

ReCap®

Total Resurfacing System



ReCap®

Technical Design Rationale

System Description

The ReCap® Metal-Metal Resurfacing System removes a minimal amount of bone from the femur and acetabulum and reproduces the patients natural anatomy. Designed to replace the similar sized femoral head/acetabular articulation, it combines a cemented femoral resurfacing device and a thin walled, one piece acetabular component.

Both components are made from 'as-cast' cobalt chrome.

Femoral Component

The outer geometry is highly polished and the inner geometry incorporates an Interlok® grit blast finish, to enhance the bone/implant interface.

The interior geometry is formed from a spherical dome that transitions to a short cylindrical region. The sphere is tangential to the cylindrical region. The implant is designed to remove a constant amount of bone from the apex of the femoral head on all sizes (6mm). The inner geometry grows with every two millimetre increment in outer diameter sizing. The central cylindrical post extends beyond the face of the spherical head and the length increases with increasing head diameter. The stem diameter is constant on all sizes, and has three flutes.



The outside geometry of the device is highly polished and held to a sphericity of less than 5 micrometres and extends approximately 23 degrees beyond a full hemisphere. Sizes of the component range from 38mm to 60mm in 2mm increments.

Fixation is obtained through a 0.5mm cement mantle. The central post is designed to aid alignment of the implant but not for load transfer.

Acetabular Component

The ReCap® cup is a one piece press-fit design that has a titanium plasma spray outer surface and a highly polished inner geometry. The exterior geometry contains 4 pairs of fins to enhance rotational stability and initial fixation. The outside geometry is hemispherical, with four recesses for attachment of the impaction device. Press-fit is achieved through under-reaming the acetabulum, typically by 2mm. The inner geometry is the bearing surface, which articulates against the femoral head.



The acetabular component comes with an outer diameter of 44mm to 66mm in 2mm increments and an inner geometry of 38mm to 60mm again in 2mm increments, to exactly match the femoral head diameters.

Material

Metal-on-metal bearing systems for hip joint replacements provide extremely low wear rates in-vivo, and avoid the problems caused by polyethylene debris generated in metal/UHMWPE articulations.

CoCrMo alloys are widely used and are available in several forms:

- Castings
- Forgings
- Powder Metallurgy

Most cast materials are Hot Isostatically Pressed (HIP) and Heat Treated (HT) to facilitate machining or because the components have a sintered porous coating. The HIP/HT processes dissolve some of the carbides, potentially compromising abrasive wear resistance.

Recent work has shown that 'as-cast' CoCrMo materials meeting the requirements of ISO 5832-4 (ASTM F75) provide superior wear resistance

The ReCap® Resurfacing System uses high carbon (>0.2%) 'as-cast' CoCrMo to the same material specification and from the same casting supplier as that of the most commonly used system.

"As-cast materials were determined to have greater abrasive wear resistance when compared to single or multiple heat treated materials"

"A tribological study of cobalt chromium molybdenum alloys used in metal-on-metal resurfacing hip arthroplasty", J. Cawley, J.E.P. Metcalf, A.H. Jones, T.J. Band and D.S. Skupien, Wear 255 (2003), 999-1006

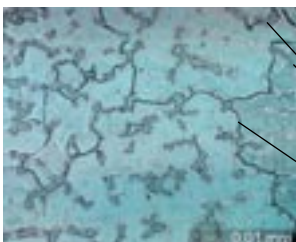
'AS-CAST'



CAST + HT



Solution treatment dissolves some of the carbides, which can reduce abrasive wear resistance



The Biomet 'as-cast' material has a combination of fine grain size for fatigue resistance and high carbide volume fraction for wear resistance

Carbides

Grain boundary

Validation of Metal on Metal

First Generation Metal on Metal

Sivash – 1959, 28 mm Diameter Head

Stanmore – 1961

Ring – 1964, 40mm Diameter Head

Müller – 1965, 37 and 42mm Diameter Heads

McKee-Farrar – 1965, 38 and 41mm Diameter Heads



First Generation M-M Experience: Design and Material Challenges

- First material was stainless steel; Philip Wiles, 1938, England
- Improper clearance; Components hand ground and lap fitted together
- Equatorial loading devices; Design tolerance, Roundness/Sphericity
- Surface finish; 0.1 to 1 micron

Devices with appropriate tolerances at more than 20 years in vivo show us a couple of key points

- Volumetric wear
 - McKee-Farrar Metal/Metal $0.7 \text{ mm}^3/\text{year}$ *in vivo* compared to Traditional Metal/UHMWPE is 50 to $100 \text{ mm}^3/\text{year}$ *in vivo*
- Benign tissue reaction of Metal/Metal vs. Metal/UHMWPE
- No noticeable tissue response with Metal/Metal

From the McKee Farrar retrievals

Average mismatch	200 μm
Average wear	3.3 $\mu\text{m}/\text{year}$
One case had a mismatch of	1728 μm
Wear rate	62 $\mu\text{m}/\text{year}$

Ref: McKellop H, et al. *In vivo* wear of 3 types of metal on metal prostheses during 2 decades of use. Clin. Orthop. **329S** 1996

Biomet has been designing and manufacturing modern metal on metal hip articulations for over eight years. This started out with the introduction of the M2a Ringloc in Europe and the launch of the M2a Taper in the United States

1. 28mm M2a-RingLoc™ System (May 1996)
2. 28mm M2a-Taper™ Acetabular Component (May 2000)
3. 32mm M2a-Taper™ Acetabular Component (September 2000)
4. M2a-38™ System (November 2001)
5. ReCap® Total Resurfacing System (June 2003)
6. M2a-Magnum™ System (October 2004)

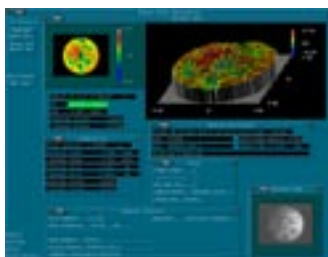


Manufacturing Processes

While casting, turning and milling are standard manufacturing processes for many orthopaedic implants, the exacting demands on Metal/Metal articulating surfaces require specialist “super-finishing”. This is achieved through honing; honing is a final finishing operation conducted on the bearing surfaces, abrasive stones are used to remove minute amounts of material in order to tighten the tolerance on sphericity and achieve the required surface finish.



Each ReCap® component is 100% inspected to ensure the precise manufacturing tolerances have been achieved. Major dimensions are checked by a co-ordinate measuring machine and the sphericity of the surface is checked using non-contacting light interferometry; the reading for each implant is recorded and stored on file.



Simulator Testing

Biomet has on file an array of wear testing carried out over the years due to our ongoing developments of metal on metal bearings, these range from simulator studies looking at the effect of radial clearance and bearing diameters from 28mm to 56mm.

When running hard bearings, a biphasic wear pattern is generally seen, with a higher initial 'run in' wear rate lasting typically 1-1.5 million cycles followed by an extremely low level of steady state wear. The 'run in' wear is during the time when the components are bedding themselves in and effectively polishing themselves into a closely conforming contact. The degree of this wear is dependent on radial clearance, material and manufacturing capability ie control of sphericity, tolerances and surface finish.

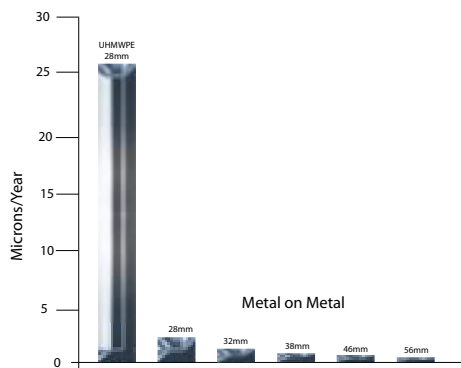
Since 38mm bearings had already been tested for the M2a-38™ system, simulator studies carried out for ReCap® and M2a-Magnum™ utilised 46mm (7 samples) and 56mm bearings (8 samples). 56mm was the largest bearing tested, as the simulator cannot accommodate bearings any larger (ReCap™ goes up to 60mm) These tests were run to 10 million cycles.



Components from these tests were manufactured with clearances such that they had a similar effective radius as previous studies on 32mm and 38mm systems. Effective radius is the radius of a ball that when loaded against a flat surface would have the same contact stress as the equivalent ball in socket with a specified clearance.

The effect of clearance and effective radius were not seen in the range of values examined, therefore it was decided that the tolerance for the radial clearance should be maintained within 53 – 247 micrometres, in fact the range of clearance used with ReCap™ and Magnum™ are 75-150 micrometres.

The 'run in' effect seen during hip simulator wear testing of metal on metal components was evident in this testing as there was a ten fold reduction in wear during steady state. Steady state volumetric wear was 0.19 and 0.20mm³/million cycles for the 46mm and 56mm bearings respectively



The 56mm components from these wear studies were also used to determine the torsional moments experienced during articulation. It was found that the torsional moments experienced by these large diameter metal on metal components was equivalent or lower than that seen with 28mm metal on UHMWPE components and several orders of magnitude less than that required to rotate a plasma spray porous coated 56mm shell (Markel et al. "Initial Scratch-Fit Stability of Acetabular Cups: Comparison of Three Porous Coating System", ISTA 1995)

Proven Fixation Methods – Plasma Spray Porous Coating

Biomet was the first orthopaedic company to introduce a plasma sprayed prosthesis with the release of the Porous Plasma Spray (PPS™) Taperloc® Hip in 1982.

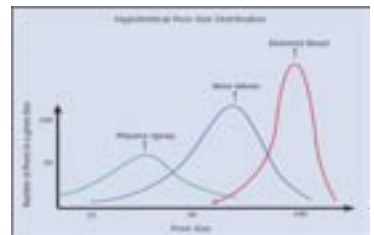
Three main features differentiate PPS™ from competing coatings;

1. The substrate's retention of fatigue strength
2. The initial scratch fit fixation of the implant
3. The sealed, anti-osteolytic "non-interconnected" pore structure.

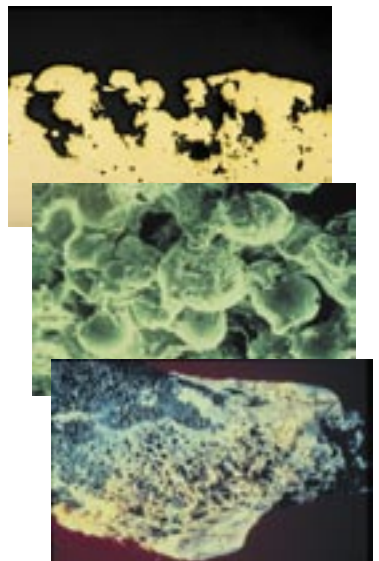


Because the heating effect in the PPS™ process is transient (lasting only for milliseconds) the substrate material remains virtually unaffected, fatigue properties are maintained such that small femoral components are possible with this process, and importantly for ReCap®, the carbide structure is unaffected.

The process leads to a random pore size distribution with both small and large pores. This allows for early and late stage fixation through mechanical interlocking (scratch-fit) followed by gradual osseointegration. During implantation the coating bites into the bone effectively providing autologous bone graft seating in the pores which provides advantageous condition for subsequent bone interdigitation.



Finally the nature of the coating means that the pores are not interconnected, this means there are no pathways for debris to migrate.



Clinical History of PPS™ Implants

- 99.5% Survivorship 12 years

- 188 THR

- No cases of Osteolysis

Head WC, et al. "Twelve Years with a Primary Press-Fit Stem" March 2001

- 100% Survivorship 10.4 years

- 105 THR

- No Cases of Osteolysis

- No Revisions

Meding, et al. "Minimum 10-Year Follow-Up of a Straight Stem, Plasma Sprayed, Titanium THR" March 2001

- 99.6% Survivorship 12 years

- 4,750 THR

- No Case of Osteolysis

Rothman RH, et al " 10 Year Minimum Follow-Up with a Titanium Cementless Femoral Component in Primary THR"

- 98% Survivorship 12 Years

- 114 THR

- 94% Bony Ingrowth

McLaughlin JR, "Total Hip Arthroplasty with an Uncemented Femoral Component" Nov 1997

Other Clinical References

Markel, D.C. et al. "Initial Scratch-Fit Stability of Acetabular Cups: Comparison of Three Porous Coating System", ISTA 1995

Bobyn, J.D. et al. "The optimal pore size for the fixation of porous surfaced metal implants by the ingrowth of bone", CORR 150:263-270, 1980



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