

CTN 5/94

**PORTLAND SQUARE** PTY LIMITED  
A.C.N. 001 243 474

42 MONTGOMERY STREET  
KOGARAH NSW 2217 AUSTRALIA

TELEPHONE: (61-2) 588 1297  
FAX: (61-2) 587 1014

**CLINICAL TRIAL NOTIFICATION**

**ST. GEORGE TOTAL CONTACT HIP  
REPLACEMENT**

17 June, 1994

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12344

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17 June, 1994

The Business Manager  
Business Management Unit  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

Dear Sir/Madam,

Re: CLINICAL TRIAL NOTIFICATION  
St. George Total Contact Hip Replacement

This Clinical Trial Notification (CTN) is submitted to the Therapeutic Goods Administration in accordance with Section 6.9 of DR3 to provide information regarding the forthcoming clinical trial of the St. George Total Contact Hip Replacement.

Sponsor

Portland Square Pty Limited  
42 Montgomery St  
KOGARAH N.S.W. 2217

Telephone: (02) 588 1297  
Facsimile: (02) 587 1014

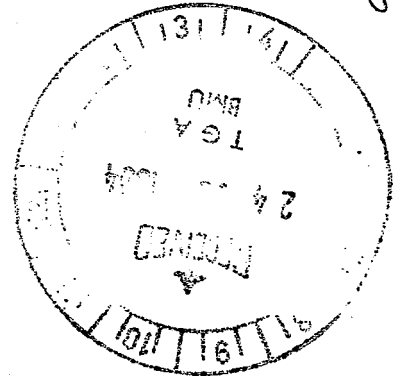
Device Description

The St. George Total Contact Hip Replacement comprises new design femoral neck and shaft hip replacement components including instrumentation for insertion of the prosthesis. The femoral component is a double-threaded tapering cone which is screwed into the femoral shaft after tapping the bone. An infinite angle neck component of double Morse taper is inserted, thereby eliminating errors of anteversion and subsequent secondary dislocation. The femoral stem and proximal neck components are manufactured from chrome-cobalt alloy with the femoral stem component having hydroxyapatite coating. The head and acetabular components are known prosthetic designs already in clinical use.

Angles and length of the neck component have been calculated from known geometry of the human hip joint. The width of the prosthesis in relation to the upper and lower taper widths has been obtained from previous knowledge of the geometry of the human femoral canal.

Included as Attachment 1 are engineering drawings of the femoral stem and proximal neck components.

Both components will be supplied sterilised by gamma irradiation.



## Clinical Trial

The St. George Total Contact Hip Replacement has been designed by and will be investigated initially at the St. George Hospital, a teaching hospital of the University of New South Wales.

The first phase of the study will comprise 50 total hip replacements followed by a complete review of the data. If the results are satisfactory, a further 50 total hip replacements will be performed. The first 100 implants will be performed at the St. George Hospital by the following investigators:

### Chief Investigator

Dr. Ronald Sekel  
Orthopaedic Surgeon  
St. George Hospital  
KOGARAH N.S.W. 2217

Telephone: (02) 588 2121  
(02) 588 1297  
Facsimile: (02) 587 1014

### Associate Investigator

Dr. Scott Newman,  
Research Orthopaedic Registrar  
St. George Hospital  
KOGARAH N.S.W. 2217

Telephone: (02) 350 1111

The purpose for which information on the new hip design is being sought is to assess whether the St. George Hip is:

- Easier to insert and remove.
- Able to eliminate the previous problems of neck anteversion errors with secondary dislocation.
- Equal to or more successful a prosthesis than current design hip replacements in use.

The routine operative Southern approach to the hip joint for joint replacement is to be undertaken. Uncemented hip femoral components currently used are extremely difficult to remove and it is believed that the St. George Hip will be easier and quicker to remove and thus decrease morbidity to the patient.

Patients to be included in this research project will be those requiring total hip replacement for degenerative changes of the hip secondary to osteoarthritis or post-traumatic. The patients should preferably be in good health suitable for anaesthesia and surgery and over the age of 65 years.

It is anticipated that the study, 93/37 Sekel, will commence in August, 1994 with the first 100 implants taking approximately 12 months to be performed. The study will be carried out according to the NH&MRC Guidelines on Human Experimentation and Supplementary Notes.

Included as Attachment 2 is a copy of the IEC approval letter dated 12 April 1994 and signed by Roselyn Drake, Secretary of the Southern Sydney Area Health Service Ethics Committee.

If any questions arise regarding this Clinical Trial Notification, please contact Ms. Jenny Forage, Regulatory Affairs Consultant who is acting on behalf of Portland Square Pty Limited on telephone/fax (02) 955 2023.

Yours sincerely,  
Portland Square Pty Limited

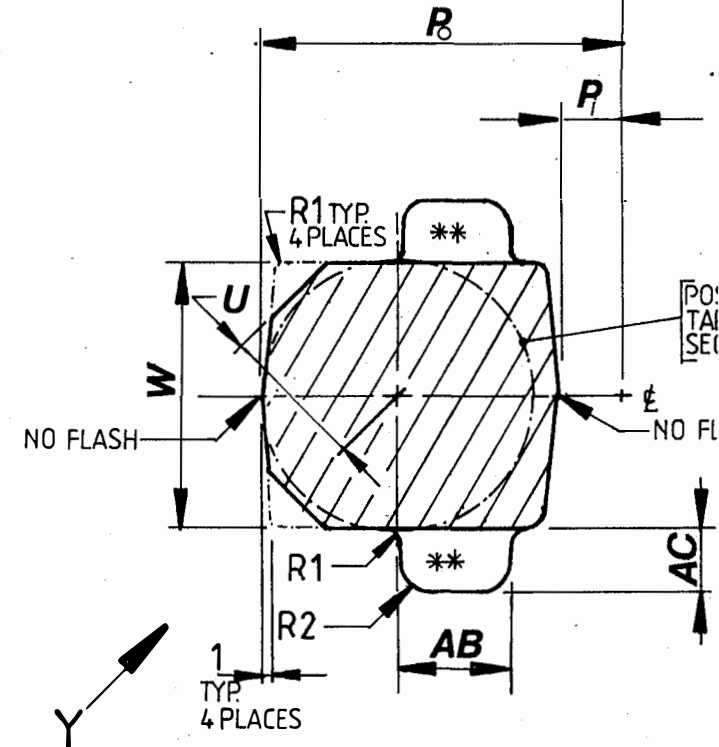
A handwritten signature in black ink, appearing to read 'Ron Sekel', with a horizontal line underneath.

Dr. Ronald Sekel  
Director

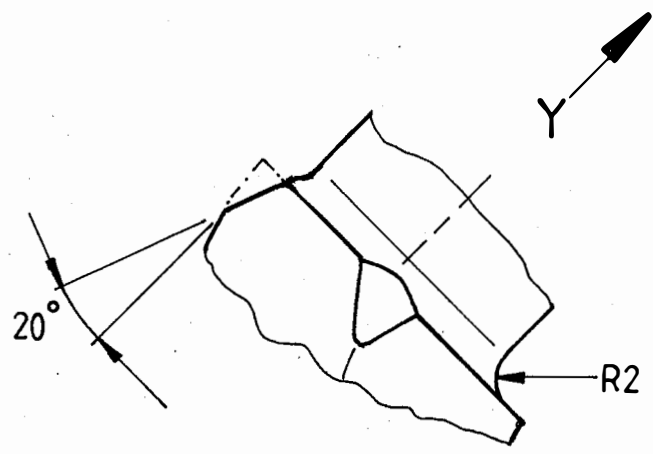
MACHINING SUPPORT IS PERMISSIBLE IF REQ'D ]

SIDE VIEW  
SCALE 2:1

FRONT VIEW  
SCALE 2:1 (OF Nº B)



SECTION Z-Z  
SCALE 2:1



VIEW Y  
SCALE 2:1

R2

VIEW X  
SCALE 2:1

SMOOTH BLEND WITHOUT UNDERCUT  
AT FORGED MACHINED SURFACE  
JUNCTION - R2 MIN. ALL ROUND  
BASE OF TAPER

OF TOP OF  
BELOW  
PLANE Z-Z

**NOTE :** AT PROTOTYPE STAGE, PRODUCTION OF FEMORAL STEM COMPONENTS (SGHP-001, ISSUE 'D') AND PROXIMAL NECK COMPONENTS (SGHP-002, ISSUE 'D') TO BE MACHINED IN MATCHED PAIRS, IDENTIFIED BY SERIAL NUMBER COMMONALITY, SO THAT :

a) DIA 'B' ON STEM AND DIA 'B' ON NECK ARE WITHIN 0.025mm.

AND

b) INCLUDED ANGLE OF DISTAL TAPER ON NECK IS  $1' \pm 30''$  LARGER THAN INCLUDED ANGLE ON TAPER BORE IN STEM.

## OPERATIONS REFEREN

1. FORGE AND FETTLE.
2. SHOT BLAST.
3. HARDNESS TEST (BATCH).
4. PROTECTIVE PACKAGING.
5. CRATE.
6. TRANSPORT.
7. UNCRATE AND UNPACK.
8. MACHINE AND DE-BURR.
9. CRACK TEST : ASTM F601-86.
10. FINISH SURFACE : ASTM F86-
11. APPLY DESIGNATION.
12. CLEAN : ASTM F86-84.
13. PACKAGE AND HEAT SEAL.
14. CRATE.
15. TRANSPORT.
16. UNCRATE.
17. DRG FINAL PACKAGING.
18. LABEL PACKAGE.
19. GAMMA IRRADIATE TO STERIL
20. CRATE.
21. TRANSPORT.

LIST

D	5/4/94	<p>ELECTRO-ETCH DESIGNATION MOVED TO END OF PROXIMAL TAPER.</p> <p>PROXIMAL TAPER ALTERED. DIMENSIONS K, L, S, φAN, AND CHAMFER CHANGED. AM REMOVED.</p> <p>TOLERANCES ADDED TO DIMENSIONS E AND F, AND CHANGED ON φB AND DISTAL TAPER.</p> <p>OPERATIONS REFERENCE LIST ORDER CHANGED.</p> <p>SURFACE FINISH ON PROXIMAL TAPER CHANGED.</p> <p>CENTRE DRILLING NOTE ADDED TO BASE OF DISTAL TAPER.</p> <p>NOTE DEFINING POINT AJ CHANGED.</p> <p>NOTE ADDED FOR PROTOTYPING.</p>	JRR	RF
ISSUE	DATE	DETAILS	DWN	CHKD

REVISIONS CONTINUED

OPTIONAL DRILLING CENTRE PAD REMOVED.

ALTERATIONS TO BALL REMOVAL REACTION PADS AND STEM REMOVAL REACTION PADS.

STEM TAPERED SECTION ON SIZE N<sup>o</sup>s 1 AND 2 REDUCED BY 1mm

ISSUE DATE DETAILS DWN CHKD

REVISIONS



CONFIDENTIAL

UNISEARCH

UNISEARCH LTD CONSULTING & RESEARCH  
 P.O. BOX 1 KENSINGTON NSW 2033 AUSTRALIA  
 TELEPHONE +61 (0)2 697 5401

CLIENT PORTLAND SQUARE PTY. LTD.

JOB ST. GEORGE HOSPITAL HIP PROSTHESIS

DRAWING PROXIMAL NECK COMPONENT  
 SET & DETAILS *PROTOTYPE, ONLY*

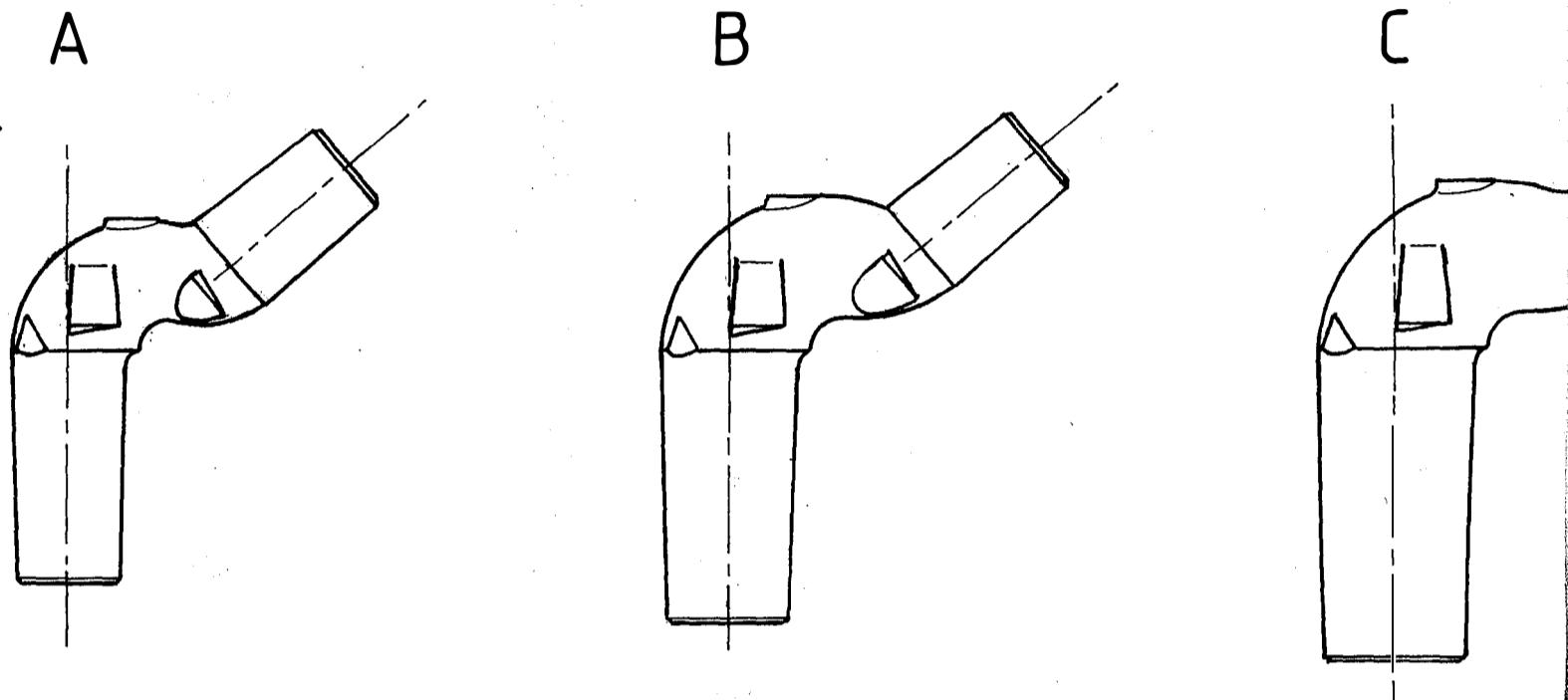
SCALE 2:1 1:1 (A1) NUMBER SGHP-002

DATE 8.11.92

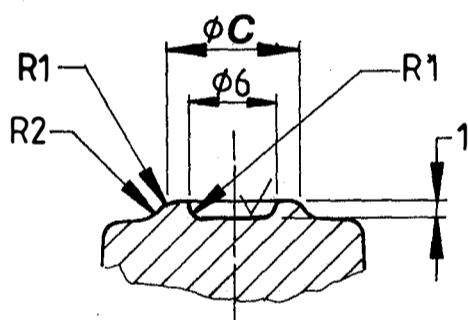
DRAWN JRR CHECKED RF ISSUE ~~XXXD~~

DO NOT SCALE. ALL DIMENSIONS TO BE CHECKED, AND ANY INCONSISTENCIES REPORTED TO UNISEARCH, BEFORE COMMENCING WORK.

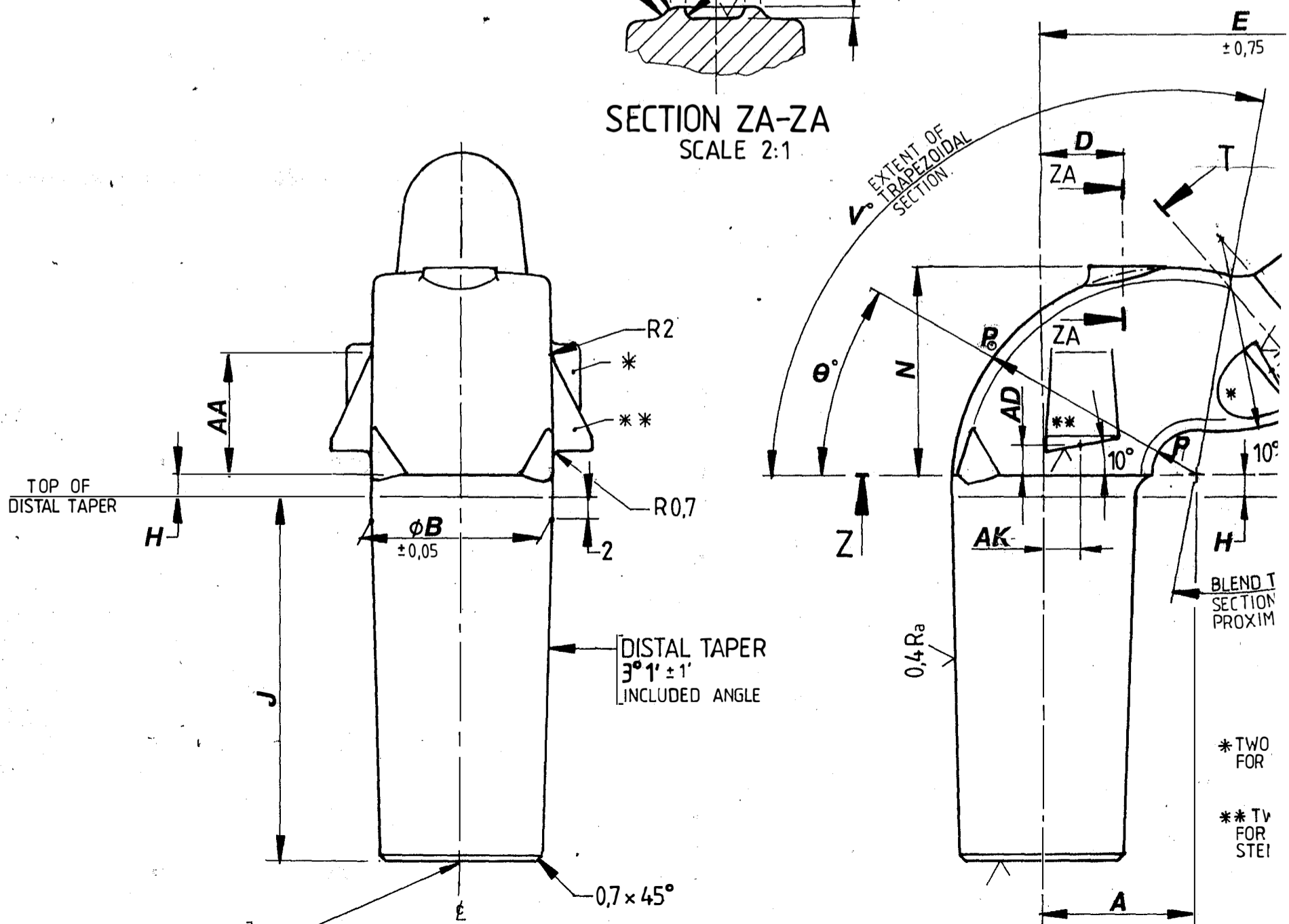
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NECK SIZE RANGE A-C  
SCALE 1:1



SECTION ZA-ZA  
SCALE 2:1



\* TWO FOR  
\*\* TV FOR STEI

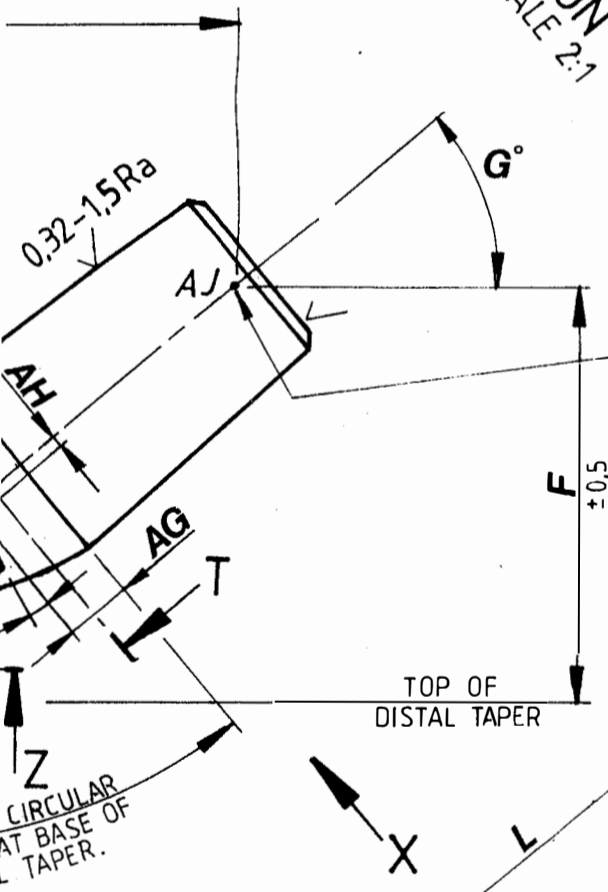
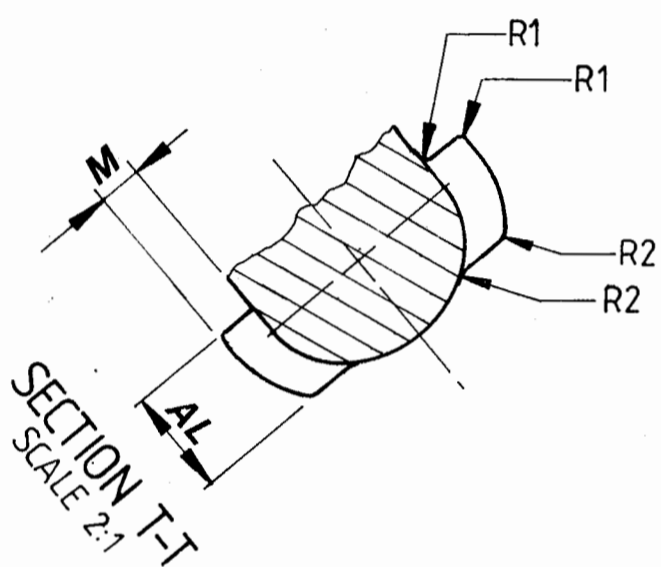


ELECTRO-ETCH DESIGNATION  
 10u DEEP MAX ON END OF  
 PROXIMAL TAPER

VIEW ON END OF  
 PROXIMAL TAPER  
 SCALE 2:1

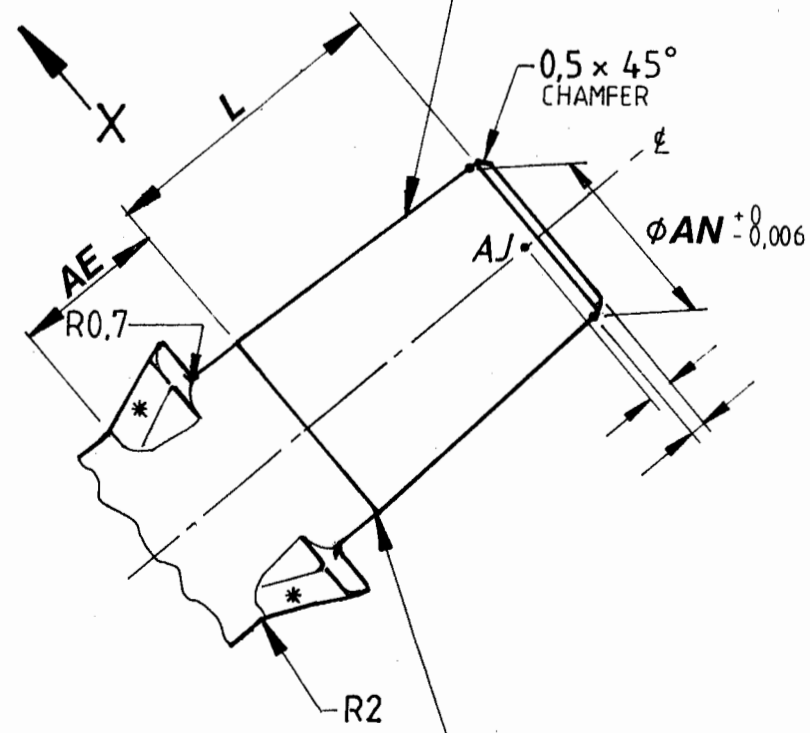


SIZE CODE: A-C  
 6 DIGIT SERIAL NUMBER  
 MATERIAL CODE FOR  
 CHROME COBALT ALLOY



NOTE: POINT AJ IS THE CENTRE OF THE  
 $\phi 32$  ZERO (MEDIUM) BALL ON  
 THE AXIS OF THE PROXIMAL  
 TAPER.

PROXIMAL TAPER  
 $5^{\circ}42'30''$  ( $\phi 1,495/15$ )  
 $5^{\circ}37'30''$  ( $\phi 1,474/15$ )  
 INCLUDED ANGLE



SMOOTH BLEND WITHOUT UNDERCUT  
 AT FORGED MACHINED SURFACE  
 JUNCTION - R2 MIN. ALL ROUND  
 BASE OF TAPER

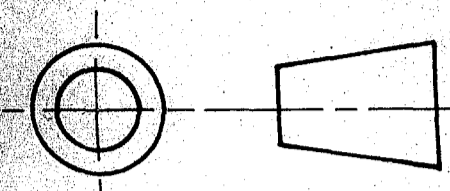
REACTION PADS  
 ALL REMOVAL.  
 REACTION PADS  
 REMOVAL FROM

VIEW X  
 SCALE 2:1

OPERATIONS REFER

ASSEMBLY COMBINATIONS

NECK SIZE	A	B	C
STEM SIZE	1 & 2	3 & 4	5 & 6



DIMENSION TABLE

SIZE NO.	1	2	3
A	12.95	14.7	16.45
B	15.0	17.5	20.0
C	9.0	9.0	9.0
D	8.0	8.0	9.0
E	35.47	39.30	46.97
F	24.29	27.49	29.93
G°	40°	40°	40°
H	2.0	2.0	2.0
J	29.0	34.0	38.5
K	2.4	2.4	2.4
L	21.0	21.0	21.0
M	3.0	3.0	3.0
N	18.0	22.2	23.5
S	1.4	1.4	1.4
U	8.5	9.75	11.0
V°	93°	100°	95°
AA	10.5	12.0	13.5
AB	7.0	7.0	7.0
AC	5.0	5.0	5.0
AD	1.0	1.0	1.0
AE	10.5	13.0	13.0
AG	5.0	5.0	5.0
AH	1.5	1.5	1.5
AK	3.5	3.5	3.5
AL	7.0	7.0	7.0
AN	12.700	12.700	12.700

ANGLE θ	P <sub>o</sub>	P <sub>i</sub>	W	P <sub>o</sub>	P <sub>i</sub>	W	P <sub>o</sub>	P <sub>i</sub>	W
0°	20.5	3.5	16.0	23.5	4.0	17.0	26.5	4.5	20.2
10°	20.1	3.5	16.0	23.1	4.0	17.0	25.9	4.5	20.2
20°	19.7	3.5	16.0	22.7	4.0	17.0	25.3	4.5	20.0
30°	19.3	3.5	16.0	22.3	4.0	17.0	24.7	4.5	19.7
40°	18.9	3.5	16.0	21.9	4.0	17.0	24.1	4.5	19.4
50°	18.4	3.5	15.9	21.5	4.0	16.8	23.5	4.5	19.1
60°	17.8	3.5	15.7	21.1	4.0	16.6	22.9	4.5	18.8
70°	17.2	3.5	15.5	20.7	4.0	16.4	22.3	4.5	18.5
80°	16.6	3.5	15.3	20.3	4.0	16.2	21.7	4.5	18.3
90°	16.0	3.5	15.1	19.9	4.0	16.0	21.1	4.5	18.1
*100°	15.6	3.5	15.0	19.5	4.0	15.8	19.9	4.5	17.9

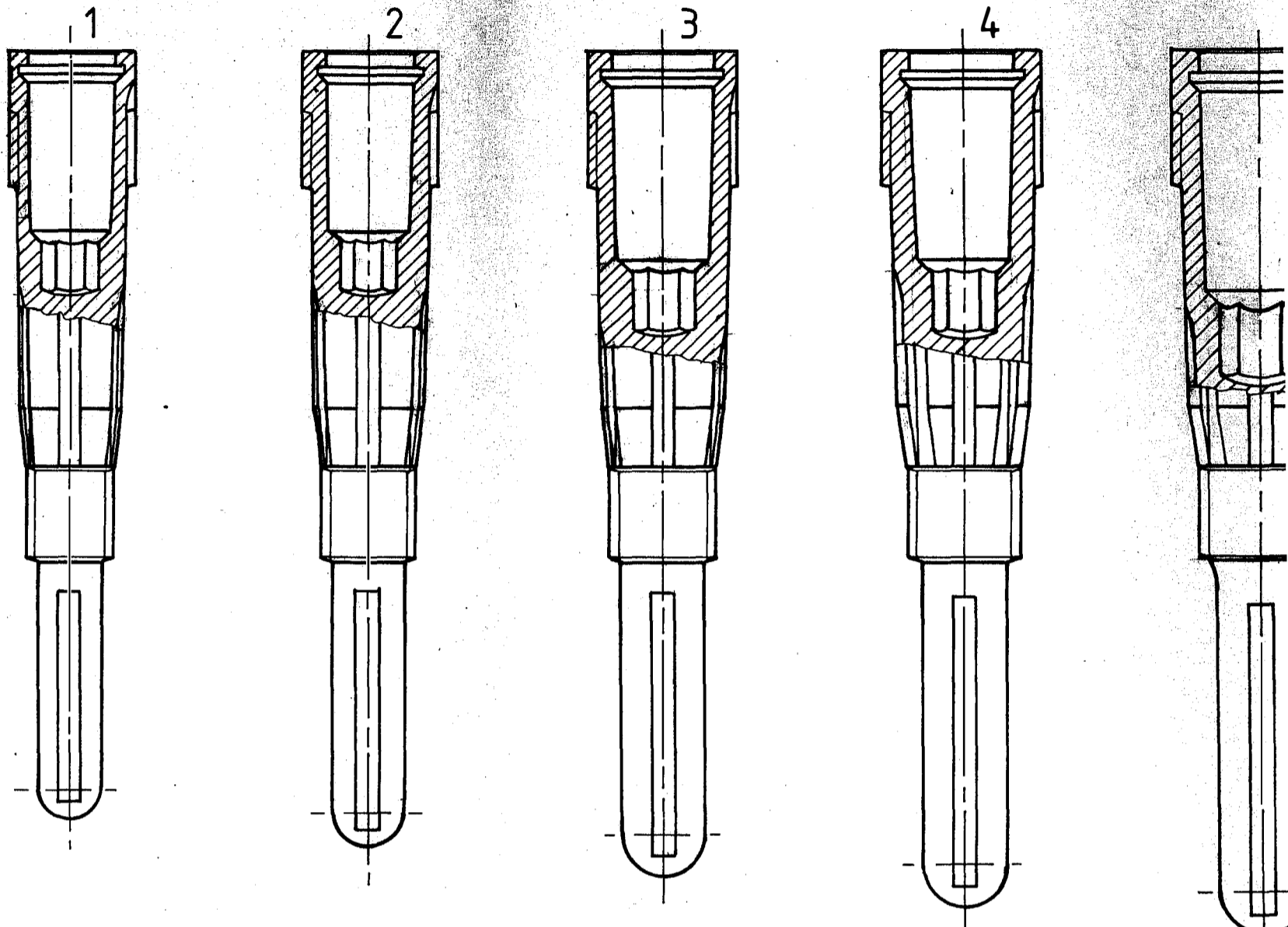
\* Note : This line not used in all cases. This figure is used for interpolation of section.

NOTES

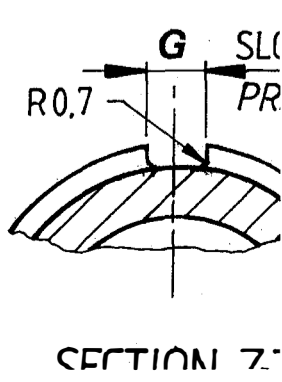
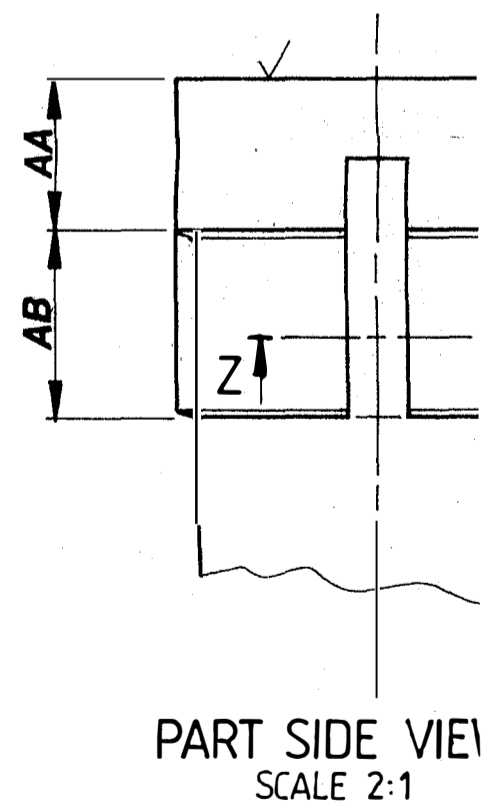
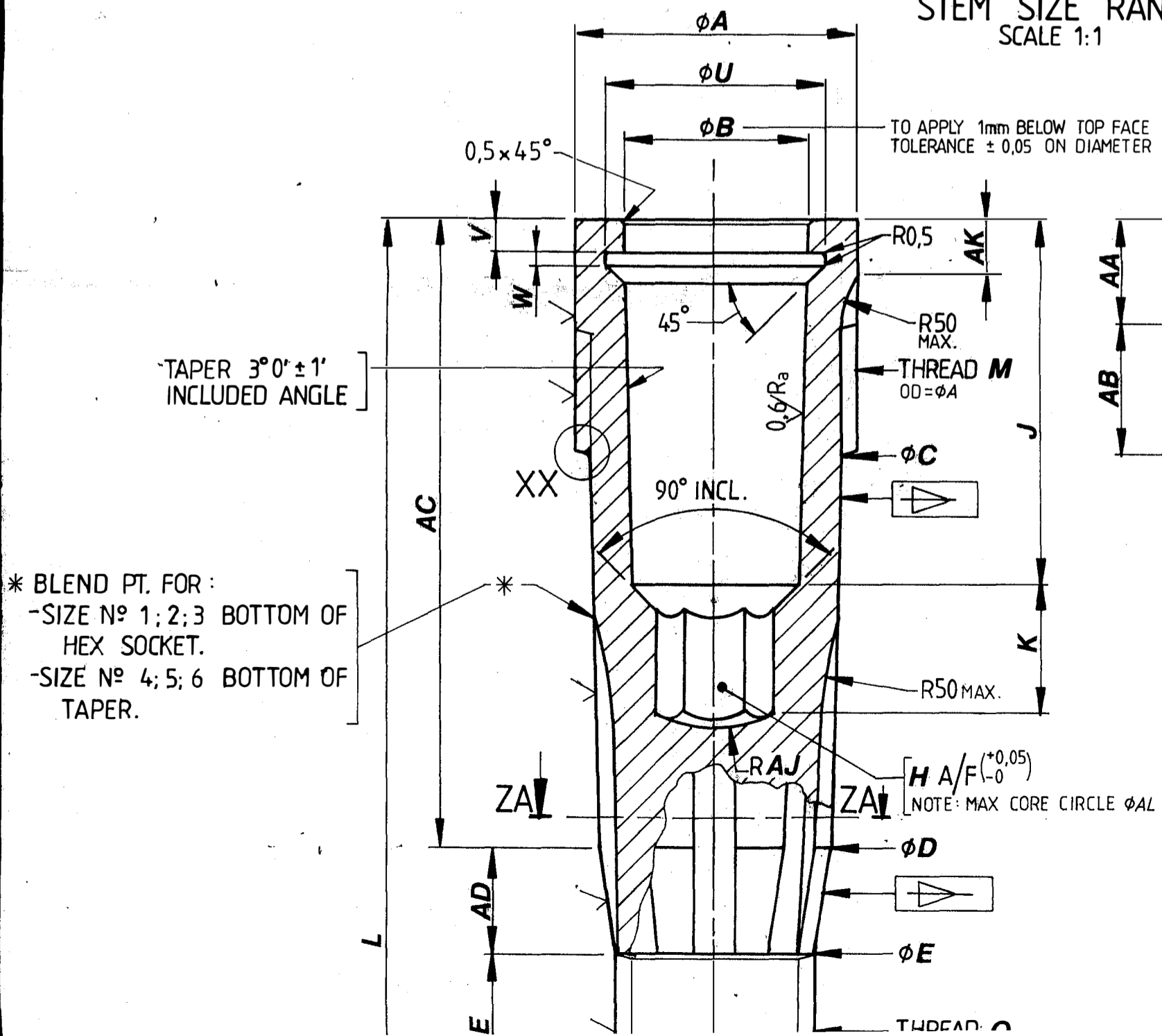
- MATERIAL :- ASTM F799 Co-Cr ALLOY SUPPLIED 1 3/8" DIA. MIN HARDNESS 38 RC HARDNESS TEST INDENTATIONS TO BE MACHINED AWAY.
- UNLESS OTHERWISE STATED ALL DIMENSIONS ARE IN MILLIMETRES.
- TOLERANCES : UNLESS OTHERWISE SPECIFIED ARE ± 0.1mm ON LENGTHS, ±0.5° ON ANGLES.
- SURFACE FINISH OF CURVED CENTRAL SECTION 2 Ra AS FORGED.
- ALL FETTLING AND MACHINING TO BE FULLY DE-BURRED.
- THESE NECKS TO BE USED ONLY WITH ST. GEORGE HIP PROSTHESIS FEMORAL STEM COMPONENTS AS PER DRAWING SGHP-001.
- MACHINING ALLOWANCE ON FORGINGS : 1.5 ± 0.5 PER SIDE ON EACH TAPER AND ON ALL FOUR REACTION PAD FACES AND ON EACH END OF EACH TAPER.
- TRAPEZOIDAL SECTION AND BLEND SECTION NOT TO BE MACHINED. FORM TOLERANCE ON THESE SECTIONS  $\begin{matrix} +1.0 \\ -0.0 \end{matrix}$  mm.

*RF 2/4/94.*

D	DATE	DESCRIPTION	INITIALS
C	10/2/94	SEE ADDITIONAL TABLE NECK SIZE NAMES CHANGED FROM NUMBERS TO LETTERS : A, B, C. ASSEMBLY COMBINATIONS ADDED TO TABLE. SIZES N, AC AND AD CHANGED, Q REMOVED. POSITIONING OF φB AND TOLERANCE CHANGED. UNDERCUT REMOVED FROM JUNCTION OF PROXIMAL TAPER AND CURVED CENTRAL SECTION. SHAPE OF HAMMER PAD CHANGED (SECTION ZA-ZA). NOTES (ABOVE) CHANGED. DESIGNATION INFORMATION ADDED TO BASE OF DISTAL TAPER. DISTAL TAPER SIZES AND SURFACE FINISH CHANGED. SURFACE FINISH NUMBER ADDED TO PROXIMAL TAPER. RADIUS ON OUTER EDGE OF REACTION PADS REMOVED. OPERATIONAL REFERENCE LIST ADDED TO THIS DRAWING.	JRR <i>RF</i>
B	22/12/92	PROXIMAL TAPER REDEFINED FOR ZERO	JRR <i>RF</i>

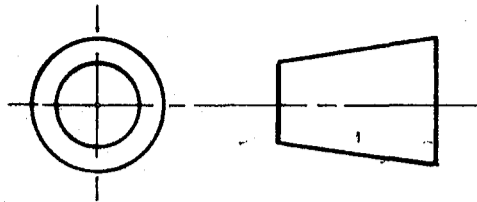


STEM SIZE RANGE 1-6  
SCALE 1:1



## OPERATIONS REFERENCE LIST

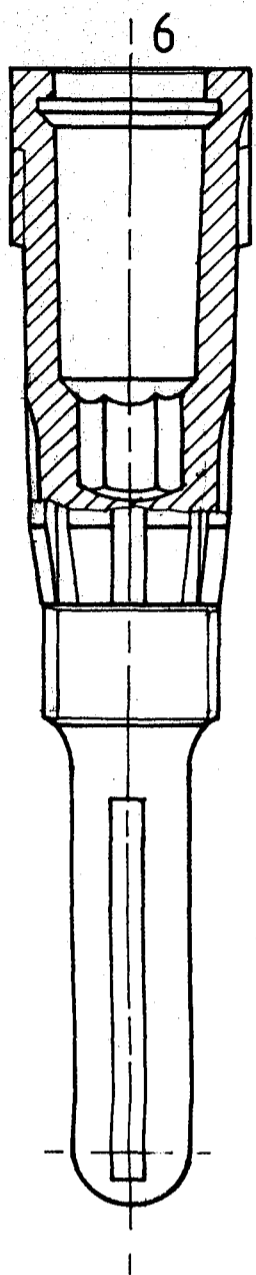
1. HARDNESS TEST (BATCH).
2. MACHINE AND DE-BURR.
3. CRACK TEST : ASTM F601-86.
4. FINISH SURFACE : ASTM F86-84.
5. APPLY DESIGNATION.
6. CLEAN : ASTM F86-84.
7. PROTECTIVE PACKAGING.
8. CRATE.
9. TRANSPORT.
10. UNCRATE AND UNPACK.
11. MASK.
12. GRIT BLAST.
13. CLEAN : ASTM F86-84.
14. HYDROXYAPATITE COAT.
15. DE-MASK.
16. DRG PACKAGE AND HEAT SEAL.
17. CRATE.
18. TRANSPORT.
19. UNCRATE.
20. DRG FINAL PACKAGING.
21. LABEL PACKAGE.
22. GAMMA IRRADIATE TO STERILISE.
23. CRATE.
24. TRANSPORT.



### NOTES

1. MATERIAL :- ASTM F799 Co-Cr ALLOY  
SUPPLIED  $1\frac{3}{8}$ " DIA.  
MIN HARDNESS : 38 RC  
HARDNESS TEST INDENTATIONS TO BE MACHINED AWAY.
2. UNLESS OTHERWISE STATED ALL DIMENSIONS ARE IN MILLIMETRES.
3. TOLERANCES : UNLESS OTHERWISE SPECIFIED ARE  $\pm 0.1\text{mm}$
4. SURFACE FINISH : UNLESS OTHERWISE SPECIFIED IS  $6\mu\text{m}$ .
5. ALL MACHINING TO BE FULLY DE-BURRED.
6. THESE STEMS TO BE USED ONLY WITH ST GEORGE HIP PROTHESIS PROXIMAL NECK COMPONENTS AS PER DRAWING SGHP-002.
7. HYDROXYAPATITE COATING TO BE APPLIED TO OUTER SURFACES OF STEM FROM OUTER EDGE TO TOP FACE FOR A DISTANCE OF 34mm. COATING CHARACTERISTICS AS FOLLOWS :  
  - THICKNESS : 50-70  $\mu\text{m}$
  - POROSITY : 90% BULK DENSITY
  - CRYSTALLINITY : > 45%
  - CHEMICAL PURITY : > TO ASTM 1185
  - TENSILE STRENGTH : > 30 MPa
  - FATIGUE LIFE :  $10^7$  TENSILE CYCLES @ 8.3 MPa.

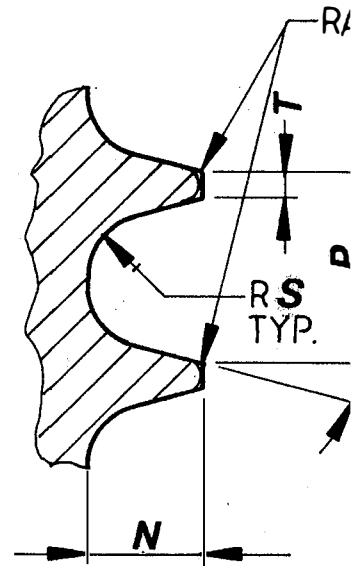
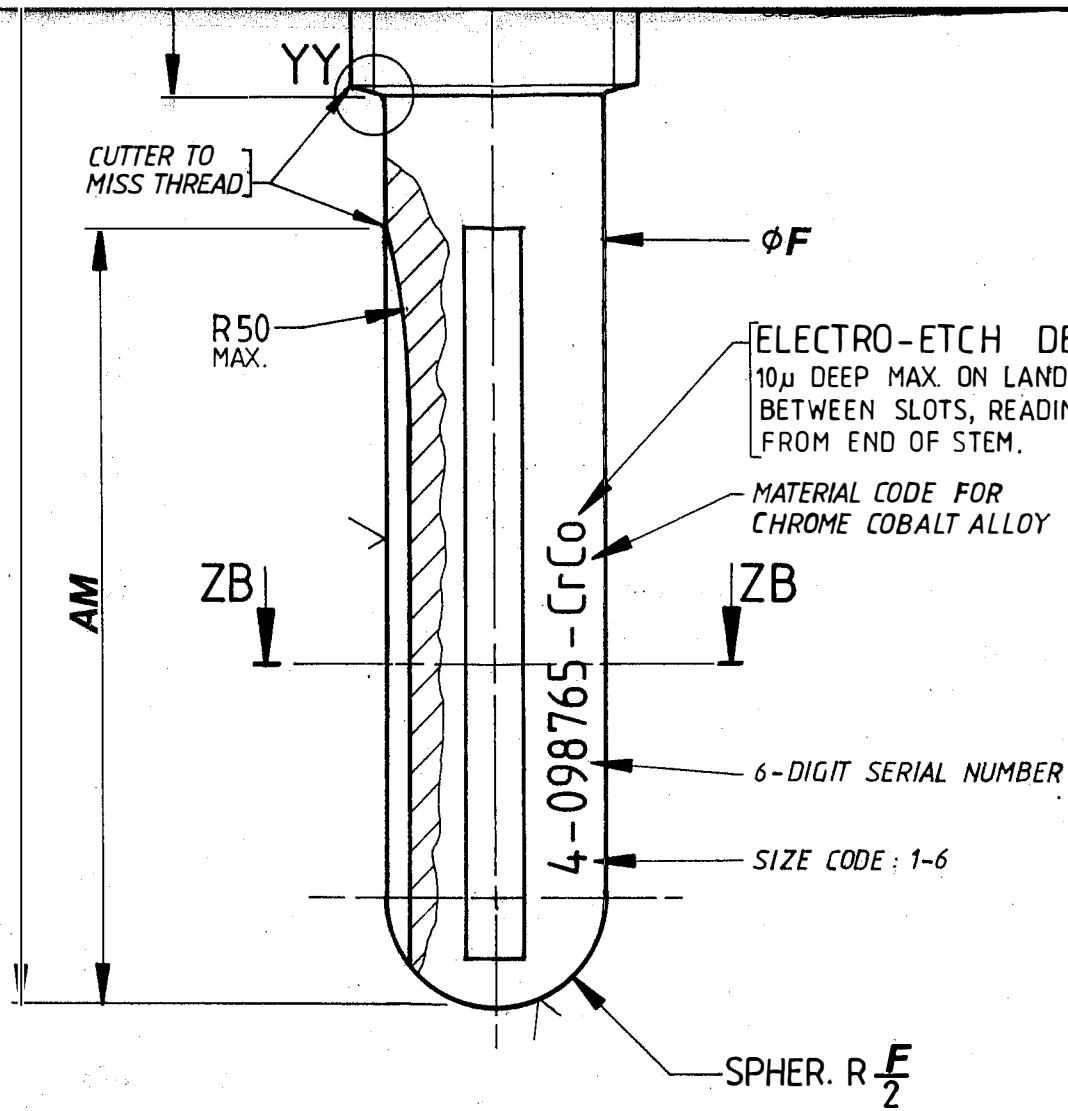
D	5/4/94	(DISTAL) TAPER ANGLE CHANGED. TOLERANCE ON $\phi B$ CHANGED. OPERATIONS REFERENCE LIST ORDER CHANGED. HYDROXYAPATITE COATING SPECIFICATIONS CHANGED. NOTE ADDED FOR PROTOTYPING.	JRR	RF
C	10/2/94	ASSEMBLY COMBINATIONS ADDED TO TABLE. SIZES <b>AM</b> ADDED TO TABLE. (DISTAL) TAPER ANGLE AND SURFACE FINISH CHANGED. NOTES (ABOVE) CHANGED. DESIGNATION INFORMATION ADDED TO AREA BETWEEN SLOTS ON LOWER PART OF STEM.	JRR	RF



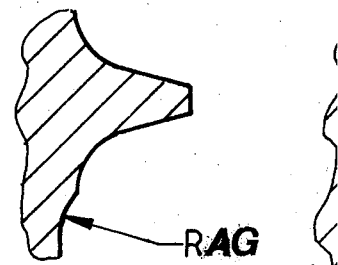
ASSEMBLY COMBINATIONS						
STEM SIZE	1	2	3	4	5	6
NECK SIZE	A		B		C	
DIMENSION TABLE						
SIZE NO.	1	2	3	4	5	6
A	21.0	23.0	25.0	27.0	29.0	31.0
B	15.0	15.0	17.5	17.5	20.0	20.0
C	17.8	19.8	21.8	23.8	25.8	27.8
D	17.0	19.0	21.0	22.0	24.0	26.0
E	14.5	16.0	18.0	19.0	21.0	23.0
F	11.0	12.5	14.0	14.5	15.0	15.0
G	4.0	4.0	4.0	4.0	4.0	4.0
GB	4.0	4.0	4.0	4.0	4.0	4.0
GC	1.5	1.5	1.5	1.5	1.5	1.5
GD	4.0	4.0	4.0	4.0	4.0	4.0
GE	1.5	1.5	1.5	1.5	1.5	1.5
H (A/F)	8.0	8.0	10.0	10.0	12.0	12.0
J	30.0	30.0	35.0	35.0	40.0	40.0
K	10.0	10.0	12.0	12.0	15.0	15.0
L	130.0	135.0	140.0	145.0	150.0	150.0
U	18.0	18.0	21.0	21.0	24.0	24.0
V	2.5	2.5	3.0	3.0	3.5	3.5
W	1.5	1.5	1.5	1.5	1.5	1.5
AA	10.0	10.0	10.0	10.0	10.0	10.0
AB	12.5	12.5	12.5	12.5	12.5	12.5
AC	60.0	60.0	60.0	60.0	60.0	60.0
AD	10.0	10.0	10.0	10.0	10.0	10.0
AE	15.0	15.0	15.0	15.0	15.0	15.0
AG	1.0	1.0	1.0	1.0	1.0	1.0
AH	1.0	1.0	1.0	1.0	10.0	10.0
AJ	12.0	12.0	12.0	12.0	12.0	12.0
AK	3.0	3.0	3.0	3.0	3.0	3.0
AL	8.5	8.5	10.6	10.6	12.7	12.7
AM	35	38	42	46	50	50
THREAD M						
N	1.5	1.5	1.5	1.5	1.5	1.5
P	2.5	2.5	2.5	2.5	2.5	2.5
S	0.6	0.6	0.6	0.6	0.6	0.6
T	0.3	0.3	0.3	0.3	0.3	0.3
THREAD Q						
N	1.5	1.5	1.5	1.5	1.5	1.5
P	3.0	3.0	3.0	3.0	3.0	3.0
S	0.6	0.6	0.6	0.6	0.6	0.6
T	0.5	0.5	0.5	0.5	0.5	0.5

-3 EQUALLY SPACED

SENT OR ABSENT AS SPECIFIED



THREAD DETAIL

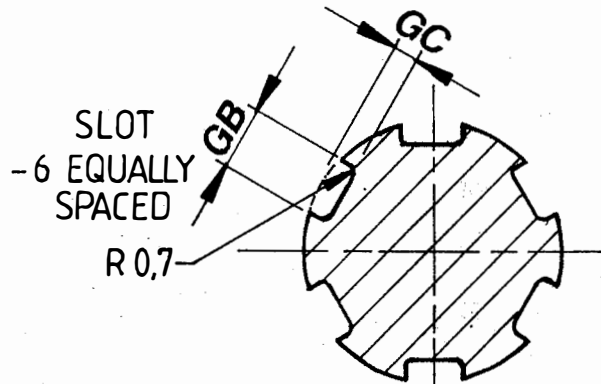


DETAIL XX

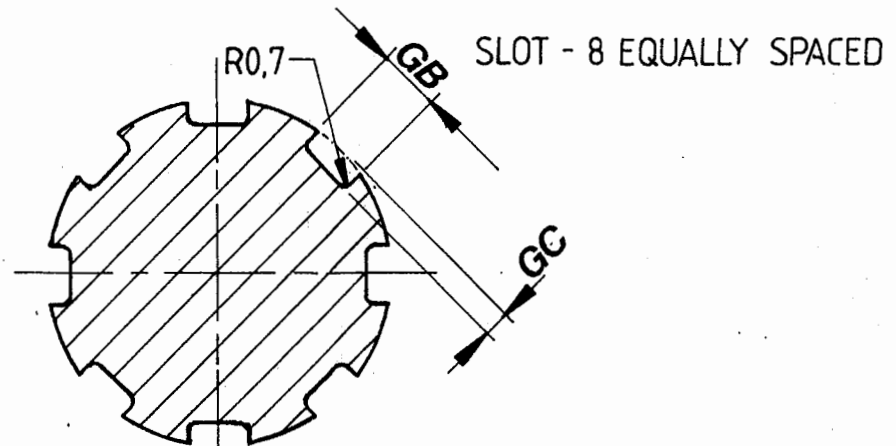
SCALE 10:

SCALE 2:1 (OF N<sup>o</sup> 4)

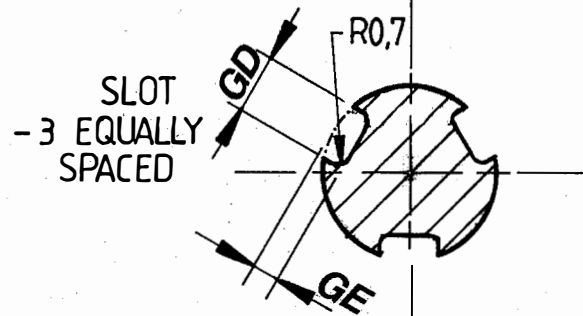
5 CREST Q THREAD ONLY



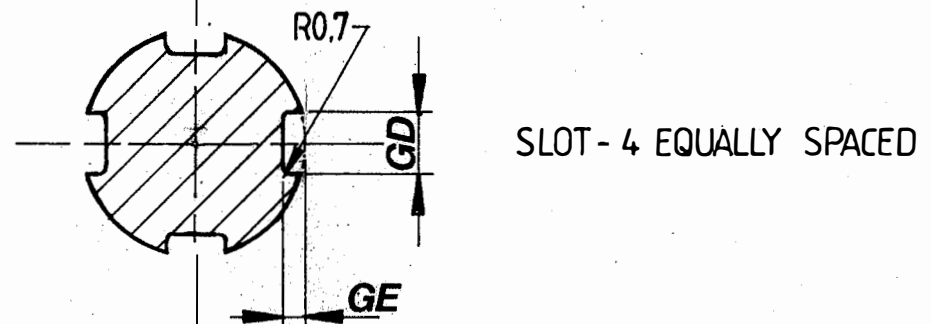
SECTION ZA-ZA  
SIZES 1;2;3  
SCALE 2:1  
(OF N°1)



SCALE 2:1 SECTION ZA-ZA SIZES 4;5;6  
(OF N°4)



SECTION ZB-ZB  
SIZES 1;2;3  
SCALE 2:1  
(OF N°1)



SCALE 2:1 SECTION ZB-ZB SIZES 4;5;6  
(OF N°4)

SCALE 10:1



RAH  
TAIL YY

		CHANGED		
B	22/12/92	CHAMFER ADDED TO TOP OF NECK TAPER. OUTSIDE SLOTS (G) WIDENED ADDITIONAL SLOTS ADDED TO MID AND LOWER SECTIONS OF STEM.	JRR	RT

ISSUE	DATE	DETAILS	DWN	CHKD
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**REVISIONS**

  
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**DRAWING**  
 FEMORAL STEM COMPONENT -  
 SET & DETAILS *PROTOTYPE ONLY*

<b>SCALE</b>	<b>NUMBER</b>
10:1 2:1 1:1 (A1)	SGHP-001
<b>DATE</b>	
2.11.92	

<b>DRAWN</b>	<b>CHECKED</b>	<b>ISSUE</b>
JRR	RT	<del>CHKD</del>

DO NOT SCALE. ALL DIMENSIONS TO BE CHECKED, AND ANY INCONSISTENCIES REPORTED TO UNISEARCH, BEFORE COMMENCING WORK.  
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TYPE STAGE, PRODUCTION OF COMPONENTS (SGHP-001, ISSUE 'D') AND COMPONENTS (SGHP-002, ISSUE 'D') TO BE MATED PAIRS, IDENTIFIED BY SERIAL NUMBER, SO THAT :

Ø AND DIA 'B' ON NECK ARE WITHIN

ANGLE OF DISTAL TAPER ON NECK IS GREATER THAN INCLUDED ANGLE ON TAPER

