# Continuum™ Metal Bearing System in Total Hip Arthroplasty
# A multi-center, prospective, non-controlled post market surveillance study

**Protocol number: 09-H03**

**Protocol date: 30 August 2012**

**NCT number: 03382652**

# 1 STUDY SYNOPSIS

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| Complete Protocol Title | Continuum™ Metal Bearing System in Total Hip Arthroplasty - A multi-center, prospective, non-controlled post market surveillance study |
| Protocol Number | 09-H03 |
| Short Protocol Title | Continuum™ Metal Bearing System in Total Hip Arthroplasty |
| Sponsor | Zimmer Biomet GmbH |
| Manufacturer | Zimmer Biomet GmbH |
| Study Device(s) | **Investigational devices**<br>1. Continuum™ Acetabular Shell<br>2. Metasul® Taper Liner<br>3. Metasul Femoral Head<br>**Combination device**<br>Zimmer® M/L Taper Hip Stem |
| Study Objectives/Endpoints | The objectives of this study are to obtain survival and outcome data on the Continuum Metal Bearing 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 survivorship, and to confirm the safety and performance of the Continuum Metal Bearing System.<br>Safety will be evaluated by monitoring the frequency and incidence of adverse events.<br>Performance will be determined by comparing the overall pain and functional performances, survivorship, subject quality-of-life and radiographic parameters of study subjects who received the Continuum Metal Bearing System.<br>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 SF-12, and radiographic parameters by analysis of x-rays.<br>In addition, metal ion levels (cobalt, chromium and titanium) and renal function (BUN, Creatinine and GFR) will also be analyzed preoperatively and again at 6 months, 1, 2 and 5 years. |
| Indications/Target Population | Patients, suffering from severe hip pain and disability requiring total hip arthroplasty. |
| Inclusion/Exclusion Criteria | **Inclusion Criteria**<br>• Patient is 18 to 75 years of age, inclusive.<br>• Patient is skeletally mature. |

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| | • Patient qualifies for primary unilateral or bilateral total hip arthroplasty (THA) based on physical exam and medical history including the following:<br>  ○ Avascular necrosis (AVN)<br>  ○ Osteoarthritis (OA)<br>  ○ Inflammatory arthritis (i.e. Rheumatoid arthritis)<br>  ○ Post-traumatic arthritis<br>• Patient has no history of previous prosthetic replacement device (any type, including surface replacement arthroplasty, endoprosthesis, etc.) of the affected hip joint(s).<br>• Patient has a Harris Hip Score <70 in the affected hip<br>• Patient is willing and able to provide written informed consent.<br>• Patient is willing and able to cooperate in the required post-operative therapy.<br>• Patient is willing and able to complete scheduled follow-up evaluations as described in the Informed Consent.<br>• Patient has participated in the Informed Consent process and has signed the Ethics Committee approved informed consent.<br><br>**Exclusion Criteria**<br>• The patient is:<br>  ○ A prisoner<br>  ○ Mentally incompetent or unable to understand what participation in the study details.<br>  ○ A known alcohol or drug abuser<br>  ○ Anticipated to be non-compliant.<br>• The patient has a neuromuscular disorder, vascular disorder or other conditions that could contribute to prosthesis instability, prosthesis fixation failure, or complications in postoperative care.<br>• The patient has a neurologic condition in the ipsalateral or contralateral limb which affects lower limb function.<br>• The patient has a diagnosed systemic disease that could affect his/her safety or the study outcome.<br>• The patient is known to be pregnant.<br>• The patient is unwilling or unable to give consent, or to comply with the follow-up program.<br>• The patient has received an investigational drug or device within the previous 6 months.<br>• The patient has an active or latent infection in or about the affected hip joint or an infection distant from the hip joint that may spread to the hip |

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| | hematogenously.<br>• The patient has insufficient bone stock to fix the component. Insufficient bone stock exists in the presence of metabolic bone disease (i.e. osteoporosis), cancer, and radiation. Note: Dual Energy X-ray Absorptiometry (DEXA) may be used to assess the presence of adequate bone stock.<br>• The patient has known local bone tumors and/or cysts in the operative hip.<br>• The patient has a known allergic reaction to one or more of the implanted material.<br>• The patient is Grade III obese with a Body Mass Index (BMI) ≥ 40.<br>• The patient has osteoradionecrosis in the affected hip joint<br>• Kidney insufficiency (Kidney insufficiency will be determined based on eGFR value.) |
| Study Design | Multi-center, prospective, non-controlled. |
| Clinical Phase | Post-market |
| Sample Size | A total of 100 patients will be enrolled into the study. |
| Length of Study | 11 years (1 years of enrollment (all sites) and 10 years of follow-up) |
| Materials and Methods | Case report forms will be completed at Pre-op, Surgery, Immediate Post-op, and the 6 weeks, 6 months, 1, 2, 3, 5, 7 and 10 years intervals. |
| Data Collection | Electronic |
| Statistical Reporting | Data collected will be summarized and reported to each participating investigator. Statistical analysis will be conducted by Zimmer Biomet or its designee. Survivorship will be evaluated using Kaplan-Meier. |
| Scores/Performance Assessments | Evaluations will be made using the Harris Hip Score (HHS), SF-12, EuroQol (EQ-5D) and Oxford Hip Score (optional). |
| Standards | The PMCF is compliant with the below:<br>• ISO 14155 Standard for the Clinical Investigation of Medical Devices (part 1 and 2)<br>• The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects. |
| Study Funding | Funding for this clinical study is made available by Zimmer Biomet to support clinical data collection, IRB/EC review fees and other expenses associated with the conduct and execution of this study protocol as outlined in the fully executed Clinical Trial Agreement. . |

# 2 STATISTICAL ANALYSIS PLAN

## 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 Continuum Metal Bearing 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 and these will be accompanied with the corresponding crude rates (expressed as percentages). 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, (e.g., males and females, at different cut-points in the body mass index continuum, etc.).

Patient confidentiality will be protected at all times, and patient identifiers will not be included in study summaries.