

# Prospective Observational Multicenter Evaluation of the Use of the G7 BiSpherical Shell

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To confirm safety and performance of the G7 BiSpherical Acetabular Shell.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44553

### Source

ToetsingOnline

### Brief title

G7 PMCS study

### Condition

- Bone and joint therapeutic procedures

### Synonym

hip prothesis, Hip wear/osteoarthritis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Zimmer GmbH

**Source(s) of monetary or material Support:** Zimmer Biomet

## Intervention

**Keyword:** G7 BiSpherical Shell, Hip

## Outcome measures

### Primary outcome

Implant survivorship: assessed with the Kaplan-Meier method according to the implant revisions.

### Secondary outcome

1) Clinical efficacy

a. Harris Hip Score

b. Oxford Hip Score

2) Radiographic evaluation

3) Safety: Complications (including dislocations, revisions and removals)

## Study description

### Background summary

The Zimmer Biomet G7 BiSpherical Acetabular Shell belongs to the G7 multi-bearing platform. It was developed to provide an additional surgical option for patients in need of a total hip replacement. The aim of the G7 BiSpherical Acetabular Shell is to increase hip function while reducing pain. This study is a PMCF study to fulfill the post-market surveillance obligations according to Medical Device Directive and MEDDEV 2.12-2.

### Study objective

To confirm safety and performance of the G7 BiSpherical Acetabular Shell.

### Study design

A multicenter, prospective, non-randomized, non-controlled post market surveillance study involving orthopedic surgeons skilled in hip arthroplasty

procedures.

## **Intervention**

Implantation of the G7 bispherical acetabular shell

## **Study burden and risks**

There are no anticipated risks specific to study participation other than the potential loss of confidentiality. There are no experimental procedures in this study, and participation in this study is not anticipated to affect the medical treatment of enrolled patients.

When used in accordance with product labeling, the risks associated with the use of G7 BiSpherical Acetabular Shell are similar to those of standard acetabular cups used for the same clinical indication or purpose.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

- Patient capable of understanding the surgeon's explanations and following his instructions, able and willing to participate in the follow-up program and who gave consent to take part in the study.
- Patients aged of 18 years or more whose skeleton reached bone maturity.
- Noninflammatory degenerative joint disease, including osteoarthritis and avascular necrosis.
- Rheumatoid arthritis.
- Correction of functional deformity.
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures where other treatment or devices have failed.;Inclusion criteria specific for patients receiving the G7 BiSpherical Shell with the Freedom Constrained Liner:
- The Biomet G7 Freedom Constrained Liner is indicated for use as a component of a total hip prosthesis in primary and revision patients at high risk of dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, or intraoperative instability, and for whom all other options to constrained acetabular components have been considered.

## Exclusion criteria

Absolute exclusion criteria are:

- Infection, sepsis, osteomyelitis.;Relative exclusion criteria include:
- Uncooperative patient or patient with neurologic disorders who is incapable of following directions.
- Osteoporosis.
- Metabolic disorders which may impair bone formation.
- Osteomalacia.
- Distant foci of infections which may spread to the implant site.
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram.
- Vascular insufficiency, muscular atrophy, neuromuscular disease.
- Patient unwilling or unable to give consent, or to comply with the follow-up program
- Patient known to be pregnant or breastfeeding.
- Patient presenting any condition that would, in the judgment of the Investigator, place the patient at undue risk or interfere with the study.
- Patient institutionalized or known drug abuser or alcoholic or anyone who cannot understand what is required of them.
- Patient belonging to a vulnerable population.;Exclusion criteria specific for patients receiving the G7 BiSpherical Shell with the G7

Freedom Constrained Liner:

- Bone or musculature compromised by disease, infection, or prior implantation that cannot provide adequate support or fixation for the prosthesis.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 35

Type: Anticipated

### Medical products/devices used

Generic name: G7 BiSpherical Acetabular Shell

Registration: Yes - CE intended use

## Ethics review

Not approved

Date: 24-11-2017

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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## Study registrations

**Followed up by the following (possibly more current) registration**

No registrations found.

**Other (possibly less up-to-date) registrations in this register**

No registrations found.

**In other registers**

Register	ID
ClinicalTrials.gov	NCT03266874
CCMO	NL63474.098.17