

DePuy

Device	Example	Ultima	Ultamet	Ultamet XL
510k Number	K06000	K001523	K002883	K062426
Femoral Heads:				
Material	Cast High-Carbon CoCrMo (ASTMF- 75)*	High-Carbon CoCrMo (ASTM F-1537)*	Wrought High-Carbon CoCrMo (ASTM F-1537)	Wrought High-Carbon CoCrMo (ASTM F-1537)
Diameter	28 & 32 mm	28 mm	28 & 36 mm	36, 40 & 44 mm
Sphericity	<5 microns	<5 microns	<5 microns	<5 microns
Surface finish	0.005 microns	0.05 microns	0.01 microns	0.005 microns
Taper Sleeve Adapters Taper Geometry	Femoral heads: 12/14 internal taper Cast High Carbon CoCrMo alloy (ASTM F-75)	Femoral Heads: 11/13 & 12/14 internal taper	Femoral Heads: 11/13 & 12/14 internal tapers	Femoral Heads: 11/13 & 12/14 internal tapers
Taper/Neck Lengths	12/14 taper; -3.5,0,+3.5	11/13 taper: +0, +6, +12 12/14 taper: +0, +3.5, +7	11/13 taper: -3, 0, +3, +6, +9, +12 12/14 taper: -2, +1.5, +5, +8.5, +12, +15.5	11/13 taper: -3, 0, +3, +6, +9, +12 12/14 taper: -2, +1.5, +5, +8.5, +12, +15.5
Acetabular Component:	Metal liner	Metal liner	Metal liner	Metal liner
Material	Cast High Carbon CoCrMo (ASTM F-75)*	High-Carbon CoCrMo (ASTM F-1537)	Wrought High-Carbon CoCrMo (ASTM F-1537)	Wrought High-Carbon CoCrMo (ASTM F-1537)
Method of Fixation (coating type)	Porous coating (Sintered beads)	Shell Ti6Al4V Grain Size ASTM 10-12	Porous coating (Sintered beads)	Porous coating (Sintered beads)
Outer diameter	44-64 mm (in 2mm increments)	48-68 mm (in 2mm increments)	38-72 mm (in 2mm increments)	50-66 mm (in 2mm increments)
Inner diameter	28 & 32 mm	28 mm	28 & 36 mm	36, 40, 44 mm
Sphericity	<5 microns	<5 microns	<5 microns	<5 microns
Surface finish	0.005 microns	0.05 microns	0.01 microns	0.01 microns

Diametrical clearances and tolerances**	28 mm: nominal 100µm ±20µm (min:80µm, max: 120µm) 32mm: nominal 120µm ±20µm (min 100µm, max: 140µm)	28 mm: nominal 60µm ±20µm (min : 40µm, max: 80µm)	28 mm: nominal 60µm ±20µm (min 60µm, max: 100µm) 36 mm : nominal 100µm ±20µm (min 80µm, max: 120µm)	36 mm: nominal 100µm ±20µm (min 80µm, max: 120µm) 40 mm: nominal 100µm ±20µm (min 80µm, max: 120µm) 44 mm : nominal 100µm ±20µm (min 80µm, max: 120µm)
Range of motion	28mm -126° 32mm-132°	NA	28mm: 146° 36mm: 151° [2, 3]	36 mm - 151° 40 mm - 151° 44 mm - 151° [4]
Wear rates	28mm-0.73 mm ³ /10 ⁶ cycles 32mm- 0.15mm ³ /10 ⁶ cycles	28mm – 0.4 mm ³ /10 ⁶ cycles [5]	28mm – 0.6 mm ³ /10 ⁶ cycles 36mm - 0.8 mm ³ /10 ⁶ cycles [6]	44mm – 0.02 mm ³ /10 ⁶ cycles [7]
Rotational frictional torque measurements	32mm-2.6Nm			
Flexion/extension frictional torque measurements	32mm-7.7Nm			

- *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.

References

- [1] Materials specification for metal shell, the material spec is MS-50401002; for head and insert, the material spec is MS-10201083
- [2] UltraMet Metal-on-Metal Articulation Technical Monograph, 0611-55-050 (rev. 1)
- [3] Pinnacle Acetabular Cup System Design Rationale, 0611-07-500 (rev. 2)
- [4] Internal data, by K. Schietelbein, Measured by UniGraph tool, March 1, 2006.
- [5] DePuy internal report RDR 009/001
- [6] Liao et al., ORS 2004, p1454
- [7] DePuy internal test, MTS 27, report pending