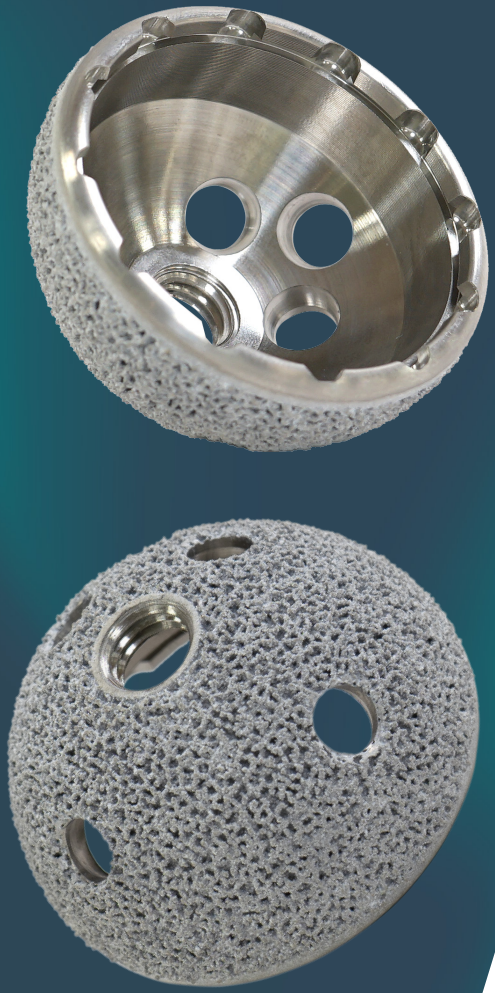
Corin

Trinity™ EVO

Instructions for use



Instructions for use

This "Instructions for Use" contains information on how to use the Trinity™ EVO Acetabular Shell.

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 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 Glossary of product label symbols, please consult the table in Section 11.

1. Device Description

The Trinity™ EVO acetabular shell forms part of a modular acetabular system. The Trinity™ EVO acetabular device is a hemispherical press fit titanium alloy shell for use with cobalt chrome alloy[1] or polyethylene liners and a dedicated range of ceramic and cobalt chrome alloy modular 12/14 taper femoral heads providing ceramic on polyethylene and metal on polyethylene articulations for use in total hip arthroplasty (THA) procedures using compatible Corin femoral stems with a 12/14 taper connection[2].

The Trinity™ EVO acetabular shell has a porous structure and is available with or without an additional layer of electrochemically deposited calcium phosphate. The Trinity™ EVO acetabular shell is provided with screw holes permitting the use of dedicated titanium bone screws to provide additional fixation, if required. The Trinity™ EVO acetabular shell is also available without screw holes. A titanium occluder is provided to occlude the apical introducer hole.

The Trinity™ EVO Acetabular System is intended for use in primary and revision THA in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged hip joint articulation when there is evidence of sufficient sound bone to seat and support the components.

[1] *Indicated only with Trinity™ Dual Mobility components, please refer to the Trinity™ Dual Mobility System's package insert (I1363).*

[2] *Ceramic femoral heads are indicated only with Corin titanium stems in the USA.*

Ancillary instruments are also provided.

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

Combination and Component Association:

It is essential to implant Trinity™ EVO acetabular shell with the Corin instrumentation specifically designed for this purpose. Trinity™ EVO acetabular shell implants must be assembled using Corin components defined as being compatible components.
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.

Where applicable mutual compatibility of components should be considered.

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.

2. Materials

Component:	Material:	Substance:	Composition: (%/mass)
Trinity™ EVO Acetabular Shell	*Titanium Alloy in accordance with the requirements of ASTM F2924-14 (Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion)*	*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*
		Yttrium	*0.005 Max*
		Other elements	*0.1 Max each, 0.4 Total*
		Titanium	*Balance*
Trinity™ EVO Acetabular Shell Coating	*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*	*100*

3. Intended use and intended performances of the implant

Trinity™ EVO acetabular shell is intended for use in primary and revision total hip arthroplasty in skeletally mature patients, to provide increased mobility, and to reduce pain by replacing the damaged hip joint articulation where there is evidence of sufficient sound bone to seat and support the components.

Trinity™ EVO acetabular shell is 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 Trinity™ EVO acetabular shell 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 Trinity™ EVO acetabular shell as a total hip arthroplasty include:

- *Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,*
- *Rheumatoid arthritis,*
- *Correction of functional deformity,*
- *Developmental dysplasia of the hip (DDH)/Congenital dislocation of the hip (CDH)*

The Trinity™ EVO acetabular shell is also indicated for use in revisions of a previously failed total hip arthroplasty.

The Trinity™ EVO acetabular shell is indicated for cementless use only.

5. Known contra-indications to date

The contraindications for the Trinity EVO Acetabular Shell are as follows:

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

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,*
- *Audible sounds during motion,*
- *Premature wear, or breakage of the implants,*
- *Bone loss around the implant,*
- *Change in the length of the treated leg,*
- *Hip pain,*
- *Stiffness and loss of flexibility of the hip joint,*

- *Disassembly or rotation of the liner from the acetabular shell, resulting in incorrect orientation, dislocation or impingement,*
- *Disassembly of the femoral head from the hip stem,*
- *Bone and soft tissue damage (including muscles, tendons, ligaments, cartilage, and nerves),*
- *Periprosthetic fracture,*
- *Superficial or deep infection,*
- *Ossification,*
- *Embolism,*
- *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, in order 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.

Only the compatible Corin 12/14 femoral stems components identified in the device description section should be used with the Corin ceramic femoral heads. The use of other femoral stem components may result in fracture or damage to the ceramic femoral head and lead to early failure of the system.

Corin CoCr modular femoral heads should only be used with polyethylene liners.

Carefully examine each component and its packaging for any signs of damage that may have occurred during shipping or handling (e.g. if dropped on the floor or if scratched by an instrument). Do not implant components if the packaging is damaged or if the implant shows signs of damage. The use of damaged components may lead to premature failure of the device.

Be careful when handling ceramic heads during assembly; due to the brittle nature of the material, ceramic components are particularly susceptible to premature failure when scratched, cracked or otherwise damaged.

Ensure that surfaces of the implant that lock together are clean and dry during implantation in order to ensure proper seating and assembly. Once the femoral stem taper has been assembled to a ceramic head, it should not be reassembled to another ceramic head. If the ceramic head is chipped, cracked, or damaged during head/stem assembly, the physician should replace both the ceramic head and the femoral stem.

Surgeons should be thoroughly familiar with the Trinity™ EVO acetabular shell 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 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 (e.g. 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

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.

b. Intra-operatively

Trinity™ EVO acetabular shell 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 manufacture.

c. Post-operatively

It is recommended that a 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.

d. Information to be conveyed to the patient

The following information should be provided to the patients:

- *Undesirable side-effects and complications.*
- *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 sensitization or allergic reaction).*

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

The Trinity™ EVO Acetabular Shell has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Trinity™ EVO Acetabular Shell in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

8. Storage and handling

There are no special storage conditions for Trinity™ EVO Acetabular Shell components. General conditions adhered to within the healthcare setting will suffice, for example:

- *Implant must be stored away from heat or moisture.*
- *Implants must not be exposed to direct sunlight, ionising radiation or particulate contamination.*

9. Packaging and sterilisation

The implants are supplied sterile by gamma irradiation delivered from a cobalt$_{60}$ source. The expiration date for sterilization 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-sterilize. 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. The templates are supplied non-sterile and should not be sterilised.

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]
	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

[1]: EN ISO 15223-1:2021 — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.

[2]: ASTM F2503-20 Standard practice for Marking Medical Device 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