

Corin



Meije Duo™

Instructions for use



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This "Instructions for Use" contains information on how to use Corin Meije Duo™ 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

Meije Duo™ hip prostheses are intended for primary replacement of the hip joint.

Meije Duo™ stems are femoral stems available with 12/14 tapers. They are rectangular in shape and have a polished neck. The Meije Duo™ stems are used with compatible femoral heads and acetabular components.

The cemented version in stainless steel is available in two models:

- *Standard stem*
- *Lateralised stem*

It is mirror polished and has no surface macro aspect.

The cementless version in titanium alloy is available in four models:

- *Standard stem*
- *Standard stem with collar*
- *Lateralised stem*
- *Lateralised stem with collar*

It has a surface macro aspect in the form of tiny waves on the metaphyseal part and longitudinal grooves on the diaphyseal part. These parts are coated with hydroxyapatite.

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.

Combination / Component Association:

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

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.

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 lifetime including, but not limited to, surgical indication, operative technique, patient weight, activity level and comorbidities.

The Meije Duo™ stem has an expected survivorship of 95% or better at 10 years for primary total hip replacements as recommended in the NICE guidance (TA304 26 Feb 2014: Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip).

The Meije Duo™ stem has an expected survivorship of 95% or better at 5 years and 93% or better at 10 years for hip hemiarthroplasty (in line with rates reported in the Australian National Joint Registry). (Australian Orthopaedics Association National Joint Replacement Registry (AOANJRR) Annual Report 2024).

2. Materials

The constituent material of the Meije Duo™ implants is included on packaging labels.

Component:	Materials:	Substance:	% (mass/mass)
<i>Meije Duo™ cemented stem</i>	<i>Stainless steel meeting the requirements of ISO 5832-9</i>	<i>Carbon</i>	<i>0.08 max.</i>
		<i>Silicon</i>	<i>0.75 max.</i>
		<i>Manganese</i>	<i>2.00-4.25</i>
		<i>Nickel</i>	<i>9.0-11.0</i>
		<i>Chromium</i>	<i>19.5-22.0</i>
		<i>Molybdenum</i>	<i>2.0-3.0</i>
		<i>Niobium</i>	<i>0.25-0.80</i>
		<i>Sulfur</i>	<i>0.01 max.</i>
		<i>Phosphorus</i>	<i>0.025 max.</i>
		<i>Copper</i>	<i>0.25 max.</i>
		<i>Nitrogen</i>	<i>0.25-0.50</i>
		<i>Iron</i>	<i>Balance</i>
		<i>Residuals, each</i>	<i>0.1 max.</i>
		<i>Residuals, total</i>	<i>0.4 max.</i>
<i>Meije Duo™ cementless stem</i>	<i>Titanium (Ti6-Al4-V) ELI (Extra Low Interstitial) Alloy meeting the requirements of ASTM F136 and ISO 5832-3</i>	<i>Aluminium</i>	<i>5.5-6.50</i>
		<i>Vanadium</i>	<i>3.5-4.5</i>
		<i>Iron</i>	<i>0.25 max.</i>
		<i>Oxygen</i>	<i>0.13 max.</i>

Component:	Materials:	Substance:		% (mass/mass)
<i>Meije Duo™ cementless stem</i>	<i>Titanium (Ti6-Al4-V) ELI (Extra Low Interstitial) Alloy meeting the requirements of ASTM F136 and ISO 5832-3</i>	<i>Carbon</i>		<i>0.08 max.</i>
		<i>Nitrogen</i>		<i>0.05 max.</i>
		<i>Hydrogen</i>		<i>0.012 max.^A</i>
		<i>Titanium</i>		<i>Balance</i>
		<i>^A Material 0.032 in (0.813mm) and under may have hydrogen content up to 0.015 %</i>		
<i>Meije Duo™ cementless stem</i>	<i>Hydroxyapatite (HA) coating meeting the requirements of ASTM F1185 and ISO 13779-2</i>		Concentration per ASTM F1185	Concentration per ISO 13779-2
		<i>Hydroxylapatite (Ca/P Ratio 1.70 ± 0.03)</i>	<i>95%</i>	<i>/</i>
		<i>Non-HA phases (α-TCP, β-TCP, TTCP, CaO)</i>	<i>5% max.</i>	<i>5% max.</i>
		<i>Cadmium</i>	<i>5 ppm max.</i>	<i>5 ppm max.</i>
		<i>Arsenic</i>	<i>3 ppm max.</i>	<i>3 ppm max.</i>
		<i>Mercury</i>	<i>5 ppm max.</i>	<i>5 ppm max.</i>
		<i>Lead</i>	<i>30 ppm max.</i>	<i>30 ppm max.</i>
		<i>Other heavy metals</i>	<i>50 ppm max.</i>	<i>50 ppm max.</i>
		<i>Crystallinity of powder</i>	<i>95%± 5%</i>	<i>/</i>
		<i>Crystallinity of coating</i>	<i>/</i>	<i>≥60%*</i>
		<i>*ISO 13779-2 specifies a minimum crystallinity index value of ≥45%</i>		

3. Intended use and intended performances of the implant

The Meije Duo™ stems are 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.

They are 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 Meije Duo™ 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:

Component	Basic UDI-DI
Meije Duo™ cemented stem	50553438HLP401BQ
Meije Duo™ cementless stem	50553438HLP402BS

4. Indications for use

The indications for a Meije Duo™ stem as a total hip arthroplasty, include:

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

The indications for a Meije Duo™ stem in hemiarthroplasty in combination with a Corin hemiarthroplasty head, include:

- *Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis in which the acetabulum does not require replacement*
- *Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur*

5. Known contra-indications to date

- *Active infection*
- *Poor bone quality*
- *Marked bone loss or bone resorption*
- *Metabolic disorders which may impair bone formation*
- *Muscular atrophy or neuromuscular disease*
- *Allergy to implant material*
- *For 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 hemi-hip 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 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,*
- *Superficial or deep infection,*
- *Fretting and crevice corrosion can occur at interfaces between components which may result in Adverse Local Tissue Reactions (ALTR),*
- *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, soft tissue and vascular damage (including muscles, tendons, ligaments, cartilage, nerves and blood vessels),*
- *Embolism,*
- *Bone cement implantation syndrome,*
- *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 Meije Duo™ 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 may not be suitable for all anatomies.*
- *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.

a. Pre-operatively

Surgeons should be thoroughly familiar with the Meije Duo™ operative technique, the implants, and the instruments prior to performing the surgery.

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 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.

Special caution for weight:

The Meije Duo™ cementless lateralised size 1 stems and cementless standard size 0 stem should not be used for patients who weigh more than 75kg.

The Meije Duo™ cementless standard size 1 stems and cementless lateralised size 2 stems should not be used for patients who weigh more than 94kg.

b. Intra-operatively

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. It is advisable to routinely test the selected head/neck configuration to ensure that there is no contact between the femoral neck and the acetabular insert.

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.

The implants coated with hydroxyapatite (HA) must be handled with care and be used according to the recommendations of the operative technique to avoid deterioration of the coating. Do not cement the HA coated implants.

The use of tooth rasps with cementless implants is not indicated, due to the risk of a mismatch between rasp and implant and of compacted bone debris in this configuration.

After careful cleaning and drying of the taper of the femoral implant, the permanent head is put in place. The metal femoral heads are impacted. The ceramic femoral heads are impacted by the orthopaedic surgeon striking them lightly with a hammer fitted with a plastic head.

A cement restrictor must be used with the cemented stem.

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. 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 – high range of motion activities should be avoided,*
- *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 – including the use of nickel which may cause skin sensitisation)*
- *The implant card filled with requested information*
- *That updates on this information will be available in the website indicated in the implant card.*

Location of the Corin Patient website site pages where further infoamtion on all of the above can be found: <https://www.coringroup.com/patients/hip-replacement/>, including a general patient information leaflet to download.

d. 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 Meije Duo™ 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 Meije Duo™ stem may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Item Name/Identification	Meije Duo™
Static Magnetic Field Strength [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m]	Cemented stem: 6 T/m (600 Gauss/cm) Cementless stem: 214 T/m (21,400 Gauss/cm)
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.

e. Post-operative follow-up

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.

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. Meije Duo™ stems are sterilised by gamma irradiation delivered from a cobalt⁶⁰ 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

KEY TO SYMBOLS USED ON PRODUCT LABELLING			
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
	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
	Device manufacture date	Indicates the date when the medical device was manufactured.	ref. 5.1.3 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

Symbol	Symbol title	Symbol description	Reference and Standard
	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
	Importer	Indicates the entity importing the medical device into the locale	ref. 5.1.8 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
	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

Symbol	Symbol title	Symbol description	Reference and Standard
	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
	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 the medical device is not made with natural rubber latex	21 CFR 801.437

Symbol	Symbol title	Symbol description	Reference and Standard
	Prescription use only	Indicates Prescription use only	21 CFR 801.109
	CE marking of conformity	Indicates that the device conforms to EU Medical Device Regulation	Regulation (EU) 2017/745
	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 safe scanning	ref 7.4.6 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			

**CORIN LIMITED**

The Corinium Centre
Cirencester,
Gloucestershire,
GL7 1YJ,
United Kingdom

Telephone: +44 (0) 1285 659866

Fax: +44 (0) 1285 658960

email: info@coringroup.com

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EC Representative

Authorised Representative in the European Community/European Union
Corin France SAS,
157, Rue Lavoisier,
38330 Montbonnot-Saint-Martin,
France

www.coringroup.com

Corin
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