Alloclassic® Variall® Cup Ceramic Bearing System in Total Hip Arthroplasty

A multi-center, prospective, non-controlled post market surveillance study

PROTOCOL NO. CME2014-03H

NCT NUMBER: NCT03672370

PROTOCOL VERSION:
2014-09 - REV. 01

STUDY SPONSOR

ZIMMER GMBH
ZÄHLERWEG 4
CH-6300 ZUG
SWITZERLAND

Title:	Alloclassic® Variall® Ceramic Bearing System in Total Hip Arthroplasty A multicenter, prospective, non-controlled post market surveillance study
Sponsor:	Zimmer GmbH
Objectives:	The objectives of this study are to obtain survival and outcomes data on the Alloclassic® Variall® Cup in combination with the BIOLOX® delta Taper Liner 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, function and survivorship, and to confirm the safety and performance of the Alloclassic® Variall® Cup Evaluation of squeaking and ceramic fracture rate will be an additional objective. Safety will be evaluated by monitoring the frequency and incidence of adverse events. Performance will be based on the implant survival, the overall pain and functional performances, subject quality-of-life and radiographic parameters of study subjects who received the Alloclassic® Variall® Cup. Pain and functional performance will be measured using the Harris Hip Score, survivorship will be based on removal or intended removal of the device. Subject quality-of-life will be determined by evaluation of the EQ-5D and the Oxford Hip Score, and radiographic parameters by analysis of x-rays.
Indication/ Target Population:	Patients, suffering from severe hip pain and disability requiring total hip arthroplasty, who meet the inclusion/ exclusion criteria.
Study Design:	Multicenter, prospective, non-controlled
Clinical Phase:	Post-market
Number of Subjects:	A total of 100 patients will be enrolled in this study
Length of Study:	12 years (2 year enrollment plus 10 years follow-up): follow-up visits at 3 months, 1, 2, 3, 5, 7, and 10 years post-operatively.
Study Device:	*Alloclassic® Variall® Cup in combination with:* *Ceramic-on-Ceramic Articulation:* *BIOLOX® delta Taper Liner and BIOLOX® delta Femoral Head* *Femoral Component:* *Avenir® uncemented Stem or Alloclassic® Variall® Stem*
Comparator Device/ Procedure:	None
Clinical Assessments:	Evaluations will be made using the Harris Hip Score, Oxford Hip Score, EQ-5D and radiographic evaluation.
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:

The assessment of efficacy for subjects receiving the total hip replacement system will be determined using the overall pain score and functional performance. Clinical success will be defined as a modified Harris Hip score of > 80 that included a rating of 'mild', or 'no pain'; a failure will be defined as a modified Harris Hip score < 80. Any study hip that required a subsequent surgical intervention where a stem head, cup, or liner was removed, or where a removal was planned, was considered a failure regardless of the Harris Hip score. Success rates will be expressed as percentages and primary summary results will be presented in tables which will contain the number and percentage of patients classified as a clinical success for the treatment group.

The assessment of safety will be evaluated by monitoring the frequency and incidence of adverse device effects in investigational subjects. As part of the safety profile, a survival analysis will be done.

Additionally, there are measures of interest which will be used to assess the investigational device such as radiographic success, all components included in the assessment of radiologic success, the EQ-5D, Oxford Hip Score, concomitant medication usage, and incidence of adverse events.