

The surgeon must tell the patient that if there is an alteration in the performance of his shoulder prosthesis, he should contact the surgeon to determine whether it is appropriate to consider an intervention, which in the circumstances mentioned above, would be considered a standard procedure and not due to a failure of the device, given that the onset of these adverse effects is a possibility.

7) Interference with other devices

Using the means at his disposal, such as radiographic images and tracings, the surgeon must verify (ensuring that the scales are consistent in both tracings and images) that insertion of the device will be compatible with other devices that have already been implanted (osteosynthesis material, elbow prosthesis, etc.).

8) Surgical technique

The device can only be implanted after the surgeon has familiarized himself with the surgical technique. The surgery should be planned on the basis of a detailed evaluation of the patient's x-rays, since these provide important information on the choice of device (adaptation of dimensions to the individual case). Preoperative tracings and the surgical technique are available from the distributor or manufacturer.

9) Sterilization

Devices are supplied sterile unless the package is opened or damaged. All the devices have been sterilized by irradiation. Before use, check the protective packaging carefully to ensure that it has not sustained any damage that could compromise the product's sterility. The products cannot be used after the sterilization validity date shown on the label.

10) Re-sterilization

Any desterilized product must be returned to the distributor. The hospital is not permitted to resterilize the devices.

11) Storage and handling of the devices

The devices must be kept in their original, unopened packaging, in a dry and clean place, away from light and at ambient temperature. The devices must be handled with extreme care, since surface damage can cause premature wear, and therefore lead to complications. As all waste material used in the surgical procedure is potentially infected, it must be

collected and disposed of in accordance with the legislation on potentially infectious healthcare waste.

Given that the product is used and inserted within the context of a surgical procedure, the surgeon and technical team must ensure that all appropriate protective measures are taken to avoid any risk of contamination, particularly as regards risks from exposure to blood. Likewise, the surgeon and the surgical team supporting him/her must ensure that they implement strict rules on asepsis at all stages, in order to avoid any risk of site contamination caused by inadequate compliance with the rules on asepsis.

12) Materials

The names of the component materials are shown on the labelling.

For more information on the chemical composition and properties of the materials used, please ask the distributor or manufacturer.

13) MRI Safety Information

The HUMELock II® devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration or image artifact in the MR environment. The safety of HUMELock II® devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

14) Ancillary





FX Solutions® devices must be implanted with the ancillary material specific to the HUMELock II® product. Instruments must be cleaned and sterilized prior to each use. The surgeon and/or technician must ensure that all instruments are present and in good working order. Cleaning must be done in accordance with the establishment's current standard sterilization protocols, which must be done in an autoclave (maintained at 132°C for 4 minutes) in accordance with a validated protocol.

15) Responsibility

These devices may not be implanted unless the rules specified in this instruction leaflet are observed. The surgeon and hospital staff who are called upon to handle the device specified in this document must be fully conversant with this document.

Important : This device has been designed and manufactured in compliance with the essential requirements of the Directive 93/42/CEE published 14 June 1993.

16) Symbols

Symbols used on the labelling	
	Sterilization by radiation
	One-time use Do not reuse
	Read the instruction leaflet carefully
	Do not use if the packaging is damaged

	Do not sterilize
	Store away from light and sunlight
	Store away from moisture
	Caution: Federal law (US) restricts this device to sale by or on the order of a physician
	Use until
	Manufacturer

In the event of not being satisfied with this product, please send your comments to the distributor or manufacturer :

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