Corin

Icona™

Instructions for use

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This "Instructions for Use" contains information on how to use Corin Icona™ hip stem.

IMPORTANT: *The manufacturer recommends that all personnel responsible for handling and implanting the devices read and understand this information before use.*

The implantation of a joint prosthesis and its associated implants requires knowledge of anatomy, biomechanics and reconstructive surgery of the musculoskeletal system and may be performed only by a qualified surgeon. The surgeon must be acquainted, prior to surgery, with the specific operative technique of the product, available from the manufacturer. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery. The patient must be properly informed about the device and the information contained in the present instructions for use.

Caution: *The Federal (United States) Law restricts this device to sale, distribution and use by or on the order of a physician.*

For the glossary of product label symbols, please consult the table at Section 11 of the present document.

1. Device Description

The Corin Icona Hip Stem is a tapered stem design manufactured from Titanium alloy (Ti6Al4V) (ASTM F136) with a layer of commercially pure titanium (ISO 5832-2, ASTM F1580) and an additional layer of electrochemically deposited calcium phosphate (ASTM F1609) applied.

The Icona Hip Stem is intended for use in hemiarthroplasty and total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

The Icona Hip Stem is available in two different offsets (Standard and Lateralised) for twelve (12) different sizes.

Ancillary instruments are also provided. A marking on the ancillary instruments allows immediate identification of the size of the ancillary instruments to be used and to ensure compatibility between the different devices.

For a more detailed description of the implants and their utilisation, please refer to the technical docu¬mentation, or contact your Corin representative.

Combination / Component Association:

It is essential to implant the Icona Hip Stem with the Corin instrumentation specifically designed for this purpose.

The selection of the appropriate implants can be made by using the recommendations of the operative technique and the trial implants and templates supplied with the instrumentation.

Where applicable mutual compatibility of components should be considered.

Recommendations for connecting the components with one another and restrictions to combinations are provided at the following link: https://www.coringroup.com/compatibility

For more details regarding the compatibility between implants, please contact your Corin representative.

2. Materials

The constituent material of the Icona Hip Stem is included on packaging labels.

Component:	Material:	Composition:	
Icona Hip Stem	*Wrought Titanium 6-Aluminium 4-Vanadium Closed Die Forging*	%(mass/mass)	ASTM F136 Section 7, Table 3
		Aluminium	*5.5-6.50*
		Vanadium	*3.5-4.5*
		Iron	*0.25 Max*
		Oxygen	*0.13 Max*
		Carbon	*0.08 Max*
		Nitrogen	*0.05 Max*
		Hydrogen	*0.012 Max* [A]
		Titanium	*Balance*
		[A] *Material 0.032in (0.813mm) and under may have hydrogen content up to 0.015 %*	

Component:	Material:	Composition:		
Icona Hip Stem	*Additional layer of electrochemically deposited calcium phosphate (CaP) coating in compliance with ASTM F1609-08 (Standard Specification for Calcium Phosphate Coatings for Implantable Materials*	*Primarily Brushite with small amount of hydroxyapatite phase yielding a Ca:P ratio of 1.1 +/-0.1*		
		ASTM F1609-08 (2014) Trace Element Limits		Ppm max
		Arsenic		*3*
		Cadmium		*5*
		Mercury		*5*
		Lead		*30*
		Total heavy metals (as lead)		*50*
	Titanium coating – Unalloyed Titanium. Meeting the requirements of BS7252 Part 2 / ISO 5832-2 and ASTM F1580-18	%(mass/mass)	ASTM F1580 Section 6.1.3, Table 1	ISO 5832-2 Section 4, Table 1
		Iron	*0.50 Max*	*0.10 Max*
		Oxygen	*0.40 Max*	*0.10 Max*
		Carbon	*0.08 Max*	*0.03 Max*
		Nitrogen	*0.05 Max*	*0.012 Max*
		Hydrogen	*0.05 Max*	*0.012 Max*[A]
		Titanium	*Balance*	*Balance*
		[A)] Except for billets, for which the maximum hydrogen content shall be of a mass fraction of 0.010%		

3. Intended use and intended performances of the implant

The Icona Hip Stem is intended for use in hemiarthroplasty and total hip arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components. It is intended to be used by appropriately qualified surgeons, who must practice in accordance with current advancements in scientific data and operative techniques.

The use of the Icona Hip Stem is intended to elicit the below clinical benefits to the indicated patients:

- *Significant decrease in Pain*
- *Increase in hip mobility*

4. Indications for use

The indications for the Icona Hip Stem as a total hip arthroplasty, and when used in combination with a Corin hemiarthroplasty head, as a hip hemiarthroplasty, include:

- *Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis*
- *Rheumatoid arthritis*
- *Correction of functional deformity*
- *Treatment of non-union and femoral neck fractures*
- *Developmental dysplasia of the hip (DDH) / congenital dysplasia of the hip (CDH)*

The Icona Hip Stem is indicated for cementless use only.

5. Known contra-indications to date

- *Active infection*
- *Marked bone loss or bone resorption*
- *Vascular insufficiency*
- *Allergy to implant material*
- *Poor bone quality*
- *Metabolic disorders which may impair bone formation*
- *Muscular atrophy or neuromuscular disease*
- *Uncorrectable deformity*

- *For hip hemiarthroplasty, any pathological condition of the acetabulum, such as distorted acetabuli with irregularities, protrusion acetabuli (arthrokatadysis), or migration acetabuli, that would preclude the use of the natural acetabulum as an appropriate articular surface for the hip hemiarthroplasty prosthesis.*

Do not use in combination with components from non-Corin approved implant systems.

6. Undesirable side effects and possible complications

Complications can potentially occur following any joint replacement surgery. The following are the most frequent adverse events after hip joint replacement surgery:

- *Hip ball (femoral head) and hip socket (Acetabulum) may separate (hip dislocation)*
- *Device loosening from the surrounding bone*
- *Superficial or deep infection*
- *Allergic reaction to the implant's materials*
- *Premature wear or breakage of the implants*
- *Bone loss around the implant*
- *Periprosthetic fracture*
- *Change in the length of the treated leg*
- *Hip pain*
- *Stiffness and/or loss of hip flexibility of the hip joint*
- *Bone and soft tissue damage (including muscles, tendons, ligaments, cartilage, and nerves)*
- *Embolism*
- *Ossification*
- *Fretting and crevice corrosion can occur at interfaces between components which may result in Adverse Local Tissue Reactions (ALTR)*

7. Warnings and cautions

Never re-use an implant, even if it seems to be in perfect condition, to avoid cross contamination or less than optimal performance. Never re-sterilise an implant delivered sterile. Never modify the implant. Never use chemical agents on the implant for cleaning prior to surgery. Clean gloves should always be worn when handling implants. Check for material / debris on the implant prior to use. Avoid scratching or denting implant surfaces.

Surgeons should be thoroughly familiar with the Icona Hip Stem operative technique, the implants, and the instruments prior to performing the surgery.

Corin designs specialised instruments for their joint replacement systems to aid in the accurate implantation of the prostheses. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, and device failure. Intra-operative fracture or breaking of instruments has been reported.

Surgical instruments are subject to wear with normal usage. Instruments which have experienced extensive use or excessive force, are susceptible to fracture.

Surgical instruments should only be used for their intended purpose. For information on instrument re-use refer to reprocessing instructions.

The following situations threaten the success of the hip replacement implant:

- *Obesity or excessive weight*
- *The age of the patient*
- *The positioning of the implant*
- *The health of the patient, such as diseases which prevent generation of new healthy bone*
- *The design of the implant*
- *Manual work*
- *Sport activity or high activity level*
- *People likely to fall*
- *Alcoholism or drug abuse*

- *Other incapacity, if relevant*
- *Insufficient bone stock*
- *Insufficient metabolism or systemic pharmacological treatment leading to progressive damage to the implant bone support (ex: diabetes, steroid treatment, immune system treatment)*
- *Sensitivity, allergy, and other reactions to implant materials*
- *Major joint deformation*
- *Inability of the patient to follow the surgeon's recommendations and the physical therapy program*
- *Selection of improper components*
- *Mal-alignment or mal-positioning of the components*
- *Inadequate fixation of components*
- *Failure to remove surgical debris prior to closure*

If there is a reason to believe that a serious incident has occurred in relation to the device, please report it to the national authority and to the manufacturer.

a. Pre-operatively

The surgeon must be fully conversant with all aspects of the operative technique and know the indications and contra-indications for this type of implant.

As part of the pre-operative examination, the surgeon must check that no biological, biomechanical, or other factors are present that will affect the correct conduct of the operation and the post-operative period. The surgeon must also check that the quality of the bone is satisfactory enough to support the implantation.

An appropriate range of implant sizes must be available at the time of the operation.

b. Intra-operatively

The Icona Hip Stem is intended for cementless use only.

The correct selection of the type and size of the implant appropriate to the patient and the positioning of the implant are extremely important. The use of trial implants may allow for the proper size selection of the implants. Frequent radioscopic checks allow the position of the prosthesis to be checked.

The prostheses must not be used if their functional surfaces have been damaged or have undergone shock, abrasion, or other deterioration.

Coated implants must be handled with care and be used according to the recommendations of the surgical technique to avoid deterioration of the coating. Do not cement coated implants.

In case of revision, special care must be taken not to damage the components that are not removed.

Always remove all surgical debris prior to closure.

If there is a reason to believe that a serious incident has occurred in relation to the device, please report it to the national authority and to the manufacturer.

c. Post-operatively

It is recommended that regular post-operative follow-up is undertaken to detect early signs of wear, loosening of the prosthesis, etc., and to consider the action to be taken. Normal wear of the implant in respect of the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or a deterioration in the characteristics of the implant.

A suitable rehabilitation program must be designed and implemented specific to the patient.

d. Information to be conveyed to the patient

The following information should be provided to the patients:

- *Undesirable side-effects and complications listed in the present document*
- *Precautions to take in daily life to guarantee maximum implant survival*
- *The fact that their weight and level of activity can affect the life span of the prosthesis*
- *Information about exposure to MRI conditions*
- *That they must inform the surgeon of any change in performance (mobility, pain etc.)*
- *That they must report any serious incident that occurred in relation to the device to the national authority and the manufacturer*
- *The overall qualitative and quantitative information on the materials and substances to which patients can be exposed and precautions related to these materials (possible sensitisation, allergic reaction or CMR substances).*
- *The implant card filled with requested information*
- *That updates on this information will be available at the website indicated on the implant card*

Location of the Corin Patient website pages where further information on all the above can be found: **https://www.coringroup.com/patients/**, including a patient information leaflet to download.

e. MRI safety information

There are inherent risks associated with the use of metallic implants in the MR environment, including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence.

Non-clinical testing of the worst-case implants has demonstrated that the Icona Hip Stem components are MR Conditional. When scanned under the following conditions, the RF heating induced by the MR environment shall cause a temperature increase no greater than 6°C. A patient with an Icona Hip Stem may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Item Name/Identification	Icona Hip Stem
Static Magnetic Field Strength [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m]	51 T/m
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil or Extremity RF transmit-receive coil
Maximum Whole-Body SAR [W/kg]	1.5 T: whole body SAR < 0.9 W/kg 3.0 T: whole body SAR < 1.9 W/kg
Maximum $B1^{+}_{rms}$ [µT]	$B1^{+}_{rms}$ < 4.8 µT at 1.5 T $B1^{+}_{rms}$ < 3.5 µT at 3.0 T
Scan Duration	For 15 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	In non-clinical testing, it has been found that the image artifact caused by the device may extend up to 105.7mm from implants when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Note: All parameters are connected by AND logical conjunction and have to be within the limits always at the same time. There are two methods of limiting RF heating induced by MR environments. The methods are either to limit the whole-body SAR exposure or utilise the fixed parameter option in the MR system to limit the permissible $B1^{+}$field value.

8. Storage and handling

Implants must be stored in their original sealed packaging. Implants must be stored away from heat or moisture. Implants must not be exposed to direct sunlight, ionising radiation, or particulate contamination. Implants must be handled with care to preserve integrity of their packaging.

9. Packaging and sterilisation

The implants are supplied sterile. Icona Hip Stems are sterilised by gamma irradiation delivered from a $cobalt_{60}$ source. The expiration date for sterilisation and integrity of the packaging must be checked.

An implant whose packaging is open or damaged or whose expiration date has passed must not be used.

Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

Do not re-sterilise. For single use only.

Some instruments may be supplied sterile.

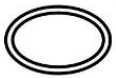
- *For handling and sterilisation of non-sterile ancillary instruments, refer to the ancillary instruments' instructions.*
- *For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.*

10. Implant retrieval and handling

In case of retrieval of the implant from the patient, the retrieved implant should be handled according to appropriate and validated hospital procedures to facilitate the safe disposal of the device and its accessories. These procedures should consider infection, microbial and physical hazards.

11. Interpretation of terms and symbols

GLOSSARY OF PRODUCT LABEL SYMBOLS			
Caution: The key for the following symbols is for reference only – some symbols listed may not apply. Please see main product label affixed to product for applicable symbols.			
Symbol	**Symbol title**	**Symbol description**	**Reference and Standard**
	Manufacturer	Indicates the medical device manufacturer	ref. 5.1.1 in ISO 15223-1[1]
	Use-by date	Indicates the date after which the medical device is not to be used.	ref. 5.1.4 in ISO 15223-1[1]
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ref. 5.1.5 in ISO 15223-1[1]
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ref. 5.1.6 in ISO 15223-1[1]
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ref. 5.1.7 in ISO 15223-1[1]
	Sterilised using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ref. 5.2.3 in ISO 15223-1[1]
	Sterilised using irradiation	Indicates a medical device that has been sterilized using irradiation.	ref. 5.2.4 in ISO 15223-1[1]

Symbol	Symbol title	Symbol description	Reference and Standard
	Do not resterilise	Indicates a medical device that is not to be resterilised.	ref. 5.2.6 in ISO 15223-1[1]
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ref. 5.2.7 in ISO 15223-1[1]
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ref. 5.2.8 in ISO 15223-1[1]
	Double sterile barrier system	Indicates two sterile barrier systems	ref. 5.2.12 in ISO 15223-1[1]
	Do not re-use	Indicates a medical device that is intended for one single use only.	ref. 5.4.2 in ISO 15223-1[1]
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ref. 5.4.3 in ISO 15223-1[1]
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ref. 5.4.4 in ISO 15223-1[1]

Symbol	Symbol title	Symbol description	Reference and Standard
	Medical Device	Indicates the item is a medical device	ref. 5.7.7 in ISO 15223-1[1]
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	ref. 5.7.10 in ISO 15223-1[1]
	Not made with natural rubber latex	Indicates that the device is not made with natural rubber latex	N/A
	Prescription use only	Indicates that Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties	ref. 5.4.10 in ISO 15223-1[1]
	MR Conditional	Indicates there are certain conditions associated with the safety of the device in the MR environment	ref 7.4.6 in ASTM F2503-20[2]

[1]: BS EN ISO 15223-1:2021 Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

[2]: ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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This "Instructions for Use" has been approved by the U.S. Food and Drug Administration