Corin

TriFit CF™

Instructions for use

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This "Instructions for Use" contains information on how to use Corin TriFit CF™ 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 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 Corin TriFit CF Hip Stem is a cementless femoral stem manufactured from Ti6Al4V titanium alloy with a layer of commercially pure titanium and calcium phosphate coating applied. The TriFit CF Hip Stem is available in standard and lateralized offsets in 127° CCD angle. The device is intended to be used with Corin 12/14 modular taper heads as a total hip arthroplasty and as a hip hemiarthroplasty.

The TriFit CF Hip Stem is intended for use 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.

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 / Component Association:

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

Each femoral stem variant is manufactured from Ti6Al4V titanium alloy with a layer of commercially pure titanium and calcium phosphate coating applied.

3. Intended use and intended performances of the implant

The TriFit CF 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.

The TriFit CF Hip Stem 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 TriFit CF Hip Stem is intended to elicit the below clinical benefits to the indicated patients:

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

4. Indications for use

The indications for the TriFit CF Hip Stem as a total hip arthroplasty and 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)*
- *Previously failed hip surgery*

The TriFit CF Hip Stem is indicated for cementless use only.

5. Known contra-indications to date

The contraindications for the TriFit CF Hip Stem are as follows;

- *Active infection*
- *Metabolic disorders which may impair bone formation*
- *Vascular insufficiency*
- *Muscular atrophy or neuromuscular disease*
- *Allergy to implant material*
- *Uncorrectable deformity*
- *Osteoporosis*
- *Osteomalacia*
- *Marked bone loss or bone resorption*
- *Poor bone quality*
- *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 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*
- *Change in the length of the treated leg*
- *Hip pain*
- *Stiffness and/or loss of flexibility of the hip joint*
- *Superficial or deep infection*
- *Bone, soft tissue and vascular damage (including muscles, tendons, ligaments, cartilage, nerves and blood vessels)*
- *Ossification*
- *Embolism*
- *Periprosthetic fracture*
- *Fretting and crevice corrosion can occur at interfaces between components which may result in Adverse Local Tissue Reactions (ALTR)*

7. Warnings and cautions

Failure of the implant may result from: selection of improper components, mal-alignment or mal-positioning of the components, inadequate fixation of components, patients with excessive weight, high levels of patient activity, likelihood of falls, disabilities of other joints and failure to remove surgical debris prior to closure.

Fracture, particularly of smaller sized stems, is most likely to occur in patients who are young, physically active, and/or heavy. The following conditions, either singly or in combination, can put the patient at higher risk of failure of their joint replacement due to severe loading of the affected extremity: obesity or excessive patient weight, manual labour, active sports participation, high levels of patient activity, likelihood of falls, alcohol or drug addiction, and other disabilities as applicable.

Surgeons should be thoroughly familiar with the TriFit CF Hip Stem surgical technique, the implant 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. Clean gloves should be worn when handling implants. Avoid scratching or denting implant surfaces. Do not modify implants. Do not reuse implants; an implant may appear undamaged but previous stress may have created imperfections that would reduce the service life of the implant. 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.

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

The TriFit CF Hip Stem is intended for cementless use only.

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

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

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

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

Always remove all surgical debris prior to closure.

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

- *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 TriFit CF Hip Stem 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 TriFit CF Hip Stem 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 the TriFit CF Hip Stem. 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. 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".

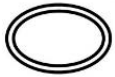
For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.

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]

Symbol	Symbol title	Symbol description	Reference and Standard
	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]
	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]

Symbol	Symbol title	Symbol description	Reference and Standard
	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]
	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	FDA
	Prescription use only	Indicates Prescription use only	FDA

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

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