HitchFit R-37 Prototype

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ENGINEERING

1) The HitchFit R-37 is a socket adapter system that allows adjustment in the Transverse Plane in two simultaneous directions. This is accomplished using 2 non-concentric cams, one rotating inside the other. The adjustments are in set radial increments of 22.5° starting from a zero position with the connection point in the center of the socket mounting pattern. The radial design allows for adjustments in all directions without removing the device from the socket. It allows up to 12.5mm of radial displacement from the zero position with various positions in that range. There is a total of 129 unique adjustment positions. See Section 4)e)ii for the complete list.

2) Parts provided for this assembly:
   a) Radial Base
   b) Outer Cam
   c) Inner Cam
   d) Mounting Plate
   e) Pyramid
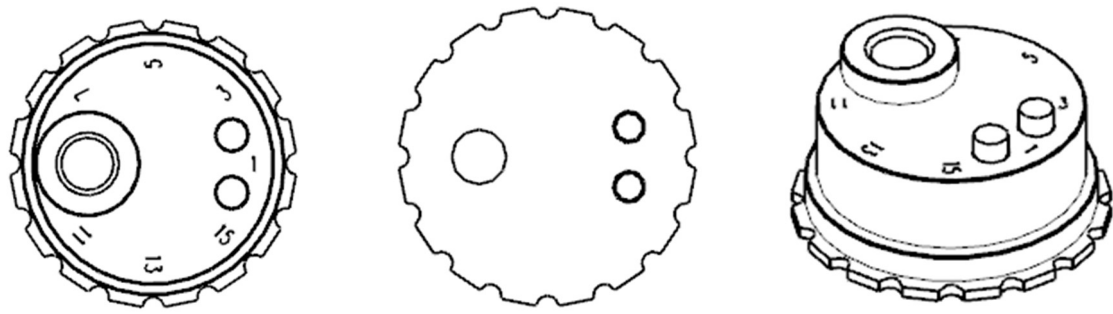   f) M6x1.0x30 Countersunk Screw

   Item a: Radial Base with locking pins installed – Top and Bottom Views Shown
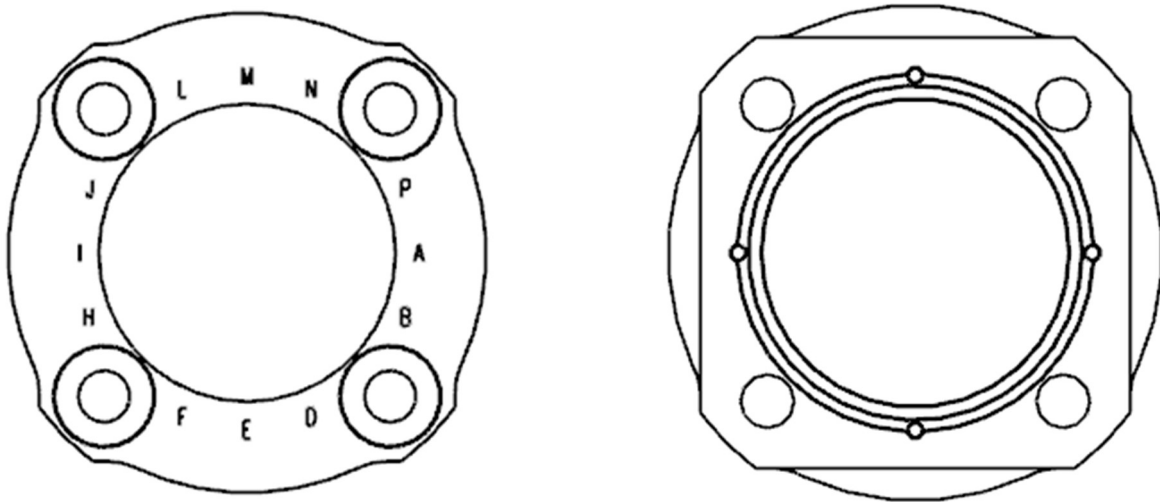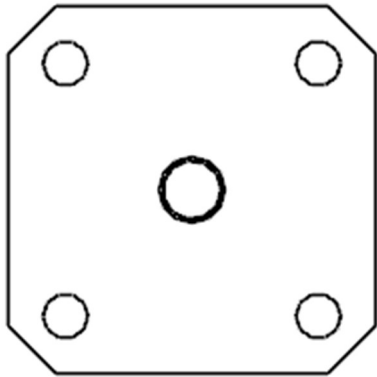

   Item b: Outer Cam with locking pins installed – Top and Bottom Views Shown
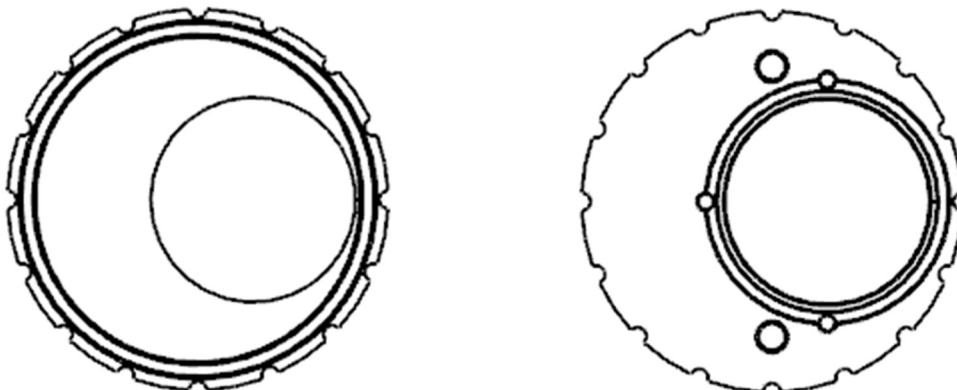
Item c: Inner Cam with clocking pins installed – Top, Bottom and Perspective Views Shown

Item d: Mounting Plate

Item e: Pyramid – Perspective View Shown
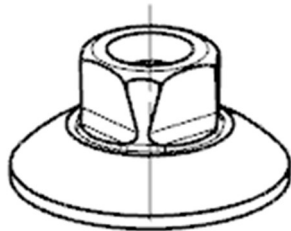
Item f: M6x1.0x30 Countersunk Screw – Perspective View Shown
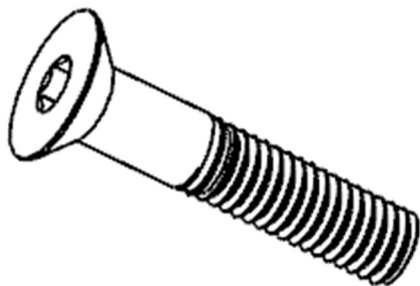
3) Additional parts needed:
   a) M6x1.00x? Countersunk Screw – Qty 4. Length to be determined by socket interface. Strength Class should be 10.9 or higher.

4) Assembly Instructions
   a) The completed assembly will include all the provided parts, and the additional parts needed to attach the adapter to the socket. It will resemble these depictions:

   i) Shown looking from the foot toward the distal end of the socket with the adapter in the A1 position and M6x1.00 screws installed and with the pyramid and mounting bolt removed:
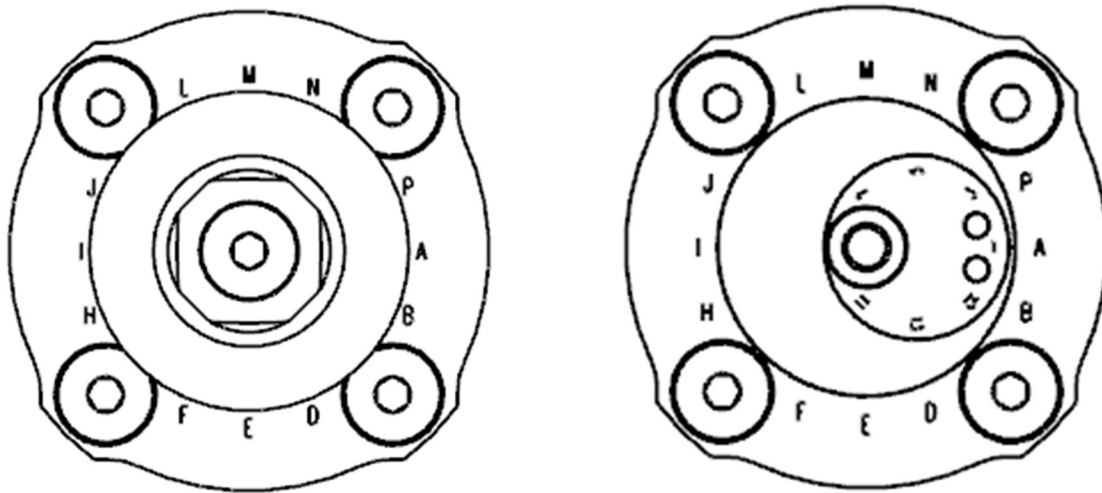
   ii) Perspective view with all parts shown depicted in the A1 position (socket not shown) and with pyramid and attachment bolt removed:
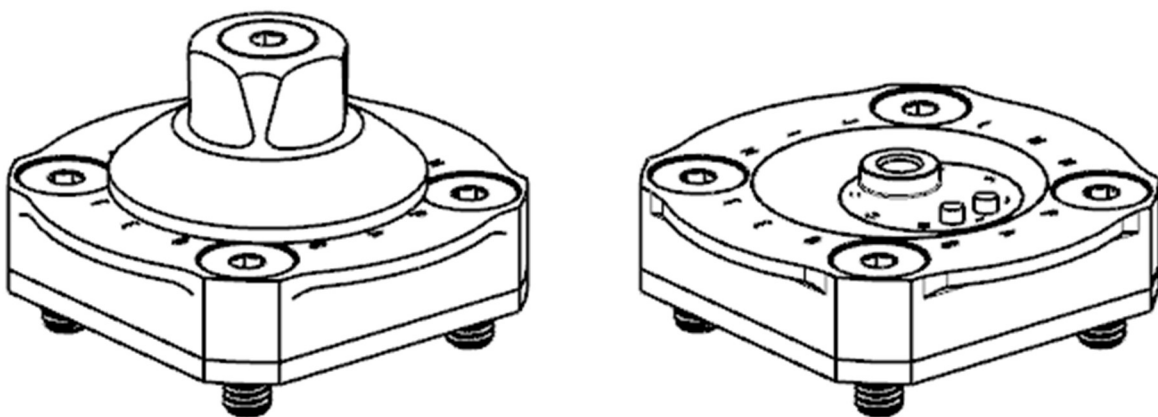
iii) Enlarged view of Inner Cam, Outer Cam, and Rotary Base position indicators:
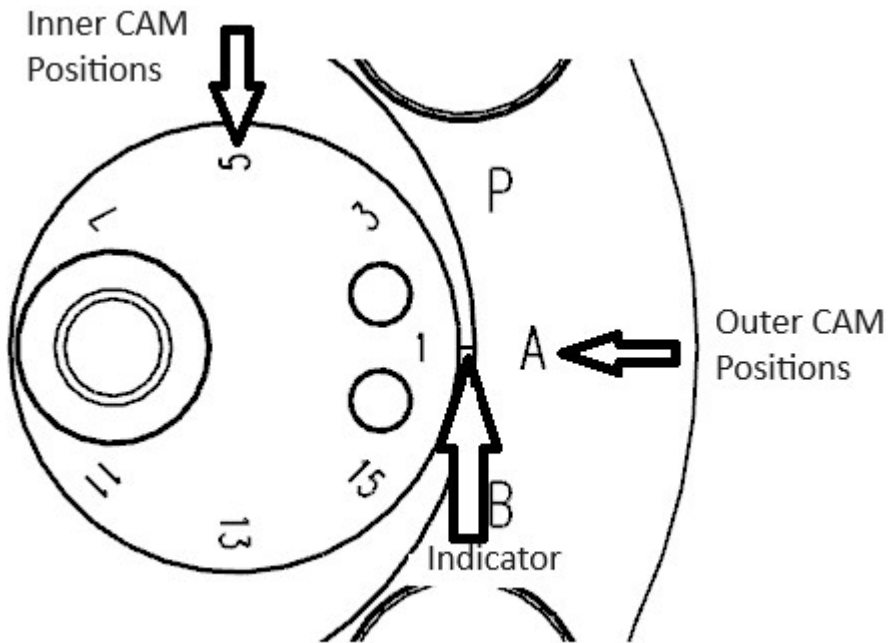
iv) Enlarged bottom view showing locking features of adapter assembly:
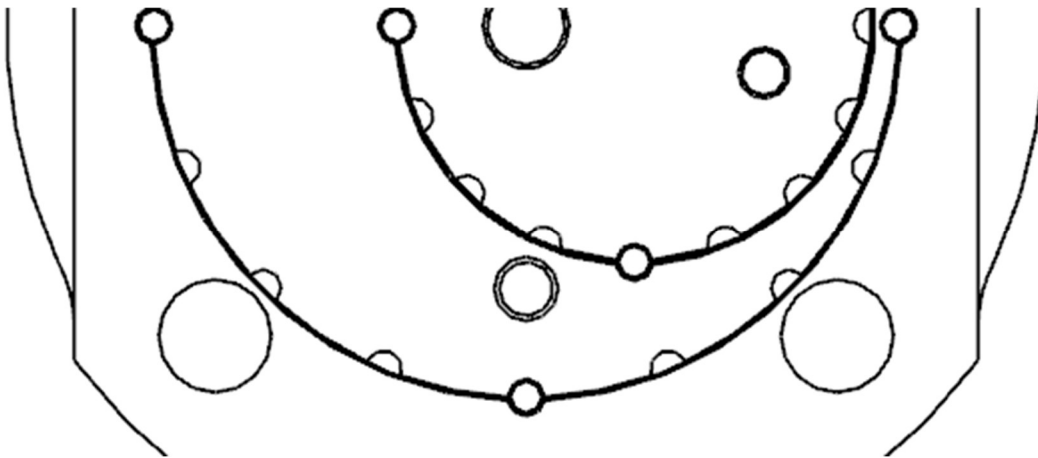
v) Perspective view with all parts shown depicting the A5,M13 position (socket not shown) and with pyramid and attachment bolt removed:
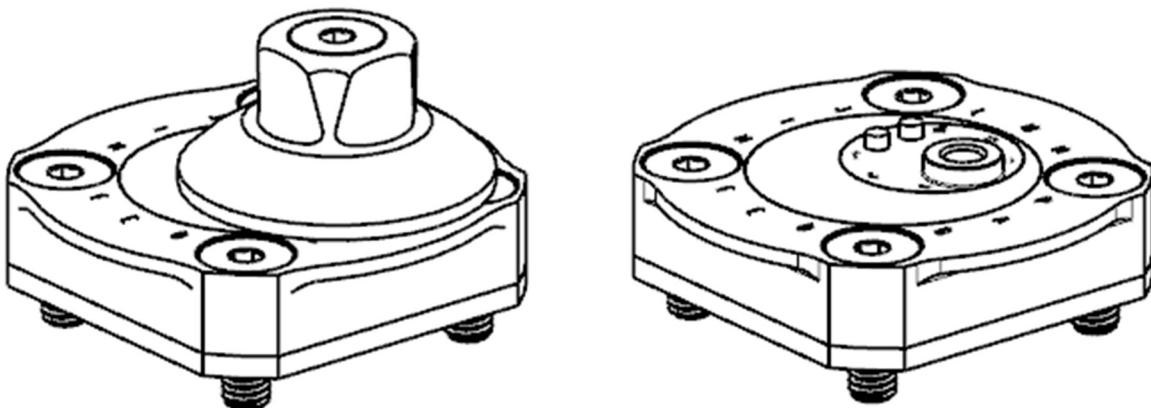
b) Orientations
   i) The adapter assembly can be oriented in 4 positions on the distal end of the socket and the same results would be obtained in any orientation, but for ease of tracking locations, attachment to match the layout in Section 4)a)i is recommended.
c) Adjustment of Offsets
   i) The direction of adjustment is entirely up to the clinician. Only position 9 of the Inner Cam will yield a unique position in any Outer Cam position. All Outer Cam positions with an Inner Cam position of 1 will yield a zero offset. All other positions (except an Inner Cam position of 9) of the Inner and Outer Cams will have two position combinations that will yield the same offset point.
   ii) Once an offset position has been chosen, it is recommended to loosely attach the adapter assembly to the socket using the 4 M6x1.00 screws. The Mounting Plate is in contact with socket on one side and with the Radial Base, Outer Cam, and Inner Cam on the side opposite. Though the offset positions of the adapter can be adjusted while the socket is attached to the patient, it is recommended that the adjustments be made while the socket is not donned by the patient.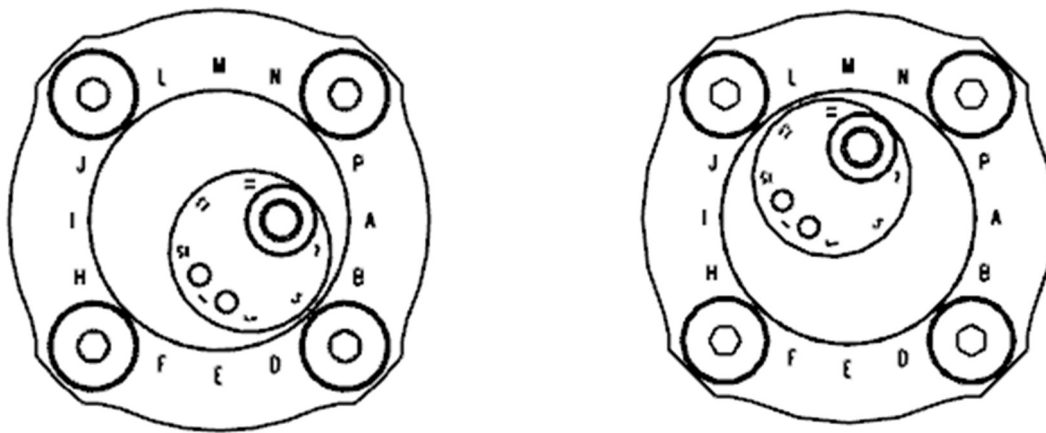 Medial, lateral, anterior and posterior directions will be determined by left or right leg and orientation of the adapter on the socket. Looking from the foot toward the distal end of the socket (socket not shown), views are shown of the adapter assembly with the pyramid or receiver and attachment bolt removed in the C5 and L12 positions:

   The clocking pins and the boss on the Inner Cam Assembly provide angular alignment for the Pyramid or Receiver when installed.
   iii) The locking features of the Outer Cam are 2½mm high while the Inner Cam locking features are 1mm high. The M6x1.00 screws have a thread pitch of 1mm. It is recommended to adjust the Outer Cam first and then adjust the Inner Cam second. To adjust the center post position, bring all 4 M6x1.0x? screws down to snug and then back all 4 screws off 2½-3 rounds, allowing enough clearance to move the Outer Cam to the desired position. Hold the socket with the distal end pointing up. Lightly lift the Radial Base up against the 4 mounting screws allowing the Outer Cam to disengage from the locking features of the Radial Base. If desired, you may use an M6x1.0 screw inserted into the threaded boss of the Inner Cam to rotate both outer and inner cams to align the indicator mark on the Outer Cam to the desired alpha location indicated on the Radial Base. Lower the Radial Base to engage with the locking features on the Outer Cam. Tighten the 4 M6x1.0x? screws down 1.5 rounds ensuring that the Outer Cam aligns with the locking pins in the Radial Base. You may use the M6x1.0 screw inserted into the threaded boss of the Inner Cam to rotate only Inner Cam until the desired numeric location aligns to the indicator mark on the Outer Cam. Lower the Inner Cam to engage the locating pins in the Outer Cam. Ensure that all alignment features are as desired then allow the Radial Base to rest on the Mounting Plate against the socket. Tighten the 4 mounting screws in a diagonal pattern to snug the entire assembly to the socket.

iv) While testing various locations for the desired alignment, torque the 4 M6x1.00 screws to 10-12 Nm or specifications from the fitting that is receiving the screws. When desired position is reached and the patient is leaving the clinic, ensure screws are torqued to 10-12 Nm or specifications from the fitting that is receiving the screws. LOCTITE® 243™ THREADLOCKER may be used if desired.

d) Attach the desired connector (Pyramid or Receiver) using the provided M6x1.0x30 screw making sure the two locking pins engage into two of the holes of the 5-hole pattern (indicated by green arrows) of the connector. (The other hole pattern is for clocking with the HitchFit L-35.) Choose the two holes that will align the sides of the pyramid or receiver into the correct orientation of the adapter as shown:
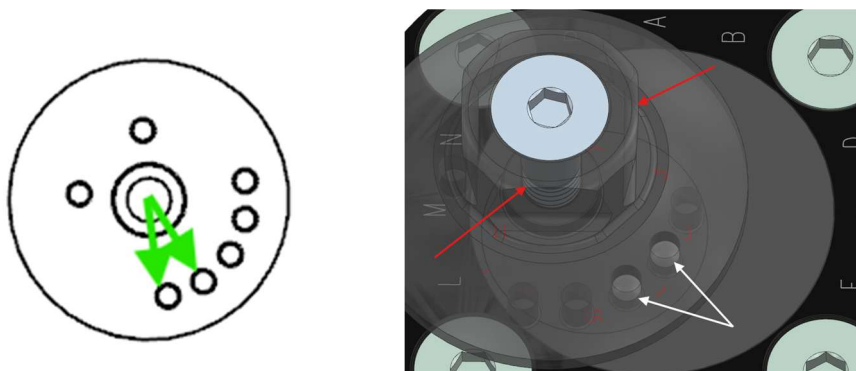
The sides of the pyramid (or receiver) indicated by the red arrows must align with the sides of the adapter. The white arrows indicate the two holes required to make the alignment correct for the L12 position. Torque the M6x1.0x30 screw to 10-12 Nm. LOCTITE® 243™ THREADLOCKER may be used for the final configuration if desired.

e) Positions
   i) All available offset positions for the HitchFit R-37 Adapter are as shown in Table 1 on the following two pages. Each possible offset position is shown for both unique and duplicated positions. The directions indicated are based on orienting the adapter as shown in Section 4)a)i) on the right leg. The first page shows the offsets from -12.5 mm to 0.0 in the medial/lateral direction with all anterior/posterior positions. The second page shows all offsets from 0.0 to 12.5 mm in the medial/lateral direction with all anterior/posterior positions. As stated earlier, the direction of offset can vary based on left or right leg and initial orientation of the adapter assembly when placed on the socket. Regardless of initial placement, all offset values can be obtained though it will be up to the clinician to determine relative directions.
   ii) There are a total of 129 unique adjustment positions achievable with the HitchFit R-37. There are 37 positions for each quadrant, 4 of which are defined by a single position, 28 of which are shared by two positions, 1 of which is shared by 16 positions (zero offset) and 4 of which are shared with an adjacent quadrant. The offset values in this table are to be used in conjunction with the information in Section 4)c - Adjustment of Offsets.

Table 1 Page 1

mm	-12.5	-12	-12	-11	-10	-9	-9	-8	-7	-6	-6	-5	-4	-4	-3	-2	-2	-2	-1	-0	0	mm
12.5																					M9	12.5
12.0															L10,M8							12.0
11.5												L9									L11,N7	11.5
10.7													K11,M7									10.7
10.2								K10,L8								K12,N6						10.2
8.8						K9															K13,O5	8.8
8.6										J12,M6												8.6
8.2								J11,L7							J13,N5							8.2
6.8				J10,K8														J14,O4				6.8
6.3							I13,M5															6.3
5.8						I12,L6						I14,N4										5.8
4.8		J9																			J15,P3	4.8
4.4			I11,K7														I15,O3					4.4
3.9										H14,M4												3.9
3.4								H13,L5							H15,N3							3.4
2.4		I10,J8																		I16,P2		2.4
2.0				H12,K6														H16,O2				2.0
1.8													G15,M3									1.8
1.4								G14,L4								G16,N2						1.4
0.5															F16,M2							0.5
0	I9		H11,J7			G13,K5						F15,L3									X1	0
-0.5															E16,L2							-0.5
-1.4								F14,K4								D16,K2						-1.4
-1.8													E15,K3									-1.8
-2.0				G12,J6														C16,J2				-2.0
-2.4		H10,I8																		B16,I2		-2.4
-3.4								F13,J5							D15,J3							-3.4
-3.9										E14,J4												-3.9
-4.4			G11,I7														C15,I3					-4.4
-4.8		H9																			B15,H3	-4.8
-5.8						F12,I6						D14,I4										-5.8
-6.3								E13,I5														-6.3
-6.8				G10,H8														C14,H4				-6.8
-8.2								F11,H7							D13,H5							-8.2
-8.6										E12,H6												-8.6
-8.8						G9															C13,G5	-8.8
-10.2								F10,G8								D12,G6						-10.2
-10.7													E11,G7									-10.7
-11.5												F9									D11,F7	-11.5
-12.0															E10,F8							-12.0
-12.5																					E9	-12.5
mm	-12.5	-12	-12	-11	-10	-9	-9	-8	-7	-6	-6	-5	-4	-4	-3	-2	-2	-2	-1	-0	0	mm

Table 1 Page 2

mm	0	0.5	1.4	1.8	2	2.4	3.4	3.9	4.4	4.8	5.8	6.3	6.8	8.2	8.6	8.8	10.2	10.7	11.5	12.0	12.5	mm
12.5	M9																					12.5
12.0						M10,N8																12.0
11.5	L11,N7							N9														11.5
10.7							M11,O7															10.7
10.2				L12,O6								N10,O8										10.2
8.8	K13,O5																O9					8.8
8.6									M12,P6													8.6
8.2						L13,P5							N11,P7									8.2
6.8			K14,P4														O10,P8					6.8
6.3									A5,M13													6.3
5.8						A4,L14							A6,N12									5.8
4.8	J15,P3																		P9			4.8
4.4				A3,K15														A7,O11				4.4
3.9								B4,M14														3.9
3.4						B3,L15						B5,N13										3.4
2.4		A2,J16																		A8,P10		2.4
2.0			B2,K16												B6,O12							2.0
1.8							C3,M15															1.8
1.4				C2,L16								C4,N14										1.4
0.5					D2,M16																	0.5
0	X1							D3,N15						C5,O13				B7,P11			A9	0
-0.5				E2,N16																		-0.5
-1.4				F2,O16								D4,O14										-1.4
-1.8							E3,O15															-1.8
-2.0			G2,P16												C6,P12							-2.0
-2.4		A16,H2																		A10,B8		-2.4
-3.4						F3,P15							D5,P13									-3.4
-3.9								E4,P14														-3.9
-4.4				A15,G3														A11,C7				-4.4
-4.8	B15,H3																		B9			-4.8
-5.8						A14,F4								A12,D6								-5.8
-6.3									A13,E5													-6.3
-6.8			B14,G4												B10,C8							-6.8
-8.2						B13,F5							B11,D7									-8.2
-8.6									B12,E6													-8.6
-8.8	C13,G5																C9					-8.8
-10.2				C12,F6									C10,D8									-10.2
-10.7							C11,E7															-10.7
-11.5	D11,F7							D9														-11.5
-12.0					D10,E8																	-12.0
-12.5	E9																					-12.5
mm	0	0.5	1.4	1.8	2	2.4	3.4	3.9	4.4	4.8	5.8	6.3	6.8	8.2	8.6	8.8	10.2	10.7	11.5	12.0	12.5	mm