

BIOMET

Device	Example	M2a-Taper System	M2a-38	Magnum (38 & 40mm)	Magnum (42mm & above)
510k Number	K061423	28mm - K993438 32mm - K003363	K011110	K042037	K042037
Femoral Heads:					
Material	Cast High-Carbon CoCrMo (ASTMF- 75)*	Wrought Hi-Carbon (ASTM F1537, C: 0.20 to 0.35%)	Cast High-Carbon CoCrMo (ASTM F- 75: C:0.20 -0.35%), HIPped and Heat Treated	Cast High-Carbon CoCrMo (ASTM F- 75: C:0.20 -0.35%), As-cast	Cast High-Carbon CoCrMo (ASTM F- 75: C:0.20 -0.35%), As-cast
Diameter	28 & 32 mm	28 & 32 mm	38mm	38 – 40 mm	42 – 60 mm
Sphericity	<5 microns	<5 microns	<5 microns	<5 microns	<5 microns
Surface finish	0.005 microns	< 5 microinch (< 0.2 microns)	< 5 microinch (< 0.2 microns)	< 5 microinch (< 0.2 microns)	< 5 microinch (< 0.2 microns)
Taper Sleeve Adapters Taper Geometry	Femoral heads: 12/14 internal taper Cast High Carbon CoCrMo alloy (ASTM F-75)	Biomet Type 1 taper geometry, 4 degree included angle	Biomet Type 1 taper geometry, 4 degree included angle	Biomet Type 1 taper geometry, 4 degree included angle	Taper Adaptor (Ti6Al4V) with a Biomet Type 1 taper geometry, 4 degree included angle
Taper/Neck Lengths	12/14 taper; -3.5,0,+3.5	Non skirted: -6, -3, 0, +3, +6 Skirted: +9, +12	Non skirted: -6, -3, 0, +3, +6, +9 Skirted: +12	Non skirted: -6, -3, 0, +3, +6, +9 Skirted: +12	Single Head; Neck lengths available with taper adaptors: -6, -3, 0, +3, +6, +9
Acetabular Component:					
Material	Cast High Carbon CoCrMo (ASTM F-75)*	Wrought Hi-Carbon (ASTM F1537, C: 0.20 to 0.35%)	Cast High-Carbon CoCrMo (ASTM F- 75: C:0.20 -0.35%), HIPped and Heat Treated	Cast High-Carbon CoCrMo (ASTM F- 75: C:0.20 -0.35%), As-cast	Cast High-Carbon CoCrMo (ASTM F- 75: C:0.20 -0.35%), As-cast
Method of Fixation (coating type)	Porous coating (Sintered beads)	Porous Plasma Spray (Ti-6Al-4V)	Porous Plasma Spray (Ti-6Al-4V)	Porous Plasma Spray (Ti-6Al-4V)	Porous Plasma Spray (Ti-6Al-4V)
Outer diameter	44-64 mm (in 2mm increments)	48-70 mm in 2mm increments	48-70 mm in 2mm increments	44 – 46 mm	48 – 66 mm in 2mm increments
Inner diameter	28 & 32 mm	28 & 32 mm	38mm	38 – 40 mm (ID always 6mm less than OD)	42-60 mm in 2 mm increments (ID always 6mm less than OD)
Sphericity	<5 microns	<5 microns	<5 microns	<5 microns	<5 microns

Surface finish	0.005 microns	< 5 microinch (< 0.2 microns)	< 5 microinch (< 0.2 microns)	< 5 microinch (< 0.2 microns)	< 5 microinch (< 0.2 microns)
Diametrical clearances and tolerances**	28 mm: nominal 100µm ±20µm (min:80µm, max: 120µm 32mm: nominal 120µm ±20µm (min 100µm, max: 140µm)	50-150 microns	50-150 microns	150-300 microns	150-300 microns
Range of motion	28mm -126° 32mm-132°	<u>28mm</u> No skirt -126° Skirted - 106° <u>32mm</u> No skirt -132° Skirted - 115°	<u>38mm</u> No skirt - 154° Skirted - 142°	151° - 163°	
Wear rates: Steady State	28mm-0.73 mm ³ /10 ⁶ cycles 32mm- 0.15mm ³ /10 ⁶ cycles	28mm-0.73 mm ³ /10 ⁶ cycles 32mm- 0.15mm ³ /10 ⁶ cycles	0.0390 mm ³ /10 ⁶ cycles	46 mm: 0.191 mm ³ /10 ⁶ cycles 56 mm: 0.209 mm ³ /10 ⁶ cycles	
Rotational frictional torque measurements	32mm-2.6Nm	28 mm: 2.7 in- lb (0.31 N-m)	Not available	56 mm: 2.5 in-lb (0.28 N-m)	
Flexion/extension frictional torque measurements	32mm-7.7Nm	Not available	Not available	Not available	Not available

- *Please define what is meant by a high carbon or a low carbon alloy and please specify a standard that must be met to certify the material is high carbon. Also, when completing this table, please ensure that the definition provided in response to this item is applied to each entry for each head and cup material.
- ** For the diametrical clearances please include the least and most tolerances for both the head and liner. In addition, please do not group all sizes together. Please list each size and each minimum and maximum clearance range for each diameter separately.