

Module4

- Soft tissue

Percutaneous Devices

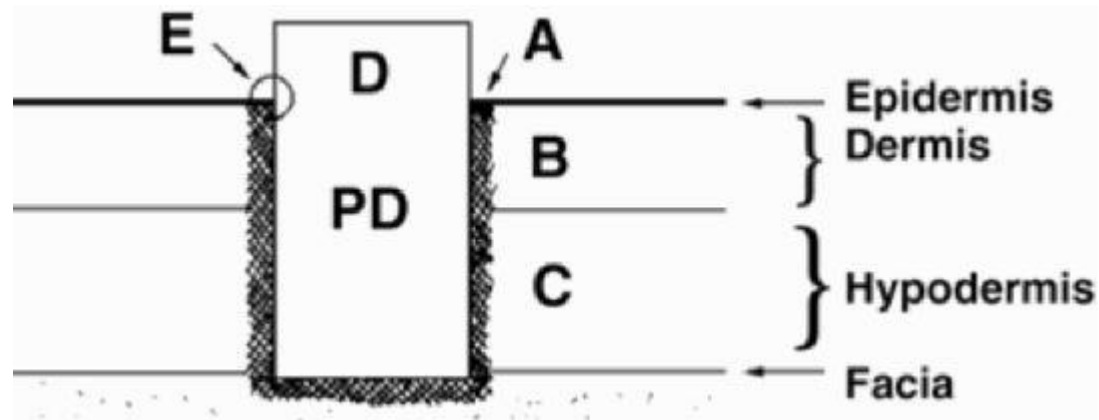
- Main Problems during implant use:
 1. although initial attachment of the tissue into the interstices of the implant surface occurs, it cannot be maintained for a long period of time, since the dermal tissue cells turn over continuously and dynamically.
 2. downgrowth of epithelium around the implant (extrusion) or overgrowth of implant (invagination) occurs.
 3. any openings large enough for bacteria to infiltrate may result in infection even though initially a complete sealing between skin and implant is achieved.

Many variables and factors are involved in the development of percutaneous devices

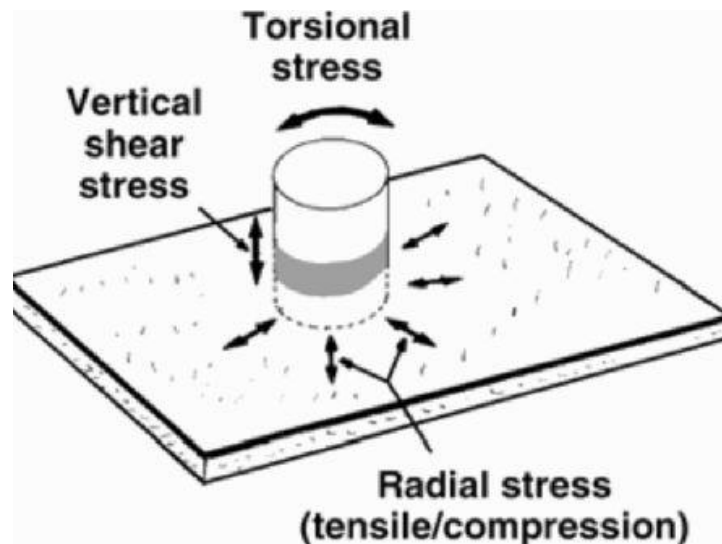
- These are:
 - **1. End-use factors**
 - a. Transmission of information: biopotentials, temperature, pressure, blood flow rate, etc.
 - b. Energy: electrical and electromagnetic stimulation, power for heart assist devices, cochlear implants, etc.
 - c. Matter: cannula for kidney dialysis and blood infusion or exchange, etc.
 - d. Load : attachment of prosthesis.
 - **2. Engineering factors**
 - a. Materials selection: polymers, ceramics, metals, and composites.
 - b. Design variations: button, tube with and without skirt, porous or smooth surface, etc.
 - c. Mechanical stresses: soft and hard interface, porous or smooth interface.
 - **3. Biological factors**
 - a. Implant host: man, dog, hog, rabbit, sheep, etc.
 - b. Implant location: abdominal, dorsal, forearm, etc.
 - **4. Human factors**
 - a. Postsurgical care.
 - b. Implantation technique.
 - c. Aesthetic outlook.

A typical PD consists of

- A. Interface between the epidermis and PD, which should be completely sealed against invasion by foreign organisms.
- B. Interface between the dermis and PD, which should reinforce the sealing of (A), as well as resist mechanical stresses. Due to the relatively large thickness of the dermis, the mechanical aspect is more important at this interface.
- C. Interface between the hypodermis and PD should reinforce the function of (B). Immobilization of the PD against piston action is a primary function of (C).
- D. Implant material per se should meet all the requirements of an implant for soft tissue replacement.
- E. The line where epidermis, air, and PD meet is called a three-phase line, similar to (A).



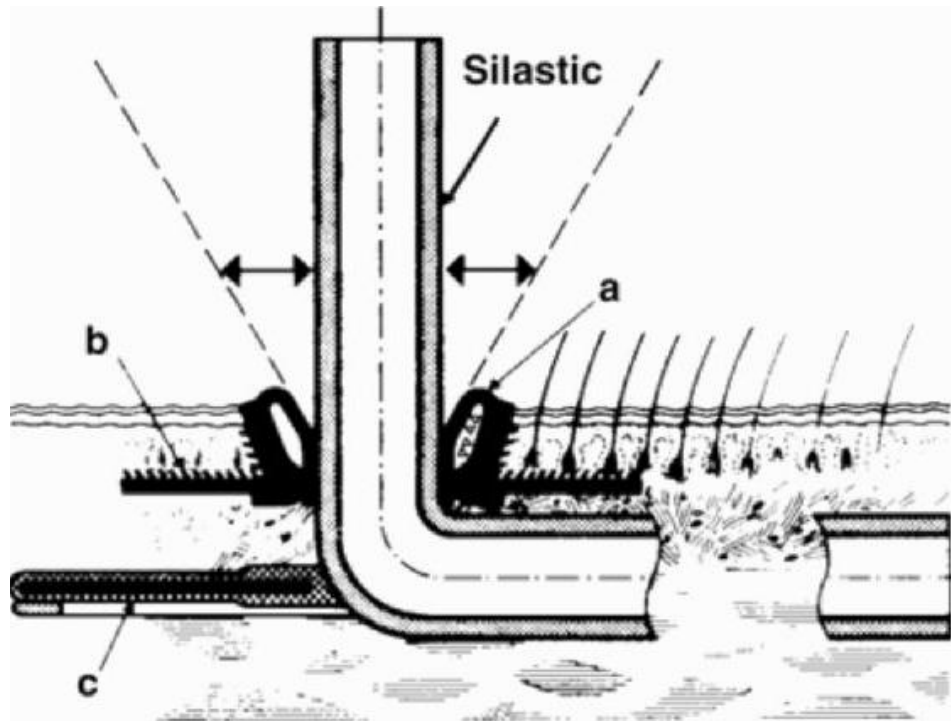
Simplified cross-sectional view of PD–skin interfaces. Reprinted with permission from von Recum and Park (1979). Copyright © 1979, Chemical Rubber Co.



Various mechanical stresses acting at the PD–skin interface. Reprinted with permission from von Recum and Park (1979). Copyright © 1979, Chemical Rubber Co.

- The stresses generated between a cylindrical percutaneous device and skin tissue can be simplified, as shown here
- The relative motion of the skin and implant results in shear stresses that can be avoided if the implant floats (or moves) freely with movement of the skin.
- For this reason PDs without connected leads or catheters function longer.
- There have been many different PD designs to minimize shear stresses.
- All designs create a good skin tissue/implant attachment in order to stabilize the implant. This is done by providing felts, velours, and other porous materials at the interface.

Schematic drawing of a Grosse-Siestrup PD.
Courtesy C. Grosse-Siestrup



The device includes making an air chamber made of a rubber balloon (a) interposed between skin and PD, and firmer fixation of the cannula by providing a large surface for tissue ingrowth (b and c).

Some designs have tried to minimize the trauma imposed by the external tubes and wires by providing a pin connector with good provision for firm tissue attachment subcutaneously.

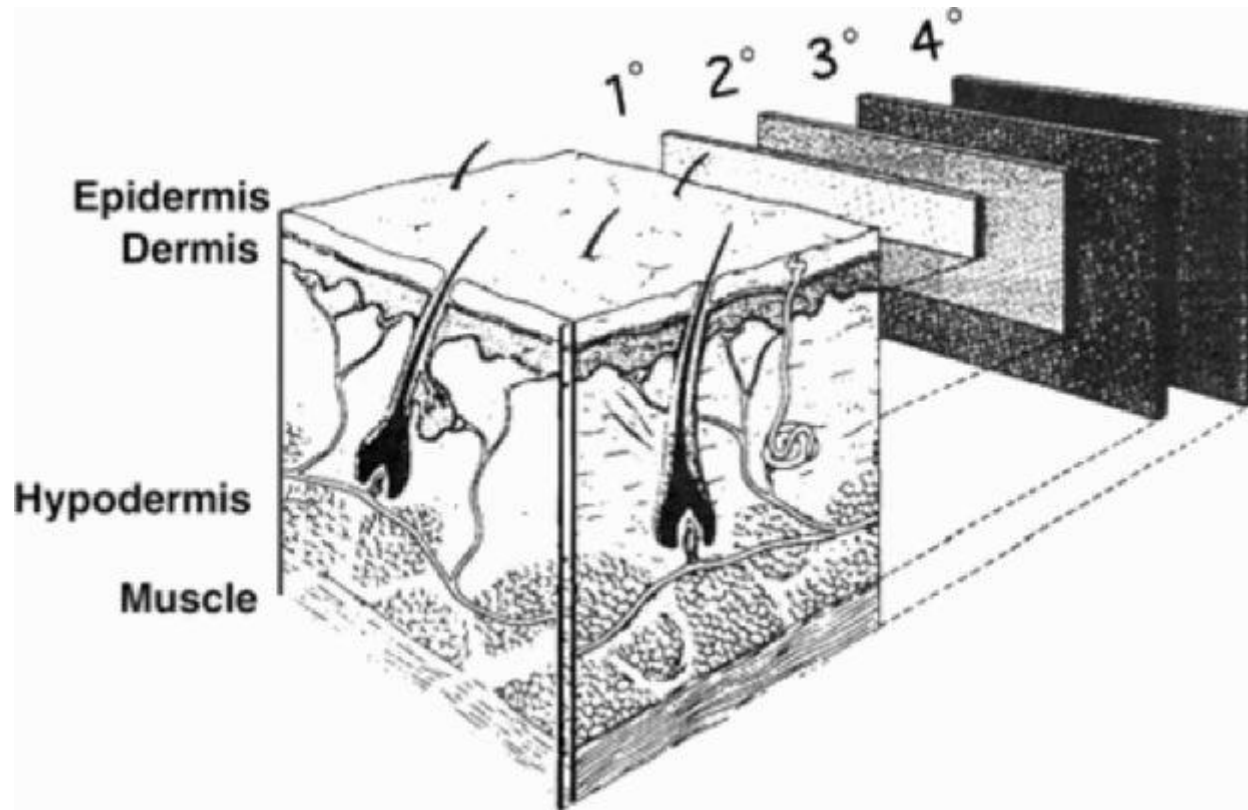
Materials used in PD

- In one experimental trial, hydroxyapatite based PDs showed very little epidermal downgrowth (1 mm after 17 months versus 4.6 mm after 3 months for the silicone rubber control specimens in dorsal skin of canines)

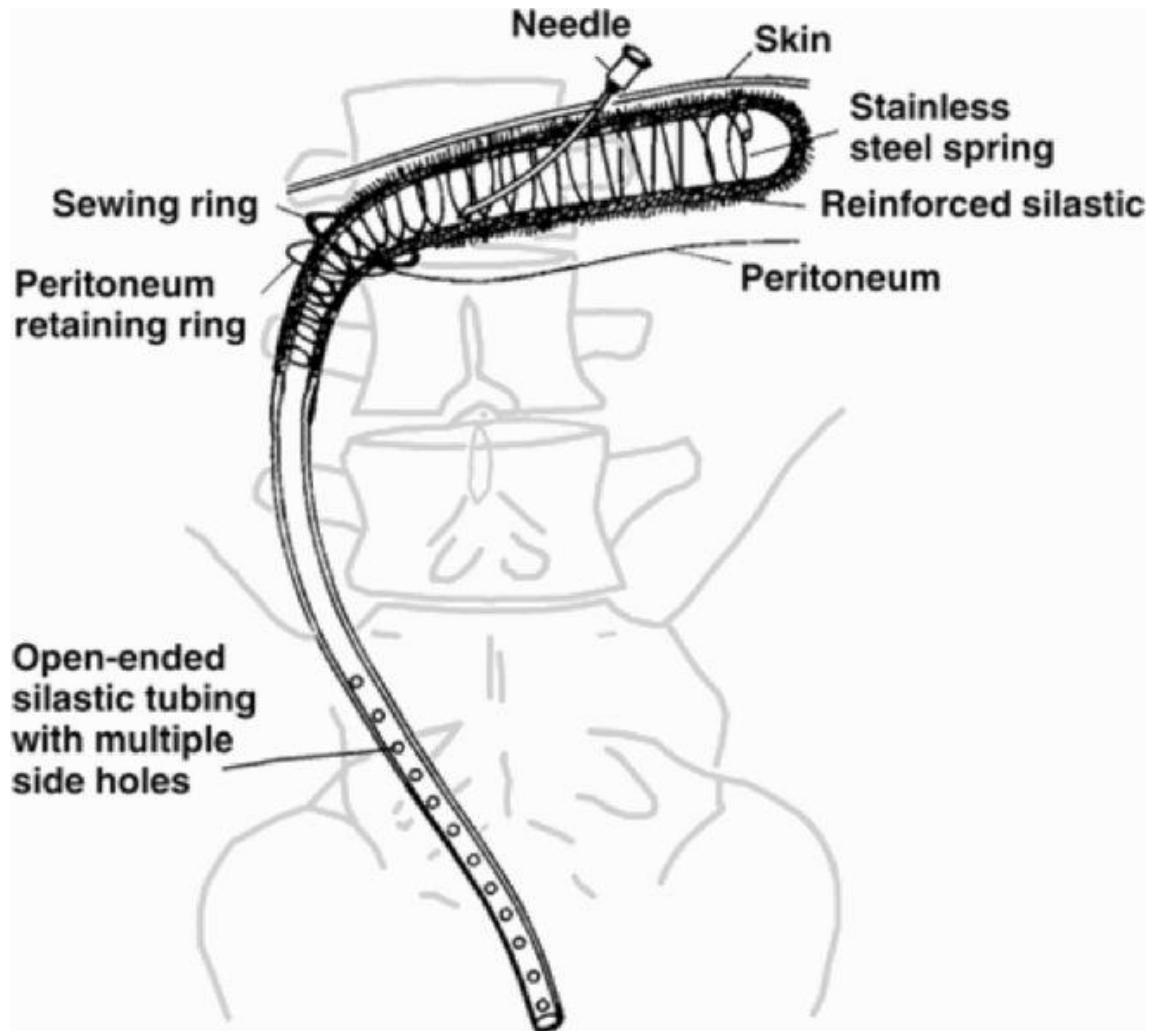
Artificial Skins and Burn Dressing

- Artificial skin can be thought of as a percutaneous implant
- Most useful for this application is a material that can adhere to a large (burned) surface and thus prevent loss of fluids, electrolytes, and other biomolecules until the wound has healed
- First- and second-degree burns can be treated with temporary burn covering membranes or dressing, while third-degree burns can be treated with autografts at present
- autografting and homografting (skin transplants) are available as a permanent solution

What do we mean by degree of burn?



Subcutaneous peritoneal dialysis assist device. Reprinted with permission from Kablitz et al. (1979). Copyright © 1979, Blackwell Science



Some Commonly Used Wound Membranes and Their Principal Characteristics

Membrane	Selected characteristics
Temporary	
Porcine xenograft	Adheres to coagulum, excellent pain control
Biobrane ^a	Bilaminate, fibrovascular ingrowth into inner layer
Split-thickness allograft	Vascularizes and provides durable temporary closure
Various semipermeable membranes	Provides vapor and bacterial barrier
Various hydrocolloid dressings	Provides vapor and bacterial barrier, absorbs exudate
Various impregnated gauzes	Provides barrier while allowing drainage
Allogeneic dressings	Provides temporary cover while supplementing growth factors
Permanent	
Epicel ^b	Provides autologous epithelial layer
Integra ^c	Provides scaffold for neoderms, requires delayed thin autograft grafting
AlloDerm ^d	Consists of cell-free human dermal scaffold, requires immediate thin autograft

^aMylan Laboratories, Inc. ^bGenzyme Biosurgery Inc., Cambridge, MA. ^cIntegra Life Sciences Corporation, Plainsboro, NJ. ^dLifeCell Inc., Branchburg, NJ.

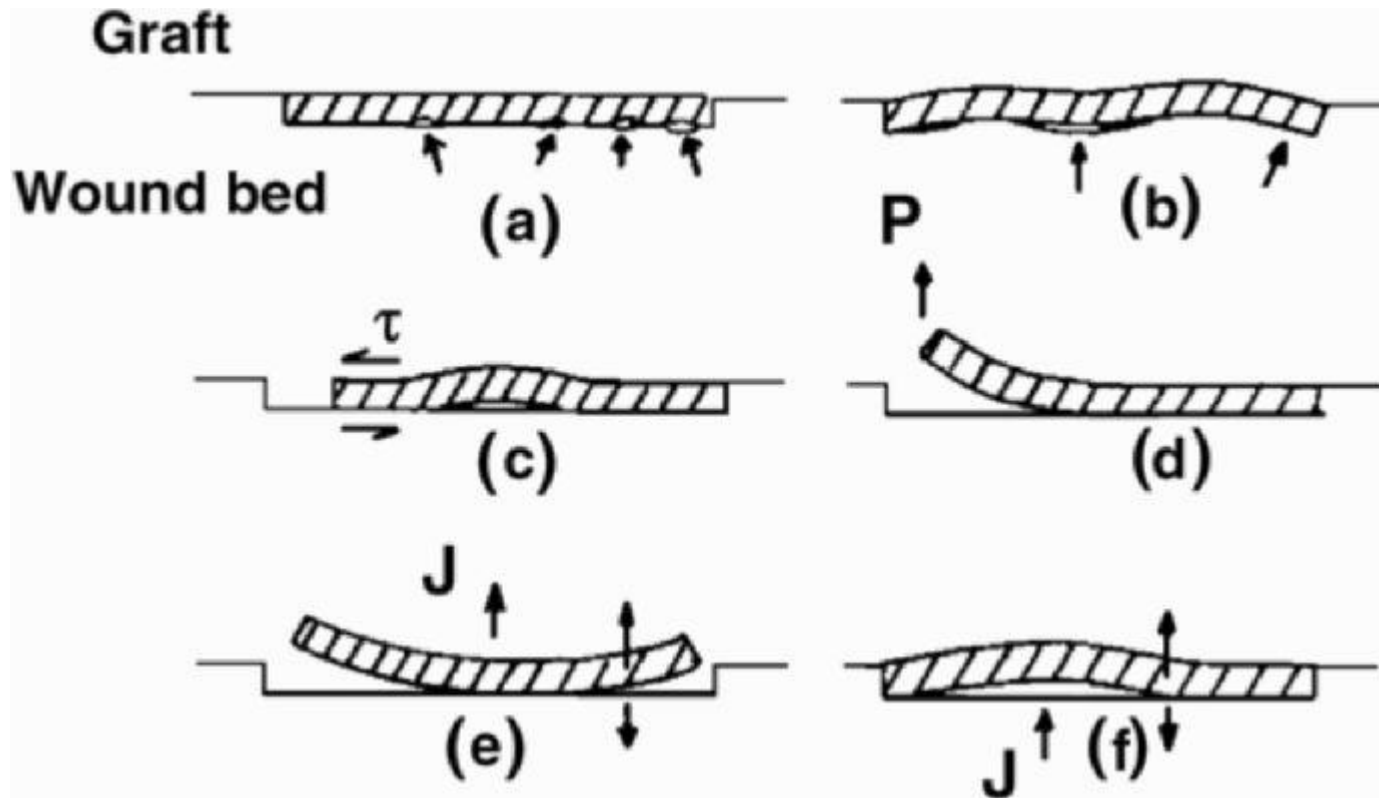
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Various skin burn membranes from bottom left-hand corners: meshed splitthickness autograft, TransCyte, Epicel, cryopreserved cadaver allograft, Biobrane, splitthickness autograft, EZ Derm, and Integra Dermal Regeneration Template. Reprinted with permission from Morgan et al. (2004). Copyright © 2004, Elsevier Science.

A composite membrane designed of a crosslinked collagen–polysaccharide (chondroitin 6-sulfate) composite membrane was chosen for ease in controlling porosity (5–150 μm in diameter), flexibility (by varying crosslink density), and moisture flux rate.

Schematic representation (not drawn according to scale) of certain physicochemical and mechanical requirements in the design of an effective wound closure

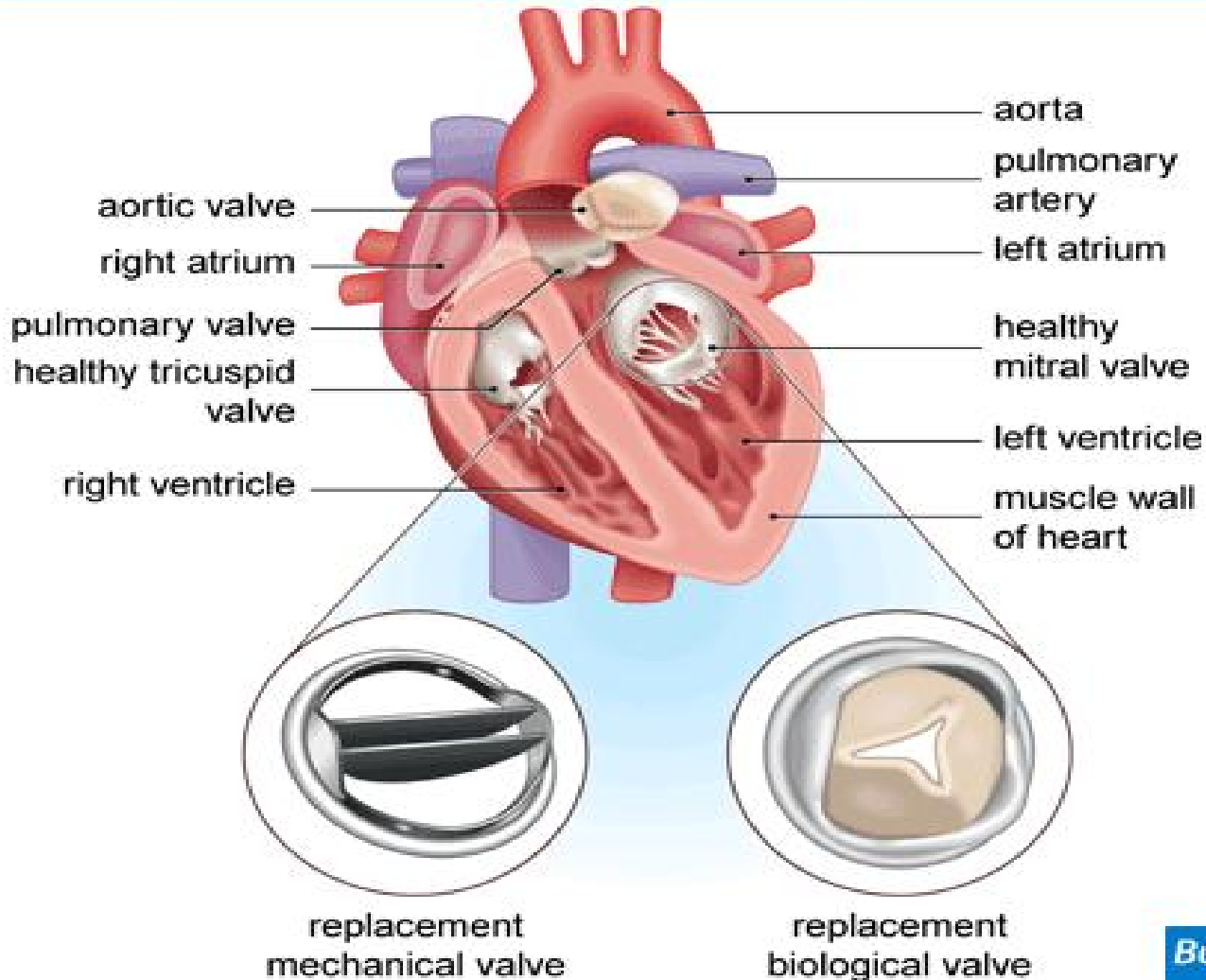


- (a) Skin graft (cross-hatched) does not displace air pockets (arrows) efficiently from the graft–wound bed interface.
 - (b) Flexural rigidity of graft is excessive; graft does not deform sufficiently under its own weight to make contact with depressions in wound bed surface, resulting in air pockets (arrows).
 - (c) Shear stresses (arrows) cause buckling of graft, ruptures of graft–wound bed bond, and formation of air pocket.
 - (d) Peeling force P lifts graft away from wound bed.
 - (e) Excessively high moisture flux rate through graft causes dehydration and development of shrinkage stresses at edges (arrows), which cause lift-off from wound bed.
 - (f) Very low moisture flux J causes accumulation (edema) at graft–wound bed interface and peeling off (arrows).
- Reprinted with permission from Yannas and Burke (1980).

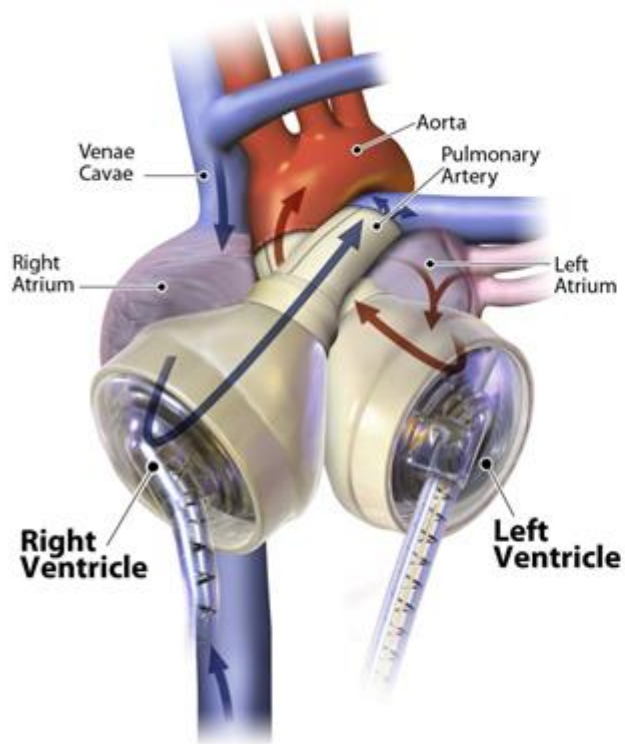
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- Several polymeric materials, including reconstituted collagen, have also been tried as burn dressings.
- Among them are the copolymers of vinyl chloride and acetate and methyl-2-cyanoacrylate. Methyl-2-cyanoacrylate was found to be too brittle and histotoxic for use as a burn dressing.
- The ingrowth of tissue into the pores of sponge (Ivalon[®], polyvinyl alcohol) and woven fabric (nylon and silicone rubber velour) was also attempted without much success.
- Sometimes plastic tapes have been used to hold skin grafts during microtoming (ultrathin sectioning) and grafting procedures.
- For severe burns, immersion of the patient into silicone fluid was found to be beneficial for prevention of early fluid loss, decubitus ulcers, and reduction of pain.

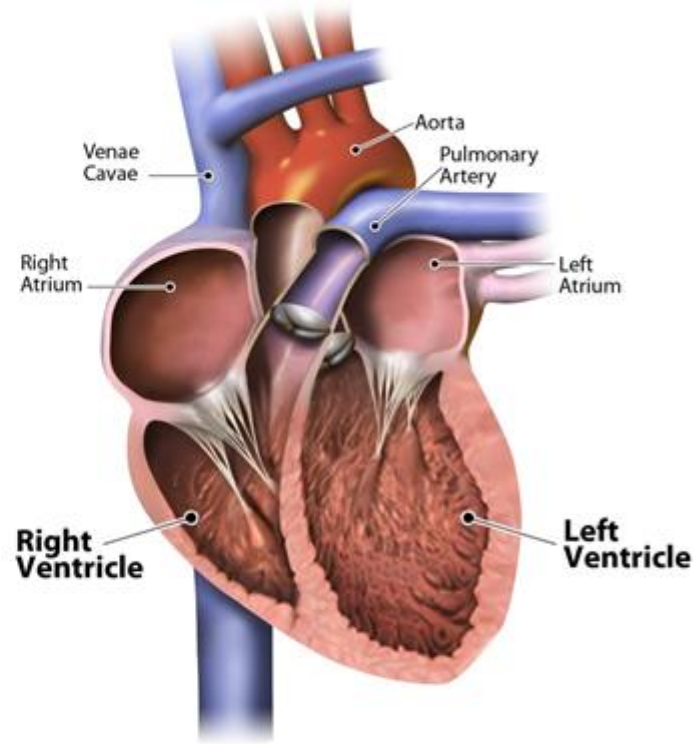
Polymers in heart implant



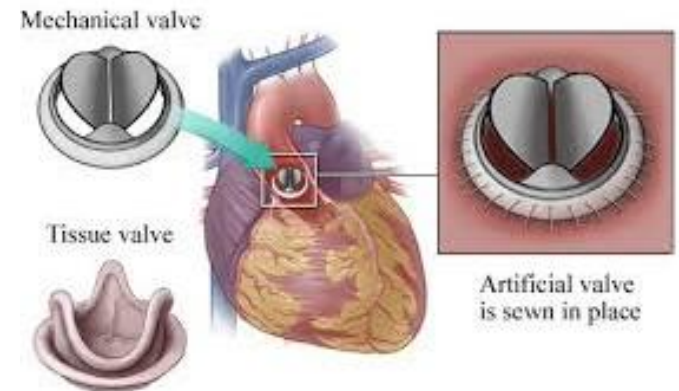
The types of heart valve replacement



Total Artificial Heart



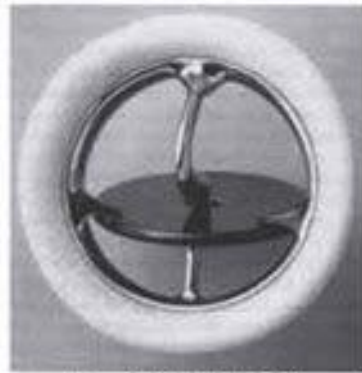
Human Heart



Artificial Heart Valves



a - upper left



b - upper right



c - mid left



d - mid right



e - lower left

Five types of prosthetic heart valves:

A. Starr-Edwards mitral caged ball valve. (Courtesy of Baxter Edwards CVS.)

B. Medtronic Hall tilting disk valve. (Courtesy of Medtronic Heart Valve Division.)

C. St. Jude bileaflet valve. (Courtesy of St. Jude Medical, Inc.)

D. Hancock porcine valve. (Courtesy of Medtronic Heart Valve Division.)

E. Carpentier-Edwards bovine pericardial valve. (Courtesy of Baxter Edwards CVS.)

TYPES OF PROSTHETIC HEART VALVES

- **Mechanical**

- Bileaflet (St Jude)(A)
- Single tilting disc (Medtronic Hall)(B)
- Caged-ball (Starr-Edwards) (C)



- **Biologic**

- **Stented**

- Porcine xenograft (Medtronic Mosaic) (D)
- Pericardial xenograft (Carpentier-Edwards Magna) (E)



- **Stentless**

- Porcine xenograft (Medtronic Freestyle) (F)
- Pericardial xenograft
- Homograft (allograft)

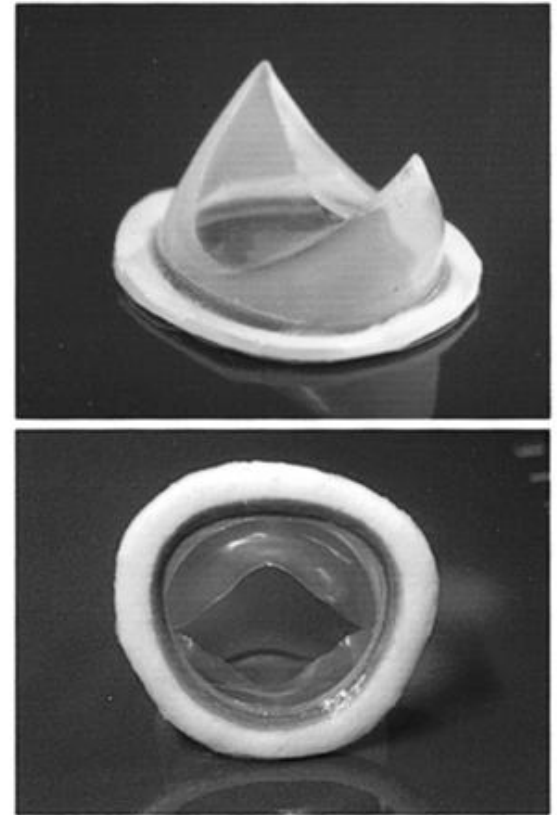
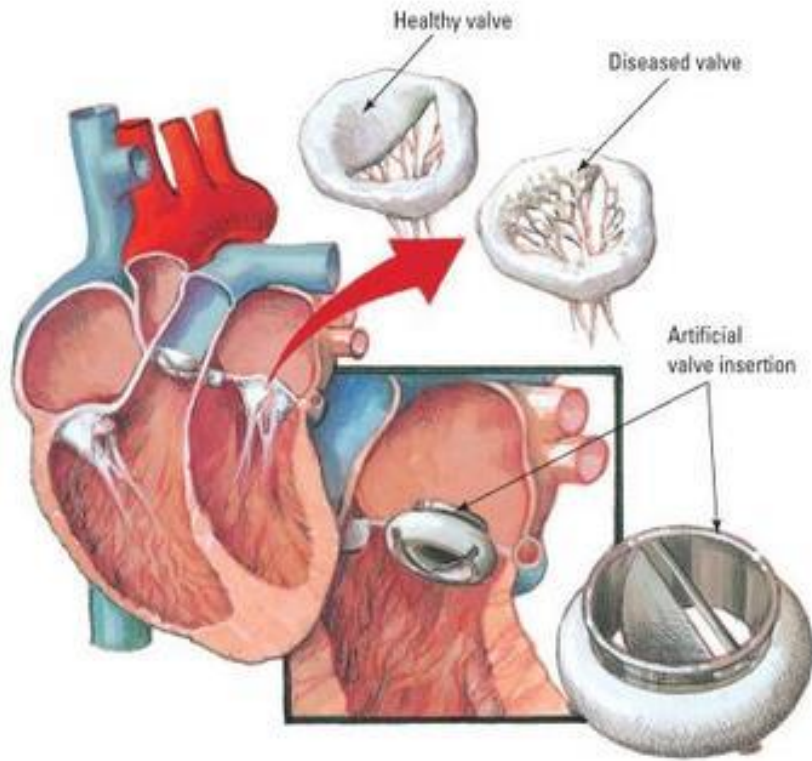


- **Percutaneous**

- Expanded over a balloon (Edwards Sapien) (G)
- Self-expandable (CoreValve) (H)

Circulation 2009, 119:1034-1048

PU based Mitral valve

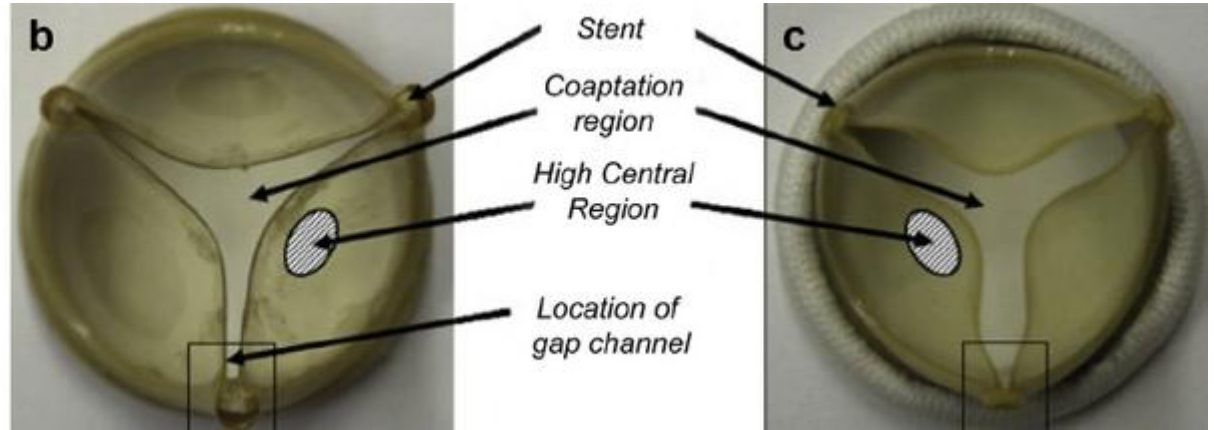
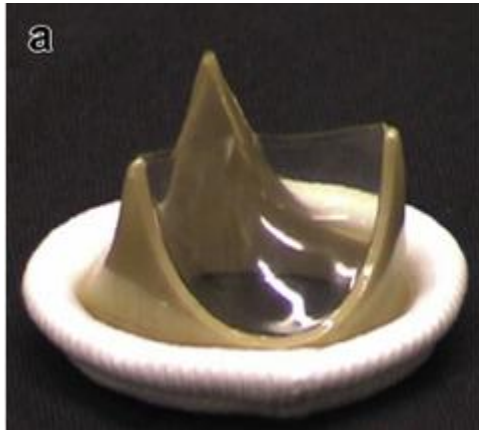


Summary of Various Heart Valve Implantations up to 1994

Types	Model	Year introduced	Total implanted up to 1994
Mechanical			
Ball-in-cage	Starr-Edwards	1965	200,000
Tilting disc	Bjork-Shiley		360,000
	Medtronic Hall	1977	178,000
	Omniscience	1978	48,000
	Monostrut	1982	94,000
Bileaflet	St. Jude	1977	580,000
	Carbomedic	1986	110,000
Tissue			
Porcine	Hancock	1970	177,000
	Hancock Modified Orifice	1978	32,000
	Carpentier Edwards (CE)	1971	400,000
	CE Supra Annular	1982	45,000
Porcine (stentless)	Toronto Stentless	1991	5,000
	Medtronic Freestyle	1992	5,000
Pericardial	Carpentier Edwards	1982	35,000
Homograft	Various	1962	28,000
Autogenous	Pulmonary	1967	2,000

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Artificial tricuspid valve



Mile Stones

- The first human implant was December 6, 1990 at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.
- In Clinical use for over 14 years.
- More than 55,000 TTK Chitra Heart Valve has been implanted so far in India, Nepal, Sri Lanka, Bangladesh and South Africa, Thailand
- Crossed over 1,00,000 patient years
- [Award for TTK Chitra heart valve prosthesis](#)
Hinduonnet
- [Award for TTK Chitra heart valve prosthesis](#)
May 17, 2001, Medindia

- **Materials of Construction**

-

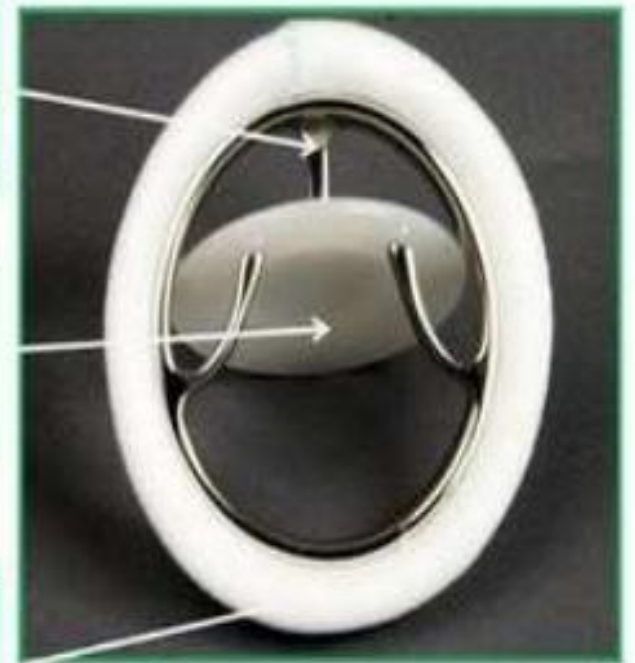
The three main components of TTK Chitra Heart Valve are:

- Frame
- Disc
- Sewing Ring

FRAME
Haynes-25 Alloy

DISC
Ultra High Molecular Weight Polyethylene

SEWING RING
Warp Knitted Polyethylene Terephthalate (Polyester) fabric



- Tilting Disc
 - pivoted eccentrically in the metallic frame.
 - MADE FROM ULTRA HMW POLY ETHYLENE
- The sewing ring
 - POLYETHYLENE TEREPHTHALATE (PET)
 - fitted snugly around the frame
 - used to suture the valve in the intended position in the heart.

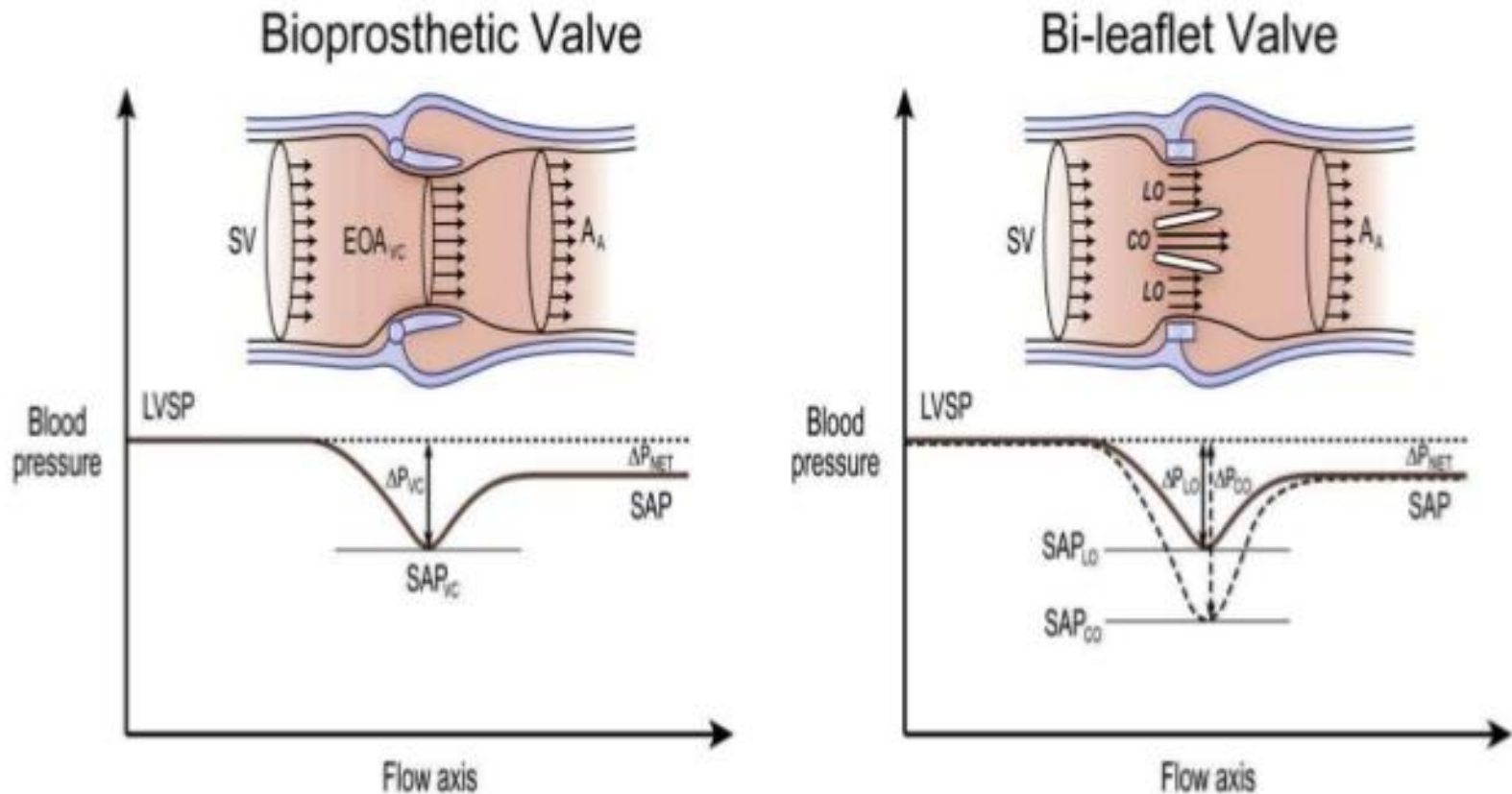
FRAME: COBALT CHROMIUM ALLOY(HAYNES 25)
- The frame and the disc are ***hydro dynamically designed to reduce drag and inertia*** and **polished** to minimize the chances of clotting.

Pyrollitic carbon is used to coat the metal frame

Requirements

- The artificial valve **must withstand the stress** of opening and closing some 40 million times a year.
- The materials used for the valve ***have to be compatible with blood*** and human tissues.
- When open, the valve **should allow the blood to flow smoothly** through.
- Once closed, the **back flow of blood had to be minimal.**

Pressure Recovery

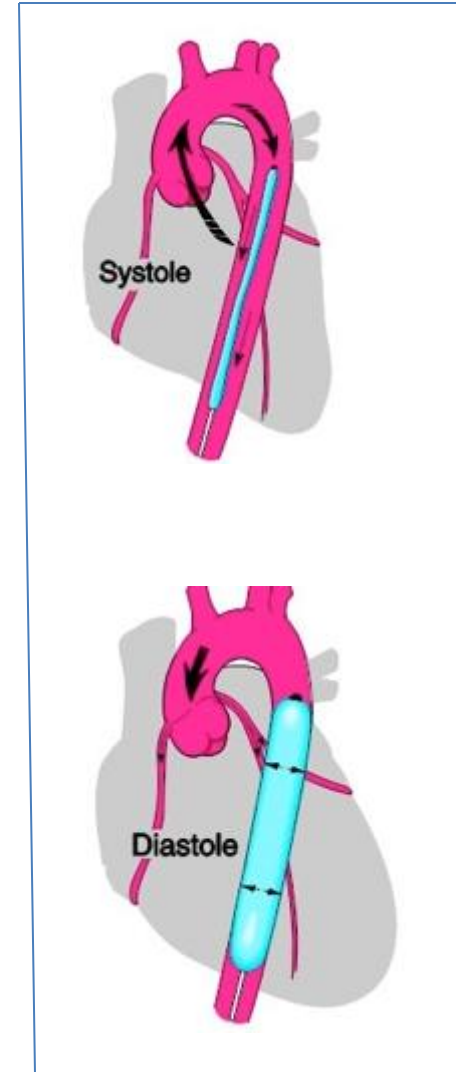
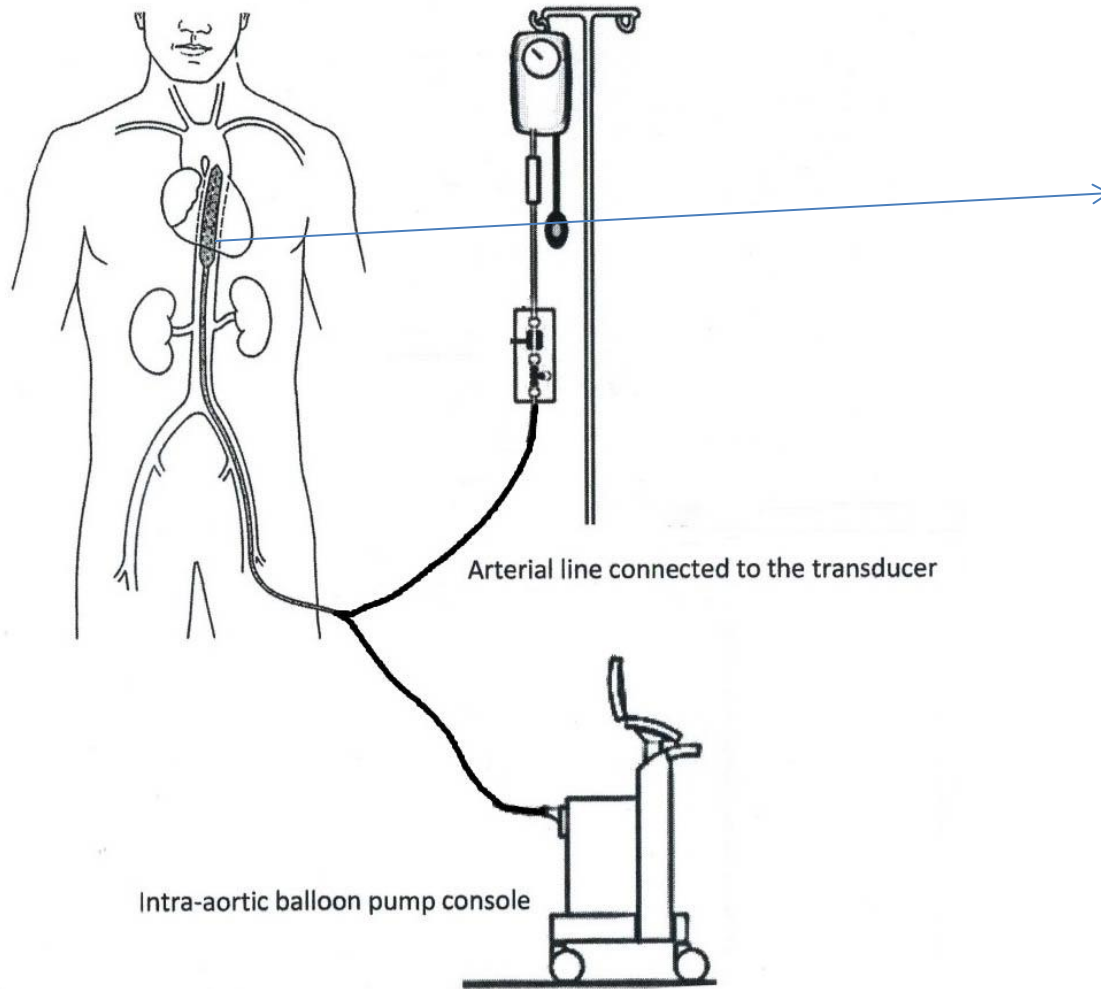


- The smaller central orifice in bileaflet valves may give rise to a high-velocity jet
- that corresponds to a localized pressure drop
- that is largely recovered once the central flow reunites with flows originating from two lateral orifices

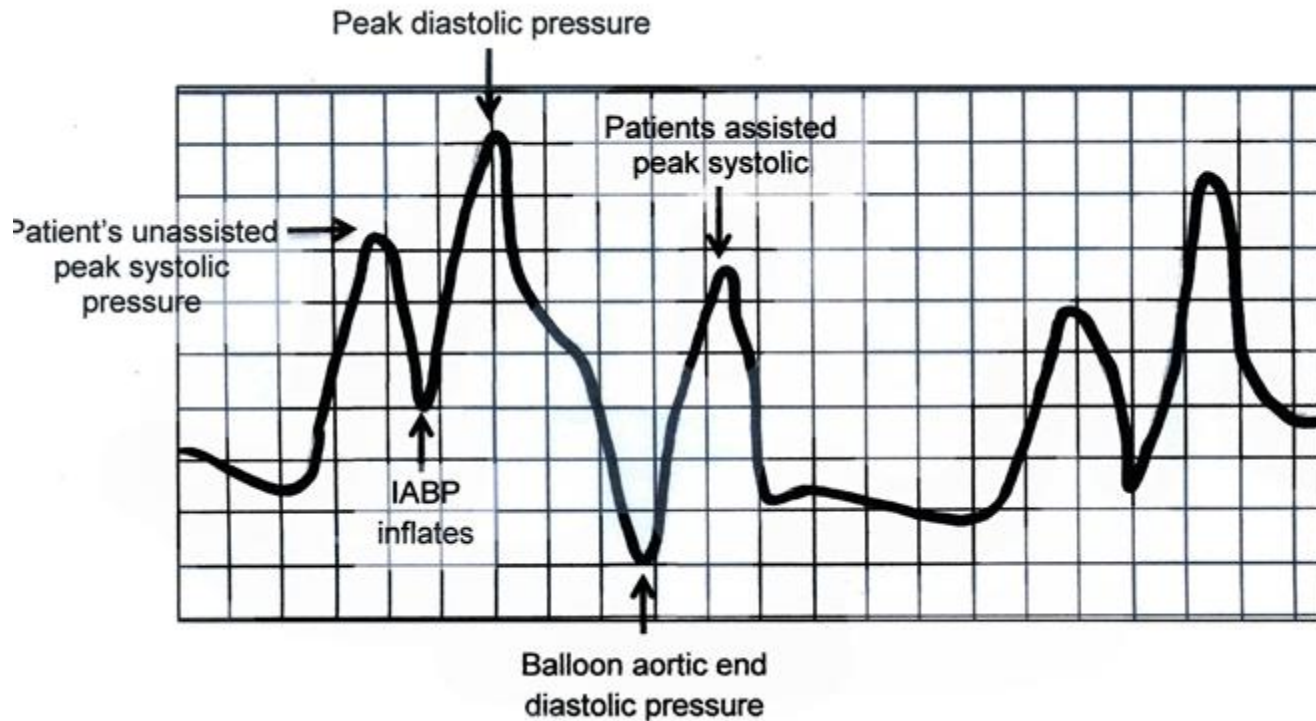
Biocompatibility Evaluation

- All the materials used in the valve have undergone ***extensive toxicological and implant evaluation*** that is applicable to permanent implants.
- As per the ISO protocol for artificial heart valves, the TTK Chitra Heart Valve has passed through ***rigorous in vivo animal trials in sheep***.
- During the trial, the valves were implanted in the mitral position without any anticoagulation regimen for the animals.
- The long time survival of these animals even under these difficult conditions was uneventful.

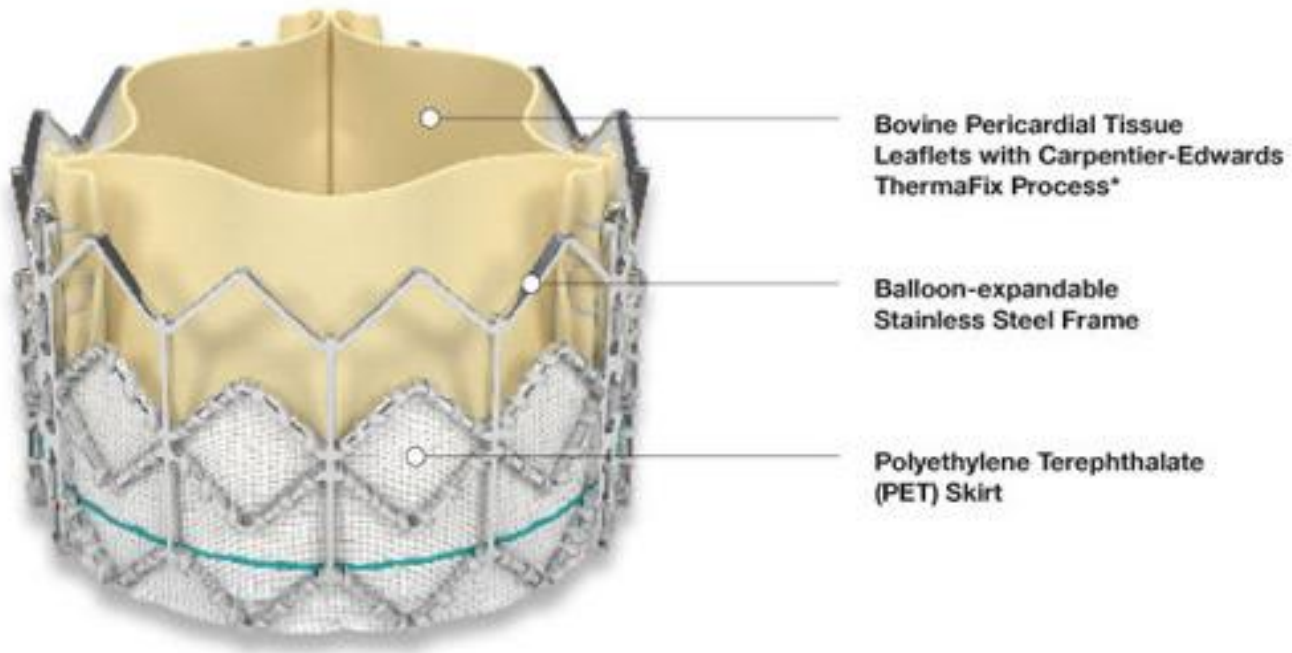
Intra Aortic Balloon Pump



Normal balloon inflation



When balloon-assisted, the diastolic pressure should always be the highest pressure recorded on the waveform. This will ensure that the coronary arteries receive the maximum blood flow. The balloon-assisted systolic pressure should be lower than the patients non-assisted, systolic pressure due to the reduction in afterload.



Xenograft

Cardiovascular stents

Stent grafts. (a) Configuration of device showing composite metal and fabric portions



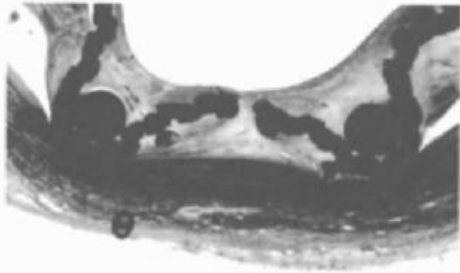
A

b) well-healed experimental device explanted from a dog aorta. The lumen is widely patent and the fabric and metal components are visible.



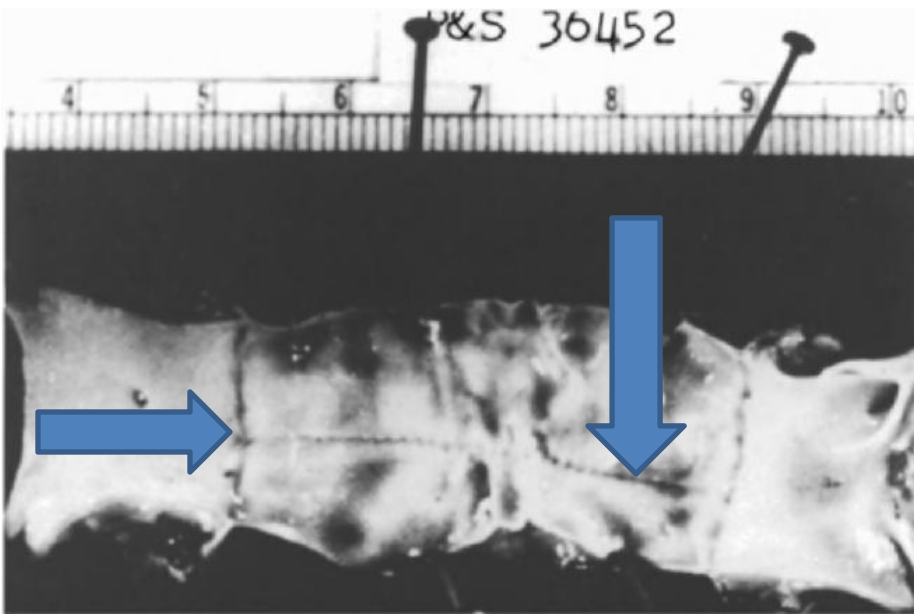
B

c) High-power photomicrograph of stent graft interaction with the vascular wall, demonstrating mild intimal thickening.

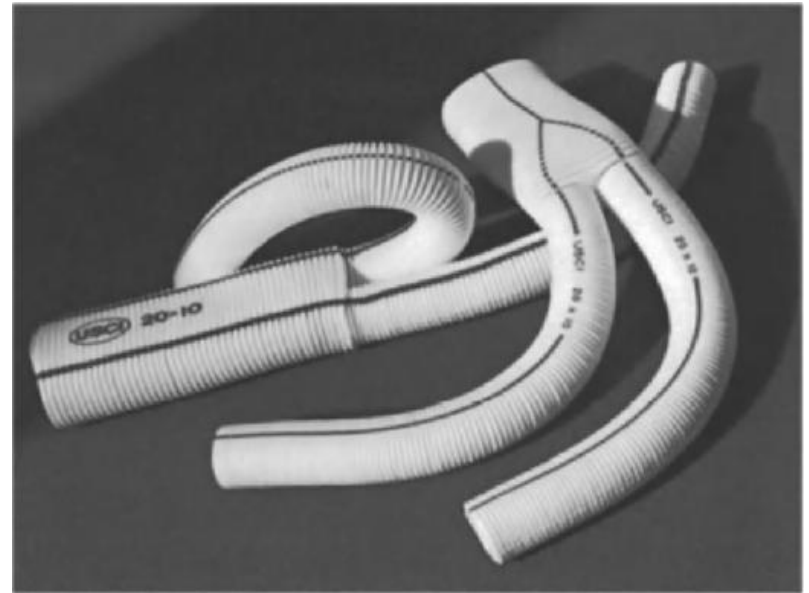


C

Porous vascular implant



First arterial implant stitching fabrics with hand



Modern arterial implant

Types

Classification on the basis of materials used:

- Bare metallic stents
- Coated stents
- Drug eluting stents
- Biodegradable stents

Metallic stents

- Requirements:

Expandable-ability to plastic deformation, sufficient elasticity to be compressed for delivery and then expanding in the target area

Radial hoop strength and negligible recoil-should not collapse after implantation

Low profile-ability to be crimped on the balloon catheter supported by a guide wire

Adequate radio-opacity/MRI compatibility

Thromboresistivity -blood compatible

Drug delivery capacity

Metals- Stainless steel , Ta, Pt-Ir alloy, Ti, Ni-Ti alloy , Co-Cr

Biodegradable metallic stents-Pure Fe, Mg alloys(+Al+Zr+rare earth metals)

Surface Characteristics of stent

- **Surface energy**-surface chemistry-wettability, thrombogenicity- PET,PTFE, PU compared-PU least surface energy,hydrophilic coating on SS stents reduces accumulation of platelets
- **Surface texture**-Polishing is essential –rough surface causes thrombosis
- **Surface potential**-Metals are electropositive and blood elements are electronegative-accentuates thrombogenicity-coating the metal surface by biological / inorganic/ polymeric materials
- **Stability of surface oxide layer**-acts as barrier to the release of ions from the bulk materials underneath the surface.

Rationale for coatings

- **Thrombosis** and **neo-intimal hyperplasia**-major problem

Effect of coating:

- Surface energy gets reduced
- Surface texture smoothed
- Surface potential neutralized
- Stability of surface oxide layer enhanced

Types of methods of Coating:

- **Galvanization**
- **Sputtering followed by bombarding ions**
- **Pulsed biased arc ion plating**
- **Dipping**
- **spraying**
- **plasma based depositions**

Materials used in coating

- Inorganic Coating-gold, silicon carbide, Iridium oxide, diamond like Carbon(ceramic)
- Endothelial cells-(Biological)
- Porous materials-PU films with 30 μ m pores
- Polymers

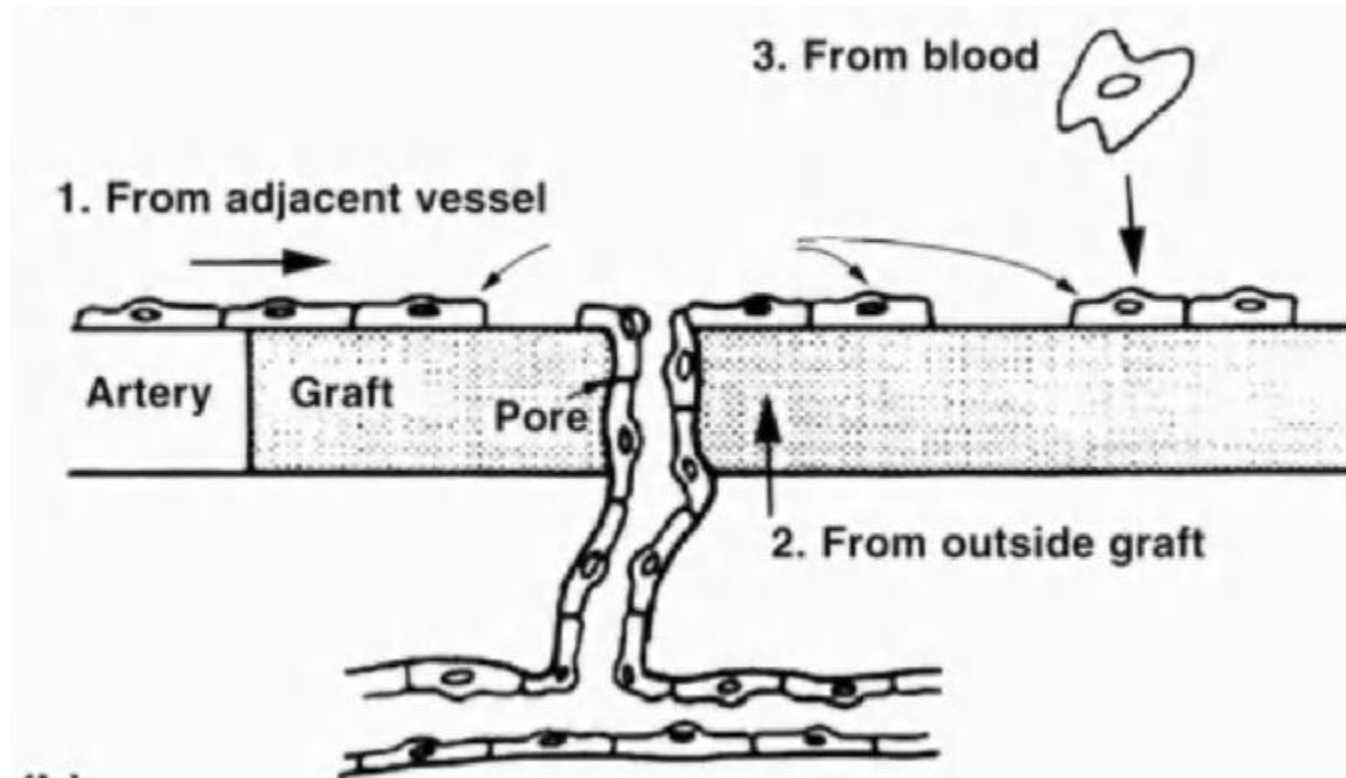
Metallic/Inorganic Coatings(ceramic)

- **Gold** –preferred on SS to enhance fluoroscopic visibility-reduced neo-intimal hyperplasia on gold coated (thermally processed) SS surface-due to smoothness and removal of embedded impurities in the gold surface for porcine coronary arteries but in human trials it was not satisfactory.
- **Iridium oxide**- It reduces inflammatory reactions of metal by the conversion of H_2O_2 to water and oxygen
- Silicon-carbide –amorphous hydrogenated SiC is a semiconductor and antithrombogenic
- Carbon- chemically inert, biocompatible

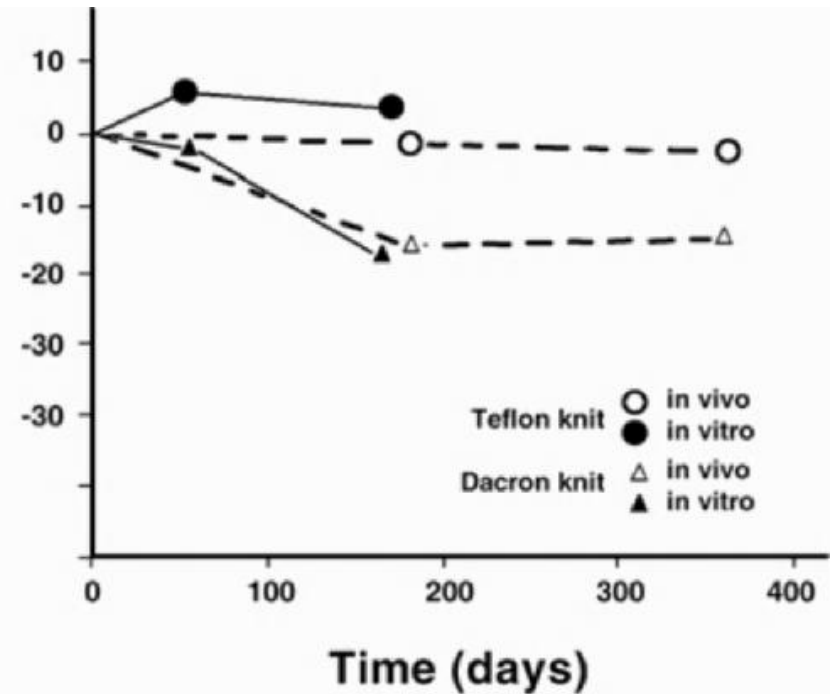
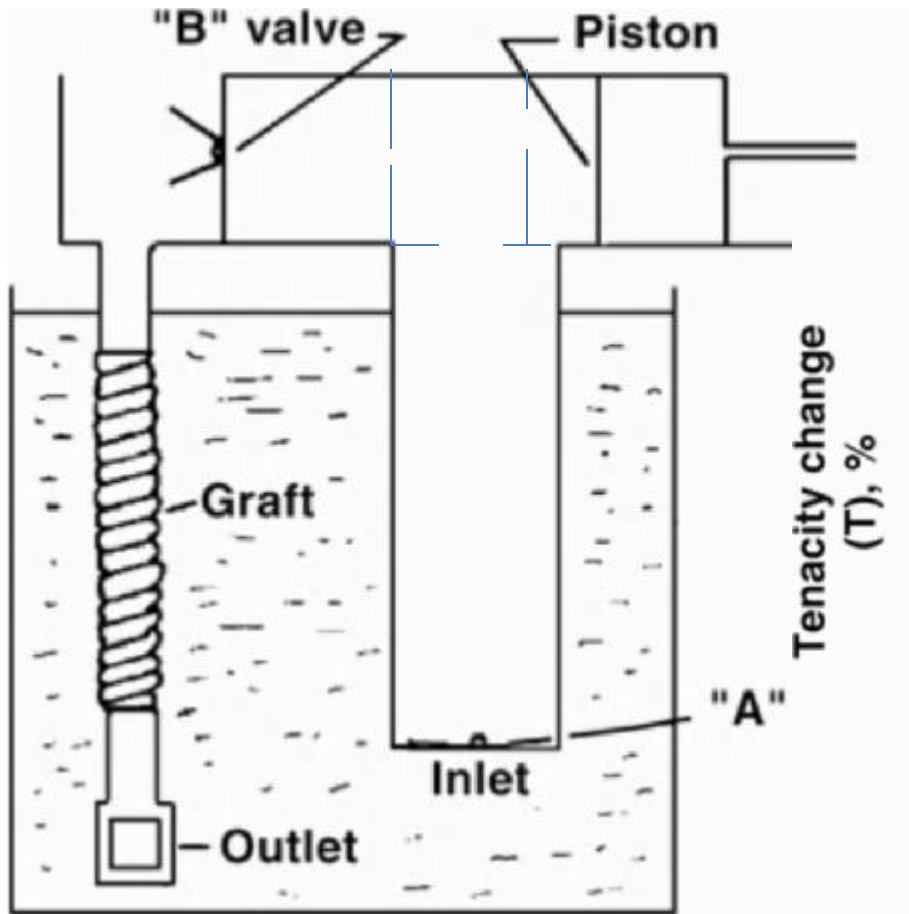
Polymer coating

- Bio-stable (not biodegradable) polymers
- Biodegradable
- Copolymers
- Biological polymers

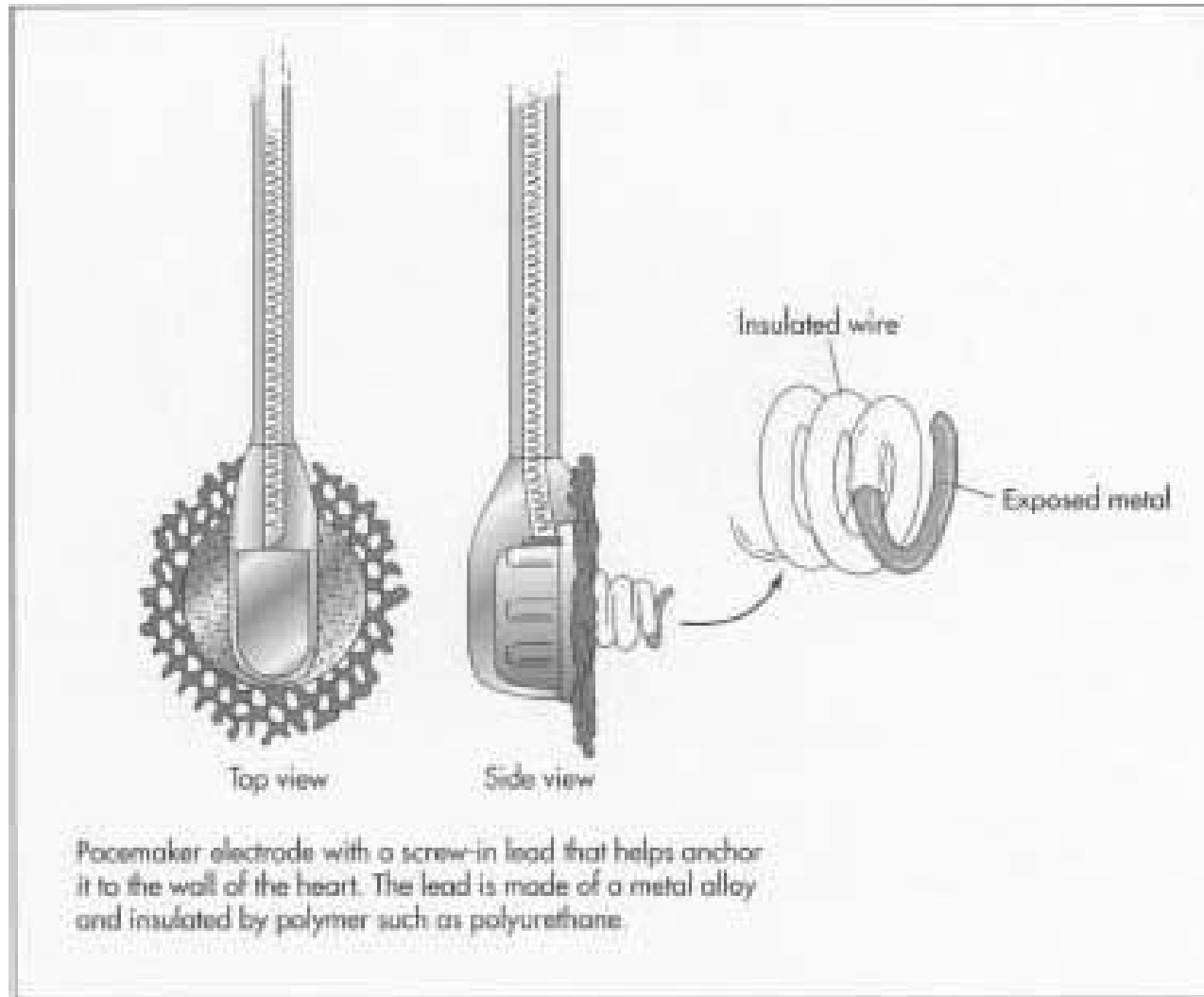
Tissue ingrowth and fixation of stents



Schematic diagram of arterial graft life tester



Artificial heart implant devices

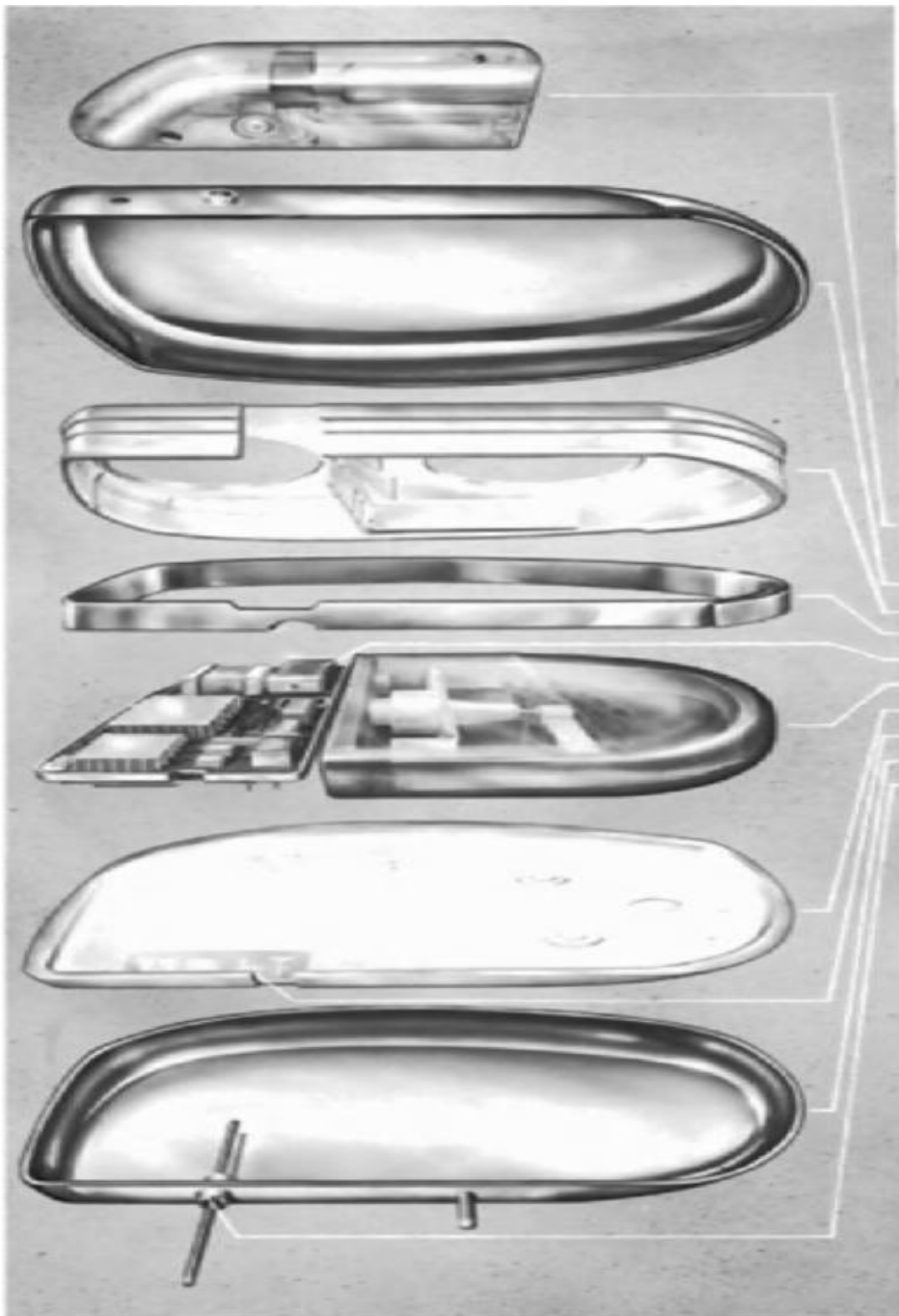


Major applications

- Catheters and tubings
- Artificial heart
- Cardiac assist device-Intra aortic balloon(IAB)

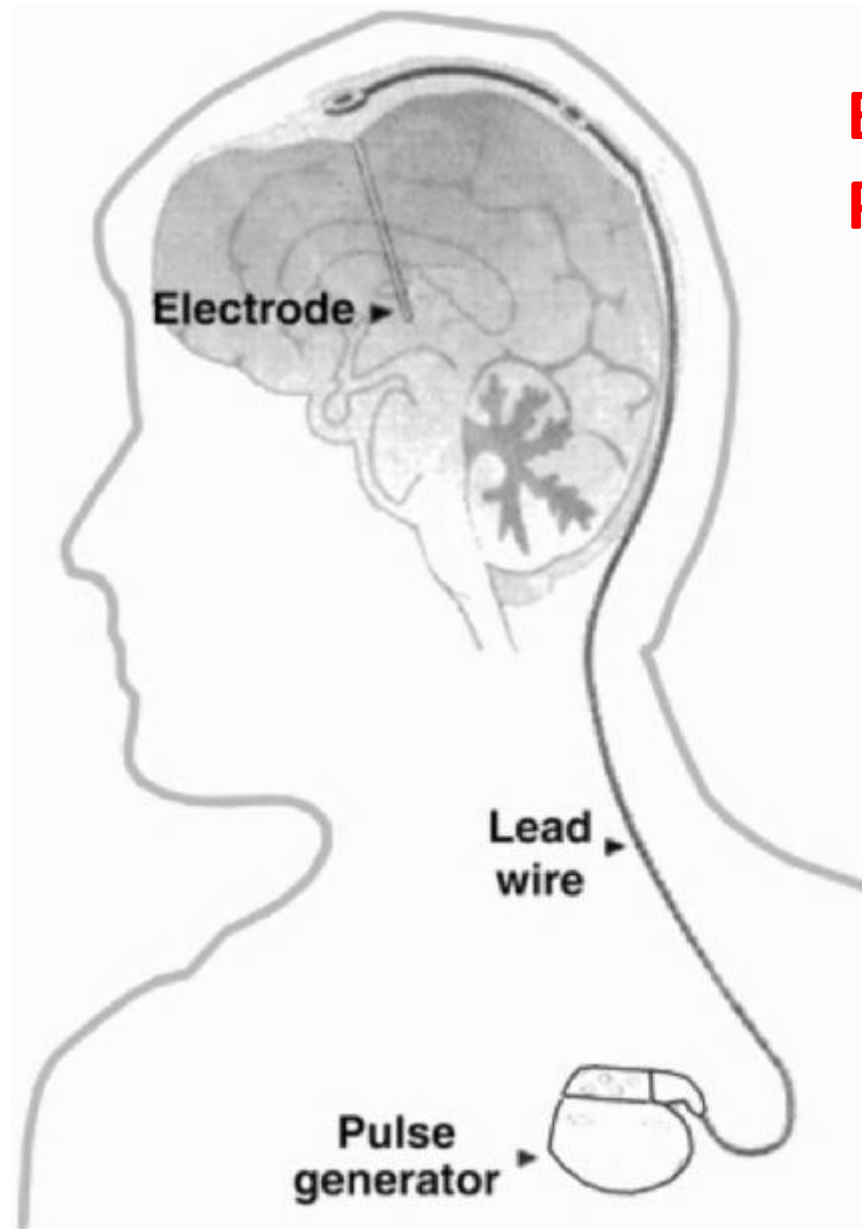


Cardiac Pacemaker



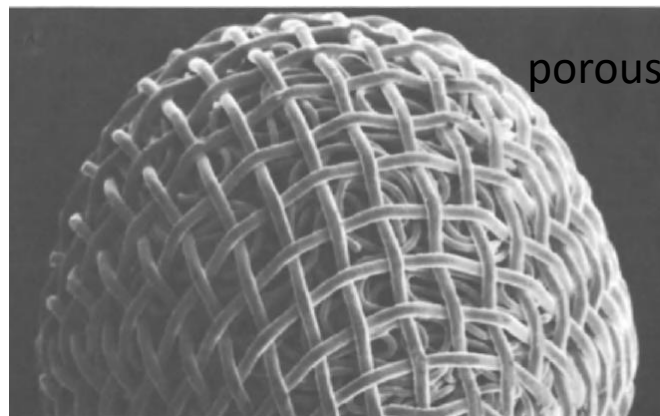
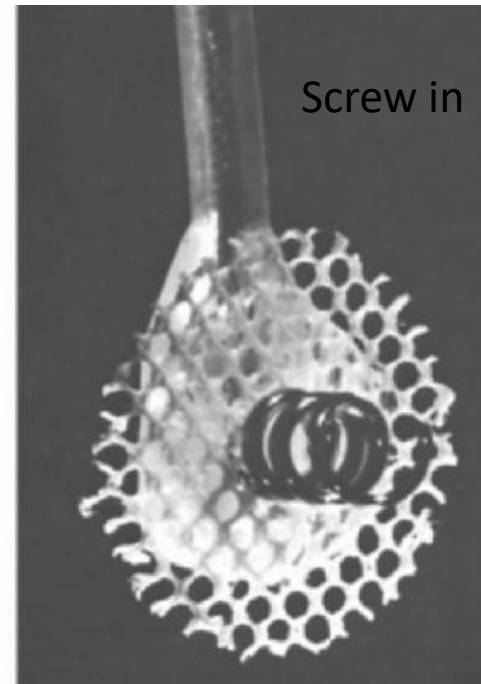
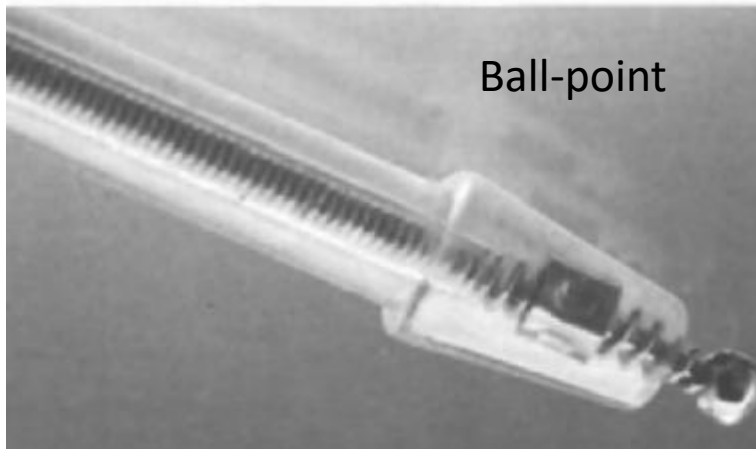
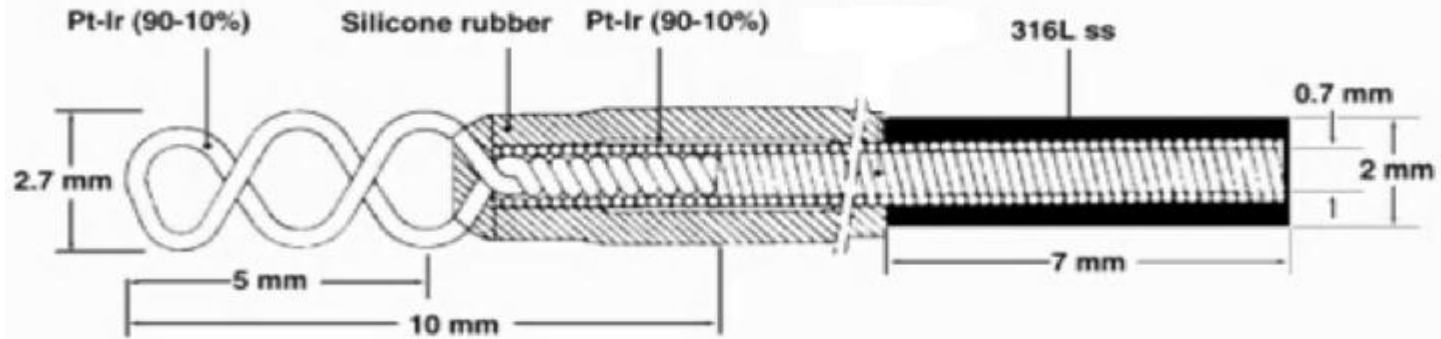
**Self-sealing connector
with two suture holes
and captured setscrews**

**Titanium shield
Polypropylene cup
Titanium weld ring
Monolithic circuit
Lithium-iodine battery
Polypropylene cup
Radiopaque ID code
Titanium shield
Feedthrough**

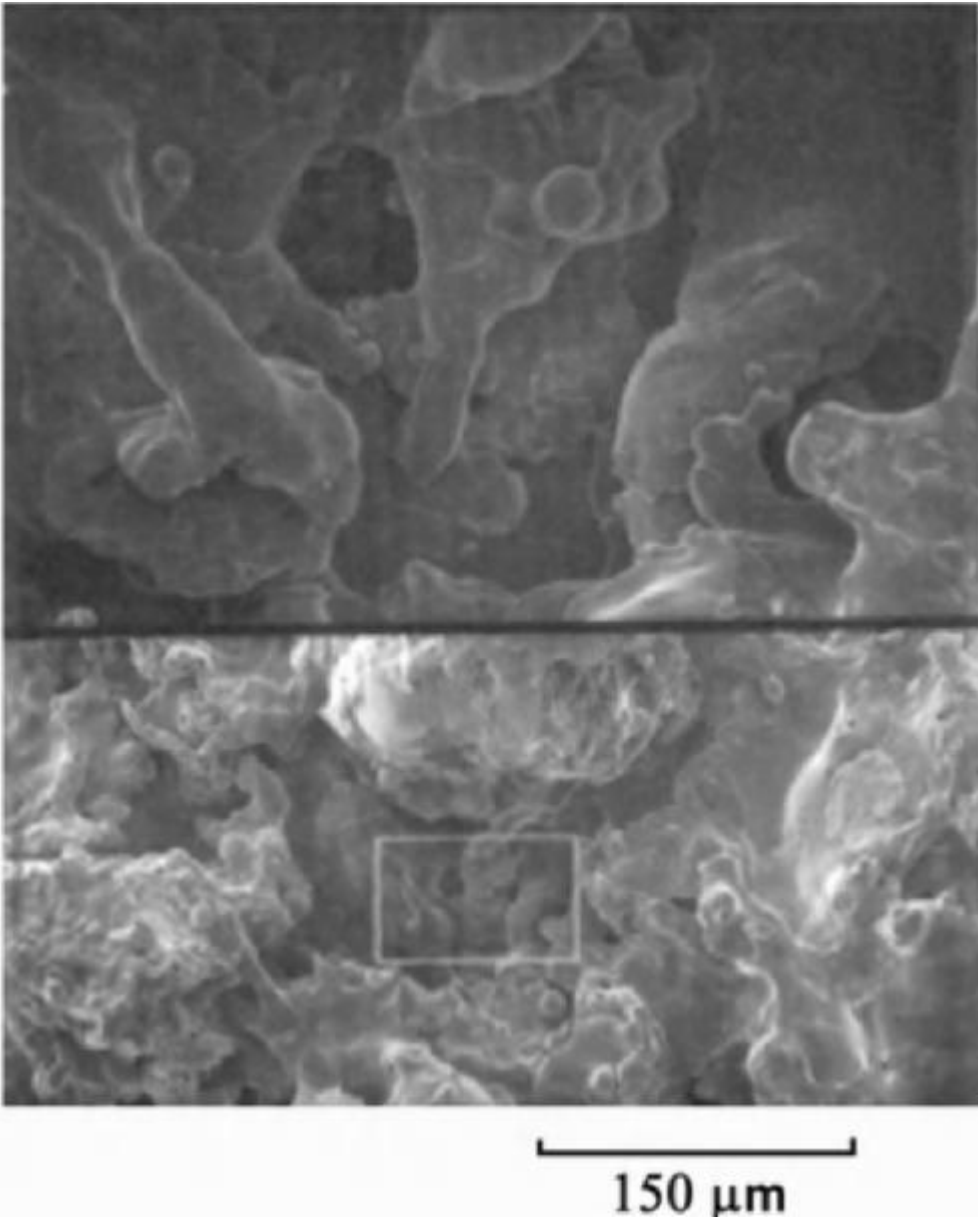


Brain Pacemaker

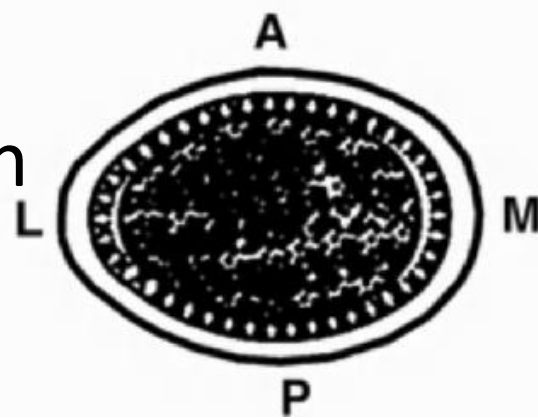
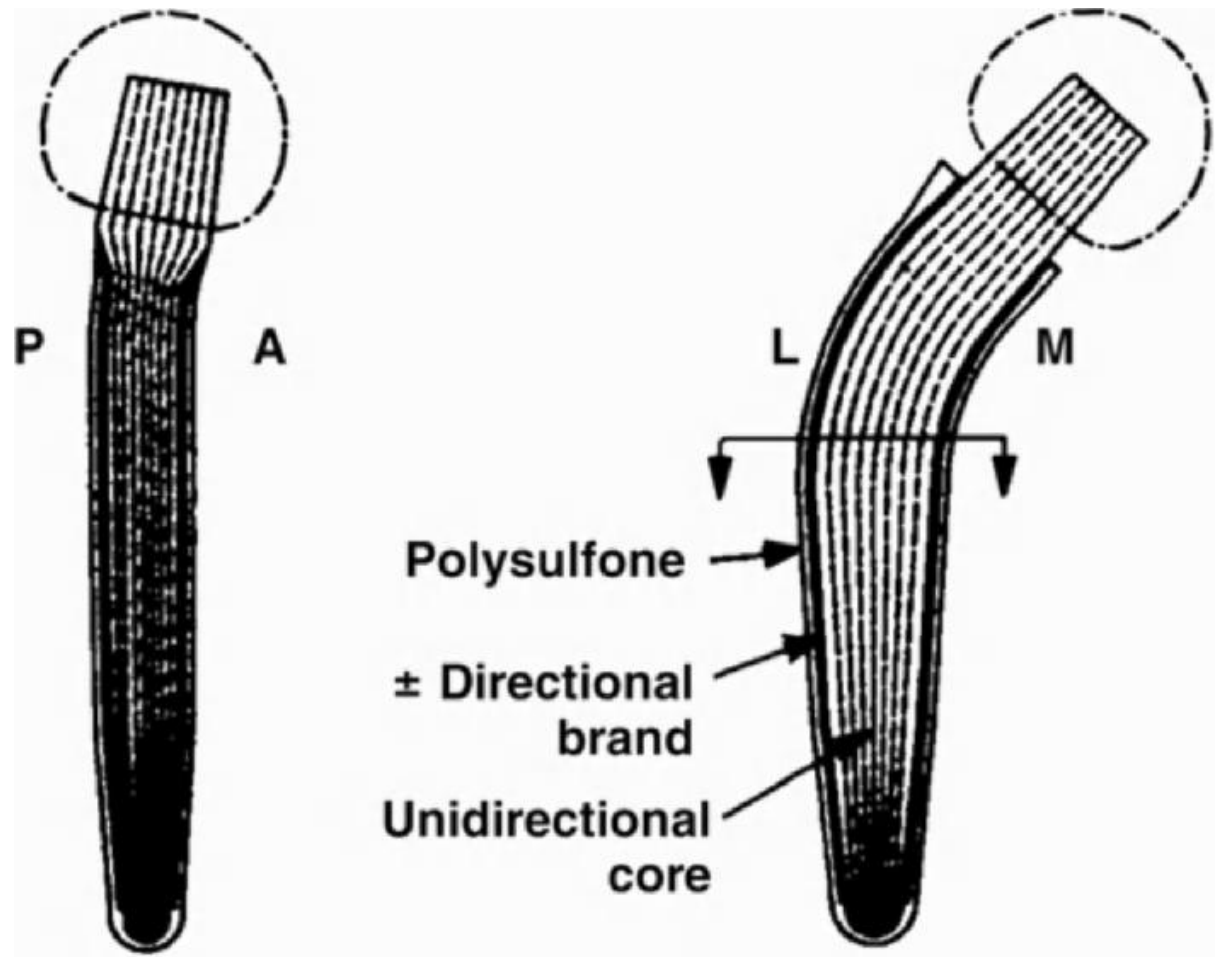
Details of an arterial electrode



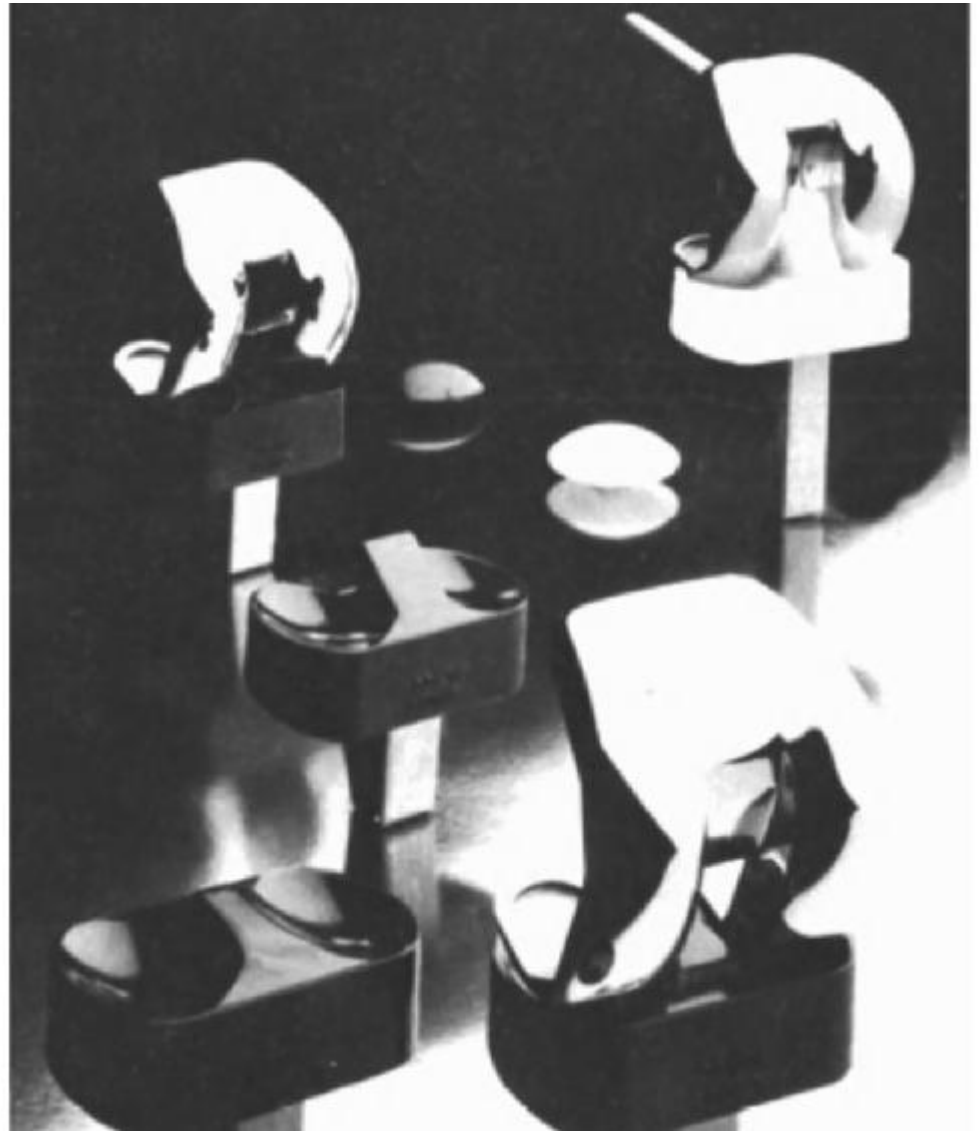
Porous implant



Structure of porous coating for bony ingrowth.



Details of carbon-polysulfone composite femoral stem construction



Knee prostheses with black carbon fiber-reinforced polyethylene tibial components

Soft Tissue Replacement

Requirements

- They should achieve a reasonably close approximation of the physical properties, especially **flexibility and texture**.
- They should not deteriorate or change properties after implantation over **time**.
- If materials are designed for **degradation**, rate and modes of degradation should follow the intended pathway.
- They should not cause adverse **tissue reaction**-They should be non-carcinogenic, non-toxic, non-allergenic, and non-immunogenic.
- They should be **sterilizable**.
- They should be **low cost**.
- Others-feasibility of **mass production and aesthetic qualities**

Sutures

Types-

- According to the physical integrity

Absorbable (biodegradable) & nonabsorbable.

- According to the source

Natural sutures (catgut, silk, and cotton), and Synthetic sutures (nylon, polyethylene, polypropylene, stainless steel, and tantalum).

- According to the physical form

Monofilament & multifilament

T, Twisted monofilament; M, monofilamene; B, multifilament braid

Table 11-1. Various Types of Sutures Quoted by Roby and Kennedy

Suture type	Generic structure	Major clinical application	Representative Type ^a	Representative product	Representative manufa
Natural materials					
Catgut	Protein	Plain: subcutaneous, rapid-healing tissues, ophthalmic	T	Surgical gut	Ethicon
			T	Surgical Gut	Ethicon
Silk	Protein	Chromic: Slower-healing tissues General suturing, ligation	T	Chromic, plain gut	Synco
			B	Perma-Hand	Ethicon
			B	Softsilk	Synco
Synthetic nonabsorbable materials					
Polyester	PET	Heart valves, vascular prostheses, general	B	Ethibond Excel	Ethicon
			B	Surgidac	Synco
			B	Ti-Cron	Synco
			B	Tevdek	Teleflex
			M	Novafil	Synco
			M	Vascufil	Synco
Polypropylene PP	Polybutester	Plastic, cuticular Cardiovascular General, vascular anastomosis	M	Prolene	Ethicon
			M	Surgipro	Synco
			M	Surgipro II	Synco
			M	Deklene II	Teleflex
Polyamide	Nylon 6, 6,6	Skin, microsurgery, tendon	M	Ethilon	Ethicon
			M	Monsof	Synco
			M	Dermalon	Synco
			B	Nurolon	Ethicon
Stainless steel	CrNiFe alloy	Abdominal and sternal	B	Surgilon	Synco
			M, T	Ethisteel	Ethicon

Shape Memory effect of Ni-Ti alloy

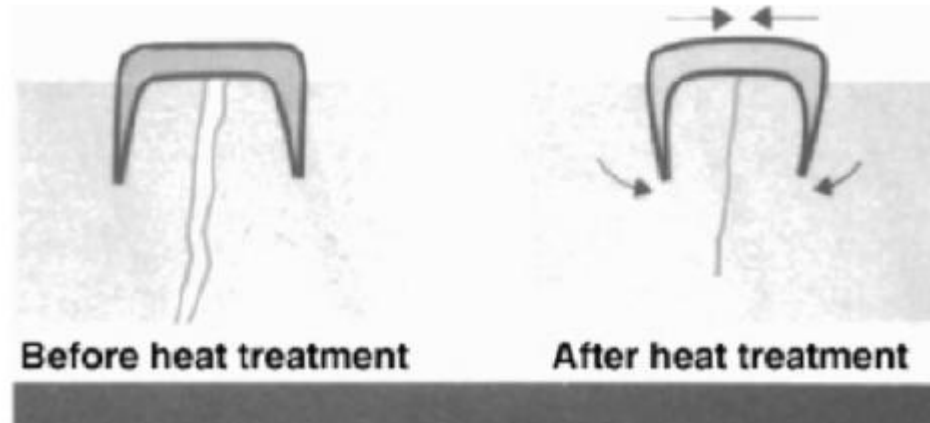
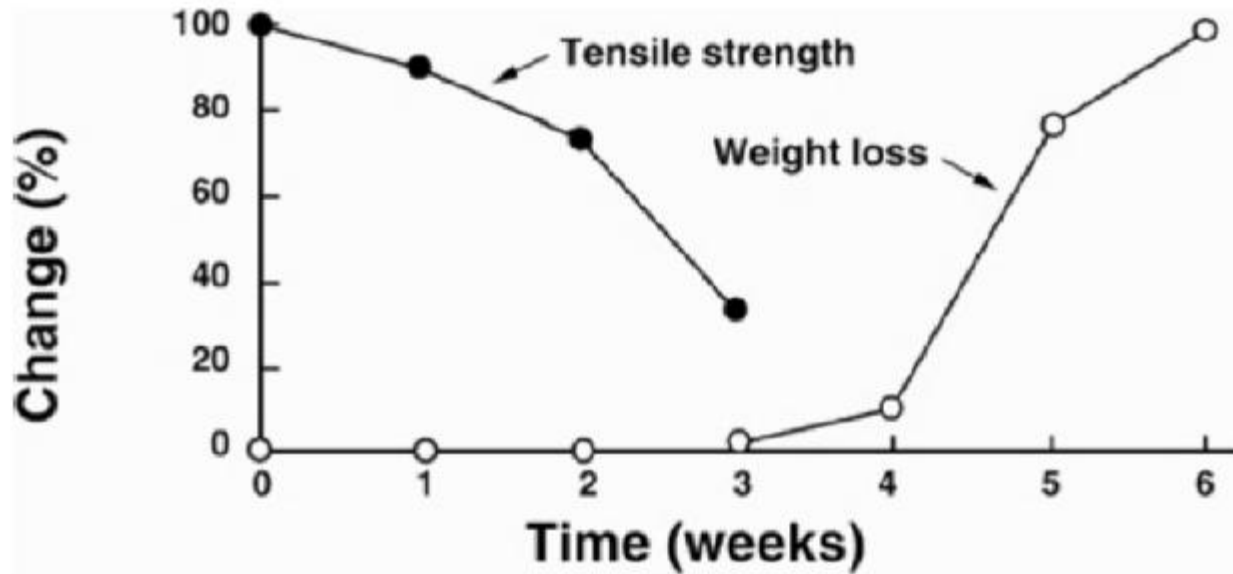


Table 11-2. Polymer Composition of Synthetic Absorbable Sutures

Suture	Block structure	Polymer composition (%)
Multifilament braids		
Dexon	PGA homopolymer	
Vicryl	PGA/PLLA random copolymer	90/10
Polysorb	PGA/PLLA random copolymer	90/10
Panacryl	PGA/PLLA random copolymer	3/97
Monofilaments		
PDS II	PDO homopolymer	–
Maxon	PGA–PTMC/PGA-PGA	100-85/15-100
Monocryl	PGA–PCL/PGA-PGA	100-45/55-100
Biosyn	PGA/PDO–PTMC/PDO–PGA/PDO	92/8-65/35-92/8
Caprosyn	PGA/PCL/PTMC/PLLA random copolymer	70/16/8/5

Absorbable synthetic suture-Vicryl –after implantation



Comparison of absorbability of sutures with time

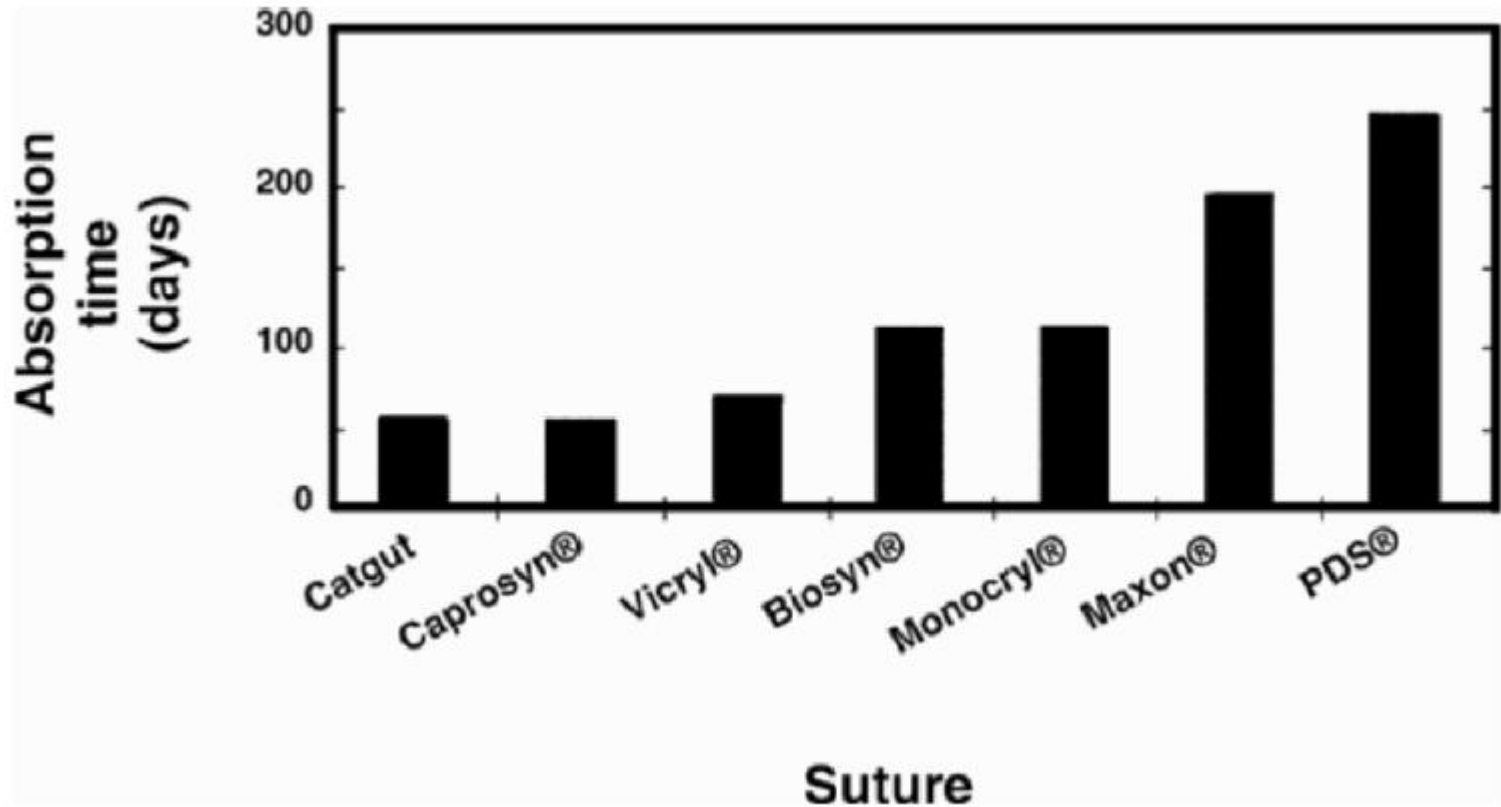


Table 11-3. Minimum Breaking Loads for British-Made Catgut

Size	Diameter (mm)		Minimum breaking load (lbf)	
	Minimum	Maximum	Straight pull	Over knot
7/0	0.025	0.064	0.25	0.125
6/0	0.064	0.113	0.5	0.25
5/0	0.113	0.179	1	0.5
4/0	0.179	0.241	2	1
3/0	0.241	0.318	3	1.5
2/0	0.318	0.406	5	2.5
0	0.406	0.495	7	3.5
1	0.495	0.584	10	5
2	0.584	0.673	13	6.5
3	0.673	0.762	16	8
4	0.762	0.864	20	10
5	0.864	0.978	25	12.5
6	0.978	1.105	30	15
7	1.105	1.219	35	17.5

Fate of suture after implantation

Absorbable

- Biological degradation by enzymes-specific functional groups
- Hydrolysis of synthetic polymers enzymes-specific functional groups

Non-absorbable

Suture material get encapsulated or walled of by fibroblasts

Surgical tapes

Surgical tape or **medical tape** is a type of [pressure-sensitive adhesive tape](#) used in medicine and [first aid](#) to hold a [bandage](#) or other [dressing](#) onto a [wound](#).



Features:

- hold firmly onto skin, dressing materials, and underlying layers of tape
- Removed easily without damaging the skin
- Surgical tape is often white because it contains [zinc oxide](#), which is added to help prevent [infections](#)
- breathable tapes such as [Kinesiology Tape](#), and other elastic bandages with adhesive are made of cotton, [microporous material](#), such as [3M Micropore](#), are widely used.
- Some types are commonly used in sports to add a non-slip wrapping to things which must be [gripped](#), such as tennis racquets, and hockey and lacrosse sticks, because of their rough texture and removability leaving little residue.

Pressure sensitive adhesive in Surgical tapes

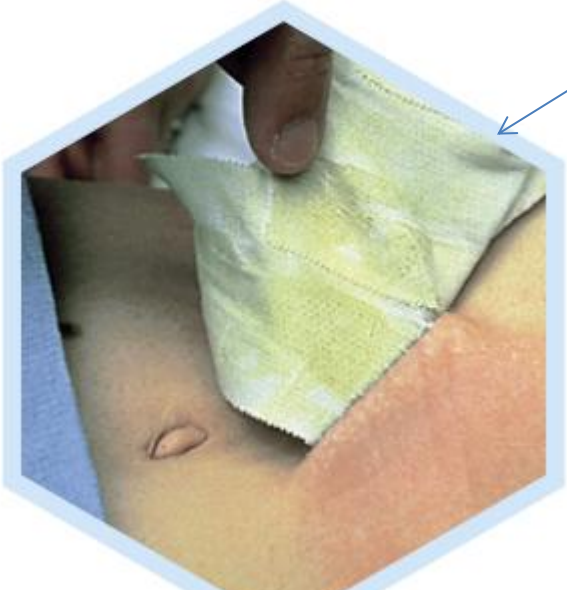
- natural rubber adhesives,
- synthetic rubber adhesives,
- acrylic adhesives

Typical applications;

single-coated tapes in wound care dressings,
surgical tapes and electrodes,

double coated tapes and transfer adhesives
diagnostic test strips, ostomy devices, surgical
drapes, advanced wound care dressings and
other

Skin Trauma due to rubber based adhesive

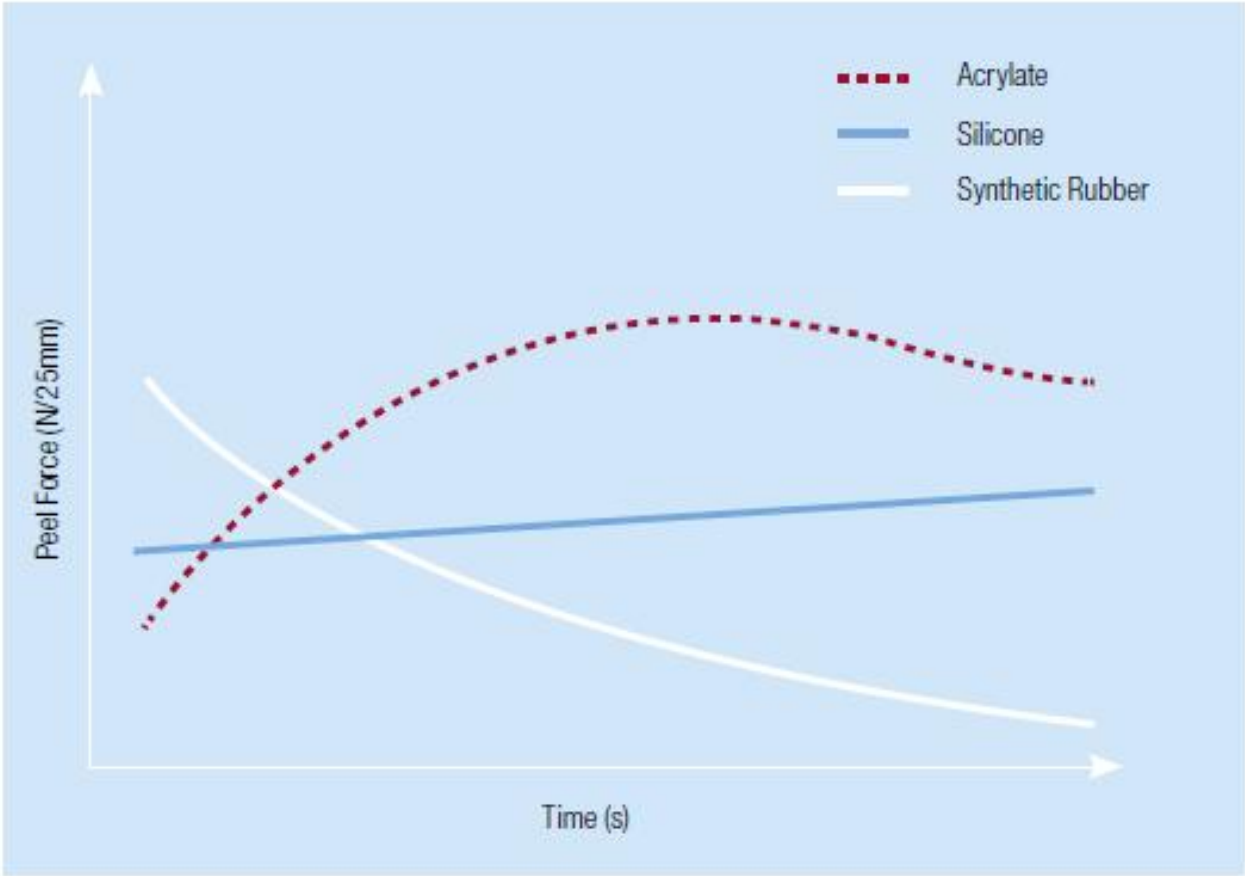


**Paper
backing
PSA**



**PU backed PSA
Breathable**

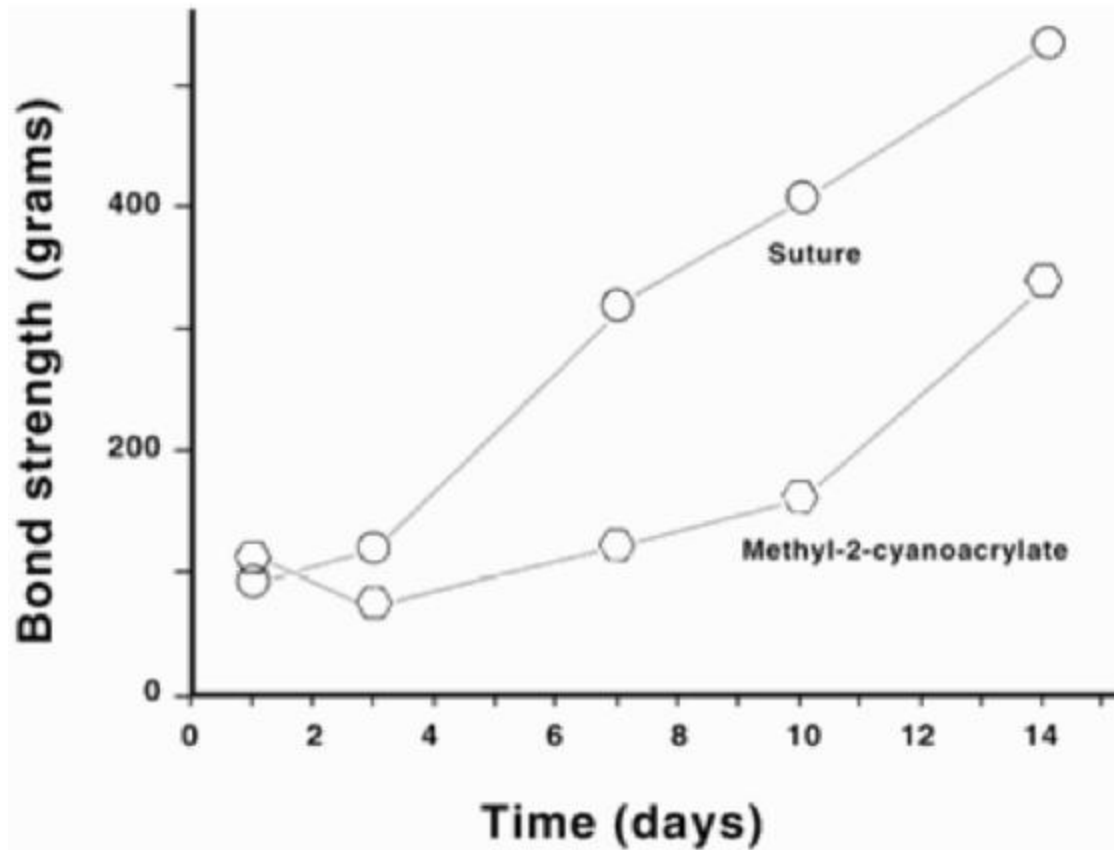
Comparison of three types of PSA



Ligament, Cartilage, tendons

- Ligament-connective tissue that joins **bone to bone**-strong, elastic, fibrous
- Tendons-connective tissue that joins **bone to muscles**-strong, elastic, fibrous
- Cartilage-connective tissue that acts as **soft cushion on bone**-strong, elastic, fibrous

Tissue Adhesives



Main Strength depends on-

- Covalent bonding
- Thickness,
- porosity
- Flexibility
- Rate of degradation

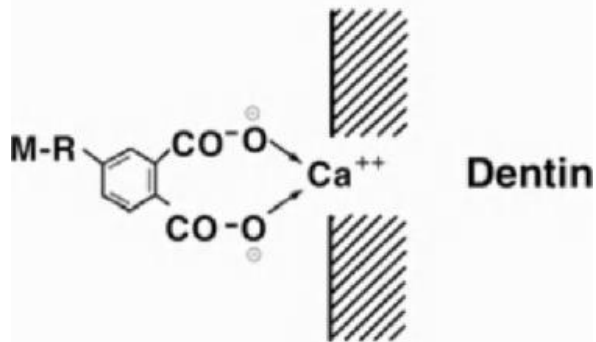
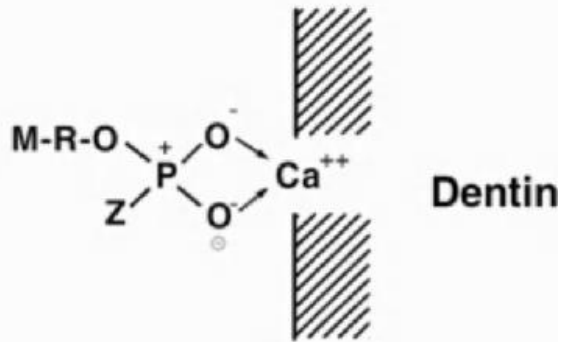
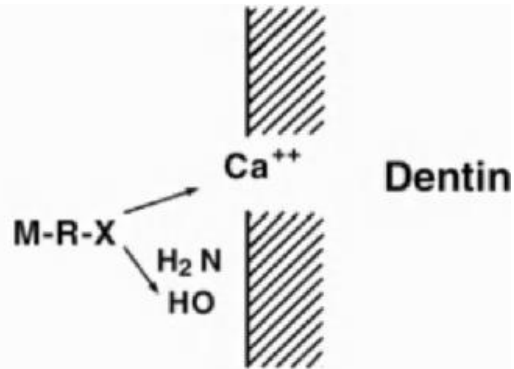
Table 11-4. Mechanical Properties of Dental Cements and Sealants

Materials	Compressive strength (MPa)	tensile strength (MPa)	Modulus (GPa)	Toughness K_{IC} (MPa m ^{1/2})
Zinc phosphate	80–100	5–7	13	~0.2
Zinc polycarboxylate	55–85	8–12	5–6	0.4–0.5
Glass ionomer	70–200	6–7	7–8	0.3–0.4
Resin sealant unfilled	90–100	20–25	2	0.3–0.4
Resin sealant filled	150	30	5	–
Resin cement	100–200	30–40	4–6	–
Composite resin filling material	350–400	45–70	15–20	1.6

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Materials indicate the nature of fillers and other additives(tackifiers, sealants etc.)

Fixation of dental resin monomers with adhesive through Ca^{+2}



M-R = Monomer

Percutaneous Devices

Skin implant

- Problems-
 - Attachment is not permanent
 - Downgrowth and/or overgrowth of epithelium around the device
 - Any opening may cause bacterial infection

Factors and variables concerned

End-use factors

- a. Transmission of information: biopotentials, temperature, pressure, blood flow rate, etc.
- b. Energy: electrical and electromagnetic stimulation, power for heart assist devices, cochlear implants, etc.
- c. Matter: cannula for kidney dialysis and blood infusion or exchange, etc.

Engineering factors

- a. Materials selection: polymers, ceramics, metals, and composites.
- b. Design variations: button, tube with and without skirt, porous or smooth surface, etc.
- c. Mechanical stresses: soft and hard interface, porous or smooth interface.

Biological factors

- a. Implant host: man, dog, rabbit, sheep, etc.
- b. Implant location: abdominal, dorsal, forearm, etc.

Human factors

- a. Postsurgical care.
- b. Implantation technique.
- c. Aesthetic outlook.

Cross-sectional Image of PD-skin interface

Figure 1

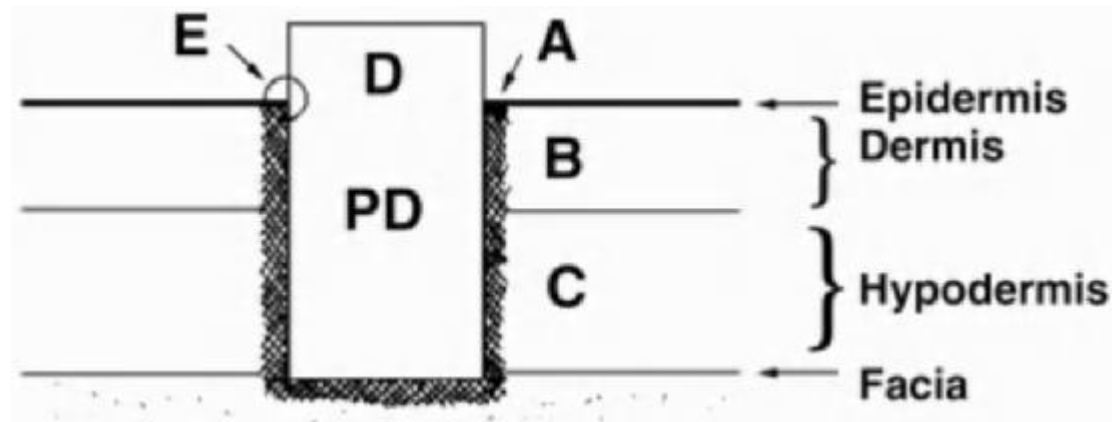


Figure 2

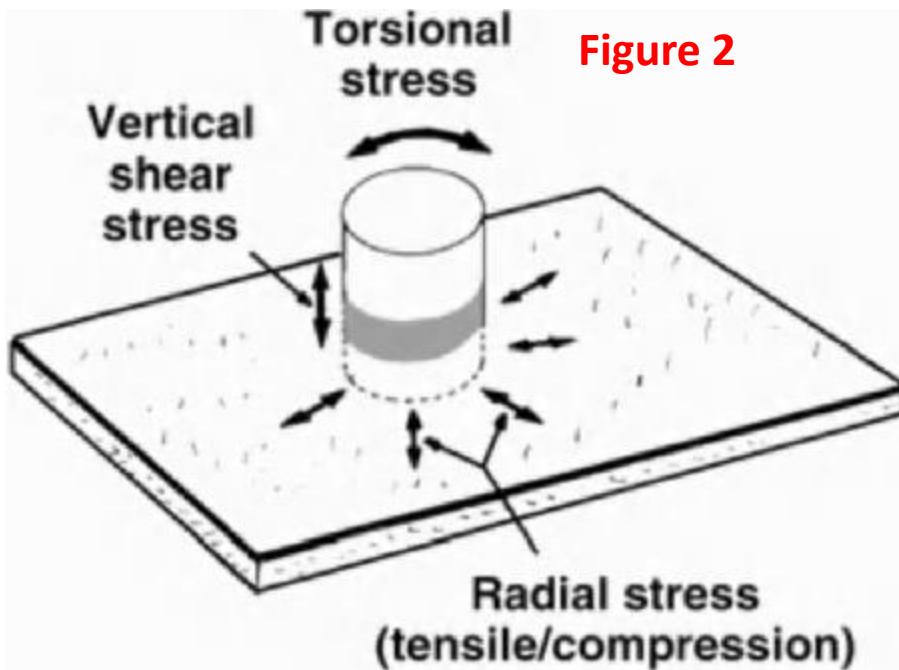
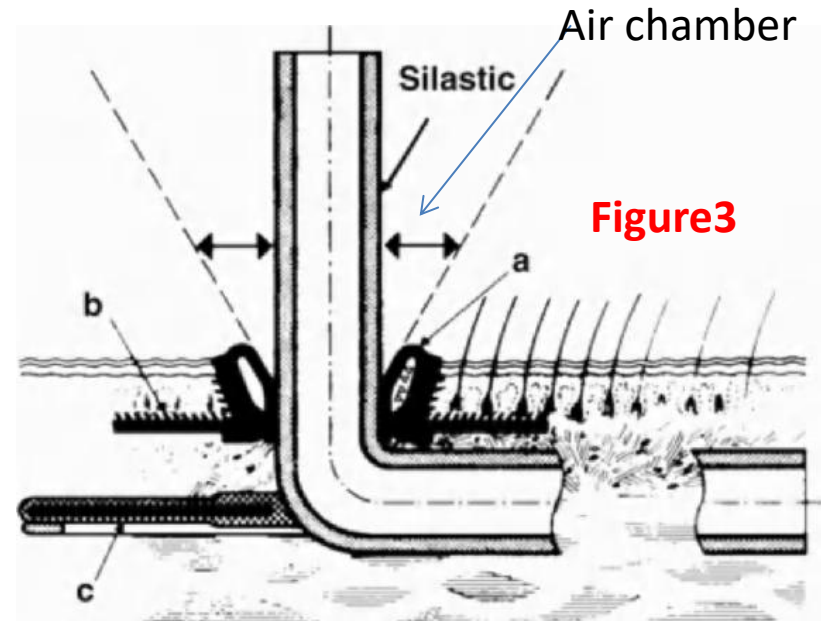
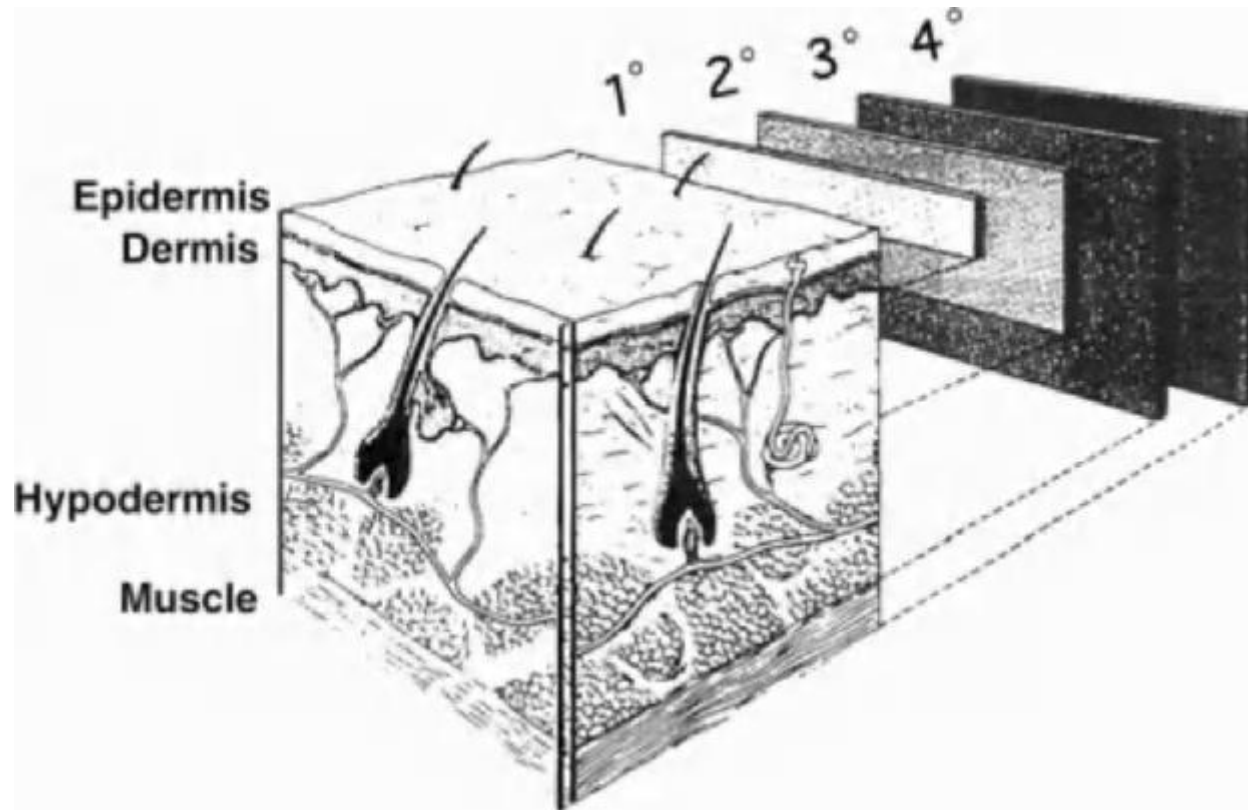


Figure 3



Artificial Skins and Burn Dressing



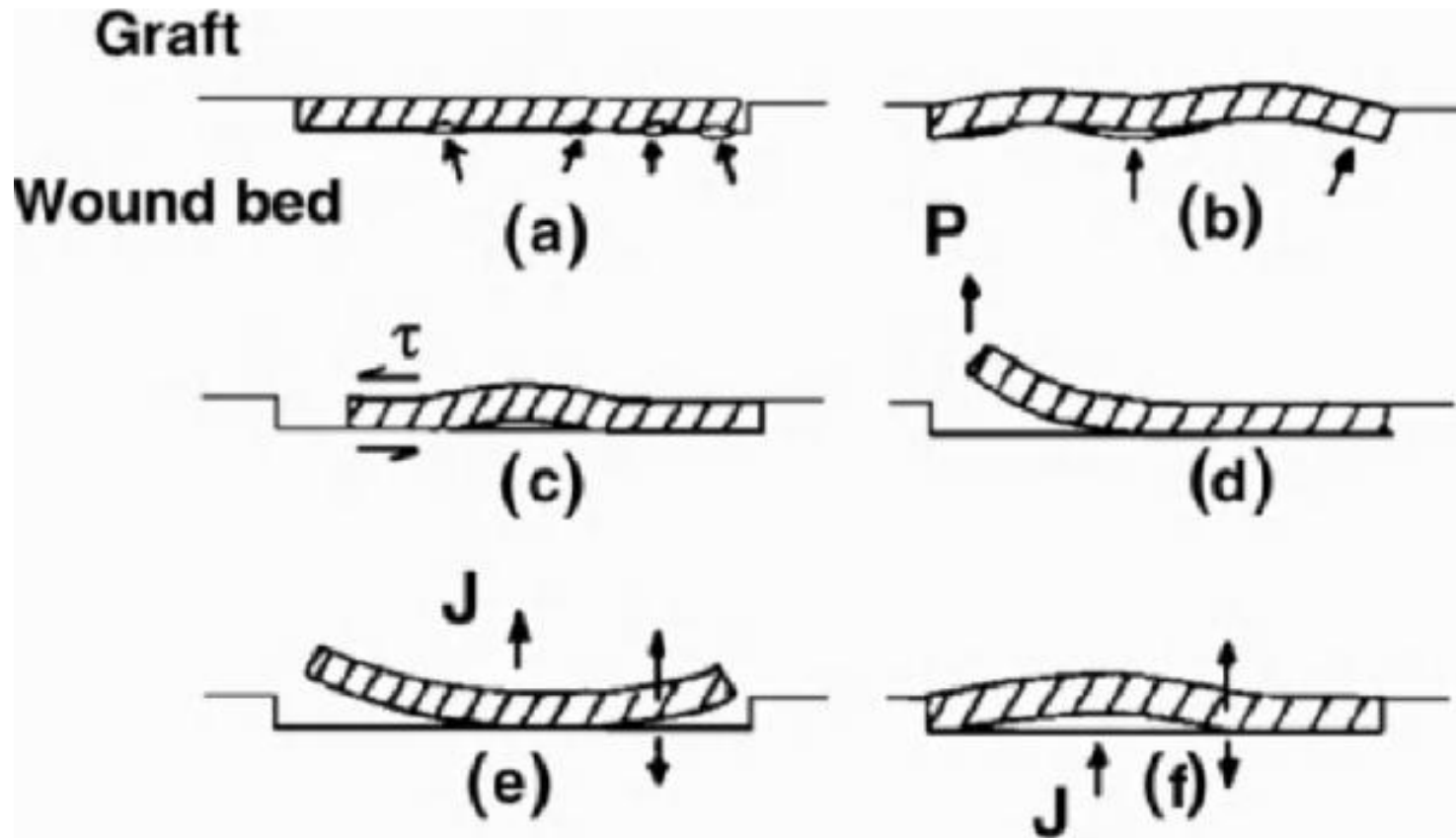
Materials Used for temporary and permanent Skin transplantation

Membrane	Selected characteristics
Temporary	
Porcine xenograft	Adheres to coagulum, excellent pain control
Biobrane ^a	Bilaminar, fibrovascular ingrowth into inner layer
Split-thickness allograft	Vascularizes and provides durable temporary closure
Various semipermeable membranes	Provides vapor and bacterial barrier
Various hydrocolloid dressings	Provides vapor and bacterial barrier, absorbs exudate
Various impregnated gauzes	Provides barrier while allowing drainage
Allogeneic dressings	Provides temporary cover while supplementing growth factors
Permanent	
Epicel ^b	Provides autologous epithelial layer
Integra ^c	Provides scaffold for neodermis, requires delayed thin autograft grafting
AlloDermd	Consists of cell-free human dermal scaffold, requires immediate thin autograft

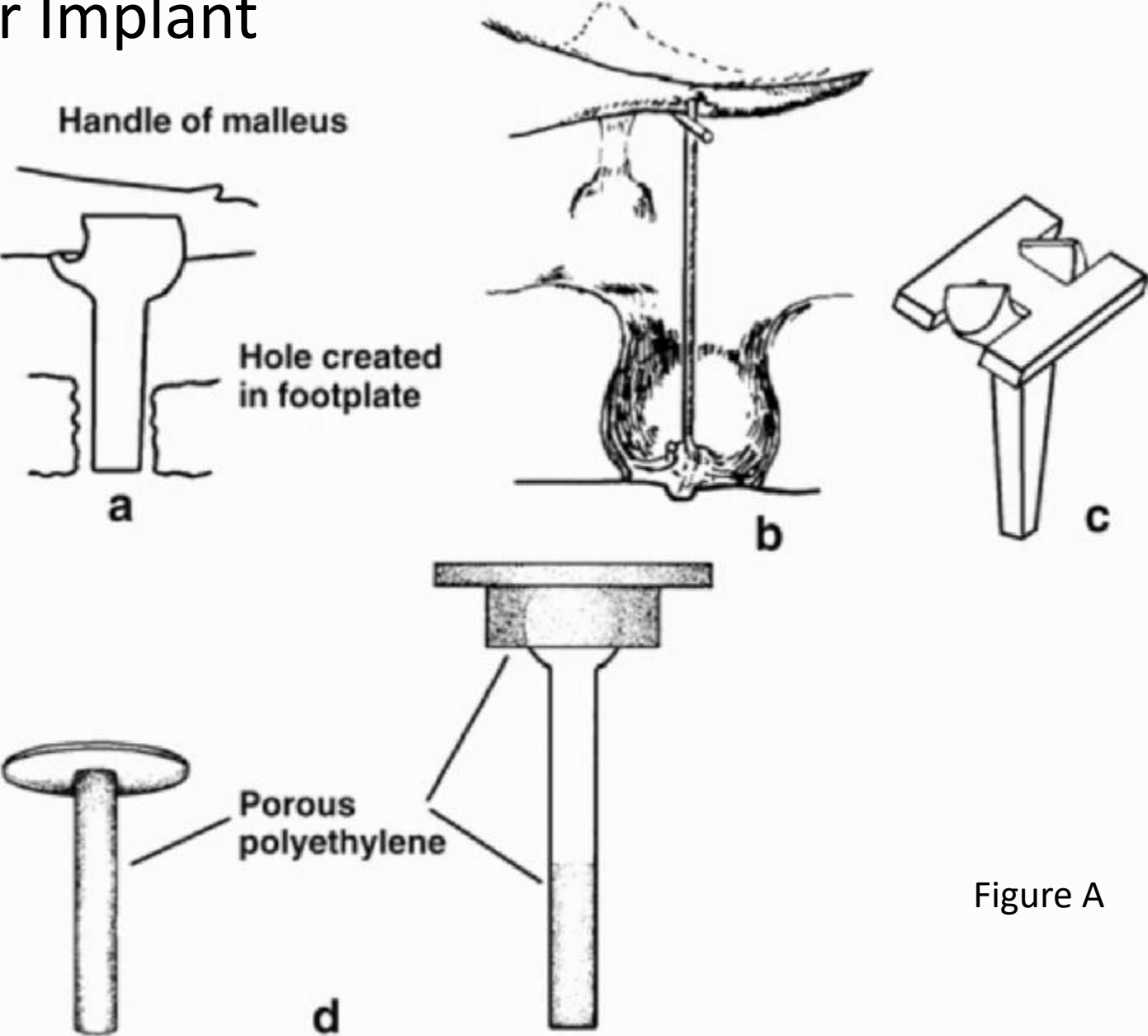
^aMylan Laboratories, Inc. ^bGenzyme Biosurgery Inc., Cambridge, MA. ^cIntegra Life Sciences Corporation, Plainsboro, NJ. ^dLifeCell Inc., Branchburg, NJ.

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Design requirements and schematic representation of skin implants



Ear Implant



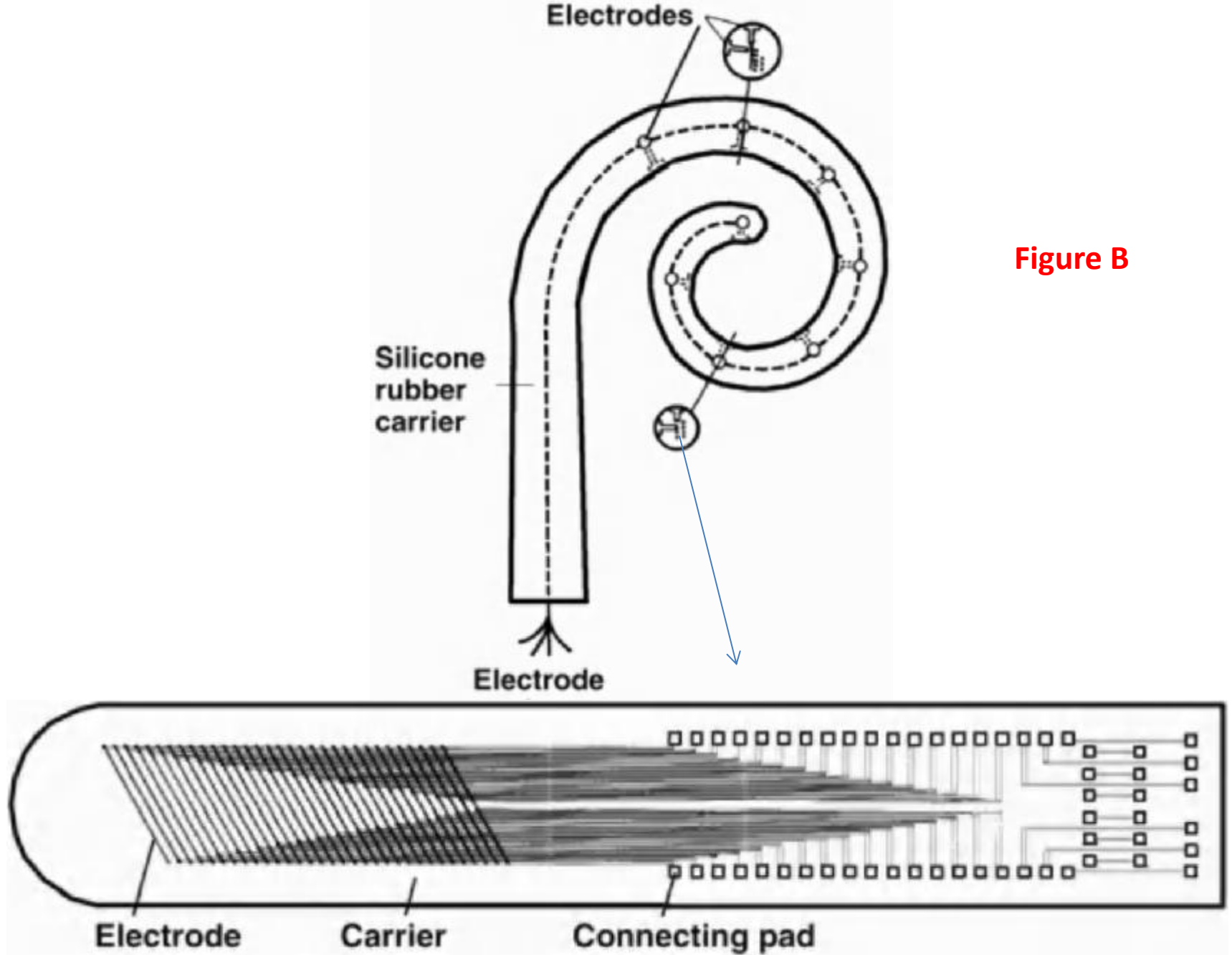


Figure B

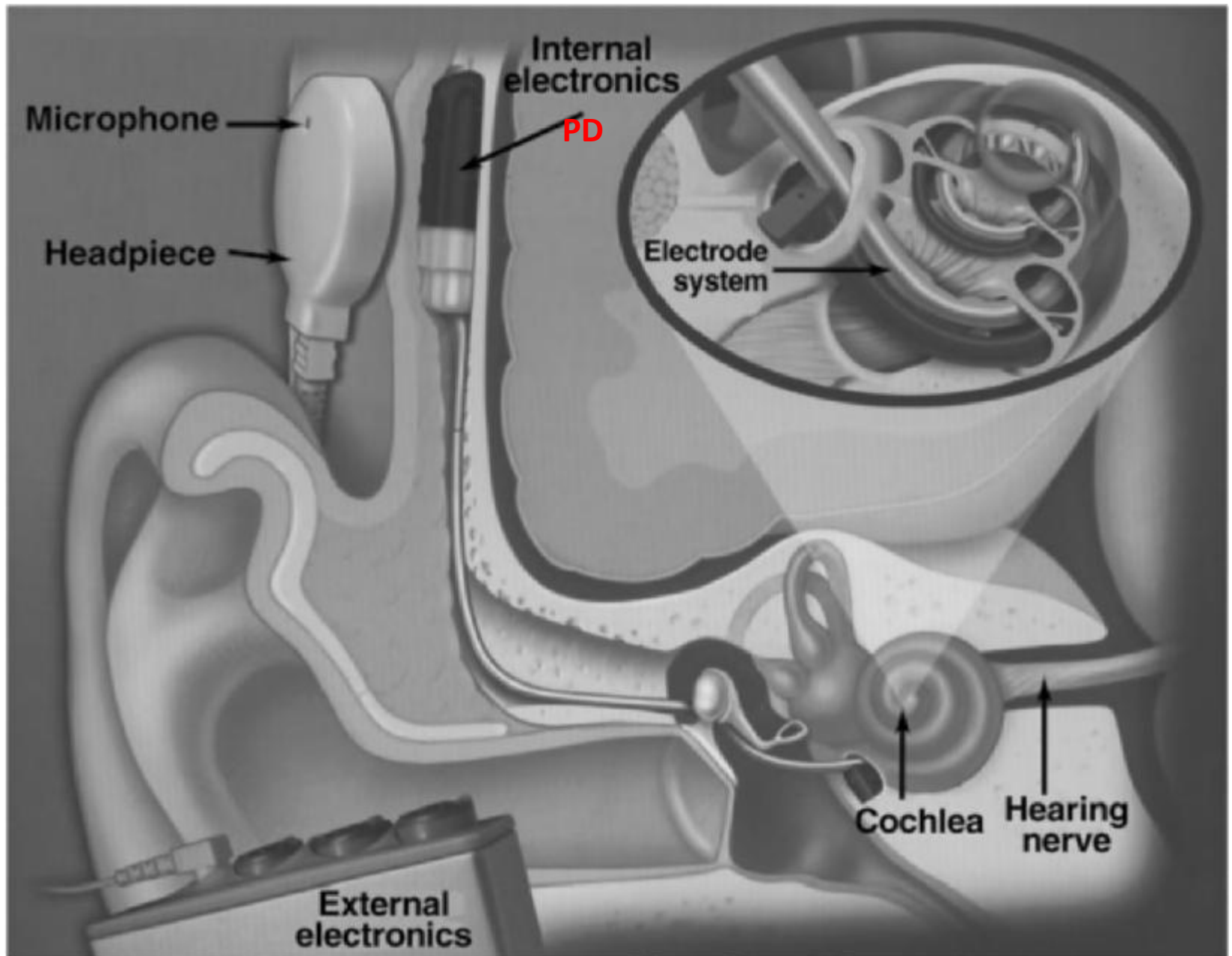


Figure C

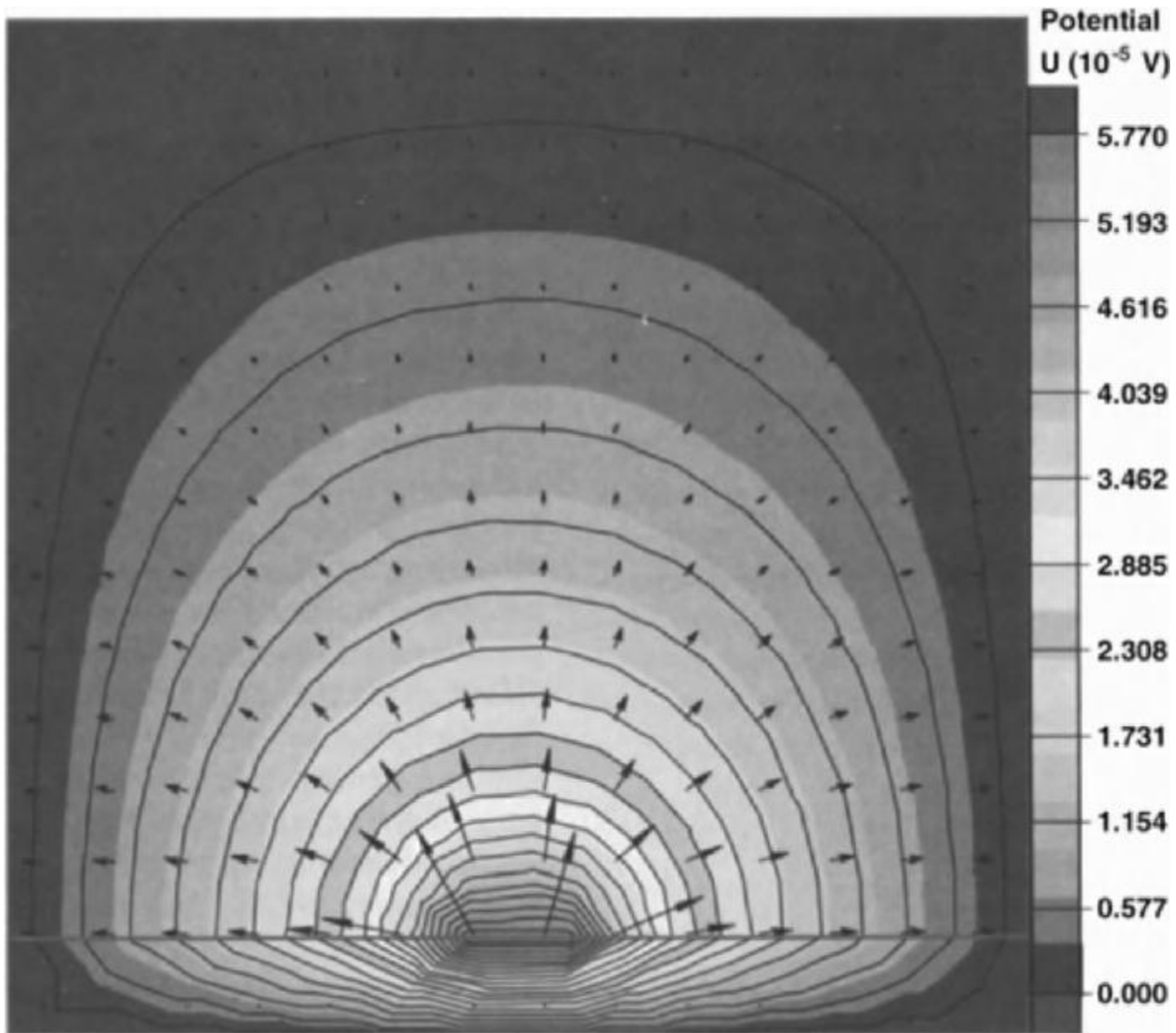


Figure D