Corin

Clinical Study Protocol

Clinical, radiographic and patient-reported outcomes using MobiliT™ cup with ECiMa™ insert in primary total hip arthroplasty surgery.

Short Title: MobiliT ECiMa PMCF study

Protocol ID: CSP2021-10
Protocol Version: 1.1
Protocol Date: 27 September 2022

Sponsor:
Corin Australia Pty Limited
17 Bridge Street Pymble 2073
Australia

GCP Statement

This clinical study is to be conducted in full compliance with this plan, the conditions of the Ethics committee, the NHMRC National Statement on Ethical Conduct in Human Research (2007) ISO14155:2020, Declaration of Helsinki (9th July 2018) and the TGA note for guidance on good clinical practice (CPMPICH-135/95)

Confidentiality Statement

Clinical Study Protocol Approval Page - Sponsor

This Clinical Study Protocol has been written by:

Clinical Research Associate, Corin Ltd

Joanne Taylor 	13-Dec-2022

Date

The Statistical considerations have been written by:

Clinical Epidemiologist - Independent Statistician, Talus Research Consulting

Lukas Staub	

Date

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Clinical Research Manager, Corin Australia Pty Ltd

Anandita Roy	

Date

Global Clinical Affairs Programme Manager, Corin Ltd

Giulia Carli	

Date

CSP Revision History (no need to complete for 1st draft)

CSP Amendment & Date	Brief description of Amendment	Brief justification of amendment

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Study Statement and Signature Page

Study Title:

Clinical, radiographic and patient-reported outcomes using MobiliT cup with ECiMa insert in primary total hip arthroplasty surgery.

Clinical Study Protocol ID:

CSP2021-10

I have read the above-named Clinical Study Protocol (CSP) and agree to conduct the study in accordance with the design and specific provisions of this Protocol; modifications to the clinical study or CSP are acceptable only with a mutually agreed upon CSP amendment. I agree to obtain all the Ethics and legal approvals for the clinical study and informed consent before initiating the clinical study, to obtain informed consent from participants prior to their enrolment, to collect and record data as required by this CSP and Case Report Forms (CRFs) and to maintain the related documentation for the period of time required.

Name of the Investigator: _____

Signature of the Investigator: _____

Date: _____
dd/mm/yyyy

List of Abbreviations

ADE	Adverse Device Effect
AE	Adverse Event
CSP	Clinical Study Protocol
CRF	Case Report Form
EDC	Electronic Data Capture
FU	Follow-Up
HHS	Harris Hip Score
ISF	Investigator Site File
HREC	Human Research Ethics Committee
MDR	Medical Device Regulation
OHS	Oxford Hip Score
PI	Principal Investigator
PICF	Patient Informed Consent Form
PROMs	Patient-reported Outcomes Measures
PMCF	Post Market Clinical Follow-Up
ROM	Range of Motion
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SMF	Study Master File
VAS	Visual Analogue Scale

1.0 SYNOPSIS

Study Reference	CSP2021-10
Study Title	Clinical, radiographic and patient-reported outcomes using MobiliT cup with ECiMa insert in primary total hip arthroplasty surgery.
Protocol Version/Date	V1.1 dated 27 September 2022
Study Sponsor	Corin Australia Pty Ltd
Study Purpose & Description	This Post-Market Clinical Follow (PMCF) study will evaluate clinical performance and safety outcomes of primary total hip arthroplasty surgeries using MobiliT cup with Paragon or TaperFit stem over a ten-year period. Participants will be selected for recruitment into the study from the general population of patients requiring a dual mobility total hip arthroplasty surgery and considered suitable to be implanted with MobiliT cup with Paragon or TaperFit stem (Corin Ltd). After the surgery, participants will be required to return for follow up visits and radiographic controls at specific timepoints and complete questionnaires for a period of 10 years.
Study Objectives	**Primary Objective** Evaluation of hip functional performance from baseline to 2 years after surgery. **Secondary Objectives** • Confirmation of safety of the study devices up to 10-year follow up (FU). • Evaluation of clinical outcomes and range of motion from baseline to 10-year FU. • Evaluation of hip functional performance from 2 to 10 years after surgery. • Assessment of health-related quality of life from baseline to 10-year FU. • Evaluation of implants stability via radiographic analysis to detect evidence of migration, subsidence or loosening of the components using standard weight-bearing AP and lateral views of the treated hip from baseline to 10-year follow-up.
Study Endpoints	**Primary Endpoint** Improvement of Oxford Hip Score (OHS) from baseline (preop) to 2 years after surgery.

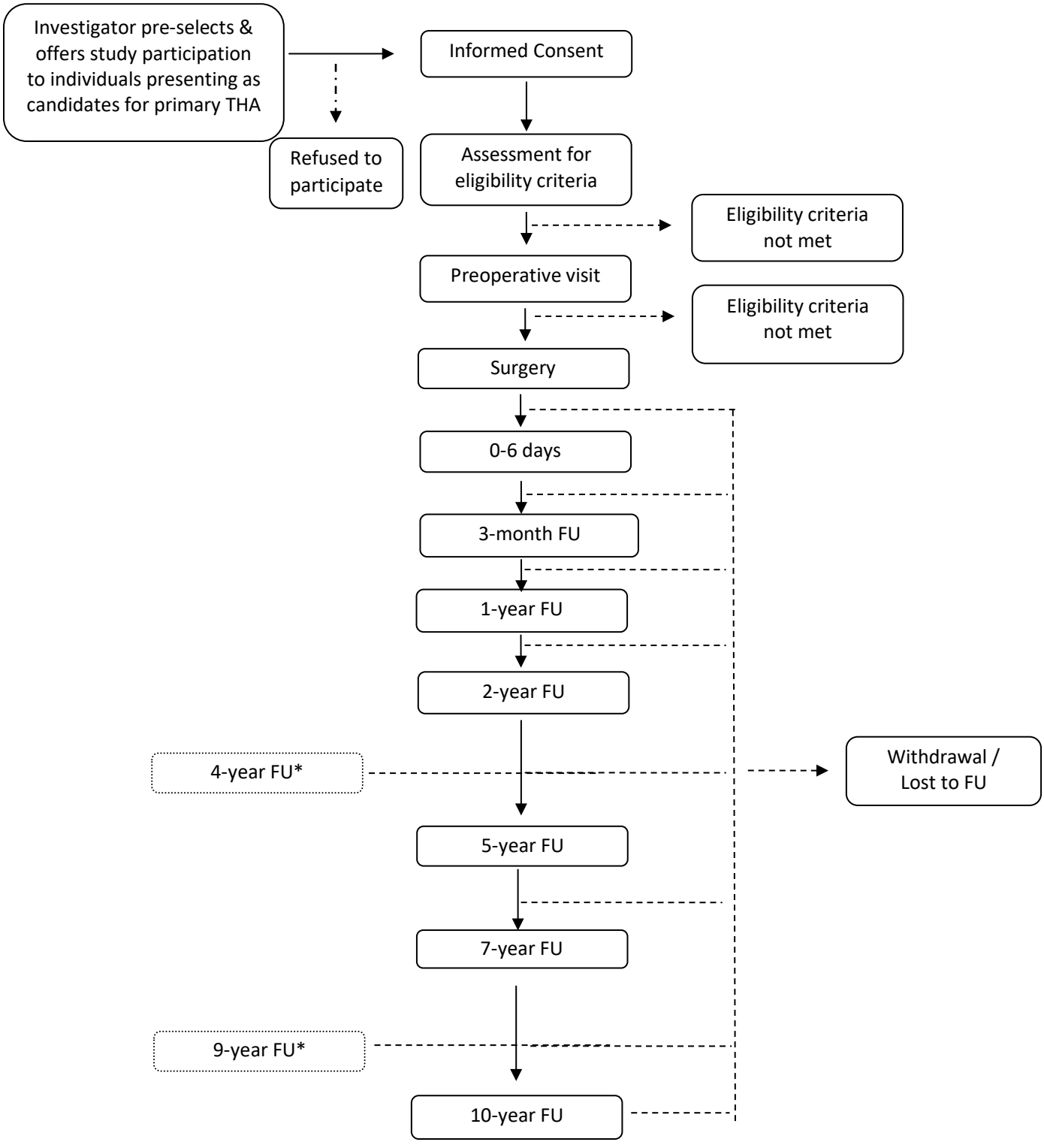
	Secondary Endpoints • Revision rate of the devices under assessment after surgery to 10-year FU. • Kaplan-Meier survival rate up after surgery to 10-year FU. • Incidence of intraoperative and post-operative adverse events (hip, medical device or surgery related) up to 10 years. • Change of Harris Hip Score (HHS) from preop to 10 years after surgery. • Change of OHS from 2 to 10 years after surgery. • Change of EQ-5D-5L from preop up to 10 years with previous follow-ups. • Patient's satisfaction after surgery using the 4-point Likert-type scale at each time-point. • Rate of continuous, progressive and symptomatic periprosthetic radiolucent lines greater than 2mm from immediate postoperative (baseline) to 2 years.
Study Rationale	This clinical study has been initiated to satisfy PMCF requirements for the study devices under MDR. Data collected from this PMCF study will be fed into the Post-Market Surveillance (PMS) and Clinical Evaluation process of the devices under assessment on annual basis. Additionally, results from this clinical study will be presented at orthopaedic congresses and/or peer-reviewed publication(s).
Treatment & Study Devices	Dual mobility total hip arthroplasty surgeries with MobiliT ECiMa cup and Paragon or TaperFit stem.
Study Design	Post-market, multi-centre, prospective, non-interventional, single-arm, open label.
Study Duration	Expected recruiting phase: 2 years Follow-up phase: 10 years
Investigators/ Sites	Appropriately trained orthopaedic surgeons in Australia familiar with dual mobility THR surgeries and the use of MobiliT ECiMa cup and Paragon or TaperFit stem will be pre-selected for participation into this PMCF study and selected as per company SOP. Note: the list of investigators/sites will be maintained separately from the protocol.
Selection Criteria	Inclusion Criteria: 1. The individual has signed a Patient Informed Consent Form (PICF), specific to this clinical study and approved by the local Human

	Research Ethics Committee. 2. Both genders. 3. Age ≥ 18 years old, maximum age of 85 years old. 4. The individual clinically qualifies for a dual mobility total hip arthroplasty surgery with MobiliT ECiMa cup with Paragon or TaperFit stem based on physical examination and medical history and has been scheduled for surgery. 5. The individual is willing to comply with the required protocol for follow-up visits. Exclusion Criteria: 1. Individuals under guardianship. 2. Individuals with any physical or psychological condition which would impair clinical investigation participation. 3. Individual with current hip infection. 4. Any patient pregnant or with plans to become pregnant during the clinical study. 5. Individuals who are already enrolled in other clinical studies.
Study Procedures	• Demographic information including gender, age, BMI. • Pre-operative assessment of the affected hip including primary diagnosis, medical history, clinical and radiographic review. • Intra-operative information including components details, surgical approach, complications. • Harris Hip Score (HHS) – which includes a functional and clinical assessment (encompassing elements for pain and ROM) • Preoperative X-rays and post-operative x-rays up to 2 years – assessment of changes in component positioning, presence, and size of radiolucent lines, osteolysis, heterotopic ossifications. • Collection of surgery-/ hip-/ devices-related AEs/SAEs during the surgery and postoperatively up to 10 years. **Patient Reported Outcomes Measures (PROMs):** - Oxford Hip Score (OHS) - EQ-5D-5L (including EQ-5D VAS) - Patient's satisfaction using the 4-point Likert-type scale.
Study Visits	Pre-operative Intra-operative Follow up (FU) visits: 0-6 days, 3 months, 1 year, 2, 5, 7 and 10 years. Telephone Interview: 4 and 9 years.

Statistical Methods and Sample Size	**Statistical methods:** It is planned to conduct a yearly data summary of the study status and available data to feed into the Clinical Evaluation process of the study devices. An interim analysis shall be performed when the data has been collected for the recruited study population at 2 years follow-up. A final analysis shall be performed when the entire study population has completed 10 years follow-up. Ad-hoc interim reports may also be performed upon request to answer regulatory questions and/or if requested by the Investigator(s), in order to improve scientific knowledge or provide data for presentations and publications. As this is not a hypothesis-testing study, the analysis of the data will be performed in a descriptive way. **Analysis of primary endpoint:** - Percent change and absolute improvement of OHS will be reported at each follow-up visit compared to pre-op and previous visit(s) using a repeated-measures t-test. **Analysis of secondary endpoints:** - The survival of the devices will be reported as crude revision rates and 95% confidence intervals, and include listing of details of revision procedures (reason, time to revision, components revised). - Hip-/ procedure-/ device- related adverse events will be listed and summarized based on the different mechanisms of classification, such as type of event, timing (operative/post-operative), seriousness and relation with the study devices. - Postoperative HHS compared to pre-op baseline and previous visits. Percent change and absolute improvement will be reported for total scores and/or sub-scores as appropriate. - Postoperative EQ-5D-5L compared to pre-op baseline and previous visits. Percent change and absolute improvement will be reported for total scores and/or sub-scores (EQ-VAS) as appropriate. - Patient's satisfaction with the results of the surgery and any change to previous visit. - Rate and extent of any radiolucent lines, osteolysis and rates of implant loosening will be reported at specified follow-up time points, as assessed by available radiographs. Statistical methods, summaries and analyses may differ for ad-hoc interim reports depending on the requirements for which the report is being prepared. The statistical methods will be described further in the study protocol or in a separate Statistical analysis plan (SAP). **Sample size:** A minimum of 100 hips will be enrolled into the study, which will be sufficient to demonstrate an OHS change over time with an alpha of 0.5 and a power >0.9.

Data Quality Control	Corin will ensure the study is conducted in accordance with the CSP and all applicable requirements through centralised and on-site monitoring of data and source documents.
Standards & Ethical Considerations	EC approval EN ISO 14155 Guidelines ICH/GCP Declaration of Helsinki (July 2018) GDPR data security compliance The study will be registered in a publicly accessible database before recruitment of the first subject (e.g. Australian New Zealand Clinical Trials Registry (ANZCTR).
Data Quality Control Methods	Site qualification visits and regular data monitoring (remote and on-site)

2.0 FLOWCHART



*Phone interview

3.0 INTRODUCTION

3.1 Background

Total hip arthroplasty (THA) is considered one of the most successful surgical procedures providing pain relief and improvement of function in patients with end-stage hip arthritis that is non-responsive to non-operative treatments[1,2]. As health care continues to improve and life expectancy increases, the demand for total joint replacement will grow to reflect a more active, aging population. With the increase in the number of THAs performed in the world in the next decades, reducing or preventing medical and mechanical complications such as post-operative THA instability will be of paramount importance, particularly in an emerging health care environment based on quality control and patient outcome. The reported incidence of instability after THA in the primary and revision setting has been reported as high as 7% and 25% respectively[3,4]. Early dislocation is defined as occurring within the first 3 months postoperatively and carries a better prognosis with a lower rate of recurrence[5]. In comparison, late dislocations have a multifactorial aetiology including polyethylene wear and soft-tissue laxity which leads to a higher recurrence rate[6].

The dual mobility concept developed by Professor G. Bousquet and the engineer A. Rambert at the end of the 1970s was innovative in the field of total hip replacement. Its goal was to decrease the dislocation rate by associating two articular surfaces: one with a larger diameter (usually 38 mm to 54 mm) situated between a metallic cup and the polyethylene insert, and the other one with a smaller diameter (usually 22 mm to 32 mm) situated between the femoral head and the retentive polyethylene insert[7].

Primary movement occurs at the inner bearing, while the outer bearing only moves at the extreme ranges of movement. The secondary articulation, between the polyethylene liner and the acetabular shell, is engaged during activities that exceed the normal range of movement (ROM), when the femoral component impinges on the rim of the liner[8,9].

The original dual mobility cup was modified in the late 1990s by changing the shape of the metal component to a hemisphere, adding a hydroxyapatite coating and titanium plasma spray to create a surface for osseointegration on the outer surface. The shape was also changed to decrease anterior overhang. The polyethylene insert was modified by adding a retentive chamfer to decrease the risk of dislocation. The femoral neck was modified to decrease impingement by making it thinner[10].

The ROM of hip implants is closely related to the diameter of the prosthetic head and the head to neck ratio. Increasing this ratio results in an increased ROM before impingement[11,12,13].

Dual mobility bearings have been extensively used in Europe as an alternative to constrained liners, together with large heads, to solve instability for more than 35 years and continue to gain popularity worldwide due to the evolution of design and materials used in these systems.

The MobiliT acetabular system is designed to reduce pain and restore the hip function, to improve the range of motion and reduce the risk for instability and dislocation after primary or revision hip replacement. Previous clinical studies assessed the survival rate and performance of MobiliT cup with standard PE insert at short-term such as the study published by Maisongrosse et al 2014[14] where they completed an analysis of 77 obese patients (BMI > 33) and 425 non-obese patients with a minimum of 2 years follow-up. Their series used a range of 4 different dual mobility cups, of which

53/77 and 329/425 were MobiliT cups. Their results indicated no statistically significant differences in performance between these cups with no patients undergoing revision surgery for loosening and only 1.3 % patients (one per group) requiring post-operative surgery for dislocation, thus, postoperative implant survival at a minimum of 2 years was 98.7% for any reason. A trend which falls well within the Kaplan Meier projection of 95% of survival at 10 years after the surgery. Torres-Pérez et al 2014[15], completed a review of 135 cases they had treated with the cementless MobiliT cup and a variety of different head sizes and stem implants. Mean follow-up was 32 months and mean age at surgery 82.1 years. 14 patients died with functional implants in situ. They reported 2 postoperative dislocations, 5 periprosthetic femoral fractures, 2 cup loosening and one subsided stem, plus a further 7 clinical but non implant related adverse events. Cup survival at 12 months was 97.03% (87.3-99.2%) giving a 5-year prediction of 96.7% (range 85.4-98.8%). The advanced age of this group suggests a low patient survival rate at 10 years.

In addition, Corin is conducting an ongoing long-term PMCF study (Study Ref: 1302-T-HIPLTO-RM) in France with the purpose to collect clinical and functional scores, PROMs, and radiographic data after THR surgeries with Corin hip prostheses including dual mobility procedures with MobiliT cup and the standard polyethylene (PE) insert. A total of 1100 primary THR surgeries with the cementless MobiliT cup have been performed between June 2014 and November 2021. Most of patients are female (68.6%) with an average age at the time of surgery of 77.6 ± 8.2 years old and a BMI of 27.5 ± 5.2. The average HHS increased from 41.1 ± 17.7 before surgery to 93.7 ± 8.8 at 2.5 years with 93% of the study population showing satisfactory (HHS≥80) results at 2.5 years. A substantial increase was already observed after 3 months from surgery providing excellent recovery post-surgery. The OHS improved considerably from 15.4 ± 8.2 before surgery to 45.3 ± 5.0 at 2.5 years. Ongoing results show that the patient's satisfaction has been achieved with overall satisfaction average score of 96.5 ± 9.0 at 2.5 years. The EQ-5D VAS scored from an average of 59.4 ± 18.4 preoperatively to 82.7 ± 15.0 at 2.5 years confirming an improved status of health. A good postoperative restoration of biomechanical parameters was observed with X-rays demonstrating good implant stability and cup integration with average cup inclination of 44.7 ± 4.5 degrees at 2.5 years. No radiolucent lines or osteolysis have been reported. Two (0.2%) cases of heterotopic ossification categorised as Brooker class III at 3 months and 2 (0.4%) at 2.5 years. A total of 62 (5.6%) postoperative complications have been reported of which 16 (1.5%) led to a revision surgery. No revisions due to dislocation were reported. Kaplan Meier Survival rate is 95.89% (95% CI: 90.08%, 98.33%) at 5 years. Ongoing results at 2.5 years seem to confirm previous published data with a significant increase in joint functionality and PROMs data. The ECiMa insert compatible with the MobiliT Cup has been added to the above-mentioned study in mid-2022 and data is being collected.

This prospective PMCF study is being initiated to collect performance and functional results of dual mobility procedures performed in primary THA surgery using the MobiliT cup and the ECiMa (highly crosslinked UHMWPE with Vitamin E) insert that received the CE mark at the end of 2020. The MobiliT ECiMa cup was approved by the TGA in 2022 for dual mobility procedures in primary THA surgery. Both femoral stems are CE marked; Paragon received TGA approval in 2017 and TaperFit in 2013.

3.2 Aim of the Study

The aim of this PMCF study is to collect performance, functional and safety outcomes of primary total hip arthroplasty surgeries using a dual mobility cup (MobiliT) with Paragon or TaperFit stem over a ten-year period.

3.3 Design of the Study

This is a prospective, multi-centre/multi-surgeon, non-interventional, internal control, post market clinical follow up (PMCF) study. The study is post-market as all study devices are CE marked and registered in Australia. Prospective patients who are eligible for a primary hip replacement surgery with Paragon or TaperFit stem in combination with MobiliT cup, will be invited to participate in this clinical study.

This is a non-interventional clinical study as the medical devices under assessment are used in accordance with its approved labelling. The assignment of a subject to the medical devices under assessment is not decided in advance by the study protocol but falls within current clinical practice. The use of the medical devices is clearly separated from the decision to include the subject in the clinical study.

Baseline measurements (pre-operative clinical analysis and radiographic analysis at 3-month FU) will serve as internal control term during the assessment of post-surgery data.

The study will be carried out in Australia. The list of participating sites will be maintained separately from this study protocol by the Sponsor.

3.4 Study Rationale

This post-market clinical follow-up study will support the MDR submission of the devices under assessment. Ongoing data analyses derived from this post-market clinical study will be fed into the clinical evaluation process for MobiliT cup with Paragon or TaperFit stem on an annual basis and upon request from Regulatory Authorities. Additionally, the data collected from this study will support presentations at orthopaedic congresses and/or peer-reviewed publication(s) on mid- and long-term performance and safety assessment.

3.5 Risk/Benefit Analysis

There are no additional risks expected in association with this clinical study. The possible risks and/or discomforts associated with a primary total hip replacement surgery with a dual mobility cup (MobiliT with ECiMa insert) with Paragon or TaperFit stem are identical to those for all standard total hip replacement surgeries with a dual mobility construct. Surgery-related risks are mitigated by the selection of qualified surgeons familiar with the use of the study devices. The risks of infection can be reduced by following correct procedures for sterile packaging and proper handling. Taking part in this study will not expose participants to any additional treatment-related risks associated with total hip replacement surgery. The study has been designed to follow the hospitals' Standard of Care (SOC) for dual mobility THR where possible to minimise risks and inconvenience associated with study participation. The study participants will have the opportunity to attend additional follow-up assessments and complete hip-specific questionnaires that might be outside of Standard of Care (SOC).

3.6 Factors to Minimise Bias

The following factors contribute to minimise potential bias in the study results:

- The surgeries will be performed by orthopaedic surgeons qualified by training, experienced in primary dual mobility total hip arthroplasty and familiar with the correct use of the MobiliT cup and compatible devices assessed in this study.
- The scores used in this post-market clinical study are internationally accepted, validated, and widely published.
- The pre-surgery management of each subject included in this post-market clinical study will be performed according to the standard clinical practice used at the study sites with respect to pre-surgical testing, admission and surgical preparation.
- The operative and post-operative medical management of each enrolled subject will be performed according to the standard clinical practice used at the study sites with respect to pain management and rehabilitation protocol therapy.

4.0 STUDY ENDPOINTS

4.1 Primary Endpoint

Improvement of Oxford Hip Score (OHS) from baseline (preop) to 2 years after surgery.

4.2 Secondary Endpoints

Secondary endpoints include:

- Revision rate of the devices under assessment after surgery to 10-year FU.
- Kaplan-Meier survival rate up after surgery to 10-year FU.
- Incidence of intraoperative and post-operative adverse events (hip, study device or surgery related) including severity and outcome up to 10-year FU.
- Change of Harris Hip Score (HHS) from preop to 10 years after surgery.
- Change of OHS from 2 to 10 years after surgery.
- Change of EQ-5-DL from preop to 10 years with previous follow-ups.
- Patient's satisfaction after surgery using the 4-point Likert-type scale at each time-point.
- Rate of continuous, progressive and symptomatic periprosthetic radiolucent lines greater than 2mm from immediate postoperative (baseline) to 2 years.

5.0 MEDICAL DEVICES USED IN THE STUDY

5.1 MobiliT™ acetabular system - Description

MobiliT™ is a monobloc dual mobility system that includes a metal shell combined with a size specific polyethylene insert. This system offers two articulating surfaces in the same joint space, one between the shell and the insert, the other between the insert and the femoral head. The shell is made of stainless steel and articulates with either an Ultra High Molecular Weight Polyethylene (UHMWPE) or HXLPE with Vitamin E (ECiMa™) polyethylene insert.

It has a spherical internal and external bearing surface. The internal diameter is retentive to maintain the head inside the insert and is also equipped with a release chamfer to prevent conflicts with the neck of the femoral stem, and a rounded edge to prevent conflicts with soft issues.

The shell exists in cementless and cemented versions. The cementless version of the MobiliT™ cup that is under assessment in this PMCF study is designed with a dual surface coating Titanium plasma spray and hydroxyapatite (HAP) (Figure 1).
The featured hemispherical 3mm extension is designed to allow for simple cup positioning and targeted coverage in at-risk positions (Figure 2).

Figure 1. MobiliT™ cementless Cup with standard PE insert and metal CoCr head

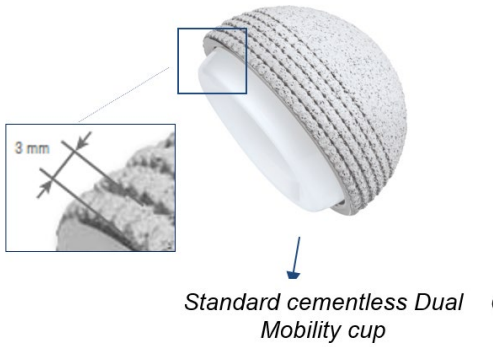


Figure 2. External diameter of the MobiliT cup extended by 3 mm.

As mentioned above, The MobiliT™ insert is made of either Ultra-High Molecular Weight polyethylene (UHMWPE) or ECiMa™ (highly crosslinked UHMWPE with Vitamin E).
Both UHMWPE and ECiMa™ inserts are available for 22.2mm and 28mm femoral heads. They are delivered sterile and are for single use. Only the ECiMa insert (Figure 3) is available in the Australian market and will be assessed in combination with the cementless MobiliT™ cup in this PMCF study.

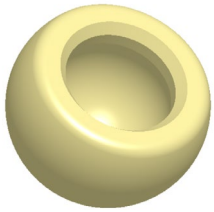


Figure 3. ECiMa™ insert for the MobiliT™ cup.

5.2 Cementless MobiliT cup with ECiMa insert- Indications and Contraindications for use

Indications

The cementless MobiliT cup is indicated for primary replacement of the hip joint:

- In degenerative pathologies: primary, secondary or post- traumatic osteoarthritis, rheumatoid arthritis
- For patients who have a high risk of dislocation
- In cases of necrosis of the femoral head
- In cases of fracture of the neck of the femur
- In cases of congenital luxation

Contraindications

To date, the known contraindications for the cementless MobiliT cup with ECiMa insert are the following:

- Fever and/or local inflammation
- Genitourinary, pulmonary, skin, dental, or other infection that may cause hematogenous dispersions toward the prosthetic site
- Neuromuscular or psychiatric diseases that may cause the failure of fixation and postoperative care
- Rapid destruction of the joint or bone resorption observed in X-rays
- Unsuitable or insufficient bone support not enabling the correct anchoring of the prosthesis in the case of a cemented metal-back
- Pelvic fracture
- Known allergy to one of the materials
- Bone immaturity
- Revision after fracture of a ceramic component

The MobiliT cup system is TGA approved.

5.3 Paragon stem - Description

The Paragon stem is a bi-planar wedge shaped monoblock stem of Titanium Alloy (Ti6Al4V), with Titanium plasma and/or Hydroxyapatite (HA) coating. The Paragon stem is available in a collared and collarless version and available in both standard and high offset in a range of sizes. The Paragon stem is compatible with Femoral Heads with a 12/14 taper, including the MobiliT acetabular system. The Paragon stem utilises a bi-planar wedge design to provide primary axial stability and a rectangular cross section to provide primary torsional stability. The stem also features a macrostructure design optimised for osseointegration, which provides secondary stability. The stem's surface along with its tapered architecture has been specifically designed to load the

metaphyseal-diaphyseal region, reproducing the natural physiological loading patterns of the femur.

It is available in twelve (12) sizes (1 through 12) in standard and high offset in 130˚ CCD angle, which allows the surgeon to preserve bone at the osteotomy level which fundamentally allows for a user-friendly stem. The progressive neck lengths allow bone preserving femoral neck resection and the low-profile neck maximises range of motion. The Paragon stem medial compression grooves are designed to resist compression and stem subsidence and the lateral tension grooves are designed to resist tensile force and prevent stem loosening. The device design incorporates a porous coating of Hydroxyapatite (PCHA), developed to resist potential stem subsidence and loosening. The stem has a polished and offset distal tip which provides a reduction in distal stem engagement and a finer insertion of the stem during the procedure.

The Paragon stem is available in either collared or collarless options. The collared stems have the same function and intended use of non-collared stems but provide those surgeons who prefer it, a more definitive reference point relative to the osteotomy line when inserting the stem into the intra-medullary canal of the patient's femur. The addition of the collar on the stem does not alter the indications for use and their selection for use is at the choice of the surgeon.

Figure 4. Paragon stem (collarless (right); collared (left).

5.4 Paragon stem- Indications and Contraindications for use

The Paragon stem is intended to provide increased patient mobility, range of motion, 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.

Indications

The indications for Paragon stem as a total hip arthroplasty and as a hip hemiarthroplasty include:

- Degenerative osteoarthritis of the hip.

- Inflammatory arthritis of the hip.
- Secondary arthritis of the hip, such as may follow trauma (e.g. fracture of the femoral neck, or fracture and/or dislocation of the hip or acetabulum), or congenital conditions (e.g. developmental dysplasia of the hip).
- Displaced intracapsular femoral neck fractures where there is a high risk of non-union or avascular necrosis and bone collapse.
- Avascular Necrosis of the femoral head.

In this PMCF study only primary total hip arthroplasty surgeries will be assessed.

Contraindications

- Infection or sepsis or osteomyelitis.
- Insufficient bone structure or quality which may affect the stability of the implant.
- Rapid joint destruction or bone absorption.
- Skeletal immaturity.
- Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, which may compromise the affected extremity.
- Alcoholism or the other addictions.
- Sensitivity to the implant materials.
- High levels of physical activity e.g. competitive sports, heavy physical labour.
- Obesity that can produce loads on the prosthesis, which can lead to failure of the fixation of the device or the device itself.

The Paragon Stem System is TGA approved.

5.5 TaperFit stem - Description

The TaperFit Hip Stem is a double tapered, polished, collarless stem designed to be implanted using bone cement. The TaperFit cemented hip system stem is manufactured from high strength stainless steel and is available in five sizes with three offset configurations: 38mm, 45mm and 50mm. The TaperFit cemented hip system stems are supplied with a PMMA centralizer which attaches to the distal part of the stem and acts to centralize the distal stem in the cement mantle and maintain correct stem alignment.

The TaperFit Hip Stem is TGA approved.

Figure 5. TaperFit Hip Stem with centraliser, a CoCr femoral head and Trinity Acetabular Cup.
Note: Trinity Acetabular cup shown for illustration purposes only.

5.6 TaperFit stem- Indications and Contraindications for use

The TaperFit cemented hip system is intended for use as a primary replacement for the hip joint, in association with acetabular components, to reduce pain and restore hip function.

Indications

- Femoral neck fracture
- Osteoarthritis
- Rheumatoid and inflammatory arthritis
- Post-traumatic disease effects,
- Avascular necrosis
- Total hip revision.

Contraindications

- Active infection
- Osteoporosis
- Marked bone loss or bone resorption
- Metabolic disorders which may impair bone formation
- Vascular insufficiency
- Muscular atrophy
- Neuromuscular disease

6.0 STUDY POPULATION

Participants will be selected for recruitment into the study from the general population of patients requiring a primary total hip arthroplasty surgery with a dual mobility construct and considered suitable for the cementless MobiliT cup with ECiMa insert with Paragon or TaperFit stem. Participants who do not meet the inclusion criteria or meet any exclusion criteria are excluded from the study participation. Bilateral participants will be included, and each hip will be assigned a specific study ID and the patient will complete separate questionnaires for each treated hip.

6.1 Selection Criteria

6.1.1 Inclusion Criteria

Participants meeting all the following inclusion criteria will be considered for participation in the study:

1. The individual has signed a Patient Informed Consent Form (PICF), specific to this clinical investigation, and approved by the Human Research Ethics Committee.
2. Both genders.
3. Age ≥ 18 years old, maximum age of 85 years old.
4. The individual clinically qualifies for a dual mobility total hip arthroplasty surgery with MobiliT ECiMa cup with Paragon or TaperFit stem based on physical examination and medical history and has been scheduled for surgery.
5. The individual is willing to comply with the required protocol for follow-up visits.

6.1.2 Exclusion Criteria

Participants will be excluded if they meet any of the following criteria:

1. Individuals under guardianship.
2. Individuals with any physical or psychological condition which would impair clinical investigation participation.
3. Individual with current hip infection.
4. Any patient pregnant or with plans to become pregnant during the clinical study.
5. Individuals who are already enrolled in other clinical studies.

6.2 Participant Consent

The Participant Information Consent Form and Information Sheet (PICF) will be drawn up according to the requirements of the responsible Ethics Committee. Each potential participant will be fully informed by the Principal Investigator (PI) or a designated and trained member of his/her team of all pertinent aspects of the study and will receive the PICF that will explain in a written way:

1. The purpose of the study.
2. Study duration.
3. Requirements of the study (follow-up visits).
4. All the subject's rights as a participant in the study.

Participants will be informed that they are free to refuse participation in the study, or to withdraw from the study at any time, without compromising their medical care. All foreseeable risks and

potential benefits related to study participation which might occur will be discussed and the PI (or designated team member) will provide the subject time and opportunity to inquire about details of the study, to discuss taking part in the study with others and to decide whether or not to participate to the study. In cases of bilateral surgery, patients will be required to consent for each hip joint.

Participants will be informed that their medical records may be reviewed by representatives of the Sponsor to ensure the study is being conducted according to the protocol. They will be assured that confidentiality of personal data will be maintained at all times and access to this information will be restricted to authorised personnel only. Consent for such access will be addressed in the written informed consent document that the subject will be requested to sign.

Documentation of the informed consent process will be obtained by the use of the study related Informed Consent. Failure to obtain or improper documentation patient consent is a violation of the regulations and the study protocol. If the subject agrees to participate in the study, then the subject should sign and date the PICF before the day of surgery. However, if the PICF is signed on the day of surgery, then it needs to state that the participant was given adequate time prior to the date of surgery consider his/her participation. The Principal Investigator (or designated team member) will also sign and date the consent form to indicate that the purpose, risks and benefits of the study were explained to the participant. Any patient data – PROMs, Standard of Care (SOC) X-Rays and other clinical assessment data performed as standard of care prior to the surgery will be collected for the purpose of the study, but only after obtaining the subject's consent. A copy of the executed PICF will be given to the participant, a copy will be filed within the participant's medical records, and the original will be filed in the Investigator's Site File at the Investigator's study site.

6.3 Participant Enrolment

The point of enrolment is the time at which a subject sign and date the informed consent form. Participants who meet all eligibility criteria for the study and provide written informed consent to participate, will be considered as enrolled in the study. Each subject enrolled in the study will be recorded in the Enrolment Log. An identification code will be assigned to each enrolled patient on all data forms, in order to guarantee anonymity.

7.0 MATERIAL and METHODS

The study will be conducted by orthopaedic surgeons qualified by training, experienced in hip replacement surgeries. The Principal Investigator (PI) has responsibility to inform all the staff involved in the study about all relevant aspects and information related to the study. Assigned members of the research team at each study site will be properly trained on the study procedures according to the protocol.

An approved and updated list of all individual members (Site Delegation Log), designated, trained and supervised by the principal Investigator to perform study-related procedures or involved in any specific task, has to be kept in the Investigator Site File (ISF).

7.1 Surgical Procedure

All the operations will be performed by orthopaedic surgeons qualified by training, experienced in dual mobility hip arthroplasty surgeries and familiar with the appropriate use of the components involved in this clinical study, and according to proper standardized surgical technique. Anaesthesia, postoperative pain management and prophylactic antibiotics will be administered to the participants according to the standard practice at each study site.

7.2 Clinical Assessment and Patient Reported Outcome Measures (PROMs)

The clinical assessment is performed before surgery, at 3 months, 1 year, 2, 5, 7 and 10 years after the surgery. Preoperative assessment is used as baseline values for score improvement.

Harris Hip Score

The Harris Hip Score (HHS) is a disease-specific scoring system originally intended as outcome score after arthroplasty surgeries that include the domains of function, pain, motion, and deformity16. The HHS is considered a clinical outcome measure. The maximum score of the absolute HHS is 100 points. Pain domain contributes 44 points, function 47, ROM 5 and absence of deformity 4 points. Function is subdivided into gait and activities of daily living. Calculation of the ROM score includes splitting the motion into categories based on utility and then multiplying the degrees of motion with a given index factor. The index scores are then added and multiplied by a factor of 0.05 to obtain the final ROM score. The ROMs of the affected hip/joint will be measured with a standard goniometer.

Oxford Hip Score

Oxford Hip Score (OHS) is a patient-centred questionnaire that is designed to assess functional ability and pain from the patient's perspective. It is a short, twelve-item questionnaire developed for completion by patients undergoing THA and is extensively referenced in the Orthopaedic literature. The OHS has been demonstrated to be highly sensitive to change in patients undergoing primary THA.[17] Each of the 12 questions on the Oxford hip score presents a score decreasing as the reported symptoms increase (ie. become worse). All questions are laid out with response categories denoting least (or no) symptoms being to the left of the page (scoring 4) and those representing greatest severity lying on the right-hand side (scoring 0). This method, when summed, produces overall scores running from 0 to 48 with 48 being the best outcome.

EQ-5D-5L

The EQ-5D-5L essentially consists of 2 pages: the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS).
The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions. This decision results in a 1-digit number that expresses the level selected for

that dimension. The digits for the five dimensions can be combined into a 5-digit number that describes the patient's health state.
The EQ VAS records the patient's self-rated health on a vertical visual analogue scale from 0-100, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine', it is requested for the patient to simply mark an X on the scale to indicate today's health and to write the number marked on the scale in the box. The VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgement.

Subject's satisfaction 4-point Likert-type scale

The overall satisfaction of the patients with the result of the surgery will be scored on a 4-point Likert-type scale with response categories consisting of very satisfied (100 points), somewhat satisfied (75 points), somewhat dissatisfied (50 points) and very dissatisfied (25 points)[18]. The satisfaction scale will be completed by the participant postoperatively and the first one will represent the baseline for the following visits.

7.3 Radiographic evaluation

The radiographic evaluation includes standard X-rays such as antero-posterior (AP) of the pelvis/ hip and lateral views of the affected hip before surgery and then at discharge (0-6 days), and 2 years. Any X-Ray imaging done between 0-6 days and 1 year post op will be done as per Surgeon's SOC. At further follow-ups 1, 5, 7, 10 years, X-rays are optional and/or will be taken only in case of subjective complaints such as pain or clinical symptoms warrants more investigation.

7.4 Survivorship Analysis

Survival analysis of the study devices is calculated with the use of Kaplan-Meier estimation and 95% confidence interval. The analysis will be performed with the following end points:

- Revision of the acetabular component due to dislocation
- Revision of the femoral and/or acetabular component due to failure of the stem (such as stem fracture)
- Revision of the femoral and/or acetabular component due to aseptic loosening
- Definite or probable radiographic evidence of loosening of the components (such as lysis).

7.5 Adverse Events

The investigator is required to report all surgical, medical device and instrument related complications/AEs; complications/AEs affecting or related to the study hip; and deaths or serious injuries including:

- Intraoperative adverse events regardless of cause, seriousness, or outcome.
- Postoperative adverse events related to the device or study hip.
- Serious postoperative adverse events resulting in death or serious injury.

Details to be recorded in the eCRF including date of occurrence, severity, event description treatment, and outcome.

Definitions[19]

1. An **adverse event (AE)** is defined as untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in *subjects*, users or other persons, whether or not related to the *investigational medical device* and whether anticipated or unanticipated

   Note 1: This definition includes events related to the investigational medical device or the *comparator*.

   Note 2: This definition includes events related to the procedures involved.

   Note 3: For users or other persons, this definition is restricted to events related to the use of investigational medical devices or comparators.

2. An **adverse device effect (ADE)** is defined as an adverse event related to the use of an investigational medical device

   Note 1: This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

   Note 2: This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

   Note 3: This includes 'comparator' if the comparator is a medical device.

3. A **serious adverse event (SAE)** is defined as an adverse event that led to any of the following:

   a) death,
   b) serious deterioration in the health of the subject, users, or other persons as defined by one or more of the following:
      1) a life-threatening illness or injury, or
      2) a permanent impairment of a body structure or a body function including chronic diseases, or
      3) in-patient or prolonged hospitalization, or
      4) medical or surgical intervention to prevent life-threatening illness or injury, or permanent impairment to a body structure or a body function,
   c) foetal distress, foetal death, a congenital abnormality, or birth defect including physical or mental impairment.

   Note 1: Planned hospitalization for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.

4. A **serious adverse device effect (SADE)** is defined as an adverse device effect has resulted in any of the consequences characteristic of a *serious adverse event.*

5. An **unanticipated serious adverse device effect (USADE) is defined as a** serious adverse device

effect which by its nature, incidence, severity or outcome has not been identified in the current risk assessment.

Note 1: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk assessment.

6. A **device deficiency** is defined as an inadequacy of a medical device with respect to its identity, quality, durability, reliability, usability, safety or performance

   Note 1: Device deficiencies include malfunctions, use errors, and inadequacy in the information supplied by the manufacturer including labelling.

   Note 2: This definition includes device deficiencies related to the investigational medical device or the comparator.

No adverse events are anticipated as a direct result of the subject participating in this study.

Should any serious adverse device effect (SADE) occur, this will be documented by the Principal Investigator (or designated team member) and reported to the Sponsor within 1 working day of the site becoming aware of the event. The Sponsor will review and notify as appropriate to relevant competent authorities.

The study site is responsible for submitting AEs to the responsible HREC in accordance with the local HREC requirements in terms of the nature of events to be submitted and the timelines for submission. Any medical devices related adverse event will be reported to Corin immediately and subsequently to all relevant competent authorities as appropriate, in parallel, and in no later than 10 working days after the investigator first learns of the event.

SAEs that are deemed to be unexpected and related to the study will be notified to the local HREC as applicable.

7.6 Study Schedule

Study activities	Preop	Surgery	Follow-up								
			0-6 days^	3 mo^. (± 2 mo.)	1 yr ^ (± 2 mo.)	2 yrs (± 3 mo.)	4 yrs (± 4 mo.)	5 yrs (± 6 mo.)	7 yrs (± 6 mo.)	9 yrs (± 7 mo.)	10 yrs (±3 mo.)
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Telephone Visit 7	Visit 8	Visit 9	Telephone Visit 10	Visit 11
Discuss study with subject	x										
Medical History review	x										
Eligibility and consent	x										
Physical Examination with Harris Hip Score (HHS)/ ROM	x			x	x Ω	x		x Ω	x Ω		x Ω
Operative and components details		x									
EQ-5D-5L	x			x	x	x		x	x		x
Oxford Hip Score (OHS)	x			x	x	x		x	x		x
Satisfaction with 4-point Likert-type scale				x	x	x		x	x		x
X-Ray views* as per SOC	x		x	x	x Ω	x		x Ω	x Ω		x Ω
Complications/ Adverse Events		x	x	x	x	x	x	x	x	x	x
Schedule next visit	x		x	x	x	x	x	x	x	x	
Telephone interview							x			x	

Table 1. Schedule of Events

Ω Optional at these time points

^ The Post Op visit between surgery and 2-year visit will be conducted in accordance with the surgeon's standard of care.

***** It is not considered a protocol deviation if Optional X Rays are not completed. These should be completed at the discretion of the surgeon.

7.7 Study Visit Management

Visit 1 (Pre-Op visit)

The patient will meet with the surgeon to discuss about their THA surgery. At this visit, the surgeon will discuss the study with the patient and will explain the advantages or disadvantages of taking

part. A copy of the Participant Informed Consent Form will be given to the patient to read and consider. The patient will be given adequate time to take the PICF home for making an informed decision about the study participation or can choose to sign the consent form during this visit. In both instances the patient will be given enough time to consider the study and request additional information from the surgeon and then provide consent. In case the patient decides to take the consent form home, the patient will return the consent form to the site after signature. One signed copy will be provided to the patient to keep. After signing the informed consent, the patient is enrolled and must be recorded on the Screening & Enrolment Log. Once the consent form is signed, the surgeon or a delegated team member will check eligibility and ensure the participant meets all criteria as per the inclusion and exclusion outlined in the study protocol. Participant demographics, primary diagnosis and relevant medical history will be recorded. All participants will then complete their pre-surgery PROMs – the Oxford Hip Score (OHS), EQ-5D-5L (EQ- VAS). Clinical assessments using standard functional parameters for physical assessment, and Harris Hip Score (including ROM) will be completed, and standard x-rays of the affected hip will be undertaken.

Visit 2 - Surgery

The dual mobility THA surgery will be performed at this visit. Intra-operative surgical details will be recorded as per standard of care including component details, and surgical approach. Deviations from the standard surgical technique will be noted. Any complications/ Adverse Events (AEs) arising from the surgery will be recorded. Any Serious Adverse Event (SAE) related to the treated hip and/or device-related incident will be recorded and reported to the Sponsor as per guidelines.

Follow Up Visit 3 (0-6 days post-surgery)

This visit will occur 0-6 days from the date of surgery while the patient is still at the hospital. Standard of care assessments will be performed which include X-rays of the treated hip. Postoperative pain management will be under the decision of the orthopaedic surgeon and support staff who will provide instructions to the patients regarding home care during the first few weeks after surgery. Medications are often prescribed for short-term pain relief after surgery. The rehabilitation program will depend on patient's goals and desired activities according to the SOC at the site. The goal of physical therapy intervention during the early post-operative phase is to decrease swelling, increase range of motion, enhance muscle control and strength in the involved lower extremity and maximize patients' mobility with a goal of functional independence.

Rehabilitation program may be individualized in function of bone quality, age, health and physical fitness of the patient. Any substantial changes to the SOC rehabilitation program will be documented. Immediate post-op complications/AEs related to the hip, or the surgery will be recorded. Any Serious Adverse Event (SAE) related to the treated hip and/or device-related incident will be recorded and reported to the Sponsor as per guidelines.

Follow Up Visits 4, 5, 6, 8, 9 and 11

The follow-up visits will be performed per the Schedule of Events table (Table 1). The study participants will be encouraged to attend site visits up to Visit 6 within the scheduled visit window to complete study assessments and questionnaires. X-rays of the treated hip will be completed as

per the schedule. When participants are unable to visit the study sites physically, participants will be encouraged to complete study questionnaires at home and provide any relevant complications/ Adverse Events information via email. When a study patient is unable to visit the study site as per the schedule of events, a protocol deviation will be reported with justification and a description of the corrective action plan to prevent a future occurrence.

Telephone Interview – Visit 7 and 10

At this contact, a designated delegated team member will telephone the participant to enquire about any complications. Any Adverse or Serious Adverse Event (SAE) or device-related incident will be recorded and reported to Corin as per guidelines. The participant will be reminded about the 10-year FU visit**.**

8.0 PATIENT WITHDRAWAL

Patient withdrawal may occur in any study phase pre-operatively, intra-operatively, and post-operatively.

8.1 Preoperative Withdrawal

Before the surgery, the study subject may revoke consent at any time without reason or the Investigator may withdraw the subject based on preoperative test results (e.g., radiographic analysis, medical history). In this case, the subject must be excluded from the participation in the study and a study withdrawal CRF should be completed indicating the date, the reason (if available) and the last visit available. As the subject has not undergone the surgery, he/she may be substituted with the enrolment of another subject.

8.2 Intraoperative Withdrawal

If the Investigator, despite the subject selection according to criteria and the preoperative planning, notices any clinical condition or complication not compatible with the investigational devices before the first bony cut during the surgery, the subject can be withdrawn.

In this case, the subject must be excluded from the participation to the study and document the date, the reason (if available) and the last visit available on the withdrawal form. As the subject has not undergone the surgery per protocol, he/she may be substituted with the enrolment of another subject.

8.3 Postoperative Withdrawal

After the surgery, the participant may voluntarily revoke consent and withdraw from the study at any time without reason. Participants may be involuntarily exited from the study for failure to comply with the study protocol, failure to attend follow-up visits or for any clinical condition, if the Investigator deems it necessary.

In all cases, the Investigator should record the withdrawal indicating the date, the reason (if available) and the last date of follow-up available. All data obtained up to consent withdrawal will be included in the analysis.

8.4 Early termination due to lost to follow up or other reason

Sites should make and document reasonable efforts to contact and schedule study visits. Participants who will not or cannot return for follow-up visits as planned in the protocol will be considered as non-compliant with the study protocol. This group includes:

- Patients who are uncooperative and/or refuse to return for follow-up for three consecutive visits
- Patients who relocate without notifying the investigator and cannot be located for continued follow-up arrangements.

These patients are considered “lost to follow up”.

Other reasons for early termination:

- Revision of the Study device - Patients who would need a revision surgery after the primary dual mobility surgery will automatically be withdrawn from the study follow up as the study device/s will no longer be in situ. This study participant will be marked as “End of Study”. However, any study data collected up to the revision surgery and reason for revision will be included in the data analysis. Data related to revisions and hip-/ procedure-/ device- related adverse events will be assessed as secondary objectives for this study.
- Death of a study Patient - Any patient who is deceased while on the study should be marked as End of Study and thus withdrawn.

Patients who are considered “lost to follow up” or have early terminated the study must have documentation indicating the date, the reason (if available) and the last date of follow-up available.

9.0 DATA MANAGEMENT

9.1 Data Collection and Review

This study will be conducted in compliance with ISO 14155:2020. Data will be collected by the study site(s) in accordance with the approved protocol. All data will be accessible to the study site(s) for use in submissions for research publications, presentations, and to Corin, as Sponsor, for use in submissions to regulatory bodies or other similar authorities.

The study patients will be able to complete the questionnaires on a paper or electronic format. In cases of the participant prefers to complete the questionnaires on paper, the data will be then transferred by the site into the eCRF.

Data will be entered into a secure, web-based, password protected application design to support electronic data capture (EDC). The application to be used for this study is Medrio R41.5. Medrio meets all global data collection regulations - such as ICH GCP, 21 CFR, GDPR, and HIPAA. Only the study investigator(s) or delegated clinical study staff should perform modifications or corrections to eCRF data. Traceability of any modification will be captured via the audit trail to reflect the reason for the change. Medical records and patients’ files will be stored electronically and retained by the study site. The study patients will be able to complete the questionnaires on a paper or electronic format. In cases of the participant prefers to complete the questionnaires on paper, the data will be then transferred by the site into the eCRF.

The Investigator should ensure the accuracy, completeness and timeliness of the data reported in the eCRFs and in all required reports. All data reported should be consistent with the source documents.
The Investigator is responsible for preserving data and documentation related to the study during the study and at the end, until Sponsor's communication. Upon request of the Sponsor or regulatory authorities, the Investigator should make available for direct access all requested study-related records.

9.2 Source Documents

The Investigator must maintain source documents for each study participant in the study, consisting of case and visit notes (hospital or clinic medical records) containing demographic and medical information, radiological, and the results of any other tests or assessments. All information in electronic/paper Case Report forms must be traceable to these source documents. The Investigator must also keep the original informed consent form signed by the study participant (a signed copy is given to the study participant). The Investigator must give the monitor access to all relevant source documents to confirm their consistency with the eCRF entries. As per ISO14155:2020 the study sites must adhere to all standards, adherence to the inclusion/exclusion criteria, documentation of SAEs, and the recording of relevant study data.

9.3 Case Report Forms

The Sponsor will provide the Case Report Forms (in paper and/or electronic form) to the site to enable collection of the study data. The Investigator is responsible for ensuring that all sections of each paper or eCRF are completed promptly and correctly and that entries can be verified against any source data. Principal Investigator should routinely review the case report forms for completeness and accuracy as well as any evidence which may be indicative of patient risk. When any discrepancies are noted, they will be resolved with the Investigator and/or individual designated by the Investigator. When the data are incomplete, attempts will be made to obtain the data whenever possible. Study monitors will perform source document verification on site and remotely to identify inconsistencies between the eCRFs and source documents. Discrepancies will be resolved in accordance with the principles of ISO14155:2020.

9.4 Archiving of Study Documents

All study related correspondence, study participant records, consent forms, study participant privacy documentation, records of the distribution and use of all investigational device, and copies of case report forms should be maintained on site files. The sponsor and principal investigator shall maintain the clinical investigation documents as required by the applicable regulatory requirement(s). The Investigator follows the principles outlined in the Clinical Study Agreement (or equivalent) for responsible archiving.

The study data will be stored for 15 years. After that the data will be archived electronically on a secure server for at least 10 years after the last product has been distributed.

10.0 STATISTICAL CONSIDERATIONS

10.1 Statistical Methods and Data Analysis

The following describes the statistical analyses foreseen at the time of study planning. Detailed statistical methods will be described in a separate Statistical Analysis Plan (SAP).

Statistical analyses will be performed when data has been collected for the study population at 2 years, 5 years, and 10 years follow-up.

Descriptive statistics will be provided in summary tables according to the type of variable summarised:

- survivorship will be calculated as Kaplan-Meier analysis with 95% confidence interval.
- quantitative variables will be summarized by using n (sample size), arithmetic mean, standard deviation (SD), median, minimum, and maximum, comparing between follow-ups and baseline values (where applicable).
- categorical variables will be summarized by using frequency count and percent distribution.

Additional analysis may include comparisons of interest across demographic and baseline characteristics.

The analyses will include:

Analysis of primary endpoint:

- Percent change and absolute improvement of OHS will be reported at each follow-up visit compared to pre-op and previous visit(s) using a repeated-measures t-test.

Analysis of secondary endpoints:

- The survival of the devices will be expressed as crude revision rates and 95% confidence intervals and include listing of details of revision procedures (reason, time to revision, components revised).
- Hip-/ procedure-/ device- related adverse events will be listed and summarized based on the different mechanisms of classification, such as type of event, timing (operative/post-operative), seriousness and relation with the study devices.
- Postoperative HHS compared to pre-op baseline and previous visits. Percent change and absolute improvement will be reported for total scores and/or sub-scores as appropriate.
- Postoperative EQ-5D-5L compared to pre-op baseline and previous visits. Percent change and absolute improvement will be reported for total scores and/or sub-scores (EQ-VAS) as appropriate.
- Patient's satisfaction with the results of the surgery and any change to previous visit.
  The rates and extent of any radiolucent lines, osteolysis and rates of implant loosening will be reported at specified follow-up time points, as assessed by available radiographs.

10.2 Sample Size

A minimum of 100 hips will be enrolled into the study according to the selection criteria. Based on a repeated-measures t-test, and assuming a mean difference of 22.6 OHS score points (SD 9.8) from pre-operative to 2 years post-operative[20], this sample size will be sufficient to demonstrate a two-tailed effect with an alpha of 0.05 and a power >0.90.

11.0 ETHICS REQUIREMENTS

11.1 Standards

This non-interventional study will be conducted in accordance with the "Declaration of Helsinki (9th July 2018) – Ethical Principles For Medical Research Involving Human Subjects, with the applicable sections of the ISO 14155:2020 and with the general principles of the ICH/GCP guideline and any applicable law governing the conduct of post-market clinical studies.

11.2 Human Research Ethics Committee (HREC) Approval

It is the Primary Investigator's responsibility to obtain Ethics approval of the study protocol, the Participant Informed Consent Form (PICF), and any relevant study related information.

A copy of the study approval letter will be maintained electronically in both electronic Investigator Site File and electronic Study Master File. Revisions or amendments to the study protocol and/or PICF that affect the scientific soundness of the investigation, or the rights, safety or welfare of the participating patients are to be submitted by the Investigator to the HREC for review and approval prior to implementation. Copies of all HREC approvals letters will be maintained electronically in both electronic Investigator Site File and electronic Study Master File.

A study progress to maintain the Ethics approval shall submitted on annual basis or according to the requirements of the local HREC. After the end of the study, the PI must submit a final report to the committee containing a summary of the study's findings and conclusions.

11.3 Data Protection

All the participating subject's health information will be collected, held, used and disclosed in accordance with the security and privacy regulations of the state laws within which the data is sourced and to which it is transferred.

If by means of a Data Protection Impact Assessment or other methodology it is established that the security and privacy regulations of state law outside of the EU member states are considered insufficient for the purpose of safeguarding participating patient health information, then the Sponsor will apply measures consistent with the data governance principles of the EU General Data Protection Regulation.

Data or information that leaves the study site will not contain identifiable information relating to the participants. The data transferred outside the study site to another location for analysis will be anonymised. Participants will not be able to be identified in any reports, presentations or publications from either the Investigators or the Sponsor.

11.4 Amendments to the Study Protocol

Any amendment to the study Clinical Study Protocol (CSP) shall be agreed between the Sponsor and the study Principal Investigators. The changes to this CSP will be recorded with a justification for the amendment. HREC review and approval will be sought prior to implementation. No changes to this CSP will be permitted without the written approval of the ethics committee. Written approval by the local Ethics Committee will be obtained before the changes are implemented.

11.5 Deviations from the Study Protocol

The study should be conducted as per the Study Schedules outlined in the Clinical Study Protocol. In case of any deviation from the study protocol including the type of deviation (informed consent, inclusion/exclusion criteria, treatment, tests not performed and follow-up) will be recorded at the time of occurrence. Any major study deviation should be informed to the sponsor immediately. The study deviations shall be recorded on the Protocol Deviation Log provided by the sponsor with an explanation for the deviation and be signed off by the Principal Investigator and reported to the Sponsor.

The Sponsor will be responsible for analysing them and assessing their significance. Deviations are reviewed to determine the need to amend the Clinical Study Protocol or to terminate the study, if necessary.

12.0 STUDY MONITORING

The study will be monitored by the sponsor per the standard operating procedures of the Clinical Affairs department at Corin Australia.

During the study period, the Principal Investigator shall allow monitoring by the Sponsor to ensure that the study is conducted and recorded in accordance with the CSP. The monitor will have access to all documents to verify data completeness and accuracy, respecting the law of personal data protection.

Both on-site and remote monitoring visits will be performed. On-site monitoring visits, where performed, will be recorded on the Monitoring Visit Log.

Monitoring of this study by the Sponsor may include the following activities:

- conducting study initiation visit to ensure the PI and his/her team clearly understands and accepts the obligations in undertaking the clinical study.
- visiting the site to ensure the PI and his/her team is fulfilling all obligations associated with the clinical study (as necessary for proper conduct of the study).
- reviewing the signed informed consent for all patients.
- reviewing all patient source documents, comparing those records with reports prepared by the Investigator, and ensuring that data submitted to the Sponsor are accurate and complete.
- maintaining a record of each on-site visit with an investigator noting findings, conclusions and actions taken to correct deficiencies.

Detailed study monitoring procedures are provided in the Clinical Monitoring Plan.

13.0 STUDY AUDITING

The investigator and the clinical site must accept monitoring and auditing by the Sponsor, as well as inspections from the HREC and relevant Regulatory Authorities. In these instances, they must provide all clinical study-related records, such as source documents when they are requested by the Sponsor monitors and auditors, the HREC or Regulatory Authorities. The confidentiality of the

subject's identities shall be well protected consistent with local and national regulations when the source documents are subject to direct access.

14.0 DISCONTINUATION OF THE STUDY

The Sponsor may terminate this clinical study prematurely, either in its entirety or at the clinical unit, for reasonable cause provided that written notice is submitted in advance of the intended termination. Advance notice is not required if the clinical study is stopped due to safety concerns. If the Sponsor terminates the clinical study for safety reasons, the Sponsor will immediately notify the investigator and subsequently provide written instructions for clinical study termination.

The clinical study may be discontinued prematurely in the event of any of the following:

- New information leading to unfavourable risk-benefit judgment of the medical device due to occurrence of significant previously unknown AEs or unexpectedly high intensity or incidence of known AEs, or other unfavourable safety findings.
- Sponsor's decision that continuation of the clinical study is unjustifiable for medical or ethical reasons.
- Poor enrolment of participants making completion of the clinical study within an acceptable time frame unlikely.
- Discontinuation of development of the Sponsor's medical device.

Regulatory Authorities and the HREC will be informed about the discontinuation of the clinical study in accordance with applicable regulations. The whole clinical study may be terminated or suspended upon request of Regulatory Authorities.

15.0 STUDY RECORDS ARCHIVING

Original consents and any locally generated site level study documents will be maintained on site per HREC requirements and/or site standard operating procedures.
The Sponsor will archive and retain all documents pertaining to the clinical study according to the company procedure.

16.0 USE OF INFORMATION AND AGREEMENTS

Information concerning the medical device, patent applications, processes, unpublished scientific data and other pertinent information is confidential and remains the property of the Sponsor. Details should be disclosed only to the persons involved in the approval or conduct of the clinical study. The investigator may use this information for the purpose of the clinical study only. It is understood by the investigator that the Sponsor will use the information obtained during the clinical study in connection with the clinical evaluation and risk assessment processes of the medical device and therefore may disclose it as required to other clinical investigators or to Regulatory Authorities. In order to allow for the use of the information derived from this clinical study, the

investigator understands that he/she has an obligation to provide the Sponsor with all data obtained during the clinical study. The terms of confidentiality are governed by the clinical study agreement as well as the publication of the clinical study results.
Funding will be provided to the study sites by the Sponsor as described in a clinical study agreement that will be signed by both parties in advance of the study initiation.

17.0 REFERENCES

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