C004287

FIRST AMENDMENT TO THE CLINICAL STUDY AGREEMENT

THIS FIRST AMENDMENT TO THE CLINICAL STUDY AGREEMENT (the "**Agreement**") is effective as of **May 1st** 2017 (the "**Effective Date**") and entered into by and amongst:

Biomet Global Supply Chain Center B.V., a company organized and existing under the laws of the Netherlands and having its registered office at Toermalijnring 600 (3316 LC), Dordrecht, the Netherlands ("**Biomet**");

Orthopaedic dep, Rigshospitalet having its registered office at Blegdamsvej 9, DK-2100 Copenhagen Ø, Denmark ("**Rigshospitalet**");

Gentofte Hospital having its registered office at Kildegardsvej 28, 2900 Hellerup, Denmark ("**Gentofte Hospital**")

Represented by

Dr. M. Petersen, investigator, with its address at Blegdamsvej 9, DK-2100 Copenhagen Ø, Denmark ("**Investigator**").

Rigshospitalet and Gentofte Hospital will be referred to together as "**Institution**". Biomet, Institution and Investigator will be referred to together as the " **Parties**" and each individually as a "**Party**" .

Preliminary Statements

A. Biomet, the Institution and the Investigator have entered into a clinical study agreement in March 1, 2015 for the following projects:

- Project A: "Prospective Randomized RSA study on Echo Bimetric Full Profile stem compared to Bimetric stem"
- Project B: "Prospective RSA study to evaluate the G7 OsseoTi Acetabular cup migration, polyethylene liner wear and patient outcome"
- Project C: "Arcos Revision stem Retrospective Data collection for publication"

("**Clinical Study Agreement**").

B. The Parties have discussed and agreed to amend the terms and conditions of the Clinical Study Agreement.

NOW, THEREFORE, Parties hereby agree as follows:

1. As of the Effective Date, Zimmer GmbH, registered at Sulzerallee 8, 8404 Winterthur, Switzerland, hereby accede and enter into the Clinical Study Agreement. The definition "Biomet or Sponsor" as included in the Clinical Study Agreement, is also deemed to include Zimmer GmbH.

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2. Project B of the Clinical Study Agreement is hereby replaced with the following project: "Arcos Revision stem single center retrospective data collection (Rigshospitalet)"

3. Schedule A of the Clinical Study Agreement is hereby amended and replaced by the following:

- Project A: the Study Protocol titled: "Evaluation of uncemented Echo® Bi-Metric® Full Proximal Profile THA stem versus uncemented Bi-Metric® Porous Primary THA stem in a randomized controlled trial using RSA and DXA" (v 5, 23.11.2015).

- Project B: the Study Protocol titled: "Arcos Revision stem single center retrospective data collection (Rigshospitalet)"

- Project C: Study Protocol titled: "Arcos Revision stem single center retrospective data collection (Gentofte)" (v 5, 7.12.15)

4. In Schedule B of the Clinical Study Agreement the budget details are amended and replaced by the following:

Project A: Complete enrolment of 40 Echo Bi-Metric patients including pre-op and op- data collection.	397 071 DKK
Project C: Complete protocol and collect all required data elements on 128 Arcos patients per the protocol	264 714 DKK **(Paid)**
FROM SIGNED AMENDMENT 2017	
Project A:	
Within 30 days as of Receipt of institution's invoice issued after a 6 months interim report for the project accepted by Zimmer Biomet.	163 909,5 DKK
Within 30 days as of Receipt of institution's invoice issued after a 12 months interim report for the project accepted by Zimmer Biomet.	81 954,75 DKK
Within 30 days as of Receipt of institution's invoice issued after an 18 months interim report for the project accepted by Zimmer Biomet.	81 954,75 DKK
Within 30 days as of Receipt of institution's invoice issued after a 24 months interim report for the project accepted by Zimmer Biomet.	81 954,75 DKK
Within 30 days as of Receipt of institution's invoice issued after a final manuscript accepted by ZB and submitted to peer review journal for publication	245 864,25 DKK
Project B:	
Within 30 days as of Receipt of institution's invoice issued after a 6 months interim report for the project accepted by Zimmer Biomet.	163 909,5 DKK
Within 30 days as of Receipt of institution's	81 954,75 DKK

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invoice issued after a 12 months interim report for the project accepted by Zimmer Biomet.	
Within 30 days as of Receipt of institution's invoice issued after an 18 months interim report for the project accepted by Zimmer Biomet.	81 954,75 DKK
Within 30 days as of Receipt of institution's invoice issued after a final manuscript accepted by ZB and submitted to peer review journal for publication	245 864,25 DKK
Project C:	
Within 30 days as of Receipt of institution's invoice issued after a 6 months interim report for the project accepted by Zimmer Biomet.	163 909,5 DKK
Within 30 days as of Receipt of institution's invoice issued after a final manuscript accepted by ZB and submitted to peer review journal for publication.	245 864,25 DKK
Total	**2 300 880 DKK**

5. During the term of this Agreement, Investigator shall submit reports to Biomet at least every six (6) months ("Reporting Period") beginning three (3) months from the Effective Date. The reports shall state the status and progress of the services in the form of an Interim Research Services Report Form attached hereto as Annex 1 of this Agreement incorporated herein by this reference ("Report"). Investigator understands and agrees that a Report submitted more than thirty (30) days after the end of Reporting Period may be subject to a reminding letter ("Reminder"). If the report is not received within thirty (30) days of such Reminder, the payment for which the Report was required may not be payable by Biomet and may be permanently forfeited by Investigator. If two or more payments are forfeited due to Biomet's receipt of Reports more than thirty (30) days after the Reminder, Biomet may terminate this Agreement pursuant to Section 14.2.

6. All other terms and conditions of the Clinical Study Agreement not specifically altered by this Agreement remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the Parties have executed this Agreement in four (4) originals. Each Party will retain one original thereof.

Biomet GSCC B.V.

Name: Ed Janssens
Title: Director
Date: 21-08-2017

Institution

Herlev og Gentofte Hospital
Hospitalsdirektionen
Herlev Ringvej 75, Opgang 115
2730 Herlev

Name: Pernille Sleszager
Title: Deputy chief executive
Date: 7/7-17

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Institution

Per E. Jørgensen
Deputy Chief Executive, M.D., D.M.Sc.,
MPM RIGSHOSPITALET
Section 9921
Blegdamsvej 9 DK-2100 Copenhagen
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Name:
Title:
Date: 21/6 2017

Investigator

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Name:
Title:
Date: June 19, 2017

Zimmer GmbH

Name: Urs Müller
Title: Sr. Legal Counsel EMEA
Date: 2.05.2017

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Annex 1

INTERIM RESEARCH SERVICES REPORT

Research Services Manager (RSM) will communicate required Interim Report elements to Institution and Investigator. The elements of this Interim Research Services Report form are required and must be provided when completing and submitting a required Interim Research Services Report to Biomet for payment. Only an individual authorized to sign for the Institution can sign as an Authorized Institution Representative. The Investigator can only sign the Institution portion of the certification if he/she is an Authorized Institution Representative.)

Project Title:

Institution:

Principal Investigator:

Co-Investigators:

Report Prepared By:

Zimmer File Number:

Zimmer Research Services Fund Manager (RSM):

Study status and progress:

Have any changes occurred in the Protocol since the last budget report was submitted?

Adverse events/concerns:

Amount of Budget Spent to Date:

Total Project Budget:

Investigator Open Comment Section:

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