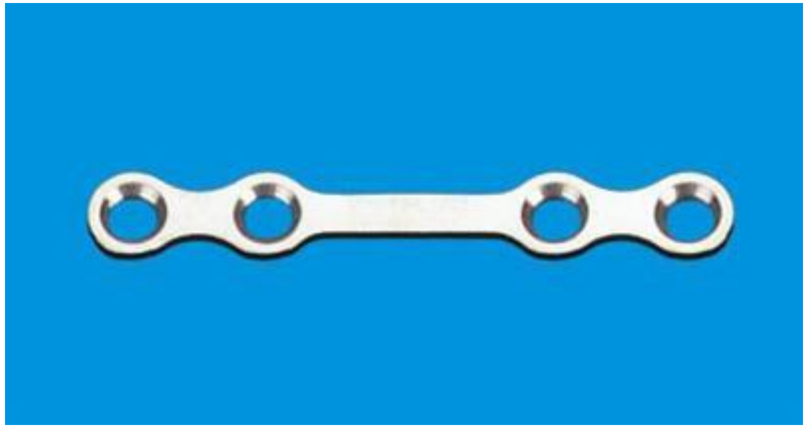
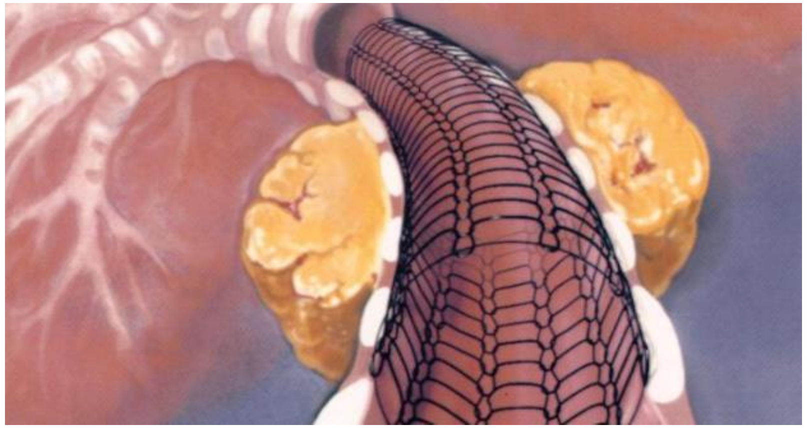




METALLIC BIOMATERIALS

Prof. Dr. Sevil YÜCEL

BIOMATERIALS USAGE AROUND THE WORLD

- 1980 ≥ 5 million dollar
- 1991 total orthopedic implant and equipments, 2 million dollar(1.4 million dollar metallic orthopoedic)
- 2000 USA 9 million dollar growth rate: 20%/year
- 2000 20 million dollar
- 2005 23 million dollar
- 12-20% increase /year

Production Steps of Implants

Mineral Source

(ore)

Mining

Seperatıon of ore/Concentratıon

Chemical extractıon of metal

Pure metal

Metalic material in volume form

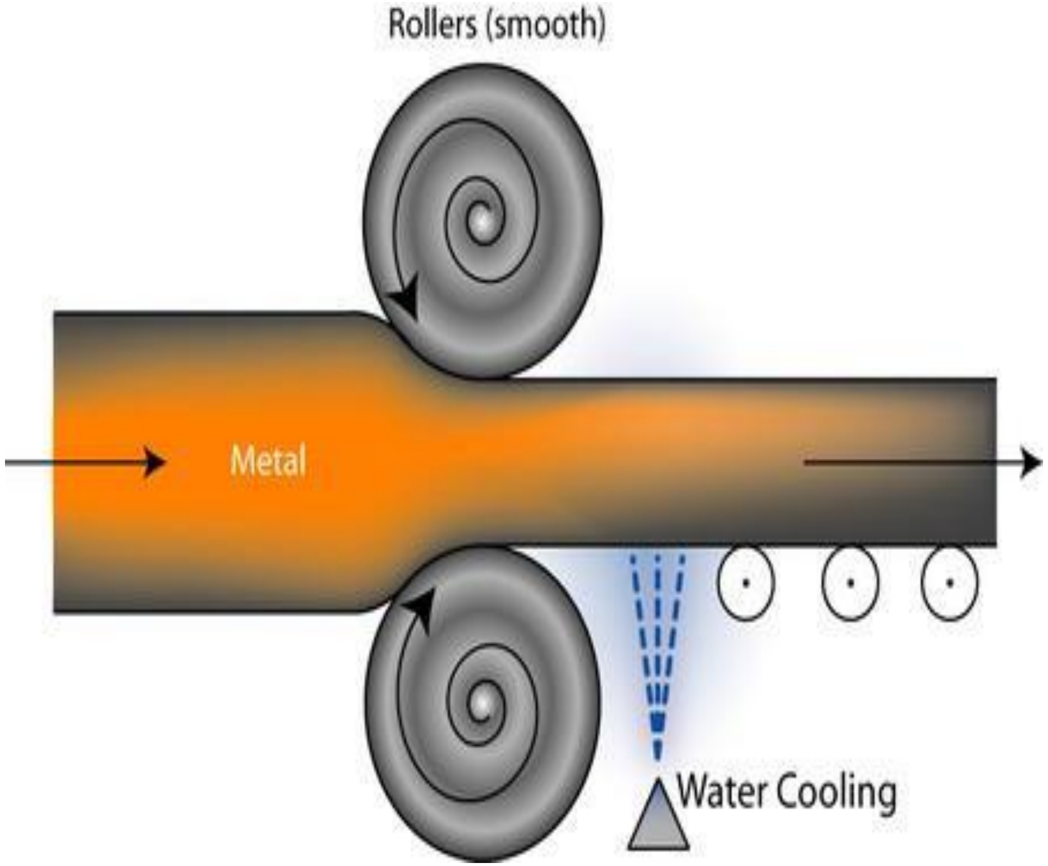
Casting is a manufacturing process by which a liquid material is usually poured into a mold, which contains a hollow cavity of the desired shape, and then allowed to solidify.

Rolling can be thought of as a local deformation process during which thickness is decreased, length increased, and width remains unchanged. The sample is pressed and advanced through the rollers, metal passing between moving surfaces.It can be shaped hot or cold.

Powder productıon

Heat transactıon

Forging is the process by which metal is heated and is shaped by plastic deformation by suitably applying compressive force.



Casting process

Rolling process

Stock Shapes(Stick, fiber, tube, powder)

Production:

İnvestment

CAD/CAM

Grinding

Powder metallurgy

Front implant equipment

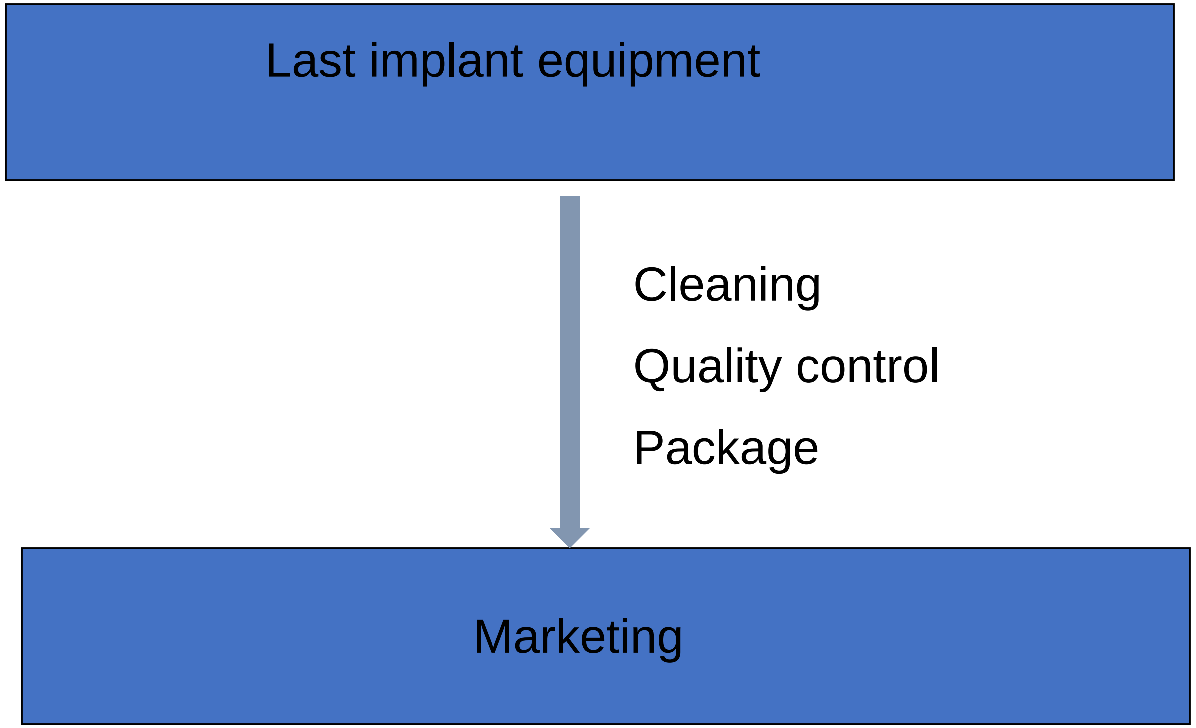
Surface Structures

Surface Coatıng

Nitriding: It is applied for hardening the steels which include less carbon.Steel surface is nitreded and rugged nitrates occors.

Polishing

Sand Blasting


Last implant equipment
Cleaning
Quality control
Package
Marketing

THE HISTORY OF METALLIC BIOMATERIALS

- The first metal alloy developed specifically for human use was 'vanadıum steel' in the early 1900's
- The earliest successful implants were bone plates**(Sherman plates)**
- In 1924 Zierald published the study on the reaction of tissues to a variety of metals.
- **Iron-steel:** Dissolve rapidly and to provoke erosion of adjacent bone.
- **Copper and Nickel**: Discoloration of tissues
- **Gold, silver or pure aluminium:** Too soft or weak

THE HISTORY OF METALLIC BIOMATERIALS

- 1926 %18 Chromium %8 Nickel stainless steel was introduced into surgical applications.
- 18/8 SMo stainless steel was introduced (316 stainless steel).
- 1947 Titanium surgical implants were considered (perfect corrosion resistance) .
- 1950 Carbon content of 316 stainless steel was reduced from 0.08% to 0.03% for better corrosion resistance.

MAIN APPLICATIONS OF METALS

1. Orthopedic applications

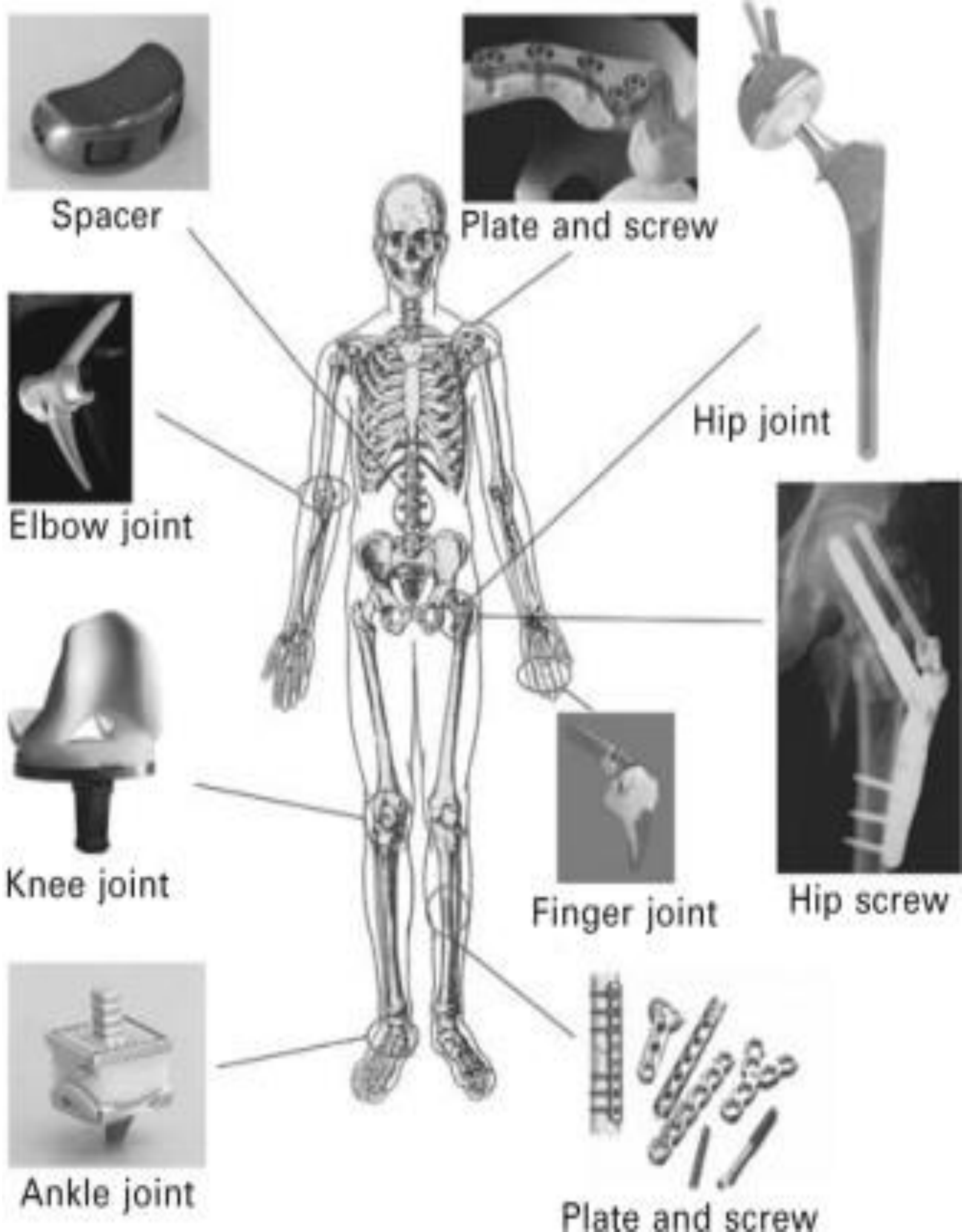
Joint prosthesis and bone replace and repair material

2.Face and jaw surgery

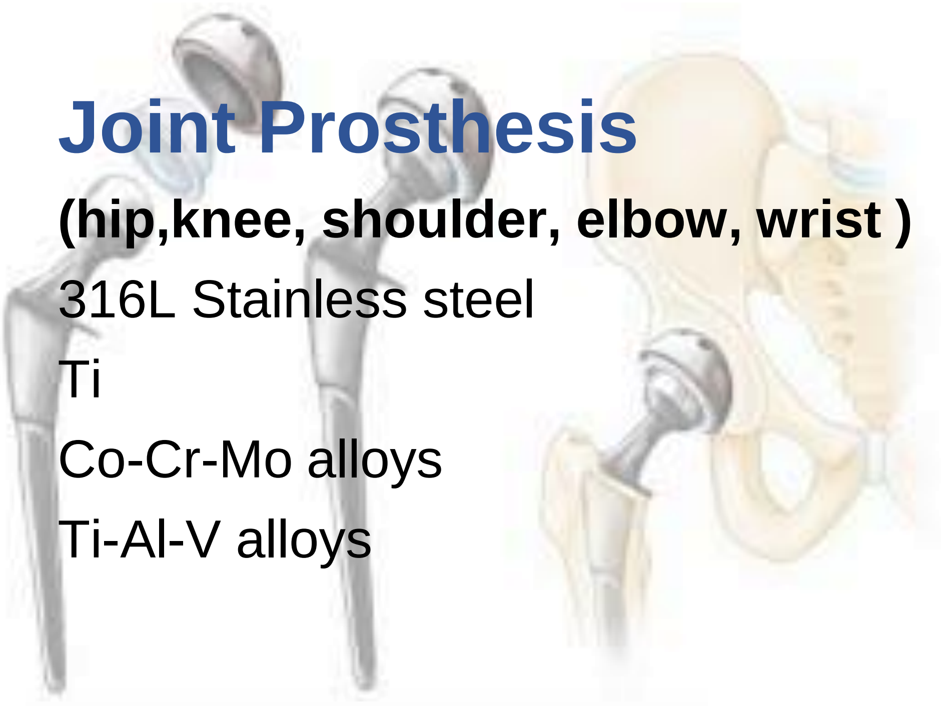
(dental implants)

3.Cardiovascular surgery

(artificial heart pieces,cathater, cardiac valve, pacemaker tips)



Medical Metallic Biomaterials



Joint Prosthesis

(hip,knee, shoulder, elbow, wrist)

316L Stainless steel

Ti

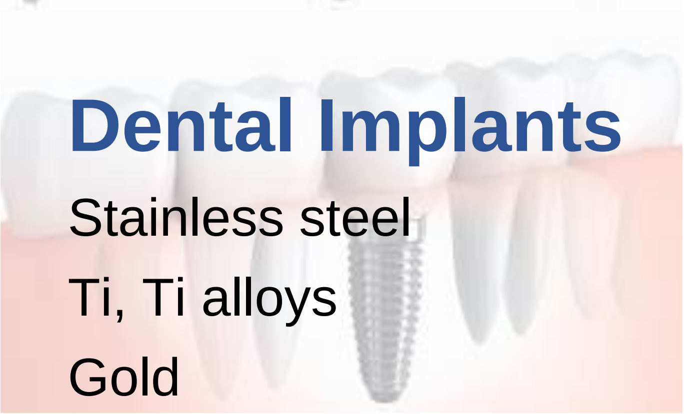
Co-Cr-Mo alloys

Ti-Al-V alloys

Fracture Repair

316L Stainless steel

Ti, Ti alloys



Dental Implants

Stainless steel

Ti, Ti alloys

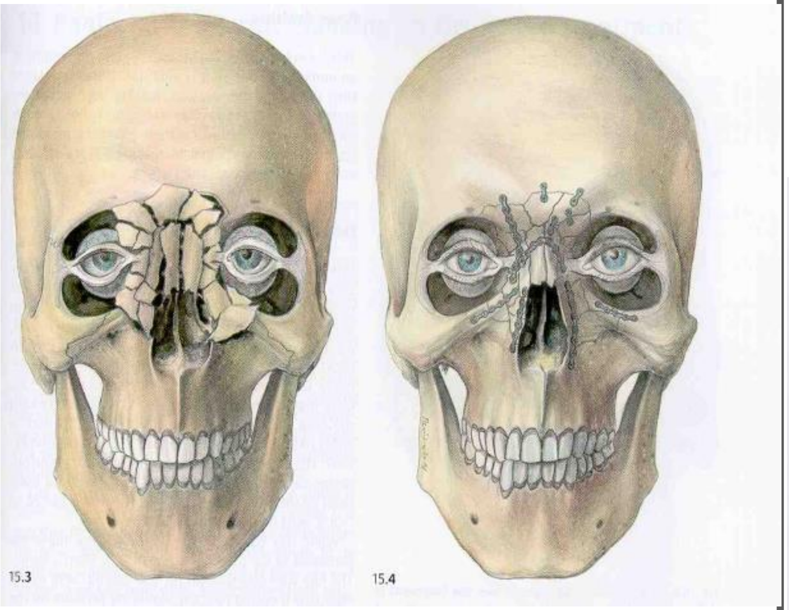
Gold

Pacemaker

316L Stainless steel

Ti, Ti alloys

Platin and Iridyum



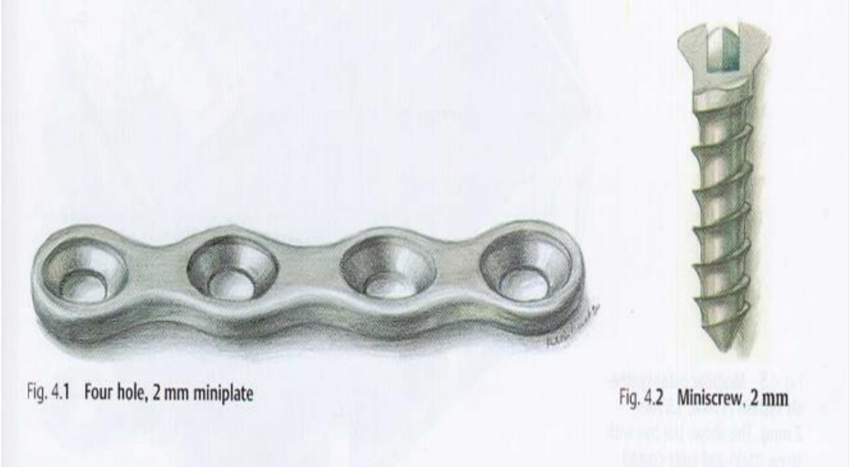
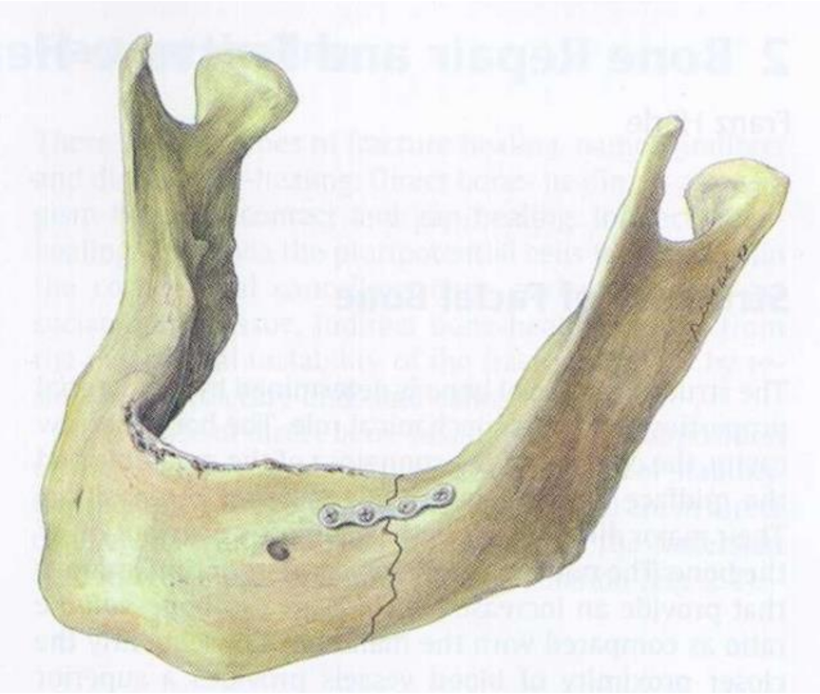


Fig. 4.1 Four hole, 2 mm miniplate

Fig. 4.2 Miniscrew, 2 mm



Bone Plates

METALLIC BIOMATERIALS

1. Steel
2. Co-based alloys
3. Ti ve Ti based alloys
4. Dental metals
5. Other metals

1. Stainless Steel

- Before the introduction of stainless steel in the biomedical industry, implants were fabricated from **pure metals**, which often displayed **lower corrosion resistance** and **mechanical strength**.
- The stainless steels, especially 316L type is the most used metallic biomaterials for biomedical applications due to their good biocompatibility, low price, excellent corrosion resistance, availability, easy processing and high strength.
- **Steel**, is an alloy consist of iron and carbon (basic component).Because of manufacturing methods and used ores it wil include manganese, silicon, phosphorus ve sulfur.

TYPES OF STAINLESS STEELS

- 18-8 (302 type first stainless steel) has more corrosion resistance and harder than vanadium steel, resulting in better long-term medical outcomes and less post-surgery complications.
- 18-8 sMO stainless steel is known as 316 stainless steel.
- 316 L: C content reduced from 0.08% to 0. 03 % has maximum protection resistance against chlorine solutions.

Chemical Composition of 316L ve 316 Stainless Steel

Chemical Composition	316L	316
Carbon	0.03	0.08
Manganese	2.00	2.00
Phosphorus	0.03	0.03
Sulfur	0.03	0.03
Silicon	0.75	0.75
Chrome	17.00-20.00	17.00-20.00
Nickel	12.00-14.00	12.00-14.00
Molibden	2.00-4.00	2.00-4.00
Iron	60.00-65.00	60.00-65.00

Stainless Steel

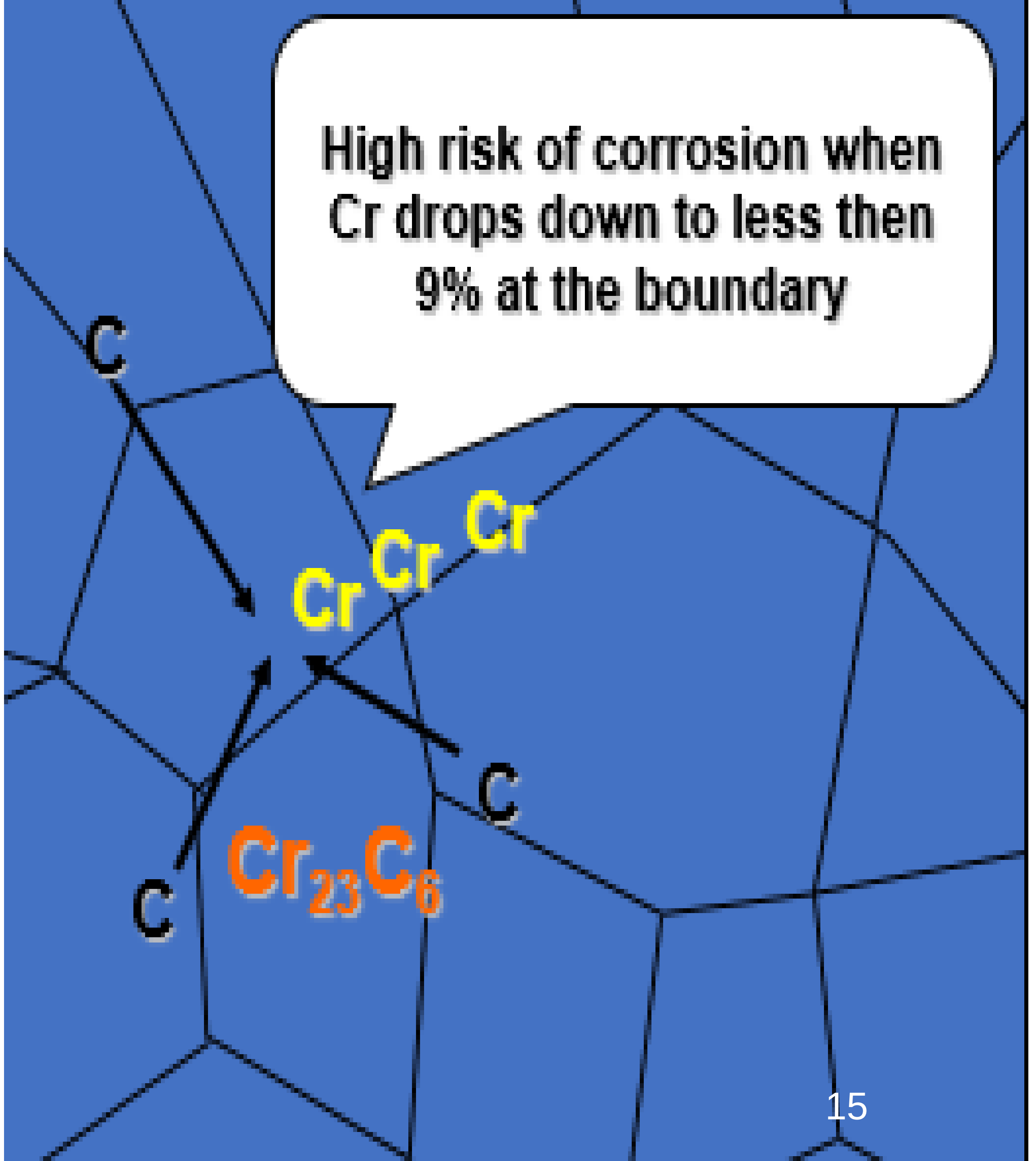
- The most prevalent stainless steel is ***316L***
  - Fe % 60-65 weight
  - Cr % 17-19 weight
  - Ni % 12-14 weight

- **Why is carbon content 0.03 w%:**

✓ Better corrosion-resistance.

- **Why is carbon content reduced?**

✓ For reducing carbide ($Cr_{23}C_6$) forming



Stainless Steel

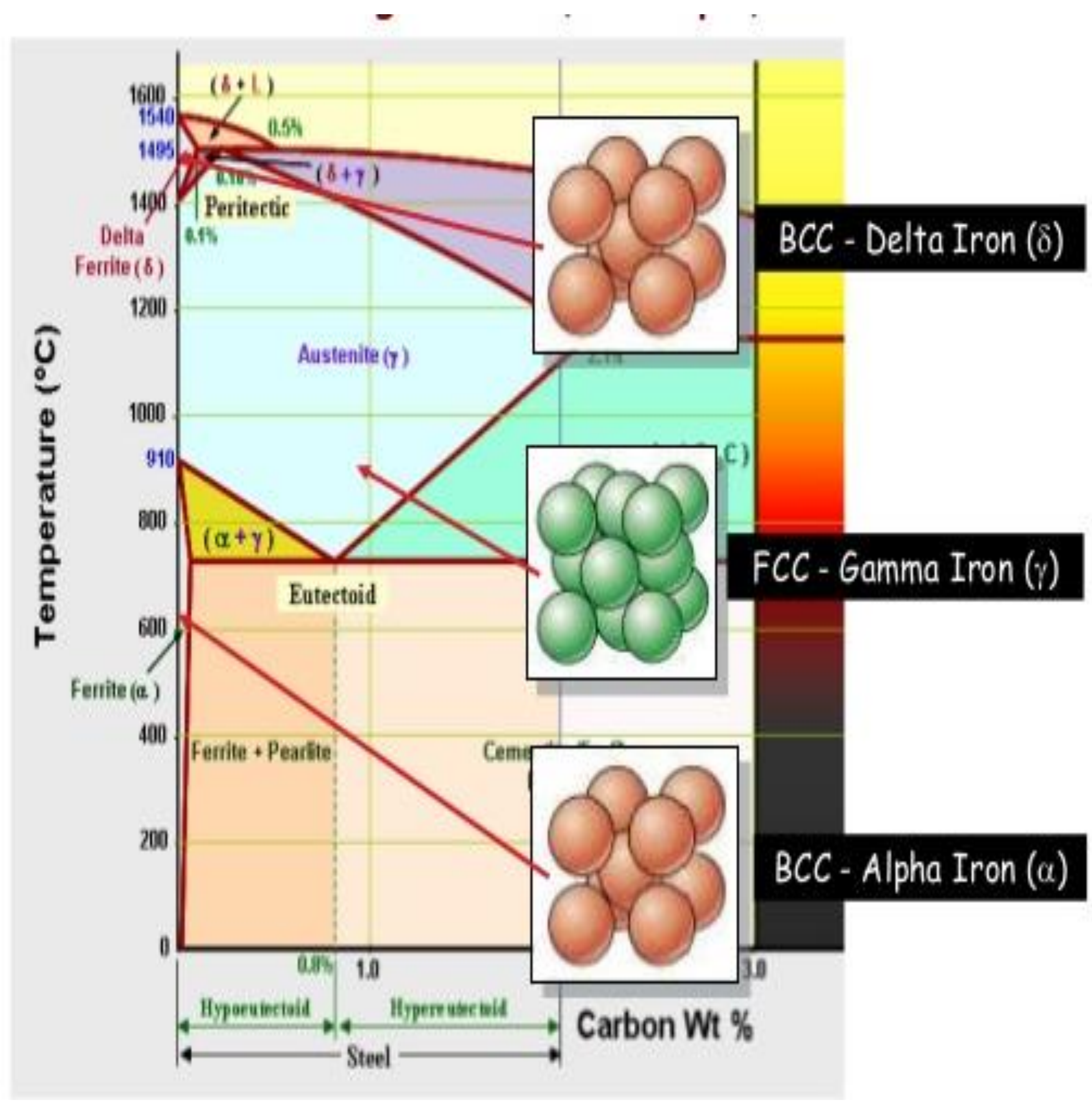
- **Why is chrome added?**

✓Corrosion resistance with high formation of oxides on the surface

- **Why is Ni added?**
  - For increasing durability(FCC)

Good Stainless Steel

- Austenit (FCC)
- None Ferritic(BCC)
- None Carbide
- Particle size <100µm
- Uniform particle size



Allotropes of Iron

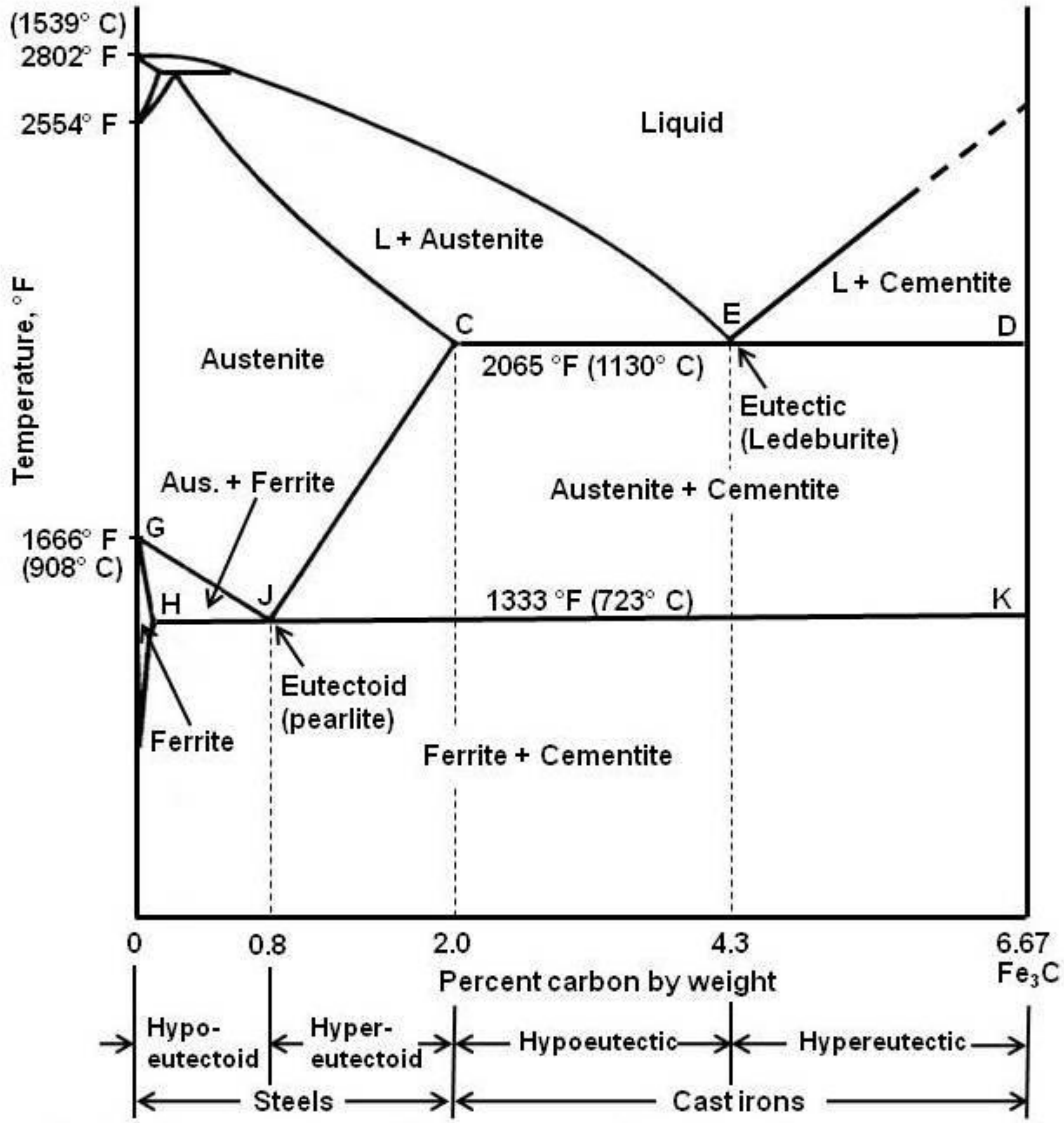
Pure Iron Crystals Structures			
Iron's allotrops	Crystal Structure	Unit Cube Edge Length,A⁰	Time Interval
Alfa Iron (α)	BCC	2,86	<910⁰C
Gama Iron (γ)	FCC	3,65	910-1403⁰C
Delta Iron (δ)	BCC	2,95	1403-1535⁰C

PHASE DIAGRAMS

- A diagram that depicts existence of different phases of a system under equilibrium is termed as *phase diagram*.
- It is actually a collection of solubility limit curves. It is also known as *equilibrium* or *constitutional diagram*.
- Equilibrium phase diagrams represent the relationships between temperature, compositions and the quantities of phases at equilibrium.
- These diagrams *do not* indicate the dynamics when one phase transforms into another.
- Phase diagrams are *classified* according to the number of component present in a particular system.

PHASE DIAGRAMS: Useful Informations

- Important information, useful in materials development and selection, obtainable from a phase diagram:
  - It shows phases present at different compositions and temperatures under slow cooling (equilibrium) conditions.
  - It indicates equilibrium solid solubility of one element/compound in another.
  - It suggests temperature at which an alloy starts to solidify and the range of solidification.
  - It signals the temperature at which different phases start to melt.
  - Amount of each phase in a two-phase mixture can be obtained.



The iron-iron carbide equilibrium diagram labeled with common names

Solid Phases Structures In Fe-Fe_3C(Iron Carbide)

Fe-Fe_3C diagram has 4 solid phase.

- **α ferrite :** Content of solid solution with carbon called ferrite or α ferrite. Maximum dissolution ratıo of carbon: 0,02% .

  -Tensile strength270 MPa

  -Deformation:%40

- **Austenite:** Solid solutıon of carbide or carbon in γ iron.

  Carbon solubility of austenite is at 1148 °C risen to maximum %2,08 and than reduce to %0,8 at 723 ° C.

  -Tensile strength: 1030 MPa

  -Deformation: %10

- **Cementite(iron carbide):** Formula ;Fe_3C . Weight includes %6.67 C % 93.03 Fe.

  -Cementite is hard and fragile.

- **δ Ferrit:** It is the solid solution of carbon in δ iron. The most solid phase.

  -Low tensile strength: 35 MPa

Stainless Steel

Mechanical Properties of Stainless Steel Surgical Implants[a]

Condition	Ultimate tensile strength, min, psi (MPa)	Yield strength (0.2% offset), min, psi (MPa)	Elongation 2 in. (50.8 mm), min, %	Rockwell hardness, max
Grade 1 (type 316)				
Annealed	75,000 (515)	30,000 (205)	40	95 HRB
Cold-finished	90,000 (620)	45,000 (310)	35	—
Cold-worked	125,000 (860)	100,000 (690)	12	300–350
Grade 2 (type 316L)				
Annealed	73,000 (505)	28,000 (195)	40	95 HRB
Cold-finished	88,000 (605)	43,000 (295)	35	—
Cold-worked	125,000 (860)	100,000 (690)	12	—

[a] From *Annual Book of ASTM Standards*, Part 46, American Society for Testing and Materials, Philadelphia, 1980, p. 579.

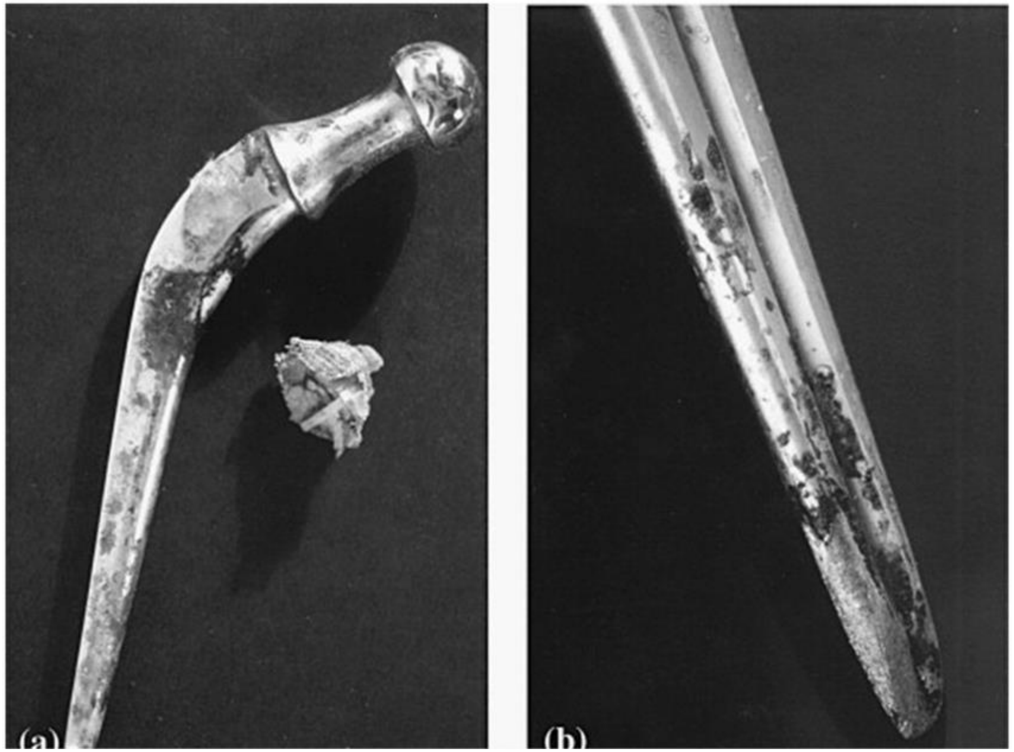
Cold working: It is an mechanical shaping operation that is made under the temperature of metallic metarial's repeat crystilization temperatures.

Annealing: A heat treatment that alters the microstructure of a material causing changes in properties such as strength and hardness and ductility.For steel it is a cold process to make steel less fragile.

Disadvantages of Stainless Steel

- Corrosion in the body(in highly stressed and oxygen-depleting regions)
- Problems in manufacturing

(cold-working)



2. Co-Based Alloys

CoCrMo (dentistry and artificial joints)

CoNiCrMo (knee and hip prosthesis)-high corrosion resistance)

	Commercial Name
1) CoCrMo (F75) Aerospace and biomedical applications	Vitallium, Haynes-Satellite21, Protasul-2, Micrograin-Zimaloy
2) CoCrMo (F799)	Forged Co-Cr-o,Thermomechanical Co-Cr-Mo, FHS
3) CoCrWNi (F90)	Hynes- Stellite 25, Wrought Co-Cr
3) CoNiCrMo(F562)	MP 35 N, Biophase, Protasul-10

Chemical Compositions of Co-Based Alloys[a]

Element	CoCrMo (F75)		CoCrWNi (F90)		CoNiCrMo (F562)	
	Min.	Max.	Min.	Max.	Min.	Max.
Cr	27.0	30.0	19.0	21.0	19.0	21.0
Mo	5.0	7.0	—	—	9.0	10.5
Ni	—	2.5	9.0	11.0	33.0	37.0
Fe	—	0.75	—	3.0	—	1.0
C	—	0.35	0.05	0.15	—	0.025
Si	—	1.00	—	1.00	—	0.15
Mn	—	1.00	—	2.00	—	0.15
W	—	—	14.0	16.0	—	—
P	—	—	—	—	—	0.015
S	—	—	—	—	—	0.010
Ti	—	—	—	—	—	1.0
Co			Balance			
Co	58.9	59.5	45.5	56.2	29	38.8

[a] From *Annual Book of ASTM Standards*, Part 46, American Society for Testing and Materials, Philadelphia, 1980.

COBALT CHROME ALLOYS

Chemical content of CoCr Alloys

CoCrMo	**%**
Co	65
Cr	27.7
Mo	5,5

CoNiCrMo	**%**
Co	35
Ni	33
Cr	19.9
Mo	9.0

Pretty high corrosion resistance

Co-Based Alloys

Mechanical Property Requirements of Co-Based Alloys[a]

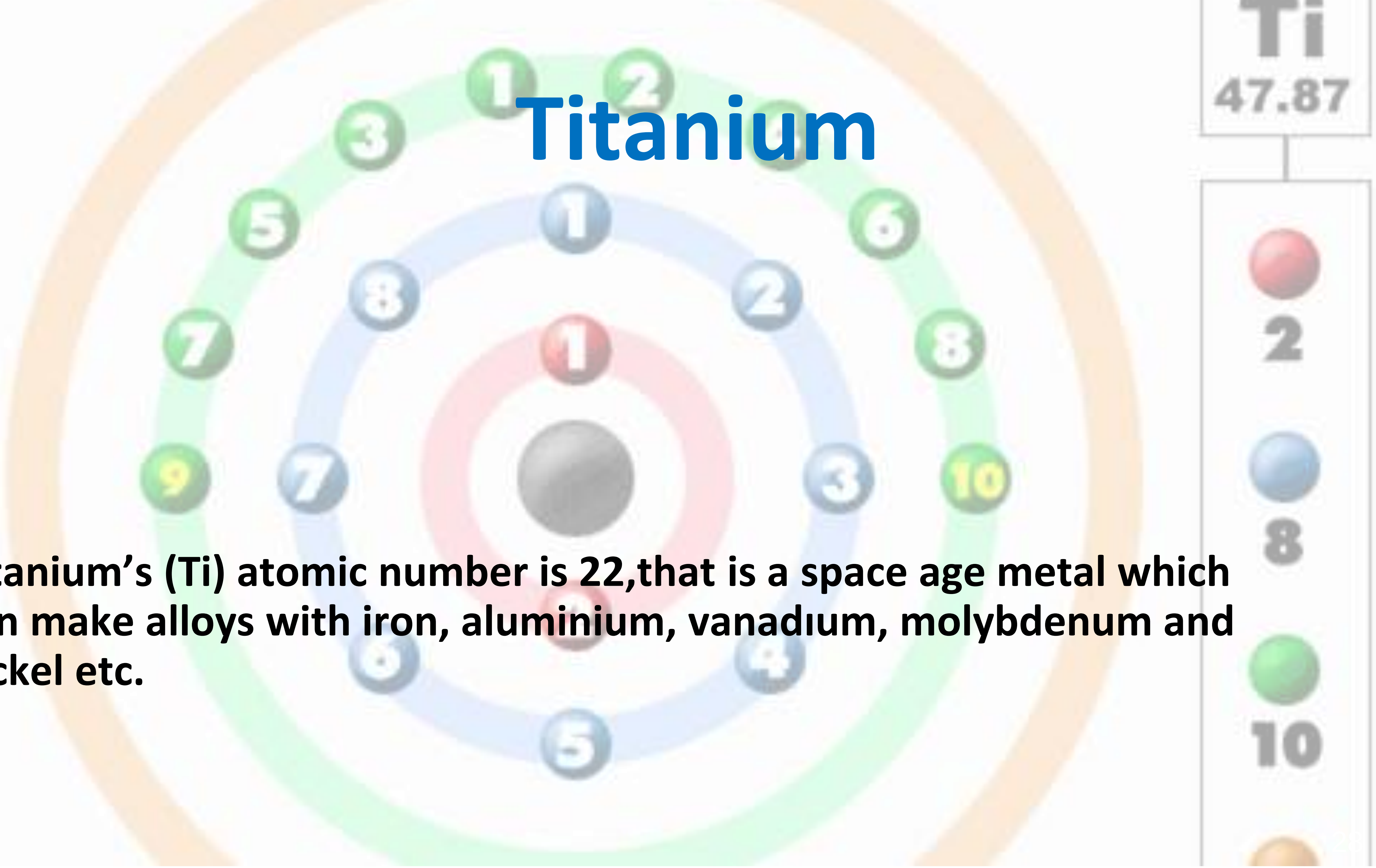
Property	Cast CoCrMo (F76)	Wrought CoCrWNi (F90)	Wrought CoNiCrMo (F562)		
			Solution annealed	Cold worked and aged	Fully annealed
Tensile strength (MPa)	655	860	795–1000	1790	600
Yield strength (0.2% offset) (MPa)	450	310	240–655	1585	276
Elongation (%)	8	10	50.0	8.0	50
Reduction of area (%)	8	—	65.0	35.0	65
Fatigue strength (MPa)[b]	310	—	—	—	340

[a] From *Annual Book of ASTM Standards*, Part 46, American Society for Testing and Materials, Philadelphia, 1980.
[b] Data from M. Semlitsch, "Properties of Wrought CoNiCrMo Alloy Protasul-10, a Highly Corrosion and Fatigue Resistant Implant Material for Joint Endoprostheses," *Eng. Med.*, *9*, 201–207, 1980.

Co-Based Alloys

- Co content of the alloy may be up to 65%.
- Only CoCrMo and CoNiCrMo alloys are extensively used in present time.
- Mo in the alloy forms finer grains which assists to have higher strength
- Difficulty in cold-working
- Young Modulus changing between 220-234 GPa

Titanium



- Titanium's (Ti) atomic number is 22,that is a space age metal which can make alloys with iron, aluminium, vanadıum, molybdenum and nickel etc.

3.Titanium and Titanium Alloys

- In the end of 1930s ımplant applicatıons were happened.
- Light Metal (4.5g/cm$^{3)}$ compared to;

  Staınless Steel (7.9g/cm^3)

  CoNiCrMo (9.2 g/cm^3)
- There are 4 different type of Ti and Ti alloys for surgery applicatıons.
- CP Ti (commercially pure) F67(ASTM)
- Ti6Al4V F136 (ASTM)
- Ti-Al%6 (we.) – V % 4(we.) Ti_6Al_4V(ASTM F136) are mostly used.
- It has impurities like N, O, Fe, H, C and these impurıties provide better durability.
- Ti yield strength is about 110 GPa. This is half value of CoCr alloys.
- Ti alloy’s spesific strength(strength per density) is higher compared to stainless steel and Co alloys.

Advantages and Disadvantages of Titanium and Titanium Alloys

✓Under in vivo conditions TiO_2 formed on the surface increase the corrosion resistance.

✓High Corrosion Resistance ,

✓ High passiving ratıo,

✓ Formation of TiO_2 as damage on surface,

✓ High resistance to chemical attacks ,

✓ Biocompatible Young Modulus properties.

✓Its Young Modulus is compatible with bone (Low Young Modulus-120 GPA)

✓By this properties Titanium is wanted as bone internal implants.

✓Ti has low yield stress, this is desired for bone plates and similar applicatıons.

✓Ti alloys only basic disadvantage is being fairly expensive.

Titanium and Titanium Alloys

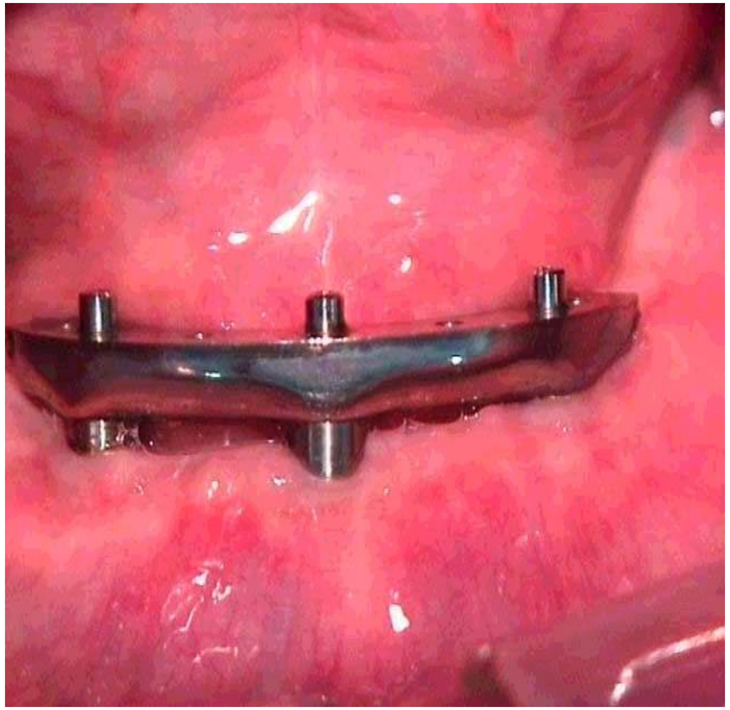
Chemical Compositions of Titanium and Its Alloy (ASTM F67, F136)

Element	Grade 1	Grade 2	Grade 3	Grade 4	Ti6Al4V[a]
Nitrogen	0.03[b]	0.03	0.05	0.05	0.05
Carbon	0.10	0.10	0.10	0.10	0.08
Hydrogen	0.015	0.015	0.015	0.015	0.0125
Iron	0.20	0.30	0.30	0.50	0.25
Oxygen	0.18	0.25	0.35	0.40	0.13
Titanium			Balance		

[a] Aluminum 6.00 wt% (5.50–6.50), vanadium 4.00 wt% (3.50–4.50), and other elements 0.1 wt% maximum or 0.4 wt% total.

[b] All are maximum allowable weight percent.

Titanium and Titanium Alloys



Ti6Al4V

	Component %
nitrogen	0.05
carbon	0.08
hydrogen	0.0125
iron	0.25
oxygen	0.13
titanium	~90
aluminum	5.5-6.5
vanadium	3.5-4.5

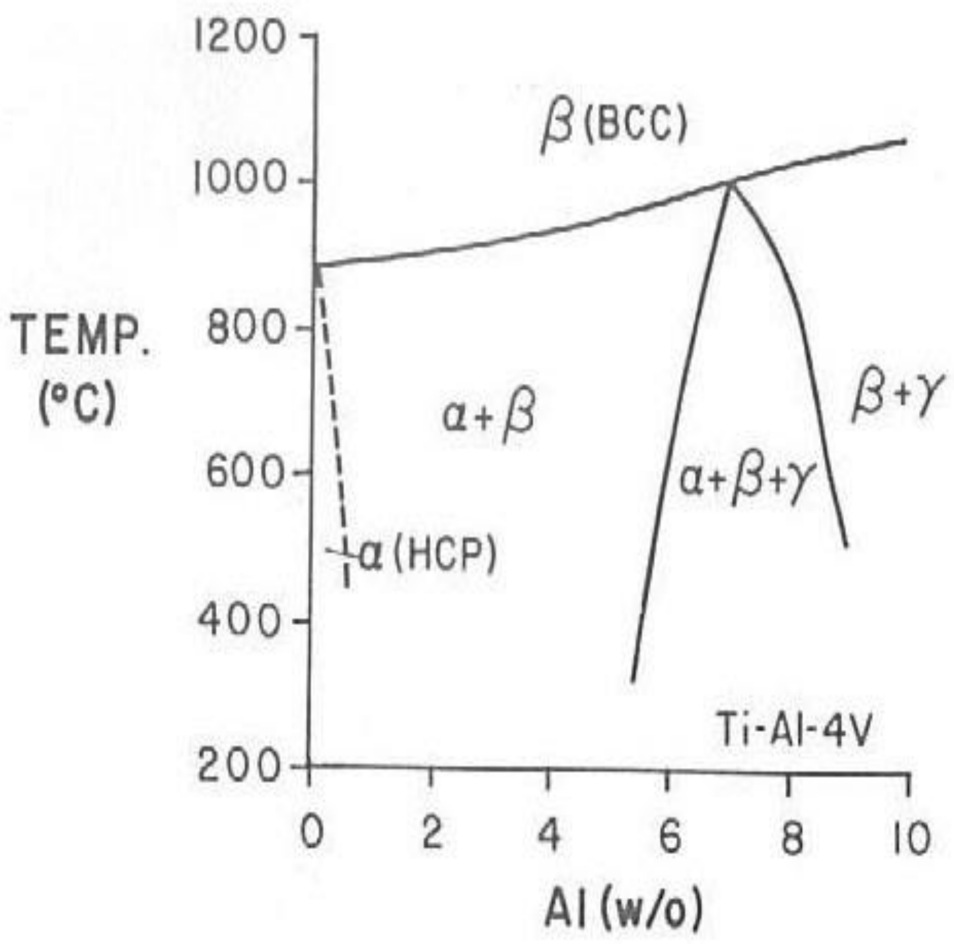
Titanium and Titanium Alloys

Titanyum is an allotropic material.It’s a Hexagor close-packed structure .

Till 882° C (alfa –Ti) -Hexagonal close-packed

Above 882° C turns BCC system and beta-Ti strucutre.

Al stabilizes alfa phase (Easy to weld with othe materials) and V stabilizes beta phase.



Mechanical Properties of Titanium and Titanium Alloys

Property	Degree 1	Degree 2	Degree3	Degree4	Ti6Al4V	Ti13Nb13Zr
Tensile Stress, Mpa	240	345	450	555	860	1030
Yield Stress, Mpa	170	275	380	485	795	900
Extension (%)	24	20	18	15	10	15

Titanium and Titanium Alloys

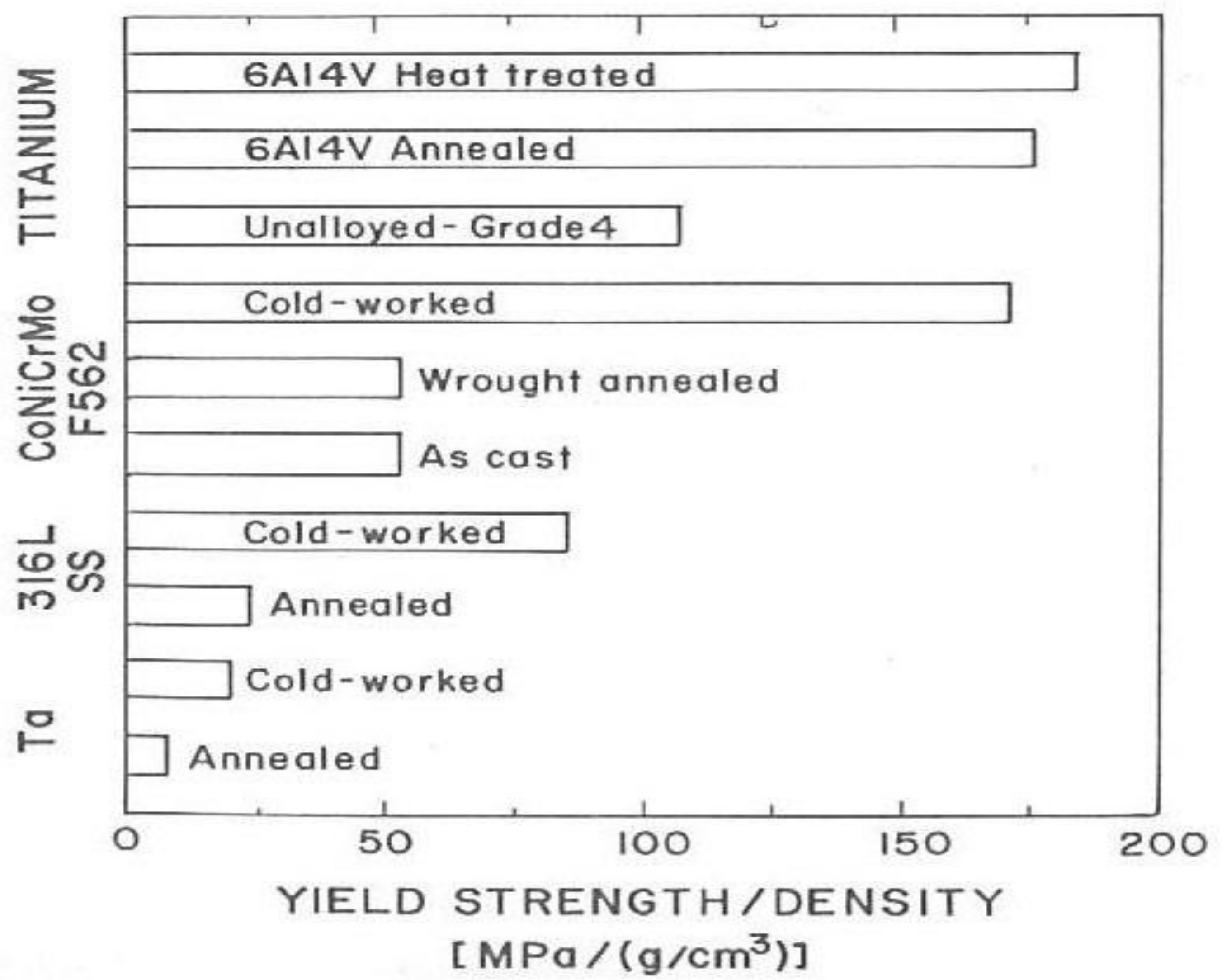
- Commercial type(99.2 %pure) titanium has about 434 MPa tensile strength.This is equal to a lot of steel alloys tensile strength but titanium is 45% ligther. Pure titanium is weak in terms of mechanical properties . It is used as porosis covering on prothesis.
- Porosis coverings;

  -Hip prothesis

  -Dental implants

  -It provides bone growth in the porosis of covering.

Titanium and Titanium Alloys



- **Spesific strength of Ti and its alloy give the best result.**

Ti-Ni Alloys

- They are shape memory metal alloys.
- They can turn their real shape and size with suitable heat treatment.

  They have 2 different shape or cristal structure above critical conversion temperature.
- Ti-Ni alloys shows shape memory structure at near room temperature.If it is softly deformed(plastic deformation) at a temperature under conversion temperature when temperature rises it will turn to its orijinal shape.
- These materials has one way shape memory only when they heated,when they colded again they called as two way shape memory materials.
- They have big commercial value.
- Applicatıons: Dental implant, vascular connection in cranial,muscles for artıfıcıal heart and ortopedic prothesis.

4.Dental Metals

- **Amalgam**:Is an alloy which contains Hg(mercury) and used for tooth filling material because of its liquid phase at room temperature.
  - Hg reacts with other metals (Ag,Sn etc.) and hardens in time.
  - Solid alloy;
    65% Ag
    <29% Sn
    6% Cu, 2% Zn, 3% Hg
  - The 25% total shrinkage happens in an hour
  - Tension finished in one day.

Gold and Gold Alloys

- Gold and gold alloys are useful in dentistry because of their:

  ✓Durability ,
  ✓Stability
  ✓Corrosion resistance

- Its mechanical properties are better than pure gold so casting will be applied.

Alloys include 75% gold and noble metals(the rest) .

-Cu risens resistance.

-Platin has same effect. (max 4%, it complicates manufacturing of alloys at melting temperature)

- Adding Zn reduces melting point.

Including more than 83% gold:soft alloy-filling material

Including less than 83% gold:hard alloy-covering material

5.Other Metals

- Tantalum is a biocompatible material but due to its poor mechanical properties and high density (16.6 g/cm3) it is restricted to be used in a few applicatıons.
  - ✓ Wire sutures
  - ✓Radioisotope for bladder tumors.
- Platinum and other noble metals are extremely corrosion resistant but they have poor mechanical properties.
- They are mostly used as alloys for electrodes such as pacemaker tips.

Advantages & Disadvantages of Metallic Biomaterials

Advantages

- Hard
- Ductile (Easily shaped)
- Strong

Disadvantages

- Corrosion
- İntense
- Problems in manufacturing
- Low biocompatible

Mechanical Properties of Implant Materials

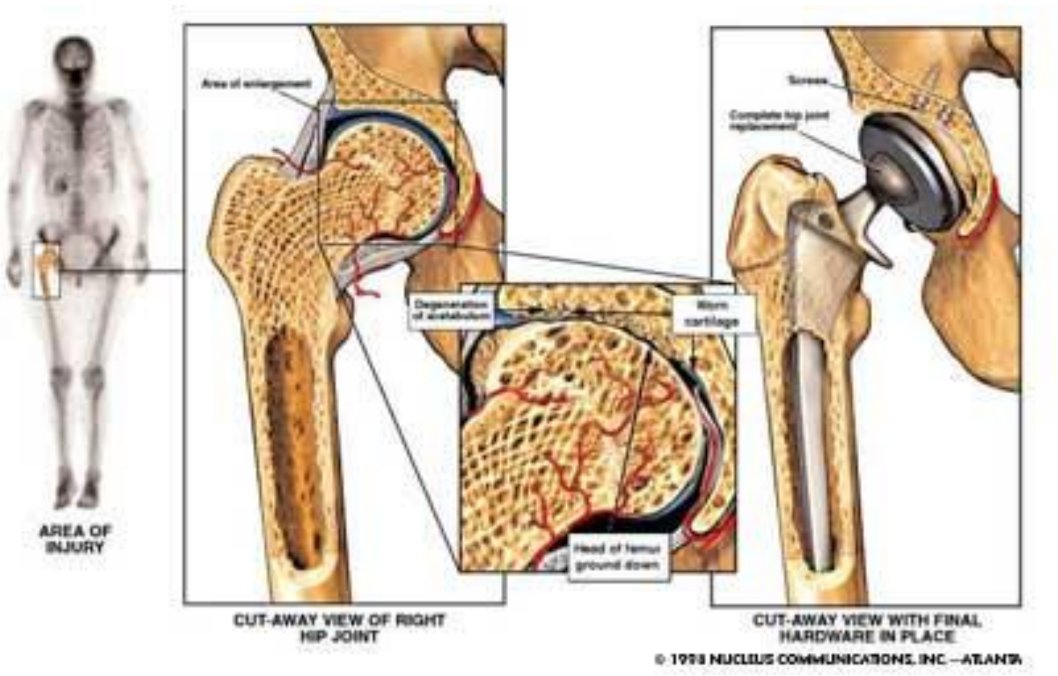
	Steel	Titanium	Ceramic	Composite
Ultimate Strength	++	+	++	++
Yield Stress	+	++	-	+
Stiffness	++	+	+++	+
Ductility	+	++	-	+
Wear resistance	+	-	+++	+
Corrosion Resistance	+	++	+++	++
Cost	++	-	-	+

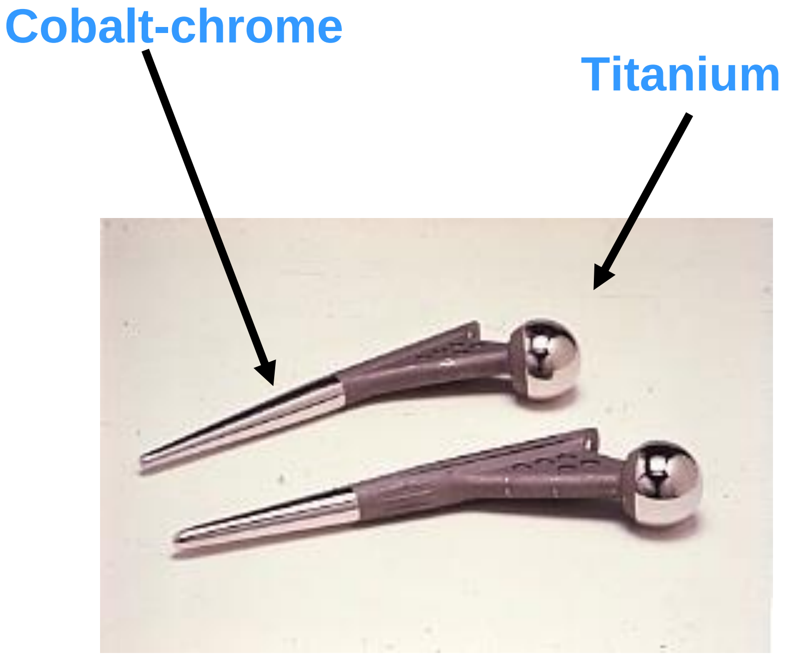
Mechanical Properties of Implant Materials

Tissue/Material	Young's Modulus (GPa)	Yield Strength (MPa)	Compression Strength (MPa)	Tensile Strength (MPa)
Cortical bone	7–30		100–230	164–240
Cancellous bone	0.01–3.0		2–12	
Ti_6Al_4V (casted)	114	760–880		895–930
Ti_6Al_4V (wrought)	114	827–1103	896–1172	860–965
Stainless steel 316L	193	170–310	480–620	540–1000
CoCrMo Alloy	240	500–1500		900–1540
Mg (99.9%, casted)	41	21	40	87
Mg (99.9%, wrought)	41	100	100–140	180

Total Hip Replacement

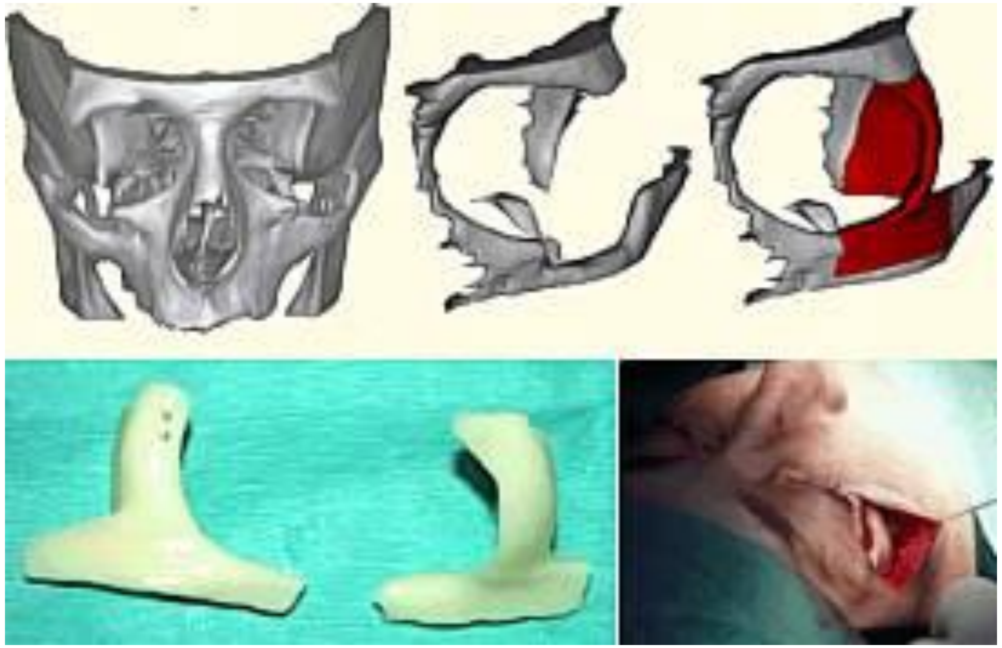
The metal parts of the implant are manufactured of Cobalt-chrome or Titanium. There is no agreement as to which is better. In some circumstances, each has advantages over the other. Cobalt-chrome has been used in the manufacture of orthopedic implants for 65 years, and is extremely well tolerated by the body. The AML stem is made of Cobalt-chrome. The socket is made of Titanium.





Oral and Maxillofacial Surgery

Custom made maxillofacial implants (Titanium)

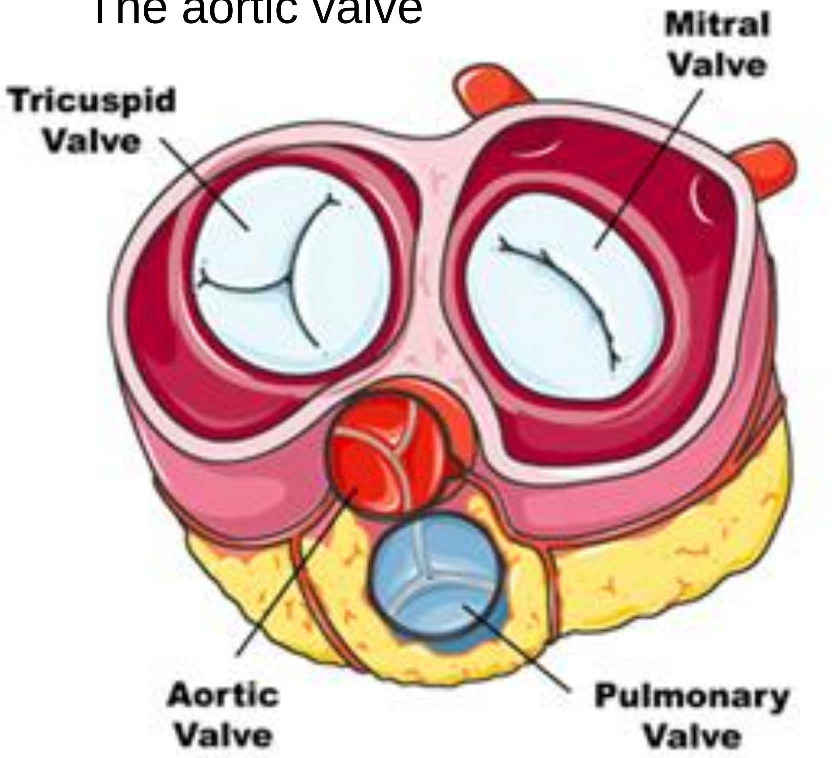


Cardiovascular Surgery

The heart is made up of four chambers, two on the right and two on the left. The chambers are known as atria and ventricles. Each side of the heart is composed of one atrium and one ventricle. The atria are the receiving chambers of the heart, receiving blood flowing back to the heart. The ventricles are the chambers of the heart that pump the blood out of the heart.

The valves of the heart are located within the chambers of the heart and are critical to the proper flow of blood through the heart. All of the valves, when functioning normally, act as one-way valves, allowing blood to flow either from one chamber to another, or allowing blood to flow out of the heart, in only one direction. The valves control the flow of blood through the heart by opening and closing during the contractions of the heart. The opening and closing functions of the valves are controlled by pressure differences generated within the heart, as well as some muscles located within the heart.

The four valves are known as:
The tricuspid valve
The pulmonic or pulmonary valve
The mitral valve
The aortic valve



A superior view of the heart showing the four valves. The

Problems with Heart Valves

If a valve doesn't open all the way, less blood moves through to the next chamber. If a valve doesn't close tightly, blood may leak backward. These problems may mean that the heart must work harder to pump the same amount of blood. Or, blood may back up in the lungs or body because it's not moving through the heart as it should.

Problems Opening

Stenosis occurs when a valve doesn't open fully. The valve may have become hardened or stiff with calcium deposits or scarring. So, it's hard to push open. Blood has to flow through a smaller opening, so less blood gets through the valve into the next chamber.

Problems Closing

Insufficiency (also called regurgitation) results when the valve doesn't close tightly. The valve's supportive structures may be loose or torn. Or, the valve itself may have stretched or thinned. Blood may then leak back the wrong way through the valve.

Heart Valve Surgery

•During heart valve surgery, one or more valves are repaired or replaced. Repair means that the valve is mended to help it work better. Replacement means your diseased valve is removed and a new valve is inserted in its place

Heart Valve Surgery

Replacing a Valve

- If a valve can't be repaired, it may be replaced with a prosthetic valve. Two kinds of prosthetic heart valves are available:

•**1.Mechanical valves** are created from man-made materials. Lifetime therapy with an anticoagulant (sometimes called a "blood thinner") is needed when these types of valves are used. This medication prevents blood clots from forming on or around the valve.

•**2.Biological (tissue) valves** are taken from pig, cow, or human donors. These valves don't last as long as mechanical valves. But when tissue valves are used, long-term use of an anticoagulant often isn't needed.

Heart Valve Surgery: Materials

- One of the major design considerations of any object to be implanted in the body is the **choice of materials.** Those used must be able to withstand the harsh and corrosive environment of the body, they must be inert, and they must be biocompatible so they do not elicit a rejection response.
- Particularly in heart valves, factors to consider are: how will the material impact hemodynamics, will it cause platelet aggregation or thrombosis, will the device damage blood cells, and are the mechanical properties sufficient to withstand the repeated cycles the valve will encounter in its lifetime.
- Many different materials are used in the creation of artificial heart valves. Metal alloys consisting of stainless steel or titanium are often used to give mechanical strength and for their corrosion resistance properties. The struts on some leaflet valves and the cage on caged-ball models are commonly made of metal alloys due to their strength and durability requirements.

Heart Valve Surgery: Materials

- Pyrolytic carbon is another valuable material for its strength and its ability to prevent clotting. This material has a similar structure to graphite and was originally developed for applications in the nuclear fuel industry as a coating for nuclear fuel particles. However, it was soon realized that pyrolytic carbon had biomedical applications. It is biocompatible, thromboresistant, resistant to wear, and has high strength and durability. It is able to stand up to the repeated opening and closing cycles it must endure when used in a mechanical heart valve. It is commonly used for the inner orifice and the leaflets of bileaflet valves. The ATS Bi-leaflet valve shown here has leaflets made of pyrolytic carbon.

Heart Valve Surgery: Materials

A material often used for the suture ring (which is used to attach the valve to the body) is **Dacron.** Dacron is a long chain polyester made from ethylene glycol and terephthalic acid. It is a synthetic fiber that has many uses in industry, including thermal insulation and sails for boats. In biomedical applications this material is also commonly used for vascular grafts. It is relatively inert and its porosity allows tissue in growth.

Another material that is commonly used for the suture ring is **Teflon**. Teflon is used in many medical applications because of its signature low coefficient of friction. Teflon is relatively inert and highly biocompatible. As with Dacron it is often used for vascular grafts.

THE HISTORY OF HEART VALVE

- The first mechanical heart valve was implanted in 1952. This first valve was **a ball valve** and it was designed by Dr. Charles Hufnagel. This valve was implanted in a 30-year-old woman who could lead a normal life after the surgery.
- The downside to this design was that it could only be placed in the descending aorta instead of the heart itself. For this reason it did not fully correct the valve problem, only alleviate the symptoms. However it was a significant achievement because it proved that synthetic materials could be used to create heart valves.
- In 1960, a new type of valve was successfully implanted: the **Starr-Edwards ball valve**. This valve was a modification of Hufnagel's original valve. The ball of the valve was slightly smaller and caged from both sides so it could be inserted into the heart itself.

From top to bottom: a caged ball mechanical valve, a tilting disc mechanical valve, Single Leaflet Valve, and a bileaflet valve

HEART VALVE: TYPES

- **Tilting discs** were introduced in the later 1960s. These valves were a great improvement over the ball designs. They allowed blood to flow in a more natural way while reducing damage to blood cells from mechanical forces. Unfortunately, the struts of these valves tended to fracture from fatigue over time.
- **Bileaflet valves** were introduced in 1979. Blood flows directly through the center of these valves (like in an intact heart valve) which makes these valves superior to other designs. The major drawback of this design is that it allows some backflow. A vast majority of mechanical heart valves used today have this design.

HEART VALVE: TYPES

- **<u>Caged Ball Valve:</u>**

-Very simple design, only moving part is the ball.

-Poor hemodynamics, blood must flow around the ball making the heart work harder

-Higher rate of thromboembolism

- **<u>Tilting Disc Valve:</u>**

-Improved hemodyanamics

-Lower rates of thromboembolism

- In 1979 a new version of the tilting disc valve, the **<u>Bjork-Shiley convexo-concave</u>** model, shown here, was introduced. This was an attempt to improve blood flow characteristics by increasing the angle at which the leaflet opened. This valve encountered major structural problems. The struts tended to fracture causing the disc to be released into the patient's bloodstream causing a major embolism. This valve was removed from the market in 1986

HEART VALVES: TYPES

- **Bi-Leaflet Valves:**

-Most implanted valve today

-Most improved hemodynamics

-Still a risk for thrombosis

-Allow some backflow

1-Mechanic Heart Valves

- ✓In cage; stainless steel, stellite-21(cobalt-chromium-molibden,nikel alloy), Titanium, pyrolitic carbon,
- ✓ wall coated ;dacron,teflon,polyproplene,disc
- ✓Ball ; silastic(silicon ve lastic mixture), 2% silastic with Ba,delrin,stellite-21,pyrolitic carbon,hifax(very high molecular weight poliethylene)

2. Tissue Heart Valves

Heart valves can be replaced with mechanical heart valves or tissue heart valves. Mechanical heart valves are made from synthetic materials that can be put into the body.

There are several designs of mechanical heart valves that all operate differently. Tissue heart valves are real heart valves taken from another person or even other animals. Tissue heart valves are commonly taken or made from porcine and bovine heart tissues. Mechanical heart valves can be superior to tissue valves because they will not wear out over time.

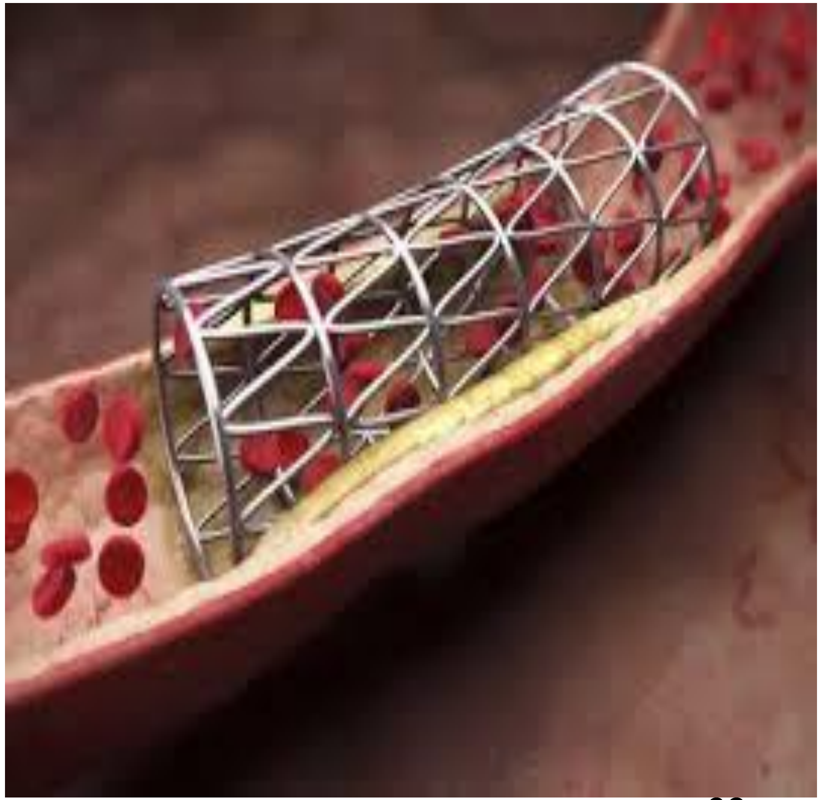
An aortic valve taken from a pig designed for human implantation

2. Tissue Heart Valves

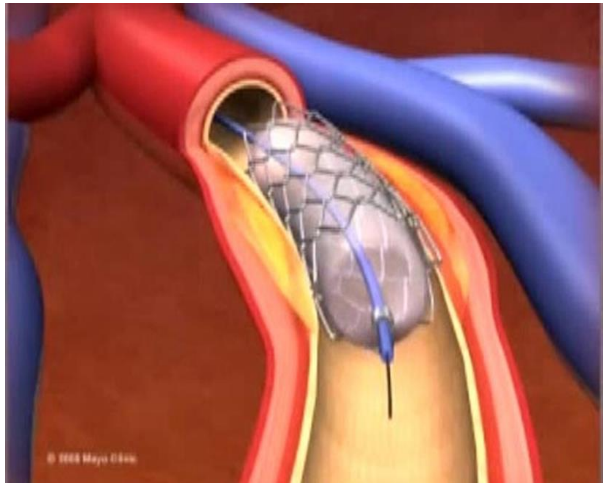
- Otolog
  - Facia Lata
  - Pulmoner
- Homolog
  - Aortik Homogrefts
  - Durameter
- Heterolog
  - Bovine aort
  - Pig aort
  - Cattle perikard

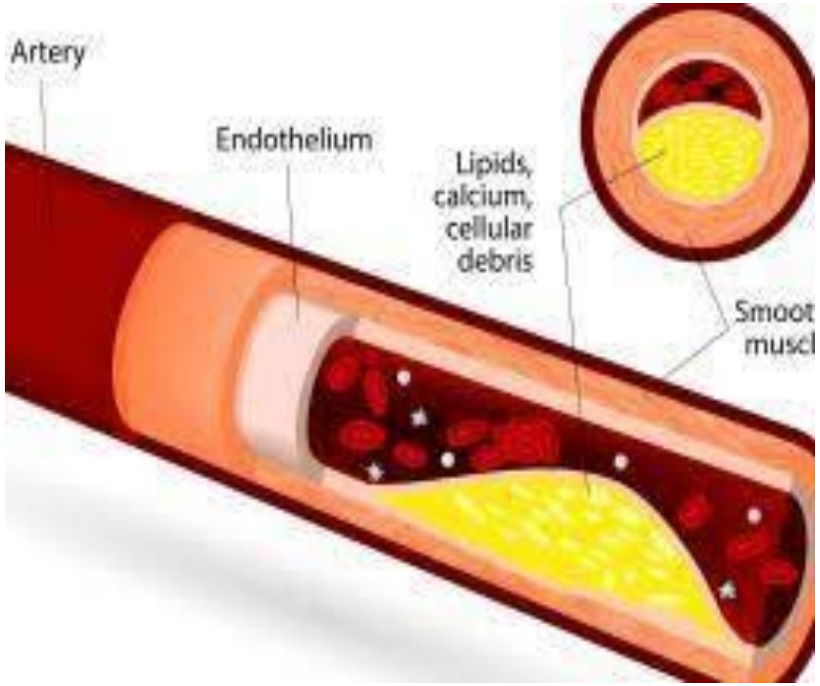
Stents

- Stents are generally used instead of – or along with – angioplasty.
- It is collapsed into a small diameter and put over a balloon catheter.
- It is moved into the area of the blockage.
- When the balloon is inflated, the stent expands, locks in place and forms a scaffold.
- Stents need to be resistant and elastic to be able to fulfill the said procedure.



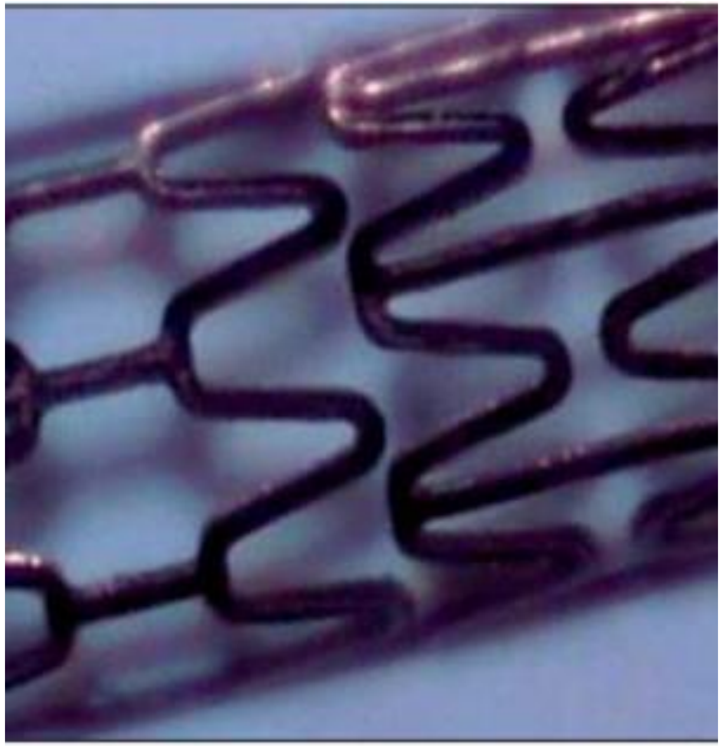
- Stents may be used with balloon and guiding catheter to treat cardiovascular blockage caused by Arteriosclerosis.





Stents:Design Requirements

A cardiovascular stent must be:



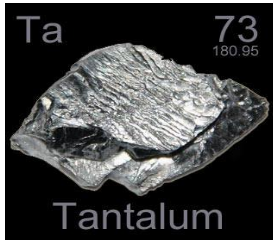
- ✓ **FLEXIBLE**: Flexibility is primarily dependent on mechanical configuration of the stent,
- ✓ **THE YIELD STRESS** of the material should be **high** enough to avoid or minimize plastic deformation.
- ✓On the other hand the yield stress of the stent material should be low enough to allow balloon expansion of the stent to occur at pressures that are low enough to avoid vessel damage.
- ✓fatigue resistance of the expanded stent must be high.
- ✓The design process for stents typically involves balancing conflicting mechanical requirements.

Lifetime of a Stent

- A metal stent actually is permanent; patient body's endothelial cells grow over the metal implant, incorporating the device into the arterial wall for the rest of patient's life. **However, sometimes stents can't permanently remain effective in treating vascular blockage**. In a minority of cases(less than 10% of cases with 2nd generation Drug-Eluting Stents), a stent can become reblocked, called **'in-stent restenosis'**

- If this happens and stended artery closes up, artery should be re-opened the blocked stent with a balloon or placed another stent inside the bloked stent. In a small number of cases, the stent itself may become fractured or may pull away from the artery wall which may be a cause of restenosis or possibly stent thrombosis, blood clotting inside the stent.

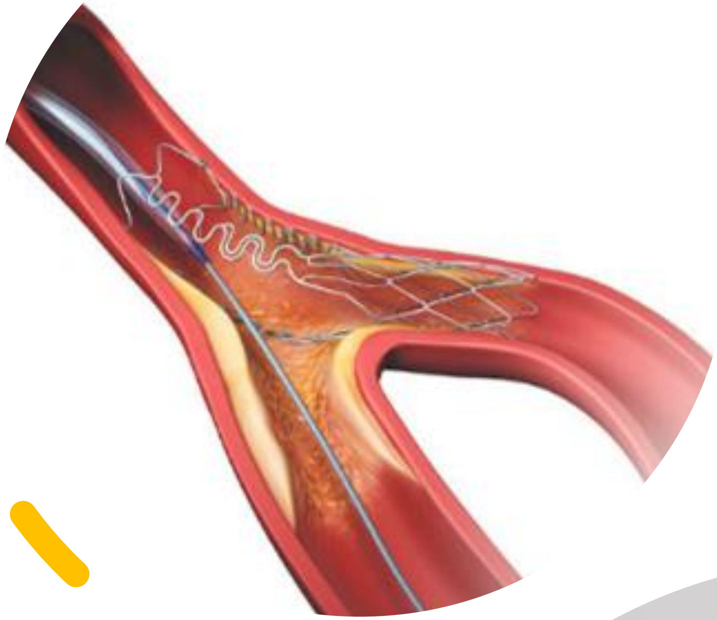
Stents: Materials



- Cobalt Chromium,
- Nitinol (Nickel- Titanium),
- Tantalum,
- 316 L Stainless Steel

1. Cobalt Chromium Stents

This material is stronger and more radiopaque than stainless steel, so a cobalt chromium stent can have similar strength and visibility as a conventional stainless steel stent with struts that are only 0.0032" thick.

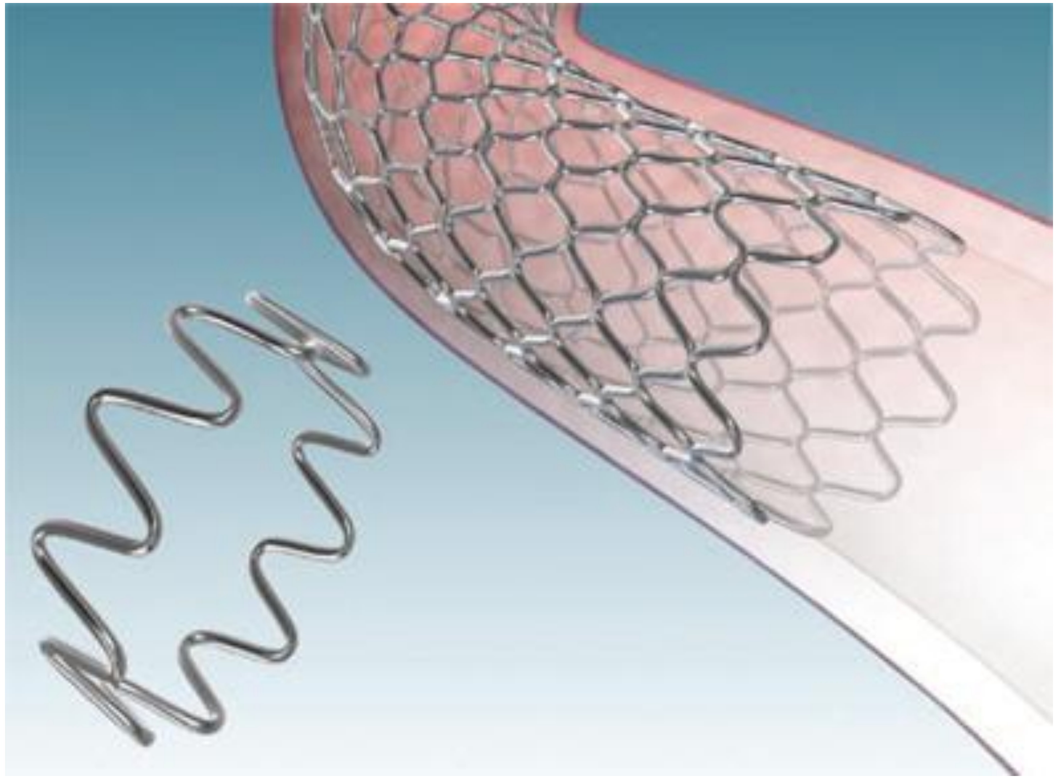


2.Ni-Ti stent alloys

- Because of Ni-Ti's unique super-elastic and shape memory properties, a stent of this alloy.. market. By taking advantage of Ni-Ti's shape memory, the thermally activated stent becomes selfexpanding and there is no need for a balloon to deploy the stent, as with stainless steel designs.

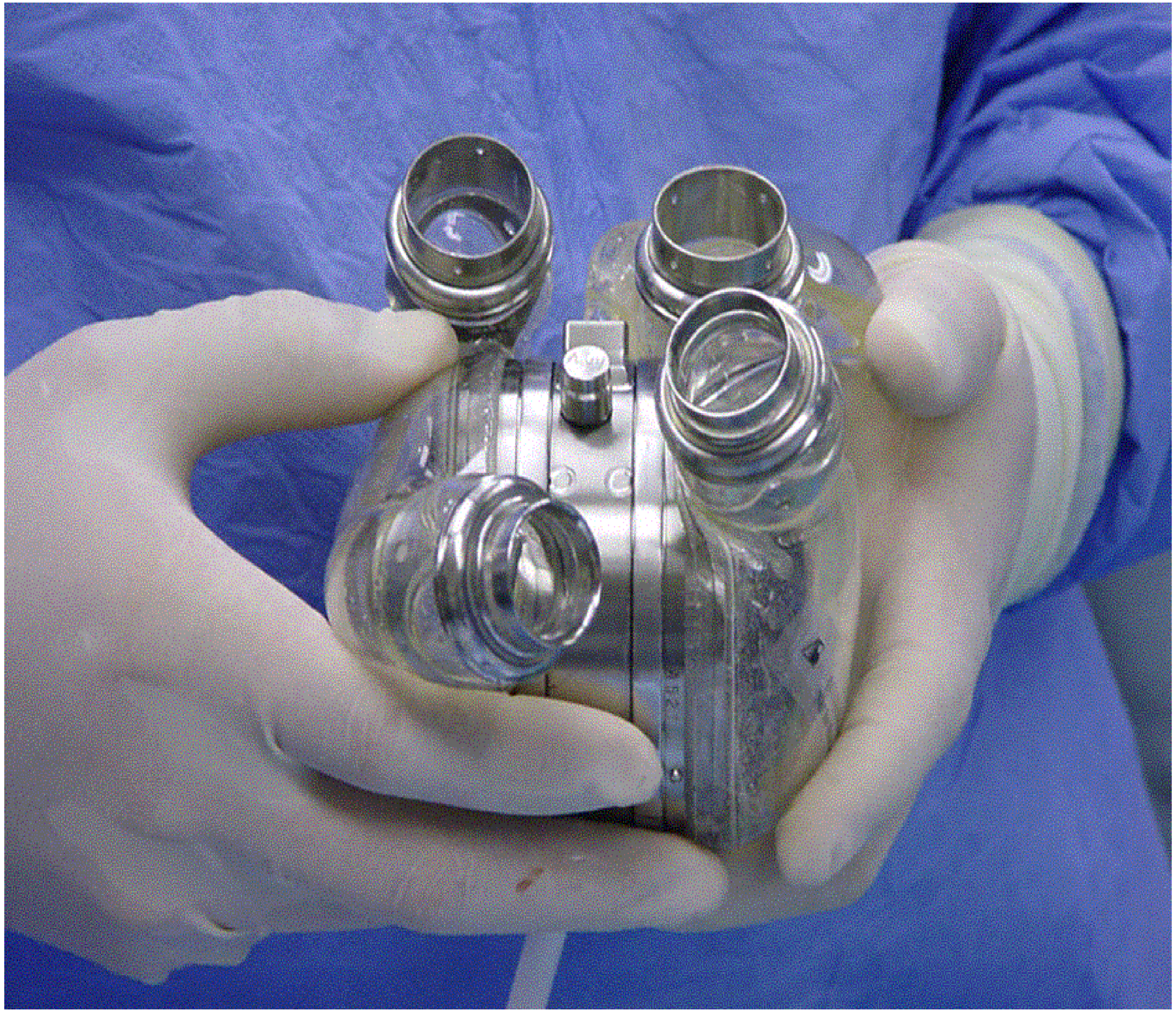
3.Stainless Steel Stents

- Stainless steels are regularly used by the medical, chemical, and pharmaceutical industries because of their *corrosion resistance, biocompatibility, and ability to withstand elevated temperatures*. They offer *superior corrosion resistance* compared with other steels and aluminum. Compared with titanium and cobalt alloys, stainless steels are *readily available* and *relatively inexpensive.*



Tantalum has a better radiopacity than steel

ARTIFICIAL HEART



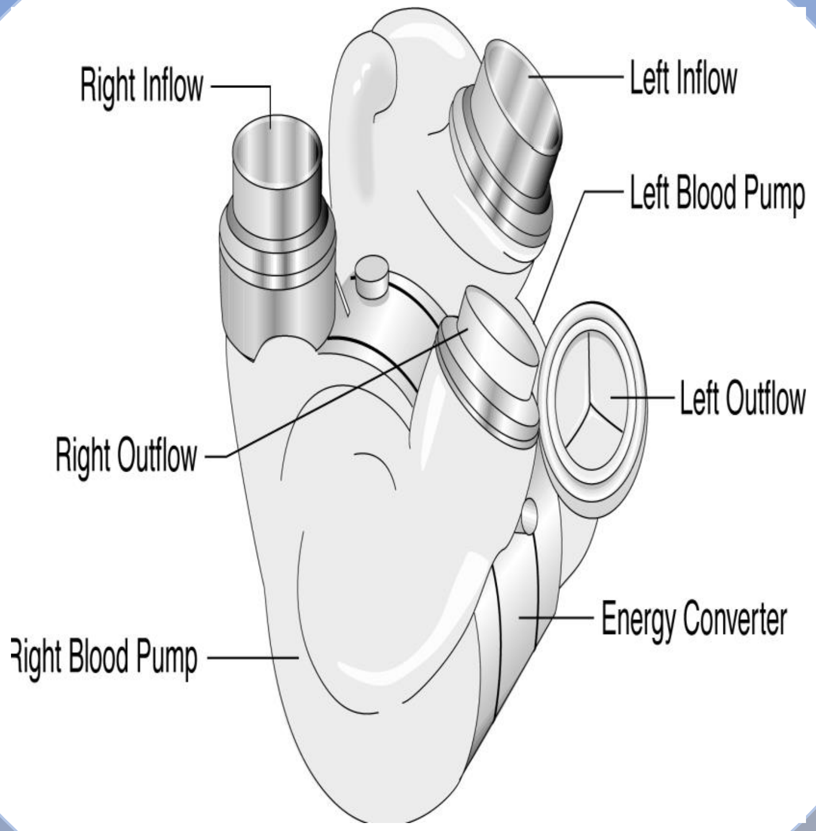
ABIOCOR TYK

- Abiocor system is a device that replaces **artificial heart instead of natural** heart.o
- **The AbioCor is the first artificial heart to be used in nearly two decades** (2001)

- If the patient have severe heart failure and his heart can' t pump enough blood around his body to keep it working, he may need an artificial heart.

AbioCor II

AbioCor Implantable Replacement Heart

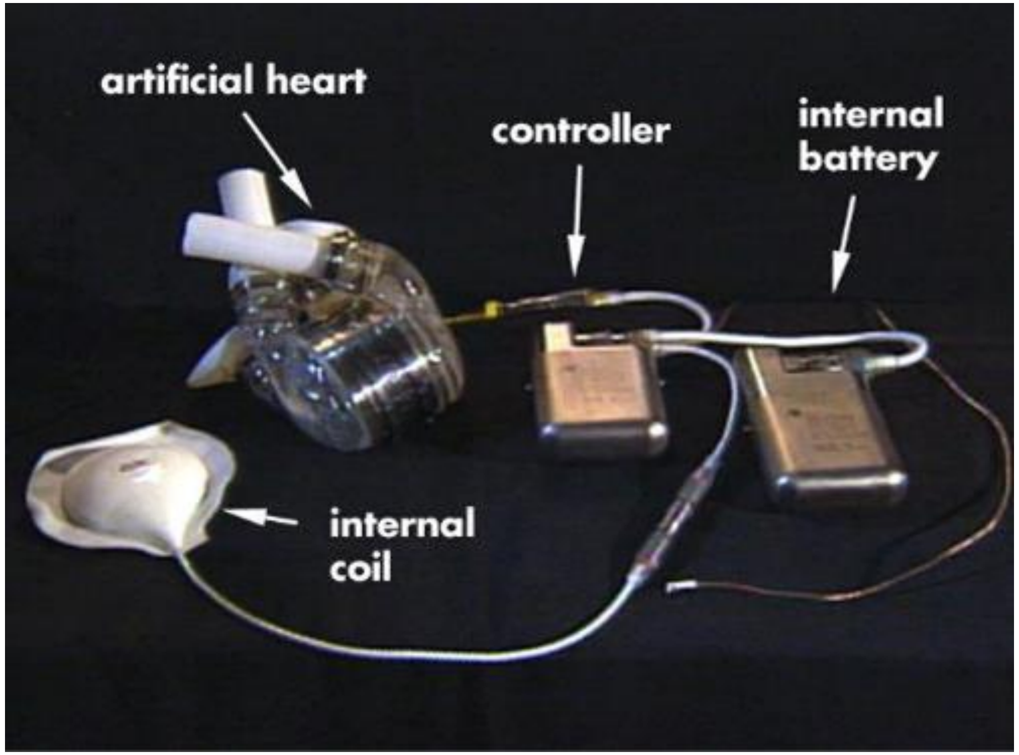


ABIOCOR TYK

- The AbioCor is primarily made of titanium and a special and specific polyether-based polyurethane plastic, Angioflex(TM), developed by ABIOMED, tested to be a dependable substance, safe for contact with blood. Due to the proven flexibility and durability (withstands beating 100000 times a day, the approximate number of beats per day of the natural heart) moving parts such as the valves and hydraulic membranes are manufactured from Angioflex. The AbioCor is designed to have relatively few moving parts and its smooth plastic construction and unique design are specifically engineered to reduce the likelihood of damage to blood cells and to prevent clotting.

ABIOCOR TYK

- Equipped with an internal motor, the AbioCor is able to move blood through the lungs and to the rest of the body, simulating the rhythm of a heartbeat. The AbioCor consists of an internal thoracic unit, an internal rechargeable battery, an internal miniaturized electronics package and an external battery pack. its internal battery can be recharged with a transduction device that sends power through the skin. The internal battery lasts for a half hour, and a wearable external battery pack lasts for four hours.



Pacemaker

- Pacemaker is a medical device that uses electrical impulses, delivered by electrodes contracting the heart muscles, to regulate the beating of the heart. The primary purpose of a pacemaker is to maintain an adequate heart rate.
- Pacemaker was introduced in 1952.

- There are about 3 million people worldwide with pacemakers
- Each year 600 000 pacemakers are implanted.

Pacemaker :Parts

A pacemaker system
two part electrical system comprised of a pulse generator one or two leads. The pulse generator is a small implantable device that is approximately the size of four stacked half dollar coins. Inside its metal shell, the pulse generator contains the electronic circuitry, which continuously analyzes the heart's rhythm and regulates the pacemaker function, as well as a lithium battery that provides the power source for the device.

The leads are thin insulated wires that are implanted inside the heart muscle in either the right atria, the right ventricle, or in both chambers. The leads receive electrical information from the heart (sensing) as well as transmit electrical impulses to the heart to stimulate it to beat (packing).