# A Multi-Centre, Prospective Study to Obtain Survival and Clinical Outcome Data on the Zimmer Hip Resurfacing System utilising the Metasul Monoblock Component™ Cup in a Hip Resurfacing Application with the Durom® Hip Resurfacing Femoral Component

**Protocol number: 09-H00**
**Protocol date: February 15, 2012**

**NCT number: 03681639**

# 1 STUDY SYNOPSIS

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| Complete Protocol Title | A multi-Centre, Prospective Study to Obtain Survival and Clinical Outcome Data on the Zimmer Hip Resurfacing System utilising the Metasul Monoblock Component (MMC) cup in a Hip Resurfacing Application with the Durom Hip Resurfacing Femoral Component |
| Protocol Number | 09-H00 |
| Short Protocol Title | MMC Resurfacing Study |
| Sponsor | Zimmer GmbH |
| Manufacturer | Zimmer GmbH |
| Study Device(s) | Zimmer Hip Resurfacing System (MMC Cup and Durom resurfacing femoral component) |
| Study Objectives/Endpoints | The objective of this study is to obtain survival and outcome data on the Zimmer Hip Resurfacing System.<br><br>This will be assessed 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 efficacy of the Zimmer Hip Resurfacing System.<br><br>Serum metal ion levels (cobalt and chromium) will also be collected pre-operatively and again at 6 months, 1 year, 2 years and 5 years. |
| Indications/Target Population | The Zimmer Hip Resurfacing System is designed for the treatment of degenerative diseases or trauma of the hip. The system is intended to reduce pain and increase hip mobility<br>The Zimmer Hip Resurfacing System may be used for the following indications:<br>➢ Non inflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, primary osteoarthritis and post traumatic arthritis<br>➢ Inflammatory joint disease (IJD), e.g. rheumatoid arthritis |
| Inclusion/Exclusion Criteria | <u>Inclusion Criteria</u><br>After patient eligibility is established and the patient has signed the Ethics Committee<br>approved Informed Consent, the patient must meet the following Inclusion/Exclusion criteria<br>to participate in the clinical study.<br>1. Patient selection without bias to race or gender. |

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| | 2. Patient is ≥ 18 and ≤ 65 years of age.<br>3. Female patients only, if<br>a. Actively practicing a contraceptive method, or<br>b. Surgically sterilized, or<br>c. Post-menopausal<br>4. Pre-operative Harris Hip Score ≤ 70.<br>5. Primary surgical hip candidate, suffering from hip pain and/or disability due to degenerative<br>joint disease (inflammatory or non-inflammatory), based on physical examination and<br>history, which may include the following diagnosis:<br>a. Non-inflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis or<br>osteoarthritis<br>b. Inflammatory joint disease (IJD), e.g., rheumatoid arthritis<br>6. Patient is willing and able to cooperate in prescribed post-operative therapy.<br>7. Patient is willing and able to complete scheduled follow-up evaluations as described in the<br>Informed Consent.<br>8. Patient has participated in the Informed Consent process and has signed an Ethics Committee<br>approved Informed Consent.<br><br><u>Exclusion Criteria</u><br>1. Patient has an acute, chronic, local or systemic infection.<br>2. Patient is skeletally immature.<br>3. Patient is known to be pregnant.<br>4. Patient has a severe muscular, neural or vascular disease that endangers the involved<br>extremity.<br>5. Patient has an insufficient acetabular or femoral bone stock in which good anchorage of<br>the implants are unlikely or impossible, including, but not limited to:<br>a. patient with severe osteopenia,<br>b. patients with a family history of severe osteoporosis or osteopenia,<br>c. patients with osteonecrosis or avascular necrosis (AVN) with >50% involvement of |

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| | the femoral head (regardless of FICAT grade), or<br>d. patients with local bone tumors and/or cysts of the femoral head > 1 cm<br>6. Patient has a total or partial absence of the muscular or ligamentous apparatus.<br>7. Patient has known moderate to severe renal insufficiency.<br>8. Patient has a known clinical condition which may interfere with the patient's outcome,<br>including but not limited to:<br>a. immuno-compromised conditions (AIDS),<br>b. organ transplant,<br>c. high doses of corticosteriods etc<br>9. Patient is severely overweight (BMI > 40)<br>10. Patient is scheduled for simultaneous bilateral total hip replacement.<br>11. OPERATIVE (IPSILATERAL) HIP: Patient has a total prosthetic hip replacement device,<br>surface arthroplasty, endoprosthesis or femoral and/or acetabular osteosynthesis.<br>12. CONTRALATERAL HIP: Patient has had a hip replacement, surface arthroplasty or<br>endoprosthesis, within the past 12 months, unless previously enrolled in this clinical<br>study.<br>13. Patient is:<br>a. a prisoner,<br>b. mentally incompetent,<br>c. a known alcohol or drug abuser,<br>d. anticipated to be non-compliant<br>14. Patient has participated in a study of any other investigational device (drug, device or<br>biologic) within the past 12 months. Exception: previous enrollment in the Zimmer Hip<br>Resurfacing clinical study.<br>15. Patient has a known allergy to one of the constituents of the implant, e.g. cobalt,<br>chromium, nickel, etc. |
| Study Design | A multi-centre, prospective, non-randomised post-market study. To reduce bias a consecutive case series will be |

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| | recruited. Patients will receive the Zimmer Hip Resurfacing System. |
| Clinical Phase | Post-market |
| Sample Size | A total of 100 patients will be enrolled into the study |
| Length of Study | 11 years, 10 year follow-up with 1 year to recruit. Follow-up visits at 6 months, 1, 2, 3, 5, 7 and 10 years post-operatively. |
| Materials and Methods | Case report forms will be completed either in-office, hospital or by phone or mail at Pre-op, Surgery, 6 months, 1-year, 2-year, 3-year 5-year, 7-year, and 10-year intervals. |
| Data Collection | Paper |
| Statistical Reporting | Data collected will be summarised and reported to each participating Investigator. Statistical analysis is conducted by Zimmer or its designee. |
| Scores/Performance 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. |
| Standards | The PMCF is compliant with the below:<br>• ISO 14155: 2020 - Clinical investigation of medical devices for human subjects - Good clinical practice.<br>• The Declaration of Helsinki (DoH) - Ethical principles for medical research involving human subjects.<br>(*) The study protocol was drafted according to another version of the ISO 14155. Adverse Event definitions and reporting are according to ISO 14155:2020. |
| 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

## 2.1 Sample Size

The primary endpoint for this study (in the following 'experimental group') is implant survival at 10 years which is assessed by revision of the Metasul Monoblock Component Cup. A success rate for the experimental group will be calculated using the Kaplan-Meier Survival Estimation.

A success rate of the experimental group of 92.5% at 10 years is assumed, equivalent to the survival rate of the historical group. The historical value is based on figures on ten-year survival data from the Australian Orthopaedic Association National Joint Replacement Registry[10].

Accordingly, a sample size of 80 achieves a 95% confidence interval of 86.7% to 98.3%. A sample size of 100 allows for a yearly attrition rate of 2% over the estimated 10-years period. This sample size estimation was calculated with PASS 11, NCSS, LLC. Kaysville, Utah

## 2.2 Statistical Analysis

Data collected in the study will be summarised descriptively. Descriptive summaries will be the basis of study reports to participants, as well as to generate an overall summary of the clinical performance of the Zimmer Hip Resurfacing System 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 understand those time differences.

Routine summaries of implant survival, return to function, etc. (e.g., time to event) will be described via the Kaplan-Meier method and these will be accompanied with the orresponding 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.