Corin

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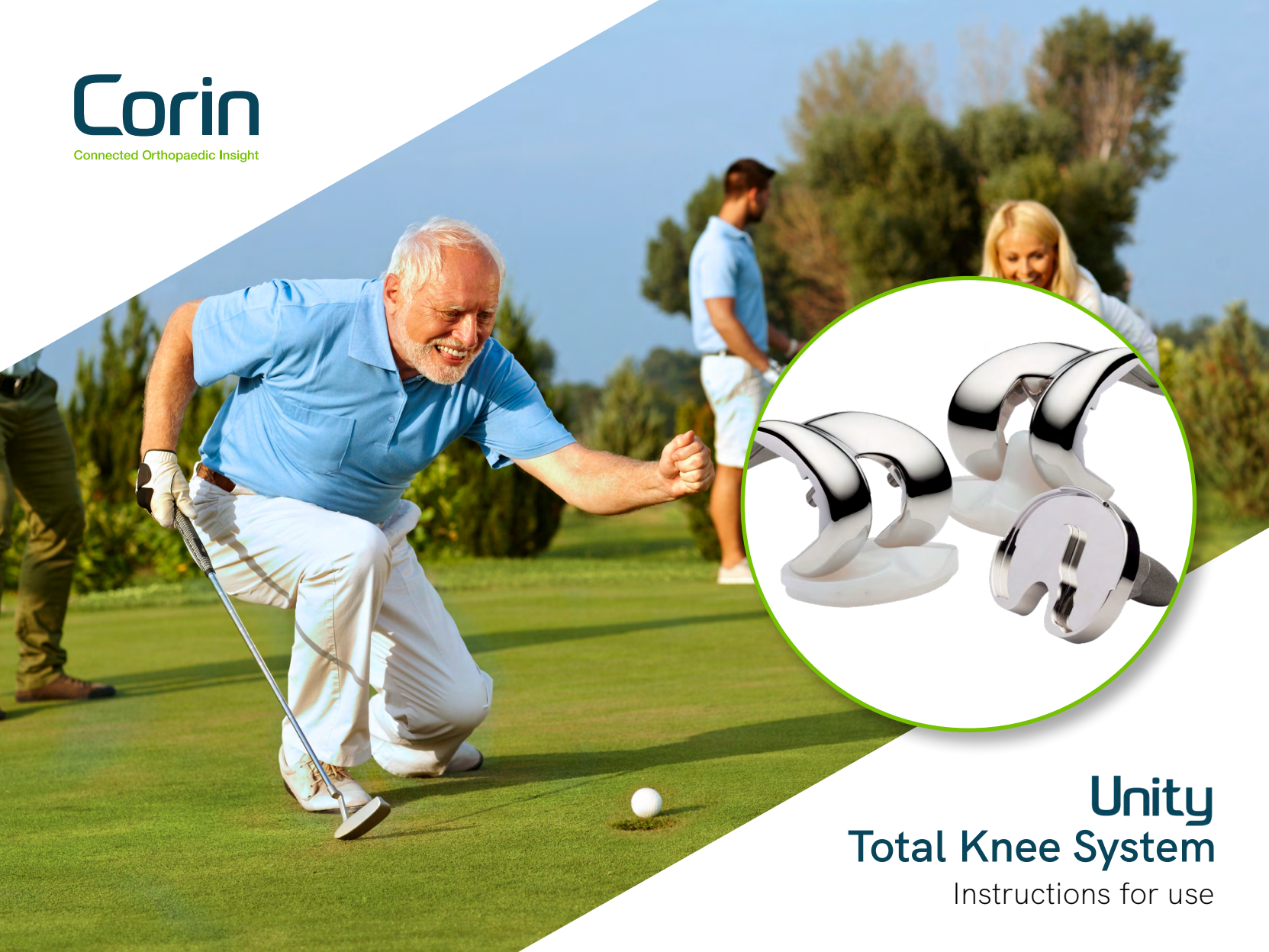
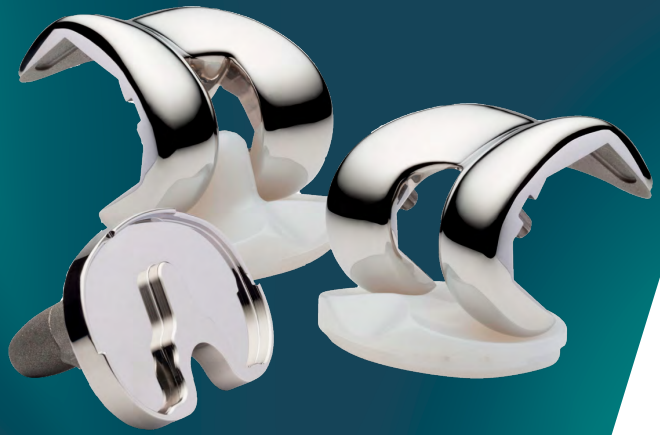


Unity
Total Knee System
Instructions for use



Instructions for use

This "Instructions for Use" contains information on how to use Unity Total Knee System.

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 Unity Total Knee System is a fixed bearing total knee replacement system that consists of a cobalt chromium alloy (CoCr) femoral component, a UHMWPE (Ultra-High-Molecular-Weight-Polyethylene) or ECiMa (Vitamin E enriched advanced polyethylene) tibial insert, a CoCr tibial tray with a titanium alloy keel extension and all-polyethylene (UHMWPE) patellar component for use in primary and revision total knee arthroplasty. The Unity Total Knee System femoral component is provided in two variants, cruciate retaining (CR) and posterior stabilised (PS).

- *The CR femoral component is intended for use in conjunction with the CR tibial insert or Medial Constrained (MC) tibial insert where the posterior cruciate ligament (PCL) is functional or in conjunction with a Condylar Stabilised (CS) tibial insert or MC tibial insert where the PCL is present but is lax or non-functioning or when the PCL is absent.*
- *The PS femoral component is intended for use in conjunction with the PS tibial insert where the posterior cruciate ligament is non-functioning or absent, resulting in joint instability, or in conjunction with the constrained posterior stabilized (PS-C) tibial insert where there is instability of the medial collateral ligament and/or lateral collateral ligament (MCL/LCL)*

The Unity Total Knee System patellar component is optional and for use with either the CR or PS femoral variants and is intended for use where replacement of the articular surface of the patella is required. The system also provides titanium alloy augment components including femoral augments, tibial augments, stem extensions and offset adapters.

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 documentation, or contact your Corin representative.

Combination and Component Association:

It is essential to implant Unity Knee™ 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.

It is possible to use a size N tibial insert with a size N-2, N-1, N, N+1 or N+2 femoral implant.*

The tibial insert must be the same size as the tibial tray.

Tibial augments (only available in 5mm thicknesses) can be combined with another tibial augment of a consecutively smaller size to create a combined, 10mm augment. E.g. a size N tibial tray may be combined with a size N tibial augment stacked with a size N-1 tibial augment. This is possible for all sizes tibial trays except size 1 where only one augmentation block thickness 5 mm can be utilised.

Femoral augments must be used with the corresponding size femoral implant.

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

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

**with 1 the exception of Unity Knee PS-C and MC tibial inserts which will use a size N tibial insert with a size N-1, N or N+1 femoral implant.*

For PS-C, there is also the exception of the two cross over sizes: size 7T-8F and size 8T-7F. This is due to the cam width of the PS femoral component changing between the size 7 and 8. The size 7 PS-C tibial insert is only compatible with the sizes 6 & 7 PS femoral component and there is a dedicated 7T-8F insert that is compatible with the size 8 femoral component. The size 8 PS-C tibial insert is only compatible with the sizes 8 & 9 PS femoral component and there is a dedicated 8T-7F insert that is compatible with the size 7 PS femoral component.

The size(s) of Unity Knee PS femoral components compatible with each Unity Knee PS-C tibial insert is listed on the product label on the implant packaging.

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 Unity Knee™ has an expected survivorship of 95% or better for primary total knee replacements at 10 years based on state-of-the-art benchmarking (Orthopaedic Data Evaluation Panel; available from: https://www.odep.org.uk/).

In the absence of long-term clinical data at 10 years, the Unity Knee™ is currently on track to achieve this expected survivorship, as supported by the following data:

The Unity Knee™ has the following ODEP rating:

- *Unity Knee CR (with CR insert) with domed patella – 7A*
- *Unity Knee CR (with CR insert) with and without offset domed patella – 7A*
- *Unity Knee PS (with PS insert) with offset domed patella – 7A*
- *Unity Knee CR (with CR insert) without patella – 5A*
- *Unity Knee CR with CS insert does not yet have an ODEP rating*

A 7A and 5A ODEP rating demonstrate that these combinations are performing as expected at 7 and 5 years follow-up, respectively, and they are on track to comply with the expected survivorship of 95% or better at 10 years.

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

Real-world evidence data shows:

- **UK NJR**
  - Unity Knee™ (all variants): 98.8% (95% CI: 98.1% - 99.3%) survivorship at 5 years, all revisions, any reasons for revision.
  - Unity Knee™ (all variants, with patella): 98.9% (95% CI: 98.0% - 99.4%) survivorship at 5 years, all revisions, any reasons for revision.
  - Unity Knee™ (all variants, without patella): 98.5% (95% CI: 96.4% - 99.4%) survivorship at 5 years, all revisions, any reasons for revision (fewer than 250 cases).

(Source: 20th Annual Report 2023 – National Joint Registry (UK NJR) for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey).

- **AOANJRR**
  - Unity Knee™ (all variants): 99.7% (95% CI: 99.0% - 99.9%) survivorship at 3 years, all revisions, any reasons for revision.

(Source: 22nd Annual Report 2023 - Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR))

2. Materials

The constituent material of the Unity Knee™ is included on packaging labels.

Component:	**Materials:**	**Substance:**	**% (mass/mass):**	
			Per ISO 5832-4	**Per ASTM F75**
*Unity Knee™ Femur**	*Cobalt Chrome Alloy (CoCr) meeting the requirements of ISO 5832-4 and ASTM F75*	*Chromium*	*26.5 - 30.0*	*27.00 - 30.00*
		Molybdenum	*4.5 - 7.0*	*5.00 - 7.00*
		Nickel	*1.0 max.*	*0.50 max.*
		Iron	*1.0 max.*	*0.75 max.*
		Carbon	*0.35 max.*	*0.35 max.*
		Manganese	*1.0 max.*	*1.00 max.*
		Silicon	*1.0 max.*	*1.00 max.*
		Tungsten	*/*	*0.20 max.*
		Phosphorous	*/*	*0.020 max.*
		Sulfur	*/*	*0.010 max.*
		Nitrogen	*/*	*0.25 max.*
		Aluminium	*/*	*0.10 max.*
		Titanium	*/*	*0.10 max.*
		Boron	*/*	*0.010 max.*
		Cobalt	*Balance*	*Balance*

Continued on next page

Component:		Materials:	Substance:	% (mass/mass):
Unity Knee™ Tibial Insert	*CR, CS, PS, PS-C*	*Ultra-High Molecular Weight Polyethylene (UHMWPE) meeting the requirements of ISO 5834-2 (Type 2) and ASTM F648 (Type 2)*	*Virgin polymer - GUR 1050*	*N/A*
			Extraneous matter particles per 300g	*3 max.*
			Ash (mg/kg)	*125 max.*
			Titanium (mg/kg)	*40 max.*
			Calcium (mg/kg)	*5 max.*
			Chlorine (mg/kg)	*30 max.*
			Aluminium (mg/kg)	*20 max.*
	MC	*ECiMa (Vitamin E enriched advanced polyethylene) meeting the requirements of ASTM F2695*	*Ash (mg/kg)*	*125 max.*
			Extraneous Matter particles per 300g	*3 max.*
			Titanium (mg/kg)	*40 max.*
			Aluminium (mg/kg)	*20 max.*
			Calcium (mg/kg)	*5 max.*
			Chlorine (mg/kg)	*30 max.*
			Alpha-tocopherol	*0.1 +/- 0.01*

Continued on next page

Component:		Materials:	Substance:	% (mass/mass):	
				Per ISO 5832-4	Per ASTM F75
*Unity Knee™ Tibial Tray**	*Tray*	*CoCr meeting the requirements of ISO 5832-4 and ASTM F75*	*Chromium*	*26.5 - 30.0*	*27.00 - 30.00*
			Molybdenum	*4.5 - 7.0*	*5.00 - 7.00*
			Nickel	*1.0 max.*	*0.50 max.*
			Iron	*1.0 max.*	*0.75 max.*
			Carbon	*0.35 max.*	*0.35 max.*
			Manganese	*1.0 max.*	*1.00 max.*
			Silicon	*1.0 max.*	*1.00 max.*
			Tungsten	*/*	*0.20 max.*
			Phosphorous	*/*	*0.020 max.*
			Sulfur	*/*	*0.010 max.*
			Nitrogen	*/*	*0.25 max.*
			Aluminium	*/*	*0.10 max.*
			Titanium	*/*	*0.10 max.*
			Boron	*/*	*0.010 max.*
			Cobalt	*Balance*	*Balance*

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Component:		Materials:	Substance:	% (mass/mass):
*Unity Knee™ Tibial Tray**	*Keel*	*Titanium Alloy (Ti6-AI4-V) meeting the requirements of ISO 5832-3*	*Aluminium*	*5.5-6.75*
			Vanadium	*3.5-4.5*
			Iron	*0.3 max.*
			Oxygen	*0.2 max.*
			Carbon	*0.08 max.*
			Nitrogen	*0.05 max.*
			Hydrogen	*0.015 max.*
			Titanium	*Balance*

Continued on next page

Component:		Materials:	Substance:	% (mass/mass):
Unity Knee™ Patella	*Patella*	*Ultra-High Molecular Weight Polyethylene (UHMWPE) meeting the requirements of ISO 5834-2 (Type 2) and ASTM F648 (Type 2)*	*Virgin polymer – GUR 1050*	*N/A*
			Extraneous matter particles per 300g	*3 max.*
			Ash (mg/kg)	*125 max.*
			Titanium (mg/kg)	*40 max.*
			Calcium (mg/kg)	*5 max.*
			Chlorine (mg/kg)	*30 max.*
			Aluminium (mg/kg)	*20 max.*
	X-ray marker ball	*Stainless Steel 316LVM meeting the requirements of ISO 5832-1*	*Carbon*	*0.030 max.*
			Silicon	*1.0 max.*
			Manganese	*2.0 max.*
			Phosphorus	*0.025 max.*
			Sulfur	*0.010 max.*
			Nitrogen	*0.10 max.*
			Chromium	*17.0-19.0 max.*
			Molybdenum	*2.25-3.00*
			Nickel	*13.0-15.0*
			Copper	*0.50 max.*
			Iron	*Balance*

Continued on next page

Component:	Materials:	Substance:	% (mass/mass):
Unity Knee™ Augments	*Titanium Alloy (Ti 6-Al4-V) meeting the requirements of ISO 5832-3*	*Aluminium*	*5.5-6.75*
		Vanadium	*3.5-4.5*
Unity Knee™ Stem Extensions		*Iron*	*0.3 max.*
		Oxygen	*0.2 max.*
Unity Knee™ Offset Adapter		*Carbon*	*0.08 max.*
		Nitrogen	*0.05 max.*
Unity Knee™ Screws		*Hydrogen*	*0.015 max.*
		Titanium	*Balance*

*contains a CMR substance (CMR - Category 1B) - refer to section 7 'Warnings and cautions' for further information.

3. Intended use and intended performances of the implant

The Unity Total Knee System is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee 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 the Unity Total Knee System is intended to elicit the below clinical benefits to the indicated patients:

- *restore a functional knee joint,*
- *reduce pain,*
- *improve mobility,*
- *improve stabilisation*

4. Indications for use

General total knee arthroplasty indications include:

- *Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis*
- *Post-traumatic loss of knee joint configuration and function*
- *Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function*
- *Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate*
- *Fracture of the distal femur and/or proximal tibia that cannot be stabilised by standard fracture management techniques*
- *The posterior stabilised (PS) variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament.*

The Unity Total Knee System is intended for cemented use, single use only.

5. Known contra-indications to date

- *Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity*
- *Infection/ distant foci of infections*
- *Osteomyelitis, osteoporosis, osteomalacia*
- *Marked bone loss or bone resorption*
- *Metabolic disorders which may impair bone formation*
- *Vascular insufficiency*
- *Muscular atrophy or neuromuscular disease*
- *Allergy to implant material*
- *Severe deformity*

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 knee arthroplasty:

- *Change in position of the components*
- *Instability*
- *Bending*
- *Fracture*
- *Infection*
- *Pain*
- *Subluxation*
- *Decreased range of motion*
- *Fibrosis*
- *Tendon damage*
- *Thrombosis / Pulmonary Embolism*
- *Loosening*
- *Tibial subsidence*
- *Cracking*
- *Deformation or wear of one or more of the components*
- *Tissue reaction to implant materials or wear debris*
- *Dislocation*
- *Flexion contracture*
- *Fractures of the femur or tibia*
- *Vascular lesions*
- *Nerve damage/ Palsy*
- *Cement associated Adverse Events*

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 Unity Knee™ 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

Surgeons should be thoroughly familiar with the Unity Knee™ 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.

b. Intra-operatively

Components labelled for "Cemented Use Only" are to be implanted only with bone cement.

The correct selection of the type and size of the implant appropriate to the patient and the positioning of the implant are extremely important. Refer to the operative technique regarding the use of augment and tibial insert components.

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 manufacturer.

c. Post-operatively

It is recommended that a regular postoperative follow-up is undertaken to detect earl 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 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 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: 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 Unity Knee™ components are MR Conditional. A patient with a Unity Knee™ may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Warning: For safe scanning, the edge of the device must be greater than 35 cm from the isocentre of the magnet.

Item Name/Identification		Unity Knee™
Static Magnetic Field Strength [T]		1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m]		40 T/m (4000G/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]	Edge of device > 35 cm away from the centre of the body coil	Whole body SAR ≤ 2 W/kg (Normal Operating Mode)
Maximum B1+rms [µT]	Edge of device > 35 cm away from the centre of the body coil	Normal Operating Mode
Scan Duration		For 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact		The presence of this implant may produce an image artifact.

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

f. Hazardous substances

Unity Knee™ components have been designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

Unity Knee™ components contain the following CMR substance in a concentration above 0.1% weight by weight (w/w) as identified on the label:

	Component	Substance	Residual Risk
	• Unity Knee™ Femur • Unity Knee™ Tibial Tray	Cobalt CAS No. 7440-48-4 EC No. 231-158-0	Cobalt is defined as a substance which is carcinogenic, mutagenic or toxic to reproduction (CMR) category 1B as per Regulation (EU) 1272/2008. Current scientific evidence supports that medical devices manufactured from cobalt do not cause an increased risk of cancer or adverse reproductive effects. Therefore, the use of cobalt is permitted where justified via risk assessment that the benefits outweigh the risks.

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. All Unity Knee™ components, except for the Unity Knee™ MC tibial insert, are sterilised by gamma irradiation delivered from a $cobalt_{60}$ source. The Unity Knee™ MC tibial insert is sterilised using Ethylene Oxide (EtO).

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.

This product is not labelled "pyrogen free".

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]
	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]

Symbol	Symbol title	Symbol description	Reference and Standard
	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]
	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]

Symbol	Symbol title	Symbol description	Reference and Standard
	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	ref. 21 CFR 801.437
	Prescription use only	Indicates that Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner	ref. 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 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 Device and other items for safety in the Magnetic Resonance Environment

Manufacturer

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

www.coringroup.com

Corin
Connected Orthopaedic Insight

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