



*M2a-38*<sup>™</sup>  
metal-on-metal

**BIOMET**  
ORTHOPEDICS, INC.

# M<sup>2</sup>a-38... The face of Me



## A New Milestone

Biomet's M<sup>2</sup>a-38™ is the next great milestone in our metal-on-metal family. The patent pending one-piece design of the M<sup>2</sup>a-38™ incorporates a 38mm articulating surface with metal-on-metal to achieve maximum range of motion, stability and minimal wear.

**The solid, cobalt chromium cup affords surgeons the ability to fit the M<sup>2</sup>a-38™ cup into smaller acetabulums, which would be too small for a modular design.**

## Innovative Design

Unique design features such as titanium plasma spray, a 17° rim flare, and four pairs of small fins provide excellent initial fixation in the anterior and

posterior columns. Rim screw options are available in size 56mm cups and above, providing supplemental fixation for difficult primary and revision surgeries.

## Maximum Stability, Minimal Wear

Unprecedented stability and ROM, without increased wear, makes the M<sup>2</sup>a-38™ the ideal hip articulation for many patients. The large 38mm bearing surface exhibits similar wear characteristics to that of the 28mm and 32mm metal-on-metal articulations, approximately 1/350th the wear of

metal-on-polyethylene.<sup>1</sup> As with all of our metal-on-metal components, 100% of the M<sup>2</sup>a-38™ bearing surface components are checked to the tightest tolerances and engineered to provide ideal fluid lubrication over the bearing surface.

**Metal-on-Metal Family**

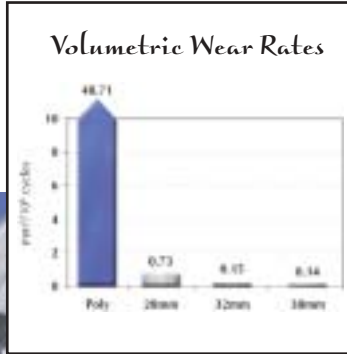
Head size	28mm	32mm	38mm
ROM	126°	132°	154°
Shell Sizes	48–70mm	52–70mm	48–70mm

# tal-on-Metal has changed!

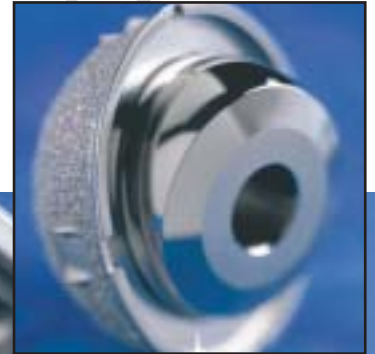
Plasma spray, 17° rim flare and paired fins work together to provide initial fixation.



Unlike polyethylene, larger head sizes with metal-on-metal components show no increase in wear. This is due to the unique characteristics of this bearing surface.



100% of the M²a-38® bearing surface tolerances are checked.



The M²a-38™ Acetabular System

# Maximum Stability . . . M

## Superior Stability and Range of Motion

---

Range of motion is essential in total hip replacements in order to provide for normal gait and function of the hip, as well as to reduce incidences of prosthetic impingement. Prosthetic impingement may increase the risk of third body wear debris, weaken the metal substrate, and potentially lead to dislocation. Primary hip dislocation rates are reported to be 3–4%<sup>2</sup>, and are as high as 23% in revisions.<sup>3</sup> Noble, in cadaveric range of motion studies, reported prosthetic impingement

rates of 87% with a 28mm head, compared to 47% with a 38mm head.<sup>4</sup> The M<sup>2</sup>a-38™ prosthesis is designed to minimize prosthetic impingement, allowing range of motion to only be impeded by bone or soft tissue — not the implant itself. **Range of motion studies performed on the M<sup>2</sup>a-38™ suggest an average of 154° range of motion — this is more than any other metal-on-metal system on the market.**

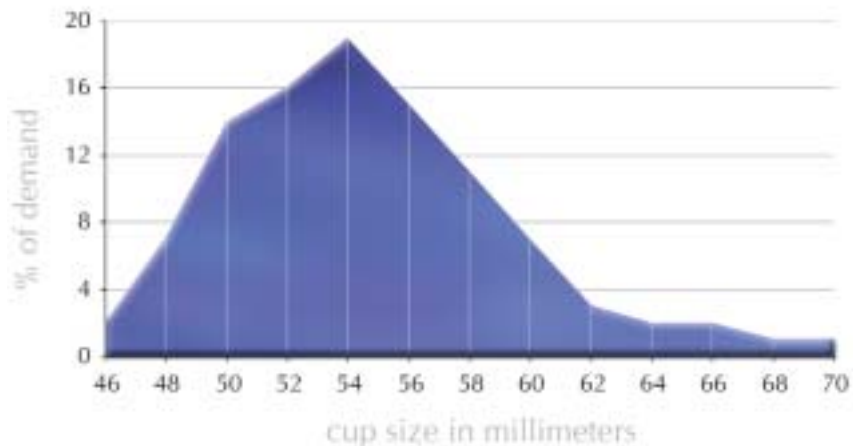
## Wide Range of Options for Primaries and Revisions

---

Seven neck lengths ranging from -6mm to +12mm are available, with only the +12mm length requiring a skirt. A non-modular design decreases surgery time, and enables a 38mm head to be used with a

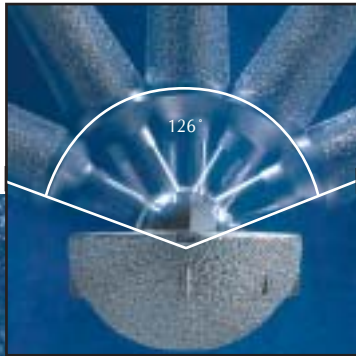
large range of cup sizes, from 48–70mm. The bell-shaped graph below shows the usage of acetabular components. The M<sup>2</sup>a-38™ system fits the demand for the most commonly used shell sizes.

### Acetabular Shell Size Distribution

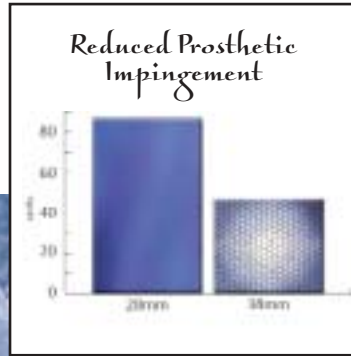


# Minimal Wear!

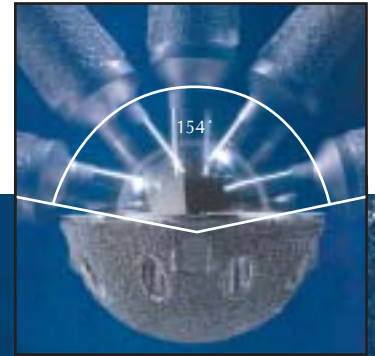
Range of motion of a 28mm head.



Forty-seven percent less prosthetic impingement.\*

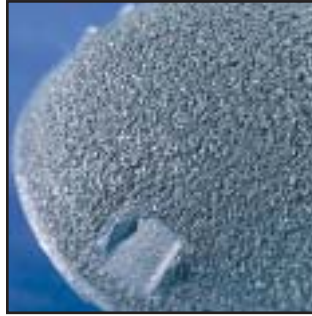


Range of motion of a M<sup>2</sup>a-38° head.



154° ROM

# Biomet's M<sup>2</sup>a family... C



## Unparalleled fit and fixation: Plasma Spray Porous Coating

Titanium plasma spray porous coating provides excellent fixation through two characteristics: surface roughness and randomized pore size. Unlike smooth beads and fiber mesh, plasma spray provides the highest coefficient of friction of any porous coating on the market, creating a "scratch fit" for excellent initial stability. This is coupled with a random distribution of pore sizes. The smallest of these pores fill up quickly with ingrown bone, providing initial stability potentially greater than that of beads and mesh, which have larger, uniform pores. The microscopic structure of the titanium plasma spray does not allow pore interconnectivity, like that seen with beads and fiber mesh. This prevents the transport of fluid and debris, creating a seal against particulate debris migration. Studies show that this may reduce osteolysis and improve fixation.<sup>5</sup> Furthermore, a comparison of the initial scratch-fit stability of acetabular cups made with beads, fiber mesh and plasma spray reveals that **plasma spray porous coating is more**

**than twice as resistant to cup displacement under rim load than the other coatings.**<sup>6</sup> Excessive heating of implant substrates during the application of beads and fiber mesh can lead to weakening of the implant by as much as 75%.<sup>7,8,10,11</sup> Plasma spray porous coating is applied to the substrate of the implant at a low relative temperature which preserves the mechanical strength of the implant by as much as 60% over that of sintered beads and wire mesh.<sup>7-11</sup> This is of particular importance in metal-on-metal implants where very strict articular bearing tolerances are necessary. Excessive heating of the substrate can cause the bearing surface to warp. Additional steps are then necessary to bring the implant back into tolerance. These extra steps expose the implant to the risk of contaminates lodging in the porous coating. **Biomet's plasma spray porous coating process protects the substrate from high heat extremes so that no additional machining steps are necessary.**

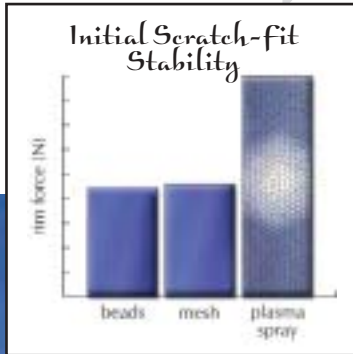
## Fixation—The Key to Stability

The solid, one-piece design does not include dome screws, as they would disrupt the metal-on-metal fluid lubrication. Instead, exceptional initial fixation is achieved through the combination of four pairs of small peripheral fins, a 17° rim flare, and titanium plasma spray porous coating. The greatly increased

stability and range of motion of the M<sup>2</sup>a-38™ acetabular system make it the implant of choice for many types of revision surgery. For cases where supplemental fixation is needed, 5.0mm rim screw holes are available in cup sizes 56mm and above and are optimally oriented to maximize screw purchase.

# Clinically proven results!<sup>12</sup>

Plasma spray exhibits twice as much resistance to cup displacement as other porous coatings.<sup>6</sup>



Titanium plasma spray porous coating.



Rim screws start at size 56mm.



The M<sup>2</sup>a Family

# Surgical Technique



Figure 1



Figure 2



Figure 3



Figure 4



## Preoperative Planning

Accurate preoperative planning and acetabular templating are essential for obtaining a successful outcome. Estimate

the acetabular size utilizing the M<sup>2</sup>a-38™ (or Universal®) templates along with the appropriate femoral templates in the A/P view.

## Incision and Surgical Exposure

The surgical approach is left to the surgeon's discretion. M<sup>2</sup>a-38™ instrumentation is

compatible with all routine hip exposures.

## Acetabular Reaming

Hemispherical reaming should commence with an acetabular reamer several sizes smaller than the templated diameter of the acetabulum. Progressive reaming is performed until bleeding bone, "reaming chatter" or desired template sizing is achieved. The specific reaming technique will vary from surgeon to surgeon and patient to patient, but in many cases a "line-to-line" ream may be used, i.e.: ream to 56mm, implant a 56mm cup (Figure 1). M<sup>2</sup>a-38™ acetabular trials should be used throughout the reaming process to help determine the

accuracy of the reaming process and the diameter of the final prosthesis. The acetabular trials will also assist in judging the final position of the implant relative to the peripheral rim (Figure 2). This is of importance as the M<sup>2</sup>a-38™ is a one-piece cup design. During the reaming process, it is important to monitor the structural integrity of the anterior and posterior columns of the acetabular rim. Care should be emphasized to maximize bone stock in order to help achieve a satisfactory press-fit.

## Acetabular Component Insertion

The M<sup>2</sup>a-38™ cup incorporates three different fixation philosophies into one implant. A 17° rim flare provides approximately 2mm press-fit at the rim, while four pairs of small peripheral fins further enhance the press-fit and provide rotational stability. Titanium plasma spray porous coating gives an initial "scratch fit" and allows bone in-growth for long-term fixation. The two-piece cup inserter is designed to lock securely into the face of the cup providing rotational and lift-out stability. The two-piece inserter is assembled in three easy steps:

**Step One:** The smaller rectangular locking bar is positioned on the face of the cup by aligning the bar into the slots in the rim of

the prosthesis, and then rotating a quarter turn to lock the bar into the groove (Figure 3).

**Step Two:** The second, disc shaped piece is then placed over the boss of the rectangular bar so that it covers the face of the cup. The disc may need to be rotated slightly to **make sure the four metal tabs fall into the four slots on the edge of the cup** (Figure 4). The tabs provide rotational stability during insertion.

**Step Three:** A standard cup inserter handle is then screwed into the hole in the boss of the two-piece inserter. This will pull the components tightly together, and provide lift out, as well as rotational stability (Figure 5).

*Trial cup and head.*



*Two-piece cup inserter.*



*Assembled two-piece cup inserter.*



# Surgical Technique



Figure 6



Figure 7



Figure 8



Figure 9



Figure 10

In order to ensure correct positioning, the Dial-A-Version guide can be utilized with the inserter handle (Figure 6). Appropriate version is dialed into the alignment guide, and the version rod is aligned parallel with the spine. In a lateral position, the inclination rod is perpendicular to the spine to obtain horizontal inclination of 45°. Once appropriate shell positioning is achieved, the version guide can be easily removed and the shell impacted into the acetabulum (see Figure 5). The two-piece inserter is removed by unscrewing the inserter rod and removing the disc-shaped piece. The rectangular bar is easily removed by gripping with a pair of cokers and rotating so that the tabs align with the slots in the cup. A ball impactor

and cup impactor plate are available as additional impaction options (Figure 7). These are particularly helpful once the two-piece inserter has been removed as it may be difficult to reassemble once the cup is placed in the acetabulum.

Should it be determined that changes need to be made to either the anteversion or inclination once the cup has been impacted, **an impactor or punch should not be used on the rim of the cup to avoid damage to the bearing surface.** Rather, utilize the two-piece cup inserter face plate or impactor plate to protect the inner diameter of the cup and tap on the edge of the face plate to gradually change cup position.

## Modular Head Selection and Impaction

The 38mm trial heads are available in seven neck sizes (-6, -3, Std., +3, +6, +9, +12mm). These can be used in conjunction with both the acetabular trials and the final implant to determine joint stability and proper cup placement. With the acetabular cup in place, and upon completion of femoral reconstruction, a trial reduction should be performed to confirm restoration of leg length and stability of the hip in all planes (Figure 8).

Based on the chosen trial head component, the corresponding 38mm modular head must now be selected and impacted.

## Final Reduction

Now the modular head and cup are ready to be mated together (Figure 10). Special care should be taken when reducing the head into the cup, so as not to scratch the

**Only modular heads labeled for the M<sup>2</sup>a-38™ articulation can be utilized.** The precision tolerances of these femoral heads are necessary for optimum wear. Taper surfaces must be clean and dry before seating the modular head onto the stem taper.

Impact the modular head onto the stem with several brisk mallet strikes using the M<sup>2</sup>a-38™ plastic head impactor only (Figure 9). Surfaces other than plastic may scratch the modular head disrupting fluid lubrication and wear. If the modular head becomes scratched or damaged in any way, it must be replaced.

head on the edge of the cup. At this time, joint stability and range of motion may be confirmed, and customary repair of the hip capsule and wound may commence.

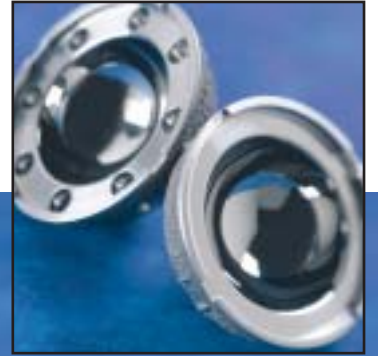
Optional cup impactor plate.



Rim screws may be used with cup sizes 56mm and above to enhance fixation.



M<sup>2</sup>a-38° cups with and without rim screw holes.



M<sup>2</sup>a-38™ Instrumentation

# Ordering Information

M <sup>2</sup> a-38™ Acetabular Cups		
Part No.	Trial	Size
15-105048	31-105048	48mm
15-105050	31-105050	50mm
15-105052	31-105052	52mm
15-105054	31-105054	54mm
15-105056	31-105056	56mm
15-105058	31-105058	58mm
15-105060	31-105060	60mm
15-105062	31-105062	62mm
15-105064	31-105064	64mm
15-105066	31-105066	66mm
15-105068	31-105068	68mm
15-105070	31-105070	70mm

M <sup>2</sup> a-38™ Modular Heads		
Part No.	Trial	Size
11-173660	31-173660	-6mm
11-173661	31-173661	-3mm
11-173662	31-173662	Std.
11-173663	31-173663	+3mm
11-173664	31-173664	+6mm
11-173665	31-173665	+9mm
11-173666	31-173666	+12mm Skirt

## Instrumentation

**RingLoc® Cup Inserter Handle**  
31-434540

**38mm Modular Head Impactor**  
31-476948

**M<sup>2</sup>a-38™ Cup Inserter**

31-103640	48–50mm
31-103642	52–54mm
31-103644	56–58mm
31-103646	60–62mm
31-103648	64–66mm
31-103650	68–70mm

**M<sup>2</sup>a-38™ Cup Impactor Plate**

31-103610	48–50mm
31-103612	52–54mm
31-103614	56–58mm
31-103616	60–62mm
31-103618	64–66mm
31-103620	68–70mm

**38mm Cup Ball Impactor**  
31-131008

**M<sup>2</sup>a-38™ Template Set**  
15-105100

5.0mm Rim Screws	
Part No.	Size
113843	15mm
113844	20mm
113845	25mm
113846	30mm
113847	35mm
113848	40mm
CP250327	45mm
CP250328	50mm
CP250329	55mm

M<sup>2</sup>a-38™, RingLoc® and Universal® are trademarks of Biomet, Inc.

<sup>1</sup> Data on file at Biomet.

<sup>2</sup> Li E, et al.; "The Natural History of a Posteriorly Dislocated Total Hip Replacement." *Journal of Arthroplasty*, 14(8): 964–8, December 1999.

<sup>3</sup> Chandler HP, et al.; "Revision Total Hip Replacement Using the S-ROM Femoral Component." *Clin Orthop*, (319): 130–40, October 1995.

<sup>4</sup> Noble PC, et al.; "Will Large Femoral Heads Increase Joint Range of Motion Following THR?" Hip Society (Abstract), September 2000.

<sup>5</sup> Emerson RH, et al.; "Effect of Circumferential Plasma-Spray Porous Coating on the Rate of Femoral Osteolysis After THR." *JBS (Am)*, 81 (9): 1291–8, September 1999.

<sup>6</sup> Markel DC, et al.; "Initial Scratch-Fit of Acetabular Cups: Comparison of Three Porous Coated Systems." ISTA (Abstract), September 1997.

<sup>7</sup> Yue S, et al.; "The Fatigue Strength of Porous-Coated Ti-6%Al-4%V Implant Alloy." *Journal of Biomedical Materials Research*, Vol. 18 (9): 1043–58, 1984.

<sup>8</sup> Luedemann; Biomet In-House Testing, 1987.

<sup>9</sup> Luedemann; "The Effect of a Plasma Sprayed Porous Ti Alloy Coating on the Rotating Beam Fatigue Strength of CoCrMo Alloy." Biomet Technical Report, 1994.

<sup>10</sup> Pilliar RM; "Powder Metal-Made Orthopedic Implants with Porous Surface for Fixation by Tissue Ingrowth." *Clinical Orthopaedics*, (176): 42–51, June 1983.

<sup>11</sup> Gustavson, in Hungerford, et al.; "Total Hip Arthroplasty: A New Approach." 1984.

<sup>12</sup> Lombardi AV, et al.; "Short-Term Results of the M2a-Taper Metal-on-Metal Articulation." *Journal of Arthroplasty*, Vol. 16, No. 8, pp.122–28, 2001.

# BIOMET

ORTHOPEDICS, INC.

P.O. Box 587, Warsaw, IN 46581-0587 • 574.267.6639 • ©2002 Biomet Orthopedics, Inc. All Rights Reserved

web site: [www.biomet.com](http://www.biomet.com) • eMail: [biomet@biomet.com](mailto:biomet@biomet.com)

Form No. Y-BMT-735/021502/K