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TEST REPORT

No.: 334.091209.10.1408
Date: 12 February 2010
rev. 0

Test Material:	Metasul® LDH® Head Adapter Metasul® LDH® Femoral Head Metasul® Durom® Acetabular Component CLS® Spotorno® Femoral Stem
Test Method:	ISO 14242-1:2002 Implants for surgery - wear of total hip prostheses - Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for tests

Customer:	Testing Laboratory:
RkK GmbH Büro Loretto-Krankenhaus;Mercystraße 6-14 79100 Freiburg	EndoLab Mechanical Engineering GmbH
Responsible: Dipl.-Ing. Thorsten Stolpe	Responsible: Dipl.-Ing. M. Hintner
	Signature: _____ M. Hintner, research engineer
	Signature: _____ Dr. Chr. Kaddick, technical director

Final reports received as soft copies are signed digitally.

Akkreditiert durch Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-P-944.98.07

1 Subcontractors

-none-

2 Specimens

Date of receipt: 08-Dec-2009
Test Period: 23-Dec-2009 to 05-Feb-2009

1 pc. CLS® Spotorno® femoral stem, Ti6Al7Nb ISO 5832-11, 9.0, 12/14, 5° 38', 135°
REF 29.00.39-090, LOT 2418963
EndoLab intern: femoral stem 1.1

1 pc. CLS® Spotorno® femoral stem, Ti6Al7Nb ISO 5832-11, 10.0, 12/14, 5° 38', 135°
REF 29.00.39-100, LOT 2419563
EndoLab® intern: femoral stem 2.1

1 pc. CLS® Spotorno® femoral stem, Ti6Al7Nb ISO 5832-11, 11.25, 12/14, 5° 38', 135°
REF 29.00.39-112, LOT 2511627
EndoLab® intern: femoral stem 2.2

2 pcs. Metasul® LDH® femoral head, CoCrMo ISO 5832-12, 50/P, 18/20, 5° 38'
REF 01.00181.500, LOT 2502542
Not used for testing

1 pc. Metasul® LDH® femoral head, diameter 54mm, CoCrMo ISO 5832-12, 54/T, 18/20, 5° 38'
REF 01.00181.540, LOT 2458362
EndoLab® intern: femoral head 1.1

2 pcs. Metasul® LDH® femoral head, diameter 48 mm, CoCrMo ISO 5832-12, 48/N, 18/20, 5° 38'
REF 01.00181.480, LOT 2495736
Femoral head box labeled with A; EndoLab® intern: femoral head 2.1
Femoral head box labeled with B; EndoLab® intern: femoral head 2.2

1 pc. Metasul® Durom® acetabular cup, CoCrMo ISO 5832-12, D=60/54 mm
REF 01.00214.060, LOT 2487029
EndoLab® intern: acetabular cup 1.1

2 pcs. Metasul® Durom® acetabular cup, CoCrMo ISO 5832-12, D=54/48 mm
REF 01.00214.054, LOT 2499279
Acetabular cup box labeled with A; EndoLab® intern: acetabular cup 2.1
Acetabular cup box labeled with B; EndoLab® intern: acetabular cup 2.2

1 pc. Metasul® head adapter, CoCrMo ISO 5832-12, size L/+4, 12/14 - 18/20
REF 01.00185.147, LOT 2494482
EndoLab® intern: head adapter 1.1

1 pc. Metasul® LDH® head adapter, CoCrMo ISO 5832-12, size M/0, 12/14 - 18/20
REF 01.00185.146, LOT 2506529
EndoLab® intern: head adapter 2.1

1 pc. Metasul® LDH® head adapter, CoCrMo ISO 5832-12, size S/-4, 12/14 - 18/20
REF 01.00185.145, LOT 2499004
EndoLab® intern: head adapter 2.2

Tab. 1: Specimens tested.

	Coupling 1.1	Coupling 2.1	Coupling 2.2
Femoral stem	1.1	2.1	2.2
Femoral stem material	TiAl7Nb	TiAl7Nb	TiAl7Nb
Femoral head	1.1	2.1	2.2
Femoral head diameter [mm]	54	48	48
Femoral head material	CoCrMo	CoCrMo	CoCrMo
Head adapter	1.1	2.1	2.2
Head adapter material	CoCrMo	CoCrMo	CoCrMo
Head adapter Size	'L' +4 12/14-18/20	'M' 0 12/14-18/20	S' -4 12/14-18/20
acetabular cup	1.1	2.1	2.2
Acetabular cup material	CoCrMo	CoCrMo	CoCrMo

Fig. 1: Specimens tested; coupling 1.1.

Fig. 2: Specimens tested; coupling 2.1.

Fig. 3: Specimens tested; coupling 2.2.

3 Objective

The purpose of this test was to determine the wear behavior of the Metasul® LDH® head adapter (size 'L' +4: coupling 1.1, size 'M' 0: coupling 2.1 and size 'S' -4: coupling 2.2) tested in combination with two different femoral head diameters (Ø 54 mm: coupling 1.1 and Ø 48 mm: coupling 2.1 and coupling 2.2).

As instructed by the customer no attempt was made to quantify the amount of wear generated by the acetabular cups.

4 Test Procedure

4.1 Test Standard

ISO 14242-1:2002 Implants for surgery - wear of total hip prostheses - Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for tests (certified)

ISO 14242 – 2: 2000-10-05 (Implants for surgery – wear of total hip prostheses Part2: Methods of measurement) (certified)

4.2 Test Equipment

EndoLab test equipment number(s) used: 249, 250, 252

Fig. 4: EndoLab® six station hip simulator according to ISO 14242-1.

4.3 Test Description

All tests have been performed according to the normative references (ISO) listed above using the parameters specified (see Tab. 2).
A servo hydraulic six station hip simulator (EndoLab, Rosenheim) according to ISO 14242-1 has been used for the test (see Fig. 4). The specimens are oriented in an anatomically correct position and the resulting hip joint force is applied vs. the cup. Consequently, the direction of the force vector is constant regarding the cup and moves regarding the head.

All three in-vivo angular displacements are simulated: Flexion/extension, abduction/adduction and rotation. Please refer to Fig. 5 for the phasing of the individual movements.

Tab. 2: Test parameters used.

Parameter	ISO 14242-1
force curve	double-peak according to PAUL
force is fixed relatively to	cup
force maximum	3.0 kN
frequency	1.0 Hz
cup inclination (reference position)	30°
inclination cup-femoral head	0°
flexion-extension	+25°/-18°
abduction-adduction	-4°/7°+
rotation	-10°/2°+
test fluid	newborn calf serum
Test fluid temperature	37°C±2°C

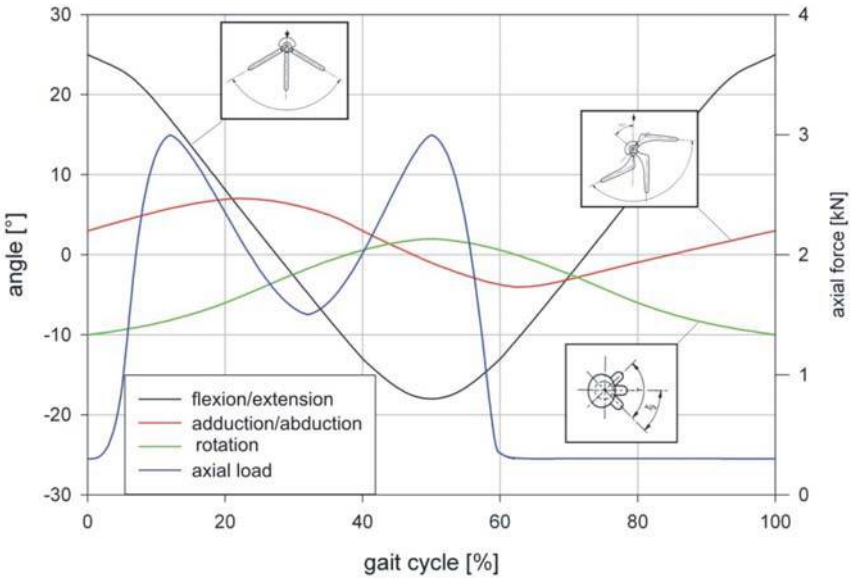

Fig. 5: Kinematics and load profile of the ISO 14242-1 EndoLab® hip simulator.

Fig. 6 shows the set-up for implant fixation and the arrangement for the exclusion of contaminant particles from the outside of the test chamber.

Fig. 6: Single test chamber.

No attempt was made to quantify the wear of the acetabular cup. Therefore the cups were fixed by means of cast resin (PUR) within the upper implant holders (see Fig. 7).

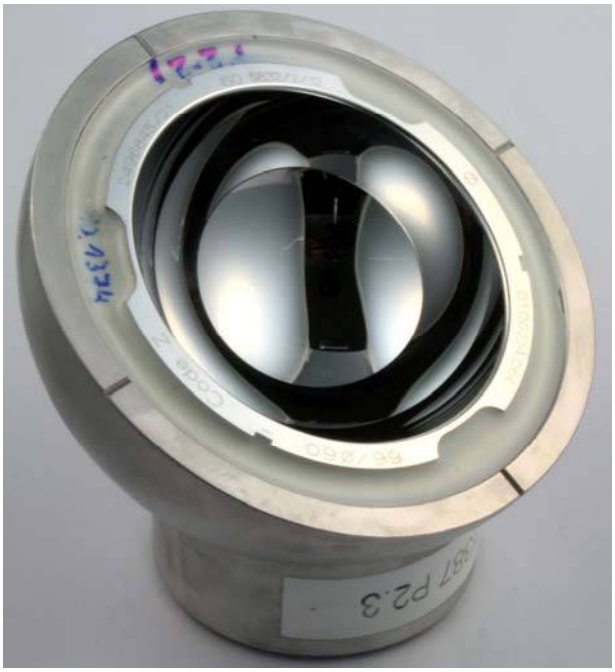

Fig. 7: Fixation of the acetabular cup within the upper implant holder.

In order to allow testing of the femoral stems within the test chamber as shown in Fig. 6 the femoral stems were shortened by EndoLab®. The femoral stems were fixed by means of a filled epoxy cast resin within the lower implant holders. In order to prevent contamination of the test fluid by embedding particles the cured resin was sealed by a silicone film (see Fig. 8).

Fig. 8: Embedded femoral stem. The cast resin was sealed by a silicone film (see red arrow).

EDTA has been added to the serum to bind the calcium phosphate. Patricin (50 µg/ml) has been added to retard bacteria-induced degradation.

Tab. 3: Composition of the serum.

Parameter	
Serum type	calf (newborn)
Lot	0618 S
Protein content	30 g/l
EDTA	2.96 g/l
Patricin (50µg/ml)	10.0 ml/l

Calf serum (Biochrom KG, Berlin, Lot 0618 S) diluted with a resulting protein content of 30 g/l has been used[1].

Cleaning procedure:

Rinse in deionized water
Vibrate for 10 min in deionized water
Vibrate for 10 min in a mixture of ultrasonic cleaning detergent
Rinse in deionized water
Vibrate for 10 min in deionized water
Rinse in deionized water
Vibrate for 3 min in deionized water
Rinse in deionized water
Soak in Isopropanol for 5 min
Dry in a vacuum (0.133 mbar) for 30 min

All mass measurements have been made using high precision balances (Sartorius CP225D and Sartorius ME614S). The technical data of the high precision balances used herein are summarized in the appendix (see Tab. 19 and Tab. 20).

The specimens have been removed at 500,000 cycles, at 1,000,000 cycles, at 2,000,000 cycles and at 2,500,000 cycles to determine the actual mass loss. The serum has been replaced every 500,000 cycles. The specimens have been changed periodically between the different stations.

Due to failure of the lower implant holder of coupling 2.1 after 0.4 million cycles (automatic stop of the simulator), the wear data of coupling 2.1 was determined after 0.4 million cycles.

[1] According to data presented by Noordin et al. (Synovial fluid from patients with prosthetic joint arthoplasty: Protein concentration and in vivo wear of polyethylene. 43 ORS. P 769), the protein concentration has been set to 30 g/l rather than diluting the serum to 25 % as indicated by ISO 14243-1. As shown by Wang et al. (The impact of lubricant protein concentration on the outcome of hip joint simulator wear testing. 25 Soc. Biomat p 178), low protein concentrations may cause unphysiological wear.

4.3.1 Assembly/Disassembly of the femoral stem / head adapter / femoral head construct

Prior to wear testing the implants were assembled with a load of 7.4 kN (see EndoLab® test report 334.091215.10.1411).
After 0.5, 1, 2 and 2.5 million cycles of wear testing the components were disassembled in order to allow mass measurements of the femoral head and head adapter. The disassembly load was determined and the samples were subsequently reassembled with 7.4 kN. The results of the disassembly load are shown in test report 334.091215.10.1411.

4.3.2 Deviation from ISO 14242-1

As instructed by the customer no attempt was made to quantify the wear of the acetabular cups.
Testing was stopped after 2.5 million cycles.

5 Results

5.1 Wear data of the head adapters tested

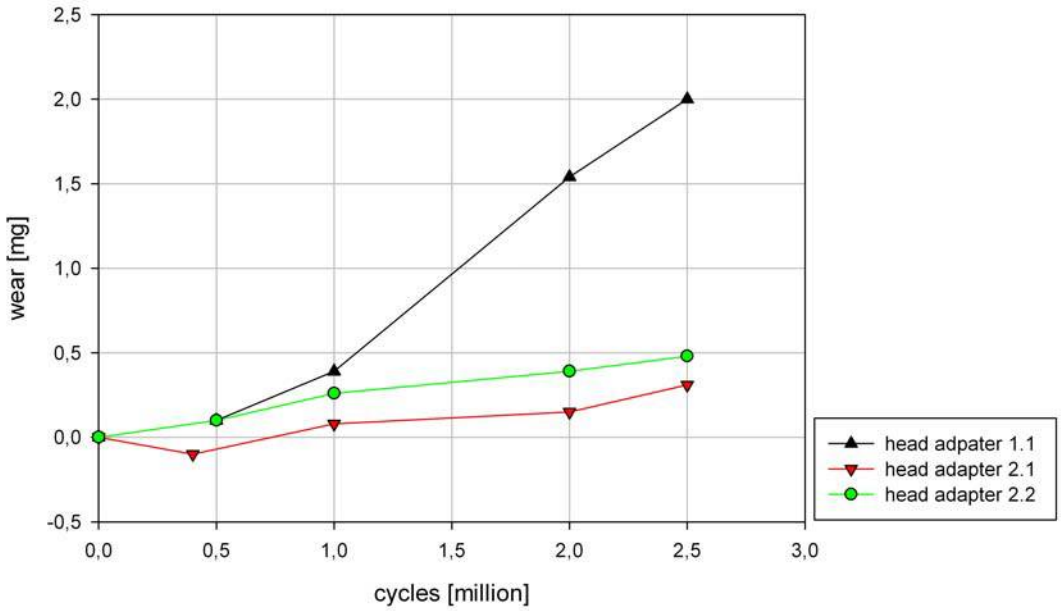

Fig. 9: Wear vs. number of cycles of the head adapters tested.

Tab. 4: Mass measurements and wear results of the head adapters tested of coupling 1.1, coupling 2.1 and coupling 2.2.

coupling ID	1.1		2.1		2.2	
head adapter	1.1	wear	2.1	wear	2.2	wear
cycles [million]	[g]	[mg]	[g]	[mg]	[g]	[mg]
0	30.15702	0.00	27.09755	0.00	21.35283	0.00
0.4 / 0.5 *)	30.15692	0.10	27.09765	-0.10	21.35273	0.10
1.0	30.15663	0.39	27.09747	0.08	21.35257	0.26
2.0	30.15548	1.54	27.09740	0.15	21.35244	0.39
2.5	30.15502	2.00	27.09724	0.31	21.35235	0.48

*) wear data of head adapter 2.1 has been determined after 0.4 million cycles and wear data of head adapter 1.1 and head adapter 2.2 have been determined after 0.5 million cycles (see section 4.3)

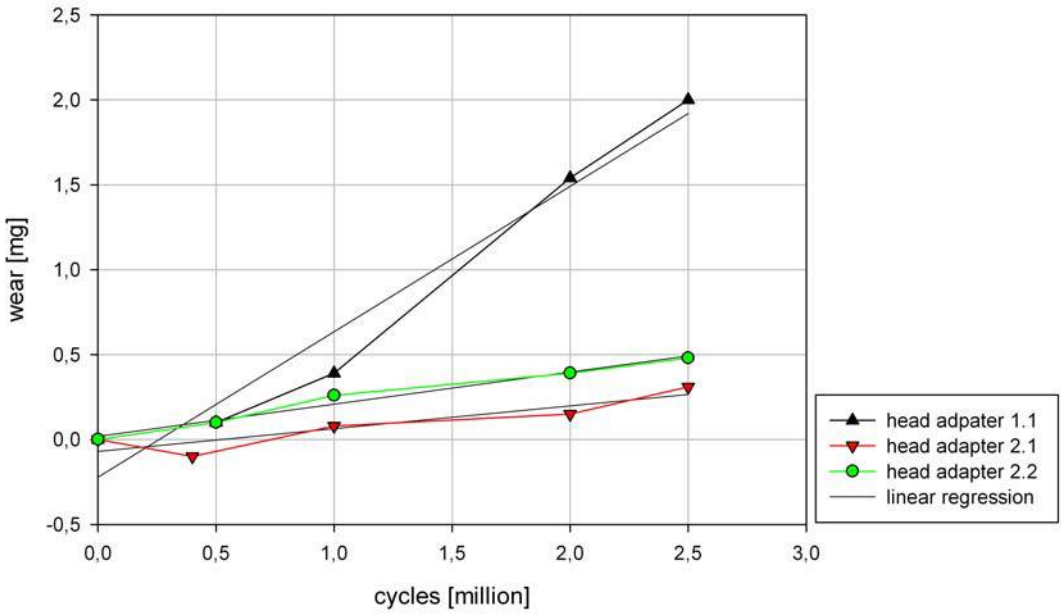

Fig. 10: Linear wear interpolation of the head adapters tested up to 2.5 million cycles, not forcing the regression to pass the origin. The linear interpolation was determined between 0 and 2.5 million cycles.

Tab. 5: Wear interpolation of the head adapter of coupling 1.1 (size 'L' +4). The linear regression was determined between 0 and 2.5 million cycles.

Head adapter ID/ coupling ID	Wear Linear Interpolation [mg/million cycles]	Regression Coefficient r^2
1.1/1.1	0.86	0.96

Tab. 6: Wear interpolation of the head adapter of coupling 2.1 (size 'M' 0). The linear regression was determined between 0 and 2.5 million cycles.

Head adapter ID/ coupling ID	Wear Linear Interpolation [mg/million cycles]	Regression Coefficient r^2
2.1/2.1	0.13	0.83

Tab. 7: Wear interpolation of the head adapter of coupling 2.2 (size 'S' -4). The linear regression was determined between 0 and 2.5 million cycles.

Head adapter ID/ coupling ID	Wear Linear Interpolation [mg/million cycles]	Regression Coefficient r^2
3.1/3.1	0.19	0.98

5.2 Wear data of the femoral heads tested

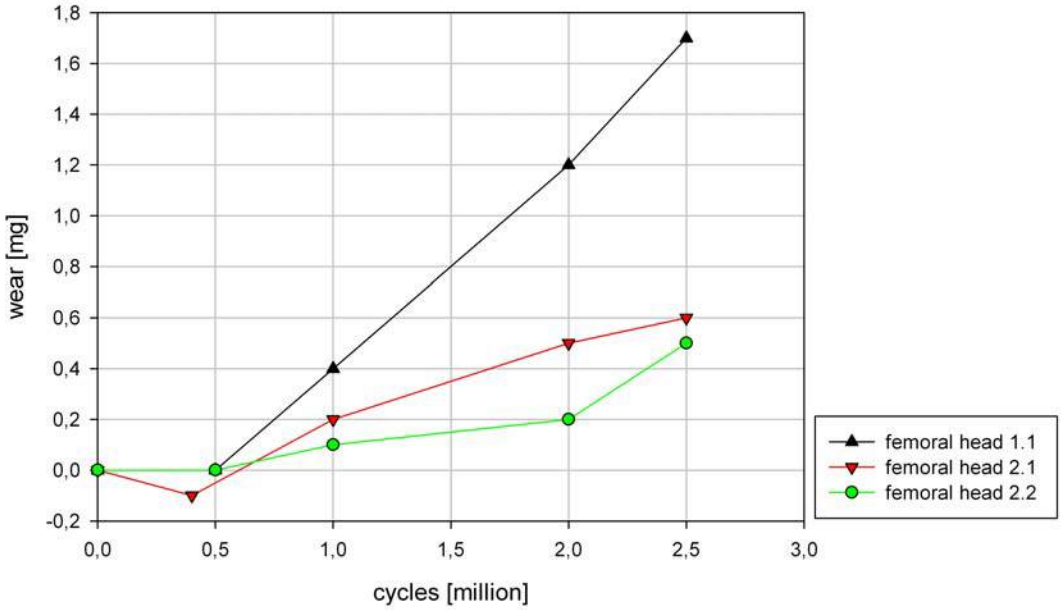

Fig. 11: Wear vs. number of cycles of the femoral heads tested.

Tab. 8: Mass measurements and wear results of the femoral heads tested of coupling 1.1, coupling 2.1 and coupling 2.2.

coupling ID	1.1		2.1		2.2	
femoral head	1.1	wear	2.1	wear	2.2	wear
cycles [million]	[g]	[mg]	[g]	[mg]	[g]	[mg]
0	301.0647	0.0	316.3881	0.0	316.3227	0.0
0.5	301.0647	0.0	316.3882	-0.1	316.3227	0.0
1.0	301.0643	0.4	316.3879	0.2	316.3226	0.1
2.0	301.0635	1.2	316.3876	0.5	316.3225	0.2
2.5	301.0630	1.7	316.3875	0.6	316.3222	0.5

*) wear data of femoral head 2.1 has been determined after 0.4 million cycles and wear data of femoral head 1.1 and femoral head 2.2 have been determined after 0.5 million cycles (see section 4.3)

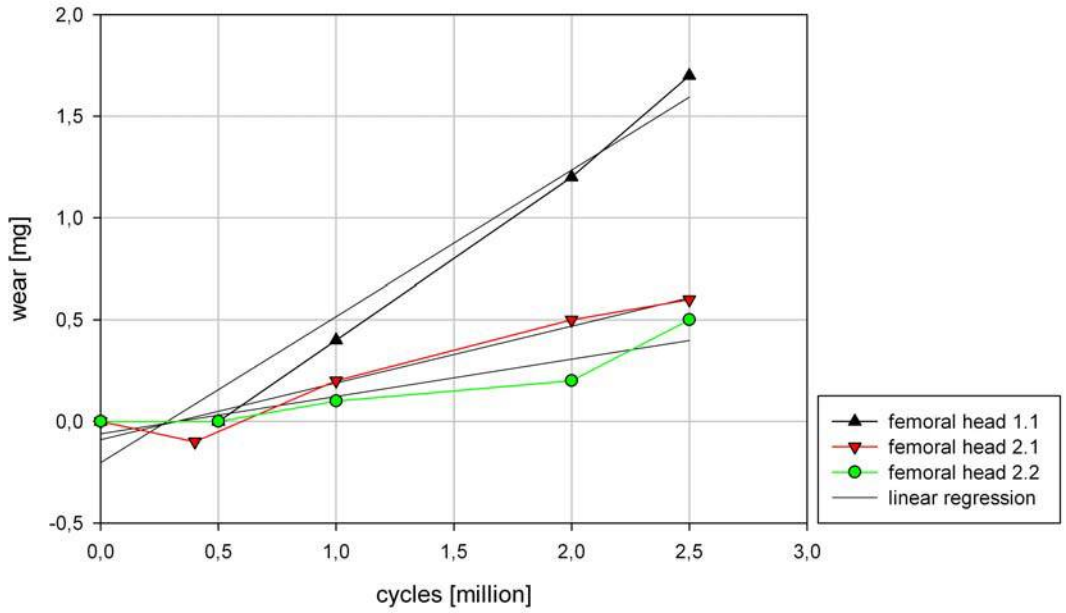

Fig. 12: Linear wear interpolation of the femoral heads tested up to 2.5 million cycles, not forcing the regression to pass the origin. The linear interpolation was determined between 0 and 2.5 million cycles.

Tab. 9: Wear interpolation of the femoral head of coupling 1.1 (diameter 54 mm, tested with head adapter size 'L' +4). The linear regression was determined between 0 and 2.5 million cycles.

Femoral head ID/ coupling ID	Wear Linear Interpolation [mg/million cycles]	Regression Coefficient r^2
1.1/1.1	0.72	0.96

Tab. 10: Wear interpolation of the femoral head of coupling 2.1 (diameter 48 mm, tested with head adapter size 'M' 0). The linear regression was determined between 0 and 2.5 million cycles.

Femoral head ID/ coupling ID	Wear Linear Interpolation [mg/million cycles]	Regression Coefficient r^2
2.1/2.1	0.28	0.94

Tab. 11: Wear interpolation of the femoral head of coupling 2.2 (diameter 48 mm, tested with head adapter size 'S' -4). The linear regression was determined between 0 and 2.5 million cycles.

Femoral head ID/ coupling ID	Wear Linear Interpolation [mg/million cycles]	Regression Coefficient r^2
2.2/2.2	0,18	0,84

6 Summary and Conclusion

The purpose of this test was to determine the wear behavior of the Metasul® LDH® head adapter (size 'L' +4: coupling 1.1, size 'M' 0: coupling 2.1 and size 'S' -4: coupling 2.2) tested in combination with two different femoral head diameters (Ø 54 mm: coupling 1.1 and Ø 48 mm: coupling 2.1 and coupling 2.2). All specimens were tested according to ISO 14242-1 up to 2.5 million cycles.

As instructed by the customer no attempt was made to quantify the amount of wear generated by the acetabular cups.

Prior to wear testing the implants (femoral head / head adapter / femoral stem) were assembled with a load of 7.4 kN (see EndoLab® test report 334.091215.10.1411).

In order to allow mass measurements of the femoral heads and head adapters the components were disassembled after 0.5, 1, 2 and 2.5 million cycles. The required disassembly load was determined and is shown in EndoLab® test report 334.091215.10.1411. After every inspection the samples were reassembled with a load of 7.4 kN before test continuation.

The results of the individual wear rates found herein are summarized in Tab. 12 to Tab. 14 and are shown in Fig. 13

Tab. 12: Summary of the wear results obtained for coupling 1.1. (Femoral head diameter 54 mm and head adapter size 'L' +4).

	wear rate head adapter [mg/million cycles]	wear rate femoral head [mg/million cycles]
coupling 1.1	0.86	0.72

Tab. 13: Summary of the wear results obtained for coupling 2.1. (Femoral head diameter 48 mm and head adapter size 'M' 0).

	wear rate head adapter [mg/million cycles]	wear rate femoral head [mg/million cycles]
coupling 2.1	0.13	0.28

Tab. 14: Summary of the wear results obtained for coupling 2.2. (Femoral head diameter 48 mm and head adapter size 'S' -4).

	wear rate head adapter [mg/million cycles]	wear rate femoral head [mg/million cycles]
coupling 2.2	0.19	0.18

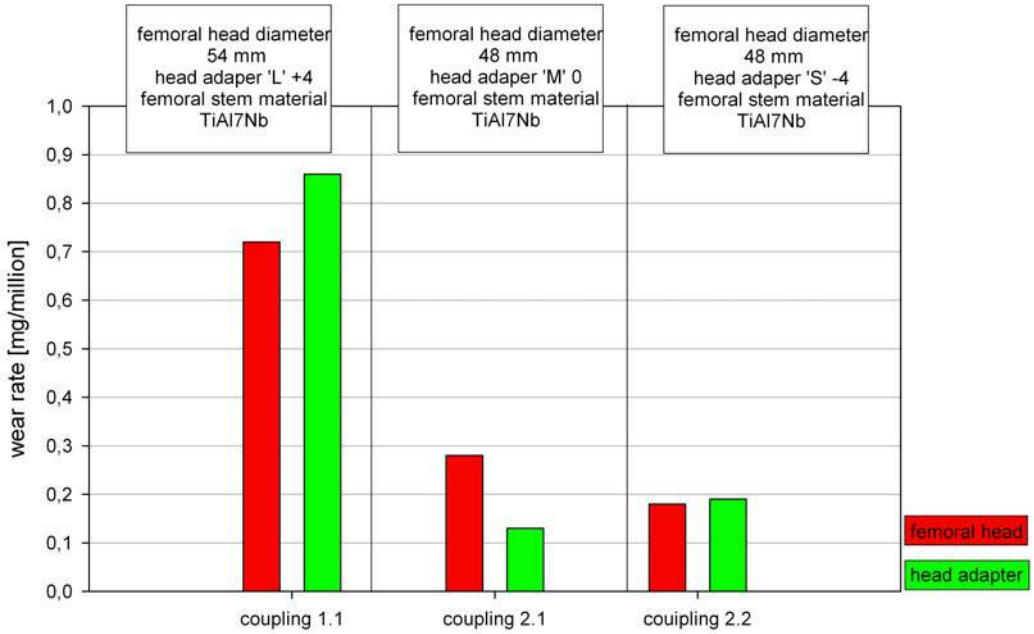

Fig. 13: Summary of the wear results established herein.

The appearance of the contact surface of the head adapters, femoral heads and femoral stems is shown in the appendix. At the femoral head side only minor contact marks were found at the surface of the head adapters. Slightly discoloration of the inner bore (contact with the femoral stem) of the head adapter surface was found.

In order to distinguish between the wear of the head adapters generated at the interface of the femoral head or at the interface of the femoral stem, geometrical measurements of these surfaces are suggested.

The worst case analysis and the implant size selection have been performed by customer.

General remarks: The significance of the test results will depend on the confidence level, reliability level and lot size. This analysis has not been performed by EndoLab® GmbH.

Ziel der Untersuchung war die Ermittlung des Verschleißverhaltens der Metasul® LDH® Kopf Adapter. Unterschiedliche Kugelkopfdurchmesser und Kopf Adapter Größen kamen zur Anwendung. Die getesteten Paarungen sind in Tabelle 15 aufgelistet. Die Prüfung erfolgen nach ISO 14242-1 und die Proben wurden 2,5 Millionen Zyklen getestet.

Die Acetabulum Komponenten (Pfannen) waren während der Testung mittels Polyurethan in den Probenhalterungen fixiert (siehe Fig. 7). Wie mit dem Kunden vereinbart, wurde der Verschleiß der Acetabulum Komponenten nicht ermittelt.

Tab. 15: Geprüfte Paarungen.

	Paarung 1.1	Paarung 2.1	Paarung 2.2
Hüftschaft	1.1	2.1	2.2
Material Hüftschaft	TiAl7Nb	TiAl7Nb	TiAl7Nb
Kugelkopf	1.1	2.1	2.2
Durchmesser Kugelkopf [mm]	54	48	48
Material Kugelkopf	CoCrMo	CoCrMo	CoCrMo
Kopf Adapter	1.1	2.1	2.2
Material Kopf Adapter	CoCrMo	CoCrMo	CoCrMo
Größe Kopf Adapter	'L' +4 12/14-18/20	'M' 0 12/14-18/20	S' -4 12/14-18/20
Acetabulum Komponente	1.1	2.1	2.2
Material Acetabulum Komponente	CoCrMo	CoCrMo	CoCrMo

Vor Versuchsstart wurden die Komponenten (Kugelkopf, Kopf Adapter und Hüftschaft) mit einer Last von 7,4 kN gefügt (siehe Prüfbericht 334.091215.10.1411).

Um eine Gewichtsmessung des Kugelkopfes und der Kopf Adapter zu ermöglichen wurden Kugelkopf, Kopf Adapter und Hüftschaft nach 0,5, 1, 2 und 2,5 Millionen Zyklen wieder getrennt. Die hierfür nötigen Abzugskräfte wurden ermittelt. Die Ergebnisse der Abzugstests sind in Prüfbericht 334.091215.10.1411 zusammengefasst.

Nach jeder Inspektion (nach 0,5, 1, 2 und 2,5 Millionen Zyklen) wurden die Komponenten erneut mit einer Last von 7,4 kN gefügt.

Die Verschleißergebnisse der einzelnen Paarungen sind in Tabelle 16, Tabelle 17, Tabelle 18 und in Abbildung 14 zusammengefasst.

Tab. 16: Zusammenfassung der Ergebnisse der Paarung 1.1. (Durchmesser Kugelkopf 54 mm, Kopf Adapter Größe ‚L' +4)

	Verschleißrate Kopf Adapter [mg/Million Zyklen]	Verschleißrate Kugelkopf [mg/Million Zyklen]
Paarung 1.1	0,86	0,72

Tab. 17: Zusammenfassung der Ergebnisse der Paarung 2.1. (Durchmesser Kugelkopf 48 mm, Kopf Adapter Größe ‚M' 0).

	Verschleißrate Kopf Adapter [mg/Million Zyklen]	Verschleißrate Kugelkopf [mg/Million Zyklen]
Paarung 2.1	0,13	0,28

Tab. 18: Zusammenfassung der Ergebnisse der Paarung 2.2. (Durchmesser Kugelkopf 48 mm, Kopf Adapter Größe ‚S' -4).

	Verschleißrate Kopf Adapter [mg/Million Zyklen]	Verschleißrate Kugelkopf [mg/Million Zyklen]
Paarung 2.2	0,19	0,18

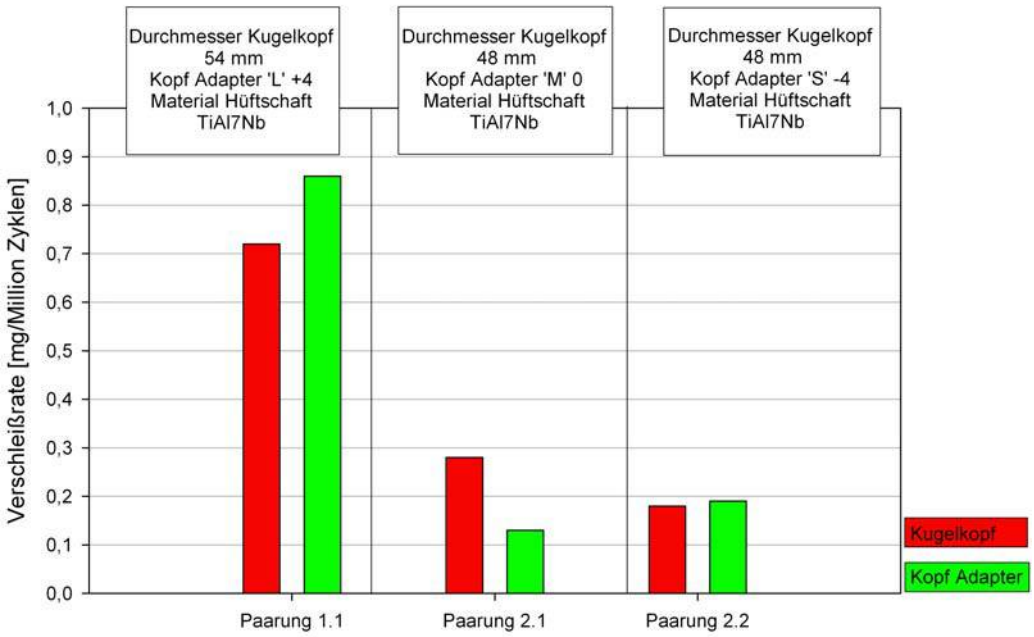

Fig. 14: Zusammenfassung der ermittelten Verschleißraten.

Bilder der Kontaktflächen der Kopf Adapter, Kugelköpfe und Hüftschäfte sind im Anhang gezeigt.

Der Verschleiß der Kopf Adapter kann zwischen Innenkonus Kugelkopf und Außenkonus Kopf Adapter beziehungsweise zwischen Innenkonus Kopf Adapter und Hüftschaftkonus entstanden sein. Um eine Gewichtung des am Innenkonus bzw. Außenkonus entstandenen Verschleißes vornehmen zu können, wird eine Vermessung der Oberfläche (Innenkonus und Außenkonus) der Kopf Adapter empfohlen.

Appendix A

Contact surface of the head adapters after 2.5 million cycles

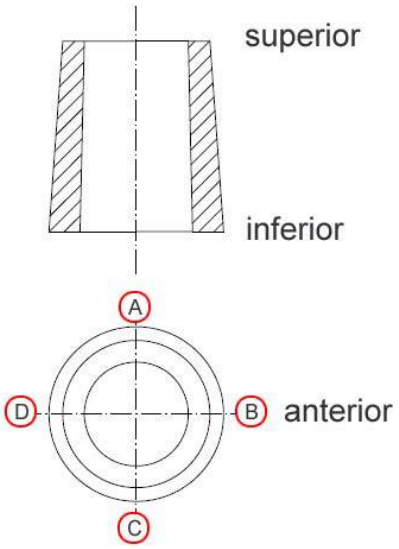

Fig. 15: Locations of the images taken of the contact surface of the head adapter (femoral head side)

Fig. 16: Head adapter 1.1. Contact surface femoral head side.
Top: at location A and at location B (from left to right)
Bottom: at location C and at location D (from left to right)

Fig. 17: Head adapter 1.1. Contact surface femoral stem side. (The red arrow marks location A, see Fig. 15)

Fig. 18: Head adapter 2.1. Contact surface femoral head side.
Top: at location A and at location B (from left to right)
Bottom: at location C and at location D (from left to right)

Fig. 19: Head adapter 2.1. Contact surface femoral stem side. (The red arrow marks location A, see Fig. 15)

Fig. 20: Head adapter 2.2. Contact surface femoral head side.

Top: at location A and at location B (from left to right)

Bottom: at location C and at location D (from left to right)

Fig. 21: Head adapter 2.2. Contact surface femoral stem side. (The red arrow marks location A, see Fig. 15)

Appendix B

Contact surface of the femoral stems after 2.5 million cycles

Fig. 22: Femoral stem 1.1 after 2.5 million cycles. Contact surface femoral head side.

Top: view from superior and view from inferior (from left to right)

Bottom: view from anterior and view from posterior (from left to right)

Fig. 23: Femoral stem 2.1 after 2.5 million cycles. Contact surface femoral head side.

Top: view from superior and view from inferior (from left to right)

Bottom: view from anterior and view from posterior (from left to right)

Fig. 24: Femoral stem 2.2 after 2.5 million cycles. Contact surface femoral head side.

Top: view from superior and view from inferior (from left to right)

Bottom: view from anterior and view from posterior (from left to right)

Appendix C

Contact surface (head adapter side) of the femoral heads after 2.5 million cycles

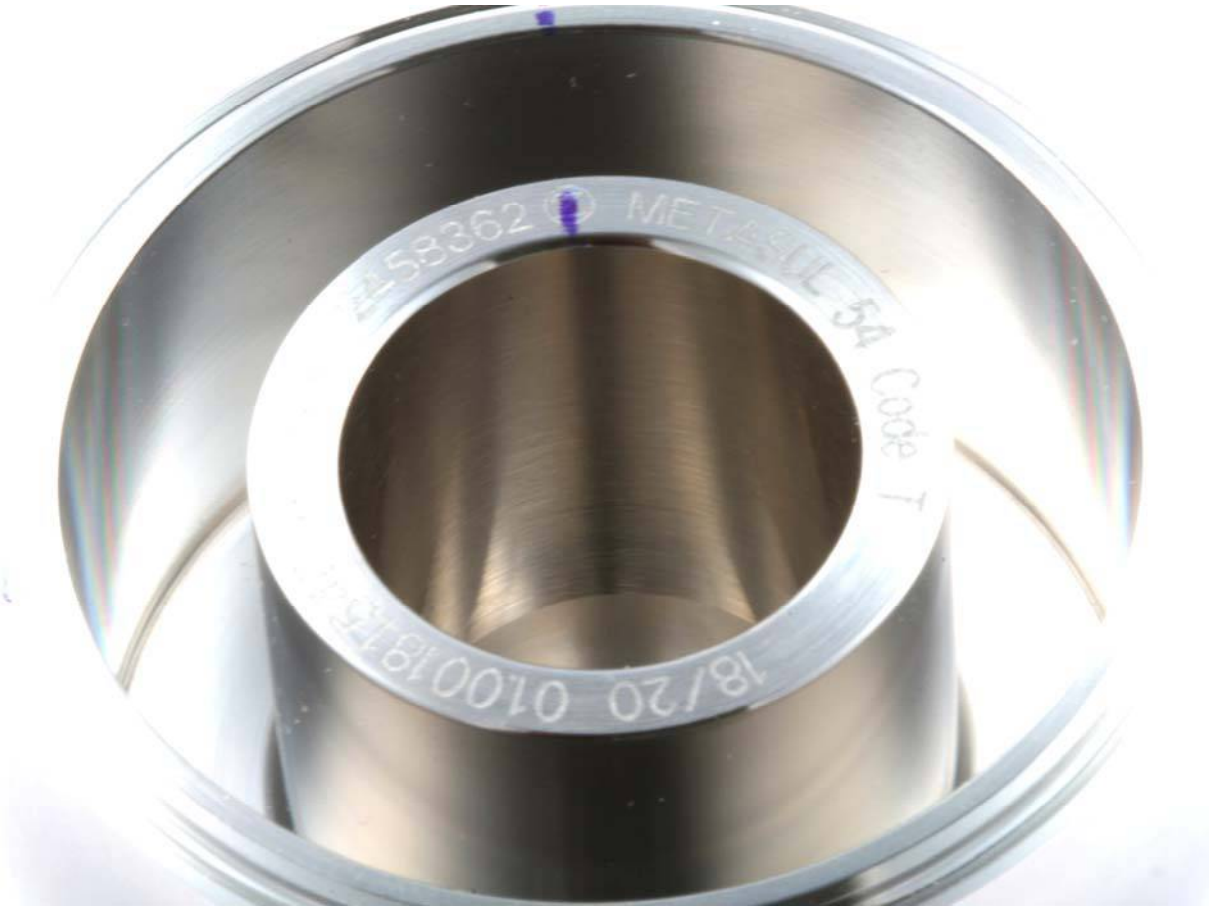

Fig. 25: Femoral head 1.1 after 2.5 million cycles. The anterior position is orientated to the left side of the picture.

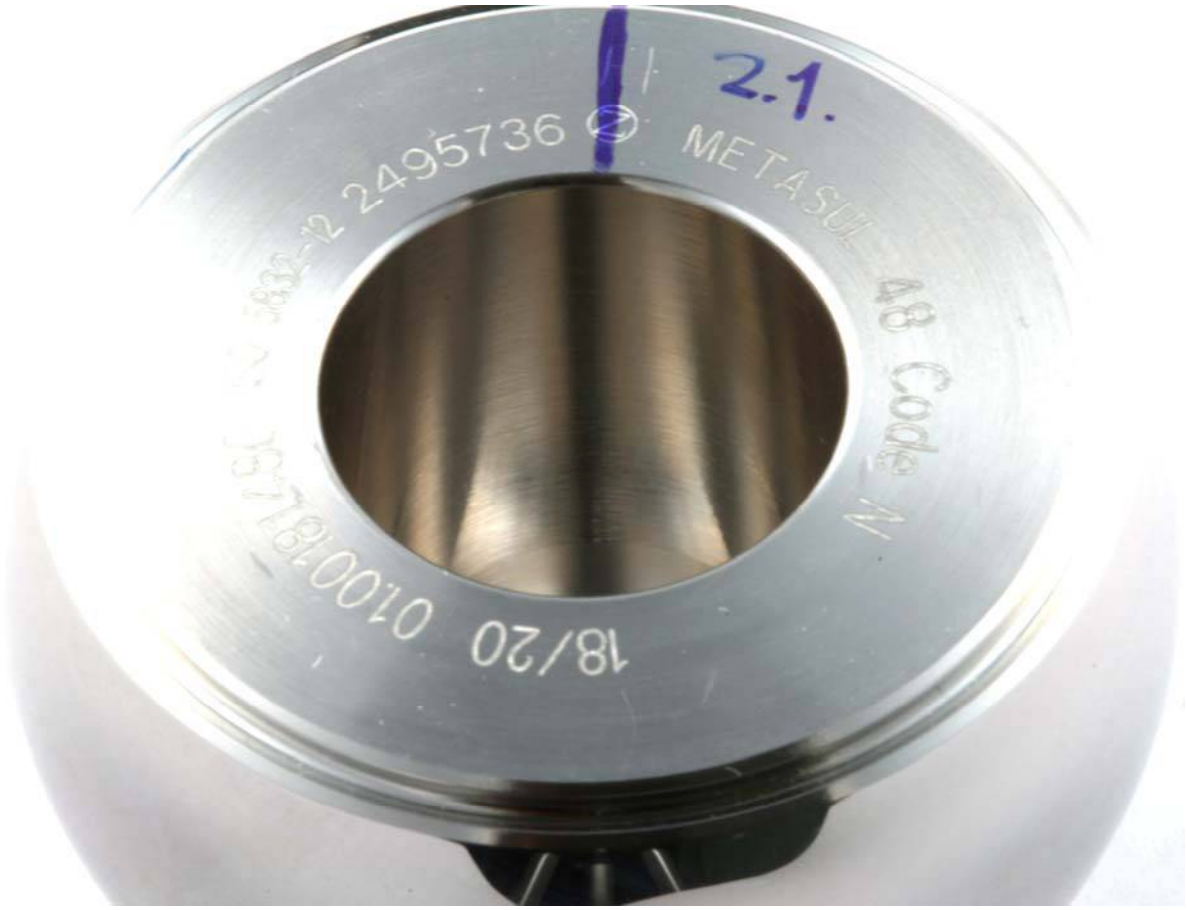

Fig. 26: Femoral head 2.1 after 2.5 million cycles. The anterior position is orientated to the left side of the picture.

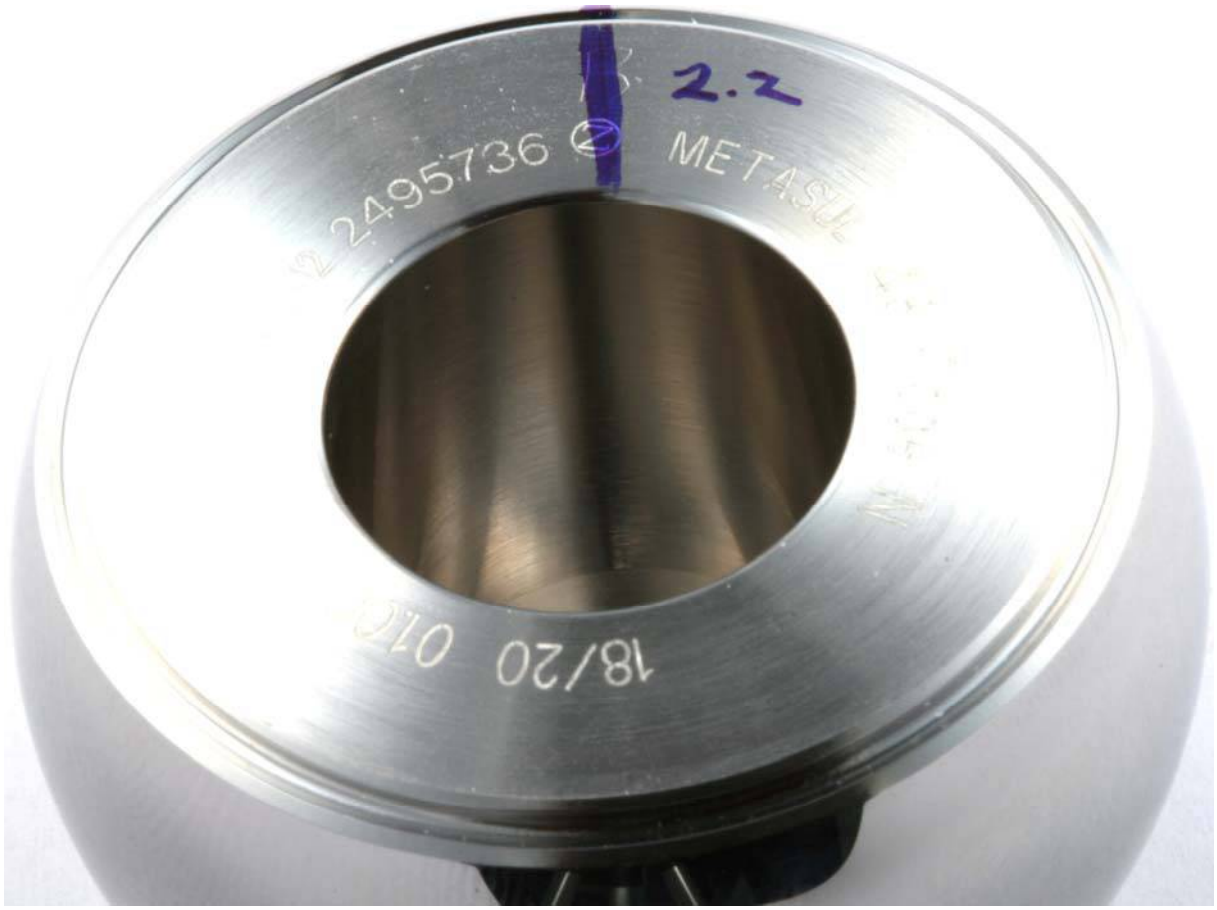

Fig. 27: Femoral head 2.2 after 2.5 million cycles. The anterior position is orientated to the left side of the picture.

Appendix D

Tab. 19: Technical data of high precision balance Sartorius CP225D.

Parameter	0-40 g	40-80 g	80-220 g
readability [mg]	0.01	0.01	0.1
repeatability ≤± [mg]	0.02	0.05	0.1
max. linearity ≤± [mg]	0.03	0.1	0.2

Tab. 20: Technical data of high precision balance Sartorius ME614S.

Parameter	0-610 g
readability [mg]	0.1
repeatability ≤± [mg]	0.1
max. linearity ≤± [mg]	0.5