Corin

Connected Orthopaedic Insight

TriFit TS™

Instructions for use

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This "Instructions for Use" contains information on how to use Corin TriFit TS™ 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 Corin TriFit TS™ hip stem is a double tapered-wedge blade stem manufactured from forged titanium alloy (Ti6Al4V) conforming to ASTM F-136-08.

It has a thin anterior/posterior stem width with a reduced lateral shoulder to facilitate implant to bone contact proximally at the medial and lateral endosteal cortices and the stem flares proximally allowing a better fit in the femur.

The TriFit TS™ hip stem is available in eleven (11) sizes (1 through 11) in standard and lateralized offsets in 127° CCD angle. Dimensions of the stem grow in equal increments across the size range (1.2mm M-L proximal section, 1.0mm M-L distal section and 0.15mm A-P width) to achieve proper fit within the femur to provide for the range of patient geometries. It has a polished, flat tapered neck design for required range of motion and a polished tapered distal tip.

The design has a Corin 12/14 tapered male trunnion to be used with Corin 12/14 modular taper heads and, when used for total hip arthroplasty, with Corin acetabular components.

The TriFit TS™ hip stem has a rough titanium plasma spray coating in compliance with BS ISO 5832-2: 2018 with an additional layer of electrochemically deposited calcium phosphate coating in compliance with ASTM F1609-08 2014. This is of sufficient thickness and roughness to achieve scratch fit of the stem in the femur.

The TriFit TS™ 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.

Ancillary instruments (dedicated and generic) 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 use, please refer to the technical documentation, or contact your Corin representative.

Combination / Component Association:

It is essential to implant Corin TriFit TS™ hip stem with the Corin instrumentation specifically designed for this purpose. Corin TriFit TS™ 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 together with the trial implants and templates supplied with any 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, surgical technique, patient weight, activity level and comorbidities.

The Corin TriFit TS™ 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: NICE Guidance TA304:26 Feb 2014: Total hip replacement and resurfacing arthroplasty for end stage arthritis of the hip.)

Real-world evidence data currently shows:

- AOA NJRR: 97.7% (95%CI: 97.1% - 98.2%) survivorship at 5 years, all revisions, any reason for revision.
  (Source: Australian Orthopaedics Association National Joint Replacement registry (AOA NJRR) Annual Report 2020, TriFit TS - Trinity cup, Table HT12, page 123)
- UK NJR: 98.% (95% CI: 96.3% - 98.7%) survivorship at 6 years, all revisions, any reason for revision.
  (Source: National Joint Registry (NJR) TriFit TS Implant Summary Report – on label - produced on 18 Feb 2021).

2. Materials

The constituent material of the TriFit TS™ hip stem is included on packaging labels.

Cementless femoral stems are made of titanium alloy (Ti6Al4V) in accordance with ISO standard 5832-3 and coated with hydroxylapatite (HAP) in accordance with ASTM standard F1185 or ISO 13779-2:

Component:	**Materials:**	**Substance:**	**W/w%:** (Weight per weight)
Standard and Lateralised Tapered Stem	*Wrought Titanium 6-Aluminium 4-Vanadium Closed Die Forging. Meeting the requirements of ISO 5832-3*	*Aluminium*	*5.5-6.5*
		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*
		Titanium	*Balance*
	Titanium coating - Unalloyed Titanium. Meeting the requirements of BS7252 Part 2 / ISO 5832- 2 and ASTM F 1580-01	*Commercially Pure titanium*	*N/A*
	Additional layer of electrochemically deposited calcium phosphate 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*	*N/A*

3. Intended use and intended performances of the implant

Intended purpose (CE only):

The TriFit TS™ 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.

Intended purpose (Global):

The TriFit TS™ hip stem is 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

**** The use of TriFit TS™ hip stem in hemiarthroplasty is not CE Marked***

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) where it will be linked to an appropriate Basic UDI-DI when applicable: https://ec.europa.eu/tools/eudamed

4. Indications for use

Indications for use (CE only):

The indications for TriFit TS™ 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)*
- *Congenital dysplasia of the Hip (CDH).*

TriFit TS™ hip stem are intended for cementless use only.

Indications for use (Global):

The indications for TriFit TS™ hip stem as a total hip arthroplasty, and, when used in combination with a Corin hemiarthroplasty head, as a hemi-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)*
- *Congenital dysplasia of the Hip (CDH).*

TriFit TS™ hip stem is intended for cementless use only.

The use of TriFit TS™ hip stem in hemiarthroplasty is not CE Marked

5. Known contra-indications to date

- *Active Infection*
- *Osteomyelitis*
- *Poor bone quality*
- *bone loss or bone resorption.*
- *Metabolic disorders which may impair bone formation.*
- *Vascular insufficiency*
- *Muscular atrophy or neuromuscular disease*
- *Allergy to implant material*
- *Un-correctable deformity*
- *Do not use in combination with components from non Corin implant systems.*

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,*
- *Periprosthetic fracture,*
- *Change in the length of the treated leg,*
- *Hip pain and stiffness,*
- *Loss of hip flexibility of the hip joint,*
- *Nerve damage,*
- *Embolism,*
- *Calcification.*

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 TriFit TS™ 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.

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

Corin TriFit TS™ hip stem 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. 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 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.*

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 TriFit TS™ hip stem 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 TriFit TS™ 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	TriFit TS™ hip stem
Static Magnetic Field Strength [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m]	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.

8. Storage and handling

Implants must be stored in their original sealed packaging. Implant 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 (TriFit TS Implant 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.

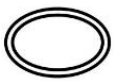
Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

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	FDA
	Sterilised using irradiation	Indicates a medical device that has been sterilized using irradiation	ref. 5.2.4 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]
	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]

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]
	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]
	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	FDA
	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]
	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]

[1]: EN ISO 15223-1:2021 Medical Devices — 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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