Global, Multicenter, and Prospective Post-Market Clinical Follow-Up Study of the Avenir Complete* Femoral Stem (Implants and Instrumentation)

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- Confirming the survivorship under normal use of the Collared and Collarless versions of the Avenir Complete* stem (Standard, High Offset, Coxa Vara) and its instrumentation used in primary total, hemi, or revision hip arthroplasty by recording the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON52310

Source
ToetsingOnline

Brief title
Avenir Complete PMCF

Condition

- Joint disorders

Synonym
arthritis; worn-out hip

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet Nederland bv

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

Intervention

Keyword: Hip Replacement, Osteoarthritis, Uncemented Hip Stem

Outcome measures

Primary outcome

The primary endpoint is defined by the survival of the implant system at 10 years, which is based on the removal or intended removal of the *study device and determined using Kaplan Meier method. The safety of the system will be assessed by monitoring the frequency and incidence of adverse events. Relation of the events to implant, instrumentation and/or procedure should be specified.

Secondary outcome

The secondary endpoints are the assessment of performance and clinical benefits by recording patient-reported clinical outcomes measures (PROMs) as well as radiographic outcomes (if available)

Study description

Background summary

The purpose of the Avenir Complete* stem is to enhance the existing Avenir Müller cementless stem, which has more than 10 years of successful clinical experience. Enhancements include a shortened distal geometry for a better fit, extra sizes, a Coxa Vara offset, and a collared version to help the surgeon reconstructing the patient*s anatomy.
This Post-Market Clinical Follow-up (PMCF) study is intended to fulfil post market surveillance obligations according to Medical Device Directive, MEDDEV 2.12-2 and the Medical Devices Regulation (MDR 2017/745

Study objective

- Confirming the survivorship under normal use of the Collared and Collarless

versions of the Avenir Complete* stem (Standard, High Offset, Coxa Vara) and its instrumentation used in primary total, hemi, or revision hip arthroplasty by recording the incidence and frequency of revisions, complications, and adverse events;
- verifying that, under normal use, the performance and clinical benefits of this device and its instrumentation conform to those intended by the manufacturer by recording patient-reported clinical outcomes measures (PROMs) and radiographic outcomes (if available).

Study design

Global, Multicenter, Prospective, Non-controlled, Non-randomized, Consecutive series of patients.

Intervention

NA

Study burden and risks

No additional risks compared to standard of care.

Contacts

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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 is at least 20 years old or older and skeletally mature.

- Patient is 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;

- Patient qualifies for total hip arthroplasty based on physical exam and medical history including at least one of the following:
o Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases;
o Failed previous hip surgery including:
* joint reconstruction (osteotomy)
* Arthrodesis
* Hemi-arthroplasty or total hip replacement (THR);
o Acute traumatic fracture of the femoral head or neck;
o Avascular necrosis of the femoral head.

Exclusion criteria

- Acute, chronic, local, or systemic infections;
- Severe muscular, neural, or vascular diseases that endanger the limbs involved;
- Lack of bony structures proximal or distal to the joint, so that good anchorage of the implant is unlikely or impossible;
- Total or partial absence of the muscular or ligamentous apparatus;
- Any concomitant diseases that can jeopardize the functioning and the success of the implant;
- Allergy to the implanted material, especially to metal (e.g. cobalt, chromium, etc.);

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2022
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Avenir Complete Hip Stem
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-06-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT04731077
CCMO	NL77682.100.21