Corin

Connected Orthopaedic Insight

MetaFix™

Instructions for use

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This "Instructions for Use" contains information on how to use Corin MetaFix™ 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 symbol glossary, please consult the table at Section 11 of the present document.

1. Device Description

The MetaFix™ Hip Stem is a tapered stem manufactured from titanium (Ti6Al4V) with a layer of hydroxyapatite (HA) Coating applied.

The MetaFix™ Hip Stem is available in:

- *Collarless Stem with Standard Offset at 125° and 135° (Sizes 0-10)*
- *Collarless Stem with Lateralised Offset 135° (Sizes 0-10)*
- *Collared Stem with Standard Offset at 135° (Sizes 0-9)*
- *Collared Stem with Standard Offset at 125° (Sizes 1-9)*
- *Collared Stem with Lateralised Offset 135° (Sizes 0-9)*
- *Collared Stem Short Neck 135° (Size 0-8)*
- *Collared Stem Short Neck 125° (Size 1-8)*

The device is intended to be used with 12/14 modular taper heads.

The MetaFix™ Hip Stem is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Note 1: 125˚ standard offset and 125˚ short neck for Size 1, and all offsets for Size 0 are not available in the USA.

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

For a more detailed description of the implants and their use, please refer to the technical documentation, or contact your Corin representative.

Basic UDI-DI, MetaFix Hip Stem: 05055343891JS*

** Note: Basic UDI-DI (or BUDI-DI) is a method of device identification, which groups together devices with multiple UDI-DIs. The BUDI-DI number links devices with the same intended purpose, risk class, essential design and manufacturing characteristics.*

Combination / Component Association:

It is essential to implant MetaFix™ Hip Stem with the Corin instrumentation specifically designed for this purpose. MetaFix™ Hip Stem implants must be assembled using Corin components defined as being compatible with one another.

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

Recommendations for connecting the components with one another are provided in the following link: https://www.coringroup.com/compatibility

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

Expected Device Lifetime:

There are several factors that can influence the product's lifetime including, but not limited to, surgical indication, surgical technique, patient weight, activity level and comorbidities.

The expected survivorship of the device is 95% or better at 10 years for primary total hip replacements (as recommended in the NICE Guidance).

(Sources: NICE Guidance TA304:26 Feb 2014: Total hip replacement and resurfacing arthroplasty for end stage arthritis of the hip)

The collarless MetaFix™ Hip Stem currently has an ODEP rating of 13A demonstrating it is performing in line with the NICE Guidance at 13 years follow-up.

The collared MetaFix™ Hip Stem currently has an ODEP rating of 5A* demonstrating it is performing in line with the NICE Guidance at 5-year follow-up and whilst the device does not yet have sufficient data to confirm performance at 10 years, it is on track to comply with the expected survivorship of better than 95%.

(Source: Latest ODEP ratings can be found at www.odep.org.uk)

Real-world evidence data currently shows:

- **AOANJRR:** 97.3% (95%CI: 96.8% - 97.7%) survivorship at 5 years, all revisions, any reason for revision.
  (Source: Australian Orthopaedics Association National Joint Replacement registry (AOA NJRR) Annual Report 2021, MetaFix stem - Trinity cup, Table HT12, page 91)
- **UK NJR:** 97.8% (95% CI: 96.7% - 98.4%) survivorship at 10 years, all revisions, any reason for revision.
  (Source: National Joint Registry (NJR) MetaFix Implant Summary Report – on label, excluding Metal on Metal bearings - produced on 20 May 2021).

- **Collarless:** 97.8% (95% CI: 97.1% - 98.3%) survivorship at 11 years, all revisions, any reason for revision.
- **Collared:** 99.5% (95% CI: 98.6% - 99.8%) survivorship at 4 years, all revisions, any reason for revision.

(Source: NJR Raw Data for MetaFix – on-label, combinations still in use – downloaded on 14 July 2021)

2. Materials

The Metafix stem and coating is composed of the following materials;

- *Wrought Titanium-6, Aluminium-4 alloys complying with ASTM F136 Standard Specification for Wrought Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.*
- *Plasma sprayed Hydroxyapatite complying with ASTM F-1185-03 Standard Specification for Composition of Hydroxylapatite for Surgical Implants.*

Component:	**Material:**	**Composition:**	
Collarless Cementless MetaFix Stem and Collared Cementless MetaFix 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 %*	

Collarless Cementless MetaFix Stem and Collared Cementless MetaFix Stem	*Thick HA coating (nominally 155 micron)*	Element	Concentration (per ASTM 1185)	Concentration (per 13779-2)
		Hydroxyapatite (Ca/P Ratio 1.70 ± 0.03)	95%	
		Non-HA phases (α-TCP, β-TCP, TTCP, CaO)	5% Max.	5% Max.
		Cadmium	5 ppm Max.	5 ppm Max.
		Arsenic	3 ppm Max.	3 ppm Max.
		Mercury	5 ppm Max.	5 ppm Max.
		Lead	30 ppm Max.	30 ppm Max.
		Other Heavy Metals	50 ppm Max.	50 ppm Max.
		Crystallinity of Powder	95%± 5%	≥60%*
		*(*ISO 13779-3 specifies a minimum crystallinity index value of ≥45%).*		

3. Intended use and intended performances of the implant

The MetaFix™ Hip Stem is intended for use in 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.

They are intended to be used by appropriately qualified surgeons, who must practice in accordance with current advancements in scientific data and surgical techniques.

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

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

For clinical performances and clinical safety claims, please check the summary of safety and clinical performances (SSCP).

The SSCP is available in the European database on medical devices (EUDAMED): https://ec.europa.eu/tools/eudamed, where it is linked to the following Basic UDI-DI: 05055343891JS.

The SSCP is also available on request, please contact your Corin representative.

4. Indications for use

Indications for use (Global):

The indications for the Corin MetaFix™ 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) and congenital dysplasia of the hip (CDH)*

The Corin MetaFix™ Hip Stem is indicated for cementless use only.

**The use of the Corin MetaFix™ Hip Stem in hemiarthroplasty is not CE Marked*

*** Explanatory Note: Functional deformity could be deformity caused by arthritic conditions or could be secondary to developmental processes, previous osteotomy or fracture.*

While certain deformities can make total hip arthroplasty more complex, total hip arthroplasty can be used to treat such conditions. Sound surgical judgement should be exercised in such cases to determine whether the THA will eliminate the functional deformity.

Indications for use (CE Only):

The indications for the Corin MetaFix™ Hip Stem as a total hip arthroplasty* 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) and congenital dysplasia of the hip (CDH)*

The Corin MetaFix™ Hip Stem is indicated for cementless use only.

The use of the Corin MetaFix™ Hip Stem in hemiarthroplasty is not CE Marked

Explanatory Note: Functional deformity could be deformity caused by arthritic conditions or could be secondary to developmental processes, previous osteotomy or fracture.

While certain deformities can make total hip arthroplasty more complex, total hip arthroplasty can be used to treat such conditions. Sound surgical judgement should be exercised in such cases to determine whether the THA will eliminate the functional deformity.

5. Known contra-indications to date

- *Active infection*
- *Metabolic disorders which may impair bone formation*
- *Muscular atrophy or neuromuscular disease*
- *Charcot's or Paget's disease*
- *Marked bone loss or bone resorption*
- *Vascular insufficiency*
- *Allergy to implant material*
- *For hemi-hip arthroplasty, 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 hemi-hip prosthesis.**

The use of the Corin MetaFix Hip Stem™ in hemiarthroplasty is not CE Marked

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

6. Undesirable side effects and possible complications

Complications can potentially occur following any joint replacement surgery. The following complications have occurred in some patients after their hip joint replacement surgery:

- *Hip ball (femoral head) and hip socket (Acetabulum) may separate (hip dislocation),*
- *Device loosening from the surrounding bone,*
- *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*

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.

Surgeons should be thoroughly familiar with the Metafix Hip Stem surgical 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.*

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.

Please note the MetaFix™ Hip stem should not be used for patients who weigh more than 80 kg for all size 0 stems and size 1 125° standard & short neck stems.

a. Pre-operatively

Surgeons should be thoroughly familiar with the Corin MetaFix™ Hip Stem surgical technique, the implants, and the instruments prior to performing the surgery.

The surgeon must be fully conversant with all aspects of the surgical 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 postoperative 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.

Please note the MetaFix™ Hip Stem should not be used for patients who weigh more than 80 kg for all size 0 stems and size 1 125° standard & short neck stems.

b. Intra-operatively

The MetaFix™ Hip Stems are 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. 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 manufacture.

c. 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 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 or allergic reaction)*
- *The implant card filled with requested information*
- *That updates on this information will be available on the website indicated in the implant card.*

Location of the Corin Patient website site pages where further information on all of the above can be found: **About Hip Replacement | For Patients | Corin Group**, including a general patient information pack to download.

d. Post-operatively

It is recommended that regular postoperative 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.

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 MetaFix™ Hip Stems 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 a MetaFix™ 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	MetaFix™ 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. MetaFix™ Hip Stem components are sterilized 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.

Some instruments may be supplied sterile.

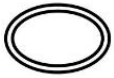
- *For handling and sterilisation of non-sterile ancillary instruments, refer to the ancillary instruments' instructions.*
- *For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.*

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**
	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]
	Do not resterilise	Indicates a medical device that is not to be resterilised	ref. 5.2.6 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]
	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]
	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
	Manufacturer	Indicates the medical device manufacturer	ref. 5.1.1 in ISO 15223-1[1]
	Not made with natural rubber latex	Indicates the medical device is not made with natural rubber latex	21 CFR 801.437
	Sterilised using irradiation	Indicates a medical device that has been sterilized using irradiation	ref. 5.2.4 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]
	Double sterile barrier system	Indicates two sterile barrier systems	ref. 5.2.12 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]

Symbol	Symbol title	Symbol description	Reference and Standard
	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]
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	ref. 5.7.10 in ISO 15223-1[1]
	Device manufacture date	Indicates the date when the medical device was manufactured.	ref. 5.1.3 in ISO 15223-1[1]
	CE marking of conformity	Indicates that the device conforms to EU Medical Device Regulation	Regulation (EU) 2017/745
	Prescription use only	Indicates Prescription use only	21 CFR 801.109
	Medical Device	Indicates the item is a medical device	ref. 5.7.7 in ISO 15223-1[1]
	Authorised Representative in the European Community / European Union	Indicates the authorised representative in the European Community / European Union	ref. 5.1.2 in ISO 15223-1[1]

Symbol	Symbol title	Symbol description	Reference and Standard
	MR Conditional	Indicates there are certain conditions associated with safe scanning	ref 7.4.6 ASTM F2503-20[2]
	Importer	Indicates the entity importing the medical device into the locale	ref. 5.1.8 in ISO 15223-1[1]
[1]: EN ISO 15223-1:2021 on Symbols to be used with information to be supplied by the manufacturer.			
[2]: ASTM F2503-20 Standard practice for Marking Medical Device and other items for safety in the Magnetic Resonance Environment.			

Manufacturer

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

Corin
Connected Orthopaedic Insight

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