Corin
Connected Orthopaedic Insight

Patient Information Leaflet

Apex Knee™ System

MODELS & COMPONENTS

Cruciate Retaining Knee

CR Femoral Component (Cemented & Uncemented)
Tibial Baseplate (Cemented & Uncemented)
Congruent and Ultra Tibial Inserts
Patella Button

Posterior Stabilised Knee

PS Femoral Component (Cemented)
PS and PS-C Tibial Inserts

Revision & Modular Knee

Modular Tibial Baseplate (Cemented)
Revision Femur (Cemented)
Revision Tibial Baseplate (Cemented)
PS-R Tibial Inserts
Modular and Revision Stems

Miscellaneous

Tibial Insert Retaining Bolts
Tibial & Femoral Augments
Femoral Stem Bolt
Modular Tibia Peg & Peg Bolt
Modular Tibia Cap Modular
Tibia Keel

INTENDED PATIENT / USE

The Apex Knee™ System is intended for use in knee replacement for adults (skeletally mature patients). The Apex Knee™ System is intended to provide increased movement and reduce pain by replacing the damaged knee joint.

BENEFITS OF KNEE REPLACEMENT

If you have chronic knee pain that restricts regular activities, chronic stiffness of the knee, constant knee instability, or a severe deformity of the knee, then you are likely a good candidate for a total knee replacement. As always, it is best to discuss possible treatments with your surgeon.

Pain relief and increased motion:

You should experience significant reduction in pain and improved mobility after knee replacement surgery. Many factors, including physical condition, weight, activity level, personal anatomy and willingness to comply with your surgeon's instructions prior to and after surgery will play an important role in your recovery.

PRECAUTIONS

Precautions to take following your knee 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 the Apex Knee™ System:

- Infection
- Dislocation
- Device loosening from the surrounding bone
- Premature wear or breakage of the implants
- Bone loss around implant
- Fracture
- Pain
- Allergic reaction to the implant's materials
- Change in the length of the treated leg
- Nerve damage
- Damage to blood vessels
- Embolism

RISK OF DEVICE INTERACTION WITH OTHER EQUIPMENT

The Apex Knee™ System includes components made of non-ferromagnetic Cobalt Chrome metal alloy and 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 knee replacement.

A patient with an implant of the Apex Knee™ System 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 57 T/m (5700 Gauss/cm)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg in the normal operating mode.
- Under the scan conditions defined the implant is expected to produce a maximum temperature rise of Whole body SAR < 0.5 W/kg at 1.5 T, Whole Body SAR < 2.0 W/kg at 3.0 T
- The image artefact caused by the implant extends approximately 53.5mm from this implant.

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 knee implant is common. Let the security officer know that you have a knee 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 some things that can influence the product lifetime including, but not limited to, surgical indication, surgical technique, patient weight, activity level and comorbidities. You should talk to a registered healthcare professional about your specific situation.

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.

You must take great care during the first eight to twelve weeks following your operation to avoid potentially damaging your new knee – 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 weeping from the wound. Walking without the aid of a stick is often possible from four to six weeks – 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.

Throughout the period immediately postoperative up to the first twelve weeks following your surgery, you may be able to continue to build up your level of exercise. You may eventually be able to start participating in a variety of low-impact activities such as walking, swimming, cycling or playing golf, (you must of course seek advice from your surgeon or physiotherapist before beginning to undertake these exercises). Avoid high-impact activities such as aerobics, squash, running or contact sports, as they can cause damage to the artificial joint.

Any symptoms that extend beyond the above description should be discussed with a registered healthcare professional.

MATERIALS

The Apex Knee™ System devices are manufactured using the following materials:

The femoral component, tibial tray and tibial tray specific augments are manufactured from cobalt chromium alloy, and the bolt that locks the tibial insert to the tibial tray is manufactured from titanium alloy. Tibial inserts and patellae are manufactured ultra high molecular weight polyethylene (UHMWPE) or UHMWPE with vitamin E additive (ECiMa). The optional porous coating on the femoral component is composed of cobalt chrome. The optional porous coating on the tibial trays is composed of titanium with an overcoat of hydroxyapatite on top. Femoral component specific augments, stems, modular pegs and augment attachment bolts are manufactured from titanium alloy.

MANUFACTURING RESIDUALS THAT COULD POSE A RISK TO THE PATIENT

The Apex Knee™ System devices are 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:

- Your Healthcare Professional
- The manufacturer (OMNI Life Science, Inc.)

Your local Corin representative may also be contacted.

Additionally, your local health authority should be contacted. Refer to the list provided on the back pages of this information leaflet for contact details.

OMNI Life Science, Inc. (Manufacturer)

Member of the Corin Group of Companies

480 Paramount Dr

Raynham

MA 02767

USA

Telephone: (508) 824-2444

email: enquiries@coringroup.com

Website: https://vigilance.coringroup.com/vigilance

www.coringroup.com/patients/

Corin

Connected Orthopaedic Insight

Doc No. IFU 046 Rev 11/21

November 2021

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 / Spains
Agencia Espaňola 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/

Corin
Connected Orthopaedic Insight

Doc No. IFU 046 Rev 11/21 November 2021

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/

Corin
Connected Orthopaedic Insight

Doc No. IFU 046 Rev 11/21 November 2021