ZIMMER

Device	**Example**	Converge®/Epsilon Metasul	Allofit™/Alpha Metasul	Durom LDH
510k Number	K06000		K003578	
Femoral Heads:				
Material	Cast High-Carbon CoCrMo (ASTMF-75)*	Wrought High-Carbon CoCrMo (ISO 5832-12) 0.20 – 0.25% carbon concentration per internal spec.	Wrought High-Carbon CoCrMo (ISO 5832-12) 0.20 – 0.25% carbon concentration per internal spec.	Wrought High-Carbon CoCrMo (ISO 5832-12) 0.20 – 0.25% carbon concentration per internal spec.
Diameter	28 & 32 mm	28 & 32 mm	28 & 32 mm	38 – 60 mm in 2mm increments
Sphericity	<5 microns	<10 microns	<10 microns	<10 microns
Surface finish	0.005 microns	0.006 microns	0.006 microns	0.006 microns
Taper Sleeve Adapters Taper Geometry	Femoral heads: 12/14 internal taper Cast High Carbon CoCrMo alloy (ASTM F-75)	12/14 internal taper No sleeve adapters	12/14 internal taper No sleeve adapters	Adapter sleeves out of wrought low Carbon CoCrMo (ISO 5832-12) 0.05 – 0.08% carbon concentration with 12/14 internal taper
Taper/Neck Lengths	12/14 taper; --.3.5,0,+3.5	12/14 taper; -4, 0, +4, +8	12/14 taper; -4, 0, +4, +8	12/14 taper; -4, 0, +4, +8
Acetabular Component:	Metal liner	Metal inlay deep seated in UHMWPE insert	Metal inlay deep seated in UHMWPE insert	Metal Monoblock Cup
Material	Cast High Carbon CoCrMo (ASTM F-75)*	Metal inlay: Wrought High-Carbon CoCrMo (ISO 5832-12) 0.20 – 0.25% carbon concentration per internal spec. UHMWPE insert to ISO 5834-2;	Metal inlay: Wrought High-Carbon CoCrMo (ISO 5832-12) 0.20 – 0.25% carbon concentration per internal spec. UHMWPE	Wrought High-Carbon CoCrMo (ISO 5832-12) 0.20 – 0.25% carbon concentration per internal spec.

		Converge shell: Ti-6V-4V alloy	insert to ISO 5834-2; Allofit shell: CP Titanium to ISO 5832-2	
Method of Fixation (coating type)	Porous coating (Sintered beads)	CSTi™ coating	Ridgelock™ surface texture of CP Titanium substrate	Poroloc™ Titanium Vacuum Plasma Spray surface coating
Outer diameter	44-64 mm (in 2mm increments)	49-81 mm (in 2mm increments)	48-68 mm (in 2mm increments)	44-66 mm (in 2mm increments)
Inner diameter	28 & 32 mm	28 & 32 mm	28 & 32 mm	38 – 60 mm in 2mm increments
Sphericity	<5 microns	<10 microns	<10 microns	<15 microns
Surface finish	0.005 microns	0.015 microns	0.015 microns	0.005 microns
Diametrical clearances and tolerances**	28 mm: nominal 100μm ±20μm (min:80μm, max: 120μm 32mm: nominal 120μm ±20μm (min 100μm, max: 140μm)	28 mm: min:70μm, max: 170μm 32mm: min 70μm, max: 170μm	28 mm: min:70μm, max: 170μm 32mm: min 70μm, max: 170μm	38 – 56 mm: min:120μm, max: 220μm 58 mm: min 140μm, max: 240μm 60 mm: min 150μm, max: 250μm
Range of motion	28mm -126° 32mm-132°	Prosthetic ROM: 28mm: 114° 32mm: 127°	Prosthetic ROM: 28mm: 114° 32mm: 127°	Prosthetic ROM: 38mm: 144° - 154° 60mm: 163° - 166°
Wear rates	28mm-0.73 $mm^3/10^6$ cycles 32mm-0.15mm^3/10	Linear 3 – 5 micron per year (clinical data)	Linear 3 – 5 micron per year (clinical data)	Linear: 12μm/10^6 cycles for 38 and 56mm (hip simulator

	^{6} cycles			data)
Rotational frictional torque measurements	32mm-2.6Nm	Unknown	Unknown	Unknown
Flexion/extension frictional torque measurements	32mm-7.7Nm	Unknown	Unknown	Unknown

- *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.