REPORT ON:

SURGICAL IMPLANTS

by

Christine Poelma

for

ACT-360
AVIATION SECURITY BRANCH

B315
FAA-ACT
-87-361

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Introduction:

Terrorist activity at airports or on aircraft necessitates increasingly sensitive concourse detection systems. The development of a better system requires knowledge about those devices or items that are not weapons that are on a person going through detection system. This report is an attempt at finding information of interest regarding surgical implants. The types of implants available, materials involved, and other physical characteristics of the implants were found by contacting manufacturers, associations, and hospitals. People sent various pieces of literature in response to requests including brochures, xeroxes of templates of implants and whole ordering catalogues. This literature is referred to in each category of implants. Because the Depuy catalog creates a clear understanding of the types and characteristics of implants, xeroxed pages from this catalog are included throughout the report to supplement a concise definition for each system.

Table of Contents

Types of Implants:

Types of devices provided by the manufacturers depend on the demand for these devices. Some joints effect the mobility of a person more than other joints. Those joints that aid mobility most will, of course, be replaced the most. The Charnley hip system is the most used system for this reason. Consisting of a femoral stem with head & acetabular cup, this system is carried by all or at least most manufacturers. It is installed at least twice as much as the next-in-line replacement, the knee. A list of manufacturers and the devices they claimed in their responses to me is now in order.

The Rothman Institute: " The most common type of devices utilized in orthopedics are total joint replacements for the hip & knee."

Dow Corning Wright: "Knee-Tibia, Femoral & Patella Replacements, Hip, Shoulder, Elbow, Ankle, Fingers, Toes, Wrist, Other: "There are many internal fixation devices sold such as bone plates, bone screws, pins and wires, intramedullary rods, spinal fixation and others that we do not manufacture but are sold by other companies.", Custom Devices.

Ronan Medical Clinic: Starr-Edwards Clinical Report about Heart Valves.

Kirschner: Hips, Knees, Ankles, Shoulders, Elbows, Wrists, Fingers, Thumbs.

John Roberts (telephone conversation): "Joint Replacement Implants (usually) Hip, Knee, Proximal Femor, Wrist, Elbow, Knuckles, Fingers, Charnley Design (40 years) Hip, etc."

Depuy: "Femoral Stem with Head, Acetabular Cup, Femoral Component-Knee, Tibial Component-Knee, Wrist, Shoulder, Elbow, Fixation Plate, Intramedullary Nail."

Nancy Almers from Bergen Community College:
"hips by far most frequently used--relatively much less for knees."
"2 or 3 hips a week to one knee a month approximately"
"Elbows and shoulders very seldom."

Besides these devices there are many other special circumstances for devices. During the Viet Nam War a plate was implanted along the scull when soldiers underwent some of the traps that decapitated them. It was, by rumor, a very effective surgery.

HIP REPLACEMENT SYSTEMS
THE CHARNLEY SYSTEM

The Charnley hip replacement system, most commonly used, consists of three elements; the hip stem, femoral head, and acetabular component. Brochures from the following companies have been submitted to ACT-360 listing invaluable information about some physical characteristics of hip replacement systems;

Dow Corning Wright
Intermedics Orthopedics
Zimmer
Johnson & Johnson

The following information has been included in letter from each respective manufacturer.

Dow Corning Wright:

Hip consisting of a hip stem & an acetabular cup (brocure enclosed)

Materials used

Titanium (Hips & Acetabular Cup)
Polyethylene (Hip & Acetabular Cup)
Chrome-Cobalt Alloy (Hips)
Ceramic (Ball of hip stem) (Richards Medical)

Sizes

Hip Stem- Approximately 6"-10" (Various Sizes)
Hip Acetabular Cup- 42mm X 64mm Dia. X 1"-1/2" high

Weight

Weight varies from a few ounces to 1 1/2 pounds

Depuy

Weight

Femoral stem with head	280 gms
Acetabular Cup	72 gms

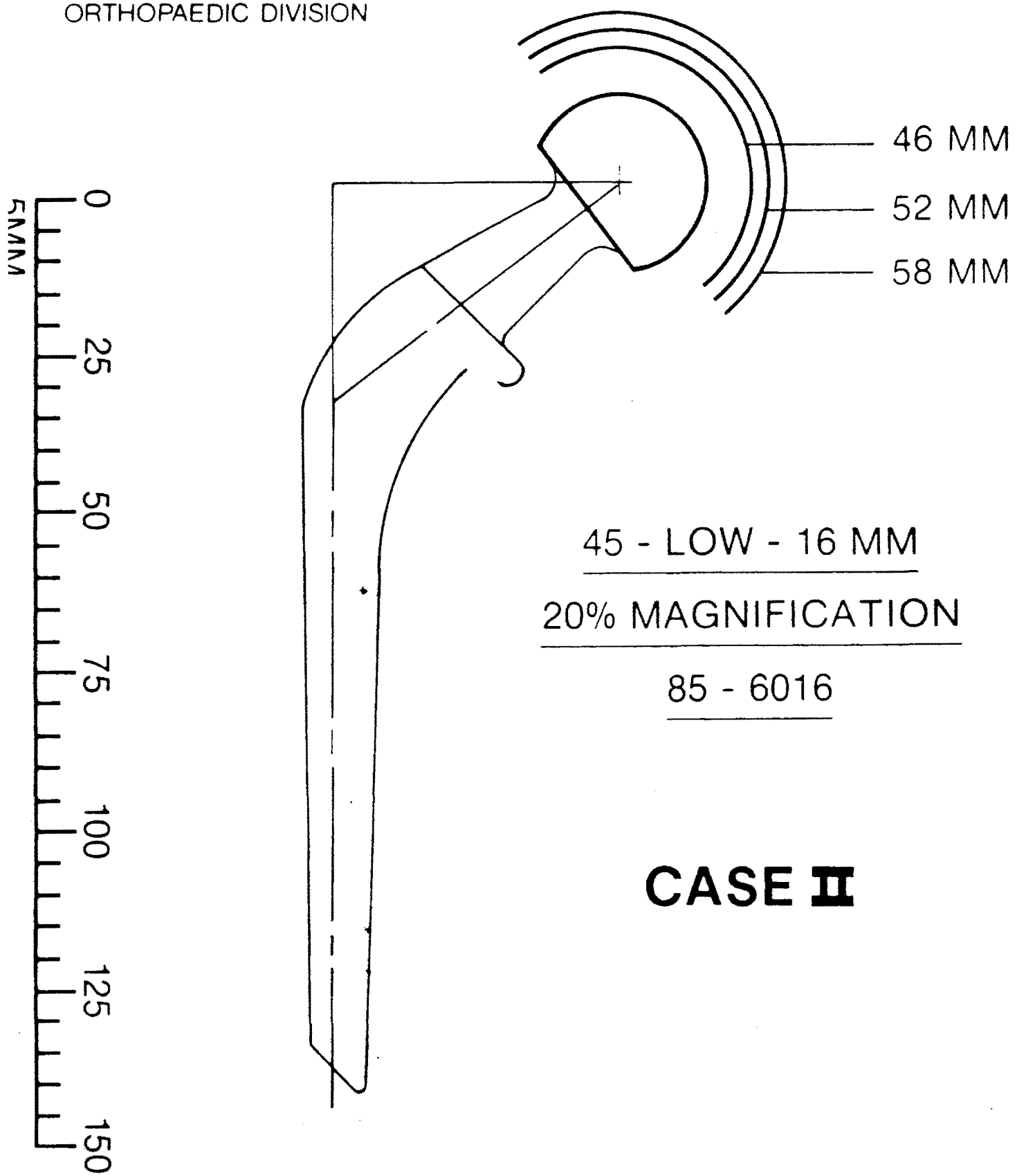
Kirschner

Hip and knee prosthesis can range from 4" to 12" in length and weigh from 1/2 to 2 pounds depending on material and design.

Johnson & Johnson
PRODUCTS INC.
ORTHOPAEDIC DIVISION

TRIAD ™

45 SERIES



45 - LOW - 16 MM

20% MAGNIFICATION

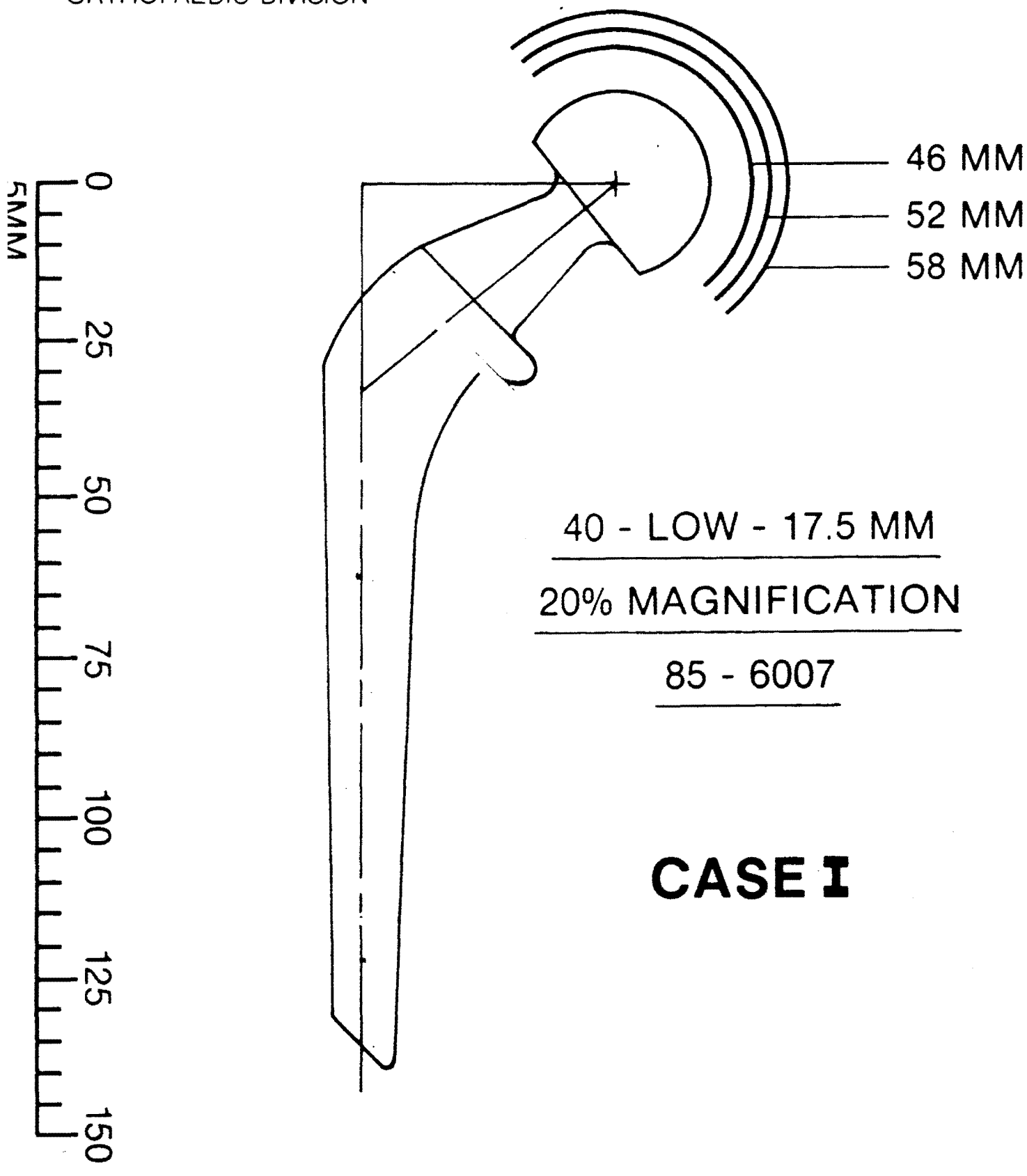
85 - 6016

CASE II

Johnson & Johnson
PRODUCTS INC.
ORTHOPAEDIC DIVISION

TRIAD ™

40 SERIES



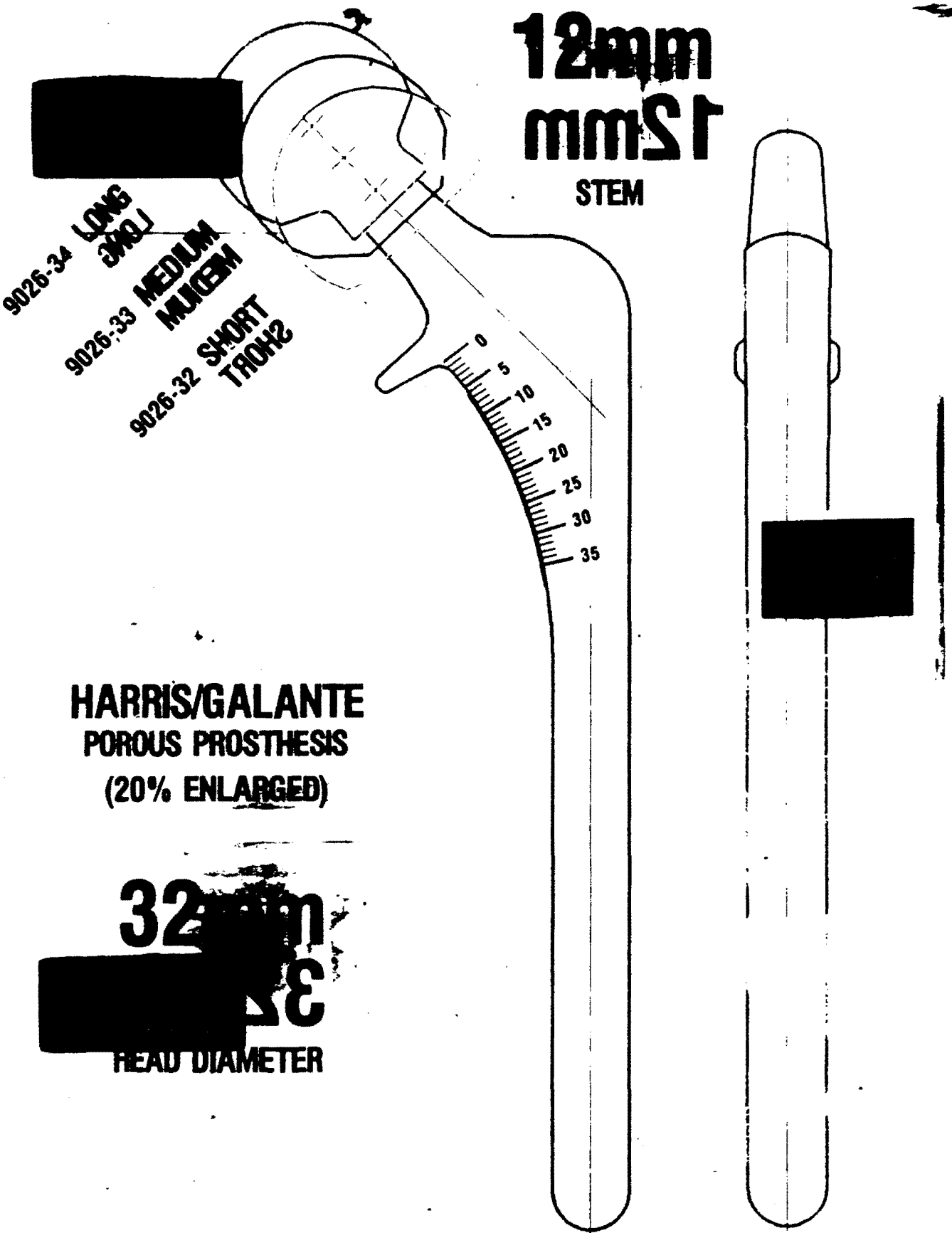
40 - LOW - 17.5 MM

20% MAGNIFICATION

85 - 6007

CASE I

6520-12



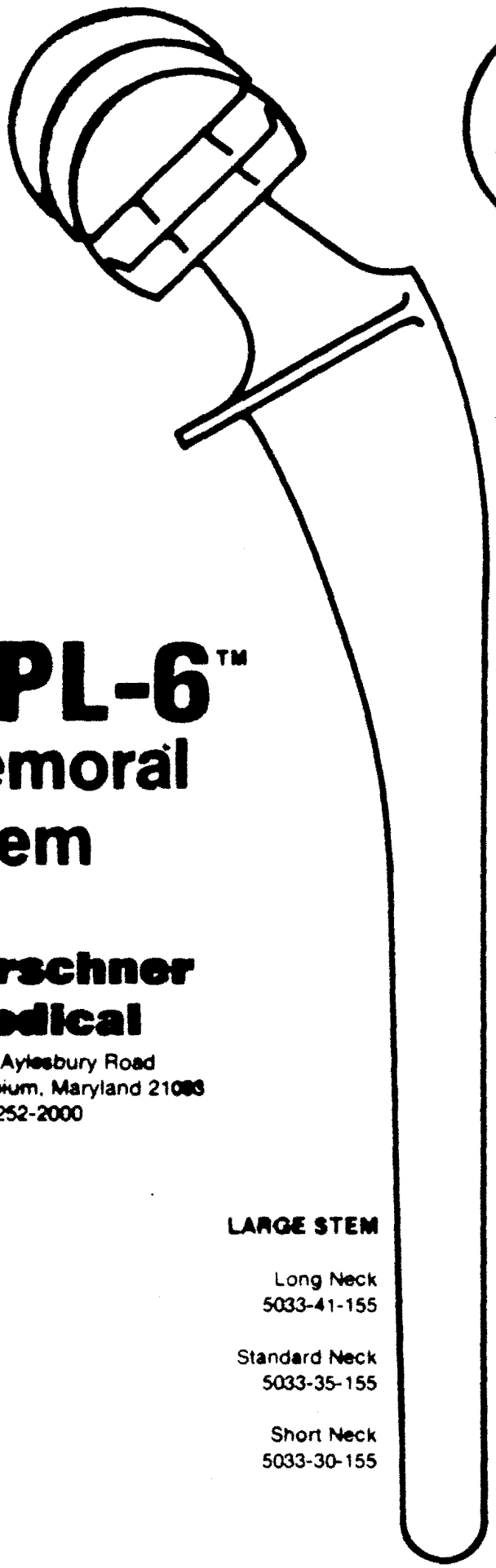
(The quality of this copy is the result of the available original. It is the best available.)

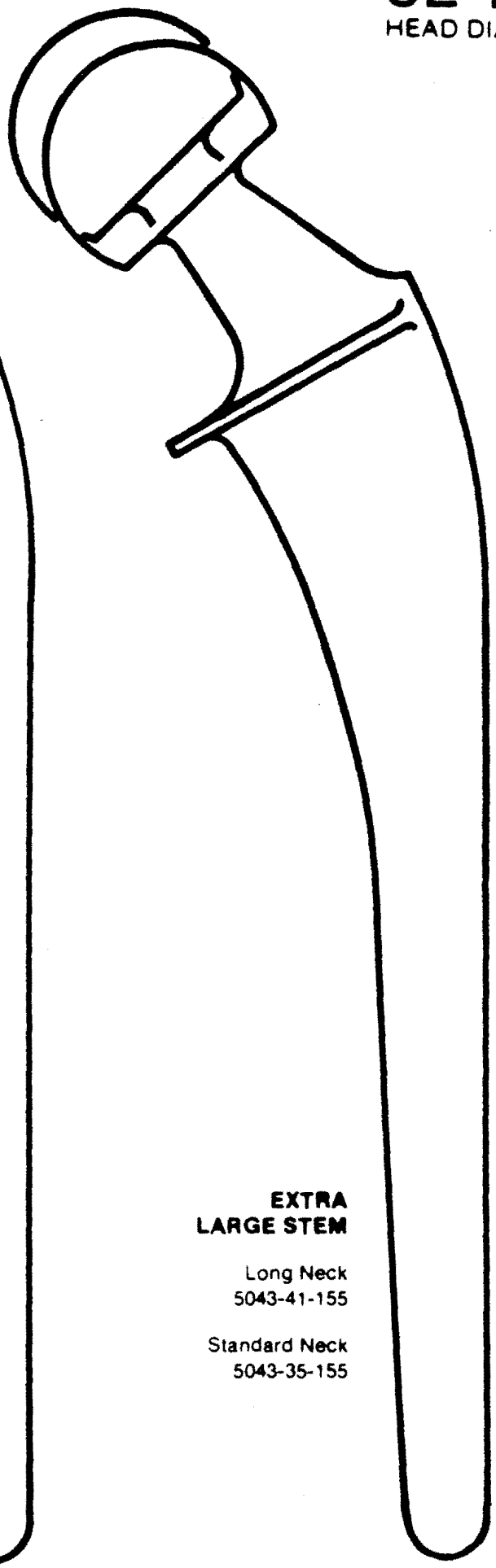
zimmer
WARSAW INDIANA

X-RAY ANALYSIS TEMPLATE

32-111111
HEAD DIAMETER

210 mm
200 mm
190 mm
180 mm
170 mm
160 mm
150 mm
140 mm
130 mm
120 mm
110 mm
100 mm
90 mm
80 mm
70 mm
60 mm
50 mm
40 mm
30 mm
20 mm
10 mm
0 mm





TPL-6™ Femoral Stem

Kirschner Medical
10 W. Aylesbury Road
Timonium, Maryland 21093
(301) 252-2000

LARGE STEM

Long Neck
5033-41-155

Standard Neck
5033-35-155

Short Neck
5033-30-155

EXTRA LARGE STEM

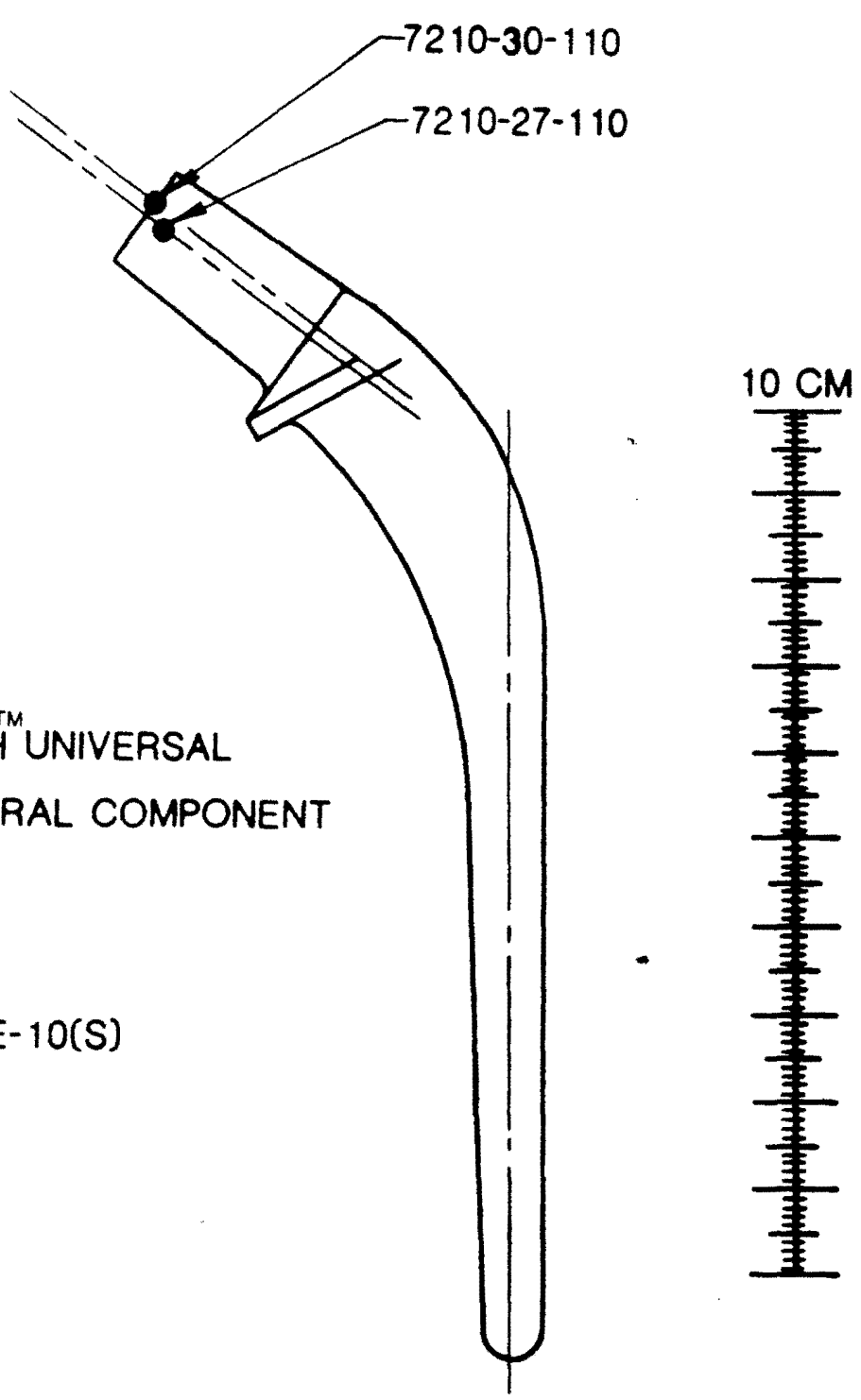
Long Neck
5043-41-155

Standard Neck
5043-35-155

*20% OVERSIZE TO ALLOW FOR X-RAY MAGNIFICATION

XT-I1185A

(mirror image is only available duplicate of original)



BDH™ UNIVERSAL
FEMORAL COMPONENT

SIZE-10(S)

20% MAG

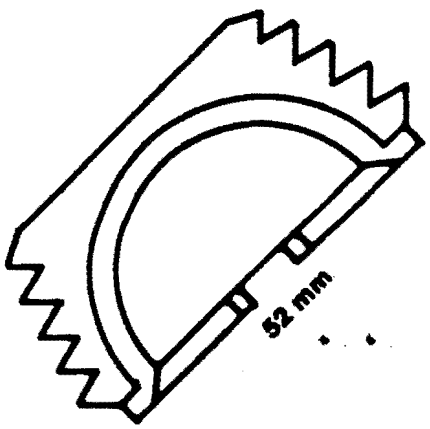
INTERMEDICS
ORTHOPEDICS

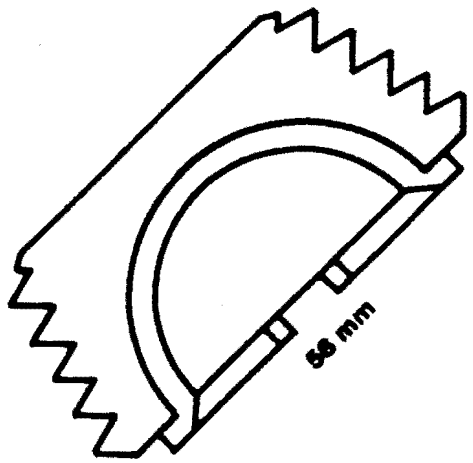
Ti-Thread™ Acetabular Cup

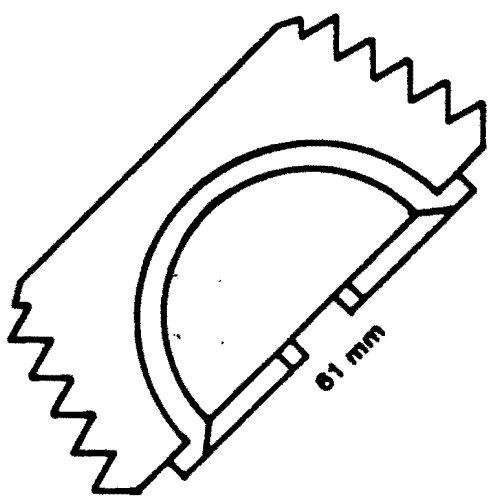
CUP X-RAY CONFIGURATION TEMPLATE

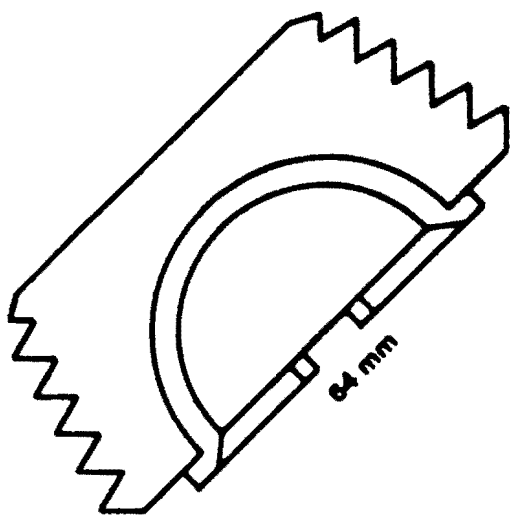
Approximate 20% oversize or 120% of actual size

This template is for x-ray estimation purposes only.





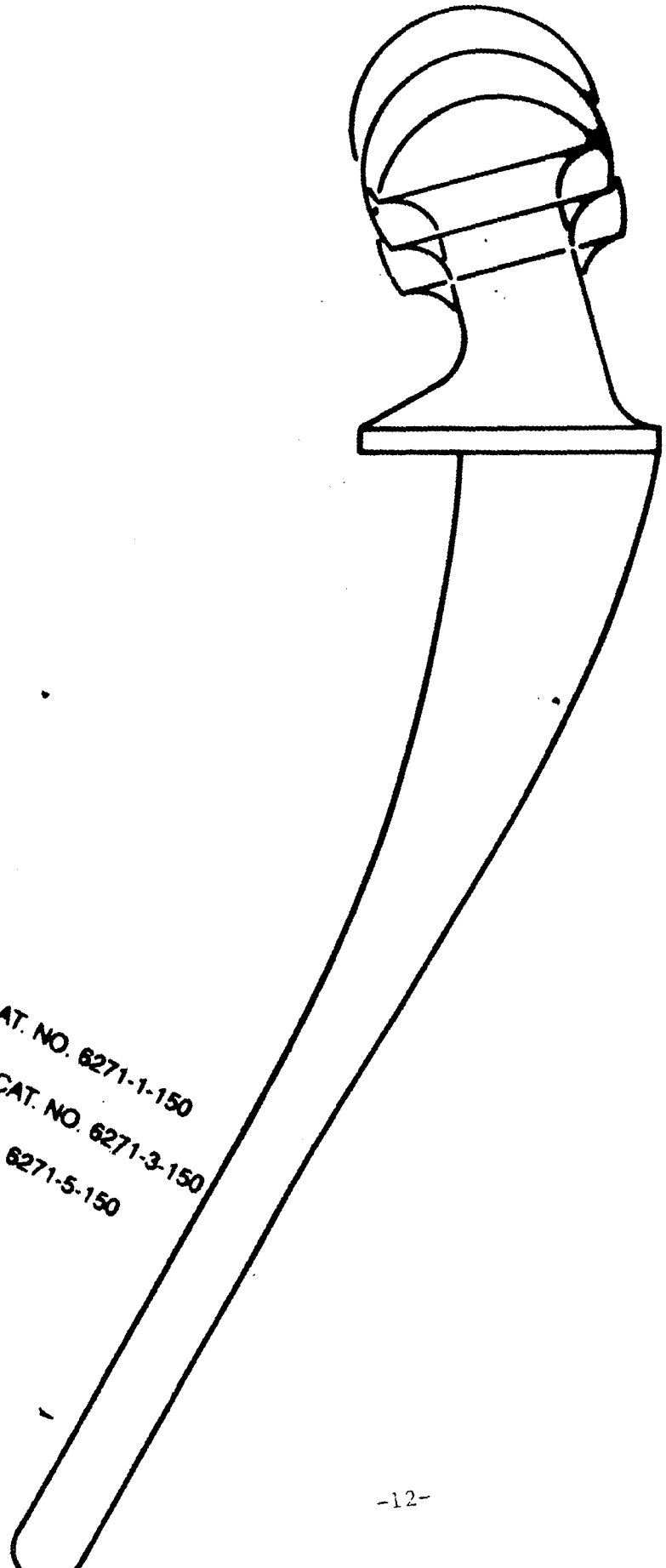




™ trademarks of Richards Medical Company

RICHARD

5

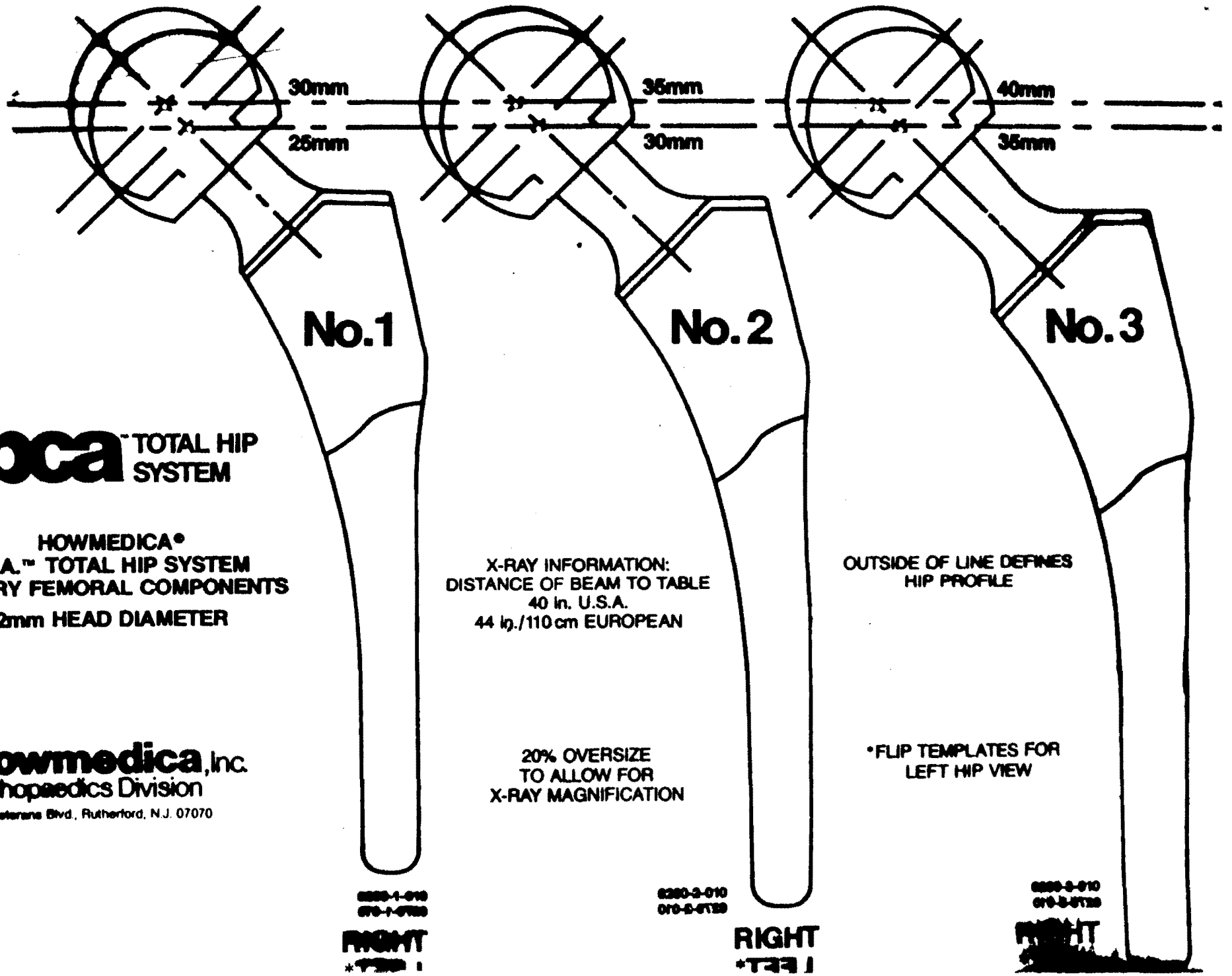


LARGE STEM

SHORT NECK — CAT. NO. 6271-1-150

STANDARD NECK — CAT. NO. 6271-3-150

LONG NECK — CAT. NO. 6271-5-150



THE pca™ TOTAL HIP SYSTEM

HOWMEDICA®
P.C.A.™ TOTAL HIP SYSTEM
PRIMARY FEMORAL COMPONENTS
32mm HEAD DIAMETER

X-RAY INFORMATION:
DISTANCE OF BEAM TO TABLE
40 in. U.S.A.
44 in./110 cm EUROPEAN

OUTSIDE OF LINE DEFINES
HIP PROFILE

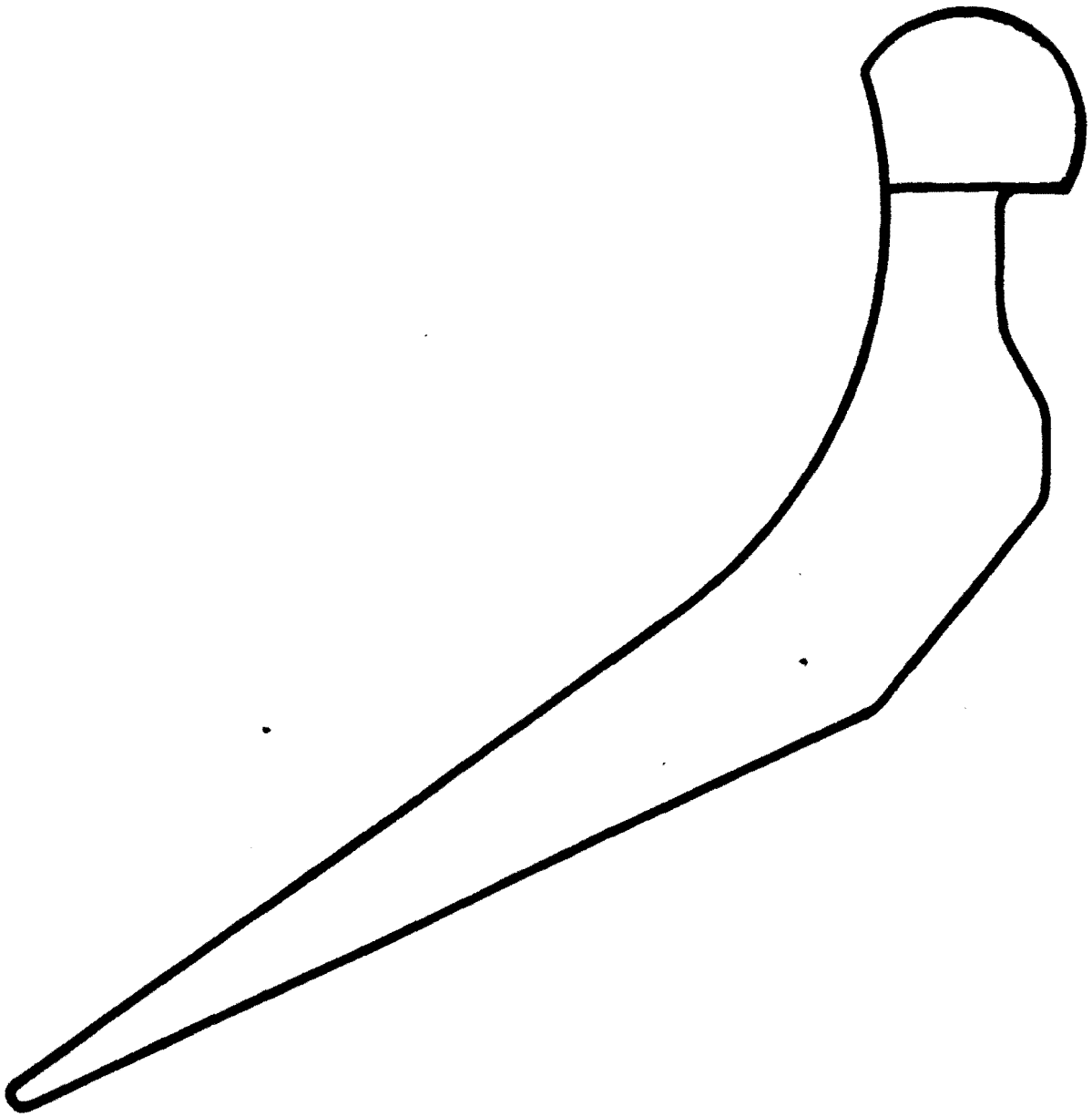
20% OVERSIZE
TO ALLOW FOR
X-RAY MAGNIFICATION

*FLIP TEMPLATES FOR
LEFT HIP VIEW

RIGHT

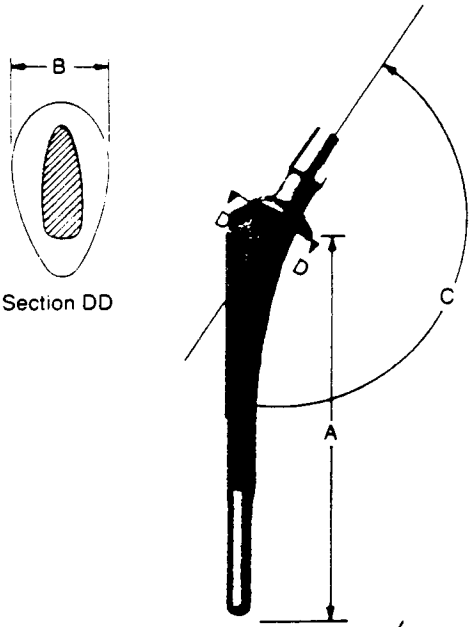
RIGHT

Howmedica, Inc.
Orthopaedics Division
359 Veterans Blvd., Rutherford, N.J. 07070



Femoral Stem, stainless steel
0925-0-000 Ultra Heavy Duty

AML® MODULAR HEAD TOTAL HIP SYSTEM WITH POROCOAT®

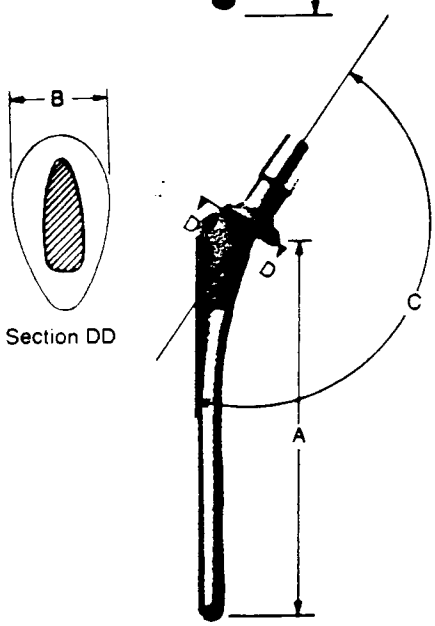


Femoral Component

Orthochrome®, 135° neck angle (C), 6½" (165mm) trial stem length, packaged sterile.

Standard Implant Cat. No.	Proximally-Coated Implant Cat. No.	Trial No.	Stem Diameter* B mm	Stem Length A mm
1354-02	1354-42	2002-51	10.5	165
1354-03	1354-43	2002-52	12.0	165
1354-04	1354-44	2002-53	13.5	165
1354-05	1354-45	2002-54	15.0	165
1354-06	1354-46	2002-56	16.5	165
1354-07	1354-47	2354-17	18.0	165
1354-08	1354-48	2354-18	19.5	165
1354-12		2354-32	10.5	200
1354-13		2354-33	12.0	200
1354-14		2354-34	13.5	200
1354-15		2354-35	15.0	200
1354-16		2354-36	16.5	200
1354-17		2354-37	18.0	200
1354-18		2354-38	19.5	200

*Measured at the most distal portion of the porous coating and including the porous surface.



Modified Medial Aspect Femoral Component

Orthochrome®, 135° neck angle (C), 165mm stem length (A).

Cat. No.	Stem Diameter* B mm	Trial No.
1357-42	10.5	2457-02
1357-43	12.0	2457-03
1357-44	13.5	2457-04
1357-45	15.0	2457-05
1357-46	16.5	2457-06
1357-47	18.0	2457-07
1357-48	19.0	2457-08

*Measured at the most distal A/P portion of the porous coating and including the porous surface.

Femoral Head

32mm Cat. No.	Trial No.	Neck Length mm
1014-67	2002-57	+0, 30 (Short)
1014-68	2002-58	+5, 35 (Medium)
1014-69	2002-59	+11, 41 (Long)
1014-71	2002-48	+15, 45 (Ex. Long)
1014-72	2002-49	+18, 48 (Ex. Ex. Long)

Packaged sterile

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

AML® MODULAR HEAD TOTAL HIP SYSTEM WITH POROCOAT® Cont'd.

Instrumentation

Broach

Cat. No.	Stem Diameter mm
2002-14	10.5
2002-15	12.0
2002-16	13.5
2002-17	15.0
2002-18	16.5
2354-27	18.0
2354-28	19.5

Modified Medial Aspect Broach

Cat. No.	Stem Diameter* mm
2457-12	10.5
2457-13	12.0
2457-14	13.5
2457-15	15.0
2457-16	16.5
2457-17	18.0
2457-18	19.5

*Measured at the most distal A/P portion of the porous coating and including the porous surface.

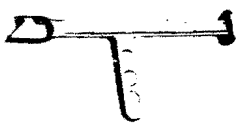
Broach Handle II

2002-67

Broach Extractor

2002-24

Hollow Chisel



2002-31 Small
2002-25 Medium
2002-27 Large

Osteotomy Guide

2002-68

Power Planer

Cat. No.	Planer O.D. in.
2454-16	1⅜
2454-17	1⅝

Ball Extractor

2354-01 Short
2354-02 Medium, Long, Ex. Long, Ex. Ex. Long

Trial Driver

2002-65

Implant Driver

2002-66

Femoral Head Driver

2127-00 Driver
2127-10 Replacement Tip

Universal Driver/Extractor

2046-10

Stem Extractor

2449-12

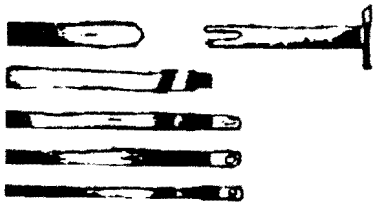
AML® MODULAR HEAD TOTAL HIP SYSTEM WITH POROCOAT® Cont'd.

Fully-Fluted Reamer

8" (203mm) flute length, 13" (330mm) overall length.

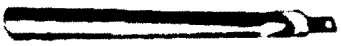
Cat. No.	Reamer Diameter mm
2105-10	8.0
2105-11	9.5
2105-12	10.0
2105-13	10.5
2105-14	11.0
2105-15	12.0
2105-16	13.0
2105-17	13.5
2105-18	14.0
2105-19	15.0
2105-20	16.0
2105-21	16.5
2105-27	17.0
2105-22	18.0
2105-28	19.0
2105-23	19.5
2105-24	21.0
2105-25	22.5
2105-26	25.0

Extra-Thin Osteotome



Cat. No.	Blade Width mm
2002-72	10.0
2002-73	12.5
2002-74	15.0
2002-75	17.5
2002-76	20.0

U-Shaped Osteotome

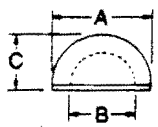


2002-71	Handle
2002-83	Small
2002-84	Medium
2002-85	Large

X-ray Overlay

2991-40	Standard Stem
2991-41	Proximally-Coated Stem
2991-51	MMA

AML® Acetabular Cup



Orthochrome® shell, UHMWPe insert, packaged sterile.

32mm I.D. Std. Profile Cat. No.	O.D. mm	Cup Height mm	Trial No.	Color
1013-44	44	27.4	2013-44	Green
1013-46	46	28.5	2013-46	Lt. Blue
1013-48	48	29.3	2013-48	Brown
1013-50	50	29.9	2013-50	Blue
1013-52	52	31.2	2013-52	Rust
1013-54	54	31.7	2013-54	Black
1013-56	56	32.2	2013-56	Gray
1013-58	58	32.7	2013-58	Lt. Green

32mm I.D. Low Profile Cat. No.	O.D. mm	Cup Height mm	Trial No.	Color
1014-44	44	24.2	2013-44	Green
1014-46	46	24.2	2013-46	Lt. Blue
1014-48	48	24.2	2013-48	Brown
1014-50	50	24.2	2013-50	Blue
1014-52	52	26.3	2013-52	Rust
1014-54	54	26.7	2013-54	Black
1014-56	56	27.2	2013-56	Gray
1014-58	58	27.7	2013-58	Lt. Green

22mm I.D. Low Profile Cat. No.	O.D. mm	Cup Height mm	Trial No.	Color
1014-36	36	19.25	2013-36	White
1014-38	38	19.38	2013-38	White
1014-40	40	20.62	2013-40	White
1014-42	42	20.75	2013-42	White

AML® MODULAR HEAD TOTAL HIP SYSTEM WITH POROCOAT® Cont'd.

Instrumentation

Drill Bit

1801-18

⅛" (3.2mm) diameter
5" (127mm) length

Acetabular Trial Handle

2013-00

AML® Acetabular Impactor

2013-14
2013-08

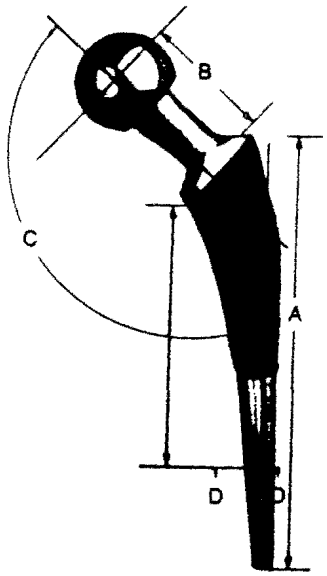
Cup Holder

2013-10 Std. Profile
2013-12 Low Profile, 32mm
2013-16 Low Profile, 22mm

X-ray Overlay

2990-55 Std. Profile
2990-93 Low Profile, 36mm-42mm
2990-37 Low Profile, 44mm-58mm

TRI-LOCK® TOTAL HIP SYSTEM WITH POROCOAT®



Femoral Component

Orthochrome®, 32mm head, 34mm std. neck length (B), 40mm long neck length (B). 135° neck angle (C), packaged sterile.

Standard Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1012-50	137	7.5	2927-20
1012-51	142	10.0	2927-21
1012-52	147	12.5	2927-22
1012-53	152	15.0	2927-23
1012-54	157	17.5	2927-24
1012-55	162	20.0	2927-25
1012-56	167	22.5	2927-26

Long Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1012-57	137	7.5	2927-60
1012-58	142	10.0	2927-61
1012-59	147	12.5	2927-62
1012-60	152	15.0	2927-63
1012-61	157	17.5	2927-64
1012-62	162	20.0	2927-65
1012-63	167	22.5	2927-66

Instrumentation

Rasp

Dual-Lock® Rasp Cat. No.	Tri-Lock® Rasp Cat. No.	Rasp Width At 100mm
2927-10	2927-03	7.5
2927-11	2927-04	10.0
2927-12	2927-05	12.5
2927-13	2927-06	15.0
2927-14	2927-07	17.5
2927-15	2927-08	20.0
2927-16	2927-09	22.5

Femoral Impactor

2927-01

Universal Driver/Extractor

2046-10

Adapter/Prosthesis Extractor

2046-34

X-ray Overlay

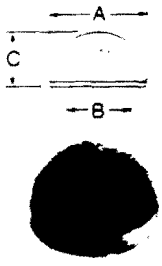
2990-72

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

TRI-LOCK® TOTAL HIP SYSTEM WITH POROCOAT® Cont'd.

Tri-Lock® Acetabular Cup

Orthochrome® shell, UHMWPe insert, 32mm I.D. (B), packaged sterile.



Low Profile Cat. No.	O.D. A mm	Cup Height C mm	Trial No.	Color
1029-44	44	24.2	2029-44	Green
1029-46	46	24.2	2029-46	Lt. Blue
1029-48	48	24.2	2029-48	Brown
1029-50	50	24.2	2029-50	Blue
1029-52	52	26.3	2029-52	Rust
1029-54	54	26.7	2029-54	Black
1029-56	56	27.2	2029-56	Gray
1029-58	58	27.7	2029-58	Lt. Green

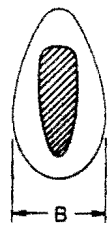
Standard Profile Cat. No.	O.D. A mm	Cup Height C mm	Trial No.	Color
1030-44	44	27.4	2029-44	Green
1030-46	46	28.5	2029-46	Lt. Blue
1030-48	48	29.3	2029-48	Brown
1030-50	50	29.9	2029-50	Blue
1030-52	52	31.2	2029-52	Rust
1030-54	54	31.7	2029-54	Black
1030-56	56	32.2	2029-56	Gray
1030-58	58	32.7	2029-58	Lt. Green

Instrumentation

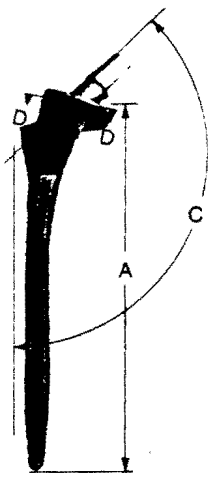
Acetabular Grater

Cat. No.	Outside Diameter mm
2440-30	Grater Shaft w/Hudson End
2440-31	Modified Adapter w/Zimmer End
2440-32	Sterilization Case
2440-36	36
2440-38	38
2440-40	40
2440-41	41
2440-42	42
2440-43	43
2440-44	44
2440-45	45
2440-46	46
2440-47	47
2440-48	48
2440-49	49
2440-50	50
2440-51	51
2440-52	52
2440-53	53
2440-54	54
2440-55	55
2440-56	56
2440-57	57
2440-58	58
2440-59	59
2440-60	60
2440-61	61
2440-62	62
2440-63	63
2440-64	64
2440-65	65
2440-66	66
2440-68	68
2440-70	70
2440-72	72

HPS® II TOTAL HIP SYSTEM



Section DD



Femoral Component

Orthochrome®, 135° stem/neck angle (C), 20° from the horizontal collar angle. Packaged sterile.

Smooth-Stemmed Cat. No.	Porous-Coated* Cat. No.	Size Code	Stem Diameter B mm	Stem Length A mm	Trial No.
1039-61	1039-01	1	9.5	165.1	2448-01
1039-62	1039-02	2	11.0	177.8	2448-02
1039-63	1039-03	3	13.0	190.5	2448-03
1039-64	1039-04	4	14.5	203.2	2448-04
1039-65	1039-05	5	16.0	215.9	2448-05

*WARNING: This device has not been approved for non-cemented application.

Femoral Head

32mm Cat. No.	Neck Length mm	Trial No.
1014-67	+0, 29 (Short)	2448-75
1014-68	+5, 34 (Medium)	2448-76
1014-69	+11, 40 (Long)	2448-77
1014-71	+15, 44 (Ex. Long)	2448-78
1014-72	+18, 47 (Ex. Ex. Long)	2448-79

43mm Cat. No.	Neck Length mm	Trial No.
1039-42	+0, 29 (Short)	2448-42
1039-43	+5, 34 (Medium)	2448-43
1039-44	+11, 40 (Long)	2448-44

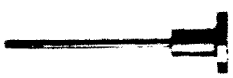
Packaged sterile

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

Instrumentation

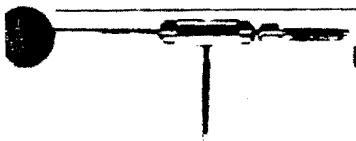
Broach

Cat. No.	Size Code
2449-01	1
2449-02	2
2449-03	3
2449-04	4
2449-05	5
2449-10	Handle



Power Planer

2454-16 1⅜"
2454-17 1⅝"

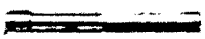


Universal Driver/Extractor

2046-10

Trial Extractor

2046-32



Femoral Head Driver

2127-00

Ball Extractor

2354-01 Short
2354-02 Medium, Long, Ex. Long, Ex. Ex. Long

Stem Extractor

2449-12

HPS® II TOTAL HIP SYSTEM Cont'd.

Acetabular Cup

Orthochrome® and UHMWPe. packaged sterile.

32mm I.D. Cat. No.	Outside Diameter mm	Trial No.
1044-18	48	2044-18
1044-20	51	2044-20
1044-22	53	2044-22
1044-24	55	2044-24
1044-26	57	2044-26
1044-28	59	2044-28
1044-30	61	2044-30
1044-33	64	2044-33

43mm I.D. Cat. No.	Outside Diameter mm	Trial No.
1044-23	53	2044-23
1044-35	57	2044-35
1044-36	61	2044-36

Instrumentation

Polyethylene Remover

2044-14

Cup Impactor

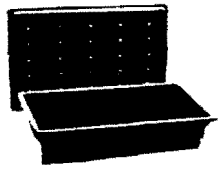
2044-10

Acetabular Punch

2044-12

X-ray Overlay

2991-38 For Femoral Stems
2991-39 For Acetabular Cups

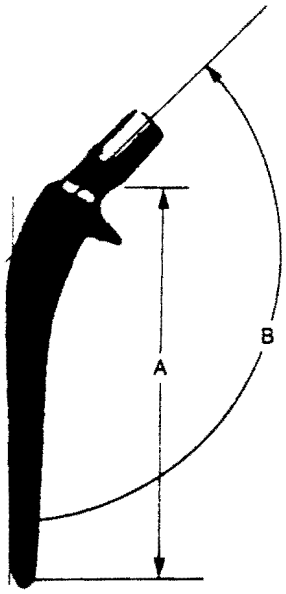


HPS II Case

2448-06 Femoral
2448-07 Acetabular

STD+ TITANIUM TOTAL HIP SYSTEM

Femoral Component



Titanium (Ti-6AL-4V), 135° neck angle (B), packaged sterile.

Cat. No.	Size	Stem Length A mm	Trial No.
1019-01	Small	110	2019-01
1019-02	Medium	110	2019-02
1019-03	Large	110	2019-03

Revision Implant

Cat. No.	Size	Stem Length A mm	Trial No.
1019-10	Large, 165	165	2019-10
1019-20	Right	200	2019-40
1019-21	Left	200	2019-41
1019-30	Right	250	2019-42
1019-31	Left	250	2019-43
1019-40	Right	300	2019-44
1019-41	Left	300	2019-45

32mm Femoral Head*

Cat. No.	Trial No.	Size mm
1014-67	2019-12	+ 0, 30 (Short)
1014-68	2019-14	+ 5, 35 (Medium)
1014-69	2019-16	+ 11, 41 (Long)
1014-71	2019-32	+ 15, 45 (Ex. Long)
1014-72	2019-34	+ 18, 48 (Ex. Ex. Long)

Packaged sterile
*28mm head size available soon.

Instrumentation

Rasp

2019-21 Small
2019-22 Medium
2019-23 Large
2019-30 Revision, 165mm

Rasp Handle

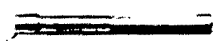
2019-20

Osteotomy Guide

2019-18

Power Planer

2454-16 1⅜"
2454-17 1⅝"



Femoral Head Driver

2127-00 Driver
2127-10 Replacement Tip

Head Extractor

2019-25 Short Neck
2019-26 Medium, Long Neck

Sterilization Case

2601-01 4" Sterilization Case
2601-22 Upper Tray
2601-23 Lower Tray

X-ray Overlay

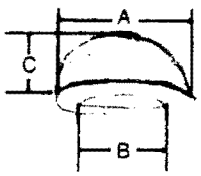
2990-85 Primary
2990-86 Revision

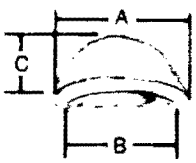
DePuy

STD+ TITANIUM TOTAL HIP SYSTEM Cont'd.

Acetabular Cup

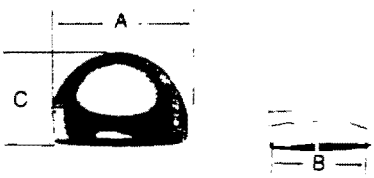
Packaged sterile.





Müller Cup
UHMWPe

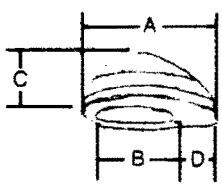
Cat. No.	Description	O.D. A mm	I.D. B mm	Cup Height C mm	Trial No.
1026-40	Standard	44	32	27	2149-10
1026-52	Standard	46	32	28	2149-11
1026-24	Standard	50	32	29	2149-12
1026-84	Standard	52	32	30	2196-08
1026-48	Standard	54	32	31	2196-10
1026-86	Standard	56	32	31	2196-11
1026-50	Standard	58	32	32	2196-12
1026-64	Snap-fit	44	32	27	2149-10
1026-66	Snap-fit	50	32	29	2149-12
1027-18	Low Profile	44	32	23	2149-44
1027-30	Low Profile	46	32	24	2149-46
1027-31	Low Profile	48	32	24	2149-48
1027-19	Low Profile	50	32	23	2149-50
1027-32	Low Profile	52	32	26	2149-52
1027-16	Low Profile	54	32	26	2149-54
1027-34	Low Profile	56	32	27	2149-56
1027-17	Low Profile	58	32	27	2149-58
1038-13	CDH Std. Eccentric	36	22	24	2149-06
1038-14	CDH Std. Eccentric	40	22	24	2149-08
1038-16	CDH Std. Concentric	44	22	24	2149-10



Self-Centering™ Universal Cup
Orthochrome® and UHMWPe

Cat. No.	O.D. A mm	I.D.* B mm	Cup Height C mm	Trial Cup	Trial Insert
1036-39	39	22	26	2037-39	2037-01
1036-41	41	22	27	2037-41	2037-01
1036-43	43	32	29	2037-43	2037-02
1036-44	44	32	28.8	2037-44	2037-02
1036-45	45	32	30	2037-45	2037-02
1036-46	46	32	31.3	2037-46	2037-03
1036-47	47	32	31	2037-47	2037-03
1036-48	48	32	32.3	2037-48	2037-03
1036-49	49	32	32	2037-49	2037-03
1036-50	50	32	33.3	2037-50	2037-03
1036-51	51	32	33	2037-51	2037-03
1036-52	52	32	33.4	2037-52	2037-04
1036-53	53	32	34	2037-53	2037-04
1036-54	54	32	34.5	2037-54	2037-04
1036-55	55	32	35	2037-55	2037-04
1036-56	56	32	35.5	2037-56	2037-04
1036-57	57	32	36	2037-57	2037-04
1036-59	59	32	37	2037-59	2037-05
1036-61	61	32	38	2037-61	2037-05
1036-63	63	32	39	2037-63	2037-05
1036-65	65	32	39	2037-65	2037-05

*28mm Available Soon



New England Baptist Eccentric Cup
UHMWPe

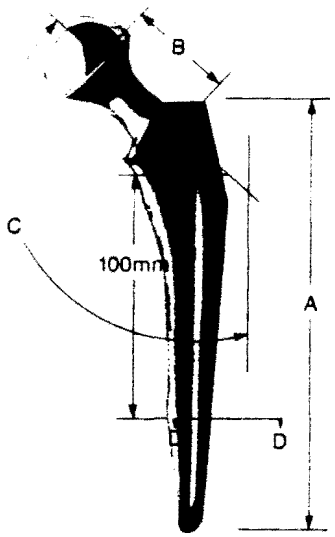
Cat. No.	O.D. A mm	I.D. B mm	Cup Height C mm	Superior Thickness D mm	Trial No.
1041-30	44	32	25	7	2453-30*
1041-32	50	32	29	11	2453-30*
1041-34	54	32	31	14	2453-32†
1041-36	58	32	32	17	2453-32†
1041-38	65	32	36	22	2453-34

*Only one trial needed for both 1041-30 and -32
†Only one trial needed for both 1041-34 and -36

Double wire system designed by Clark N. Hopson, M.D. and protected by U.S. Patent No. 4,244,698.

DUAL-LOCK® TOTAL HIP

32mm Head Femoral Component



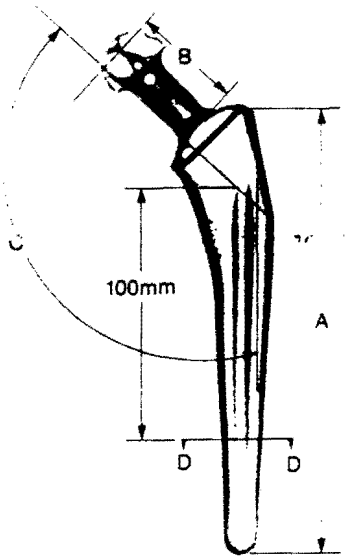
Orthochrome® HSF, 135° neck angle (C), 34mm standard neck length (B), 40mm long neck length (B), 40mm lateralized neck length (B), packaged sterile.

Standard Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1023-20	137	7.5	2927-20
1023-21	142	10.0	2927-21
1023-22	147	12.5	2927-22
1023-23	152	15.0	2927-23
1023-24	157	17.5	2927-24
1023-25	162	20.0	2927-25
1023-26	167	22.5	2927-26

Long Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1023-60	137	7.5	2927-60
1023-61	142	10.0	2927-61
1023-62	147	12.5	2927-62
1023-63	152	15.0	2927-63
1023-64	157	17.5	2927-64
1023-65	162	20.0	2927-65
1023-66	167	22.5	2927-66

Laterialized Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1023-40	137	7.5	2927-40
1023-41	142	10.0	2927-41
1023-42	147	12.5	2927-42
1023-43	152	15.0	2927-43
1023-44	162	17.5	2927-44
1023-45	167	20.0	2927-45

22mm Head Femoral Component



Orthochrome® HSF, 135° neck angle (C), 34mm standard neck length (B), 40mm long neck length (B), packaged sterile.

Standard Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1022-20	137	7.5	2022-20
1022-21	142	10.0	2022-21
1022-22	147	12.5	2022-22
1022-23	152	15.0	2022-23
1022-24	157	17.5	2022-24
1022-25	162	20.0	2022-25

Long Neck Cat. No.	Stem Length A mm	At 100mm Stem Width D mm	Trial No.
1022-60	137	7.5	2022-60
1022-61	142	10.0	2022-61
1022-62	147	12.5	2022-62
1022-63	152	15.0	2022-63
1022-64	157	17.5	2022-64
1022-65	162	20.0	2022-65

DUAL-LOCK® TOTAL HIP Cont'd.

Rasp

Cat. No.	Width at 100mm mm
2927-10	7.5
2927-11	10.0
2927-12	12.5
2927-13	15.0
2927-14	17.5
2927-15	20.0
2927-16	22.5

Instrumentation

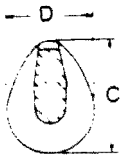
Femoral Impactor/Extractor

2927-01

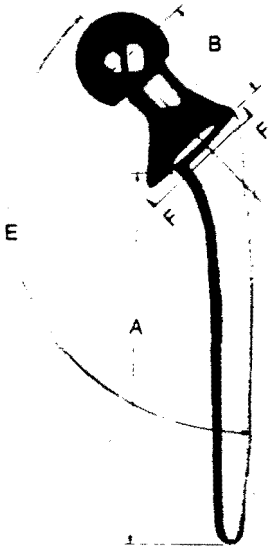
X-ray Overlay

2990-33 Std. Neck, 32mm
2990-34 Std. Neck, 22mm
2990-35 Long Neck, 32mm
2990-47 Lateralized Neck, 32mm

N.E.B. TOTAL HIP SYSTEM



Section FF

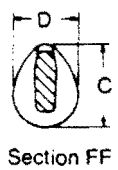


Femoral Component

Orthochrome* HSF, 135° neck angle (E), packaged sterile

Cat. No.	Description	Stem Length A mm	Neck Length B mm	Seat Length C mm	Seat Width D mm	Trial No.
1041-08	Small	*20	30	31	25	2453-03
1041-10	Small	*20	36	71	25	2453-05
1041-20	Std.	*20	36	37	29	2453-11
1041-22	Std.	*20	42	37	29	2453-13
1041-16	Thick	*40	36	41	32	2453-07
1041-18	Thick	*40	42	41	32	2453-09

Long Stem Femoral Component



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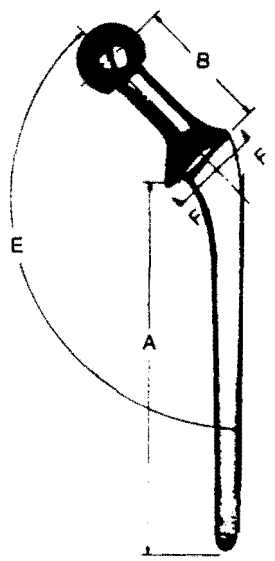


Orthochrome* HSF, 135° neck angle (E), 29mm seat width (D), 37mm seat height(C).

Cat. No.	Stem Length A mm	Neck Length B mm	Trial Stem*	Head/ Neck Trial
1041-40	165	36	2453-41	2453-50
1041-42	165	42		2453-52
1041-44	165	48		2453-54
1041-46	165	58		2453-56
1041-50	203	36	2453-43	2453-50
1041-52	203	42		2453-52
1041-54	203	48		2453-54
1041-56	203	58		2453-56
1041-60	254	36	2453-45	2453-50
1041-62	254	42		2453-52
1041-64	254	48		2453-54
1041-66	254	58		2453-56
1041-70	305	36	2453-47	2453-50
1041-72	305	42		2453-52
1041-74	305	48		2453-54
1041-76	305	58		2453-56

*Trial Stems have interchangeable heads/necks.

Instrumentation

Rasp

Cat. No.	Stem
2453-16	Small
2453-18	Thick
2453-21	Standard
2453-22	Long

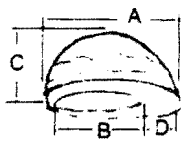
Adapter/N.E.B. Trial Extractor

2046-32

N.E.B. TOTAL HIP SYSTEM Cont'd.

Acetabular Cup

UHMWPe with 316 LVM stainless steel x-ray wire, 32mm I.D. (B), packaged sterile.



Cat. No.	O.D. A mm	Cup Height C mm	Superior Thickness D mm	Trial No.
1041-30	44	25	7	2453-30*
1041-32	50	29	11	2453-30*
1041-34	54	31	14	2453-32†
1041-36	58	32	17	2453-32†
1041-38	65	36	22	2453-34

*Only one trial needed for both 1041-30 and -32
†Only one trial needed for both 1041-34 and -36

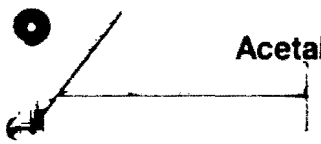
Double wire system designed by Clark N. Hopson, M.D. and protected by U.S. Patent No. 4,244,698.

Instrumentation

Acetabular Trial

2453-30 44-50mm
2453-32 54-58mm
2453-34 65mm

Acetabular Positioner/Inserter



2453-14

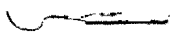
Angled Bone Curette

2453-28

Gouge

2453-36

Wire Passer



2453-26

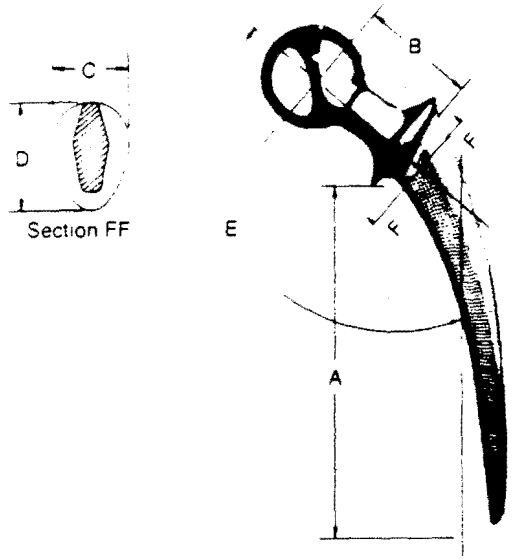
Wire Tightener

2453-24

X-ray Overlay

2990-60

M.E. MÜLLER TYPE TOTAL HIP SYSTEM

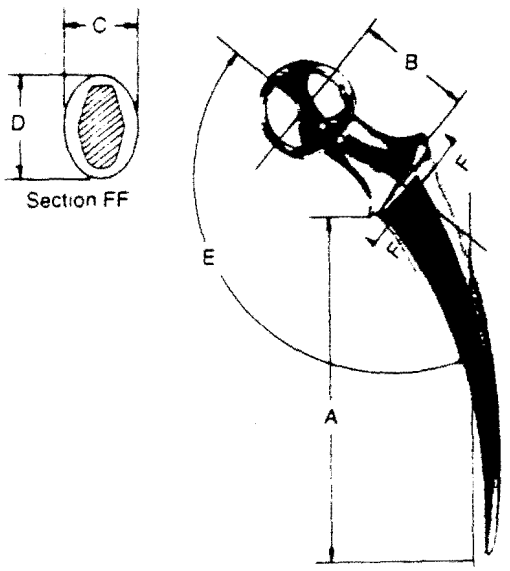


Standard, Structured Stem Femoral Component

Orthochrome® HSF, 32mm head size, 135° neck angle (E).

Cat. No.	Stem Length A mm	Neck Length B mm	Seat Height C mm	Seat Width D mm	Trial No.
1027-07	111	29	34	25	2435-22
1027-09	111	34	34	25	2435-16
1027-11	111	39	34	25	2435-18

Recommended Rasp: 2126-00

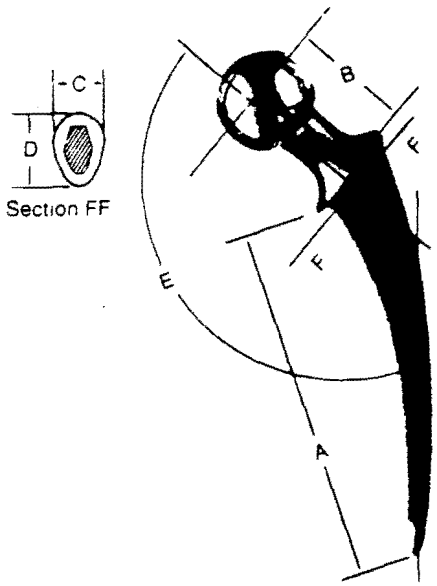


Standard Stem, Standard and Long Neck Femoral Component

Orthochrome®, 32mm head size, 135° neck angle (E).

Cat. No.	Stem Length A mm	Neck Length B mm	Seat Height C mm	Seat Width D mm	Trial No.
1026-26	111	34	33	26	2137-10
1026-28	111	40	33	26	2137-12

Recommended Rasp: 2126-00



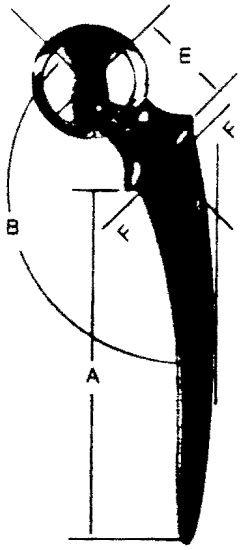
Thick Stem – Small, Standard and Long Neck Femoral Component

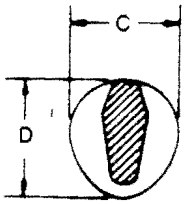
Orthochrome®, 32mm head size, 135° neck angle (E).

Cat. No.	Stem Length A mm	Neck Length B mm	Seat Height C mm	Seat Width D mm	Trial No.
1026-32	111	34	33	26	2435-10
1026-34	111	40	33	26	2435-12
1026-36	111	29	33	26	2435-14

Recommended Rasp: 2191-10

M.E. MÜLLER TYPE TOTAL HIP SYSTEM Cont'd.





Section FF

Extra Short Neck, Short Stem Femoral Component

Orthochrome®, 32mm head, 135° neck angle (B), 27mm neck length (E).

Cat. No.	Stem Length A mm	Seat Height C mm	Seat Width D mm	Trial No.
1026-30	91	28	18	2137-14

Recommended Rasp: 2175-00

Instrumentation

Cement Mixing Bowl and Spatula

2173-00

Orthochrome® Cement Restrictor

2146-10

Bone Cement Syringe

2190-00 Bone Cement Syringe, Complete
2189-00 Disposable Replacement Tubes

M.E. MÜLLER TYPE TOTAL HIP SYSTEM Cont'd.

Lexer Chisel


2132-02


2132-10


2132-16

Cat. No.	Width mm
2132-02	4
2132-04	8
2132-06	12
2132-10	20
2132-13	25
2132-14	30
2132-16	200x10
2132-18	280x8

Chisel


2132-12


2133-10


2135-00


2143-12

Cat. No.	Description	Width mm
2132-12	Flat, Stretch	16
2132-20	Bone, Ground, 1 Side	12
2132-22	Bone, Ground, 1 Side	20
2133-10	Curved	8
2133-12	Curved	16
2135-00	Flat, Bent	16
2135-10	Curved	20
2143-10	Flat	10
2143-12	Flat	50

Gouge


2133-04


2136-00


2142-12


2145-00

Cat. No.	Description	Width mm
2133-04	Curved	5
2133-06	Curved	10
2133-08	Curved	15
2136-00	Swan Neck	16
2142-10	Straight	5
2142-12	Straight	10
2142-14	Straight	15
2145-00	Bent	9

Corkscrew

2125-00

Curette

2134-10 Small
2134-12 Medium
2134-14 Large

Femoral Head Driver

2127-00 Driver
2127-10 Replacement Tip

Universal Driver/Extractor

2046-10

Nicholls Hip Extraction Adapter

2046-34

Pestle Driver

2144-00

Dislocation Lever

2140-00

DePuy

M.E. MÜLLER TYPE TOTAL HIP SYSTEM Cont'd.

Positioning and Aiming Device

Cat. No.	Description
2138-00	Positioning and Aiming Device Includes:
2138-10	Aimer
2138-12	Inserter
2129-10	32mm, w/Brim, Standard Profile
2129-11	32mm, w/Brim, Low Profile Optional
2129-12	32mm
2129-09	22mm
2129-14	32mm, w/Brim Threaded

Cement Pusher

2129-17

Müller Rake Retractor, 38mm

2177-00

Rasp

2126-00 Standard Stem
2191-10 Thick Stem

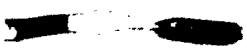
Müller Type Awl Reamer

2354-10 Hudson End

Handle, Hudson End

2172-14

Müller Retractor, Complete



Cat. No.	Description
2176-00	Müller Retractor Includes:
2176-10	Retractor
2176-12	Weight Hook
2176-13	Weight Hanger
2176-14	Weight

Double Angled Retractor, 15mm

2176-20

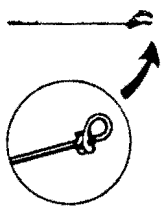
Retractor with Impactor Hole

2176-22 2 Tips, 40mm
2176-24 40mm
2176-26 22mm

Hohmann Retractor

2131-10 Small
2131-12 Medium
2131-14 Large

Trochanteric Wire, Orthochrome®

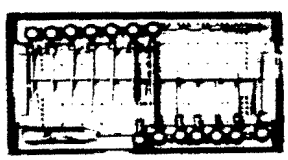


Cat. No.	Diameter		Gauge	Length	
	in.	mm		in.	mm
1713-10	039	1	19	19½	500
1713-12	047	1 20	18	19½	500

Vent Tubes, 6/Pkg.

2124-00

Dual Lock® Trial Tray



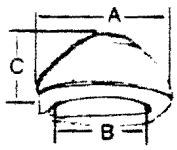
2601-10

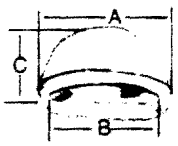
Sterilization Case

2601-01 4" Case, Universal
2601-02 7" Case, Universal

M.E. MÜLLER TYPE TOTAL HIP SYSTEM Cont'd.

Acetabular Cup





UHMWPe with 316 LVM stainless steel x-ray wire, packaged sterile

Cat. No.	Description	O.D. A mm	I.D. B mm	Cup Height C mm	Trial No.
1026-40	Standard	44	32	27	2149-10
1026-52	Standard	46	32	28	2149-11
1026-24	Standard	50	32	29	2149-12
1026-84	Standard	52	32	30	2196-08
1026-48	Standard	54	32	31	2196-10
1026-86	Standard	56	32	31	2196-11
1026-50	Standard	58	32	32	2196-12
1026-64	Snap-fit	44	32	27	2149-10
1026-66	Snap-fit	50	32	29	2149-12
1027-18	Low Profile	44	32	23	2149-44
1027-30	Low Profile	46	32	24	2149-46
1027-31	Low Profile	48	32	24	2149-48
1027-19	Low Profile	50	32	23	2149-50
1027-32	Low Profile	52	32	26	2149-52
1027-16	Low Profile	54	32	26	2149-54
1027-34	Low Profile	56	32	27	2149-56
1027-17	Low Profile	58	32	27	2149-58
1038-13	CDH Std. Eccentric	36	22	24	2149-06
1038-14	CDH Std. Eccentric	40	22	24	2149-08
1038-16	CDH Std. Concentric	44	22	24	2149-10

Instrumentation

X-ray Overlay

2990-30 Müller Type Stems/Cups
2990-27 Low Profile Cup
2990-55 Standard Profile Cup

Capsule Clamp

2148-00

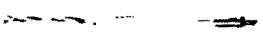
Capsule Scissors

2147-00

CDH Cup Inserting Device

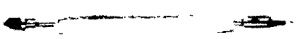
2129-18

Acetabular Anchorage Hole Drill



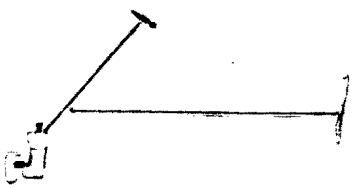
Cat. No.	Overall Length in.	Overall Length mm	Diameter mm
2023-06	7⅝	193	6

Stop Drill Acetabular Anchorage



Cat. No.	Overall Length in.	Overall Length mm	Diameter mm	Drilling Depth in.
2023-09	8¼	209	9	7/16
2023-12	8½	216	12	⅝

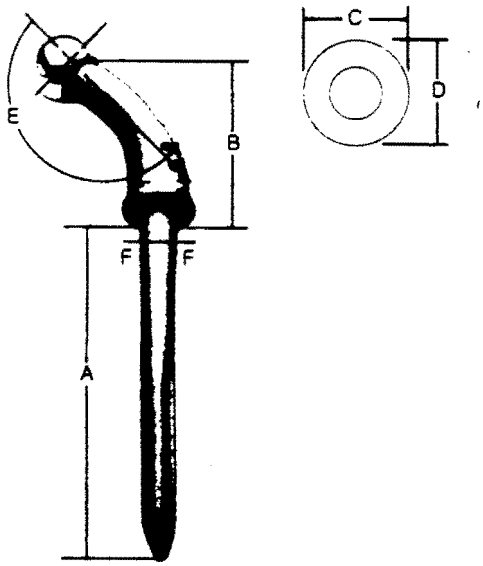
Acetabular Positioner



2138-14

Accepts trials for Müller type/ Tri-Lock™ acetabular cups and 32mm with brim (2129-10, 11) for implant positioning.

PROXIMAL THIRD FEMORAL PROSTHESIS



Femoral Component

Orthochrome*, 32mm head, 135° neck angle (E), 32mm seat width (D) and height (C), 152mm stem length (A).

Cat. No.	Neck Length B mm
1031-30	80
1031-31	90
1031-32	100
1031-33	110
1031-34	120
1031-35	130
1031-36	140
1031-37	150
1031-38	160
1031-39	170
1031-40	180
1031-41	190
1031-42	200
1031-43	210
1031-44	220

Instrumentation

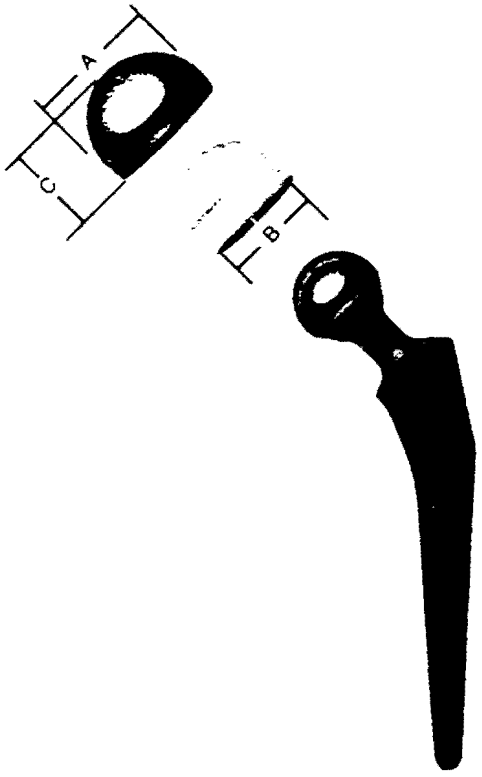
Upper Third Femoral Reamer

2197-00

X-ray Overlay

2990-31

SELF-CENTERING™ UNIVERSAL HIP SYSTEM Patent Pending



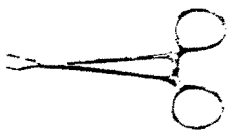
Self-Centering™ Universal Hip

Orthochrome® outer cup,
UHMWPe insert, packaged sterile.

Cat. No.	O.D. A mm	I.D.* B mm	Cup Height C mm	Trial Cup	Trial Insert
1036-39	39	22	26	2037-39	2037-01
1036-41	41	22	27	2037-41	2037-01
1036-43	43	32	29	2037-43	2037-02
1036-44	44	32	28.8	2037-44	2037-02
1036-45	45	32	30	2037-45	2037-02
1036-46	46	32	31.3	2037-46	2037-03
1036-47	47	32	31	2037-47	2037-03
1036-48	48	32	32.3	2037-48	2037-03
1036-49	49	32	32	2037-49	2037-03
1036-50	50	32	33.3	2037-50	2037-03
1036-51	51	32	33	2037-51	2037-03
1036-52	52	32	33.4	2037-52	2037-04
1036-53	53	32	34	2037-53	2037-04
1036-54	54	32	34.5	2037-54	2037-04
1036-55	55	32	35	2037-55	2037-04
1036-56	56	32	35.5	2037-56	2037-04
1036-57	57	32	36	2037-57	2037-04
1036-59	59	32	37	2037-59	2037-05
1036-61	61	32	38	2037-61	2037-05
1036-63	63	32	39	2037-63	2037-05
1036-65	65	32	39	2037-65	2037-05

*28mm Available Soon

Instrumentation

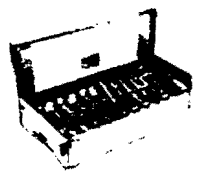


Release Forceps

2037-11

Acetabular Gauge

Cat. No.	Description mm
2037-28	38-40
2037-12	39-41
2037-20	42
2037-14	43-45
2037-15	44-46
2037-16	47-49
2037-17	48-50
2037-18	51-53
2037-19	52-54
2037-20	55-57
2037-21	56-59
2037-30	60
2037-22	61-63
2037-23	65



Sterilization Case

2601-01 4" Case
2601-18 Trials Tray

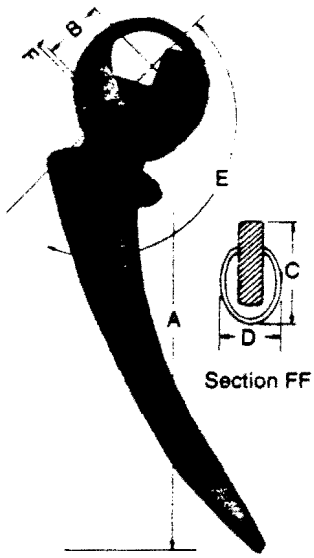
X-ray Overlay

2991-57

CATHCART ORTHOCENTRIC™ HIP SYSTEM U.S. Patent No. 3,510,883

Orthocentric™ Femoral Component Modified M.E. Müller Type Stem Design

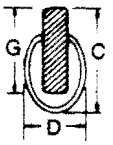
Orthochrome®, 112mm stem length (A), 33mm neck length (B), 35mm seat height (C), 28mm seat width (D), 135° neck angle (E), packaged sterile.



Section FF

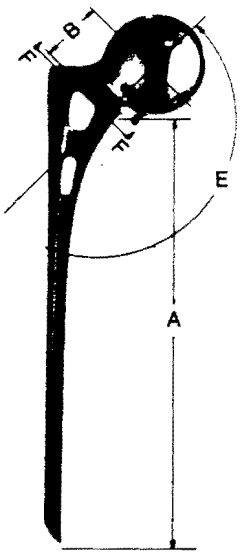
Cat. No.	Head Size mm
1046-10	41
1046-11	42
1046-12	43
1046-13	44
1046-14	45
1046-15	46
1046-16	47
1046-17	48
1046-18	49
1046-19	50
1046-20	51
1046-21	52
1046-22	53
1046-23	54
1046-24	55
1046-25	56
1046-26	57

Femoral Component



Section FF

Orthochrome®, 35mm seat height (C), 27mm seat width (D), 135° neck angle (E), 32mm M/L stem width (G), packaged sterile.



Cat. No.	Head Size mm	Stem Length A mm	Neck Length B mm
1045-10	41	173	22
1045-12	42	173	22
1045-14	43	173	23
1045-16	44	173	23
1045-18	45	173	23
1045-20	46	198	25
1045-22	47	198	25
1045-24	48	198	25
1045-26	49	198	27
1045-28	50	198	27
1045-30	51	198	27
1045-32	52	198	29
1045-34	53	198	29
1045-36	54	198	29
1045-38	55	198	29
1045-40	56	198	30
1045-42	57	198	32

Instrumentation

Corkscrew

2125-00

Driver for I-Beam Cathcart Hip

2116-00

Rasp

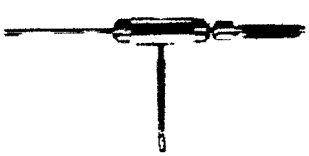
2002-10 Use with Narrow Stem
2003-10 Use with 173mm Stem
2003-12 Use with 198mm Stem
2126-00 Use with Müller Type Stem

Driver for Müller Type Stem

2001-10 Driver with Delrin Insert
2001-12 Replacement Delrin Insert

Radius Gauge

2118-10 Odd Size mm
2118-12 Even Size mm



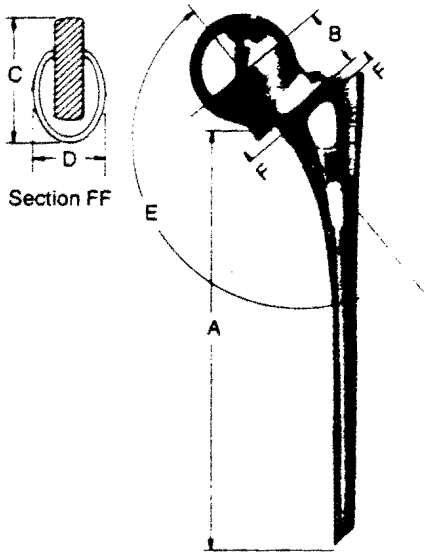
Universal Driver/Extractor

2046-10

For I-Beam Prosthesis

2046-28

I-BEAM HEMI-ARTHROPLASTY HIP



Femoral Component

Orthochrome®, 35mm seat height (C), 27mm seat width (D), 135° neck angle (E).

Cat. No.	Head Size mm	Stem Length A mm	Neck Length B mm
1024-10	41	165	24
1024-12	43	165	25
1024-14	44	165	26
1024-16	46	165	26
1024-18	48	165	27
1024-20	49	165	28
1024-22	51	190	27
1024-24	54	190	29
1024-26	57	190	30
1024-28	60	190	32
1024-29	63	190	36

Instrumentation

Corkscrew

2125-00

Driver for I-Beam

2116-00

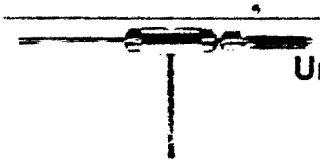
Locks into driving platform.

I-Beam Rasp

Cat. No.	Description
2003-10	Use with 6½" (165mm) Stems
2003-12	Use with 8½" (216mm) Stems

Prostheses Measuring Instrument

2006-00 Inches
2006-10 Millimeters



Universal Driver/Extractor

2046-10

For I-Beam Prosthesis

2046-28

TABLE 1 Chemical Requirements

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012[A]
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.5
Titanium[B]	balance

[A] Material 0.032 in. (0.813 mm) and under may have hydrogen content up to 0.0150 %.

[B] The percentage of titanium is determined by difference and need not be determined or certified.

TABLE 2 Permissible variation in product analysis

Nitrogen	0.02
Carbon	0.02
Hydrogen	0.002
Iron	0.10
Oxygen	0.02
Aluminum	0.40
Vanadium	0.15

TABLE 3 Annealed Mechanical Properties[A]

Size	Tensile Strength min, psi (MPa)	Yield Strength (0.2 % offset), min psi (MPa)	Elongation in 4d or 4w min, %[B]	Reduction of Area min, %[C]
Under 0.187 in. (4.75 mm) thickness or diameter	130 000 (896)	120 000 (827)	10	...
0.187 (4.75 mm) to 1.75 in. (44.45 mm) incl	125 000 (860)	115 000 (795)	10	25
	Bend Test[D]			
Under 0.070 in. (1.778 mm) in thickness	9 T		...	...
0.070 in. (1.778 mm) to 0.187 in. (4.750 mm) incl in thickness	10 T		...	

[A] Mechanical properties for conditions other than annealed may be established by agreement between the supplier and the implant manufacturer.

[B] Elongation on material under 0.125 in. (0.813 mm) in thickness may be obtained by negotiation.

[C] Applies to bar, plate, and forgings only.

[D] Bend test applicable to sheet and strip products; T = thickness of bend specimen in reference to diameter of bend.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The purpose of this specification is to characterize the chemical, physical, mechanical, and metallurgical properties of wrought annealed Ti-6Al-4V E.L.I. alloy to be used in the manufacture of surgical implants.

X1.2 The alloy composition covered by this standard has been employed successfully in human implants, exhibiting a well characterized level of local biological response, for over a decade.

X1.3 The microstructural requirements contained in this standard represent the current general consensus of opinion with respect to optimization of mechanical properties for implant applications.

X1.4 The minimum mechanical properties specified assure a baseline of strength and ductility for the highly stressed devices for which this alloy is typically used.

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4.1.2 Applicable ASTM designation,

4.1.3 Form (sheet, strip, plate, wire, bar, or forging),

4.1.4 Condition (See 5.1),

4.1.5 Mechanical properties (if applicable, for special conditions),

4.1.6 Finish (see 5.2),

4.1.7 Applicable dimensions including size, thickness, width, or print number,

4.1.8 Special tests, and

4.1.9 Special requirements.

5. Materials and Manufacture

5.1 The various titanium mill products covered in this specification are normally formed with the conventional forging and rolling equipment found in primary ferrous and nonferrous plants. The ingot metal for such mill operations is usually melted in arc furnaces of a type conventionally used for reactive metals.

5.2 *Finish*—Annealed material may be furnished to the implant manufacturer as descaled or pickled, sandblasted, ground, or combinations of these operations.

6. Chemical Requirements

6.1 The heat analysis shall conform to the chemical composition of Table 1. Ingot analysis may be used for reporting all chemical requirements, except hydrogen. Samples for hydrogen shall be taken from the finished mill product.

6.2 The product analysis tolerances shall conform to the check tolerances of Table 2.

6.3 For referee purposes, Methods E 120 shall be used.

6.4 Samples for chemical analysis shall be representative of the material being tested. The utmost care must be used in sampling titanium for chemical analysis because of its affinity for elements such as oxygen, nitrogen, and hydrogen. Therefore, in cutting samples for analysis, the operation should be carried out insofar as possible in a dust-free atmosphere. Chips should be clean and sharp. Samples for analysis should be stored in suitable containers.

7. Mechanical Requirements

7.1 Material supplied under this specification shall conform to the mechanical property requirements given in Table 3.

7.2 Specimens for tension tests shall be machined and tested in accordance with Methods E 8. Tensile properties shall be determined using a strain rate of 0.003 to 0.007 in./in. min (metric equivalent mm/mm/min) through the specified yield strength.

7.3 For sheet and strip, the bend test specimen shall withstand being bent cold through an angle of 105° without fracture in the outside surface of the bent portion. The bend shall be made on a diameter equal to that shown in Table 3. Test conditions shall conform to Method E 290.

8. Special Requirements

8.1 The microstructure shall be a fine dispersion of the alpha and beta phases resulting from processing in the alpha plus beta field. There shall be no continuous alpha network at prior beta grain boundaries. There shall be no coarse, elongated alpha platelets. There shall be no alpha case.

8.2 The beta transus temperature shall be measured by a suitable method and reported on the materials certification.

9. Quality Program Requirements

9.1 The producer shall maintain a quality program, such as, for example, is defined in Specifications C1-1968.

9.2 The manufacturer of surgical implants or medical applicances shall be assured of and may audit the producer's quality program for conformance to the intent of Specifications C1-1968, or other recognized program.

10. Marking, Packing, Certification, and Rejection

10.1 Marking, packing, certification, and rejection shall be as specified in Specifications B 265, B 348, and B 381.

Designation: F 136-84

Standard Specification for WROUGHT TITANIUM 6A1-4V ELI ALLOY FOR SURGICAL IMPLANT APPLICATIONS[1]

This standard is issued under the fixed designation F 136; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the chemical, mechanical, and metallurgical requirements for wrought annealed Ti-6A1-4V E.L.I. (extra low interstital) titanium alloy to be used in the manufacture of surgical implants.

1.2 The material in this specification has been subjected to testing in laboratory animals.[2,3] The results of these studies and the clinical history indicate a well characterized level of local biological response.[4,5]

1.3 The values stated in inch-pound units are to be regarded as the standard. The metric equivalents in parentheses are provided for information only.

2. Applicable Documents

2.1 *ASTM Standards:*

B 265 Specification for Titanium and Titanium Alloy Strip, Sheet and Plate[4]

B 348 Specification for Titanium and Titanium Alloy Billets[4]

B 381 Specification for Titanium and Titanium Alloy Forgings[4]

E 8 Methods of Tension Testing of Metallic Materials[5]

E 120 Methods for Chemical Analysis of Titanium and Titanium Alloys[6]

E 290 Method for Semi-Guided Bend Test for Ductility of Metallic Materials[7]

F 620 Specification for Titanium 6A1-4V E.L.I Alloy Forgings for Surgical Implants[8]

2.2 C1-1968 Specifications of General Requirements for a Quality Control Program[9]

3. Product Classification

3.1 *Strip*—Any product under 0.1875 in. (4.75 mm) in thickness and under 24 in. (610 mm) wide.

3.2 *Sheet*—Any product under 0.1875 in. (4.75 mm) in thickness and 24 in. (610 mm) or more in width.

3.3 *Plate*—Any product 0.1875 in. (4.75 mm) thick and over and 10 in. (254 mm) wide and over, with widths greater than five times thickness. Plate up to 1.75 in. (44.45 mm), thick inclusive is covered by this specification.

3.4 *Bar*—Rounds from 3/16 in. (7.9 mm) to 1.75 in. (44.45 mm) in diameter. (Other sizes by special order.)

3.5 *Forging bar*—Bar as described in 3.4, used for production of forgings, may be furnished in the hot rolled condition.

3.6 *Wire*—Rounds less than 3/16 in. (4.8 mm) in diameter.

4. Ordering Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces).

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved June 29, 1984. Published September 1984.

[2] Laing, P. G., Ferguson, Jr., A. B., and Hodge, E. S., "Tissue Reaction in Rabbit Muscle Exposed to Metallic Implants," J. Biomed. Materials Research, Vol. 1, 1967, pp. 135–149.

[3] Laing, P. G., "Compatibility of Biomaterials," Orthopedic Clinics of North America, Vol. 4, No. 2, April, 1973, pp. 249–273.

[4] *Annual Book of ASTM Standards*, Vol 02.04.

[5] *Annual Book of ASTM Standards*, Vols 02.01–02.03, and 03.01.

[6] *Annual Book of ASTM Standards*, Vol 03.05.

[7] *Annual Book of ASTM Standards*, Vol 03.01.

[8] *Annual Book of ASTM Standards*, Vol 13.01.

[9] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

Fig. 19 Creep-rupture data for Ti-6Al-4V bar

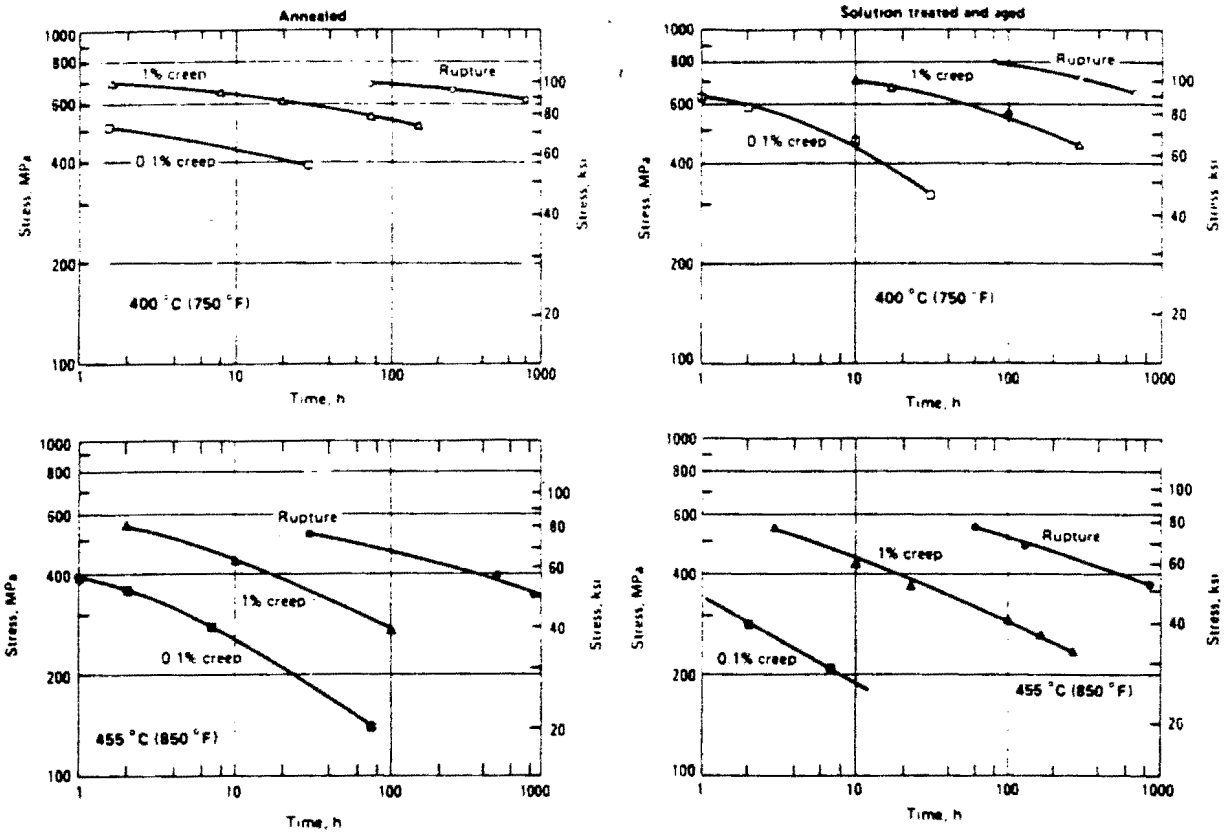
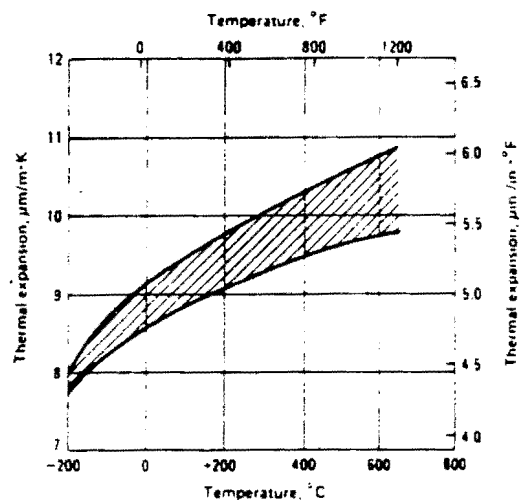


Fig. 20 Mean coefficient of thermal expansion for Ti-6Al-4V



Expansion data are for room temperature to indicated temperature for both mill annealed and solution treated and aged stock.

Fig. 21 Threshold stress for solid salt stress-corrosion cracking in Ti-6Al-4V

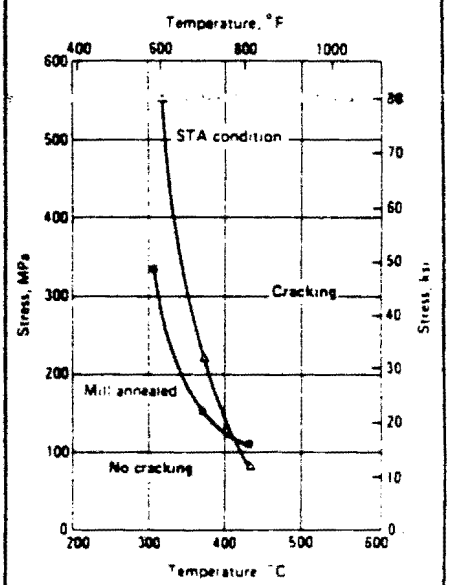
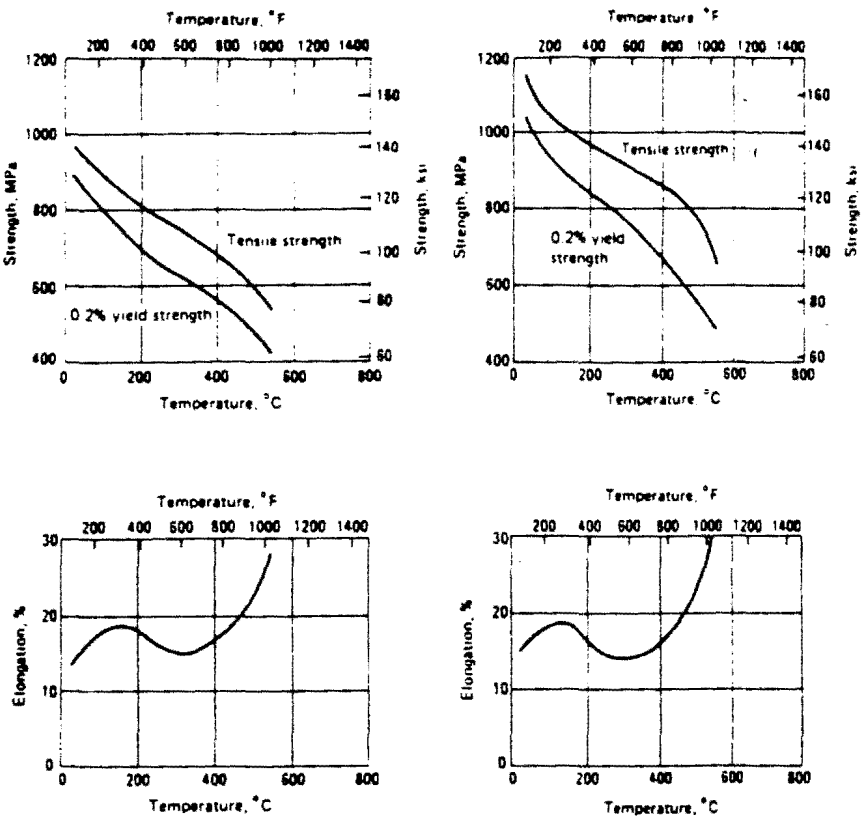
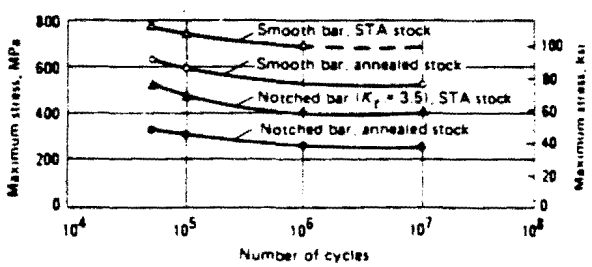


Fig. 17 Typical tensile properties of Ti-6Al-4V



Left: Mill annealed condition. Right: STA condition—1 h at 955 °C (1750 °F), water quench, age 4 h at 525 °C (975 °F) and air cool.

Fig. 18 Typical rotating-beam fatigue curves for Ti-6Al-4V bar stock



history. Martensitic structure can also be produced.

Mass Characteristics

Density. 4.43 Mg/m³ (0.160 lb/in.³) at 25 °C (77 °F)

Thermal Properties

Liquidus temperature. 3020 ± 25 °F (1660 ± 14 °C)

Solidus temperature. 2920 ± 20 °F (1604 ± 11 °C)

Phase-transformation temperature. Beta transus, 955 to 1010 °C (1750 to 1850 °F)

Coefficient of thermal expansion. See Fig. 20.

Specific heat:

Temperature		Specific heat	
°C	°F	J/kg·K	Btu/lb·°F
20	68	580	0.14
205	400	610	0.15
425	800	670	0.16
650	1200	760	0.18
870	1600	930	0.22

Thermal conductivity:

Temperature		Conductivity	
°C	°F	W/m·K	Btu/ft·h·°F
Mill annealed			
20	68	6.6	3.8
93	200	7.3	4.2
205	400	9.1	5.3
315	600	10.6	6.1
425	800	12.6	7.3
540	1000	14.6	8.4
650	1200	17.5	10.1
Solution treated and aged			
20	68	6.8	3.9
93	200	7.5	4.3
205	400	8.5	4.9
315	600	9.6	5.5
425	800	10.9	6.3
540	1000	12.6	7.3
650	1200	14.1	8.1

Electrical Properties

Electrical resistivity. 1.71 μΩ·m at room temperature

Magnetic Properties

Magnetic permeability. 1.00005 at 1.6 kA/m

Chemical Properties

General corrosion behavior. Same as commercially pure titanium

Resistance to specific corroding agents. Not attacked by 10% boiling

HCl; 1.8 mm/yr (70 mils/yr) corrosion rate in boiling 15% H_2SO_4. See also Fig. 21.

Fabrication Characteristics

Machinability. Same as commercially pure titanium
Annealing temperature. 705 to 785 °C (1300 to 1450 °F)
Solution temperature. 900 to 955 °C (1650 to 1750 °F)
Aging temperature. 540 °C (1000 °F)
Hot working temperature. 870 to 1010 °C (1650 to 1850 °F)

Ti-6Al-4V
Ti-6Al-4V-ELI

Commercial Names

Trade names. C-120AV; HA-6510
UNS number. Ti-6Al-4V, R56400; Ti-6Al-4V-ELI, R56401

Specifications

AMS. Standard grade: 4906, 4911, 4928, 4934, 4935, 4954, 4965, 4967. ELI grade: 4907, 4930, 4956
ASTM. Bar and billet: B348. Castings: B367. Forgings: B381. Sheet, strip and plate: B265
AWS. A5.16
Government. MIL-T-9046, MIL-T-9047, MIL-T-8884, MIL-T-14557, MIL-T-14558, MIL-T-81556, MIL-T-81588, MIL-F-83142

Chemical Composition

Composition limits. Ti-6Al-4V: 5.5 to 6.75 Al; 3.5 to 4.5 V; 0.05 max N; 0.10 max C; 0.015 max H; 0.40 max Fe; 0.20 max O; 0.1 max others (each); 0.5 max others (total); rem Ti

Applications

Typical uses. Ti-6Al-4V is the most widely used titanium alloy. It is specially processed to both standard and ELI compositions to provide mill-annealed or beta-annealed structures, and is sometimes solution treated and aged. It is used for aircraft gas turbine disks and blades; is extensively used, in all mill product forms, for airframe structural components and other applications requiring strength at temperatures up to 315 °C (600 °F); and is also used for high-strength prosthetic implants and chemical-processing equipment.
Precautions in use. Rolled sheet may exhibit strong directionality of physical and mechanical properties. In other ways, similar to Ti-5Al-2.5Sn.

Mechanical Properties

Tensile properties. Annealed bar: tensile strength, 895 MPa (130 ksi); yield strength, 825 MPa (120 ksi); elongation, 10%; reduction in area, 20%. Solution treated aged bar and forgings, 2.54 to 5.08 cm (1 to 2 in.) thick: tensile strength, 1035 MPa (150 ksi); yield strength, 965 MPa (140 ksi); elongation, 8%; reduction in area, 20%. See also Fig. 17.
Compressive yield strength. Annealed bar: 860 MPa (125 ksi). Solution treated and aged bar: 1070 MPa (155 ksi)
Hardness. 36 to 39 HRC
Poisson's ratio. 0.33
Elastic modulus. Tension, 110 GPa (16×10^6 psi); compression, 117 GPa (17×10^6 psi)

Impact strength:

Temperature °C	Temperature °F	Fracture energy J	Fracture energy ft·lb
-185	-300	20.3	15
-70	-94	24.4	18
-20	-4	25.7	19
90	194	29.8	22
205	400	54.2	40
315	600	74.5	55

Fatigue strength. See Fig. 18.
Plane-strain fracture toughness. At 25 °C (77 °F): annealed plate, 74.6 MPa$\sqrt{m}$ (68 ksi$\sqrt{in.}$); solution treated and aged, 42.9 MPa$\sqrt{m}$ (39 ksi$\sqrt{in.}$)
Creep-rupture characteristics. See Fig. 19.
Velocity of sound. 4.987 km/s at 25 °C (77 °F)

Structure

Crystal structure. cph, a_0 = 2.925 $\times 10^{-8}$ m at 25 °C (77 °F). c = 4.644 $\times 10^{-8}$ m at 25 °C (77 °F)
Slip planes. $\{10\bar{1}0\}\langle 11\bar{2}0\rangle$, $\{10\bar{1}1\}\langle 11\bar{2}0\rangle$, $\{0001\}\langle 11\bar{2}0\rangle$ at 25 °C (77 °F)
Twinning planes. $\{10\bar{1}2\}$, $\{11\bar{2}1\}$, $\{11\bar{2}2\}$ at 25 °C (77 °F)
Microstructure. Predominantly cph alpha phase with some bcc beta phase at room temperature. Morphology and relative amounts of alpha and beta depend upon thermal

Table 9 Comparison of typical room-temperature properties of wrought, cast and P/M titanium products

Product and condition	Tensile strength MPa	Tensile strength ksi	Yield strength MPa	Yield strength ksi	Elongation, %	Reduction in area, %	Impact strength (a) J	Impact strength (a) ft·lb
Unalloyed Ti								
Wrought bar, annealed	550	80	480	70	18	33	35	26
Cast bar, as cast	635	92	510	74	20	31	26	19
P/M compact, annealed(b)	480	70	370	54	18	22	...	...
Ti-5Al-2.5Sn-ELI								
Wrought bar, annealed	815	118	710	103	19	34	...	...
Cast bar, as cast	795	115	725	105	10	17	...	...
P/M compact, annealed and forged(c)	795	115	715	104	16	27	...	...
Ti-6Al-4V								
Wrought bar, annealed	1000	145	925	134	16	34	22	16
Cast bar								
As cast	1025	149	880	128	12	19	19	14
Annealed	1015	147	890	129	10	16	...	...
Solution treated and aged(d)	1180	171	1085	157	6	11	...	...
P/M compact								
Annealed(b)	825-855	120-124	740-785	107-114	5-8	8-14	...	...
Annealed and forged(c)	925	134	840	122	12	27	...	...
Solution treated and aged(d)	965	140	895	130	4	6	...	...
Ti-6Al-6V-2Sn								
Wrought bar, annealed	1125	163	1055	153	16	38	20	15
Cast bar, as cast	1105	160	965	140	6	11	14	10
P/M compact, annealed(b)	965	140	840	122	5	5	...	...

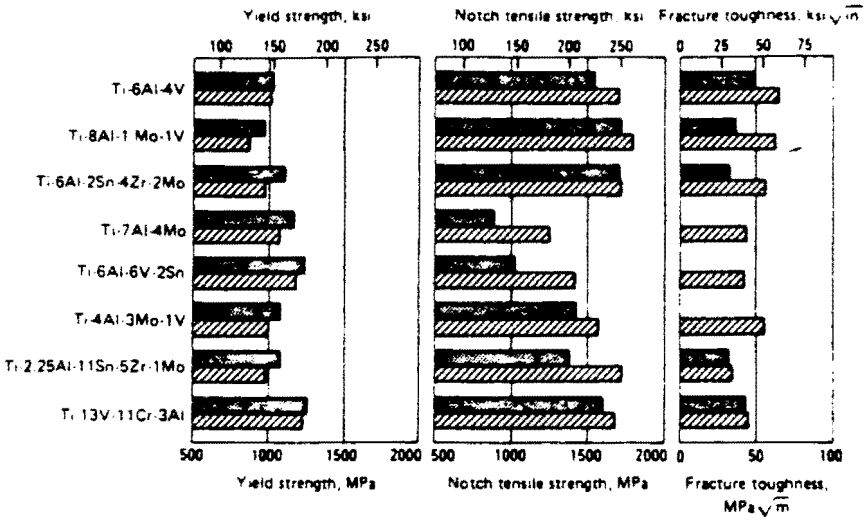
All data from Ref. 3. (a) Charpy, at −40 °C (−40 °F), (b) About 94% dense. (c) Almost 100% dense. (d) Aging treatment not specified.

Table 10 Typical room-temperature tensile properties of titanium P/M compacts

Powder manufacturing process	Oxygen content, ppm	Tensile strength MPa	Tensile strength ksi	Yield strength MPa	Yield strength ksi	Elongation, %
Ti-6Al-4V						
Mechanical attrition	1750	1000	145	940	136	1.5
Rotating electrode	900	1000	145	925	134	7.5
Hydride-to-hydride	1570	1025	149	970	141	2.0
Ti-5Al-2.5Sn						
Rotating electrode	980	905	131	905	131	4.0
Gas attrition	3530	895	130	...	...	...

All data from Ref 4 for compacts hot pressed to 1380 MPa (100 tons/in.^{2}) at 1010 °C (1850 °F).

Fig. 4 Comparison of mechanical properties of alpha-beta forged and beta forged titanium alloys



Shaded bars represent alpha-beta forged material; striped bars, beta forged material. (Ref 2)

Table 8 Typical properties of welded Ti-6Al-6V-2Sn after postweld heat treatment

Heat treatment	Tensile strength, MPa	Tensile strength, ksi	Yield strength, MPa	Yield strength, ksi	Elongation, %	Bend radius (min)
None						
Base metal	1060	154	1010	146	9.8	2.8*t*
Single-bead weld	1300	188	1250	182	0.3	25.6*t*
Furnace cool from 830 °C (1525 °F)						
Base metal	1030	149	970	141	8.1	...
Single-bead weld	1050	152	990	144	3.7	15.5*t*
Furnace cool after 6 h at 700 °C (1300 °F) in vacuum						
Base metal	1120	163	1040	151	9.8	2.0*t*
Single-bead weld	1170	169	1100	159	3.8	12.2*t*
Air cool after ½ h at 700 °C						
Base metal	1050	152	1000	145	9.8	...
Single-bead weld	1230	178	1160	168	1.3	14.5*t*

Table 7 Typical tensile, bend and hardness data for as-welded titanium and several titanium alloys

Material condition	Tensile strength MPa	Tensile strength ksi	Yield strength MPa	Yield strength ksi	Elongation, %	Minimum bend radius	Hardness Knoop	Hardness Rockwell
Ti Grade 1								
Unwelded sheet	315	46	215	31	50.4	0.7*t*	140	63.5 HRB
Single-bead weld	345	50	255	37	37.5	1.0*t*	140	55.8 HRB
Multiple-bead weld	365	53	270	39	37.7	...	...	...
Transverse weld	325	47(a)	...	...	...	...	...	...
Ti Grade 2								
Unwelded sheet	460	67	325	47	26.2	2.9*t*	165	80.6 HRB
Single-bead weld	505	73	380	55	18.3	2.9*t*	175	83.1 HRB
Multiple-bead weld	510	74	385	56	13.3	...	...	...
Transverse weld	475	69(a)	...	...	...	...	...	...
Ti Grade 3								
Unwelded sheet	545	79	395	57	25.9	1.9*t*	175	94.4 HRB
Single-bead sheet	605	88	475	69	15.5	4.7*t*	220	92.4 HRB
Multiple-bead weld	615	89	480	70	14.7	...	...	...
Transverse weld	560	81(a)	...	...	...	...	...	...
Ti Grade 4								
Unwelded sheet	660	96	530	77	22.3	3.2*t*	215	23.4 HRC
Single-bead weld	695	101	580	84	16.4	5.6*t*	240	21.2 HRC
Multiple-bead weld	710	103	585	85	16.0	...	...	...
Transverse weld	660	96(a)	...	...	...	...	...	...
Ti-5Al-2.5Sn-ELI								
Unwelded sheet	850	123	805	117	15.7	3.8*t*	265	33.2 HRC
Single-bead weld	920	133	770	112	9.8	5.9*t*	310	28.0 HRC
Multiple-bead weld	935	136	820	119	7.5	...	...	...
Transverse weld	850	123(a)	...	...	...	...	...	...
Ti-6Al-2Cb-1Ta-1Mo								
Unwelded sheet	895	130	855	124	9.7	2.8*t*	275	29.6 HRC
Single-bead weld	930	135	800	116	5.9	7.7*t*	300	27.7 HRC
Multiple-bead weld	945	137	815	118	5.7	...	...	...
Transverse weld	890	129(a)	...	...	...	...	...	...
Ti-3Al-2.5V								
Unwelded sheet	705	102	670	97	15.2	4.0*t*	230	23.6 HRC
Single-bead weld	705	102	600	87	12.7	5.4*t*	250	19.6 HRC
Multiple-bead weld	745	108	625	91	11.2	...	...	...
Transverse weld	710	103(a)	...	...	...	...	...	...
Ti-6Al-4V								
Unwelded sheet	1000	145	945	137	11.0	2.6*t*	320	32.2 HRC
Single-bead weld	1060	154	920	133	3.5	10.5*t*	350	35.9 HRC
Multiple-bead weld	1090	158	945	137	3.2	...	...	...
Transverse weld	1015	147(a)	...	...	...	...	...	...
Ti-8Al-1Mo-1V								
Unwelded sheet	1060	154	1020	148	15.0	2.9*t*	325	36.0 HRC
Single-bead weld	1085	157	930	135	5.5	7.0*t*	345	35.2 HRC
Multiple-bead weld	1115	162	960	139	3.2	...	...	...
Transverse weld	1060	154(a)	...	...	...	...	...	...
Ti-6Al-6V-2Sn								
Unwelded sheet	1060	154	1005	146	9.8	2.8*t*	350	34.0 HRC
Single-bead weld	1295	188	1255	182	0.3	25.6*t*	420	46.8 HRC
Multiple-bead weld	1280	186	...	...	0.1	...	...	...
Transverse weld	1103	160(a)	...	...	...	...	...	...
Ti-13V-11Cr-3Al								
Unwelded sheet	965	140	910	132	13.9	2.7*t*	300	30.6 HRC
Single-bead weld	950	138	925	134	11.6	2.7*t*	320	30.1 HRC
Multiple-bead weld	925	134	875	127	9.1	...	...	...
Transverse weld	950	138(a)	...	...	...	...	...	...

(a) Fracture occurred in base metal.

Table 4 Typical rolling temperatures for several titanium metals

Alloy	Rolling temperatures: Bar °C	Bar °F	Plate °C	Plate °F	Sheet °C	Sheet °F
Commercially pure titanium						
Grades 1 to 4	760-815	1400-1500	760-790	1400-1450	705-760	1300-1400
Alpha and near-alpha alloys						
Ti-5Al-2.5Sn	1010-1065	1850-1950	980-1040	1800-1900	980-1010	1800-1850
Ti-6Al-2Sn-4Zr-2Mo	955-1010	1750-1850	955-980	1750-1800	925-980	1700-1800
Ti-8Al-1Mo-1V	1010-1040	1850-1900	980-1040	1800-1900	980-1040	1800-1900
Alpha-beta alloys						
Ti-8Mn	...	...	705-760	1300-1400	705-760	1300-1400
Ti-4Al-3Mo-1V	925-955	1700-1750	900-925	1650-1700	900-925	1650-1700
Ti-6Al-4V	955-1010	1750-1850	925-980	1700-1800	900-925	1650-1700
Ti-6Al-6V-2Sn	900-955	1650-1750	870-925	1600-1700	870-900	1600-1650
Ti-7Al-4Mo	955-1010	1750-1850	925-955	1700-1750	925-955	1700-1750
Beta alloy						
Ti-13V-11Cr-3Al	955-1065	1750-1950	980-1040	1800-1900	730-900	1350-1650

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Table 5 Tensile properties of unidirectionally rolled Ti-6Al-4V sheet

Gage mm	Gage in.	Tensile strength MPa	Tensile strength ksi	Yield strength MPa	Yield strength ksi	Elongation(a), %	Tensile modulus GPa	Tensile modulus 10^6 psi
Longitudinal direction								
0.737	0.029	945	137	870	126	7.0	100	14.5
1.016	0.040	970	141	855	124	6.5	106	15.4
1.168	0.046	915	133	860	125	6.5	105	15.2
1.524	0.060	985	143	925	134	6.5	104	15.1
1.778	0.070	995	144	915	133	8.0	105	15.3
Transverse direction								
0.737	0.029	1105	160	1061	154	7.5	130	18.8
1.016	0.040	1195	173	1105	160	7.5	145	21.1
1.168	0.046	1225	178	1165	169	7.5	140	20.2
1.524	0.060	1125	163	1090	158	8.0	125	18.2
1.778	0.070	1095	159	1055	153	9.5	135	19.5

(a) In 50 mm or 2 in.

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Table 6 Thermomechanical schedules for producing various combinations of properties in Ti-6Al-4V forgings

Initial microstructure	Blocker forging temperature range	Finish forging temperature range	Finish forging reduction	Cooling after forging	Heat treated condition	Final microstructure
Best combinations of properties						
...	Alpha-beta	Alpha-beta	...	Air cooled	Annealed	6% equiaxed alpha plus fine platelet alpha
Grain-boundary alpha	Alpha-beta	Alpha-beta	...	Air cooled	Annealed	26% elongated partly broken up grain-boundary primary alpha plus fine platelet alpha
Grain-boundary alpha	Alpha-beta	Alpha-beta	...	Water quenched	Annealed	23% elongated partly broken up primary alpha plus very fine platelet alpha
...	Beta	Alpha-beta	10%	Air cooled	Annealed	63% fine elongated primary alpha plus fine platelet alpha
Subnormal properties						
Spaghetti alpha	Alpha	Alpha	...	Air cooled	STOA	25% blocky primary alpha plates plus very fine platelet alpha
...	Beta	Alpha-beta	10%	Water quenched	STOA	43% coarse elongated primary alpha plates plus very fine platelet alpha
...	Beta	Beta	...	Slow cooled	Annealed	92% alpha basket-weave structure

All data from Ref 1.

Table 2 Standard forging temperatures for several titanium metals

Alloy	Beta transus °C	Beta transus °F	Forging temperatures: Ingot breakdown °C	Ingot breakdown °F	Intermediate °C	Intermediate °F	Finish °C	Finish °F
Commercially pure titanium								
Grades 1 to 4	900-955	1650-1750	955-980	1750-1800	900-925	1650-1700	815-900	1500-1650
Alpha and near-alpha alloys								
Ti-5Al-2.5Sn	1030	1890	1120-1175	2050-2150	1065-1095	1950-2000	1010-1040	1850-1900
Ti-6Al-2Sn-4Zr-2Mo-0.08Si	995	1820	1095-1150	2000-2100	1010-1065	1850-1950	955-980	1750-1800
Ti-8Al-1Mo-1V	1040	1900	1120-1175	2050-2150	1065-1095	1950-2000	1010-1040	1850-1900
Alpha-beta alloys								
Ti-8Mn	800	1475	925-980	1700-1800	845-900	1550-1650	815-845	1500-1550
Ti-6Al-4V	995	1820	1095-1150	2000-2100	980-1040	1800-1900	925-980	1700-1800
Ti-6Al-6V-2Sn	945	1735	1040-1095	1900-2000	955-1010	1750-1850	870-940	1600-1725
Ti-7Al-4Mo	1005	1840	1120-1175	2050-2150	1010-1065	1850-1950	955-980	1750-1800
Beta alloy								
Ti-13V-11Cr-3Al	720	1325	1120-1175	2050-2150	1010-1065	1850-1950	925-980	1700-1800

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Table 3 Variation of typical room-temperature tensile properties with section size for four titanium alloys

Section size(a) mm	Section size(a) in.	Tensile strength MPa	Tensile strength ksi	Yield strength MPa	Yield strength ksi	Elongation(b), %	Reduction in area, %
6Al-4V(c)							
25-50	1-2	1015	147	965	140	14	36
102	4	1000	145	930	135	12	25
205	8	965	140	895	130	11	23
330	13	930	135	860	125	10	20
6Al-4V-ELI(c)							
25-50	1-2	950	138	885	128	14	36
102	4	885	128	827	120	12	28
205	8	885	128	820	119	10	27
330	13	870	126	795	115	10	22
6Al-6V-2Sn(c)							
25-50	1-2	1105	160	1035	150	15	40
102	4	1070	155	965	145	13	35
205	8	1000	145	930	135	12	25
8Al-1Mo-1V							
25-50	1-2(d)	985	143	905	131	15	36
102	4(e)	910	132	840	122	17	35
205	8(f)	1000	145	895	130	12	23
6Al-2Sn-4Zr-2Mo + Si(g)							
25-50	1-2	1000	145	930	135	14	33
102	4	1000	145	930	135	12	30
205	8	1035	150	940	136	12	28
330	13	1000	145	825	120	11	21

(a) Properties are in longitudinal direction for sections 50 mm (2 in.) or less, and in transverse direction for sections 100 mm (4 in.) or more, in section size. (b) In 50 mm or 2 in. (c) Annealed 2 h at 700 °C (1300 °F) and air cooled. (d) Annealed 1 h at 900 °C (1650 °F), air cooled, then heated 8 h at 600 °C (1100 °F) and air cooled. (e) Annealed 1 h at 1010 °C (1850 °F), air cooled, then heated to 566 °C (1050 °F). (f) Annealed 1 h at 1010 °C (1850 °F) and oil quenched. (g) Annealed 1 h at 954 °C (1750 °F), air cooled, then heated 8 h to 600 °C (1100 °F) and air cooled.

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Table 1 Summary of commercial and semicommercial grades and alloys of titanium

Designation	Tensile strength (min) MPa	Tensile strength (min) ksi	0.2% yield strength (min) MPa	0.2% yield strength (min) ksi	Impurity limits, wt % N (max)	C (max)	H (max)	Fe (max)	O (max)	Nominal composition, wt % Al	Sn	Zr	Mo	Others
Unalloyed grades														
ASTM Grade 1	240	35	170	25	0.03	0.10	0.015	0.20	0.18	...	...	...	...	...
ASTM Grade 2	340	50	280	40	0.03	0.10	0.015	0.30	0.25	...	...	...	...	...
ASTM Grade 3	450	65	380	55	0.05	0.10	0.015	0.30	0.35	...	...	...	...	...
ASTM Grade 4	550	80	480	70	0.05	0.10	0.015	0.50	0.40	...	...	...	...	...
ASTM Grade 7	340	50	280	40	0.03	0.10	0.015	0.30	0.25	...	...	...	...	0.2Pd
Alpha and near-alpha alloys														
Ti Code 12	480	70	380	55	0.03	0.10	0.015	0.30	0.25	...	...	...	0.3	0.8Ni
Ti-5Al-2.5Sn	790	115	760	110	0.05	0.08	0.02	0.50	0.20	5	2.5	...	...	...
Ti-5Al-2.5Sn-ELI	690	100	620	90	0.07	0.08	0.0125	0.25	0.12	5	2.5	...	...	...
Ti-8Al-1Mo-1V	900	130	830	120	0.05	0.08	0.015	0.30	0.12	8	...	...	1	1V
Ti-6Al-2Sn-4Zr-2Mo	900	130	830	120	0.05	0.05	0.0125	0.25	0.15	6	2	4	2	...
Ti-6Al-2Nb-1Ta-0.8Mo	790	115	690	100	0.02	0.03	0.0125	0.12	0.10	6	...	...	1	2Nb, 1Ta
Ti-2.25Al-11Sn-5Zr-1Mo	1000	145	900	130	0.04	0.04	0.008	0.12	0.17	2.25	11.0	5.0	1.0	0.2Si
Ti-5Al-5Sn-2Zr-2Mo(a)	900	130	830	120	0.03	0.05	0.0125	0.15	0.13	5	5	2	2	0.25Si
Alpha-beta alloys														
Ti-6Al-4V(b)	900	130	830	120	0.05	0.10	0.0125	0.30	0.20	6.0	...	...	...	4.0V
Ti-6Al-4V-ELI(b)	830	120	760	110	0.05	0.08	0.0125	0.25	0.13	6.0	...	...	...	4.0V
Ti-6Al-6V-2Sn(b)	1030	150	970	140	0.04	0.05	0.015	1.0	0.20	6.0	2.0	...	...	0.75Cu, 6.0V
Ti-8Mn(b)	860	125	760	110	0.05	0.08	0.015	0.50	0.20	...	...	...	...	8.0Mn
Ti-7Al-4Mo(b)	1030	150	970	140	0.05	0.10	0.013	0.30	0.20	7.0	...	...	4.0	...
Ti-6Al-2Sn-4Zr-6Mo(c)	1170	170	1100	160	0.04	0.04	0.0125	0.15	0.15	6.0	2.0	4.0	6.0	...
Ti-5Al-2Sn-2Zr-4Mo-4Cr(a)(c)	1125	163	1055	153	0.04	0.05	0.0125	0.30	0.13	5.0	2.0	2.0	4.0	4.0Cr
Ti-6Al-2Sn-2Zr-2Mo-2Cr(a)(b)	1030	150	970	140	0.03	0.05	0.0125	0.25	0.14	5.7	2.0	2.0	2.0	2.0Cr, 0.25Si
Ti-10V-2Fe-3Al(a)(c)	1170	170	1100	160	0.05	0.05	0.015	2.5	0.16	3.0	...	...	...	10.0V
Ti-3Al-2.5V(d)	620	90	520	75	0.015	0.05	0.015	0.30	0.12	3.0	...	...	...	2.5V
Beta alloys														
Ti-13V-11Cr-3Al(c)	1170	170	1100	160	0.05	0.05	0.025	0.35	0.17	3.0	...	...	...	11.0Cr, 13.0V
Ti-8Mo-8V-2Fe-3Al(a)(c)	1170	170	1100	160	0.05	0.05	0.015	2.5	0.17	3.0	...	...	8.0	8.0V
Ti-3Al-8V-6Cr-4Mo-4Zr(a)(b)	900	130	830	120	0.03	0.05	0.020	0.25	0.12	3.0	...	4.0	4.0	6.0Cr, 8.0V
Ti-11.5Mo-6Zr-4.5Sn(b)	690	100	620	90	0.05	0.10	0.020	0.35	0.18	...	4.5	6.0	11.5	...

(a) Semicommercial alloy; mechanical properties and composition limits subject to negotiation with suppliers. (b) Mechanical properties given for annealed condition; may be solution treated and aged to increase strength. (c) Mechanical properties given for solution treated and aged condition; alloy not normally applied in annealed condition. Properties may be sensitive to section size and processing. (d) Primarily a tubing alloy; may be cold drawn to increase strength.

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Table 1 Tensile properties of annealed titanium sheet as influenced by oxygen and iron contents

Material	Maximum impurity content, % Oxygen	Iron	Minimum tensile strength MPa	ksi	Minimum yield strength(a) MPa	ksi
Unalloyed Ti, grade 1	0.18	0.20	240	35	170	25
Unalloyed Ti, grade 2	0.25	0.30	345	50	275	40
Unalloyed Ti, grade 3	0.35	0.30	450	65	380	55
Unalloyed Ti, grade 4	0.40	0.50	655	95	485	70
Ti-6Al-4V	0.20	0.30	925	134	870	126
Ti-6Al-4V-ELI	0.13	0.25	900	130	830	120
Ti-5Al-2.5Sn	0.20	0.50	830	120	780	113
Ti-5Al-2.5Sn-ELI	0.12	0.25	690	100	655	95

(a) At 0.2% offset.

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Properties of Titanium Alloy
Type: Ti-6Al-4V

From: Metals Handbook
Ninth Edition
Volume 3

TABLE 3 Chemical Requirements, Heat Analysis

Element	Composition, %	
	Grade 1	Grade 2
Carbon	0.08 max	0.030 max
Manganese	2.00 max	2.00 max
Phosphorus	0.025 max	0.025 max
Sulfur	0.010 max	0.010 max
Silicon	0.75 max	0.75 max
Chromium	17.00 to 19.00	17.00 to 19.00
Nickel	12.00 to 14.00	12.00 to 14.00
Molybdenum	2.00 to 3.00	2.00 to 3.00
Nitrogen	0.10 max	0.10 max
Copper	0.50 max	0.50 max
Iron[A]	balance	balance

[A] Approximately equal to the difference between 100 % and the sum percentage of the other specified elements. The percentage iron content by difference is not required to be reported.

APPENDIX

(NONMANDATORY INFORMATION)

X1. Rationale

X1.1 The primary reason for this standard is to characterize composition and properties to assure consistency in the starting material used, directly or as modified by forging, in the manufacturing of medical devices.

X1.2 The material has been shown to produce a well-characterized level of local biological response following long-term clinical use and has been used as control material in Practice F 361. The low-carbon Grade 2 is generally selected to provide an extra measure of assurance that the material will be free from susceptibility to intergranular corrosion.

X1.3 There is a general consensus that a homogeneous metallurgical structure will be superior with respect to corrosion and fatigue resistance. Based upon this, metallurgical requirements include fine-grained austenitic structure free of ferrite, with low micro-inclusion content and capability of passing an intergranular corrosion susceptibility test.

X1.4 Acceptable metal conditions supplied to the implant manufacturer include hot-worked, annealed, and all cold-worked conditions, the choice dependent upon the implant design and application.

X1.5 Upper composition limits for chromium and molybdenum have been decreased to more realistic limits in order to minimize the tendency to form delta ferrite in this material. This does not affect the nominal analysis.

X1.6 A maximum nitrogen limit has been included in accordance with the specified element requirements of similar austenitic stainless steels standardized by ASTM.

X1.7 The maximum copper value is considered a practical limit based on a statistical evaluation of commercially available material. Published information has shown no adverse clinical effect for compositions containing up to 1.0 % copper content.

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This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, 1916 Race St., Philadelphia, Pa. 19103.

TABLE 1 Mechanical Requirements, Wire and Bar

Condition	Grade	Diameter or Thickness, in (mm)	Ultimate Tensile Strength, min, psi (MPa)	Yield Strength (0.2 % offset), min, psi (MPa)	Elongation[B] in 4D or 4W, min, %	Brinell[C] Hardness, max, HB
Hot-worked[A]	1	all	...	...	...	275
	2	all	...	...	...	250
Annealed	1	all	75 000 (515)	30 000 (205)	40	...
	2	all	70 000 (480)	25 000 (170)	40	...
Cold-worked	1	1/16 to 3/4 (1.59 to 19.1), incl	125 000 (860)	100 000 (690)	12	...
	2	1/16 to 3/4 (1.59 to 19.1), incl	125 000 (860)	100 000 (690)	12	...
	1	over 3/4 to 1 (19.1 to 25.4), incl	115 000 (790)	80 000 (550)	15	...
	2	over 3/4 to 1 (19.1 to 25.4), incl	115 000 (790)	80 000 (550)	15	...
	1	over 1 to 1 1/4 (25.4 to 31.8), incl	105 000 (725)	65 000 (450)	20	...
	2	over 1 to 1 1/4 (25.4 to 31.8), incl	105 000 (725)	65 000 (450)	20	...
	1	over 1 1/4 to 1 1/2 (31.8 to 38.1), incl	100 000 (690)	50 000 (345)	28	...
	2	over 1 1/4 to 1 1/2 (31.8 to 38.1), incl	100 000 (690)	50 000 (345)	28	...
	1	over 1 1/2 to 1 3/4 (38.1 to 44.2), incl	95 000 (655)	45 000 (310)	28	...
	2	over 1 1/2 to 1 3/4 (38.1 to 44.2), incl	95 000 (655)	45 000 (310)	28	...

[A] Typically supplied as hot-rolled bar for forging applications.
[B] 4D = 4 × diameter; 4W = 4 × width.
[C] 29-kN (3000-kgf) load.

TABLE 2 Mechanical Requirements, Fine Wire

Condition	Diameter, in. (mm)	Ultimate Tensile[C] Strength psi (MPa)	Elongation in 10 in. (254 mm) min, %
Annealed[A]	0.002 to 0.005 (0.051 to 0.127), incl	145 000 (1000) max	30
	over 0.005 to 0.009 (0.127 to 0.229), incl	135 000 (930) max	30
	over 0.009 to 0.015 (0.229 to 0.381), incl	130 000 (895) max	35
	over 0.015 to 0.020 (0.381 to 0.508), incl	125 000 (860) max	40
	over 0.020 to 0.025 (0.508 to 0.635), incl	120 000 (825) max	40
	over 0.025 to 0.035 (0.635 to 0.889), incl	115 000 (795) max	40
	over 0.035 to 0.043 (0.889 to 1.09), incl	110 000 (760) max	45
	over 0.043 to 0.062 (1.09 to 1.57), incl	105 000 (725) max	45
Cold-drawn[B]	over 0.020 to 0.062 (0.508 to 1.57), incl	125 000 to 150 000 (860 to 1035)	15

[A] Annealed fine wire requirements do not apply to suture wire. Separate ASTM specifications cover flexible wire for surgical fixation of soft tissue and bone.
[B] Wire ordered in the cold-drawn condition can be supplied to a higher tensile strength and corresponding lower elongation levels as specified by the purchaser.
[C] Recommended crosshead speed for annealed fine wire is 10 in./min (4.2 mm/s). Recommended crosshead speed for cold drawn fine wire is 1 in./min (0.4 mm/s).

thickness, width, and length (exact, random or multiples) or print number, and

4.1.9 Special requirements.

5. Manufacture

5.1 *Condition*:

5.1.1 Bar and wire shall be furnished to the implant manufacturer, as specified, in the hot-worked, annealed, or cold-worked condition (see Table 1).

5.1.2 Fine wire shall be furnished to the implant manufacturer, as specified, in the annealed, or cold-drawn condition (see Table 2).

5.2 *Finish*:

5.2.1 Types of finish available in bar and wire products are cold-drawn, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

5.2.2 Types of finish available for fine wire products are cold-drawn, bright-annealed, pickled, ground, ground and polished, or as specified in the implant manufacturer's purchase order.

6. Chemical Requirements

6.1 The heat analysis shall conform to the requirements as to chemical composition specified in Table 3.

6.2 Methods and practices relating to chemical analysis required by this specification shall be in accordance with Methods A 751.

7. Metallurgical Requirements

7.1 The material shall contain no free ferrite phase when it is examined metallographically at 100× magnification.

7.2 The microcleanliness of the steel as determined by Practice E 45, Method A, except using Plate III, on representative billet or bar samples from the heat shall not exceed the following:

Inclusion Type	A (Sulfide)	B (Alumina)	C (Silicate)	D (Globular Oxide)
Thin	1.5	1.5	1.5	1.5
Heavy	1.0	1.0	1.0	1.0

8. Mechanical Requirements

8.1 Material shall conform to the appropriate requirements as to mechanical properties specified in Tables 1 and 2. The level of mechanical properties for material in other than the annealed condition shall be specified in the implant manufacturer's purchase order.

8.2 Brinell hardness number (HB) is the preferred method of reporting the hardness of hot worked material.

8.3 When desired, Rockwell hardness, B scale (HRB) or Rockwell hardness, C scale (HRC), limits may be specified. Hardness determination on cold-worked material shall be made on a product cross section, midway between the center and surface, if cross section size is adequate.

9. Special Tests

9.1 The steel shall be capable of passing the intergranular corrosion susceptibility test in accordance with Practices A 262, Practice E.

9.1.1 Samples in the hot-worked condition shall be annealed prior to Practices A 262, Practice E, sensitization heat treatment.

9.2 The grain size shall be five or finer when tested in accordance with Methods E 112.

9.2.1 It is preferred that samples for grain size determination be selected after the hot-working operation or after the final annealing operation prior to the final cold-working operation.

9.2.2 If samples are selected after a final cold-working operation, transverse specimens shall be prepared.

9.3 Any other special requirements shall be specified on the purchase order.

10. Certification

10.1 The manufacturer's certification that the material was manufactured and tested in accordance with this specification together with a report of the test results shall be furnished at the time of shipment.

11. Quality Program Requirements

11.1 The producer shall maintain a quality program, such as defined in ASQC C1-1968.

11.2 The manufacturer of surgical implants may audit the producer's quality program for conformance to the intent of ASQC C1-1968, or other recognized program.

Designation: F 138 – 82

Standard Specification for STAINLESS STEEL BAR AND WIRE FOR SURGICAL IMPLANTS (SPECIAL QUALITY)[1]

This standard is issued under the fixed designation F 138; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This specification has been approved for use by agencies of the Department of Defense and for listing in the DoD Index of Specifications and Standards.

1. Scope

1.1 This specification covers the requirements for two compositions of special quality stainless steel bar and wire, except suture wire, used for the manufacture of surgical implants.

NOTE 1—Exposure to temperatures above 800°F (425°C) during fabrication may impair corrosion resistance unless such exposure is followed by a solution-annealing treatment.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Applicable Documents

2.1 *ASTM Standards:*

A 262 Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels[2]

A 484/A 484M Specification for General Requirements for Stainless and Heat-Resisting Bars, Billets and Forgings[3]

A 555/A 555M Specification for General Requirements for Stainless and Heat-Resisting Steel Wire and Wire Rods[2]

A 751 Methods, Practices, and Definitions for Chemical Analysis of Steel Products[2]

E 45 Practice for Determining the Inclusion Content of Steel[4]

E 112 Methods for Determining Average Grain Size[4]

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue[6]

2.2 *American Society for Quality Control (ASQC) Standard:*

C1-1968 Specification of General Requirements for a Quality Program[7]

3. General Requirements for Delivery

3.1 In addition to the requirements of this specification, all requirements of the current editions of Specifications A 484/A 484M and A 555/A 555M shall apply.

3.2 In the case where a conflict exists between this standard and those listed in 2.1 and 2.2, this standard shall take precedence.

4. Order Information

4.1 Inquiries and orders for material under this specification shall include the following information:

4.1.1 Quantity (weight or number of pieces),

4.1.2 Grade (1 or 2),

4.1.3 ASTM designation,

4.1.4 Form (bar, wire, fine wire),

4.1.5 Condition (see 5.1),

4.1.6 Mechanical properties (if applicable, for special conditions),

4.1.7 Finish (see 5.2),

4.1.8 Applicable dimensions including size,

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[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.02 on Resources.

Current edition approved March 26, 1982. Published May 1982. Originally published as F 138 – 71. Last previous edition F 138 – 76.

[2] *Annual Book of ASTM Standards*, Vol 01.03.

[3] *Annual Book of ASTM Standards*, Vol 01.05.

[4] *Annual Book of ASTM Standards*, Vol 03.03.

[5] *Annual Book of ASTM Standards*, Vol 03.05.

[6] *Annual Book of ASTM Standards*, Vol 13.01.

[7] Available from American Society for Quality Control, 161 W. Wisconsin Ave., Milwaukee, WI 53203.

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Table 6 (continued)

Product form(a)	Condition	Tensile strength MPa	Tensile strength ksi	0.2% yield strength MPa	0.2% yield strength ksi	Elongation, %	Reduction in area, %	Hardness, HRB	ASTM specification
Type 316L (UNS S31603)									
B	Hot finished and annealed	480	70	170	25	40	50	...	A276
B	Cold finished(b) and annealed	620	90	310	45	30	40	...	A276
B	Cold finished(c) and annealed	480	70	170	25	30	40	...	A276
W	Annealed	480	70	170	25	...	...	...	A580
W	Cold finished	620	90	310	45	...	...	...	A580

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Typical Physical Properties of Stainless Steels, Annealed Condition

Type	UNS Designation	Density (Mg/m^3)	Density (lb/in^3)	Magnetic Permeability(b)	Melting Range °C	Melting Range °F
316l	S31603	8.0	0.29	1.02	1400-1450	2550-2650

Resistance of Standard Types of Stainless Steel to Various Classes of Environments

Type	Mild Atmosphere & Fresh Water	Atmosphere		Salt	Chemical		
		Industrial	Marine	Water	Mild	Oxidizing	Reducing
316L	X	X	X	X	X	X	X

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Table 5 (continued)

Diameter mm	Diameter in.	Tensile strength MPa	Tensile strength ksi
Types 305 and 316			
Up to 0.25	Up to 0.010	1689 to 1896	245 to 275
Over 0.25 to 0.38	Over 0.010 to 0.015	1655 to 1862	240 to 270
Over 0.38 to 1.04	Over 0.015 to 0.041	1620 to 1827	235 to 265
Over 1.04 to 1.19	Over 0.041 to 0.047	1586 to 1723 *	230 to 260
Over 1.19 to 1.37	Over 0.047 to 0.054	1551 to 1758	225 to 255
Over 1.37 to 1.58	Over 0.054 to 0.062	1517 to 1724	220 to 250
Over 1.58 to 1.85	Over 0.062 to 0.072	1482 to 1689	215 to 245
Over 1.85 to 2.03	Over 0.072 to 0.080	1448 to 1655	210 to 240
Over 2.03 to 2.34	Over 0.080 to 0.092	1413 to 1620	205 to 235
Over 2.34 to 2.67	Over 0.092 to 0.105	1379 to 1586	200 to 230
Over 2.67 to 3.05	Over 0.105 to 0.120	1344 to 1551	195 to 225
Over 3.05 to 3.76	Over 0.120 to 0.148	1276 to 1482	185 to 215
Over 3.76 to 4.22	Over 0.148 to 0.166	1241 to 1448	180 to 210
Over 4.22 to 4.50	Over 0.166 to 0.177	1172 to 1379	170 to 200
Over 4.50 to 5.26	Over 0.177 to 0.207	1103 to 1310	160 to 190
Over 5.26 to 5.72	Over 0.207 to 0.225	1069 to 1276	155 to 185
Over 5.72 to 6.35	Over 0.225 to 0.250	1034 to 1241	150 to 180
Over 6.35 to 7.92	Over 0.250 to 0.312	931 to 1138	135 to 165
Over 7.92 to 12.68	Over 0.312 to 0.499	793 to 1000	115 to 145
Over 12.68	Over 0.499	Consult producer	

Composition of standard stainless steels

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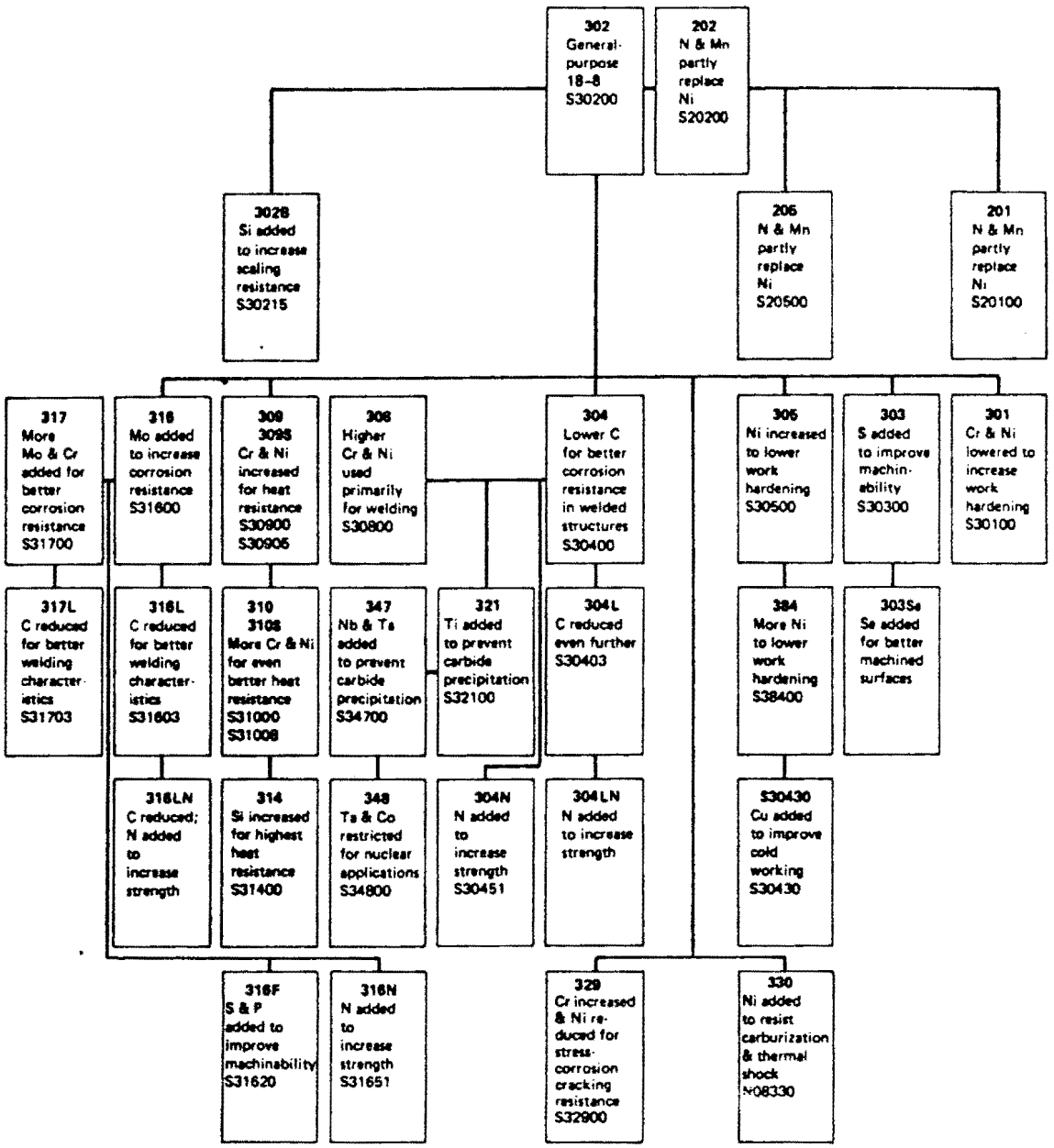
Type	UNS#	Composition,%(a)							
		C	Mn	Si	Cr	Ni(b)	P	S	Others
316L	S31603	0.03	2.00	1.00	16-18	10-14	0.045	0.03	2.0-3.0Mo

p.7

Fig. 2 Family relationships for standard austenitic stainless steels



Properties of Stainless Steel
Type: 316L

From: Metals Handbook
Ninth Edition
Volume 3

5.2 *Hardness:*

5.2.1 Material conforming to this specification typically will have Rockwell C-Scale hardness of 25 to 35 HRC as in the as-cast condition. The hardness determination shall be performed in accordance with Methods E 18.

5.2.2 Hardness values are for guidelines only, and shall not be used as a criteria for rejection.

6. Certification

6.1 A certification shall be provided by the manufacturer of the material that the material was manufactured and tested in accordance with this specification. A report of the test results shall be furnished at the time of shipment.

7. Quality Program Requirements

7.1 The producer shall maintain a quality program, such as, for example, is defined in ASQC C1-1968.

7.2 The manufacturer of surgical implants or medical appliances shall be assured of the producer's quality program for conformance to the intent of ASQC C1-1968 or other recognized programs.

TABLE 1 Chemical Requirements

Element	Composition, %	
	min	max
Chromium	27.0	30.00
Molybdenum	5.0	7.00
Nickel	...	1.00
Iron	...	0.75
Carbon	...	0.35
Silicon	...	1.00
Manganese	...	1.00
Cobalt	balance	balance

TABLE 2 Product Analysis Tolerances[A]

Element	Tolerance Under the Minimum Limit or Over the Maximum Limit[B]
Chromium	0.30
Molybdenum	0.15
Nickel	0.05
Iron	0.03
Carbon	0.02
Silicon	0.05
Manganese	0.03

[A] Refer to AMS Standard 2269B for Chemical Check Analysis Limits.

[B] For elements where only a maximum percentage is indicated, the "under minimum limit" is not applicable.

TABLE 3 As-Cast Mechanical Property Requirements

Property	
Tensile strength, min, psi (MPa)	95 000 (655)
Yield strength (0.2 % offset), min, psi (MPa)	65 000 (450)
Elongation, min, %	8
Reduction of area, min, %	8

APPENDIX
(Nonmandatory Information)

X1. RATIONALE

X1.1 The primary reason for this standard is to characterize composition and properties to assure consistency in the starting material used in the manufacturing of orthopedic implants.

X1.2 The material has been shown to produce a well characterized level of local biological response following long term clinical use and has been used as controlled material in Recommended Practice F 361.

X1.3 Upper composition limits for nickel have been decreased to realistic limits practiced by industry.

X1.4 The upper limit for the hardness has been increased to realistic limits for the material having chemical composition on the upper side of the limit.

The American Society for Testing and Materials takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, 1916 Race St., Philadelphia, Pa. 19103

Designation: F 75 – 82

Standard Specification for CAST COBALT-CHROMIUM-MOLYBDENUM ALLOY FOR SURGICAL IMPLANT APPLICATIONS[1]

This standard is issued under the fixed designation F 75, the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the requirements for cast cobalt-chromium-molybdenum alloy, shot, bar, or ingot for surgical implant applications.

1.2 The values stated in inch-pound units are to be regarded as the standard.

2. Applicable Documents

2.1 *ASTM Standards:*

E 8 Methods of Tension Testing of Metallic Materials[2]

E 18 Test Methods for Rockwell Hardness and Rockwell Superficial Hardness of Metallic Materials[2]

E 354 Methods for Chemical Analysis of High-Temperature, Electrical, Magnetic, and Other Similar Iron, Nickel, and Cobalt Alloys[3]

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue[4]

2.2 *American Society for Quality Control Standard:*

ASQC C1-1968 General Requirements for a Quality Program[5]

3. Ordering Information

3.1 Inquiries and orders for material under this specification shall include the following information:

3.1.1 Quantity (weight),

3.1.2 ASTM designation,

3.1.3 Mechanical properties (if applicable),

3.1.4 Form (shot, bar, ingot),

3.1.5 Applicable dimensions or print number,

3.1.6 Condition,

3.1.7 Special tests, and

3.1.8 Other requirements.

4. Chemical Requirements

4.1 The heat analysis shall conform to the requirements as to chemical composition prescribed in Table 1. The product analysis tolerances shall conform to the requirements prescribed in Table 2.

4.2 For referee purposes, Methods E 354 shall be used.

5. Mechanical Requirements

5.1 *Tensile Properties:*

5.1.1 Tensile properties shall be determined in accordance with Methods E 8.

5.1.2 Tension specimens shall be melted and cast from the metal under test by the same general procedure used in casting surgical implants and shall be in accordance with the ¼-in. (6.35-mm) diameter specimen in Fig. 8 of Methods E 8 which may have a ground finish on the reduced section.

5.1.3 A minimum of two test specimens shall be tested. If one specimen falls below the specified tensile requirements or breaks outside the gage limits, two additional specimens shall be tested and both must pass.

5.1.4 The material shall conform to the requirements as to mechanical property prescribed in Table 3.

---

[1] This specification is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices, and is the direct responsibility of Subcommittee F04.20 on Resources.

Current edition approved Nov. 26, 1982. Published April 1983. Originally published as F 75 – 67. Last previous edition F 75 – 76.

[2] *Annual Book of ASTM Standards*, Vol 03.01.

[3] *Annual Book of ASTM Standards*, Vol 03.05.

[4] *Annual Book of ASTM Standards*, Vol 13.01.

[5] Available from American Society for Quality Control, 161 West Wisconsin Ave., Milwaukee, WI 53203.

MATERIALS USED

Common materials used for each component in each system is listed in each section representing each joint. These particular materials listed in the following pages are those that meet the specifications by the government and have been approved by most manufacturers. A description of each material xeroxed from a few sources is hopefully adequate for the purposes of the Aviation Security Division.

NON-JOINT REPLACEMENT DEVICES

Joint replacement systems account for only a part of surgical implants found on a body. Metal rods, both permanent and temporary con be found inside and along a bone. Staples and pins as listed in the catalog made available by Howmedica can be found in many places. Paraplegics often have a spine full of this kind of metal, the spine being a very sensitive component of the body which is one of the only components irreplaceable. As mentioned earlier, supply is reliant on demand. If there is a demand, it will be taken care of in one way or another. Therefore, synthetic components will always be found in common "trouble" areas. Research on surgical techniques, catalogs on non-joint devices and literature on heart valves have all been made available upon request from U.S. manufacturers and research organizations.

Dow Corning Wright:

"There are many internal fixation devices sold such as bone plates, bone screws, pins and wires, intramedullary rods, spinal fixation and others that we do not manufacture but are sold by other companies."

Ronan Medical Clinic: Starr-Edwards Report about Heart Valves

Howmedica: 1987 Annual Product Catalog

Synthesis: Catalog, Original Instruments, of the Swiss Association for the Study of Internal Fixation.

EATON TRAPEZIUM FINGER JOINT REPLACEMENT

Eaton Trapezium Implant*

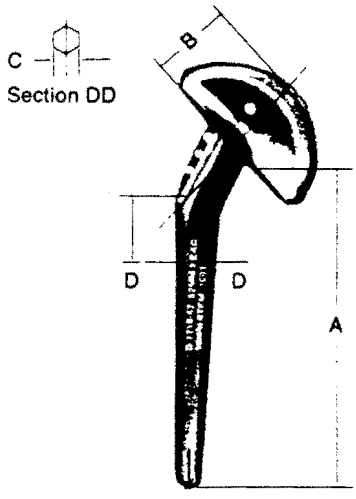
A one-piece, high-strength silicone elastomer spacer used for replacement of the trapezium bone. Provides an articular surface for the scaphoid bone for restoration of thumb function. A slip of the abductor pollicis longus (APL) tendon is passed through the hole in the body of the implant to anchor the implant. Packaged sterile.

Cat. No.	Size	Trial No.
1167-00	Std.	2959-00
1167-10	Small	2959-10

*Designed by Richard Eaton, M.D.

DePuy

NEW JERSEY HEMI-ARTHROPLASTY SHOULDER

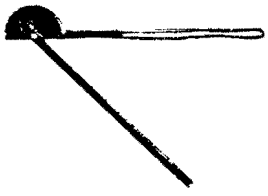


Humeral Component

Functions as an articular replacement for the humeral head, provides maximum range of motion and secure fixation. Orthochrome® 4 7/16" (112mm) stem length (A).

Cat. No.	Head Size in.	Head Size mm	Head Height B in.	Head Height B mm	Stem Size C in.	Stem Size C mm	Trial No.
1158-02	1 3/4	44	3/4	19	5/16	8	2858-02
1158-04	1 3/4	44	3/4	19	13/32	10	2858-04
1158-06	1 3/4	44	3/4	19	1/2	13	2858-06
1158-08	2 1/16	52	7/8	22	5/16	8	2858-08
1158-10	2 1/16	52	7/8	22	13/32	10	2858-10
1158-12	2 1/16	52	7/8	22	1/2	13	2858-12

Instrumentation



Protractor

2204-10 Small
2204-12 Large

Rasp

2858-14 8mm
2858-16 10mm
2858-18 13mm

X-ray Overlay

2990-52

DePuy

PRITCHARD TOTAL ELBOW SYSTEM Cont'd.

Mark II Total Elbow, Complete

U.S. Patent No. 3,990,117

Designed for use with or without humeral condyles. Used as a primary or revision prosthesis. Hinge design allows for 5°-7° of medial lateral laxity and 5° rotation. Forces are transmitted to surrounding soft tissues and bone rather than to the cement/stem interface to help prevent loosening of the stems. Orthochrome® humeral and ulnar component and parts, UHMWPe hinge pin assembly. Packaged sterile.

Cat. No.	Size	Trial No.
1192-06	Small, Right w/Curved Humeral Stem	2936-06
1192-08	Small, Left w/Curved Humeral Stem	2936-08
1192-10	Std., Right w/Curved Humeral Stem	2936-10
1192-12	Std., Left w/Curved Humeral Stem	2936-12
1192-14	Pin Assembly	2936-14

Mark II Pin Assembly

1192-14

Available as a separate set for use with the individual humeral and ulnar components to make a complete elbow. Can also be used as a back-up in the event the bushing and poly pin become contaminated. Orthochrome® pin, UHMWPe bushing and pin jacket.

Mark II Humeral Component

Used with Mark II Total Elbow. An extra bushing is packaged with every humeral component. 6½" (166mm) stem length, 1 1/32" (26mm) width at condyles.

Cat. No.	Size	Trial No.
1192-16	Curved, Small	2936-18
1192-18	Straight, Std.	
1192-20	Curved, Std.	

Ulnar Component

Used with both Mark II Total Elbows.

1191-20 Small, Right
1191-22 Small, Left
1191-24 Std., Right
1191-26 Std., Left

Instrumentation

Ulnar Rasp

Used to prepare the ulnar canal for the Mark II ulnar component.

2915-00 Std.
2915-08 Small

Humeral Reamer

2894-00

Prepares the humeral canal for the small and standard Mark II.

Pin Seating Forceps – Mark II

2894-10

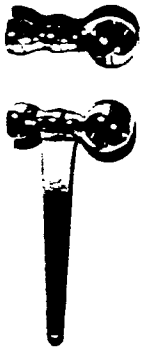
Used to snap pin together in Mark II prostheses. The poly sleeve half of the pin is inserted from either side and the metal stem is inserted from the other side of the humeral component. The forcep is then used to ensure that the snap fit interlock occurs.

X-ray Overlay

2990-14 Straight Stem
2990-19 Curved Stem

PRITCHARD TOTAL ELBOW SYSTEM

ERS™ Humeral Component with Porocoat®



Cat. No.	Description	Trial No.
1192-33	Universal, Std.	2292-33
1192-34	Universal, Large	2292-34
1192-35	Left, Std.	2292-35
1192-36	Left, Large	2292-36
1192-37	Right, Std.	2292-37
1192-38	Right, Large	2292-38

ERS™ Ulnar Component with Porocoat®

Cat. No.	Description	Trial No.
1192-30	Left	2292-30
1192-31	Right	2292-31

ERS™ Ulnar Bearing

Cat. No.	Description mm	Trial No.
1192-40	Left, 10	2292-40
1192-41	Left, 12	2292-41
1192-42	Left, 14	2292-42
1192-43	Right, 10	2292-43
1192-44	Right, 12	2292-44
1192-45	Right, 14	2292-45

ERS™ Radial Component with Porocoat®

Cat. No.	Description	Trial No.
1192-32	Universal	2292-32

ERS™ Radial Bearing

Cat. No.	Description mm	Trial No.
1192-48	8	2292-48
1192-49	10	2292-49
1192-50	12	2292-50
1192-51	14	2292-51

Instrumentation

X-ray Overlay
2990-15

Humeral Saw
2292-60

Fits Stryker® reciprocating saw.

Humeral Saw Guide
2292-62

Humeral Cutting Guide
2292-64 Left
2292-65 Right

Humeral Impactor
2292-66

Ulnar Rule
2292-68

Bearing Seating Forceps
2292-70

Radial Driver
2292-72

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

Dow Corning Wright

Materials Used

Silicon

Weight

Weight varies from a few ounces to 1 1/2 pounds

Depuy

Average Estimated Weight

SHOULDER

BROCHURES AVAILABLE FROM:

Depuy (Xeroxes on pages 63 & 64)

Depuy

Average Estimated Weight

Shoulder(total)	177 g

JOINT REPLACEMENT SYSTEMS

Dow Corning Wright

Materials Used

Silicon

Weight

weight varies from a few ounces to 1 1/2 pounds

TOES

BROCHURES AVAILABLE FROM:

Dow Corning Wright

Dow Corning Wright

Materials Used

Silicon

Physical Size

See Brochure

Weight

Varies from a few ounces to 1 1/2 pounds

WRIST

BROCHURES AVAILABLE FROM:

Dow Corning Wright

Depuy

ANKLE

BROCHURES AVAILABLE FROM:

Depuy (xeroxes from catalog on page 65)

ELBOW

BROCHURES AVAILABLE FROM:

Dow Corning Wright

Depuy (xeroxes from catalog on page 61 & 62)

Dow Corning Wright

Elbow-"consists of humeral and ulnar components"

Physical Size

Elbow humeral - approximately 4" X 1" X 1"

Elbow ulnar - approximately 2 1/2" X 1" X 1 1/2"

Weight

few ounces to 1 1/2 pounds

Depuy

Approximate Average Weight

Elbow (total) 104 g

FINGERS

BROCHURES AVAILABLE FROM:

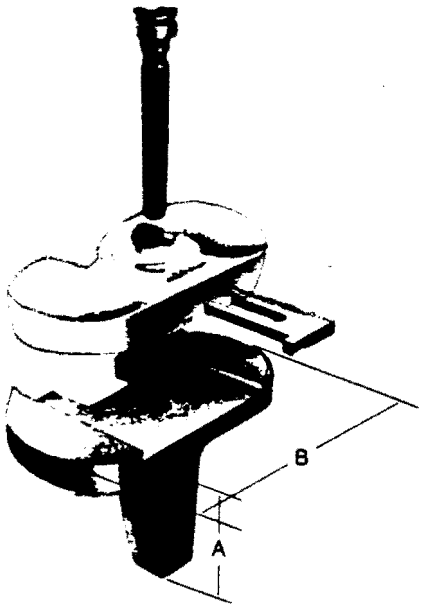
Dow Corning Wright

Depuy

JOINT REPLACEMENT SYSTEMS

More literature is found from more manufacturers on knee and hip replacement systems than on any other replacement system because of the frequency of use. For the most variety of implants, catalogs proved to be most useful. The Depuy catalog provides dimensions, styles, and descriptions clearly. For this reason I have included xeroxed pages from this catalog in my report. It offers literature on hips, knees, fingers, shoulders, ankles and elbow replacement systems. These xeroxed pages are following the next three which briefly describes various systems.

TOWNLEY TOTAL KNEE SYSTEM Cont'd.



Arizona Condylar Tibial Plateau

U.S. Patent No. 4,257,129

A total tibial plateau which permits retention of the posterior cruciate ligament and is especially designed to accommodate anatomical and pathological variation, through interchangeable metal retainers and polyethylene bearings. Utilized with the Townley femoral components. UHMWPe tibial inserts, packaged sterile. Orthochrome® tibial retainer, clip and pin tibial retainer.

Cat. No.	Size	Stem Length A mm	Plateau Width B mm
1188-01	Small, Std. Stem	38	65.5
1188-02	Small, Long Stem	75	65.5
1188-03	Medium, Std. Stem	38	71.5
1188-04	Medium, Long Stem	75	71.5
1188-05	Large, Std. Stem	38	78.0
1188-06	Large, Long Stem	75	78.0

Instrumentation

Townley Angle Guide

Employed for accurate correction of varus/valgus deformity due to femoral condyle deficiency.

2932-00 Angle Guide
2932-10 Angle Guide (Mechanical)

Townley Multi-Purpose Instrument

Functions as a measuring device, positioner, template and marker. Accurately delineates condylar cuts to assure a precise, stable femoral component fit. 3/pkg.

Cat. No.	Size	Replacement Blades
2893-00	Ex. Small	2893-10
2895-00	Small	2895-10
2896-00	Medium	2896-10
2897-00	Large	2897-10
2899-00	Ex. Large	2899-05

Anterior Femoral Chisel

2899-20

Chisel with guide spike extending from the cutting edge which is used when resecting the anterior portion of the femoral condyles.

Femoral Pusher

2898-00 Std.
2898-02 Ex. Large

Replacement Delrin Insert

2898-10 Std.
2898-12 Ex. Large

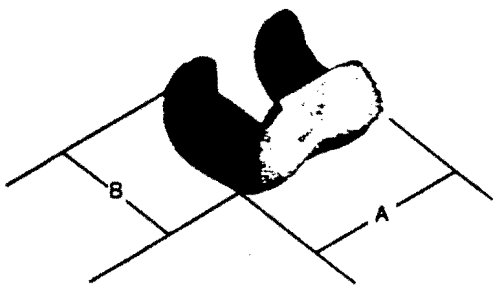
X-ray Overlay

2990-24 Townley Femoral
2990-48 Arizona Tibial Plateau

TOWNLEY TOTAL KNEE SYSTEM

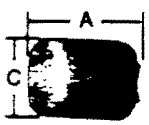
Femoral Component with Porocoat®

The Townley Femoral component is designed to resurface the degenerated articular surfaces of the femur. The system is designed to provide five widths of prosthesis for more accurate anatomical fit. The grooved patello-femoral flange provides for improved tracking and stability of patello-femoral articulation. Orthochrome®, packaged sterile.



Cat. No.	Size	M/L A mm	A/P B mm	Trial No.
1181-00	Ex. Small, Right	62	32	2937-06
1181-07	Ex. Small, Left	62	32	2937-06
1181-01	Small, Right	62	40	2937-10
1181-02	Small, Left	62	40	2937-12
1181-03	Medium, Right	68	44	2937-14
1181-04	Medium, Left	68	44	2937-16
1181-05	Large, Right	74	49	2937-18
1181-06	Large, Left	74	49	2937-20
1181-08	Ex. Large, Right	80	54	2937-22
1181-09	Ex. Large, Left	80	54	2937-24
1181-10	Std., Small	62	40	2930-10
1181-12	Std., Medium	68	44	2930-12
1181-14	Std., Large	74	49	2930-14

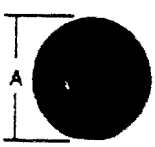
Butterfly Patella Component



The "butterfly" design provides increased contact area to reduce surface stress. It provides more accurate patello-femoral articulation and the three available sizes permit more precise conformance to anatomic requirements. UHMWPe, packaged sterile.

Cat. No.	Description	M/L A mm	Thickness B mm	Height C mm	Trial No.
1181-40	Small	34	7	22	2957-10
1181-41	Medium	37	9	24	2957-11
1181-42	Large	39	10	25	2957-12

Universal Patella Component



Spherical design allows ease of insertion. This component is compatible with all Townley Anatomical Femoral Components. UHMWPe, packaged sterile.

Cat. No.	Description	M/L A mm	Thickness B mm	Trial No.
1181-44	Universal	35	9	2934-00

NOTE: The universal patella and Townley patella must only be used with a total knee prosthesis with a patellar flange. The universal patella and the Townley patella must not be allowed to articulate against bone or cartilage.

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

SYNATOMIC® TOTAL KNEE SYSTEM WITH POROCOAT® Cont'd.

Instrumentation

Contained Tibial Plateau Template

2898-40 Small, Medium
2898-41 Large, Ex. Large

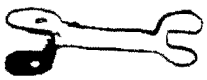
Contained Tibial Plateau Impactor

2898-58

Contained Tibial Plateau Insert Replacement

2898-59

Standard Tibial Plateau Template

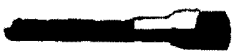


2898-30 Small, Medium
2898-31 Large, Ex. Large

Standard Tibial Plateau Punch

2898-32

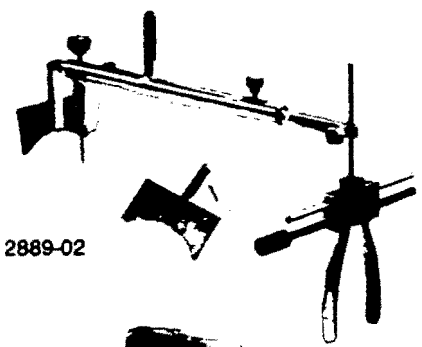
Standard Tibial Plateau Impactor



2898-33

Standard Tibial Plateau Insert Replacement

2898-34



2889-02

2889-04

2889-06

2889-08

2889-10

2889-12

2889-14

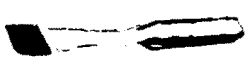
2889-16

2889-18

2889-20

2889-22

2889-24



2889-26

FIRST™ Instrumentation for Total Knee Arthroplasty

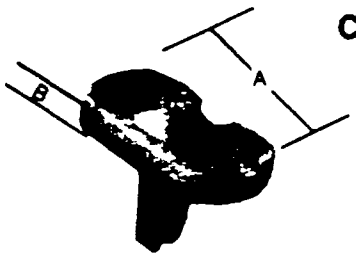
The FIRST System takes full advantage of the surgeon's judgment in evaluating the complex three-dimensional problems associated with knee mechanics, one dimension at a time, while holding the limb in anatomic alignment with stable instruments. The system consists of six instruments numbered according to the order in which they are used, and a special rasp.

Cat. No.	Description
2889-02	Tibial Cutting Guide (right, left)
2889-04	Tenser
2889-06	Distal Femoral Cutting Guide
2889-08	A/P Positioner
2889-10	A/P Cutting Guide, Small
2889-12	A/P Cutting Guide, Medium
2889-14	A/P Cutting Guide, Large
2889-16	A/P Cutting Guide, Ex. Large
2889-18	Beveling Guide, Small
2889-20	Beveling Guide, Medium
2889-22	Beveling Guide, Large
2889-24	Beveling Guide, Ex. Large
2889-26	Rasp

X-ray Overlay

2990-94

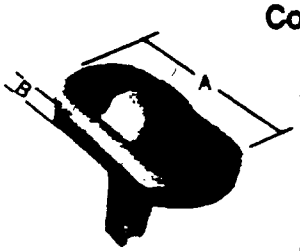
SYNATOMIC® TOTAL KNEE SYSTEM WITH POROCOAT® Cont'd.



Contained Tibial Plateau, Cruciate Retention

Enables the surgeon to retain the posterior cruciate ligament when indicated and incorporate the use of a metal stem for added stability. The polyethylene is supported by metal to minimize potential cold flow. UHMWPe encased by Orthochrome®, Porocoat®, packaged sterile.

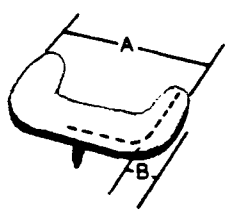
Cat. No.	Size	M/L A mm	Effective Thickness B mm	Trial Tray	Trial Bearing
1189-40	Small	68	8.5	2939-50	2939-52
1189-42	Small	68	11.5	2939-50	2939-53
1189-44	Small	68	15.0	2939-50	2939-54
1189-46	Small	68	18.0	2939-50	2939-55
1189-50	Medium	75	8.5	2939-56	2939-58
1189-52	Medium	75	11.5	2939-56	2939-59
1189-54	Medium	75	15.0	2939-56	2939-60
1189-56	Medium	75	18.0	2939-56	2939-61
1189-60	Large	81	8.5	2939-62	2939-64
1189-62	Large	81	11.5	2939-62	2939-65
1189-66	Large	81	15.0	2939-62	2939-66
1189-66	Large	81	18.0	2939-62	2939-67
1189-64	Ex. Large	87	8.5	2939-68	2939-70
1189-67	Ex. Large	87	11.5	2939-68	2939-71
1189-69	Ex. Large	87	15.0	2939-68	2939-72
1189-71	Ex. Large	87	18.0	2939-68	2939-73



Contained Tibial Plateau, Noncruciate Retention

Totally resurfaces the tibial plateau incorporating a metal stem for patients needing extra stability. The polyethylene is supported by metal to minimize potential cold flow. UHMWPe encased by Orthochrome®, Porocoat®, packaged sterile.

Cat. No.	Size	M/L A mm	Effective Thickness B mm	Trial Tray	Trial Bearing
1289-10	Small	68	8.5	2939-50	2989-10
1289-12	Small	68	11.5	2939-50	2989-12
1289-14	Small	68	15.0	2939-50	2989-14
1289-16	Small	68	18.0	2939-50	2989-16
1289-20	Medium	75	8.5	2939-56	2989-20
1289-22	Medium	75	11.5	2939-56	2989-22
1289-24	Medium	75	15.0	2939-56	2989-24
1289-26	Medium	75	18.0	2939-56	2989-26
1289-30	Large	81	8.5	2939-62	2989-30
1289-32	Large	81	11.5	2939-62	2989-32
1289-34	Large	81	15.0	2939-62	2989-34
1289-36	Large	81	18.0	2939-62	2989-36
1289-40	Ex. Large	87	8.5	2939-68	2989-40
1289-42	Ex. Large	87	11.5	2939-68	2989-42
1289-44	Ex. Large	87	15.0	2939-68	2989-44
1289-46	Ex. Large	87	18.0	2939-68	2989-46



Standard Tibial Plateau

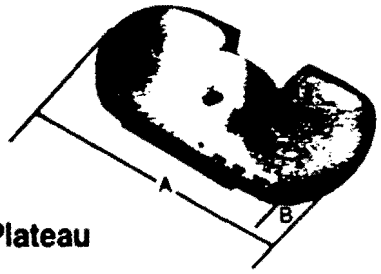
Designed to enhance fixation and retain the cruciate ligaments with a minimal amount of bone resection. Metal undersurface reduces the possibility of polyethylene deflection in extreme loading conditions. Molded UHMWPe encapsulated in Orthochrome®, Porocoat®, packaged sterile.

Cat. No.	Size	M/L A mm	Effective Thickness B mm	Trial No.
1189-70	Small	60	6.5	2939-75
1189-76	Medium	67	6.5	2939-81
1189-86	Large	72	6.5	2939-86
1189-93	Ex. Large	78.5	6.5	2939-91
1189-72	Small	60	8.5	2939-78
1189-78	Medium	67	8.5	2939-83
1189-88	Large	72	8.5	2939-87
1189-94	Ex. Large	78.5	8.5	2939-93
1189-74	Small	60	11.5	2939-77
1189-84	Medium	67	11.5	2939-84
1189-91	Large	72	11.5	2939-89
1189-96	Ex. Large	78.5	11.5	2939-94

SYNATOMIC® TOTAL KNEE SYSTEM WITH POROCOAT® Cont'd.

Variable Fit Tibial Plateau

Cat. No.	Description	Trial No.
1188-41	Small	2888-41
1188-43	Medium	2888-43
1188-45	Large	2888-45
1188-47	Ex. Large	2888-47



Variable Fit Tibial Insert

Cat. No.	Size	M/L A mm	Effective Thickness B mm	Trial No.
1188-11	Small	65.5	8	2888-11
1188-25	Small	65.5	10	2888-25
1188-12	Small	65.5	12	2888-12
1188-13	Small	65.5	16	2888-13
1188-14	Small	65.5	20	2888-14
1188-16	Medium	71.5	8	2888-16
1188-26	Medium	71.5	10	2888-26
1188-17	Medium	71.5	12	2888-17
1188-18	Medium	71.5	16	2888-18
1188-19	Medium	71.5	20	2888-19
1188-21	Large	78.0	8	2888-21
1188-27	Large	78.0	10	2888-27
1188-22	Large	78.0	12	2888-22
1188-23	Large	78.0	16	2888-23
1188-24	Large	78.0	20	2888-24
1188-33	Ex. Large	82.0	8	2888-33
1188-34	Ex. Large	82.0	10	2888-34
1188-35	Ex. Large	82.0	12	2888-35
1188-36	Ex. Large	82.0	16	2888-36
1188-37	Ex. Large	82.0	20	2888-37

Variable Fit Clip

1188-30

Variable Fit Pin

1188-32

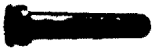
Variable Fit Tibial Drill Guide

2888-52 Small
2888-53 Medium
2888-54 Large
2888-55 Ex. Large

Instrumentation

Variable Fit Tibial Impactor

2888-50



Variable Fit Drill Guide Pin

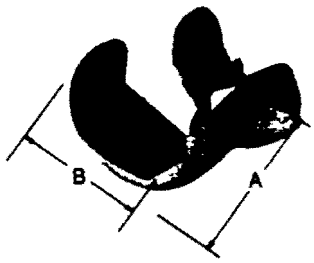
2888-56

X-ray Overlay

2990-96

SYNATOMIC® TOTAL KNEE SYSTEM WITH POROCOAT®

Femoral Component



Cat. No.	Size	M/L A mm	A/P B mm	Trial No.
1189-01	Small, Right	62	36.3	2937-10
1189-02	Small, Left	62	36.3	2937-12
1189-03	Medium, Right	68	42.4	2937-14
1189-04	Medium, Left	68	42.4	2937-16
1189-05	Large, Right	74	47.6	2937-18
1189-06	Large, Left	74	47.6	2937-20
1189-07	Ex. Large, Right	80	52.5	2937-22
1189-08	Ex. Large, Left	80	52.5	2937-24

Packaged sterile.

Dome Patella

Spherical design allows ease of insertion. This component is metal-backed and porous-coated to enhance fixation. The four fixation pins provide stability and reduce the possibility of stress risers. UHMWPe, packaged sterile.

Cat. No.	Description	M/L A mm	Thickness B mm
1189-65	Dome Patella	34	10

Instrumentation

Femoral Impactor

2898-20

Femoral Insert Replacement

2898-21

Patellar Clamp

2898-25

Patellar Template/Trial

2989-65

X-ray Overlay

2990-94

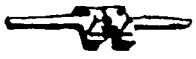
Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

DePuy

NEW JERSEY LCS® TOTAL KNEE SYSTEM WITH POROCOAT® Cont'd.

Template

Std./Std.+ Cat. No.	Large/ Large+ Cat. No.	Description
2277-16	2277-40	Cruciate Retaining Tibial
2277-48	2277-49	Posterior Cruciate Retaining Tibial
2277-17	2277-41	Rotating Platform Tibial
2277-15	2277-15	Patellar
2277-51	2277-51	Femoral



Femoral Resection Guide

2277-26 Std.
2277-50 Large

Oblique Osteotomy Guide

2277-13 Std.
2277-37 Large

Osteotomy Position Adapter

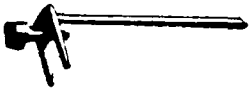
2277-14 Std.
2277-38 Large

Femoral Recessing Guide

2277-22 Std.
2277-46 Large

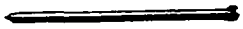
X-ray Overlay

2990-12



Alignment Hole Guide Yoke

2277-67



Femoral Alignment Rod

2277-74

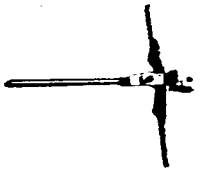
Femoral Guide Positioner

2277-23

Instrumentation

Tibial Spacer

2277-75 12.5mm
2277-65 15.0mm
2277-76 17.5mm
2277-66 20.0mm



Tibial Resection Guide

2277-61

Extension/Tension Femoral Guide

2277-63

Femoral Resection Adapter

2277-69

Tibial Hole Punch

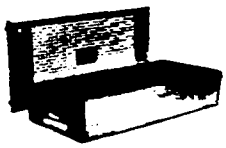
2277-68

Femoral Impactor

2277-70

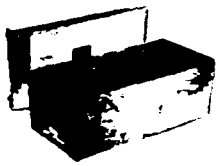
Patellar Clamp

2277-64



Sterilization Case

2601-01 4" Trial Case
2602-01 Upper Trial Tray
2602-02 Lower Trial Tray
2602-06 Revision Trial Tray

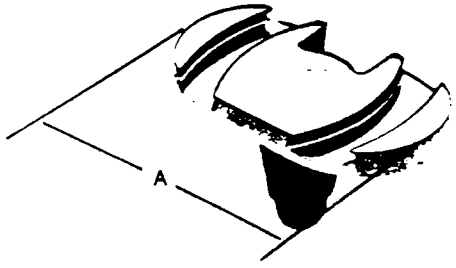


Sterilization Case

2601-02 7" Trial Case
2602-03 Upper Instrument Tray
2602-04 Middle Instrument Tray
2602-05 Lower Tray

NEW JERSEY LCS® TOTAL KNEE SYSTEM WITH POROCOAT® Cont'd.

Posterior Cruciate Retaining Tibial Plateau

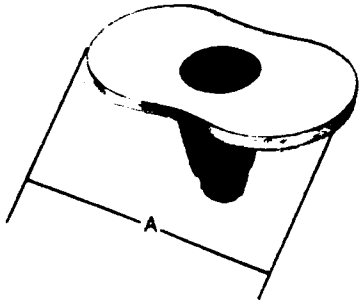


Cat. No.	Size	M/L A mm	Trial No.
1178-16	Std.	65	2278-16
1178-17	Std.+	70	2278-17
1178-18	Large	75	2278-18
1178-19	Large+	80	2278-19

Rotating Platform Bearing

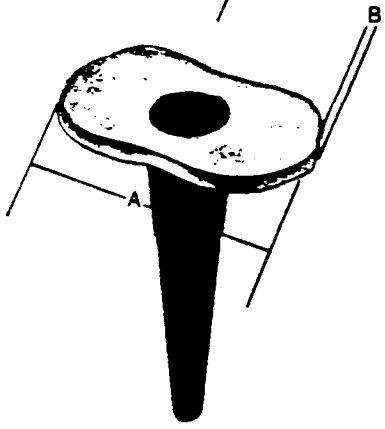
Designed for non-cruciate retention or revision arthroplasty. Packaged sterile.

Standard Bearing Cat. No.	Thickness mm	Trial No.
1178-46	10.0	2278-46
1178-47	12.5	2278-47
1178-48	15.0	2278-48
1178-49	17.5	2278-49
1178-50	20.0	2278-50



Large Bearing Cat. No.	Thickness A mm	Trial No.
1178-56	10.0	2278-56
1178-57	12.5	2278-57
1178-58	15.0	2278-58
1178-59	17.5	2278-59
1178-60	20.0	2278-60

Rotating Platform Tibial Plateau



Standard Implant Cat. No.	Size	M/L A mm	Trial No.
1179-37	Std.	65	2278-37
1179-38	Std.+	70	2278-38
1179-39	Large	75	2278-39
1179-40	Large+	80	2278-40

Revision Implant Cat. No.	M/L A mm	Thickness B mm	Trial No.
1179-91	65	5	2278-91
1179-96	65	15	2278-96
1179-93	75	5	2278-93
1179-94	75	15	2278-94

Instrumentation

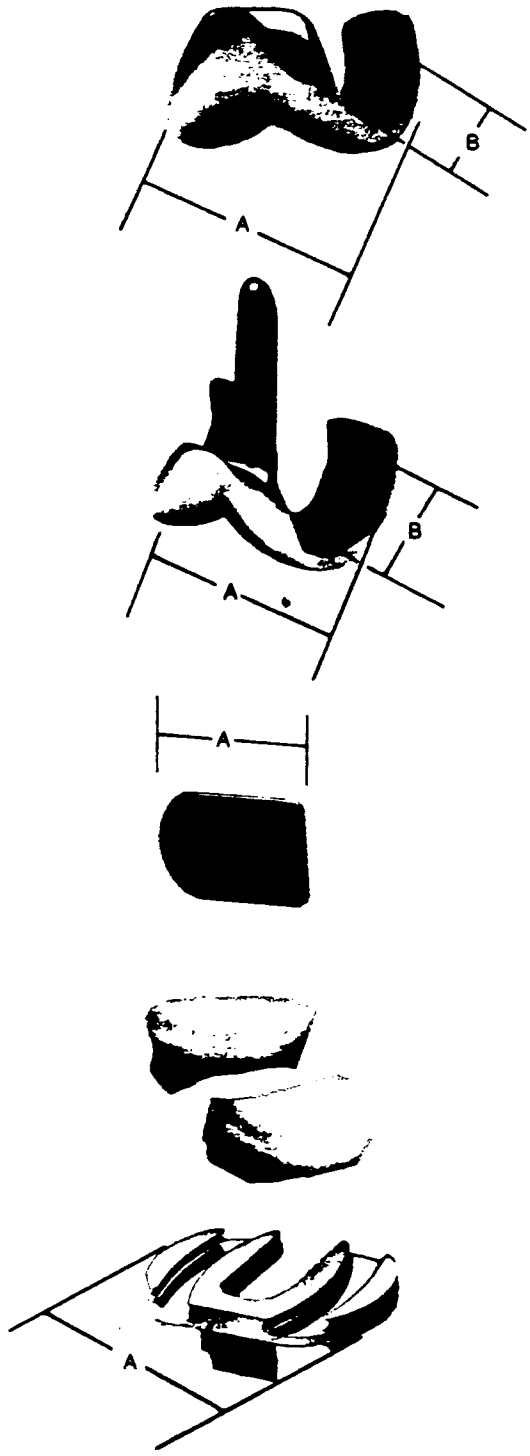
Spacer Block

2277-71
2277-72

Distal Femoral Guide

2277-60

NEW JERSEY LCS® TOTAL KNEE SYSTEM WITH POROCOAT®



Femoral Component

Used for primary or revision surgery. Packaged sterile.

Standard Implant Cat. No.	Size	M/L A mm	A/P B mm	Trial No.
1179-03	Std., Right	65	46	2278-03
1179-04	Std., Left	65	46	2278-04
1179-07	Large, Right	75	53	2278-07
1179-08	Large, Left	75	53	2278-08

Revision Implant Cat. No.	Size	M/L A mm	A/P B mm	Trial No.
1179-86	Std., Right	65	46	2278-86
1179-85	Std., Left	65	46	2278-85
1179-89	Large, Right	75	53	2278-89
1179-88	Large, Left	75	53	2278-88

Rotating Patella

The metal-backed rotating patella congruently matches the anterior flange of the femoral component, allowing for axial rotation. Packaged sterile.

Cat. No.	Size	M/L A mm	Trial No.
1179-67	Std.	36	2278-67
1179-69	Large	41	2278-69

Meniscal Bearing

Interchangeable bearings facilitate soft tissue balancing. Packaged sterile.

Std. Bearing Cat. No.	Trial No.	Large Bearing Cat. No.	Trial No.	Thickness mm
1178-20	2278-20	1178-28	2278-28	10.0
1178-21	2278-21	1178-29	2278-29	12.5
1178-22	2278-22	1178-30	2278-30	15.0
1178-23	2278-23	1178-31	2278-31	17.5

Cruciate Retaining Tibial Plateau

Cat. No.	Size	M/L A mm	Trial No.
1179-12	Std.	65	2278-12
1179-13	Std.+	70	2278-13
1179-14	Large	75	2278-14
1179-15	Large+	80	2278-15

Packaged sterile.

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents.

Howmedica, Inc.
Orthopaedics Division
359 Veterans Blvd . Rutherford. N J 07070

TOTAL CONDYLAR KNEE, LARGE

CATALOG NO. 6436-0

15% OVERSIZE TO ALLOW FOR X-RAY MAGNIFICATION

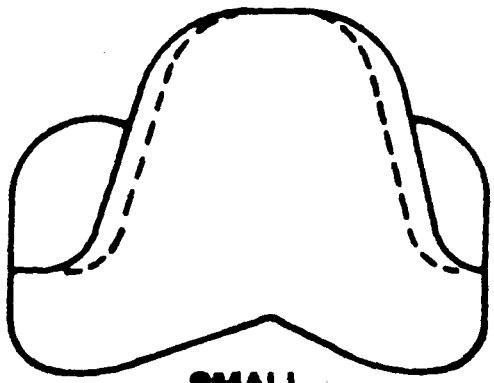
(mirror image is the result of the original available)

[illegible] Femoral Configuration Template (left side)
Approximately 5% oversize or 105% of actual size

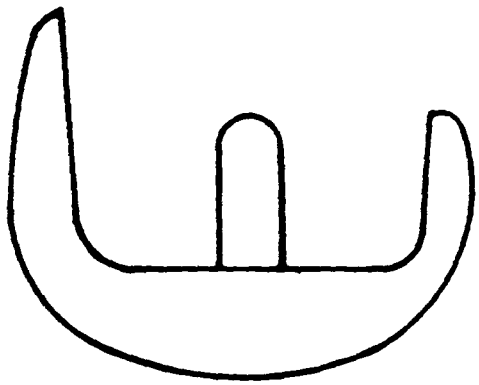
This template is for radiographic estimation only. Actual size and configuration should be determined by use of the trial prosthesis during surgery.

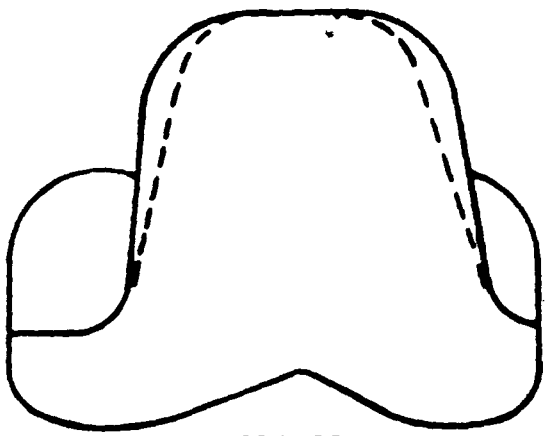
STANDARD
12-3370 Small (58 mm)
12-3374 Medium (64 mm)
12-3378 Large (70 mm)

FLAT-TOP
12-3381 Small (58 mm)
12-3383 Medium (64 mm)
12-3385 Large (70 mm)

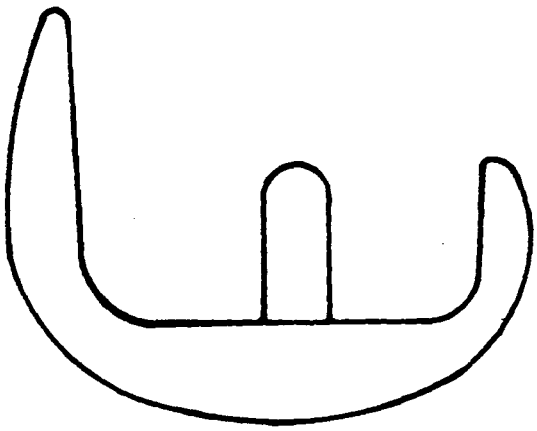


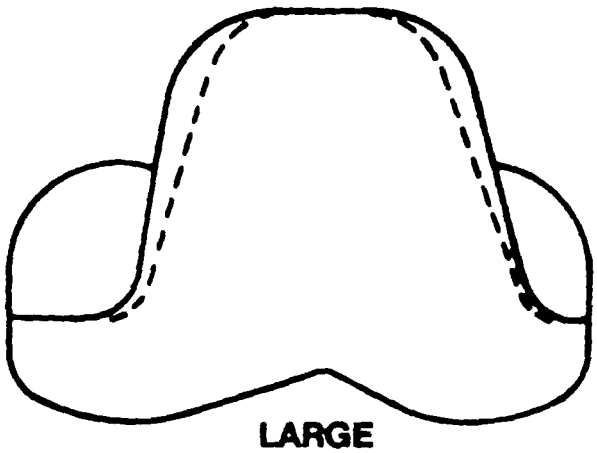
SMALL



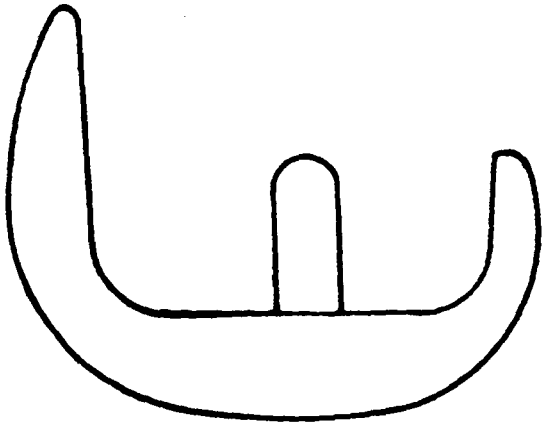


MEDIUM

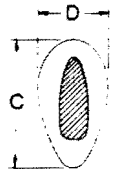




LARGE



THOMPSON HEMI-ARTHROPLASTY HIP SYSTEM



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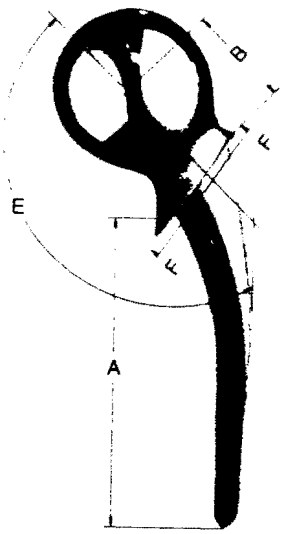


Femoral Component

Orthochrome®, 104mm stem length (A), 45mm seat height (C), 27mm seat width (D), 135° neck angle (E), packaged sterile.

Cat. No.	Head Size mm	Neck Length B mm
1008-08	38	1 1/32 - 26
1008-10	41	1 1/32 - 26
1008-12	43	1 5/32 - 29
1008-14	44	1 5/32 - 29
1008-16	46	1 7/32 - 31
1008-18	48	1 7/32 - 31
1008-20	49	1 9/16 - 33
1008-22	51	1 9/16 - 33
1008-23	52	1 13/32 - 36
1008-24	54	1 13/32 - 36
1008-26	55	1 13/32 - 35
1008-27	57	1 13/32 - 35
1008-28	60	1 15/32 - 37
1008-30	63	1 1/2 - 38

Recommended Rasp: 2091-00

Instrumentation

Corkscrew
2125-00

Driver for Hip Prosthesis

2001-10 Driver with Delrin Insert
2001-12 Replacement Delrin Insert

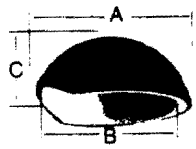
Thompson Rasp
2091-00

Prostheses Measuring Instrument

2006-00 Inches
2006-10 Millimeters

Metal Backed Acetabular Cup

UHMWPe insert, titanium shell, packaged sterile.

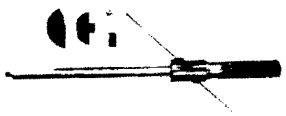


Cat. No.	O.D. A mm	I.D. B mm	Cup Height C mm	Trial No.
1044-41	52	41	22	2044-41
1044-43	54	43	23	2044-43
1044-45	56	45	24	2044-45
1044-47	59	47	25	2044-47
1044-49	62	49	26	2044-49
1044-51	62	51	28	2044-51

Instrumentation

Femoral Trial Cup/Osteotome Assembly

Cat. No.	Description
2223-26	Complete Set Includes:
2223-29	Osteotome Stem, Narrow
2223-28	Handle
2223-41	Femoral Trial Cup, 41mm
2223-43	Femoral Trial Cup, 43mm
2223-45	Femoral Trial Cup, 45mm
2223-47	Femoral Trial Cup, 47mm
2223-49	Femoral Trial Cup, 49mm
2223-51	Femoral Trial Cup, 51mm
2223-54	Femoral Trial Cup, 54mm



T.A.R.A.™ Acetabular Positioner LP Set

Cat. No.	Description
2223-68	Complete Set Includes:
2220-52	Handle Acetabular Cup Positioner
2220-53	Aimer Only ICH Acetabular Cup Positioner
2220-66	Handle Cup Pusher
2223-69	T.A.R.A.™ Acetabular Positioner Ball 41 LP
2223-70	T.A.R.A.™ Acetabular Positioner Ball 43 LP
2223-71	T.A.R.A.™ Acetabular Positioner Ball 45 LP
2223-72	T.A.R.A.™ Acetabular Positioner Ball 47 LP
2223-73	T.A.R.A.™ Acetabular Positioner Ball 49 LP
2223-74	T.A.R.A.™ Acetabular Positioner Ball 51 LP

Townley Punch

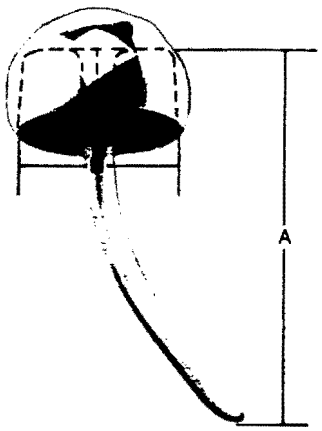
Cat. No.	Diameter mm
2223-60	6.3
2223-61	9.5

Townley Acetabular Cup Pusher

Cat. No.	Diameter mm
2223-62	41-43
2223-63	45-47
2223-65	49-51
2223-67	54

T.A.R.A. TOTAL HIP SYSTEM

Femoral Component with Porocoat*



Cat. No.	Head Diameter mm	Size No.	Trial No.
1044-01	41	1	2223-41
1044-03	43	2	2223-43
1044-05	45	3	2223-45
1044-07	47	4	2223-47
1044-09	49	5	2223-49
1044-11	51	6	2223-51
1044-14	54	7	2223-54

Instrumentation

Femoral Template

Cat. No.	mm
2223-10	41, 43
2223-12	45, 47
2223-14	49, 51
2223-15	54

Alignment Guide and Planer Stem

2223-19

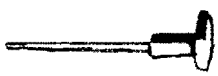
Facing Planer

2223-16

Handle for Alignment Guide and Stem

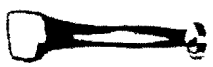
2223-18

Power Planer (2″ Dia.)



2454-18

Driver



2001-10

Drill

Cat. No.	Diameter mm	Length mm
1821-11	8	178

X-ray Overlay

2990-38

Porocoat* is protected by U.S. Patent No. 3,855,638 and foreign patents.

AUSTIN MOORE HEMI-ARTHROPLASTY HIP SYSTEM Cont'd.

Extension for Universal Driver/Extractor

2046-36

Adapter

2046-22

Rasp for Moore Prosthesis

Cat. No.	Description
2002-00	Standard Stem
2002-10	Narrow Stem
2003-10	Rasp 6½"
2003-12	Rasp 8"
2003-14	Rasp 10"
2003-16	Rasp 12"

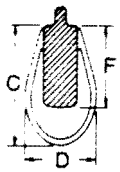
Murphy Bone Skid

2004-00

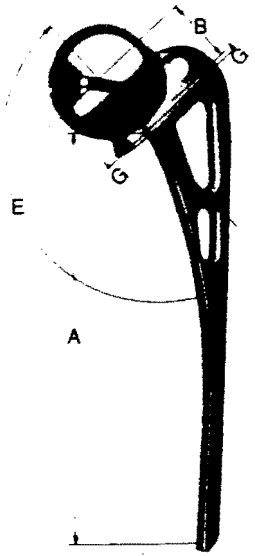
Stainless steel, 30mm large blade width, 19mm small blade width, 336mm length.

DePuy

AUSTIN MOORE HEMI-ARTHROPLASTY HIP SYSTEM Cont'd.



Section GG

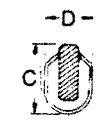


Narrow Stem Femoral Component

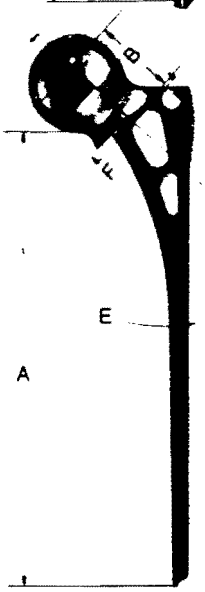
Orthochrome®, 41mm seat height (C), 24mm seat width (D), 135° neck angle (E), 27mm M/L stem width (F), packaged sterile.

Cat. No.	Head Size mm	Stem Length A mm	Neck Length B mm
1025-08	38	140	21
1025-10	41	140	23
1025-12	43	140	23
1025-14	44	140	24
1025-16	46	152	25
1025-18	48	152	26
1025-20	49	152	26
1025-22	51	152	27

Recommended Rasp: 2002-10



Section FF



Long Straight Stem Femoral Component

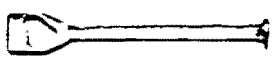
Orthochrome®, 203mm stem length (A), 41mm seat height (C), 27mm seat width (D), 135° neck angle (E).

Cat. No.	Head Size mm	Neck Length B mm
1001-10	41	25
1001-12	43	26
1001-14	44	27
1001-16	46	28
1001-18	48	28
1001-20	49	29
1001-22	51	30
1001-24	54	32

Recommended Rasp: 2003-12

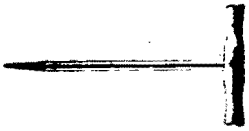
A standard Austin Moore hip instrument set should be used when implanting this hip.

Instrumentation



Mortising Chisel

2090-00



Corkscrew

2125-00

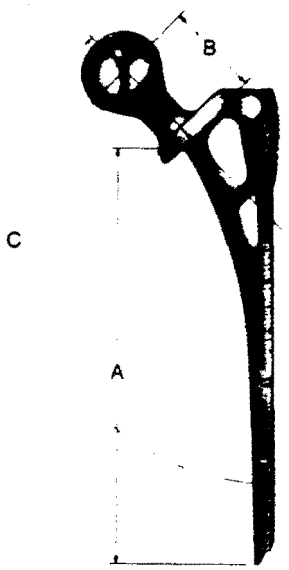
Driver for Hip Prosthesis

2001-10 Driver with Delrin Insert
2001-12 Replacement with Delrin Insert

Universal Driver/Extractor

2046-10

AUSTIN MOORE TYPE TOTAL HIP



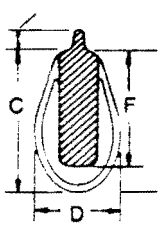
Moore Femoral Component

Orthochrome®, 152mm stem length (A), 135° neck angle (C).

Cat. No.	Head Size mm	Neck Length B mm
1003-21	32	34
1003-22	32	40
1003-24	22	34
1003-25	22	40

Recommended Rasp 2003-10

AUSTIN MOORE HEMI-ARTHROPLASTY HIP SYSTEM



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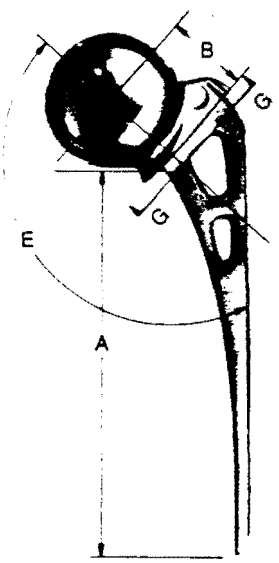

Femoral Component

Orthochrome®, 40mm seat height (C), 135° neck angle (E), 39mm M/L stem width (F), packaged sterile.

Cat. No.	Head Size mm	Stem Length A mm	Neck Length B mm	Seat Width D mm
1000-08	38	124	21	24
1000-10	41	124	23	26
1000-12	43	124	23	26
1000-14	44	130	24	26
1000-16	46	130	25	26
1000-18	48	140	26	26
1000-20	49	140	26	26
1000-22	51	148	27	26
1000-23	52	159	28	26
1000-24	54	159	29	26
1000-26	55	159	29	26
1000-28	57	159	30	26
1000-30	60	159	32	26
1000-32	63	159	34	26

Recommended Rasp: 2002-00

HUMAN SURGICAL IMPLANT STRUCTURAL DEVICES OF CARBON FIBER REINFORCED ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE

Robert D. Ainsworth
Gene M. Farling
Denes I. Bardos

Zimmer.USA
Warsaw, Indiana

(The quality of pages 92-108 is the result of a deficit in good-quality originals

INTRODUCTION

One of the more dramatic developments in orthopedic surgery in recent history has been the total joint prosthesis, which is frequently used to replace a diseased or traumatized joint. The type of prosthesis most often used today consists of an ultra-high molecular weight polyethylene (UHMWPE) component articulating against the polished surface of a metallic component. Widespread use of such devices in the human hip began in the 1960's, however, these were generally restricted to elderly patients because the longevity of these devices were unknown(1). Since the early outstanding success of the total hip prostheses, this concept has been applied to other joints, particularly the knee, and the use of total joint prostheses in younger patients with longer life expectancies has increased.

The requirements of these materials when used in knee prostheses have proven to be more severe than in hip prostheses, and recently it is becoming evident that the creep and wear properties of UHMWPE may limit the longevity of knee prostheses(2,3). While adequate wear performance of UHMWPE in hip prostheses is now proven for over 10 years(1), the wear of this material after the 30 or 40 years of use, which may be required by younger patients, is unknown. These observations have prompted the development of a carbon fiber reinforced UHMWPE material (C-PE), with improved creep and wear properties, for application to these devices. In this paper, the requirements of materials in total joint prostheses are briefly reviewed, C-PE is described, and results of the laboratory evaluation of C-PE are presented.

TOTAL JOINT PROSTHESES

The use of the present concept and materials in total joint surgery was first developed by Charnley(1) in the early 1960's by the introduction of a total hip prosthesis. The human hip is essentially a ball-in-socket joint, and replacement prostheses are of the same configuration, with the ball being an alloy (usually 316 SS or Co-Cr-Mo) and the socket being a polymer (Figure 1). Initially the polymer of choice was polytetraflouroethylene. Although PTFE has a low coefficient of friction, relatively large amounts of stringy PTFE wear debris were produced by these early prostheses(4). This debris caused extreme reactions by the tissue surrounding the implanted prosthesis, which was attributed to the debris quantity and shape rather than to the material(4). Approximately two years later, polyethylene was substituted for PTFE, and has since been used successfully in a number of prosthesis designs which incorporate the ball-in-socket principle. Presently, Hercules Hifax 1900® is compression molded, or extruded and machined, into finished prosthesis components, or RCH 1000® is machined into finished parts.

After the success with hip prostheses, knee replacement surgery began to expand in the late 1960's. Unlike the hip

joint, the knee is not intrinsically stable, instead, stability is provided primarily by the ligaments surrounding the joint. A number of knee prosthesis designs are currently used (Figure 2) which offer varying degrees of stability, and the use of a particular prosthesis design often depends upon the condition of the ligamentous structures of the patient's knee. Different stress distributions and articulating motions arise from these various prostheses designs, and requirements of the materials used in hip and knee prostheses differ as a result.

The environment in which these devices operate result from a number of variables, including the loading conditions and the relative motions between the components. Figure 3 illustrates typical curves of loads transmitted across the normal hip and knee joint during walking(5). During other activities as walking down stairs, loads at these joints can be significantly greater(5). These loads and the prosthesis design determine stress distributions in UHMWPE components of the prostheses. Contact stresses are minimized in conforming designs, like the hip prosthesis, and somewhat greater in the nonconforming total knee prostheses. Relative motions between prosthesis components are also influenced by prosthesis design. The ball-in-socket design of hip prostheses permits only sliding movements, whereas in nonconforming knee prostheses, the center of rotation of the metal component moves with respect to the surface of the UHMWPE tibial component, permitting both sliding and rolling movement to occur.

Performance criteria of UHMWPE components of total joint prostheses include resistance to creep and wear, and these are affected by prosthesis design. In the intrinsically stable hip prostheses, creep has not caused problems, and although some wear has been measured and polyethylene debris does accumulate in the area of the joint(6), wear has been considered acceptable after over 10 years of use(7). Knee prostheses, however, have shown significantly greater creep and wear of the UHMWPE components during shorter periods of use. Examples of such components which had been in vivo less than two years are illustrated in Figure 4. These differences between total hip and knee prostheses have been attributed to many factors, including the lack of stability and greater stresses of the knee prostheses(3).

These observations indicate that the longevity of presently used total knee prostheses is limited by the use of UHMW polyethylene. Replacing this with a material with improved creep and wear resistance would increase this longevity. In total hip prostheses, less wear debris would be produced, improving the likelihood for successful use in younger patients.

C-PE CHARACTERIZATION

To improve these properties, a composite of polyethylene reinforced with carbon fibers has been developed. The UHMWPE matrix of this composite is Hercules Hifax 1900®, having an

average limiting viscosity number of 17 dl/g. This is reinforced with from 10 to 20% by weight of high tensile strength, high modulus graphite fibers. The cross-sectional shape of the fibers has major and minor diamters of approximately 15 and 6 micrometers respectively.

These components (Figure 5) are compression molded directly into the final prosthesis shape, examples of which are illustrated in Figure 6. The mean fiber length in the composite is approximately 0.75 mm, and the fiber distribution and orientation within the matrix is random. The nature of the matrix fiber interface is illustrated in Figure 7, in which the matrix has been etched away from the fiber.

TESTING AND EVALUATION

Various tests of molded C-PE specimens were performed and the results compared to those obtained from similar tests of UHMWPE specimens. In addition to standard mechanical testing, creep and wear properties were also evaluated.

Mechanical Properties

Three test series were conducted to compare the tensile, compressive, and bending properties of UHMWPE and C-PE with 10, 15, and 20 weight % reinforcement. Tests were performed with an Instron Universal Testing Machine, and the procedure and results are summarized in Table I. Significant increase in these properties are evident. While the specific value of these properties to prosthesis performance is not clear, these results indicate that the matrix-fiber bond is sufficient such that strengthening of the UHMWPE matrix occurs.

Creep Properties

Creep resistance influences the performance of total knee prostheses, and the testing summarized in Table II indicates the resistance to creep of C-PE as compared to UHMWPE. The tests were conducted according to ASTM D621. Specimens were loaded for 24 hours, and the deformation percent after 90 minutes relaxation was determined. Under these testing conditions, C-PE was significantly more resistant to creep than UHMWPE, particularly with the higher percentages of reinforcement.

Wear Testing

In order to provide wear testing results that can be related to the prosthesis in use performance, testing under conditions similar to those which occur *in vivo* is necessary. The majority of the wear testing of C-PE was conducted using a hip simulator. This device provides a flexion-extension motion at 40 cycles per minute, and a loading curve similar to Figure 3, with maximum loads of 500 pounds. Tests were run in distilled water, and approximately every 200,000 cycles, the wear debris was filtered from the water, desicated, and weighed, enabling wear rates to be determined. T-28 type total hip prostheses were used in these tests, and the performance of various C-PE

acetabular cups was compared to standard UHMWPE cups.

The acetabular cup prosthesis material and corresponding wear rates are presented in Table III, and indicate that significantly lower wear rates are provided by C-PE than by UHMWPE. Figure 8 illustrates representative wear debris from a C-PE cup tested in the hip simulator. The debris ranges in size from fine graphite powder to flakes of a polyethylene-graphite powder of similar size and shape to debris from a standard UHMWPE acetabular cup prosthesis. Very few carbon fibrous shapes are seen in the wear debris. Because the debris size and shape is similar to that produced from standard cups, and since a smaller volume of debris is produced, the tolerance to C-PE wear debris is expected to be similar to, if not better than, UHMWPE debris.

DISCUSSION

An accepted method of improving material properties is by reinforcement with a second material of higher strength. An important aspect of composite materials is that there be a sufficient interfacial bond so that reinforcement results. It is likely that the bond between the carbon fibers and UHMWPE is primarily mechanical, and the apparent wetability of the fibers by the matrix illustrated in Figure 7, and the improvement in mechanical properties indicate that significant reinforcement of the UHMWPE is obtained.

The concept of this material in orthopedic applications is not new. Sclippa and Piekarski(8) described carbon fiber reinforced HDPE, and Tetik, Galante, and Rostoker(9) investigated carbon powder filled UHMWPE. Sclippa and Piekarski reported improvements for their material in a number of mechanical properties, including creep resistance, however, wear resistance was similar to plain HDPE. Their wear tests were conducted in a sand slurry medium, and the test methods used is the likely reason for the differences between the wear properties reported for their composite and C-PE. The composite discussed by Tetik, et. al., was graphite powder in a matrix of UHMWPE, and while improved short-term wear properties were found, upon extended wear testing, a breakdown of the material was found(10). The mechanical bond of the powder to the matrix, and the differences between reinforcement properties of powder and fibers, likely contributed to differences between this composite and C-PE. The longest term hip simulator testing on C-PE has been approximately 4 million cycles (1660 hours at 40 cycles per minute), and no indication of material breakdown was evident.

The results of testing reported above encourage the application of C-PE to total joint prostheses. While there are many potential causes of prosthesis failure in addition to creep and wear of UHMWPE component, use of C-PE should reduce the likelihood of prosthesis failures contributed to by these mechanisms.

REFERENCES

1. "A Conversation with John Charnley, F.R.C.S."; Orthopaedic Review; Vol. II No. 4, 1973, p. 51.

2. Reckling, Asher, Mantz, Helton; "Performance Analysis of an ex vivo Geometric Total Knee Prostheses; J.B.J.S., Vol. 57-A, Jan. 1975, pp 109-112.

3. Trent, P.S. and Walker, P.S.; "Wear and Conformity in Total Knee Replacement"; Wear, 36(1976), pp 175-187.

4. Leidholt, J.D., Gorman, H.A.; "Teflon Hip Prostheses in Dogs"; J.B.J.S. 47A, 1965, p. 1414.

5. Paul, J.P., "Forces Transmitted by Joints in the Human Body"; Proc. Inst. of Mech. Engr.; Vol. 181, Part 35, 1966-67, pp 8-15.

6. Escalas F., Galante J., Rostoker W., Coogan P.; "Biocompatibility of Materials for Total Joint Replacement"; J. Biomed. Mat. Res.; Vol. 10, pp 179.

7. Charnley J.; "The Wear of Plastic Materials in the Hip Joint"; Plastics in Medicine and Surgery; Plas. and Rubber Inst. Conference, 24-25 Sept., pp 3.1-3.10.

8. Sclippa, E. and Piekarski, K.; "Carbon Fiber Reinforced Polyethylene for Possible Orthopedic Uses"; J. Biomed. Materials Research; Vol. 7, 1973, pp 59-70.

9. Tetik, R.; "Preliminary Evaluation of Polyethylene Graphite as a Material for use in Total Hip Replacement"; Proc. Inst. Med. Chic., 1973, 29.

10. W. Rostoker, J.O. Galante; "Some New Studies of the Wear Behavior of UHMWPE"; J. Biomed. Mat. Res., Vol. 10, March 1976, p 303.

TABLE I: COMPARATIVE MECHANICAL PROPERTY DATA

Property	UHMWPE	C-PE 10%	C-PE 15%	C-PE 20%
[a] Tensile Y.S.(psi)	3,050	3,800	--	--
[b] Compressive Y.S.(psi)	2,150	2,720	2,840	3,200
[c] Flexural Y.S.(psi)	3,030	4,300	4,500	5,620
[c] Tangent E (psi)	145,000	230,000	290,000	385,000

a: average of 5 tests; strain rate 0.2 in/min.; b: ASTM D695 average of 4 tests; specimens were 0.5 inch cubes; c: ASTM D790, 4 point bending, average of 2 tests, L/d ratio: 16 to 1.

TABLE II: COMPARATIVE CREEP DATA[a] OF UHMWPE AND C-PE

Material	Applied Stress(psi)	Deformation % (After 90 min. Relaxation)
UHMWPE	1,000	1.14
C-PE 10%	1,000	0.36
C-PE 15%	1,000	0.35
C-PE 20%	1,000	0.26
UHMWPE	1,500	2.17
C-PE 10%	1,500	0.42
C-PE 15%	1,500	0.32
C-PE 20%	1,500	0.22
UHMWPE	2,000	3.96
C-PE 10%	2,000	0.61
C-PE 15%	2,000	0.55
C-PE 20%	2,000	0.48

a: ASTM D621: specimens were 0.5 inch cubes.

TABLE III: COMPARATIVE HIP SIMULATOR DATA OF UHMWPE AND C-PE

Prosthesis Material	Number of Test Cycles	Wear Rate (gms/cycle)
UHMWPE	3.1×10^6	3.80×10^{-8}
UHMWPE	1.8×10^6	4.78×10^{-8}
UHMWPE	2.2×10^6	2.00×10^{-9}
C-PE 10%	3.5×10^6	3.80×10^{-9}
C-PE 10%	2.7×10^6	4.40×10^{-9}
C-PE 10%	1.8×10^6	4.40×10^{-9}
C-PE 15%	3.5×10^6	5.20×10^{-9}
C-PE 20%	3.5×10^6	4.80×10^{-9}

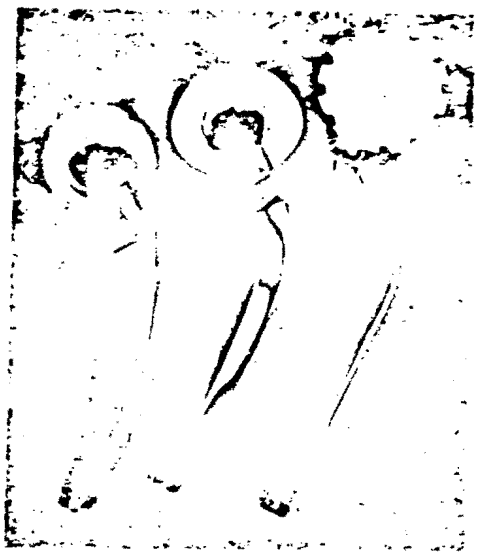

Figure 1: Various total hip prostheses.

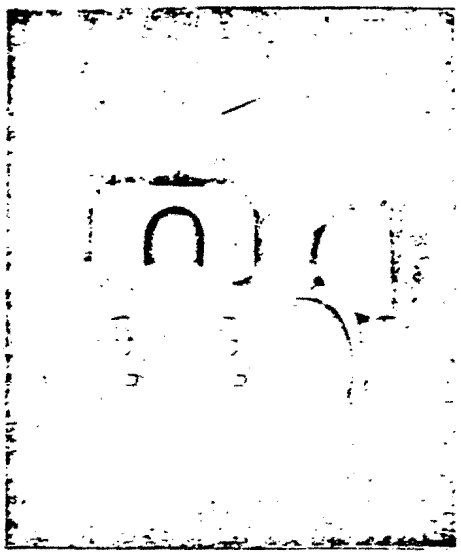

Figure 2: Various total knee prostheses.

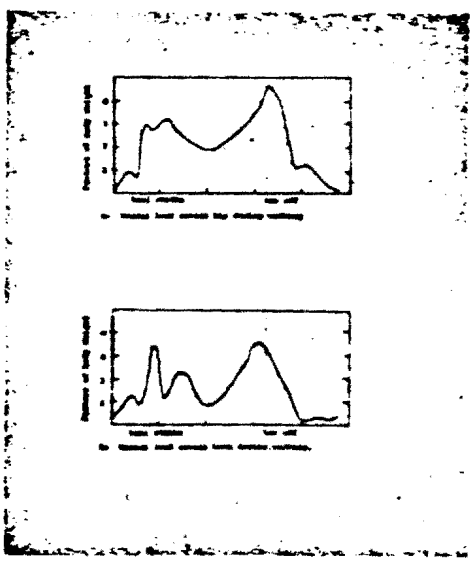

Figure 3: Representative load curves for normal hip and knee during walking.

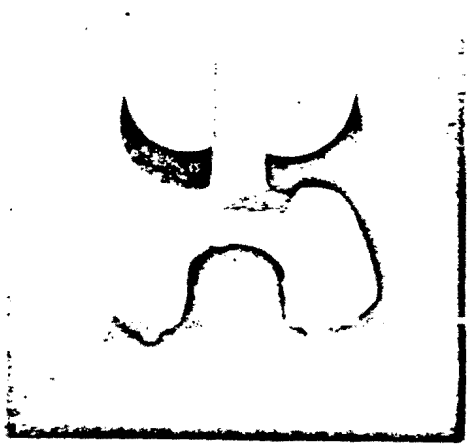

Figure 4: UHMWPE components of knee prostheses which were <u>in vivo</u> less than 2 years.

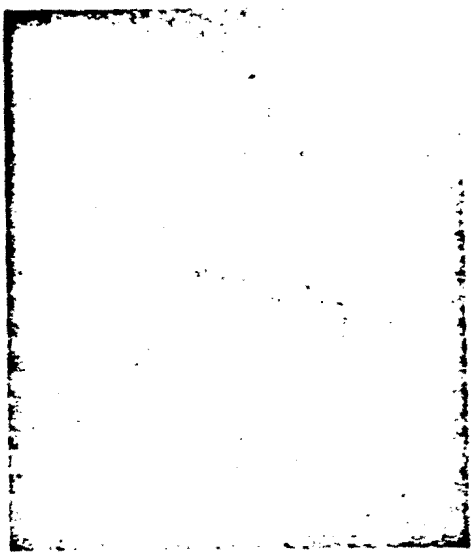

Figure 5: Components of C-PE

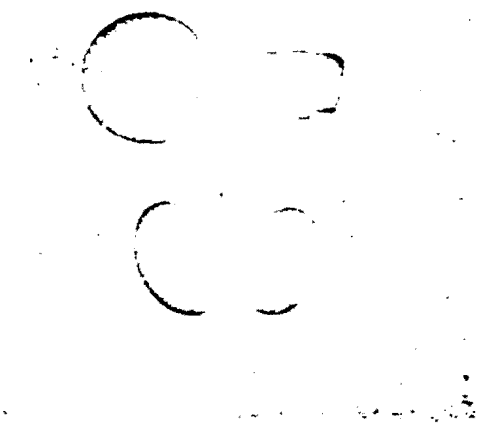

Figure 6: Various compression molded C-PE prostheses.

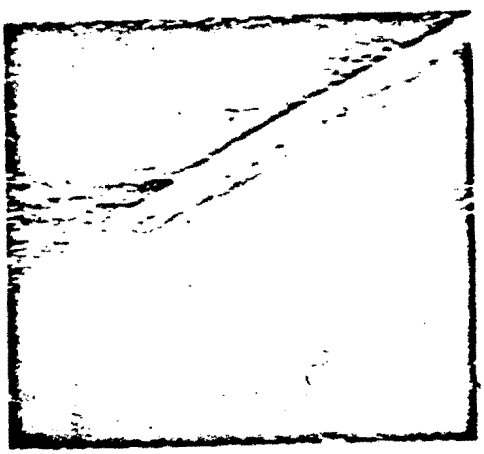

Figure 7: S.E.M. of fiber-matrix interface, UHMWPE etched with O_2 plasma etch.

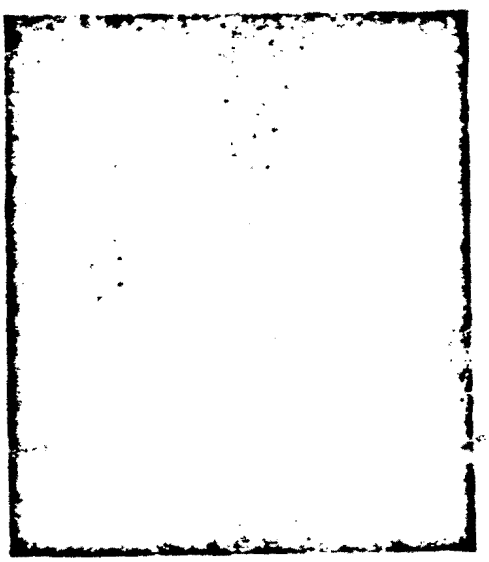

Figure 8: Representative wear debris from C-PE acetabular cup prosthesis.

HUMAN SURGICAL IMPLANT STRUCTURAL DEVICES OF CARBON FIBER REINFORCED ULTRA—HIGH MOLECULAR WEIGHT POLYETHYLENE

Robert D. Ainsworth
Gene M. Farling
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Zimmer. USA
Warsaw, Indiana

INTRODUCTION

One of the more dramatic developments in orthopedic surgery in recent history has been the total joint prosthesis, which is currently used to replace a diseased or traumatized joint. The type of prosthesis most often used today consists of an ultra high molecular weight polyethylene (UHMWPE) component articulating against the polished surface of a metallic component. Widespread use of such devices in the human hip began in the 1960's; however, these were generally restricted to elderly patients because the longevity of these devices were unknown. Since the early outstanding success of the total hip prosthesis concept has been applied to other joints, particularly the knee, and the use of total joint prostheses in younger patients with longer life expectancies has increased.

The requirements of these materials when used in knee prostheses have proven to be more severe than in hip prostheses, and recently it is becoming evident that the creep and wear properties of UHMWPE may limit the longevity of knee prostheses(2,3). While adequate wear performance of UHMWPE in hip prostheses is now proven for over 10 years(1), the wear of this material after the 30 or 40 years of use, which may be required by younger patients, is unknown. These observations have prompted the development of a carbon fiber reinforced UHMWPE material (C-PE), with improved creep and wear properties, for application to these devices. In this paper, the requirements of materials in total joint prostheses are briefly reviewed, C-PE is described, and results of the laboratory evaluation of C-PE are presented.

TOTAL JOINT PROSTHESES

The type of the present concept and materials in total joint surgery was first developed by Charnley(1) in the early 1960's by the use of a total hip prosthesis. The human hip is essentially a ball-in-socket joint, and replacement prostheses are the same configuration, with the ball being an alloy (usually SS or Co-Cr-Mo) and the socket being a polymer (Figure 1). Initially the polymer of choice was polytetrafluoroethylene (PTFE). Although PTFE has a low coefficient of friction, relatively large amounts of stringy PTFE wear debris were produced by these early prostheses(4). This debris caused extreme reactions by the tissue surrounding the implanted prosthesis, which was attributed to the debris quantity and shape rather than to the material(4). Approximately two years later, polyethylene was substituted for PTFE, and has since been used successfully in a number of prosthesis designs which incorporate the ball-in-socket principle. Presently, Hercules Hifax 1900® is compression molded, or extruded and machined, into finished prosthesis components, or Hoechst RCH 1000® is machined into finished parts.

After the success with hip prostheses, knee replacement surgery began to expand in the late 1960's. Unlike the hip joint, the knee is not intrinsically stable, instead, stability is provided primarily by the ligaments surrounding the joint. A number of knee prosthesis designs are currently used (Figure 2) which offer varying degrees of stability, and the use of a particular prosthesis design often depends upon the condition of the ligamentous structures of the patient's knee. Different stress distributions and articulating motions arise from these various prostheses designs, and requirements of the materials used in hip and knee prostheses differ as a result.

The environment in which these devices operate result from a number of variables, including the loading conditions and the relative motions between the components. Figure 3 illustrates typical curves of loads transmitted across the normal hip and knee joint during walking(5). During other activities as walking down stairs, loads at these joints can be significantly greater(5). These loads and the prosthesis design determine stress distributions in UHMWPE components of the prostheses. Contact stresses are minimized in conforming designs, like the hip prosthesis, and somewhat greater in the nonconforming total knee prostheses. Relative motions between prosthesis components are also influenced by prosthesis design. The ball-in-socket design of hip prostheses permits only sliding movements, whereas in nonconforming knee prostheses, the center of rotation of the metal component moves with respect to the surface of the UHMWPE tibial component, permitting both sliding and rolling movement to occur.

Performance criteria of UHMWPE components of total joint prostheses include resistance to creep and wear, and these are affected by prosthesis design. In the intrinsically stable hip prostheses, creep has not caused problems, and although some wear has been measured and polyethylene debris does accumulate in the area of the joint(6), wear has been considered acceptable after over 10 years of use(7). Knee prostheses, however, have shown significantly greater creep and wear of the UHMWPE components during shorter periods of use. Examples of such components which had been in vivo less than two years are illustrated in Figure 4. These differences between total hip and knee prostheses have been attributed to many factors, including the lack of stability and greater stresses of the knee prostheses(3).

These observations indicate that the longevity of presently used total knee prostheses is limited by the use of UHMW polyethylene. Replacing this with a material with improved creep and wear resistance would increase this longevity. In total hip prostheses, such a material would produce less wear debris, improving the likelihood for successful use in younger patients.

C-PE CHARACTERIZATION

To improve these properties, a composite of polyethylene reinforced with carbon fibers has been developed. The UHMWPE matrix of this composite is Hercules Hifax 1900®, having an average limiting viscosity number of 17 dl/g. This is reinforced with from 10 to 20% by weight of high tensile strength, high modulus graphite fibers. The cross-sectional shape of the fibers has major and minor diameters of approximately 15 and 6 micrometers respectively.

These components (Figure 5) are compression molded directly into the final prosthesis shape, examples of which are illustrated in Figure 6. The mean fiber length in the composite is approximately 0.75 mm, and the fiber distribution and orientation within the matrix is random. The nature of the matrix fiber interface is illustrated in Figure 7, in which the matrix has been etched away from the fiber.

TESTING AND EVALUATION

Various tests of molded C-PE specimens were performed and the results compared to those obtained from similar tests of UHMWPE specimens. In addition to standard mechanical testing, creep and wear properties were also evaluated.

Mechanical Properties

Three test series were conducted to compare the tensile, compressive, and bending properties of UHMWPE and C-PE with 10, 15, and 20 weight % reinforcement. Tests were performed with an Instron Universal Testing Machine, and the procedure and results are summarized in Table I. Noticeable increases in all of these properties are evident. While the specific value of these properties to prosthesis performance is not clear, these results indicate that the matrix-fiber bond is sufficient such that strengthening of the UHMWPE matrix occurs.

Creep Properties

Creep resistance influences the performance of total knee prostheses. The testing summarized in Table II indicates the resistance to creep of C-PE in comparison to UHMWPE. The tests were conducted according to ASTM D621. Specimens were loaded for 24 hours, and the deformation percent after 90 minutes relaxation was determined. Under these testing conditions, C-PE was noticeably more resistant to creep than UHMWPE, particularly with the higher percentages of reinforcement.

Wear Testing

In order to provide wear testing results that can be related to the prosthesis in use performance, testing under conditions similar to those which occur in vivo is necessary. The majority of the wear testing of C-PE was conducted using a hip simulator. This device provides a flexion-extension motion at 40 cycles per minute, and a loading curve similar to Figure 3, with maximum loads of 500 pounds. Tests were run in distilled water, and approximately every 200,000 cycles, the wear debris was filtered from the water, desicated, and weighed, enabling wear rates to be determined. T-28 type total hip prostheses were used in these tests, and the performance of various C-PE acetabular cups was compared to standard UHMWPE cups.

The acetabular cup prosthesis material and corresponding wear rates are presented in Table III, and indicate that significantly lower wear rates are provided by C-PE than by UHMWPE. Figure 8 illustrates representative wear debris from a C-PE cup tested in the hip simulator. The debris ranges in size from fine graphite powder to flakes of a polyethylene-graphite powder of similar size and shape to debris from a standard UHMWPE acetabular cup prosthesis. Very few carbon fibrous shapes are seen in the wear debris. Because the debris size and shape is similar to that produced from standard cups, and since a smaller volume of debris is produced, the tolerance to C-PE wear debris is expected to be similar to, if not better than, UHMWPE debris.

DISCUSSION

An accepted method of improving material properties is by reinforcement with a second material of higher strength. An important aspect of composite materials is that there be a sufficient interfacial bond so that reinforcement results. It is likely that the bond between the carbon fibers and UHMWPE is primarily mechanical, and the apparent wetability of the fibers by the matrix illustrated in Figure 7, and the improvement in mechanical properties indicate that significant reinforcement of the UHMWPE is obtained.

The concept of this material in orthopedic applications is not new. Sclippa and Piekarski(8) described carbon fiber reinforced HDPE, and Tetik, Galante, and Rostoker(9) investigated carbon powder filled UHMWPE. Sclippa and Piekarski reported improvements for their material in a number of mechanical properties, including creep resistance, however, wear resistance was similar to plain HDPE. Their wear tests were conducted in a sand slurry medium, and the test methods used is the likely reason for the differences between the wear properties reported for their composite and C-PE. The composite discussed by Tetik, et. al., was graphite powder in a matrix of UHMWPE, and while improved short-term wear properties were found, upon extended wear testing a breakdown of the material was found(10). The mechanical bond of the powder to the matrix, and the differences between reinforcement properties of powder and fibers, likely contributed to differences between this composite and C-PE. The longest term hip simulator testing on C-PE has been approximately 4 million cycles (1660 hours at 40 cycles per minute), and no indication of material breakdown was evident.

The results of testing reported above encourage the application of C-PE to total joint prostheses. While there are many potential causes of prosthesis failure in addition to creep and wear of UHMWPE component, use of C-PE should reduce the likelihood of prosthesis failures contributed to by these mechanisms.

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TABLE I: COMPARATIVE MECHANICAL PROPERTY DATA

Property	UHMWPE	C-PE 10%	C-PE 15%	C-PE 20%
a Tensile Y.S.(psi)	3,050	3,800	--	--
b Compressive Y.S.(psi)	2,150	2,720	2,840	3,200
c Flexural Y.S.(psi)	3,030	4,300	4,500	5,620
c Tangent E (psi)	145,000	230,000	290,000	385,000

a: average of 5 tests; strain rate 0.2 in/min.; b: ASTM D695 average of 4 tests; specimens were 0.5 inch cubes; c: ASTM D790, 4 point bending, average of 2 tests, L/d ratio: 16 to 1.

TABLE II: COMPARATIVE CREEP DATA[a] OF UHMWPE AND C-PE

Material	Applied Stress(psi)	Deformation % (After 90 min. Relaxation)
UHMWPE	1,000	1.14
C-PE 10%	1,000	0.36
C-PE 15%	1,000	0.35
C-PE 20%	1,000	0.26
UHMWPE	1,500	2.17
C-PE 10%	1,500	0.42
C-PE 15%	1,500	0.32
C-PE 20%	1,500	0.22
UHMWPE	2,000	3.96
C-PE 10%	2,000	0.61
C-PE 15%	2,000	0.55
C-PE 20%	2,000	0.48

a: ASTM D621: specimens were 0.5 inch cubes.

TABLE III: COMPARATIVE HIP SIMULATOR DATA OF UHMWPE AND C-PE

Prosthesis Material	Number of Test Cycles	Wear Rate (gms/cycle)
UHMWPE	3.1×10^6	3.80×10^{-8}
UHMWPE	1.8×10^6	4.78×10^{-8}
UHMWPE	2.2×10^6	2.00×10^{-8}
C-PE 10%	3.5×10^6	3.80×10^{-9}
C-PE 10%	2.7×10^6	4.40×10^{-9}
C-PE 10%	1.8×10^6	4.40×10^{-9}
C-PE 15%	3.5×10^6	5.20×10^{-9}
C-PE 20%	3.5×10^6	4.80×10^{-9}

Figure 1: Various total hip prostheses.

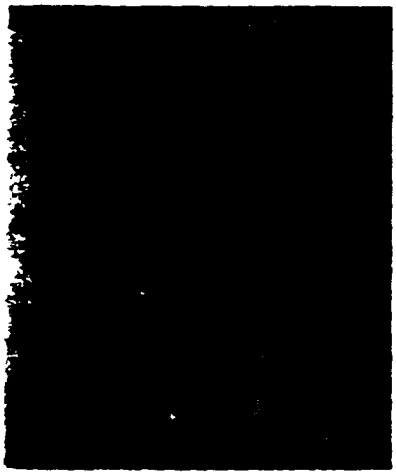

Figure 3: Representative load curves for normal hip and knee during walking.

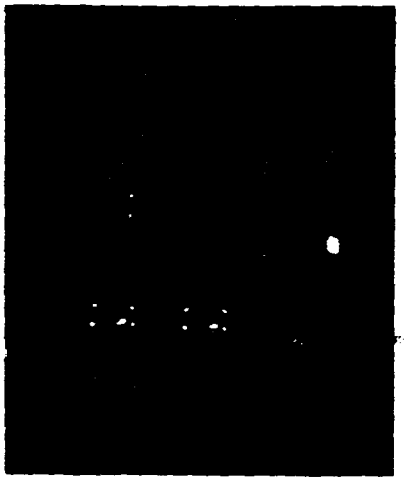

Figure 2: Various total knee prostheses.

Figure 4: [illegible] components of knee prostheses which were in vivo less than 2 years.

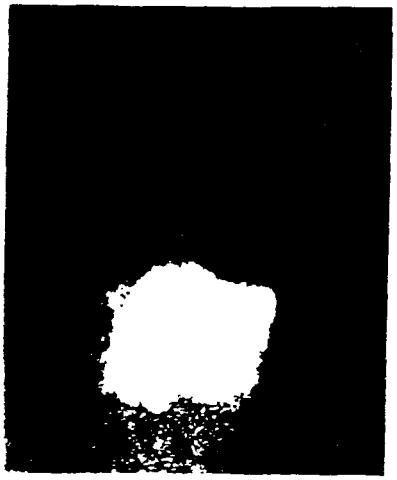

Figure 5: Components of C-PE

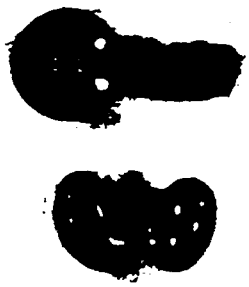

Figure 6: Various compression molded C-PE prostheses.

Figure 7: S.E.M. of fiber-matrix interface, UHMPE etched with O_2 plasma etch.

Figure 8: Representative wear debris from C-PE acetabular cup prosthesis.

specimens were removed from their environmental exposure conditions. Tests of this type were referred to as "current properties". The residual properties were also tested on specimens removed from their environment, after a complete and partial drying at 60°C under vacuum, to drive out the absorbed water.

The current and the residual mechanical properties were measured in order to distinguish between reversible property changes resulting from the plasticizing of the matrix and irreversible permanent degradation, resulting from matrix cracking, interface and fiber deterioration.

Interlaminar Shear Strength

The tests were conducted in accordance with ASTM D2344-72. The specimens were short beams in the form of segments cut from the rings. The shear specimen dimensions are shown in Figure 12. Although this test is not ideal for shear strength measurements, it was the only reasonable test which could be employed. The span to thickness ratio was 4. The testing was done in an Instron testing machine at room temperature. The specimens were loaded at a rate of 0.05 inch per minute. Only specimens that failed in horizontal shear were considered and a minimum of 5 specimens were tested in order to obtain an average. The apparent horizontal shear strength results are summarized in Table 9.

The results indicate that the specimens exposed to a dry environment for 11 years suffered only a slight decrease in the shear strength, as compared to the reference values. Drying the specimens resulted in a slightly higher residual strength. A strong strength reduction was observed in specimens exposed for 11 years to humid environments. The current strength was 30 to 40% lower than the reference. The residual strength determined on completely dry specimens was higher than the current strength by only 16% in specimens with distilled water history and 11% in specimens with sea water history.

Strength reductions determined at high temperatures as reported in reference (3) were mainly attributed to the lowering of the glass transition temperature of the matrix as a result of the moisture content, resulting in a decrease of the matrix modulus and shear strength at temperatures close to the glass transition temperature. The results shown in Table 9 were conducted at temperatures much lower than the glass transition and, hence, the results indicate that irreversible changes occurred in the composite during the 11 years of humid environmental exposure. Irreversible damage could be caused as a result of microstructural damage of the epoxy resin and the interface bonds, due to the long time exposure to water and swelling stresses. The exposure to water for 11 years might cause hydrolitic degradation of the epoxy, as well as stress cracking. No evidence was found indicating an irreversible microbial degradation in the case of sea water exposure.

The shear strength reduction and the moisture absorption characteristics on re-exposed dried specimens can be related. The moisture absorption rate should be affected by the presence of microcracks inside the composite, caused as a result of the long time exposure. These microcracks should also lower the shear strength unless the strength is limited by a low interfacial strength. Hence, the moisture diffusion rate was correlated with strength reduction. This correlation is shown in Table 10.

The results listed in Table 10 clearly show a strong dependence between initial weight gain and diffusion coefficients. The interrelationship between shear strength reduction and higher moisture absorption rate can be explained by the microcracks created in the composite under long term water exposure. These effect the shear strength which is very sensitive to matrix defects, void content and interface strength and also accelerate moisture diffusion by "opening" more channels which facilitate the penetration of the small water molecules.

The graphite-epoxy specimens were also tested, in order to determine the current and the residual shear strength. The experimental results are quite different from the results on carbon fiber composites. The shear strength of the wet specimens was higher than the reference and also higher than the strength found on dried specimens. This is consistent with other studies (4, 5,6). Also, the shear strength is considerably lower than for the carbon fiber composites indicating that failure is controlled by the interface characteristics in the case of the graphite composites. The results are shown in Table 11.

As discussed earlier, the composite properties can be affected in several ways by the penetration of the water molecules. Water molecules may act as a matrix plasticizer and cause relaxation of the internal stresses resulting from the fabrication process. The stress relaxation may improve the material performance reflected by higher shear strength. The influence of swelling stresses caused by water absorption is more difficult to predict but should be a reversible effect. In the case of the carbon fiber composites if shear failure was matrix dominated, then degradation of the matrix can account for the reduction of the strength. In the case of graphite composites, relaxation of interfacial stresses may offset any interfacial degradation which might occur and as a result only slight changes in shear strength will be produced. The increase in shear strength upon drying is consistent with the reintroduction of stresses upon drying.

Flexural Strength

Flexural strength tests were performed on specimens cut from the rings and the test variables were in accordance with ASTM D790-66. The specimens were 2½" by 1/8" by 1/4" tested on a 2" span. The span to thickness ratio was 16 and the length to thickness ratio was 20. Since specimens were not flat, flat supports were used for the flexural test, instead of the cylindrical supports conventionally recommended. The test apparatus is shown in Figure 13. The load was applied by an Instron machine at a crosshead speed of 0.05 in/min. Two specimens were tested for each condition. The results are listed in Table 12.

It is important to note that very little difference in strength exists between dry and exposed water specimens over this 11 year exposure period. This is further verification of the long term stability of carbon fibers and those composite properties which are dominated by fiber properties such as the above longitudinal flexural strength.

CONCLUSIONS

Specimens of both carbon and graphite fiber reinforced epoxies exposed to distilled water for 11 years showed slightly higher equilibrium moisture content and shorter drying time (at 60°C under vacuum) than specimens exposed to sea water history. The salts and impurities usually found in sea water caused a white "coating" on the specimen surfaces which acted as a "barrier" restraining moisture absorption and desorption. No microbial effect was observed in sea water environmental exposure.

The long term water exposure influence on moisture absorption characteristics has been determined. The 11 years of immersion in distilled water and sea water considerably affected the initial moisture weight gain and the diffusion coefficients upon reexposure to humid environments. The higher initial weight gain and diffusion coefficient found for specimens having water environmental history may indicate that microdamage occurred in the specimens during the long term exposure.

A considerable shear strength reduction (current and residual) was found for carbon-epoxy specimens having humid long term environmental history. This strength reduction might indicate that microdamage and irreversible degradation of the matrix and interfaces occurred during the 11 years of water immersion. The strength degradation has been qualitotively correlated and interpreted with the moisture absorption characteristics. No irreversible damage in the fiber properties was observed as concluded from flexural strength results.

The shear strength of graphite-epoxy composites was considerably lower than that found for carbon-epoxy composites. Also, the current strength of wet specimens having humid history exposure was higher than the reference and than the strength found in dried specimens. This higher wet strength is probably due to internal stress relaxation in the case where shear strength is dominated by interfacial failure rather than by matrix failure.

ACKNOWLEDGMENTS

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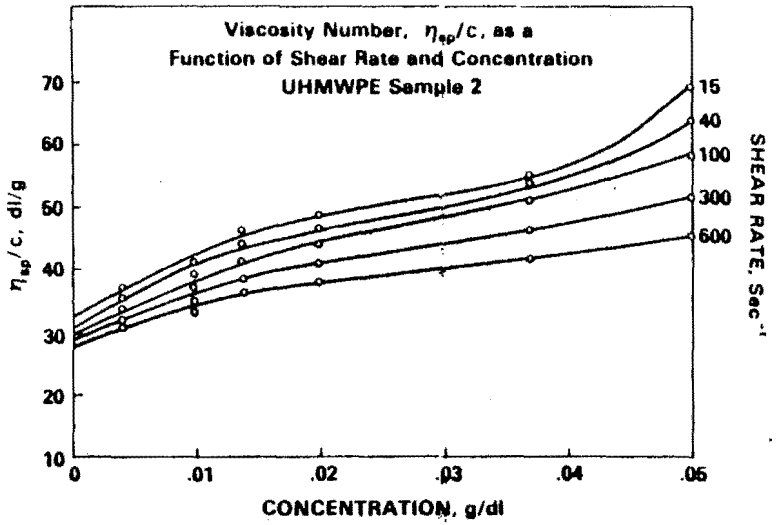

Fig. 1. Viscosity number as a function of concentration using the same Ubbelohde viscometer for all measurements. Shear rate is variable, and depends on flow rate.

it cannot be specified since it varies from point to point depending on flow time, the limiting viscosity number obtained is 23.6 dl/g, over 25% less than the zero shear rate value. This in turn leads to over a 35% error in molecular weight if the conventional Mark–Houwink relationship is employed. As pointed out above, this relationship may be incorrect even for zero shear data at these high molecular weights. Data on other samples of UHMWPE show similar behavior, the extent of the error depending on the viscosity of the sample.

Samples of UHMWPE can be compared or ranked on the basis of viscosity numbers obtained at a single concentration with viscometers of standardized dimension. However, it would not be prudent to associate an absolute molecular weight with the samples based on such measurements. The method we have employed is outlined below and is similar to the one being proposed by ASTM Committee D 20.12 as a standard method.

RECOMMENDED PROCEDURE

A procedure for measuring the viscosity number at one concentration with a precision of approximately 1% is the following:

A sample of about 0.125 g of the UHMWPE is weighed into a 250 ml glass stoppered Erlenmeyer flask and a volume of decalin, containing 0.2% phenyl-β-naphthylamine as an antioxidant, is added from a burette to give the concentration desired. The volume required to give a 0.05% solution is approximately 225 ml and is determined from the ratio of the density of decalin at 135°C to the density at room temperature which we took to be 0.90.[4] For interlaboratory comparison this value should be de-

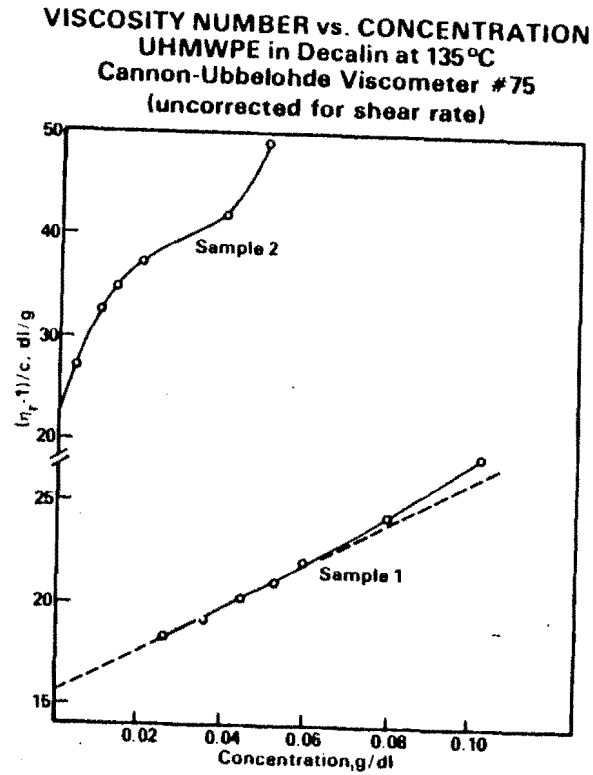

Fig. 2. Viscosity number as a function of shear rate for a sample of UHMWPE.

termined for each batch of solvent, since the *cis-trans* ratio and hence the density will vary. Smaller samples may be used if due attention is provided to weighing the sample and to measuring the solvent to give the precision desired.

The polymer is dissolved over a period of 4 hr at 135°–150°C with occasional, gentle swirling.

About 7 or 8 ml of the hot polymer solution is added to a clean dry Cannon-Ubbelohde (#75) viscometer suspended in an oil bath at 135°C (±0.05). We did not find it necessary to filter the solutions. After a period of about 15 min, long enough to attain thermal equilibrium, flow times are determined. For our work, photoelectric cells are employed to time the readings to 0.1 sec, but this was done for convenience and readings to 0.1 sec by eye would be sufficient. At least 5 flow time readings are made per filling, the flow times ranging from about 130 sec for the solvent to as much as 530 sec for the higher molecular weight polymer.

The viscometer is cleaned after each run by removing the solution with a long stainless steel needle and hypodermic syringe, rinsing several times with hot decalin, and aspirating to dryness. Care is always taken to keep the viscometer free of dust or other particles, and the air used for aspirating was first passed through a sintered glass filter.

For every viscosity reported, three completely separate solutions are prepared and measured. The standard deviations of the mean viscosity numbers, which ranged from 22 to 50, were generally less than 0.2, and hence, less than 1% for three samples.

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NOTES

Indentation Creep of Polymers for Human Joint Applicat.

Both reversible and irreversible creep under conditions of indentation (constrained compression) loading have been measured for three polymer materials which are used or are planned for use in human joint prostheses. The three materials are ultrahigh-molecular-weight (UHMW) polyethylene, UHMW polyethylene reinforced with graphite fibers and polyacetal (Delrin 150). Up to about 3000 psi (20.7 MPa) the plastic creep or cold flow of the latter two materials are about equal and substantially less than the unreinforced UHMW polyethylene. Above this contact pressure the plastic creep of the reinforced polyethylene rapidly approached that of the unreinforced material.

Unlike most metals at or near body temperature, the strain response of polymers to applied stress is both instantaneous and time-dependent (creep). Creep strains are a combination of reversible (elastic) and irreversible (plastic) components. Creep would not be desirable, particularly in an artificial knee joint, because by indentation relative lateral motion and rotation of the articulating surfaces are restrained. This allowance for limited relative sliding motion and rotation is one of the purposes for the use of nonconformal metal to plastic profiles.[1,2] Cold flow or the plastic component of creep has been observed in the tibial components of knee joints, which, for various reasons, had to be removed from patients.[2]

Two candidate materials are either being offered or consideredTor the tibial component of knee joints. One is a graphite-fiber-reinforced UHMW polyethylene (a product of Zimmer–USA). The other candidate is a polyacetal resin (designated Delrin 150, a trademark of E. I. du Pont de Nemours Company). The purpose of this study was to determine the indentation creep behavior of the commonly used medical grade of UHMW polyethylene with these two new alternatives. The medical grade UHMW polyethylene was supplied as typical of material used by Zimmer–USA of Warsaw, Indiana, in the form of a block from which a disk specimen was machined. The graphite-fiber-reinforced UHMW polyethylene was also supplied by Zimmer–USA in the form of smaller disks which were representative of their product. The polyacetal disk was supplied as a block (from which a disk specimen was machined) by Howmedica International, Inc., of Limerick, Ireland.

We have previously reported[3,4] on a wear-testing system that involves measurement of wear depth on a flat plate (disk) of polymer produced by the rubbing motion of a rotating metal disk (with a flat face) oriented perpendicular to the polymer disk. A constant contact force is applied by dead weights on a lever arm. The polymer–metal contact zone is immersed in 37°C circulating and continuously filtered water. If the metal disk is not rotated, the system serves equally well in measuring indentation creep. An LVDT sensor reads displacements and can be continuously recorded. Displacements in the range $0 - 50 \times 10^{-3}$ in. ($0 - 1.3 \times 10^{-1}$ mm) can be read to within 5×10^{-4} in. (0.013 mm). The readings can be calibrated by feeler gages both before and after a test.

The graphite-filled UHMW polyethylene specimens were machined to form inserts

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NOTES

A Specification Method for Ultra High Molecular Weight Polyethylene for Implant Use

Ultra high molecular weight polyethylene has gained wide acceptance as an implant material with excellent resistance to creep, stress cracking and wear. Because many of these desirable properties are a function of its high molecular weight, a reliable specification method of determining molecular weight of the order of 10^6–10^7 is needed for controlling and optimizing these properties. The methods commonly used for determining the molecular weight of lower molecular weight polymers, such as light scattering, osmotic pressure or gel permeation chromatography, are either too difficult or too insensitive in this molecular weight range to be used routinely. However, as in the case of lower molecular weight polymers, molecular weights may also be estimated by viscosity measurements which are empirically related to molecular weight.

The purpose of this note is to point out that the estimated molecular weight of ultra high molecular weight polyethylene (UHMWPE) obtained from single point viscosity measurements may be significantly in error when these estimates are derived by methods[1] which are appropriate for lower molecular weight polymers. Single point viscosity measurements, carried out under standardized conditions, should be used only as molecular weight indices, without any quantitative association with absolute molecular weights.

When single point viscosity measurements are used to determine the molecular weights of UHMWPE, errors arise from three principal sources:

(1) The Mark–Houwink constants relating molecular weight to limiting viscosity number (intrinsic viscosity) which are available in the literature have been determined only for low molecular weight polymers. It is now believed that these constants are not the same for high molecular weight polymers[2] and, in the case of polystyrene, this has been verified experimentally.[3]

(2) The extrapolation to zero concentration from measurements at finite concentration is very dependent on molecular weight. This may be seen in Figure 1 where the viscosity number is plotted against concentration for two UHMWPE samples differing substantially in viscosity. The empirical constants which are often used to calculate the limiting viscosity number from the viscosity number at a fixed concentration were determined only for low molecular weight polyethylenes.[4] The feasibility of making such an extrapolation and determining the correct constants has yet to be determined for UHMWPE.

(3) The limiting viscosity number of UHMWPE varies significantly with shear rate. To determine this dependence, viscosity measurements using a multibulb variable shear viscometer were made in technical grade decalin at 135°C over a range of concentrations (up to 0.05%) and shear rates (from 15 to 600 sec^{-1}). As shown in Figure 2, for one sample of UHMWPE, the viscosity number increases from 28.9 to 32.2 dl/g as the shear rate decreases from 600 to 0 sec^{-1}, a variation of 10%. If the data in Figure 1 are extrapolated to zero concentration as is customarily done, ignoring the shear rate because

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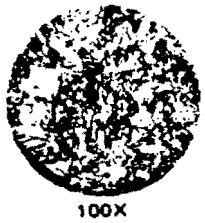
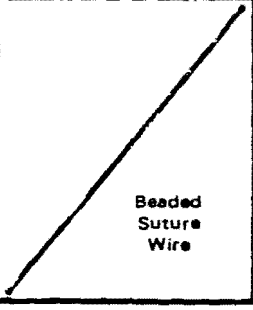
SPECIFICATIONS OF ZIMMER® IMPLANT METALS

	ZIMMER® CERTIFIED STAINLESS STEEL	ZIMALOY® (Cobalt-Chromium-Molybdenum) ASTM F-75	MICRO-GRAIN™ ZIMALOY® (Cobalt-Chromium-Molybdenum) ASTM F-75	WROUGHT T-ZIMALOY® (Cobalt-Chromium-Tungsten-Nickel) ASTM F-90	TIVANIUM® TITANIUM ALLOY (Ti-6Al-4V Alloy) ASTM F-136
PHOTO-MICROGRAPH	 100X	 100X	 1000X	 100X	 1000X
CHEMICAL ANALYSIS	ELEMENT PERCENT MIN. MAX. Chrom. 17.00 20.00 Nickel 12.00 14.00 Moly. 2.00 4.00 Mang. 2.00 Silicon .75 Carbon .03 Phos. .025 Sulphur .010	ELEMENT PERCENT MIN. MAX. Chrom. 27.00 30.00 Moly. 5.00 7.00 Nickel 2.50 Mang. 1.00 Silicon 1.00 Iron .75 Carbon .35 Cobalt bal.	ELEMENT PERCENT MIN. MAX. Chrom. 27.00 30.00 Moly. 5.00 7.00 Nickel 2.50 Mang. 1.00 Silicon 1.00 Iron .75 Carbon .35 Cobalt bal.	ELEMENT PERCENT MIN. MAX. Al. 5.50 6.50 Vanad. 3.50 4.50 Iron 0.25 Carbon 0.08 Oxygen 0.13 Nitrogen 0.05 Hydrogen 0.0125 Others 0.1 each max. (total not over 0.40) Titanium Balance	ELEMENT PERCENT MIN. MAX. Chrom. 19.00 21.00 Tungsten 14.00 16.00 Nickel 9.00 11.00 Carbon 0.05 0.15 Iron 3.00 Mang. 2.00 Silicon 1.00 Cobalt bal.
HARDNESS (Typical)	Annealed R_B 85 Cold Reduced R_C 30	R_C 29	R_C 42	Annealed 27 Cold Reduced 45	R_C 35
TENSILE STRENGTH (Typical)	Annealed 80,000 PSI Cold Reduced 140,000 PSI	105,000 PSI	185,000 PSI	Annealed 170,000 Cold Reduced 260,000	140,000 PSI
YIELD STRENGTH (0.2% Offset) (Typical)	Annealed 35,000 PSI Cold Reduced 115,000 PSI	75,000 PSI	133,000 PSI	Annealed 100,000 Cold Reduced 245,000	130,000 PSI
ELONGATION IN 2" % (Typical)	Annealed 55 Cold Reduced 22	10	14	Annealed 50 Cold Reduced 10	10
REDUCTION IN AREA % (Typical)	Annealed 65 Cold Reduced 55	10	16	Annealed – Cold Reduced –	25
TYPICAL APPLICATIONS				 Beaded Suture Wire	

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