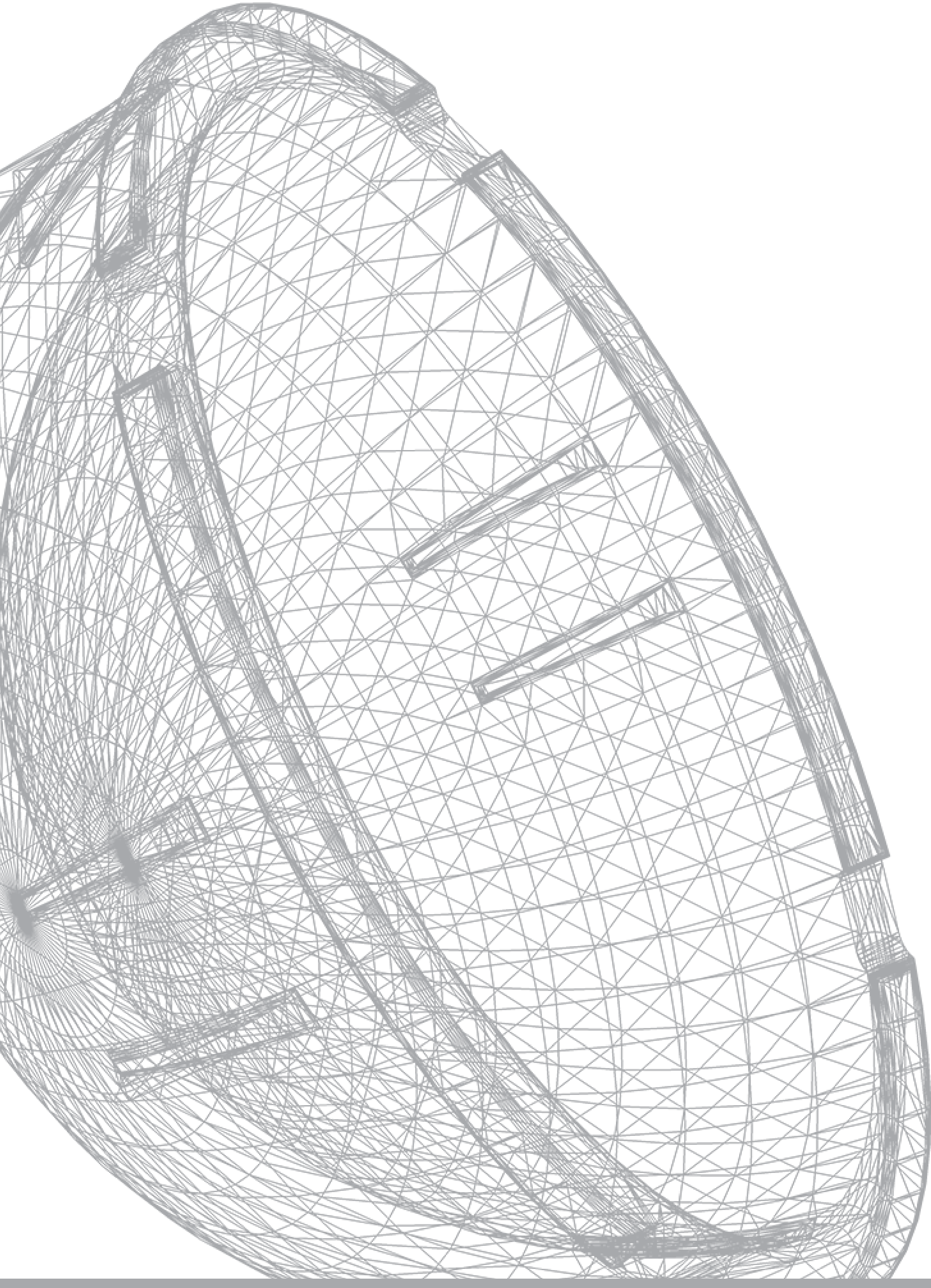


M^{2}a-Magnum™

Large Metal Articulation

Design Rationale

BIOMET®

Knees • Hips • Extremities • Cement and Accessories • PMI® • Technology

M²a-Magnum™ Large Metal Articulation

History of Metal-on-Metal

Early metal-on-metal (MoM) designs of the 1950s and 1960s were encouraging in terms of stability and low wear but, as a whole, did not meet expectations due to primitive manufacturing and improper clearance levels.[1] Therefore, most metal-on-metal designs fell out of favor until the mid 1990s. During this time, Biomet began designing new bearing technologies with innovative materials, improved manufacturing capabilities and optimal clearance.

System Description

The M²a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates *in vivo*.[2] Unlike ceramic-on-ceramic or traditional metal-on-polyethylene bearings, the M²a-Magnum™ system offers excellent stability, dislocation resistance, decreased wear (Figure 1) and a potential maximum range of motion exceeding 160°.[3] This is achieved with a constant 6mm mismatch between the head and cup which allows for the maximum head size to be inserted into the smallest possible cup. For example, a head size as large as 60mm can be inserted into a 66mm cup.

Figure 1: Representative of 25 years cumulative metal-on-metal wear debris vs. 25 years cumulative polyethylene wear debris.[1,4]

Material

Most metal-on-metal bearing systems for hip replacements are manufactured from CoCrMo alloy material. However, the process of manufacturing metal-on-metal systems varies. Although many orthopedic manufacturers use a casting process, some apply post-manufacturing processes to their metal-on-metal components known as hot isostatic pressing (HIP) and solution annealing (SA) in an attempt to improve homogeneity and reduce porosity. SA works to homogenize the chromium and molybdenum-rich inter-dendritic regions and, as a result, many of the carbides are dissolved to leave a finer carbide distribution. Carbides are vital for fatigue and wear resistance. According to McMinn *et al*., HIP and SA post processes may lead to increased metal wear generation due to depletion of surface carbides.[5]

The M²a-Magnum™ system features articulating surfaces made from high carbon CoCrMo alloy (carbon content .23–.28 percent) using an 'as-cast' manufacturing process. 'As-cast' refers to the metal forming process, where molten metal is poured into a mold, cooled and solidified to take on the final shape of the mold and no further heat treatment is applied. By leaving the metal in its 'as-cast' form, the larger carbides remain intact (Figure 2). According to Crawly *et al*., 'as-cast' materials have shown to provide enhanced protection against abrasive wear and reduced overall wear rates compared to single or multiple heat treated materials.[6,7]

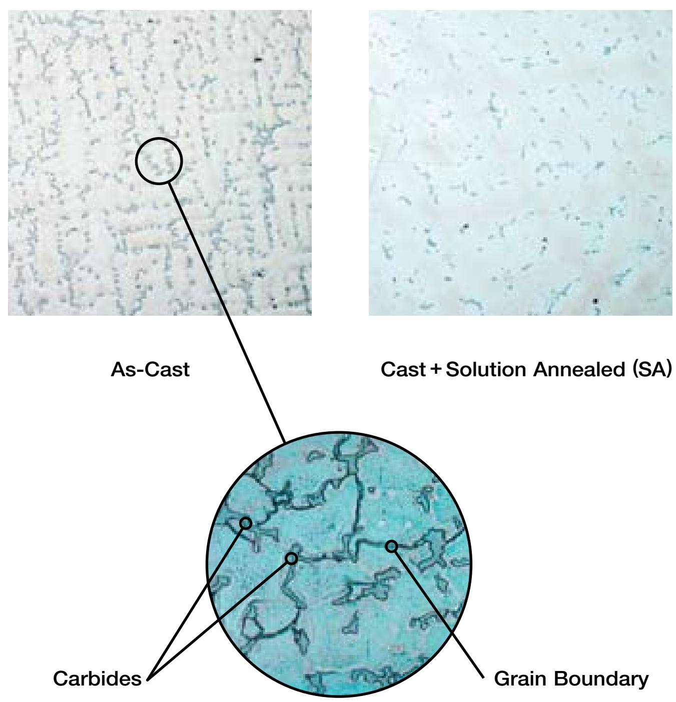


Figure 2: The Biomet 'as-cast' material has a combination of fine grain size for fatigue resistance and high carbide volume for wear resistance.

Cup Design

The M^2a-Magnum™ cup is an 'as-cast' high carbon cobalt chrome molybdenum (CoCrMo) alloy press-fit design, with a titanium PPS® Porous Plasma Spray outer surface and a highly polished inner geometry. The exterior geometry contains four pairs of peripheral fins to enhance rotational stability and aid initial fixation (Figure 3). The outer diameter of the cup is fully hemispherical (180°), with four rim indentations for the stable attachment of the locking impaction device. The interior geometry is honed and buffed to a high polish to achieve a strict spherical tolerance of 200µin. When the appropriate M^2a-Magnum™ head and cup are combined, the highly polished surfaces allow the hydrodynamic fluid film layer to build in a manner optimal for reduced wear.

Figure 3

In order to resist deformation forces, the cup is manufactured with a 6mm thickness at the dome and an average of 3mm thickness at the rim (Figure 4). This design is specific to the M^2a-Magnum™ component and allows for the maximum head to cup ratio.

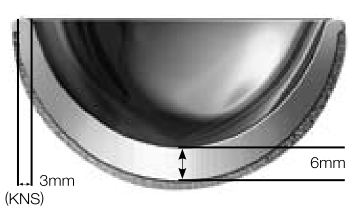


Figure 4

Head Design

The M^2a-Magnum™ head is an 'as-cast', high carbon CoCrMo alloy. This is essential to maintaining the fatigue and wear resistance characteristics of the M^2a-Magnum™ articulation. All M^2a-Magnum™ heads are honed and buffed to achieve a strict spherical tolerance of 200µin. This sphericity is measured using more than 100,000 inspection points across the entirety of the articulating surface within a temperature-controlled, humidity and vibration-isolated environment.

Tapered Insert Design

Head sizes 38 and 40mm are monoblock and do not use a modular taper insert due to the small diameter (Figure 5). Head sizes 42mm and larger use a titanium tapered insert identical in angle to the traditional Biomet® Type 1 trunnion (Figure 6). The 12/14 taper insert option is also available to allow for operative flexibility. These inserts provide for six neck length options to restore the proper joint mechanics for varying patient anatomy.

Figure 5

Figure 6

M^{2}a-Magnum™ Large Metal Articulation

Manufacturing Processes

While casting, turning and milling are standard manufacturing processes for many orthopedic implants, the precise demands on metal-on-metal articulating surfaces require specialized "super-finishing" called honing. Honing is a final finishing operation conducted on the bearing surfaces where abrasive stones are used to remove small amounts of material in order to tighten the tolerance of all major dimensions. After honing, the head and inner diameter of the cup are buffed to a very smooth mirror finish.

100% Dimensional Control

Once the manufacturing process is complete, all M^{2}a-Magnum™ components undergo a thorough inspection process to ensure precise manufacturing tolerances have been achieved. Major dimensions such as sphericity (roundness) and roughness are verified using non-contacting light interferometry through the use of ZygoPCI Laser (Figure 7). The M^{2}a-Magnum™ articulation is manufactured to a 5 micron deviation, compared to the ISO standard of 10 microns. Roughness (Ra value) is a measure of the texture of a surface quantified by vertical deviations. All M^{2}a-Magnum™ components are tested to ensure that the Ra value does not exceed .005 microns. These key measurements are necessary to maintain low wear and optimal clearance found in M^{2}a-Magnum™ components.

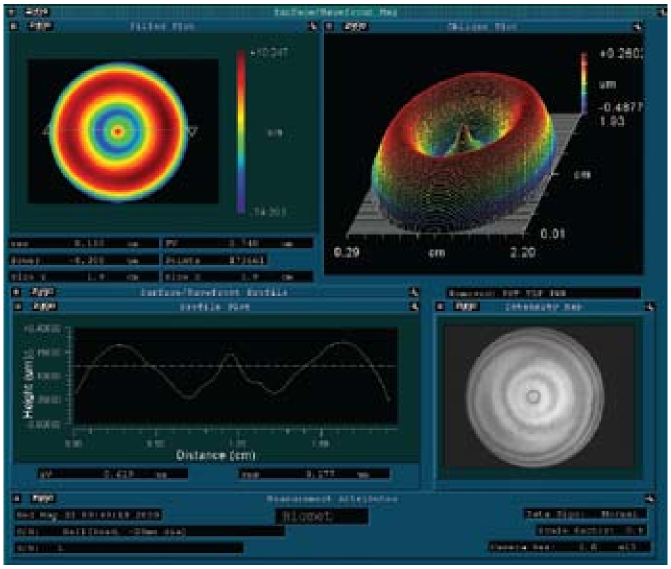
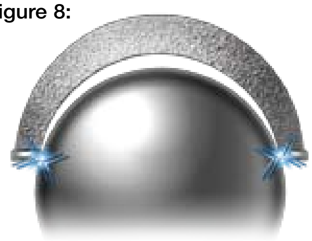


Figure 7: Sphericity (roundness) and roughness are checked using non-contacting light interferometry through the use of Zygo PCI Laser.

Importance of Clearance

Clearance can be defined as the space between the outer diameter of the head and inner diameter of the shell, allowing for fluid film lubrication in metal-on-metal articulations. Inadequate clearance increases the chance of equatorial contact and the potential for components to lock together and seize (Figure 8). Excessive clearance produces high contact stresses and disrupts fluid lubrication (Figure 9). Either of these scenarios may result in elevated wear rates and cup loosening. The radial clearance level of the M^{2}a-Magnum™ articulation is maintained at 75–150 microns to capture the ideal amount of fluid lubrication and space for debris removal (Figure 10).

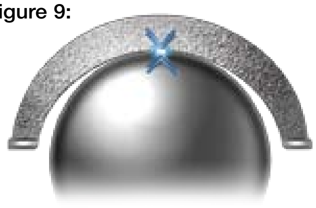
Figure 8:



Inadequate Clearance

- Chance of components locking together[8]
- Creates high frictional torque[9,10]
- Leads to early loosening and increased run-in wear[9,10]

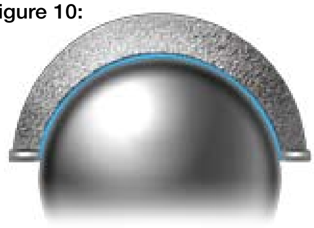
Figure 9:



Excessive Clearance

- High contact stresses[9,10]
- Poor fluid film lubrication design
- Leads to increased wear[9,10]

Figure 10:



Optimal Clearance

- Allows proper fluid lubrication
- Low wear and low frictional torque[9,10]
- Room for removal of wear debris

Wear Testing

When testing the run-in wear of hard bearings, a biphasic pattern is typically seen, with a higher initial 'run-in' wear rate usually lasting 1–1.5 million cycles followed by an extremely low level of steady state wear, that is inversely proportional to head size (Figure 11).[11]

Size	mm^3/MC
28mm	.73
32mm	.30
38mm	.12
46mm	.18
56mm	.13
28mm ArCom® Poly	27.9

97–98% less wear than ArCom® polyethylene

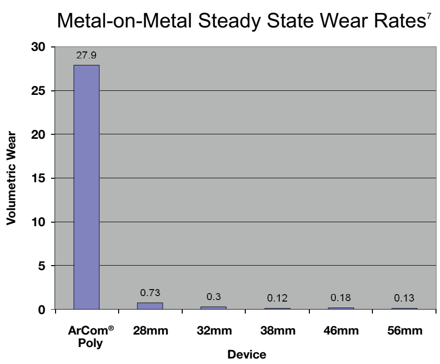


Figure 11

'Run-in' wear occurs 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 upon radial clearance, material and manufacturing capability; such as control of sphericity, tolerance and surface finish.

Proven Fixation — PPS® Porous Plasma Spray Coating

Biomet was the first orthopedic company to introduce a plasma-sprayed prosthesis with the release of the PPS® coated Taperloc® hip stem in 1982.

The M²a-Magnum™ cup features Biomet's PPS® coating, a proprietary process that is instrumental to our clinical success. Biomet's process not only helps guard against osteolysis but allows both immediate and long-term fixation.[12–15] Biomet's proprietary plasma spray application is unique in that only the titanium powder used to create the coating is heated, while the implant's substrate is retained at near ambient temperatures. This unique process enables the implant to maintain its mechanical properties.

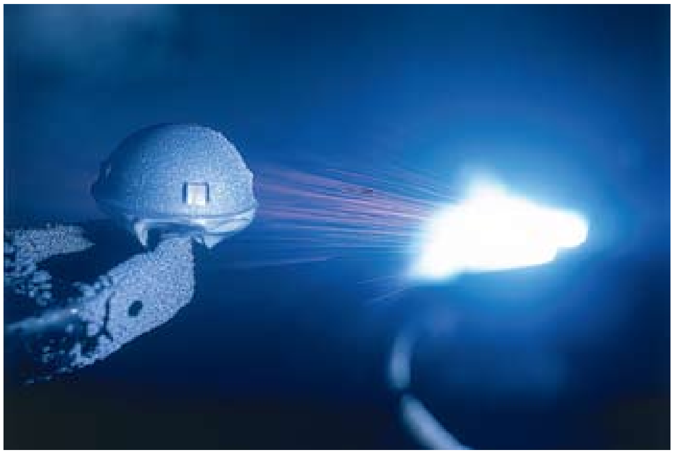


Figure 12: Titanium PPS® Porous Plasma Spray being applied through a heated plasma arc.

The heating effect of the PPS® process is transient (lasting only for milliseconds). Therefore, the substrate material remains virtually unaffected, fatigue properties are maintained such that small femoral components are possible with this process and, importantly for M²a-Magnum™ articulation, the carbide structure is unaffected.

Biomet's PPS® coating has irregularly shaped molten titanium particles that splatter upon impaction with the substrate surface. This generates a random distribution of pore size between 100 and 1,000 microns providing a larger contact area between particles and substrate (Figure 13). The larger distribution of pore size in conjunction with the enhanced biocompatibility of titanium, allows immediate fixation via mechanical interlocking and long-term fixation through bone in-growth.

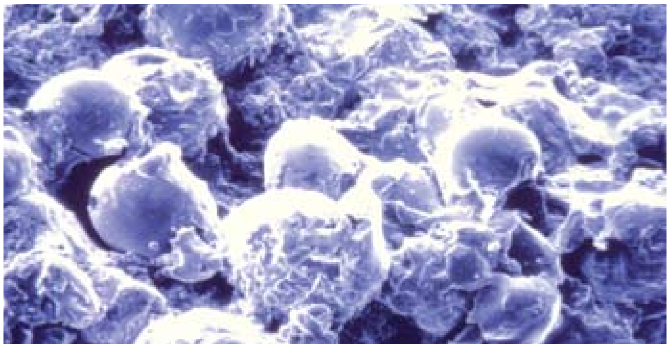


Figure 13: The irregularly shaped titanium particles sprayed onto the substrate result in a wide pore size distribution.

The presence of a distributed pore size induces higher initial fixation for Biomet's PPS® coated implants in comparison to other coated devices such as sintered bead or fiber-mesh coatings, which have much larger pores with a very narrow distribution of pore size.[16,17]

Biomet's PPS® coating has been clinically proven for over 20 years as seen in a variety of published clinical papers.[12–15,19–23] A study comparing the scratch-fit stability of acetabular shells with three different porous coatings concluded that PPS® coated cups were twice as strong in resistance to rim failure as the beaded or fiber mesh cups.[24]

Ion Release

Despite the positive clinical history of the M²a-Magnum™ articulation, there have been concerns regarding the long-term biological consequences of metal-on-metal wear debris, particularly the release of cobalt chromium ions into the body. Ion release is not limited to metal-on-metal hips. Metal ions are a natural by-product of virtually every metallic implant and may lead to higher than normal levels of cobalt and chromium in the bloodstream. Nails, plates, screws and even total knees will release ions of their respective metals.[25] Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants.[26–31]

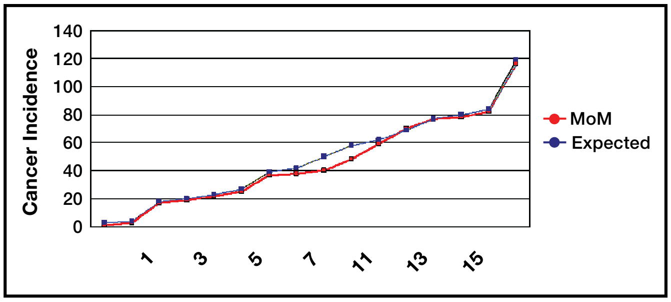


Figure 14: Dr. Visuri reported no statistically significant increase in cancer of any type with either a metal-on-metal or metal-on-polyethylene articulation hip replacement compared to the expected cancer rate of the general population at a 16-year follow up.[27]

Clinical Performance

Author	Title	Publication/Date	Summary
Lombardi, A. *et al*.	Midterm Results of Polyethylene-Free Metal-on-Metal Articulation	*Journal of Arthroplasty* 19(7): 42–7, 2004.	• 98 patients • 5 year follow-up • 98% survivorship • 53 metal liners and 46 poly liners • All components well-fixed and stable
Dowson, D. *et al*.	A Hip Joint Simulator Study of the Performance of Metal-on-Metal Joints: Part II: Design	*Journal of Arthroplasty* 19(8): 124–30, 2004.	• 16–54mm head diameters and various clearance levels studied • Low wear achieved with careful design and proper fluid lubrication • Large heads and low diametrical clearances ensure that joint will function with proper fluid film lubrication
Reina, R. *et al*.	Fixation and Osteolysis in Plasma-Sprayed Hemispherical Cups with Hybrid Total Hip Arthroplasty	*Journal of Arthroplasty* 22(4): 531–4, 2007.	• 145 Porous Plasma Spray RingLoc® cups implanted • Average follow-up 8.5 years • 2% revision rate for non-crosslinked poly wear • Cups remained well-fixed
Cuckler, J.	The Rationale for Metal-on-Metal Total Hip Arthroplasty	*Clinical Orthopaedics and Related Research* 441: 132–6, 2005.	• Long-term clinical results of MoM hips • Retrieval analysis indicated 1–5 microns of wear per year after initial wear-in compared to 100–200 microns per year of metal-on-polyethylene wear • No adverse physiologic effects

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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet's website.

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