

The Global Cup™ System



MODELS & COMPONENTS

Global Cup
Ceramic Insert
Polyethylene Insert
Cancellous Bone Screw
Hole Covers

INTENDED PATIENT / USE

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

BENEFITS OF HIP REPLACEMENT

If you have chronic and persistent hip pain that limits regular activity, it is likely you are a good candidate for a 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 the Global Cup™ System:

- Infection,
- Hip ball and hip socket may separate (hip dislocation),
- Device loosening from the surrounding bone,

- Premature wear or breakage of the implants,
- Bone loss around implant,
- Fracture,
- Hip pain and stiffness,
- Allergic reaction to the implant's materials,
- Change in the length of the treated leg,
- Loss of hip flexibility of the hip joint,
- Audible sounds during motion,
- Nerve damage,
- Damage to blood vessels,
- Embolism,
- Calcification (a process in which calcium builds up causing hardening).

RISK OF DEVICE INTERACTION WITH OTHER EQUIPMENT

The Global Cup™ System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment.

The safety of the Global Cup™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 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.

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 Global cup, dome hole cover, screw hole cover and bone screw are manufactured from Titanium alloy.

The Global cup is available with several coating options:

- Pure titanium beads
- Two-layer coating of Hydroxyapatite over pure titanium beads

The ceramic liners are manufactured from BIOLOX® delta. The polyethylene liners are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE) plastic.

MANUFACTURING RESIDUALS THAT COULD POSE A RISK TO THE PATIENT

The Global Cup™ System 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:

- Your Healthcare Professional
- The manufacturer (Global Manufacturing Technology)

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.

Global Manufacturing Technology (Manufacturer)

Member of the Corin Group of Companies

17 Bridge Street

Pymble NSW

2073

Australia

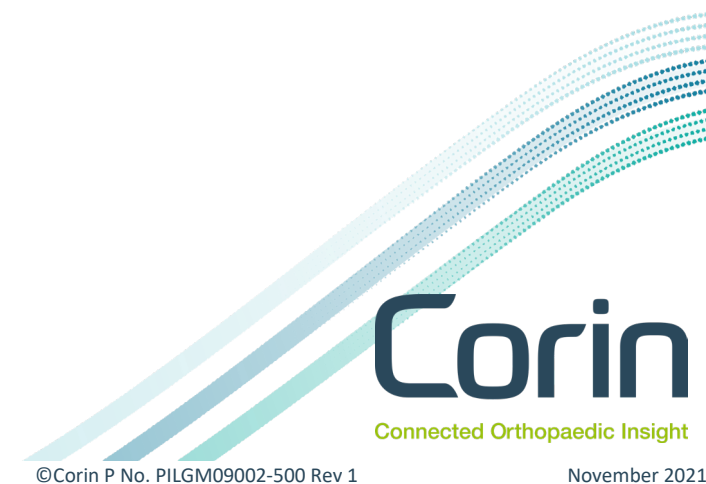
Telephone: +61 (0)2 9497 7400

Fax: +61 (0)2 9497 7498

email: enquiries@coringroup.com

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

www.coringroup.com/patients/



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/mpms.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 médicaments

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>

Magyarország / 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/>

