

# BIOMATERIALS

## PRESENT AND FUTURE DEVICES



THE GOAL:

IMPROVED PROPERTIES:

INITIALLY AND

AFTER USE

Materials and Design are immutably linked:

Design expresses the properties of

Materials, New Materials thus

call forth New Designs

# PROPERTIES OF CURRENTLY USED ALLOYS

## CHEMICAL PROPERTIES

### MAJOR ELEMENT COMPOSITION (%)

LOW CARBON STAINLESS STEEL 316L	(1)	IRON	Cr 17-30	Ni 10-30
CARBON CO-BASED ALLOY & NICKEL ALLOY	(2)	COBALT	Cr 22-30	Ni 7-12
WROUGHT CO-C ALLOY	(3)	COBALT	Cr 18-21	Ti 14-20
FORGED CO-C ALLOY		COBALT	Cr 20-28	Ni 7
TITANIUM UNALLOYED	(4)	TITANIUM		
TITANIUM 6 AL - 4V	(5)	TITANIUM	Al 5.5-6.5	Ni 0.5-1.5
MP - 30N (MULTIPHASE)		COBALT	Cr 18-21	Ni 8-10.5

- 1. ASTM Standard: F 136-70 & F 136M-70
- 2. ASTM Standard: F 136-70
- 3. ASTM Standard: F 26-70
- 4. ASTM Standard: F 26-70
- 5. ASTM Standard: F 26-70

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### ALLOYS

### ADVANTAGES

### USES

#### IRON-BASE

GOOD FATIGUE STRENGTH  
INEXPENSIVE  
GOOD MACHINABILITY

PINS, PLATES, NAILS  
SOME PROSTHESES

#### COBALT-BASE

HIGH CORROSION RESISTANCE  
BIOCOMPATIBILITY  
EXCELLENT MECHANICAL  
PROPERTIES WITH NEW  
PRODUCTION TECHNIQUES

MOST PROSTHESES  
MANY DIFFERENT  
IMPLANTS

#### TITANIUM BASE

VERY HIGH CORROSION  
RESISTANCE  
LIGHT IN WEIGHT  
(40% LOWER DENSITY)  
HIGH ELASTICITY  
(YOUNG'S MODULUS 1/2 OF STEEL)

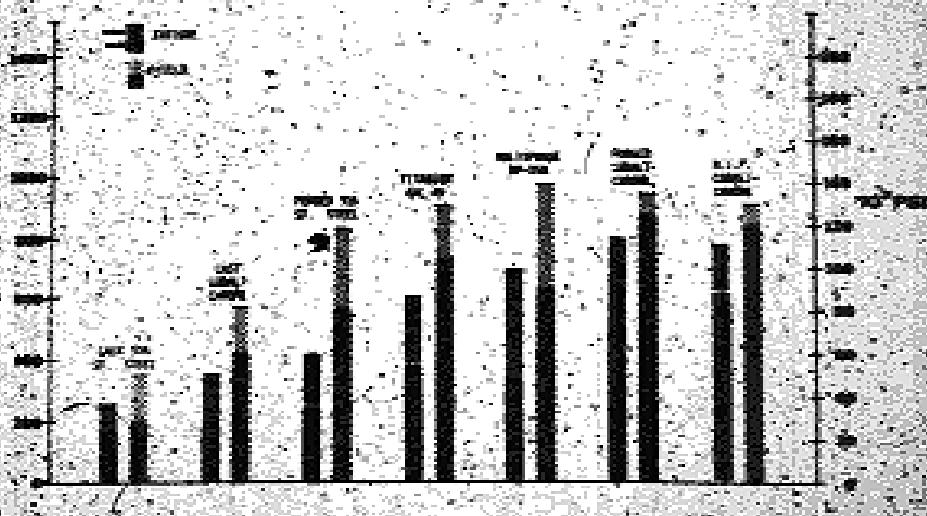
PROSTHESES, PLATES  
SOME IMPLANTS

# PROPERTIES OF CURRENTLY USED ALLOYS

## MECHANICAL/PHYSICAL PROPERTIES

This graph is a composite of values received from manufacturers. Only the yield strengths of 316 Cast Stainless Steel, 316 Forged Stainless Steel, Cast Cobalt Chrome and Titanium 6Al-4V reflect ASTM minimum specifications.

STRENGTHS OF IMPLANT ALLOYS

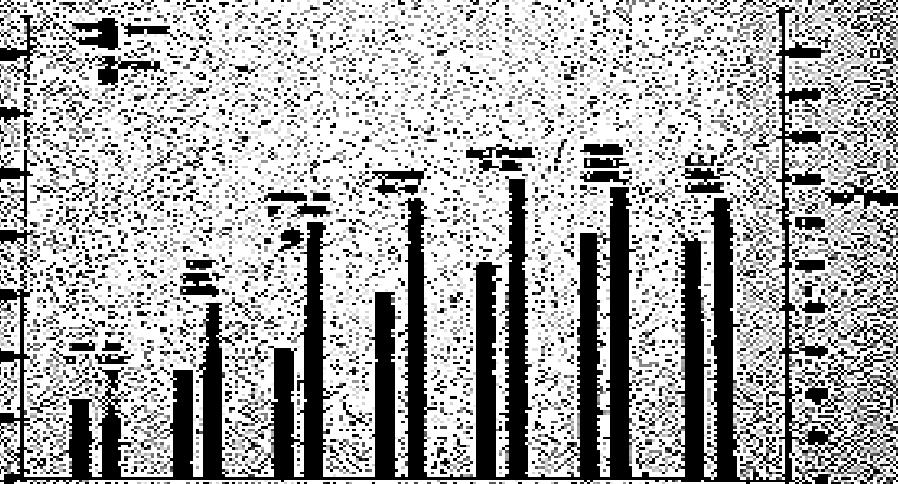


The "super alloys" (Multiphase MP-35N, Forged Cobalt Chrome, and H.I.P. Cobalt Chrome) show superior strengths. Universal testing standards have not as yet been established for fatigue strength, most important for prosthetic implants.

## MECHANICAL PROPERTY TESTS

These tests are a continuation of previous work done by the same group. Only the mechanical properties of the new Biomaterials used, i.e. Forged Titanium, Cold Drawn Cobalt-Chromium and Titanium Alloy (ASTM specifications).

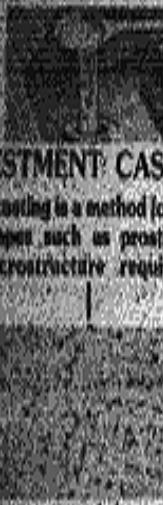
### STRENGTHS OF IMPLANT ALLOYS



The figure shows the following mechanical properties for the different materials:  
Forged Ti: Tensile Strength ~850 MPa, Yield Strength ~750 MPa  
Cold Drawn Co-Cr: Tensile Strength ~650 MPa, Yield Strength ~550 MPa  
Ti Alloy: Tensile Strength ~850 MPa, Yield Strength ~750 MPa  
Forged Ti: Tensile Strength ~850 MPa, Yield Strength ~750 MPa  
Cold Drawn Co-Cr: Tensile Strength ~650 MPa, Yield Strength ~550 MPa

# HOW ARE METALS TREATED TO ACHIEVE DESIRED SHAPE AND PHYSICAL PROPERTIES?

## CAST



### INVESTMENT CASTING

Investment casting is a method for fabricating complex shapes such as prostheses. Non-uniform microstructure requires further processing.

As Cast Co-Cr (100x)

### SOLUTION HEAT TREATING

One method of heat treating castings by re-dissolving non-uniform regions in the metal to improve the homogeneity of the microstructure.

Annealed Heat Treated Co-Cr (100x)

MACHINING Removing metal particles with a machine such as a drill or lathe to achieve certain dimensional tolerances as screw threads, holes, etc. The actual shape of the implant is usually not changed here.

## WROUGHT



### HEAT TREATING

**ANNEALING** heating and cooling without mechanical working to change the microstructure and relieve internal stresses. Provides desired physical and mechanical properties by ductility, machinability and corrosion resistance.

Annealed MP-35N (310x)

### MECHANICAL WORKING

Mechanical shaping of metal to improve homogeneity and impart mechanical strength by refining its crystalline structure.

#### COLD WORKING

The shape is changed at room temperature. Used for pins, plates and wires. (Only for very simple shapes). As a result mechanical properties are raised. (ductility decreases). (example: Cold Rolling or Drawing)



Cold Worked MP-35N (310x)

Forged MP-35N (310x)

#### HOT WORKING

Mechanical shaping of a metal in a heated state (usually above its recrystallization temperature). The grain size of the metal is refined resulting in better mechanical qualities. The stems of femoral components of total hips are sometimes made this way. (example: Hot Forging)



H.F. Co-Cr (310x)

## POWDER METALLURGY



### HOT ISOSTATIC PRESSING

Consolidation of metal powders under high pressure and temperature to form a dense material of fine grain size.



## **SUMMARY**

1. There is no ideal metal for all implants.
2. The physical, mechanical and biochemical properties of each metal determine its selection for a specific implant.
3. Fatigue strength is a most important mechanical quality for implants such as prostheses subjected to stresses for unlimited time.
4. Elasticity and ductility can be important in some fracture fixation devices.
5. All metals must be biocompatible and corrosion resistant.
6. Stronger metals and improved designs have provided better implants in recent years, but success depends on high manufacturing standards, proper patient selection, application and surgical technique.

## SELECTED PROPERTIES OF NOMINAL NITINOL 55

TREATMENT	TENSILE STRENGTH, PSI	YIELD STRENGTH, PSI	ELONGATION %	ELASTIC MODULUS, PSI
ANNEALED SPECIMEN AT ROOM TEMP. (BELOW TRANS TEMP.)	125,000	15,000 to* 20,000	60	$10.2 \times 10^6$ *
COLD WORKED SPECIMEN AT ROOM TEMP.	200,000	50,000	12	---

\* STRONGLY DEPENDENT ON TEMPERATURE AND  $A_s$  TEMPERATURE OF TRANSITION

# THE EVOLVING TECHNOLOGY OF MOLDED POLYETHYLENE

THE MOLDING PROCESS PRODUCES A SMOOTHER WEARING SURFACE, ENSURES CONSISTENT DIMENSIONS AND PERMITS UNIQUE DESIGN CAPABILITIES.

ZIMMER<sup>®</sup> polymer molding technology produces highly consistent Ultra-High Molecular Weight (UHMW) polyethylene implants offering improved control over many critical factors: molecular weight, molecular structure, absence of impurities or contamination, surface finish and dimensional variations. Unlike conventional polyethylene production techniques which rely upon machining of bar stock produced by outside production sources, ZIMMER molding technology permits almost total control over every phase - from receipt of high quality, pure virgin polymer resin to the finished polyethylene implant.



- MICRO-FINISH<sup>®</sup> ultra-smooth wearing surface to within 20 millionths of an inch results in reduced friction and wear. Machining grooves or tool marks inherent in machining of conventional polyethylene are eliminated.
- Controlled molecular weight to ensure uniform properties throughout the implant.
- More intricate implant and implant surface designs (undercuts, interlocks, lugs, etc.) to enhance function and cement fixation.
- Radiographic wires or internal metal supporting structures molded into UHMW polyethylene prevent their being loosened or dislodged during insertion.
- Controlled processing to eliminate contamination from machining compounds, extrusion contaminants and other foreign particles.
- Molding minimizes dimensional variations of finished components - implant to implant.

Now, use of the unique molding process is combined with the benefits of a new technology developed in the ZIMMER<sup>®</sup> plant.

## poly two<sup>TM</sup> carbon polyethylene composite



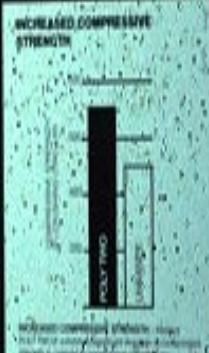
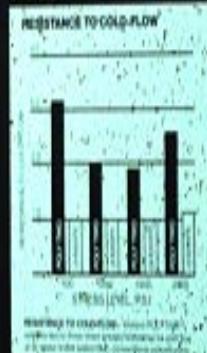
POLY TWO™ carbon-UHMW polyethylene composite has already been clinically utilized over a number of years in total joint applications. This biomaterial is a patented technological advancement available exclusively through your ZIMMER USA representatives.  
U.S. Patent No. 4,605,862

### Mechanical Tests Demonstrate POLY TWO<sup>TM</sup>'s Significant Improvements Over Conventional Polyethylene.

The technology of reinforcement of polyethylene with inert, high-modulus carbon fibers has made possible an improved biomaterial for total joint arthroplasty . . . POLY TWO. Mechanical tests show that this carbon-UHMW polyethylene composite material can offer significant improvements over conventional polyethylene.

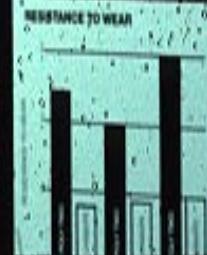
#### I. INCREASED COMPREHENSIVE STRENGTH

The mechanical integrity of molded POLY TWO was evaluated by comparing compressive test results against conventional polyethylene. These tests were performed to determine the load required to produce a five percent decrease in length (Fig. 1).



#### II. INCREASED RESISTANCE TO WEAR

Wear debris from generator studies of the hip, ankle<sup>®</sup> and knee<sup>\*\*</sup> was measured, comparing molded POLY TWO and conventional polyethylene (Fig. 3).



#### IV. BIOMATERIALITY

Biocompatibility and toxicity studies performed on molded POLY TWO show the carbon-polyethylene composite to be non-toxic. Tissue response to the composite shows no significant difference in cellular response to wear particles than that encountered with conventional polyethylene. Historically, in vivo responses demonstrate that implants made of UHMW polyethylene have generally been accepted as biocompatible. Testing of the molded POLY TWO composite involved both acute and chronic toxicity tests using conventional polyethylene and standard UHMWPE test strips as controls. The molded POLY TWO composite and each of its individual components were tested for biocompatibility (Fig. 4).

# Micro-grain™ ZIMALOY®

**Biocompatibility**  
MICRO-GRAIN ZIMALOY® has  
highly similar properties to  
cemented cobalt chrome.  
Ceramic testing has confirmed  
the same level of biological  
response as the cast, more  
grained version of the alloy.

**Elastic Modulus**  
Maintains the same strong  
modulus as the cast, more  
cost version of the alloy, but  
with improved ductility to  
reduce the potential for  
cyclic fatigue.

**Tensile Strength**  
MICRO-GRAIN ZIMALOY ex-  
hibits the highest load bear-  
ing capacity of all the  
materials tested without  
prior deformation or  
fracture.



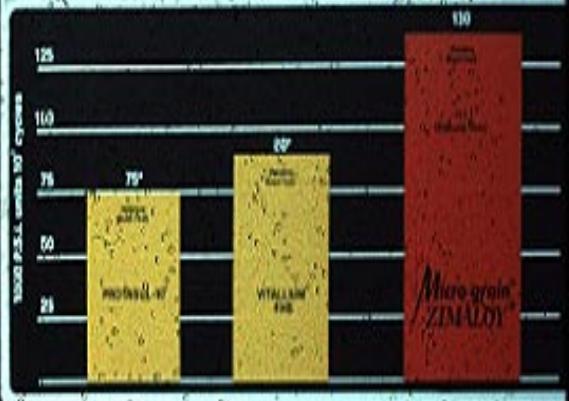
**Tensile Strength**  
MICRO-GRAIN ZIMALOY offers  
the surgeon a high strength implant alloy to meet  
the demands of increased  
patient activity and weight  
bearing by improving the load  
bearing capacity resulting in  
a reduced potential for cyclic  
fatigue secondary to loosening.

**Wave-Finish® Surface**  
The unique microstruc-  
ture of MICRO-GRAIN  
ZIMALOY facilitates smooth  
surface finishing of the  
implant surface.

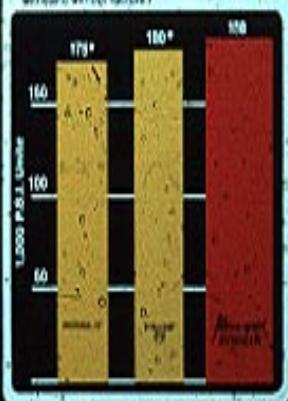
## A High Strength Alloy Designed to Meet Demand of Increased Patient Activity and Weight.

Offering biocompatibility proven over nearly four decades, this ultra-fine grained version of cobalt chromium molybdenum offers the surgeon a material with increased load bearing capacity and reduced opportunity for fracture of femoral stems by metal fatigue secondary to loosening.

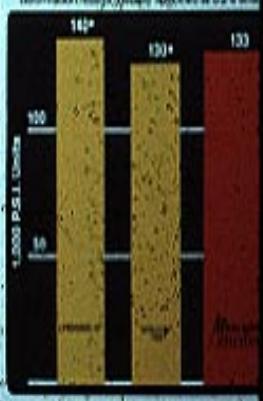
**FATIGUE STRENGTH** Measure of the maximum cyclic stress a material can withstand without fracture.



**ULTIMATE TENSILE STRENGTH** The maximum stress a material can withstand without fracture.



**YIELD STRENGTH** The stress level at which measurable permanent deformation begins typically applied at 0.2% strain.



Source from International Standard ISO/IEC 17025:2005, Accredited Laboratory of Sylmar Research, Inc. The results of a strength test of Micro-grain ZIMALOY compared to a standard of PROSTYL® and VITALLIUM®. The Co-Cr-Mo alloy PROSTYL® is registered trademark of Zimmer Incorporated, Inc., and VITALLIUM® is registered trademark of DePuy Synthes Product LLC. © 2007 Sylmar Research, Inc. All rights reserved. Sylmar Research, Inc. is a wholly owned subsidiary of Zimmer Incorporated, Inc.

## OLCOTT

**TABLE I**  
**Representative Properties of Candidate Biocharbons**

	Tensile Strength (psi)	Modulus of Elasticity (psi x 10 <sup>3</sup> )	Strain to Fracture (percent)
AT&T	5,000	1.0	0.5
Glassy Carbon	17,000	4.0	0.4
Isotropic Carbon	30,000 <sup>a</sup>	3.4	0.9
Pyrestrand	4,000-35,000	1.4/2.0	1.0/1.8
PE/SiC	12,000-25,000	3.4/5.7	0.3/0.5

<sup>a</sup> Estimated from flexure data.