Avenir Muller Hip Stem Post-Market Surveillance Study

A multi-center, non-comparative, retrospective post-market surveillance study

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STUDY SPONSOR

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Title:	A multi-centre, non-comparative, retrospective post-market surveillance study to obtain clinical outcomes data on the Zimmer Avenir Müller Hip Stem.
Sponsor:	Zimmer GmbH
Objectives:	The objective of this study is to obtain outcome data on the Avenir Müller Hip Stem by analysis of adverse events records, standard scoring systems, and radiographs. Data will be used to monitor survival, pain and mobility and to confirm safety and efficacy of the Avenir Müller Hip Stem.
Indication/ Target Population:	Patients suffering from severe hip pain and disability requiring a total hip arthroplasty.
Study Design:	Multi-centre, non-comparative, retrospective.
Clinical Phase:	Post-market
Number of Subjects:	A total of 150 patients will be enrolled in a multi-centre setting within Europe.
Length of Study:	Prospectively collected pre and peri-operative baseline data available. Follow-up visits at 3, 5 (optional), 7 and 10 years post-operatively.
Study Device:	Avenir Müller Hip Stem
Comparator Device/ Procedure:	None
Clinical Assessments:	Evaluations will be made using the Harris Hip Score (and/or PMA), and radiographically.
Safety Assessments:	Safety will be assessed by appropriate recording and reporting of adverse events throughout the study. All system components are CE marked and commercially available.
Statistical analysis:	Data collected will be summarized and reported to each participating Investigator. Statistical analysis is conducted by Zimmer or its designee.

General Statistical Method:
Data collected in the study will be summarized. Descriptive summaries will be the basis of study reports to participants.
Summaries will routinely describe categorical data as counts and percentages, and describe continuous data in the form of means, medians, standard deviations, minima, and maxima.
Summaries of variables such as implant survival, return to function or time to event will generally be described via the Kaplan-Meier method and will be accompanied with the corresponding rates (expressed as percentages). Complication data will be summarized in the form of frequencies and percentages. Summaries may be further generated for strata within the study population, such as males/females, body mass index or primary diagnosis.