Post Market Clinical Follow-Up of the Zimmer Stafit Acetabular System

A multicenter, prospective, non-controlled study

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STUDY SPONSOR

ZIMMER GMBH
SULZERALLEE 8
P.O. BOX
CH-8404 WINTERTHUR
SWITZERLAND

Title:	Post Market Clinical Follow-Up Study of the Zimmer Stafit Acetabular System. A multicenter, prospective, non-controlled study.
Sponsor:	Zimmer GmbH
Objectives/ Endpoints:	The objective of this study is to obtain outcome data on the Zimmer Stafit Acetabular System when used in primary total hip arthroplasty. This will be done by analysis of standard scoring systems, radiographs and adverse event records. Data will be used to monitor pain, mobility and implant survival, and to confirm the safety and performance of the Zimmer Stafit Acetabular System. Primary endpoints: • implant survival (Kaplan Meier) • dislocation rate at 2 years Secondary endpoints: • pain and functional performance (HHS) • safety (adverse events) • radiographic parameters
Indication/Target Population:	Patients, suffering from severe hip pain and disability, requiring primary total hip arthroplasty with high risk of dislocation, who meet the inclusion/exclusion criteria (see Section **Error! Reference source not found.**).
Study Design:	Multi-center, prospective, non-controlled.
Clinical Phase:	Post-market
Number of subjects:	A total of 250 patients will be enrolled into the study.
Length of Study:	11.5 years (18 months enrollment plus 10 years follow-up): follow-up visits at 6-12 weeks, 1, 2, 3, 5, 7 and 10 years post-operatively.
Study Device:	Stafit Acetabular System
Scores:	Harris Hip Score (HHS)
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.
Documentation:	Paper

General Statistical Method:

Data collected in the study will be summarized descriptively. Descriptive summaries will be used for the basis of all study reports, including a summary of the clinical performance of the Stafit Acetabular System in primary total hip arthroplasty, and may be used for reports and to support presentations and publications as needed.
Summaries will routinely describe categorical data as counts and percentages, and ninety-five percent confidence limits will be generally used to assess differences over time. Routine summaries describing continuous data will be in the form of means, medians, standard deviations, minima, and maxima, and ninety five percent confidence intervals will be used to contrast differences.
Routine summaries of implant survival will be described using the Kaplan-Meier method. Routine summaries of complication data will be 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.