Corin

Connected Orthopaedic Insight

TriFit TS™

Patient Information Leaflet

Intended Patient Use

The TriFit TS™ hip stem is intended for use in total hip replacement for adults (skeletally mature patients). The TriFit TS™ hip stem is intended to provide increased movement and reduce pain by replacing the damaged hip joint.

Benefits of Hip Replacement

If you have chronic and dogged hip pain that limits regular activity, it is likely you are a good candidate for a total hip replacement. As always, it is best to discuss possible treatments with your surgeon.

Pain relief and increased motion:

You should have reduction in pain and better mobility after surgery, within the first few weeks. Many factors, including physical condition, weight, activity level, anatomy and will to comply with your surgeon's instructions before and after surgery will play a key role in your recovery.

Precautions

Precautions to take following your hip replacement are dependent on your unique condition and are best advised by your healthcare provider. Seek guidance from a healthcare professional about:

- *precautions to take in daily life to guarantee maximum implant survival*
- *your weight and level of activity can affect the life span of the prosthesis*
- *you must inform the surgeon of any change in performance (mobility, pain etc.)*

Potential Undesirable Side Effects and Possible Complications

Side effects and possible complications related to the placement of this device:

- *Hip ball and hip socket 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,*
- *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 (a process in which calcium build up causing hardening).*

Risk of Device Interaction with Other Equipment

The TriFit™ TS Hip Stem is made of titanium metal alloy. If your doctor has requested for you to have an MRI scan (Magnetic Resonance Imaging), you must inform them and any radiotherapy personnel that you have a hip replacement.

The TriFit TS implants have MR conditional status. A patient with a TriFit™ TS Hip Stem may be safely scanned under certain conditions. The MRI specialist should refer to the following conditions:

- *Static magnetic field of 1.5 T or 3.0 T*
- *Maximum spatial gradient field of 214T/m (21,400Gauss/cm)*
- *Maximum whole body averaged specific absorption rate (SAR) of Whole-Body SAR < 0.9 W/kg at 1.5 T, Whole-body SAR < 1.9 W/kg at 3.0 T*
- *Maximum B1+RMS field strength of B1+RMS < 4.8 µT at 1.5 T and B1+RMS < 3.5 µT at 3.0 T.*
- *Under the scan conditions defined the implant is expected to produce a maximum temperature rise of 6°C.*
- *The presence of this implant may produce an image artefact extending up to 105.7mm from implants when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.*

The MRI specialist should consult the device's 'Instructions for Use' for further details of these conditions. Typically, airport screening detectors will identify patients with these metal implants. Having a hip implant is common. Let the security officer know that you have a hip replacement and where it is located. Having a metal implant does not prevent you from traveling by air.

Expected Device Lifetime / Intended Performance

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 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%.

(NICE Guidance TA304:26 Feb 2014: Total hip replacement and resurfacing arthroplasty for end stage arthritis of the hip.)

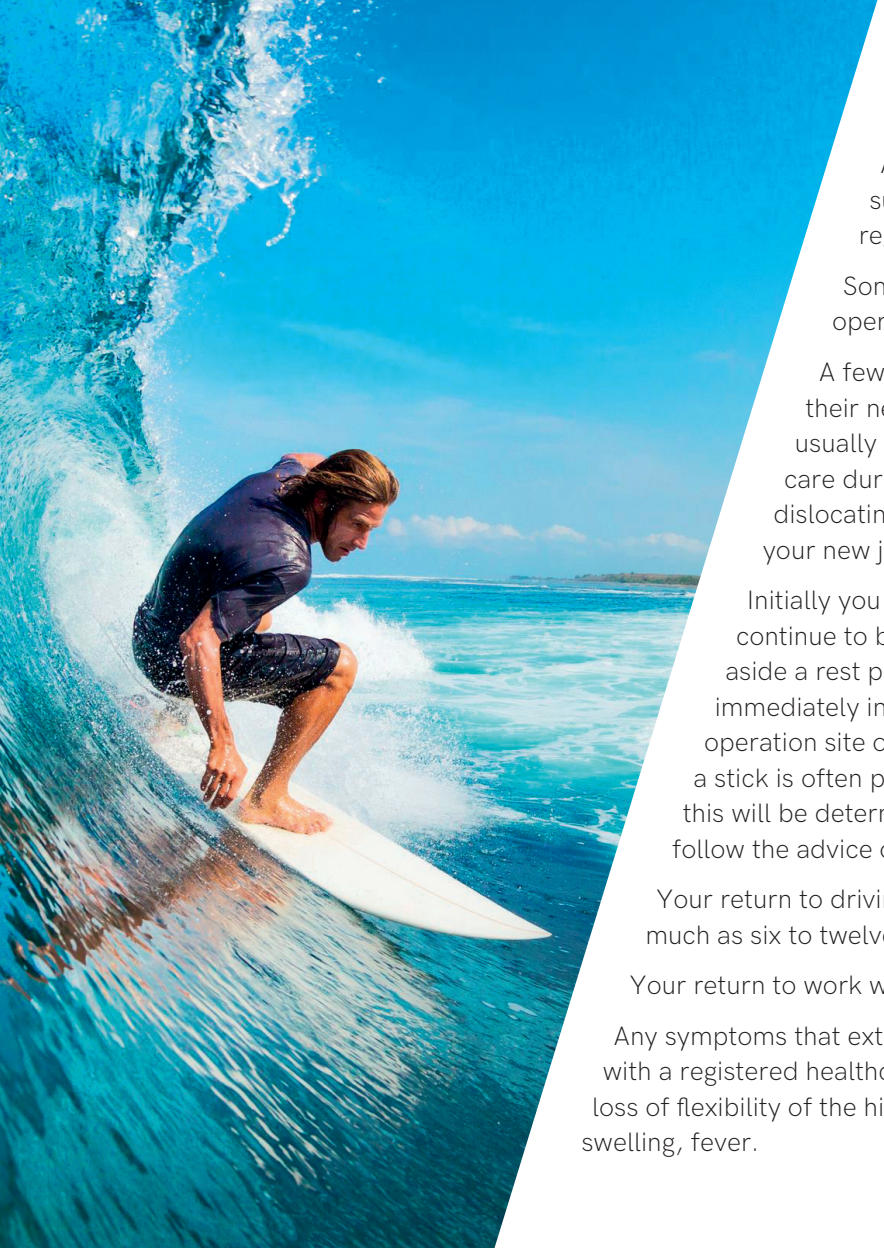
Real-world evidence data currently shows:

- AOA NJRR: 97.7% (95%CI: 97.1% - 98.2%) survivorship at 5 years, all revisions, any reason for revision.

  (Source: Australian Orthopedics Association National Joint Replacement registry (AOA NJRR) Annual Report 2020, TriFit TS - Trinity cup, Table HT12, page 123)

- UK NJR: 98.% (95% CI: 98.7%-96.3%) 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).



Post Operative Follow-Up

As determined necessary by a healthcare professional a suitable rehabilitation program should be put in place and regular follow-up checks should be carried out.

Some patients experience swelling of the thigh on the operated side, but this usually disappears quite quickly.

A few patients may experience clicking or other sounds from their new hip, but this rarely causes serious problems and usually disappears after a few months. You must take great care during the first eight to twelve weeks to avoid potentially dislocating your new hip – you must be patient and not try to test your new joint to see how far it will go.

Initially you will tire more easily, not least because there will continue to be traces of anaesthesia in your body for some time. Set aside a rest period each afternoon. You should contact your doctor immediately in the case of any undue pain, severe redness around the operation site or drainage from the wound. Walking without the aid of a stick is often possible from four to six weeks after surgery – although this will be determined by your confidence and progress, and you should follow the advice of your surgeon or physiotherapist.

Your return to driving will be determined by your surgeon which may be as much as six to twelve weeks.

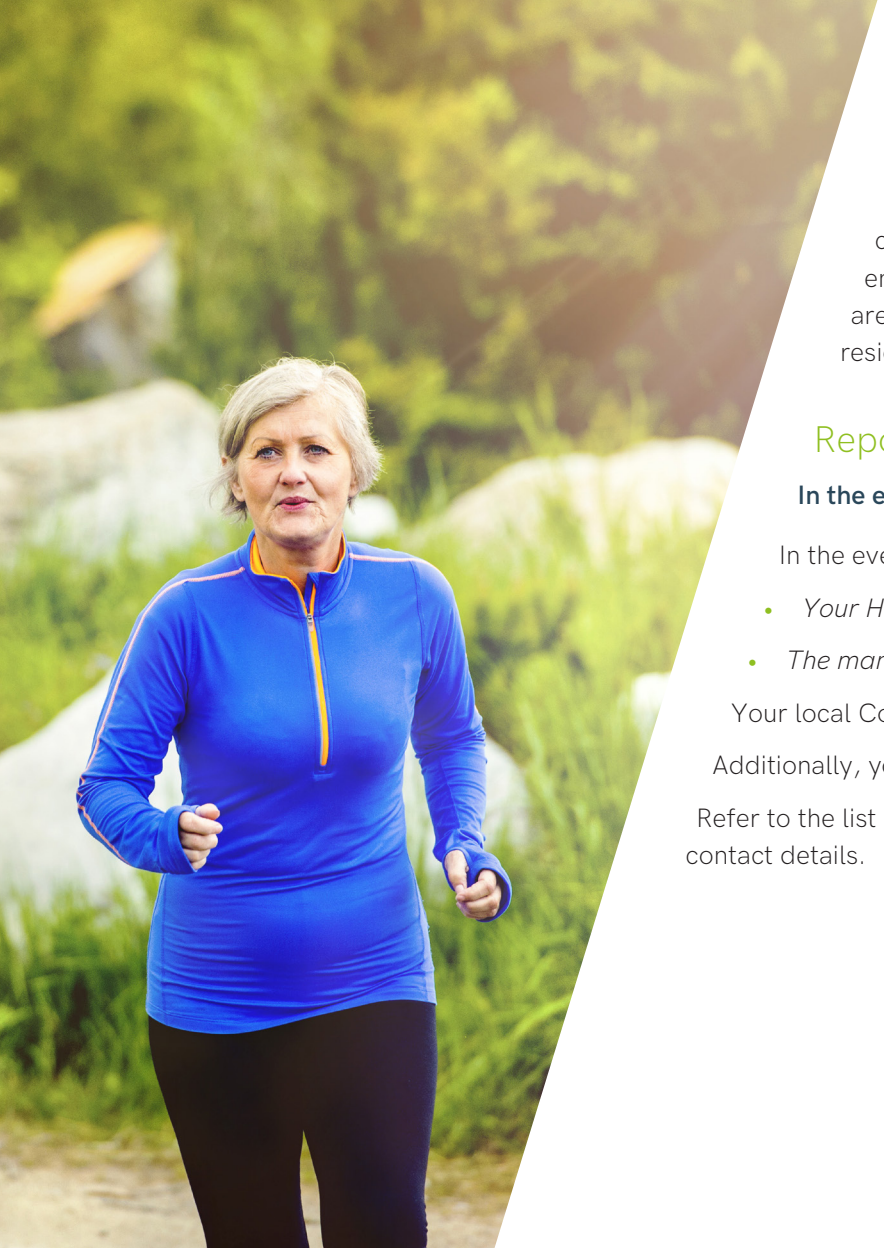
Your return to work will also be determined by your surgeon.

Any symptoms that extend beyond the above description should be discussed with a registered healthcare professional. For example: hip pain and stiffness, loss of flexibility of the hip joint, audible sounds during motion, hip dislocation, swelling, fever.

Materials

The TriFit TS™ Hip is manufactured from forged titanium alloy (Main constituent material) with a layer of pure Titanium plasma spray and a calcium phosphate coating.

Component:	**Materials:**	**Substance:**	**W/w%:** (Weight per weight)
TriFit TS hip stem	*Wrought Titanium 6-Aluminium 4-Vanadium (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 (BS7252 Part 2 / ISO 5832 – 2 and ASTM F 1580-01)	*Commercially Pure titanium*	*N/A*
	Calcium phosphate coating (ASTM F1609-08)	*Primarily Brushite with small amount of hydroxyapatite phase yielding a Ca:P ratio of 1.1 +/-0.1*	*N/A*



Manufacturing Residuals that Could Pose a Risk to the Patient

The TriFit TS™ Hip Stem is cleaned using validated cleaning processes taken from industry standards to ensure that any residuals from the manufacturing process are removed. Testing has demonstrated that there are no residuals that pose a particular risk to the patient.

Reporting Any Serious Incident

In the event of a serious incident related to the device contact:

In the event of a serious incident related to the device contact:

- *Your Healthcare Professional*
- *The manufacturer (Corin Ltd)*

Your local Corin representative may also be contacted.

Additionally, your local health authority can also be contacted.

Refer to the list provided on the back pages of this information leaflet for contact details.

Local Health Authority List

Australia
The Therapeutic Goods Administration (TGA)
Website: http://www.tga.gov.au

België / Belgique / Belgien / Belgium
Federal Agency for Medicines and Health Products (FAMHP)
Website: https://www.afmps.be/fr

България / Bulgaria
Bulgarian Drug Agency
Website: https://www.bda.bg/bg/

Ceska Republika / Czech Republic
State Institute for Drug Control, Medical Devices Branch
Website: http://www.niszp.cz/

Danmark / Denmark
Danish Medicines Agency
Website: https://laegemiddelstyrelsen.dk/da/udstyr/

Deutschland / Germany
Federal Institute for Drugs and Medical Devices
Website: https://www.bfarm.de/DE/Home/_node.html

Eesti / Estonia
Health Board, Medical Devices Department
Website: https://www.terviseamet.ee/et

Eire / Ireland
Health Products Regulatory Authority (HPRA)
Website: https://www.hpra.ie/

Ellada / Greece
National Organization for Medicines
Website: https://www.eof.gr/web/guest/home

España / Spain
Agencia Española de Medicamentos y Productos Sanitarios
Website: https://www.aemps.gob.es/

France
Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM)
Website: https://ansm.sante.fr/

Hrvatska / Croatia
Agency for Medicinal Products and Medical Devices
Website: https://www.halmed.hr/?ln=en

Iceland / Island
Icelandic Medicines Agency
Website: https://www.lyfjastofnun.is/

Italia / Italy
Ministry of Health Directorate General of Medical Devices and Pharmaceutical Services
Website: https://www.salute.gov.it/portale/p5_11.jsp

Japan
Pharmaceuticals and Medical Devices Agency (PMDA)
Website: https://www.pmda.go.jp/english/

Kypros / Kibris / Cyprus
Cyprus Medical Devices Competent Authority
Website: https://www.moh.gov.cy/moh/mphs/mphs.nsf/All/A82FE3D75F4BF2CAC225850A0036075A?OpenDocument

Latvija / Latvia
Medical Device Evaluation Department State Agency of Medicines
Website: https://www.zva.gov.lv/en

Liechtenstein
Office of Public Health
Website: https://www.llv.li/inhalt/1908/amtsstellen/amt-fur-gesundheit

Lietuva / Lithuania
The State Health Care Accreditation Agency under the Ministry of Health of the Republic of Lithuania
Website: https://vaspvt.gov.lt/

Luxembourg
Ministère de la Santé, Direction de la Santé Division de la pharmacie et des medicaments
Website: https://sante.public.lu/fr/politique-sante/ministere/sante/index.html

Malta
Malta Medicines Authority - Medical Devices Unit
Website: http://www.medicinesauthority.gov.mt/medicaldevices

Magyarorszag / Hungary
National Institute of Pharmacy and Nutrition
Website: https://ogyei.gov.hu/main_page/

Nederland / Netherlands
Ministry of Health, Welfare and Sports CIBG Farmatec-BMC
Website: https://www.farmatec.nl/

New Zealand
Medsafe - New Zealand Medicines and Medical Devices Safety Authority
Website: http://www.medsafe.govt.nz/

Norway / Norge
Statens legemiddelverk/ Norwegian Medicines Agency
Website: https://legemiddelverket.no/EnglishÖsterreich/

Austria
Austrian Federal Office for Safety in Health Care (BASG)
Website: https://www.basg.gv.at/

Polska / Poland
Office for Registration of Medicinal Products, Medical Devices and Biocidal Product
Website: http://www.urpl.gov.pl/pl

Portugal
Infarmed - National Authority of Medicines and Health Products
Website: https://www.infarmed.pt/web/infarmed/entidades/dispositivos-medicos

Romania
National Agency for Medicines and Medical Devices of Romania
Website: https://www.anm.ro/

Slovenija / Slovenia
Agency for Medicinal Products and Medical Devices of the Republic of Slovenia JAZMP
Website: https://www.jazmp.si/en/

Slovenska Republika / Slovakia
State Institute for Drug Control, Medical Devices Section
Website: https://www.sukl.sk/hlavna-stranka/english/version?page_id=256

Suomi / Finland
Finnish Medicines Agency Fimea Medical Devices Unit
Website: https://www.fimea.fi/

Sverige / Sweden
Swedish Medical Products Agency´ 'Läkemedelsverket' Department of Medical Devices
Website: https://www.lakemedelsverket.se/sv

Switzerland
Swissmedic, Swiss Agency of Therapeutic Products Medical Devices Division
Website: https://www.swissmedic.ch/swissmedic/de/home.html

Turkey
Turkish Medicines and Medical Devices Agency (TITCK) Ministry of Health
Website: https://www.titck.gov.tr/

United Kingdom
Medicines & Healthcare products Regulatory Agency (MHRA)
Website: https://www.gov.uk/government/organisations/medicines and-healthcare-products-regulatory-agency

United States of America
Food and Drugs Administration (FDA)
Website: https://www.fda.gov/

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Reporting Website: https://feedback.coringroup.com/

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