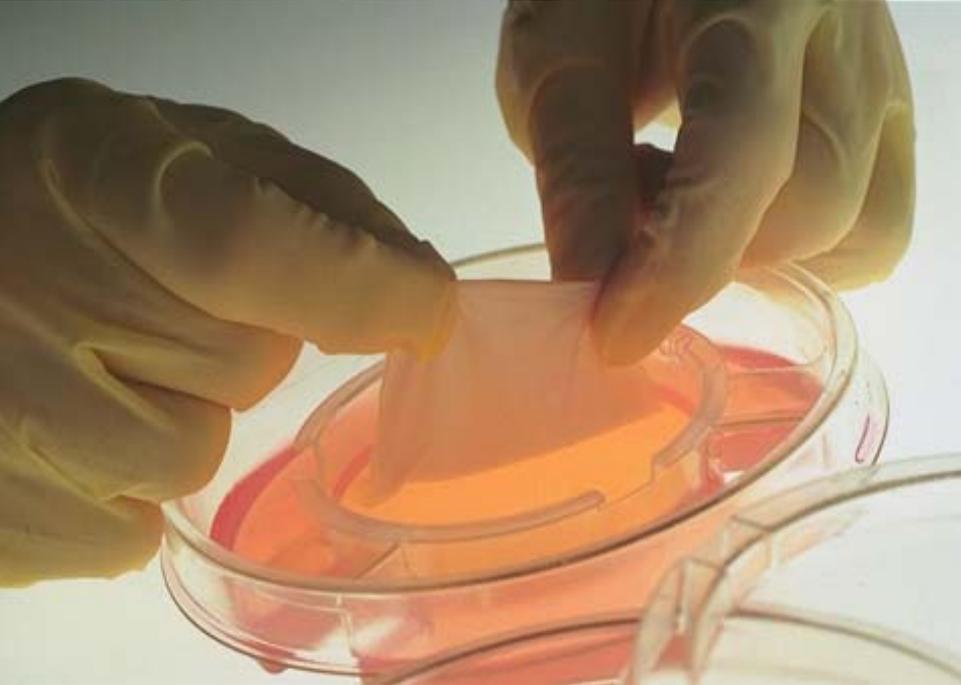




Sutures & Wound Dressings



Wound Care and Management



- > million Americans suffer from non-healing wounds annually,
- Cost: \$750 million;
- Etiology: trauma, inactivity, disease and surgery;
- 3,852 wound care products on the market;
- Some classified as drugs or biologics, while others are classified as devices;

Wound Care Products



Goals:

- Bind surface epithelium and underlying connective tissues when possible;
- Protect wound from infection;
- Maintain moist wound environment; and,
- Permit gas exchange

Principles of Wound Healing



- Achieve Hemostasis
- Initiate Inflammation
- Build Granulation Tissue
- Mature matrix

Keys to Wound Care

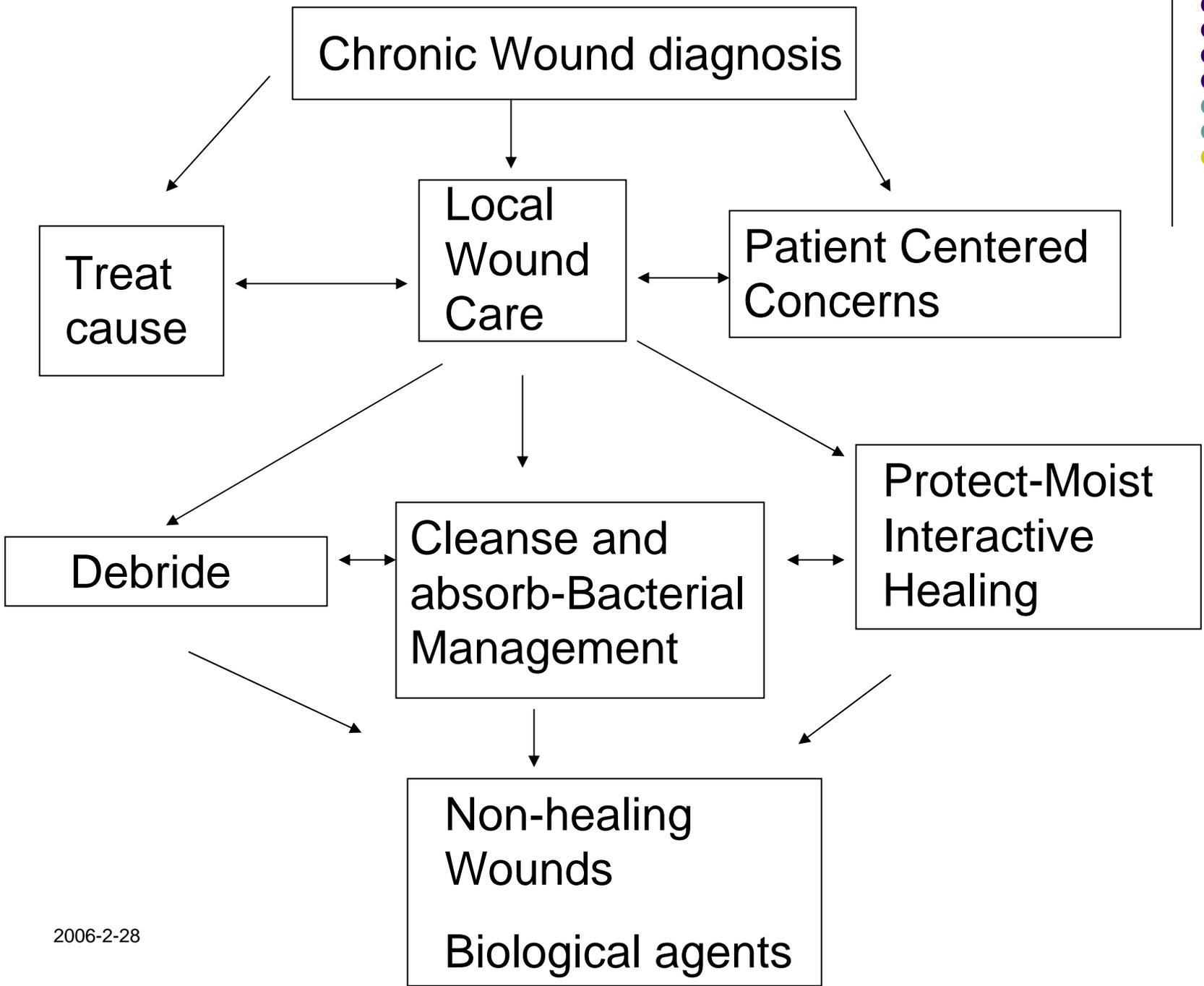
- Identify the causative factors
- Improve the local environment



Common Underlying Causes of Wounds



- Trauma-accident or intentional (surgery)
- Scalds and burns (chemical and physical)
- Animal bites or insect stings
- Pressure (spinal injured)
- Vasculature related, arterial, venous, mixed
- Immunodeficiency
- Malignancy
- Connective tissue disorders
- Metabolic or endocrine disorders (diabetes)
- Nutritional deficiencies
- Psychosocial
- Adverse effects of medications



Wound Color



● **Black.** Necrotic tissue is non-viable, and it must be removed before healing can take place.

● **Yellow.** Yellow wounds may contain moist necrotic tissue (slough) and/or contain purulent drainage. The primary objective is to remove unhealthy tissue, any contaminants, debris and excess exudate which deter the healing process. Once a clean, moist and viable wound bed is achieved, healing can begin.

● **Red.** Is good-the actively healing phase of a wound, cells proliferate, fibroblasts form collagen and eventually small, red, fleshy masses called granulation tissue (angiogenesis) begin to form.

Traditional Wound Closure



- Sutures
- Staples
- Adhesives / Glues

Sutures

- A suture is a strand of material that is used to approximate tissues or to ligate blood vessels during the wound healing process
- Classified according to three characteristics
 - Origin (Natural vs. Synthetic)
 - Absorption (Absorbable vs. Non)
 - Fiber Construction (Multi vs. Monofilament)



Commercially Available Sutures



Natural Sutures

- Cellulose Based
(cotton and linen)

- Protein Based
(silk and collagen)

Commercially Available Sutures



Synthetic Nonabsorbable Sutures

- Polyester
- Polypropylene (Prolene)
- Polyamide (Nylon)
- Polytetrafluorethylene (Teflon)
- Stainless Steel

Commercially Available Sutures



Synthetic Absorbable Sutures

- Polyglycolic acid (Dexon)
- Poly L-lactic Acid
- Polytrimethylene carbonate (PDS)
- Polydioxanon
- Polycaprolactone
- Copolymers ex. PGA/PTMC (Maxon)

Suture Properties



Physical

- Tensile strength
- Elongation-to-break
- Young's modulus
- Knot security
- Swelling

Suture Properties



Handling

- Knot Tie Down
- Tissue Drag
- Memory
- Suppleness

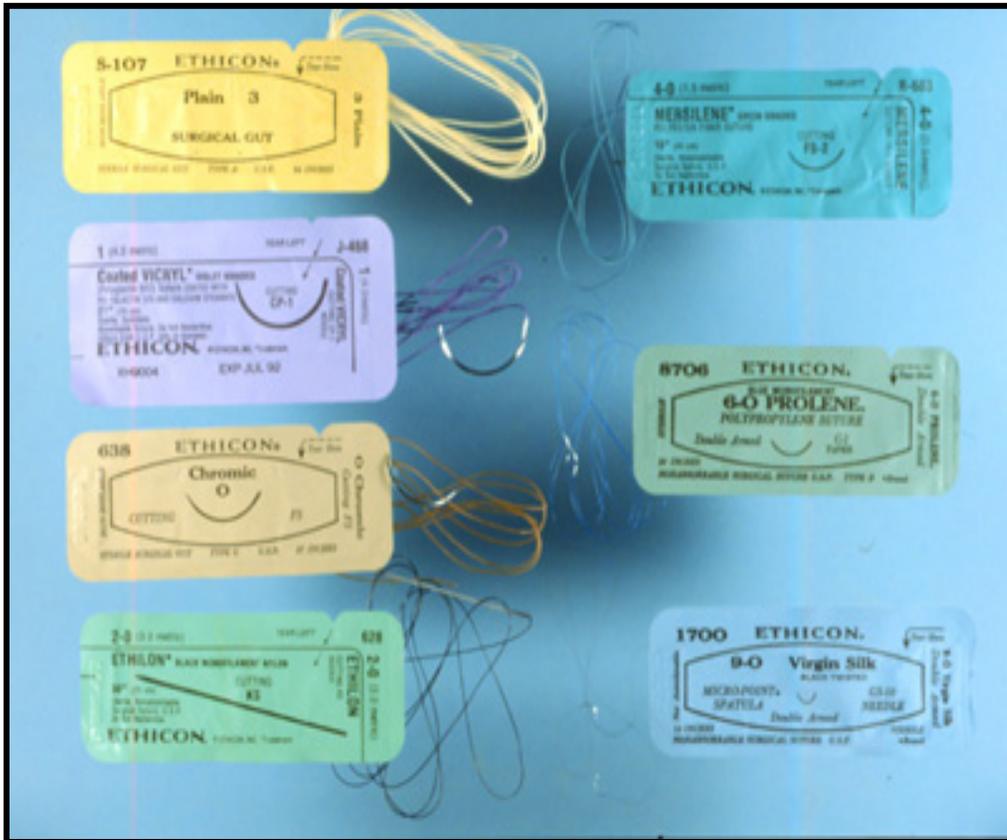
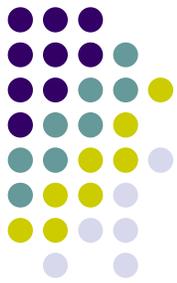
Suture Properties



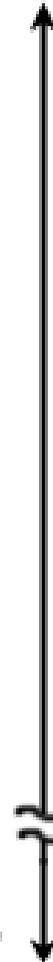
Biological

- Absorption
 - enzymatic vs. hydrolysis
- Biocompatibility
 - chronic toxicity
 - teratologics
 - mutagenicity
 - carcinogenicity
 - allergenicity
 - immunigenicity

Suture Size



Larger



- 5 *Tow a car!!*
- 4
- 3
- 2 *Horse abdominal repair*
- 1
- 0 *Average size*
- 2-0
- 3-0 *Subcutaneous*
- 4-0 *Subcutaneous*
- 5-0 *Vein/Artery repair*
- 9-0 *Ophthalmic*

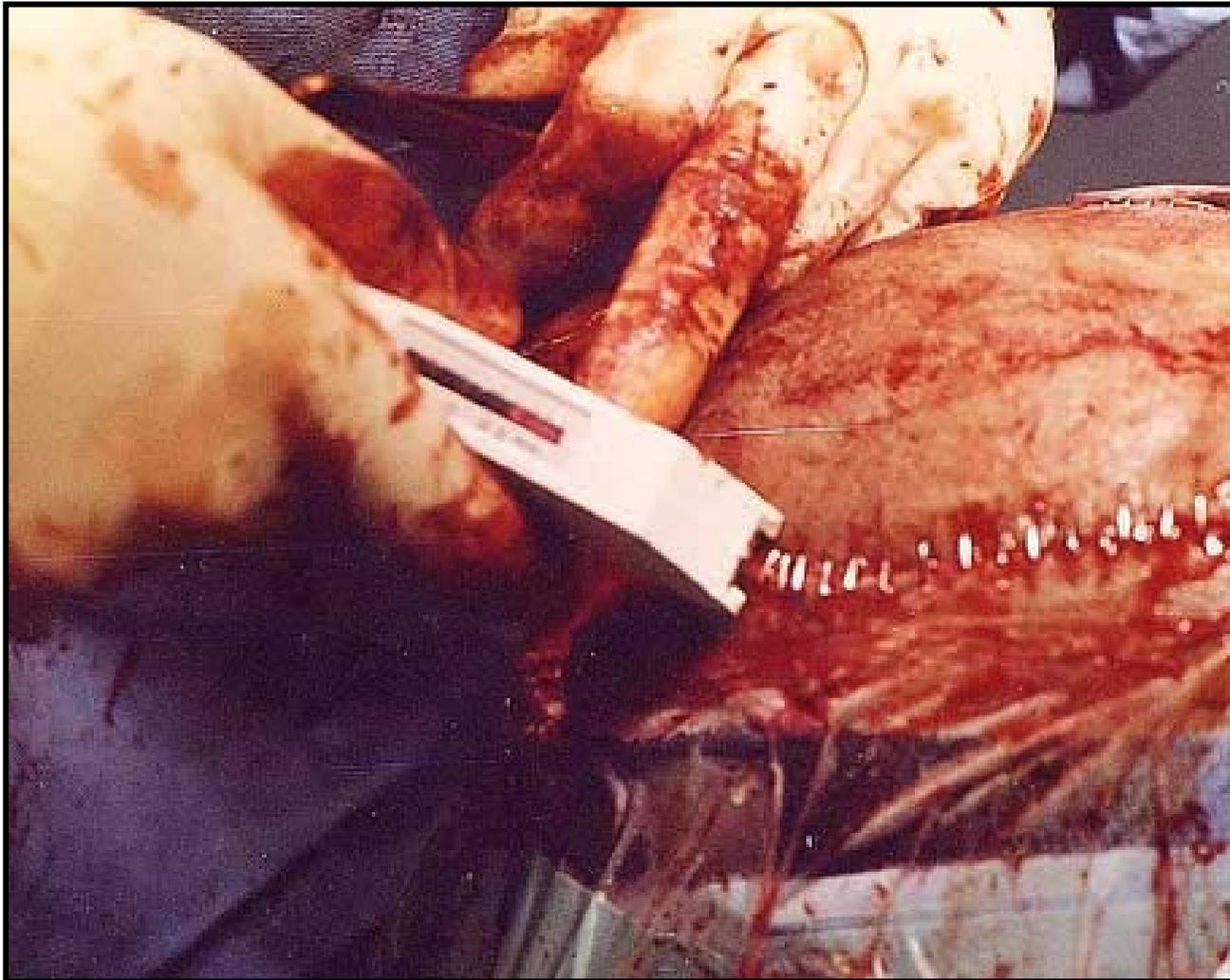
Smaller
(Add "0's")

Staples

- Thin metal prongs are used to approximate the edges of the skin (area must be anesthetized);
- Staple applicators push the two prongs of the staple down through the epidermis and dermis into the subdermal layer and then bend these prongs inward;
- The major advantages are speed of closure and reduced infection rate.
- Indicated on scalp and abdomen (tendons, nerves deep)



Stapling a Craniotomy Skin Incision

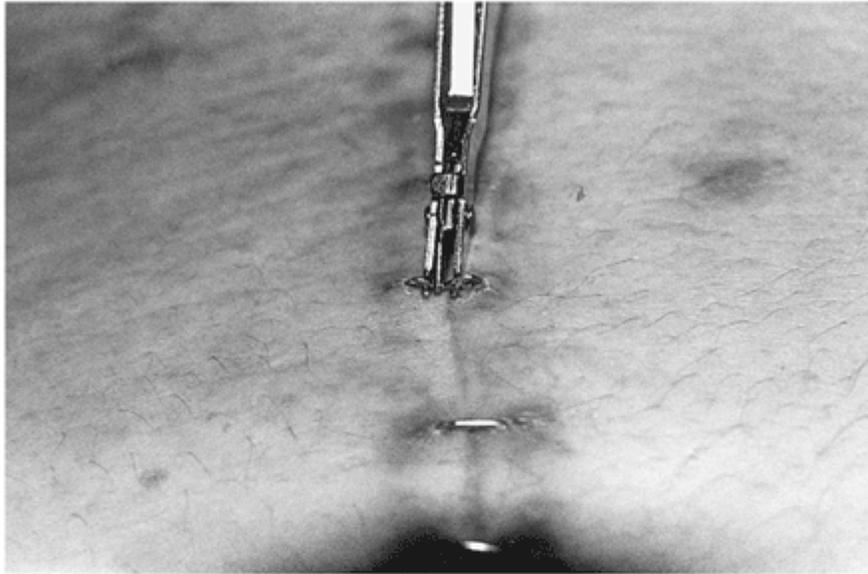


Staples



Removal

Removed 3 to 14 days after they are put in.





Tissue Adhesive

- Indicated for the closure of simple skin incisions including laparoscopic incisions, and trauma-induced lacerations in areas of low skin tension and have easily approximated skin edges.
- **Cyanoacrylate Based Monomers**
 - Indermil, Dermabond, Histoacryl
- May be used in conjunction with, but not in place of, deep dermal stitches.

Device Description

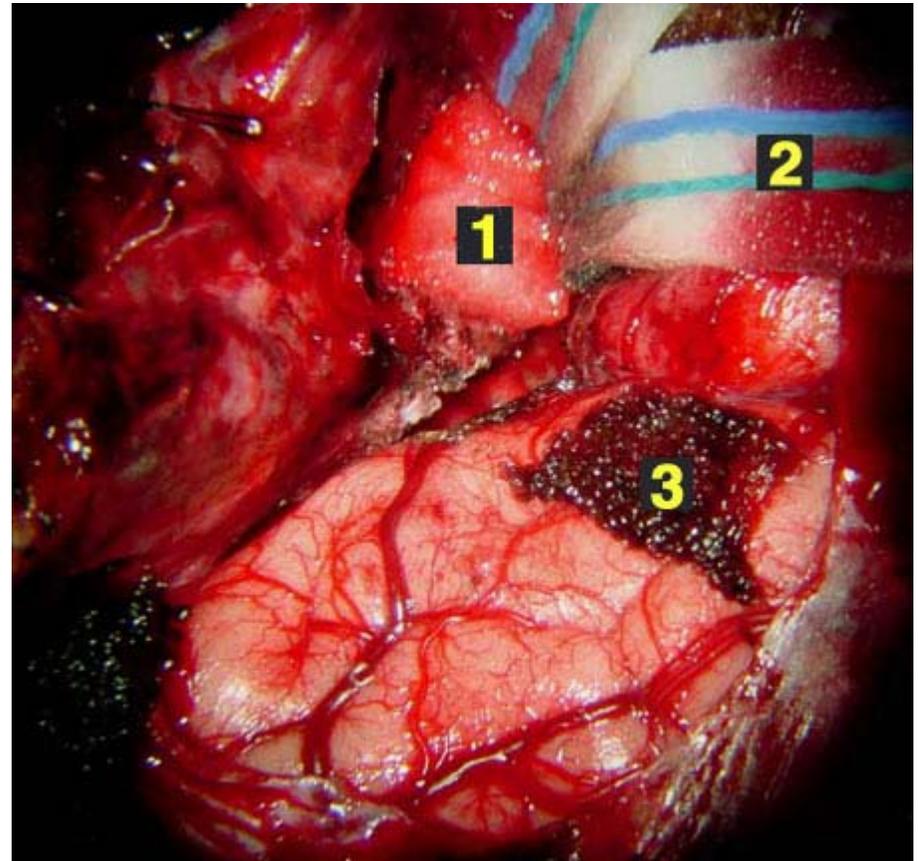


- Tissue adhesives are sterile, liquid topical cyanoacrylate monomers supplied in a single patient use, plastic ampule.
- Each ampule is sealed within a foil packet so the exterior of the ampule is also sterile.
- Remains liquid until exposed to water or water-containing substances / tissue, after which it cures (polymerizes) and forms a film that bonds to the underlying surface.

Materials Used for Hemostais



Surgical cellulose is a material that is comes in thin sheets of interwoven specially treated cellulose that provides a matrix to which platelets and clotting factors can adhere leading to formation on the cellulose of a dense clot which can act as a patch over an area of bleeding.



Traditional Wound Care Products



Protective and gas permeable

- Transparent Films
- Foams
- Hydrocolloids or Hydrogels
 - Carboxymethylcellulose
 - Alginate
- Specialty Absorptive Dressings

Transparent Films



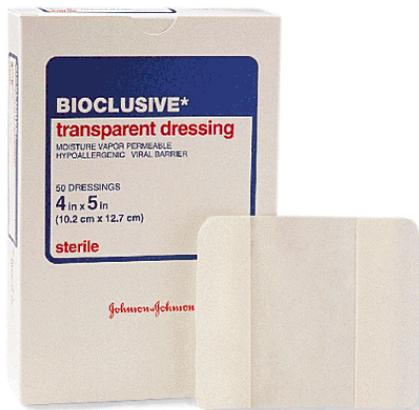
- Advantages:
 - Waterproof and Bacteria-proof
 - Allows visualization of the wound.
 - Won't traumatize wound when removed.
- Disadvantages
 - Not recommended for wound with moderate/heavy exudate.
 - Not recommended for wound with fragile surrounding skin.
 - Provides no cushioning to wound.

Infection Control Products

-Dressings to Secure Catheters



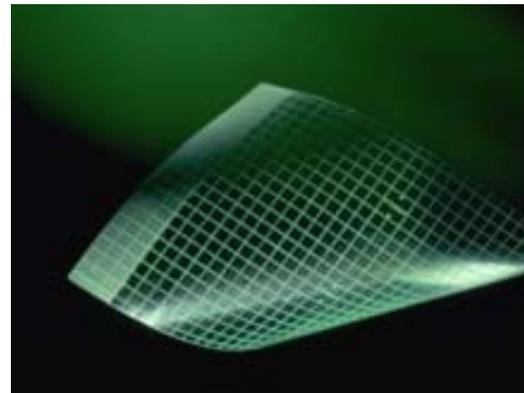
- a thin, semi-occlusive, transparent polyurethane film dressing that provides a bacterial/viral barrier and helps secure catheters, reducing mechanical irritation.





Transparent Films

- Acu-derm
- Bioclusive
- Blisterfilm
- Polyskin II
- Pro-Clude
- Op-Site
- Opraflex
- Tegaderm (3M)
- Transeal
- Transite
- Uniflex
- Ventex





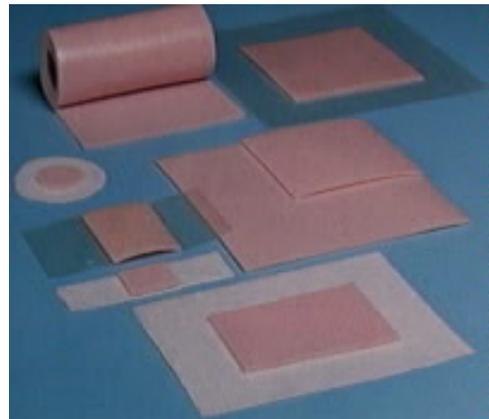
Foams-polyurethane pads

-Indications: Noninfected, draining granular wound

- Advantages
 - Non-adherent
 - Won't injure surrounding skin
 - Can repel contaminants
 - May be used under compression
 - Cushions wound surface
 - Maintains moist wound environment
 - Highly conforming
 - Gas permeable

Foams

- Examples
 - Allevyn (Smith & Nephew)
 - Cutinova Foam
 - Epilock
 - Flexzam
 - Hydrasorb
 - Lyofoam
 - Mitraflex
 - Nu-derm
 - Polymem
 - Tielle



Hydrocolloids

in pad, sheet or filler form for occlusive use.

Forms a “gel” as it absorbs water from the wound bed that sits on wound

Indications: Small, solitary non-draining ulcers or light-to-moderate exudate wounds

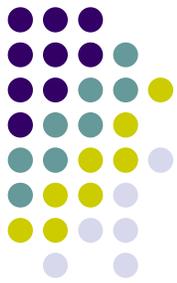
- Advantages

- Impermeable to bacteria and other contaminants
- Promotes autolysis, angiogenesis, and granulation
- Self-adhesive and molds well
- Limited-to-moderate absorption
- Creates moist environment
- May be left in place for up to 5 days
- May be worn in the shower



Hydrocolloids

- AquaCel
- Comfeel
- Cutinova Hydra
- **Duoderm CGF**
- Hydrapad
- Intrasite
- J&J Ulcer Dressing
- Procol
- Replicare
- Restore
- Triad
- Ultec





Hydrogels

-cross-linked hydrophilic matrix impregnated into gauze-type pads which allows transmission of water, vapor and CO₂ but discourages dehydration.

Indications: full thickness wounds with moderate drainage

- Soothing and conforms to wound
- Fills in dead spaces
- Highly absorptive
- Can be used on infected wounds
- Disadvantages
 - Difficult to keep in place
 - Encourages gram negative organisms



Hydrogels

- AquaSorb
- Carrington Gel
- Carrasyn-V
- Clear-Site
- Curasol Gel
- Flexderm
- Hydron
- Intrasite Gel
- Solosite
- SAF-Gel
- Transorb
- Woundres



Specialty Absorptive Dressings/Therapies



- Adhesive Gel Sheets (Cica-Care; Smith & Nephew)
- Resorbing Matrices (Promogran Prisma; Johnson & Johnson)
- Combinatorial Therapies
 - Foams + Vacuum Assisted Closure (V.A.C.)
 - Utilizing Negative Pressure Wound Therapy (NPWT; Kinetic Concepts Inc.)

Adhesive Gel Sheets for Scar Treatment



- Flexible, adhesive, semi-occlusive silicone gel sheet.
- Reduces raised scars and redness of the scar so it fades and becomes less noticeable.
- Self-adhesiveness and durability mean that application is simple and the gel sheet can be washed and used several times.



Cica-Care; Smith & Nephew



Resorbing Matrices

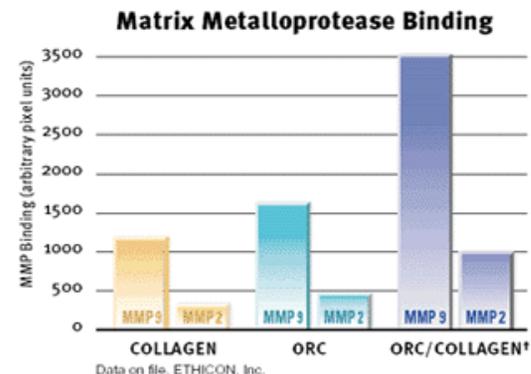
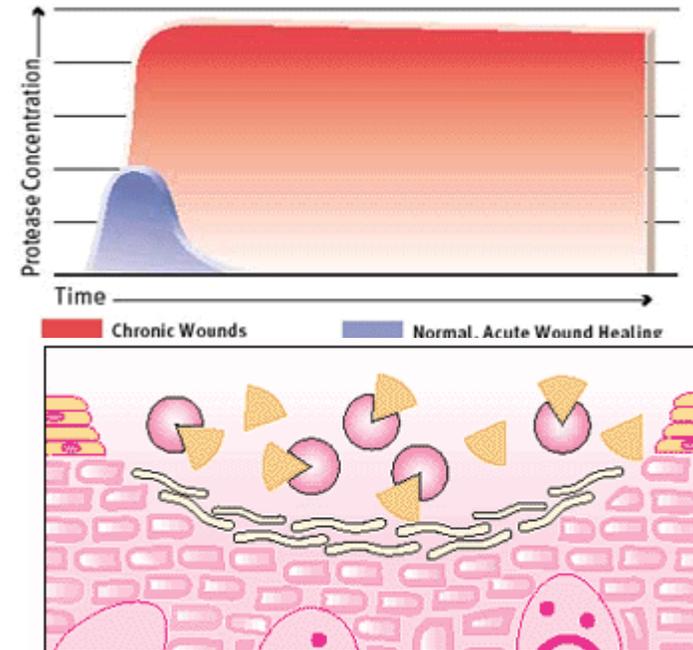
- Matrix is a primary dressing which transforms into a soft, conformable gel, allowing contact with the entire wound bed;
- Consists of 45% regenerating cellulose and 55% type I collagen



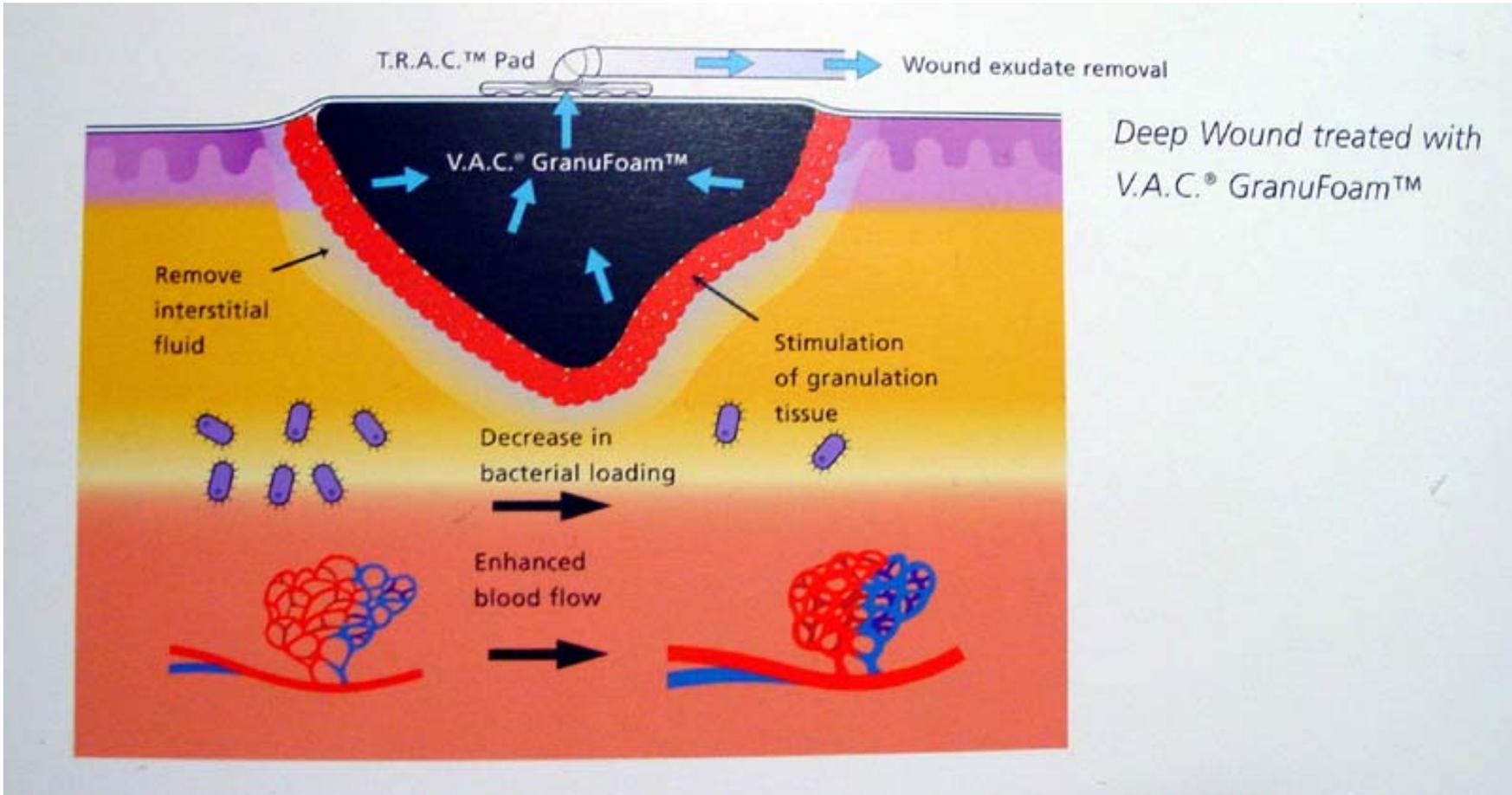
Resorbing Matrices



- The persisting inflammatory phase in chronic wounds contributes to exudate with high concentrations of matrix metalloproteases (MMPs);
- Excess MMPs result in degradation of extracellular matrix proteins;
- Excess MMPs inactivate growth factors;
- cellulose/collagen combination binds more MMPs than ORC or collagen alone



Combinatorial Therapies (Foams + V.A.C.)



Apligraf®

human skin-like products comprised of living human skin cells



Organogenesis



Living Skin Equivalents

- Living bi-layered skin substitutes
 - Apligraf (formerly Graftskin; Organogenesis)
 - Type I bovine collagen, extracted and purified from bovine tendons, and viable allogenic human fibroblast and keratinocyte cells.
 - Dermagraft (Smith & Nephew)
 - Human neonatal fibroblasts derived from fetal foreskin, extracellular matrix and a bioabsorbable suture like scaffold.
- Alternatives
 - Integra Dermal Regeneration Template
 - OASIS Wound Matrix

Living Skin Equivalents



Indications: diabetic foot ulcer care of full-thickness ulcers of neuropathic etiology of at least three weeks duration and burns

Contraindications:

- infections
- exposed bone, capsule, muscle or tendon



Elastomers

Elastomers



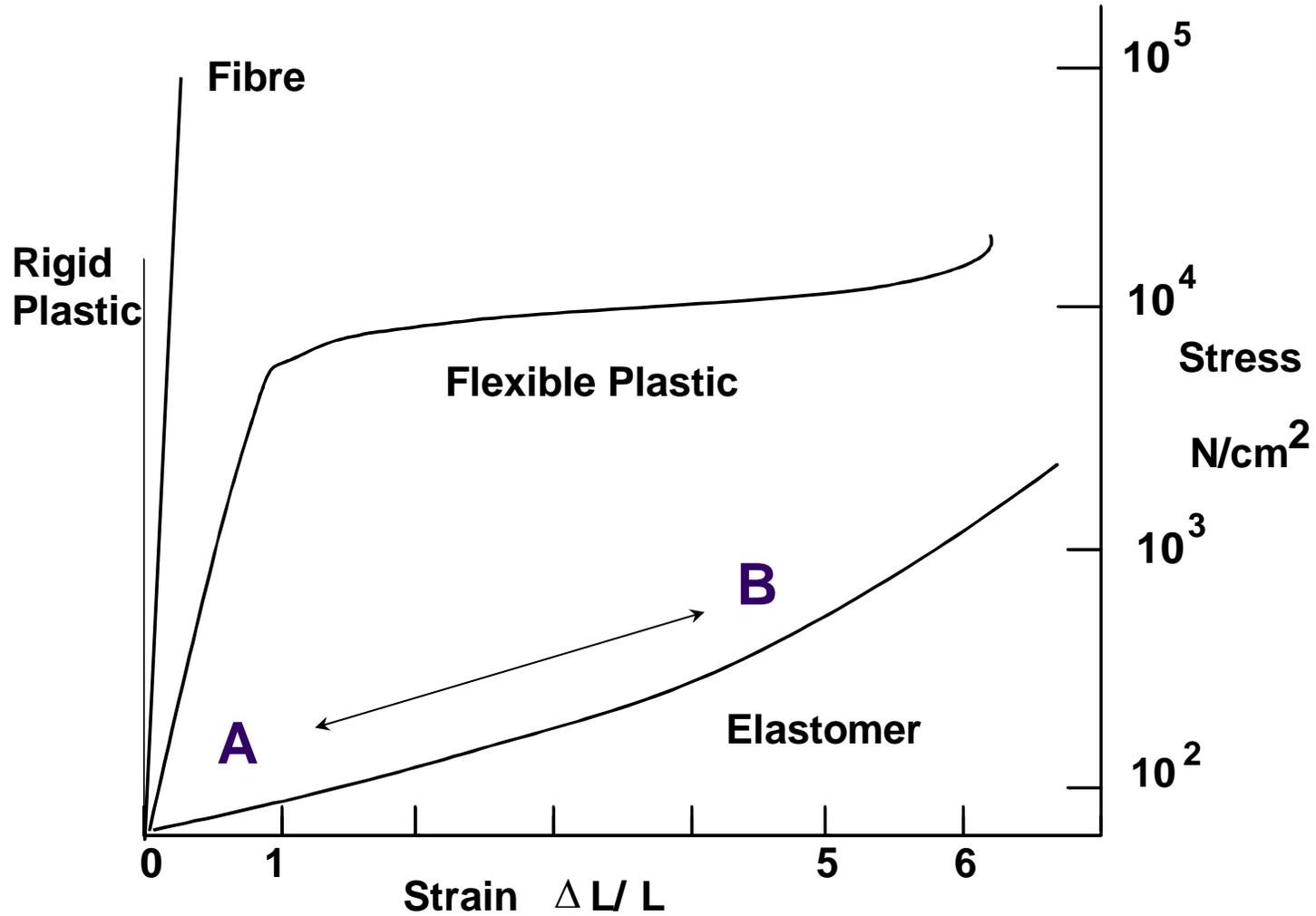
- Definition- materials capable of reversible change in length at operating temperatures, that is, once a load is removed the material returns to its original dimensions;
- a rubbery compound;
- Generally amorphous thermosets with T_g below room temperature to allow full chain mobility- the restoring force is entropic;
- referred to as “memory”

Types

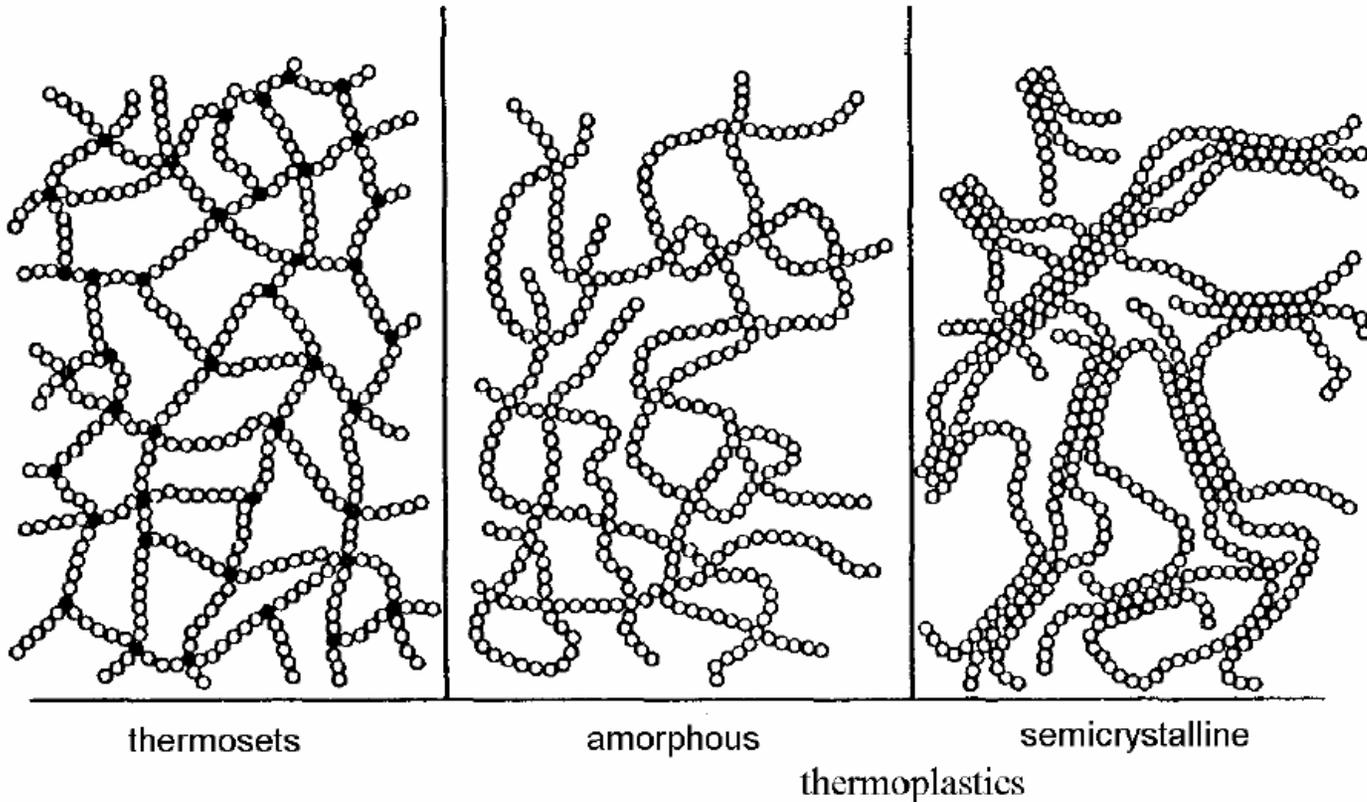


- Natural and synthetic rubber-Thiokol, Buna, Neoprene
- Polyurethanes
- Silicone-polysiloxanes
- Natural proteins-elastin

Mechanical Properties



Elastomers have properties that can be explained by a model that shares characteristics of thermosets and thermoplastics -have all of the domains shown below

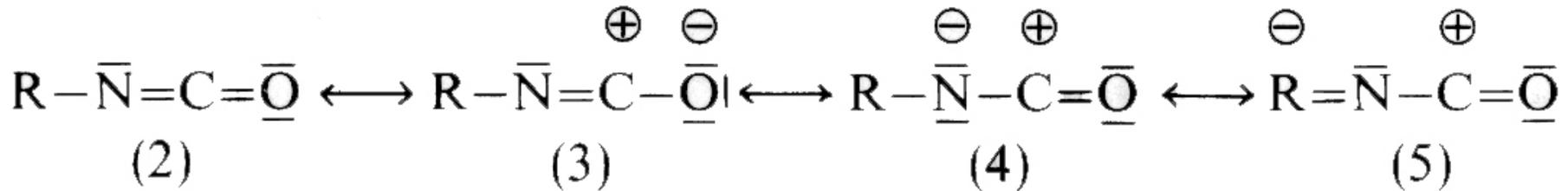


Principles of Polyurethane Chemistry



High molecular weight polymers based isocyanate chemistry

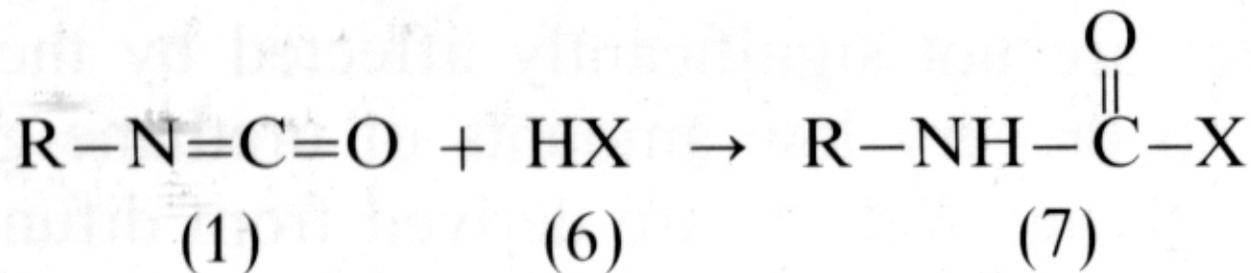
Polyisocyanates have the following general formula:



Addition of Nucleophilic Reactants

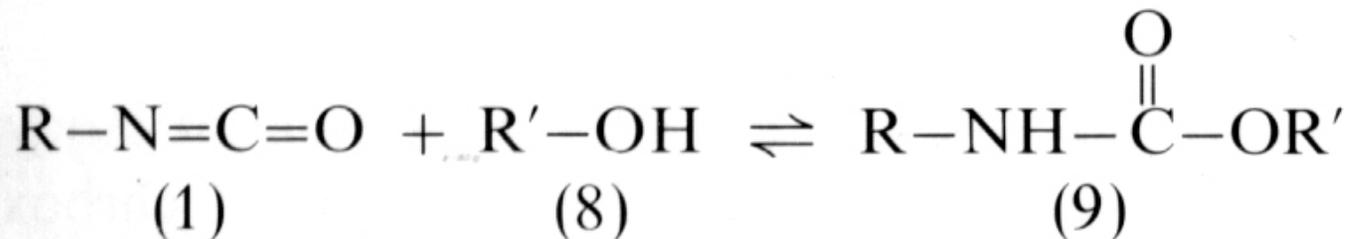


The most important reactions of isocyanates is the formation of carbamic acid derivatives (7) by the addition of components with an acidic H-atom (6) across the C=N double bond (1).



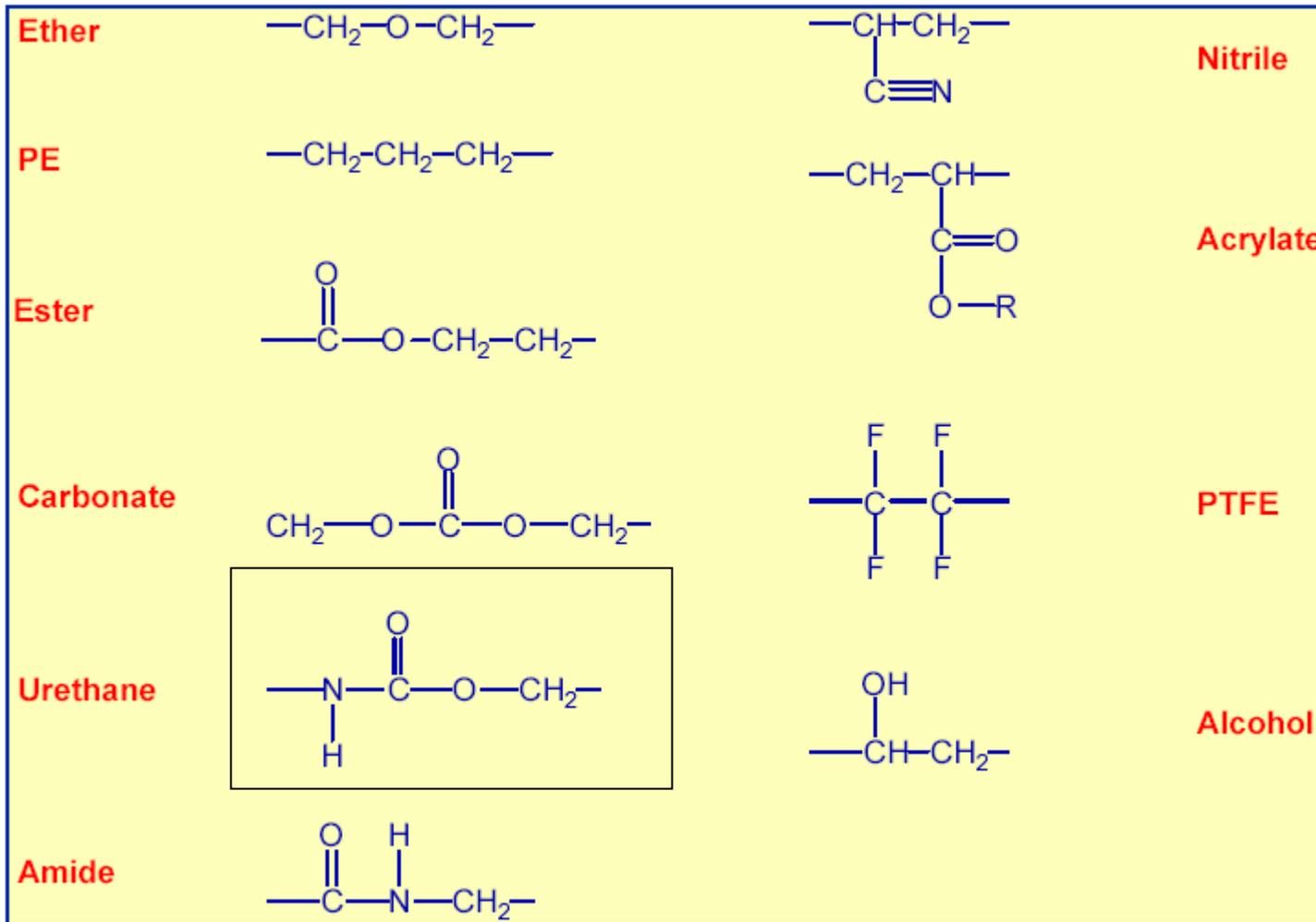
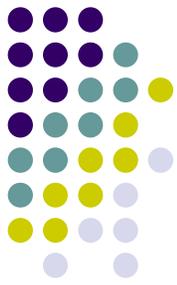


OH group-containing compounds (8) are by far the most important reactants for isocyanates. They are added under mild conditions, forming carbamic esters (9). Primary alcohols, secondary alcohols, and phenols show decreasing reactivity in that order.

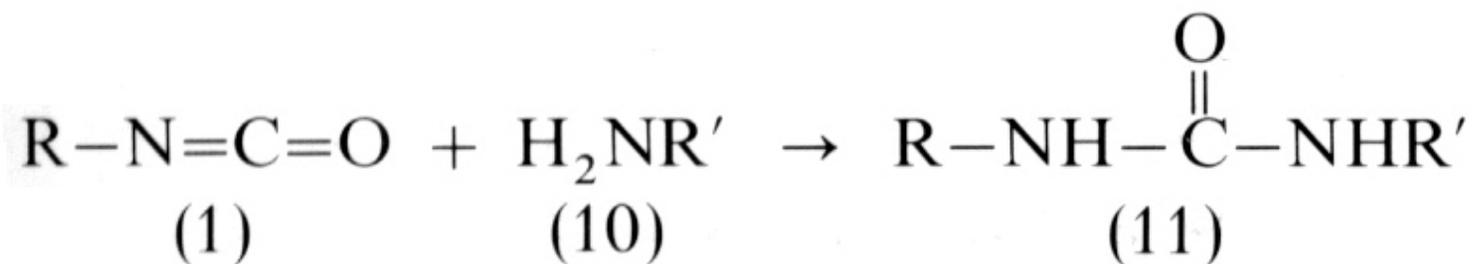


The trivial name urethane which is used for the compound ethyl carbamate, gave the whole polyurethane chemistry its name: polyisocyanates and polyols form polyurethanes.

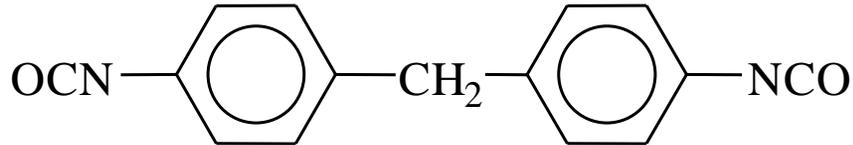
Intermolecular Bonds in Polymers



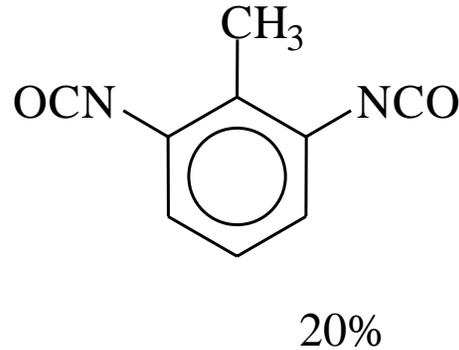
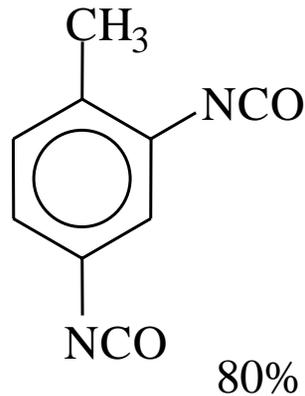
The more nucleophilic primary and secondary amines react much more vigorously with isocyanates. In this reaction, ureas are formed (11).



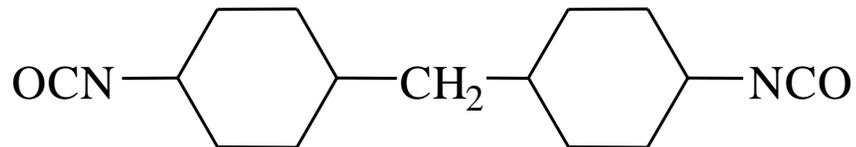
Important Building Blocks for Polyurethanes- Isocyanates



MDI or aromatic polyisocyanate



TDI-80



H₁₂MDI



HDI

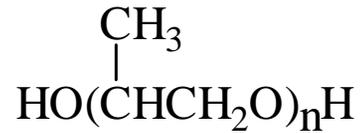
Polyols



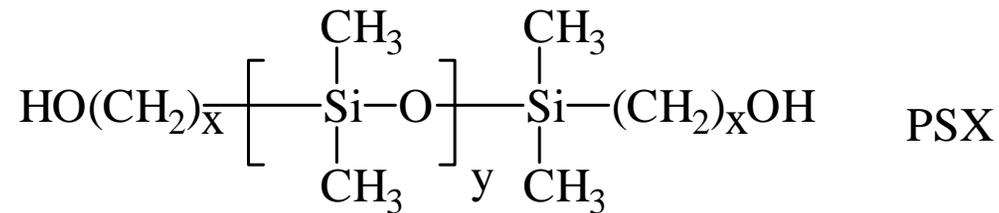
PTMO



PEO

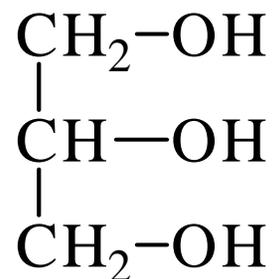
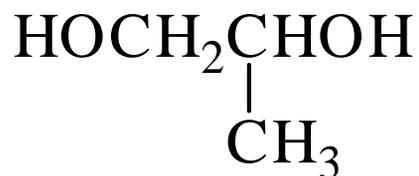


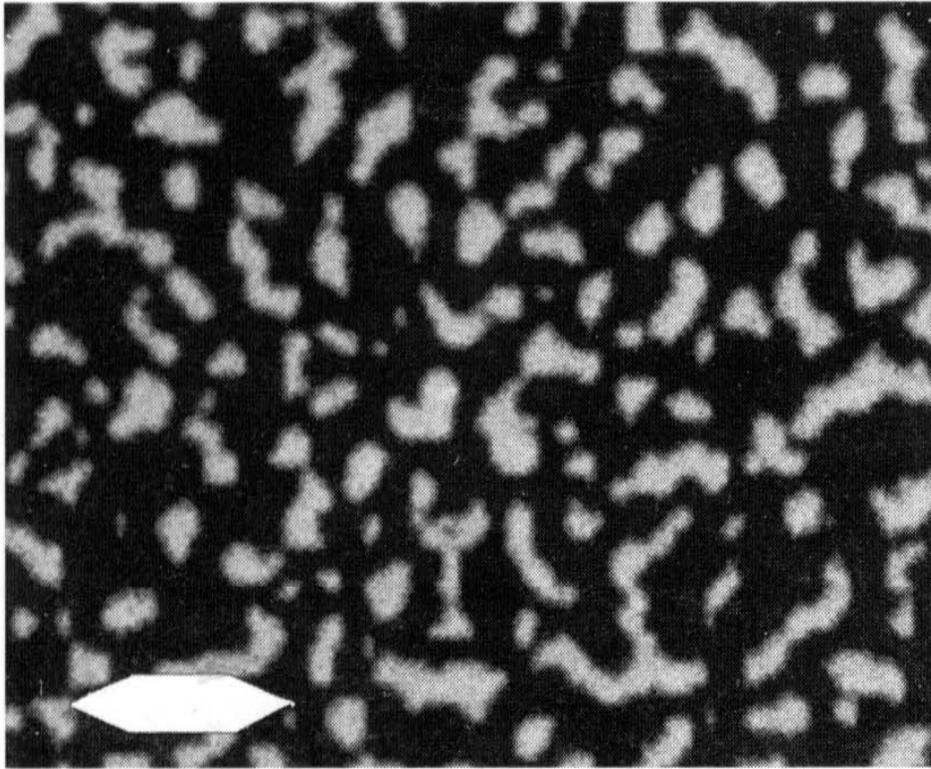
PPG



PSX

Typical Chain-extenders

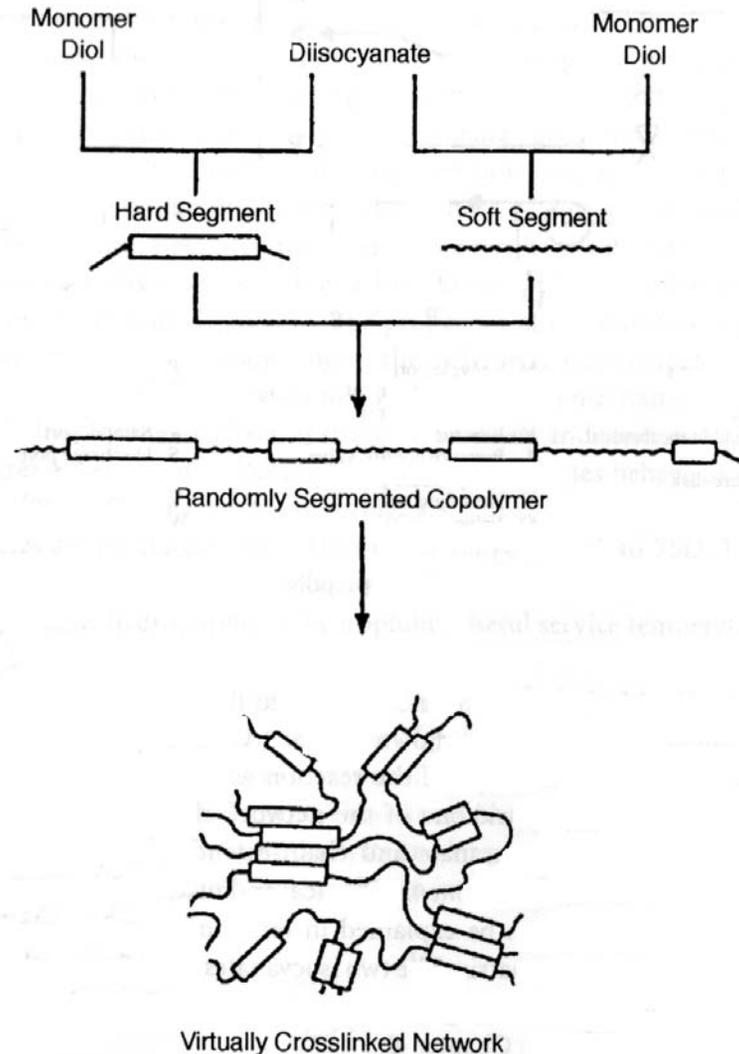




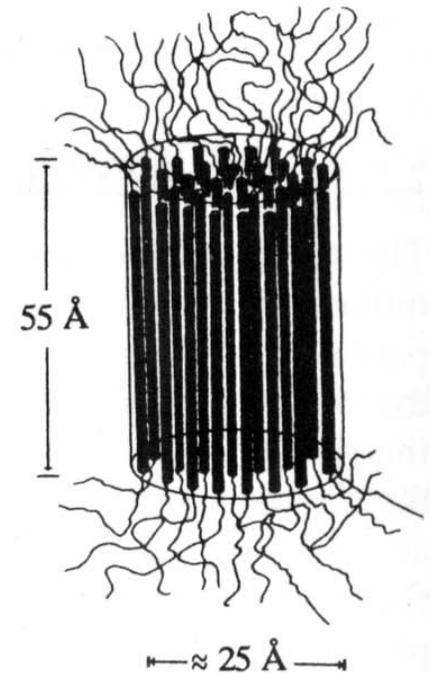
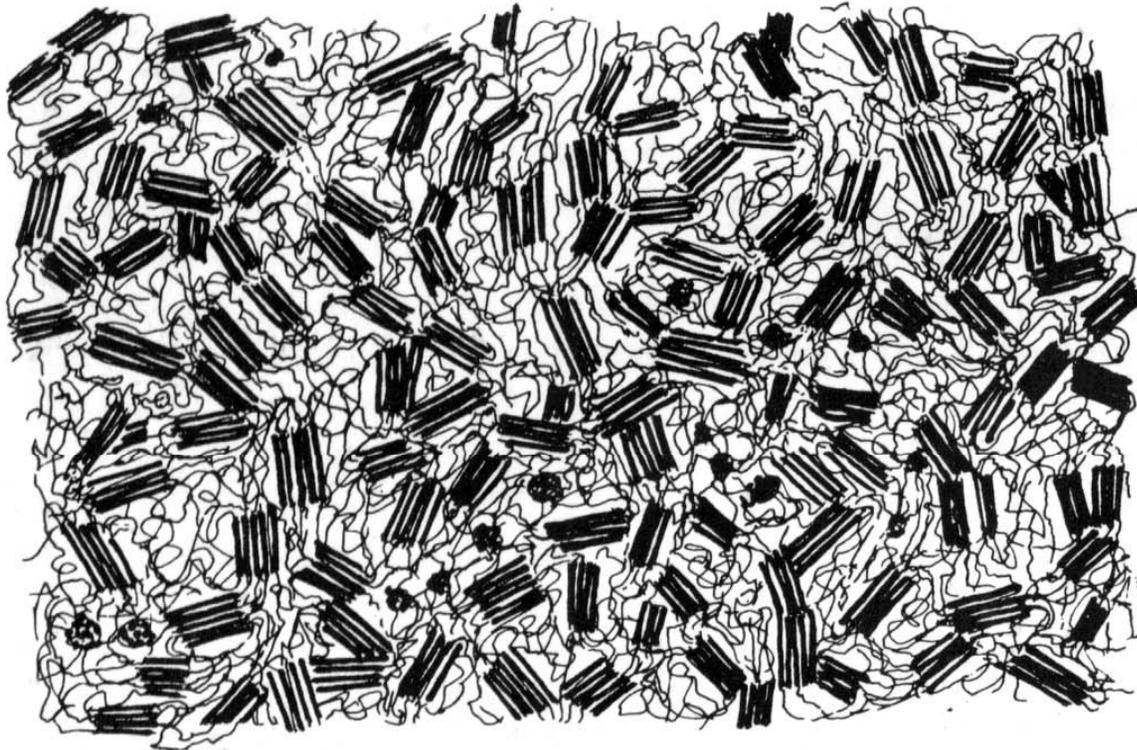
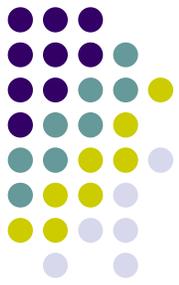
Transmission-electron-micrograph (TEM) of a film of a segmented polyurethane elastomer with a polydisperse poly(oxytetramethylene)-soft segment ($M_n = 2000$) and a uniform molecular hard segment based on bis-(4-isocyanato phenyl)methane (MDI) and 1,4-butanediol. Each hard segment contains three MDI building blocks, respectively exactly two carbonyliminophenylmethylene-phenylimino carbonyloxytetramethylene oxy-repeat units (compare structural formula). Shown is the element specific (nitrogen) picture (ESI) of the film thickness $\sim 200 \text{ \AA}$ casted from DMF solution (0.2 weight % solids) without special contrast; the cylinder shaped hard domains are represented by the white areas (bars). The scale – arrow on the picture corresponds to 200 \AA



Polyurethane Structural Model

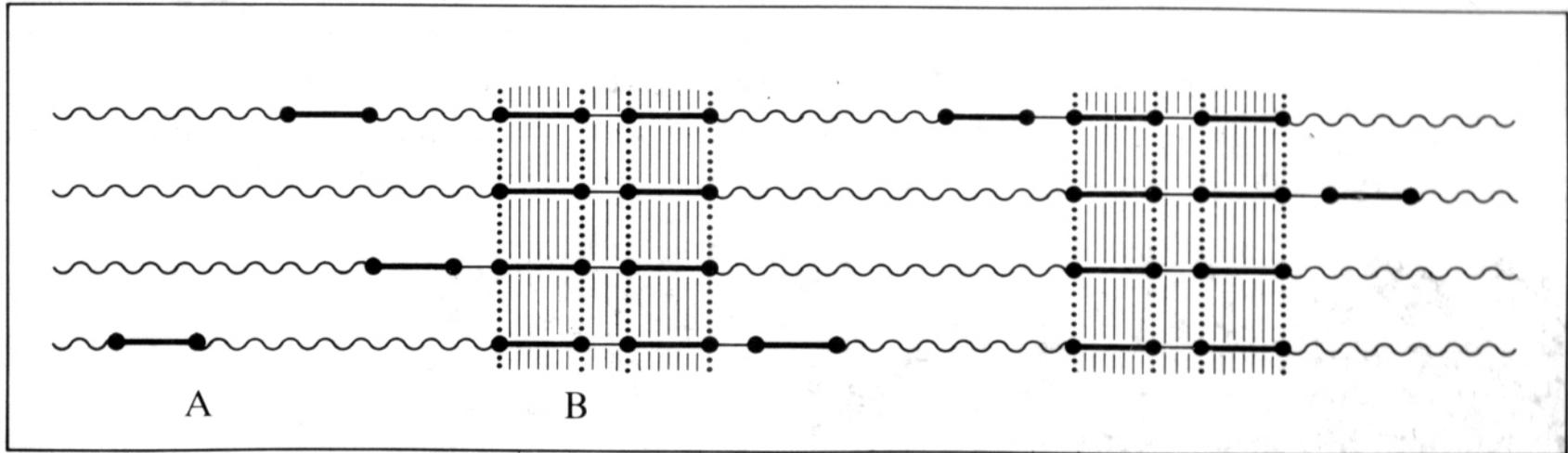


Schematic Model Domain Structure

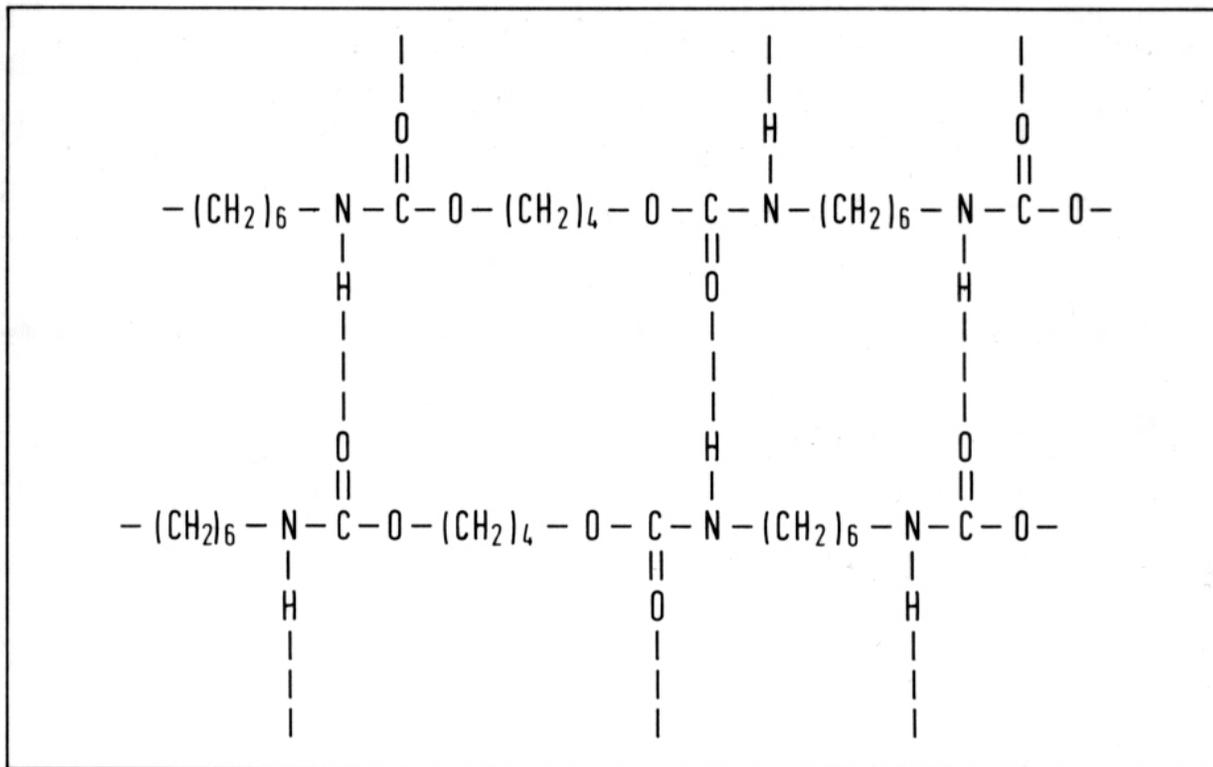


Schematic representation of the superstructure (domain and chain formation) for the segment outlined in the TEM and the cylinder model [226a] of the hard domains

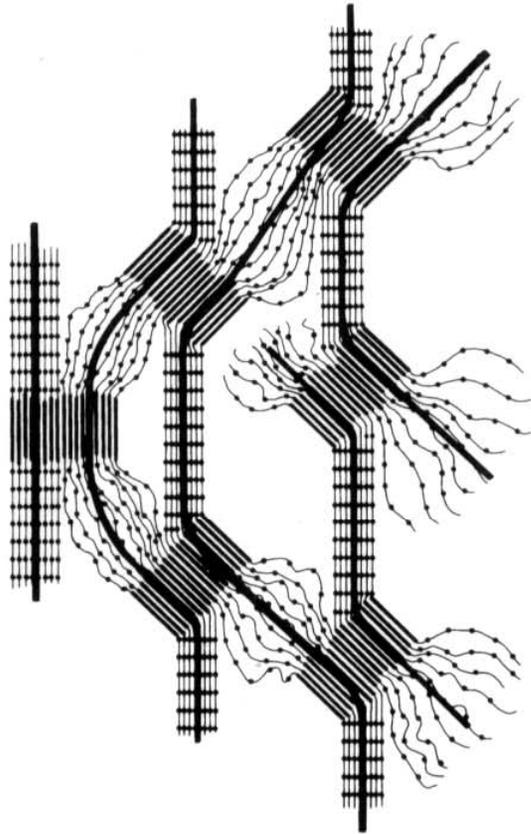
Hard Segment Interactions affect Mechanical Performance



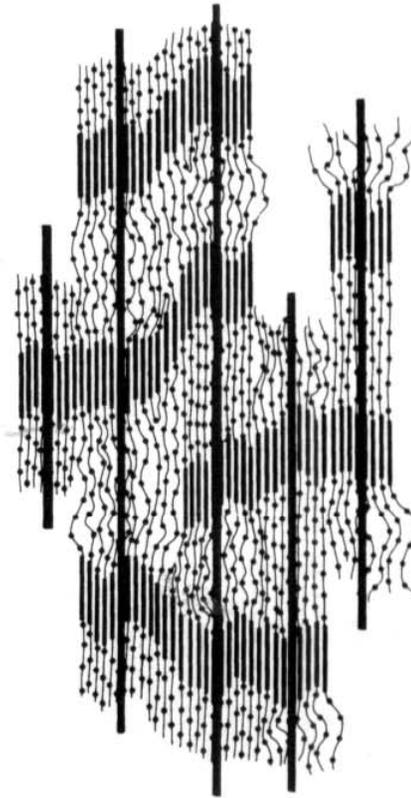
Interchain interaction between the hard segments.



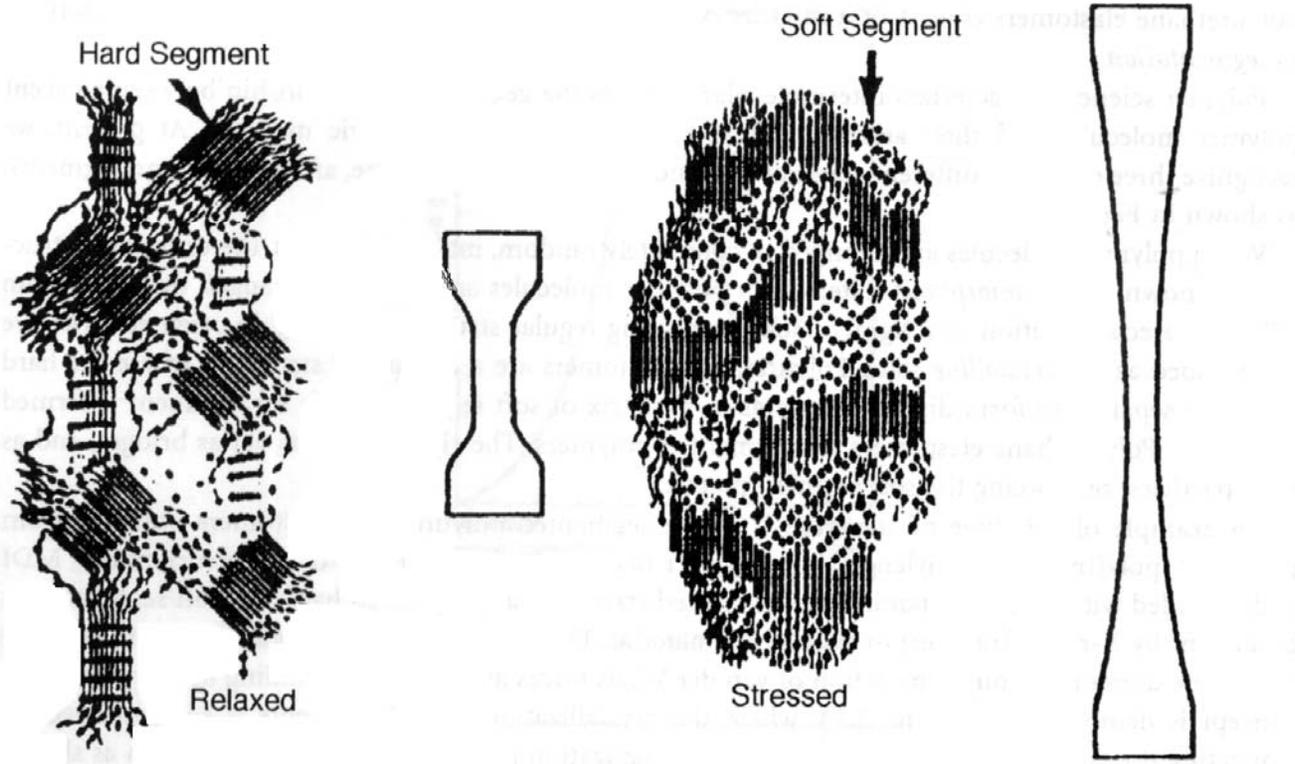
Hydrogen bonding between the chains of a polyurethane based on 1,6-hexane diisocyanate and 1,4-butane diol.



Upon stretching, a portion of the soft segments are stressed by uncoiling; hard segments are oriented in the stress direction.



Reorientation after stress and thermofixation.



Strain-induced elongation of polyether soft segments in a segmented polyurethane elastomer by elongating to 200% elongation.

Segmented polyurethane elastomer at 500% extension and placed in warm water at 80° C.



Polyol with short chains (about 6 atoms/chain) and high functionality (3–8 reactive groups/molecule)



gives high cross-linking



rigid PU foam

Polyol with long chains (about 70 atoms/chain) and low functionality (2–3 reactive groups/molecule)

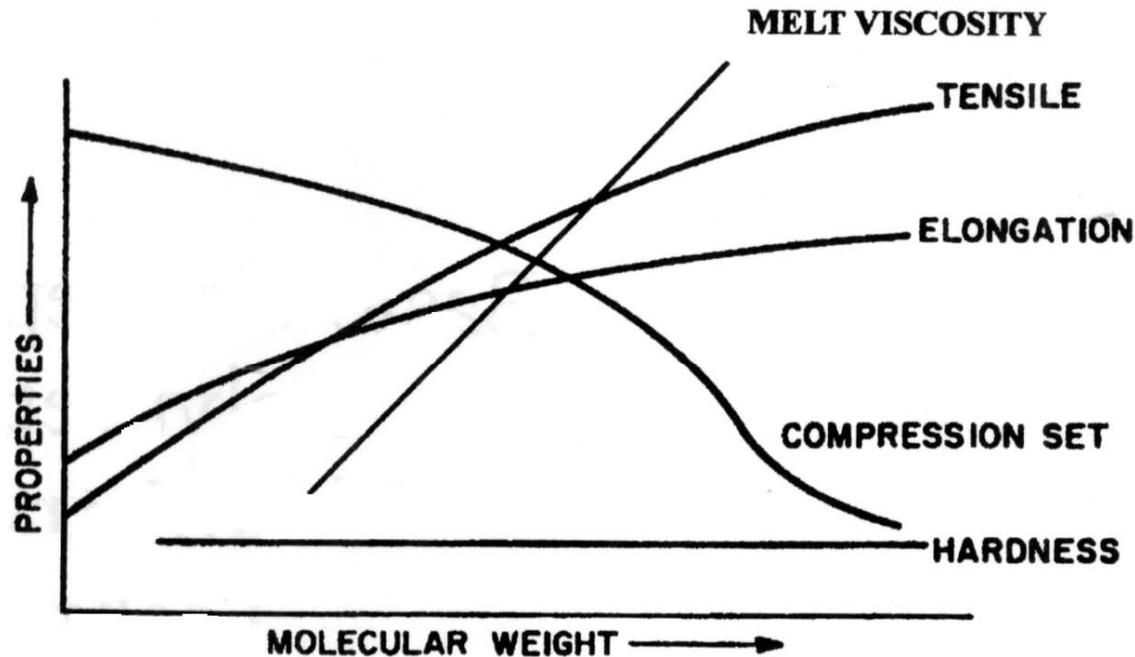


lower cross-linking



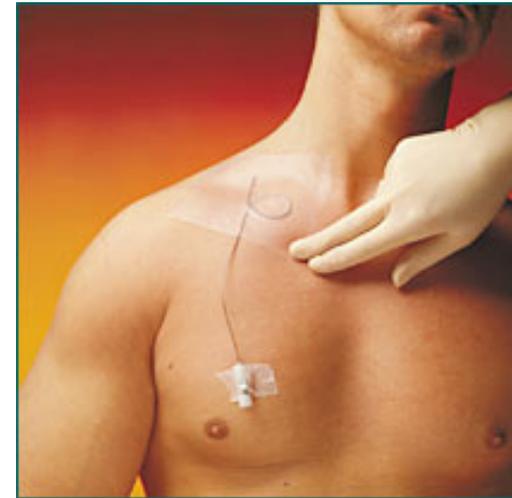
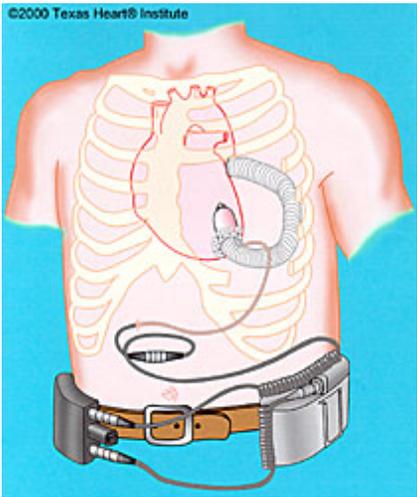
flexible PU foam

Effect of Polyurethane MW on Mechanical Properties



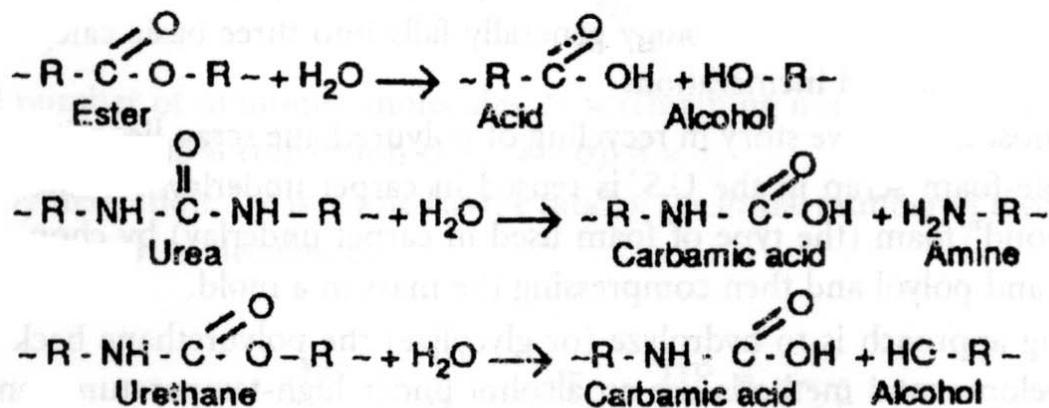


Applications in Cardiology



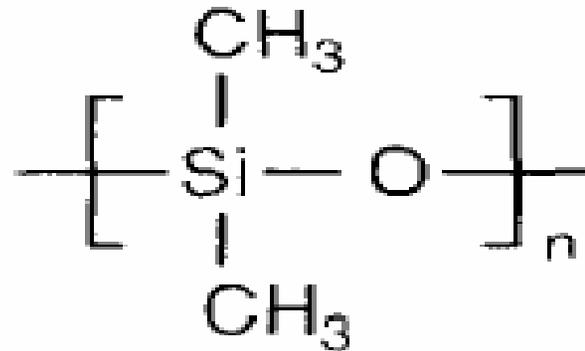


Polyurethanes are Degradable



Bonds susceptible to hydrolytic attack.

Silicone (Silastic)



Poly(dimethyl siloxane)-PDMS

Compounds with Si-O-Si linkages are called siloxanes and their polymers are called polysiloxanes. They were incorrectly named silicones in the 1920's, the misnomer continues....



Silicone

- One of the least attractive properties of conventional silicone elastomers in device manufacturing is that the materials require covalent cross-linking to develop useful properties;
- The precursors of silicones are homopolymers -viscous liquids or millable gums at room temperature used as lubricants;
- (polydimethylsiloxane (PDMS-most common precursor));
- Fabrication of device components must include, or be followed by, cross-linking to form chemical bonds among adjacent polymer chains;
- The infinite network formed gives the polymer its rubbery, elasticity and characteristic physical-mechanical properties.

Silicone

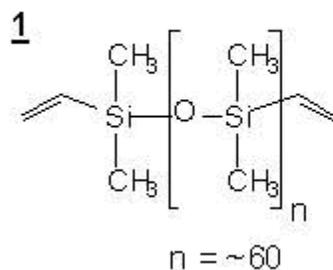
- cross-linking process



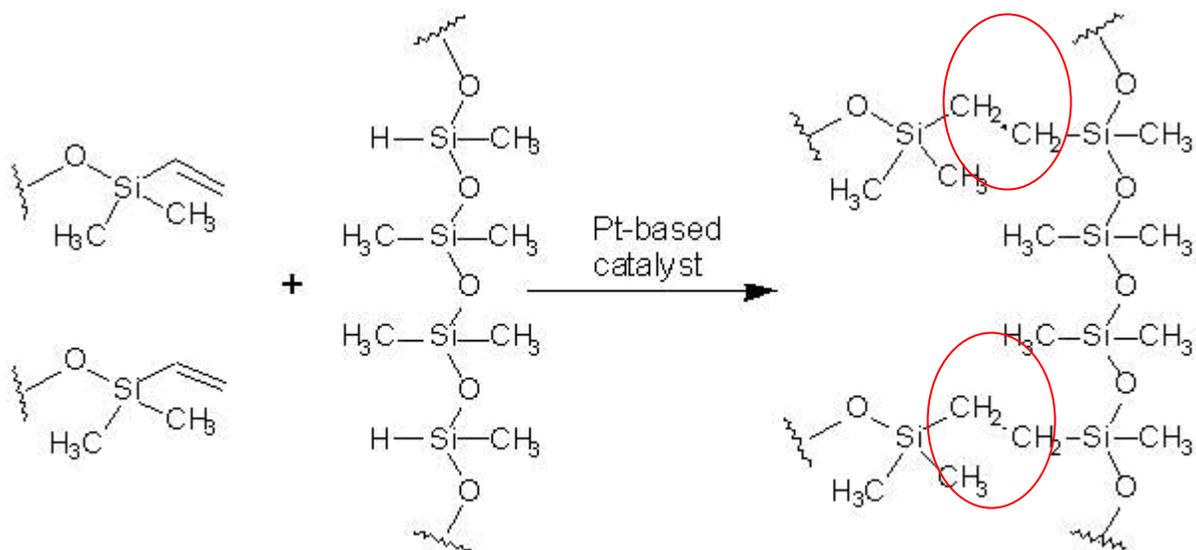
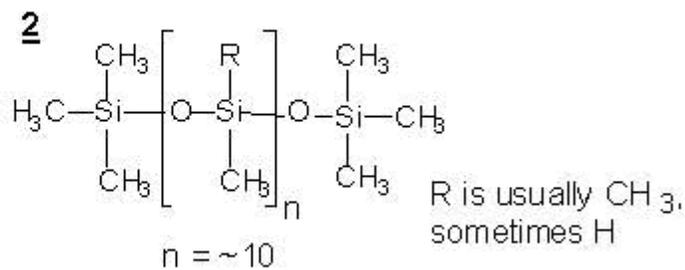
- PDMS is cured by an organometallic crosslinking reaction-
- The siloxane base oligomers contain vinyl groups;
- The cross-linking oligomers contain at least 3 silicon hydride bonds each;
- The curing agent contains a platinum-based catalyst that catalyzes the addition of an SiH bond across the vinyl groups, forming Si-CH₂-CH₂-Si linkages;
- The multiple reaction sites on both the base and crosslinking oligomers allow for three-dimensional crosslinking.



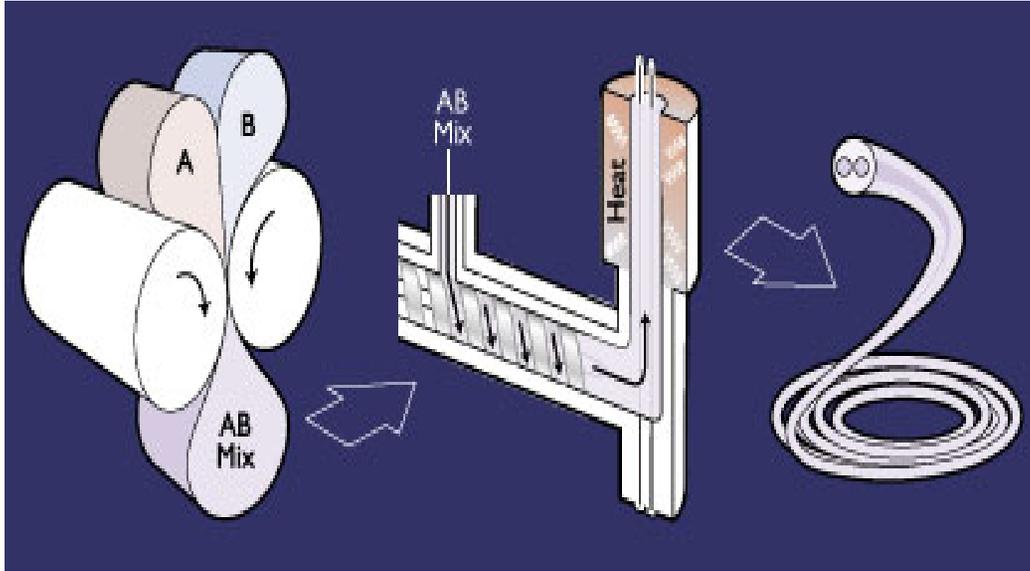
siloxane oligomers



siloxane cross-linkers



Silicone Extrusion



The extrusion process begins with the blending of a two-part gumstock (catalyst and crosslinker) on a two-roll mill. The blending process yields a homogeneous compound that is formed into strips and fed continuously into the extruder. A variable speed screw feed is used to maintain proper pressure at the pin and die. During the extrusion process, dual-axis laser micrometer checks are performed to help ensure proper dimensional control. Once extruded, the tubing passes through vulcanization ovens (HAVs), where heated air or radiant heat cures the product.

Catheters



- Specialty two- and three-way catheter mainshafts
- Surgical drainage tubes, wound drains
- Feeding catheters, spring reinforced catheters, peritoneal catheters
- Vascular loops
- Foley mainshaft and balloon cuffs

Silicone-biocompatibility



- Superior compatibility with human and animal tissue and body fluids - does not irritate skin or other organs.
 - Is extremely soft and pliable, easily conforms to different cavity shapes.
 - Biologically inert - Does not support the growth of bacteria
 - Does not stain or corrode other materials which it contacts.
 - Withstands common sterilization methods - alcohol wash, dry heat, steam autoclave, ethylene oxide, gamma radiation and electron beam.
 - Most silicones have been shown to meet the requirements for USP Class VI, FDA Tripartite Biocompatibility Guidelines and ISO 10093 requirements.



Uses

- Catheters and tubing
- Joint replacement
- Thermal /electrical insulation
- Cosmetic surgery
- Cardiovascular applications
- Lubricants for biomedical devices
- Adhesion of dressings and prosthetics
- Medical device encapsulant or used in mold making
- Balloons , molded and extruded parts
- Condoms and diaphragms



Pt-cured Silicone tubing



Uses-continued

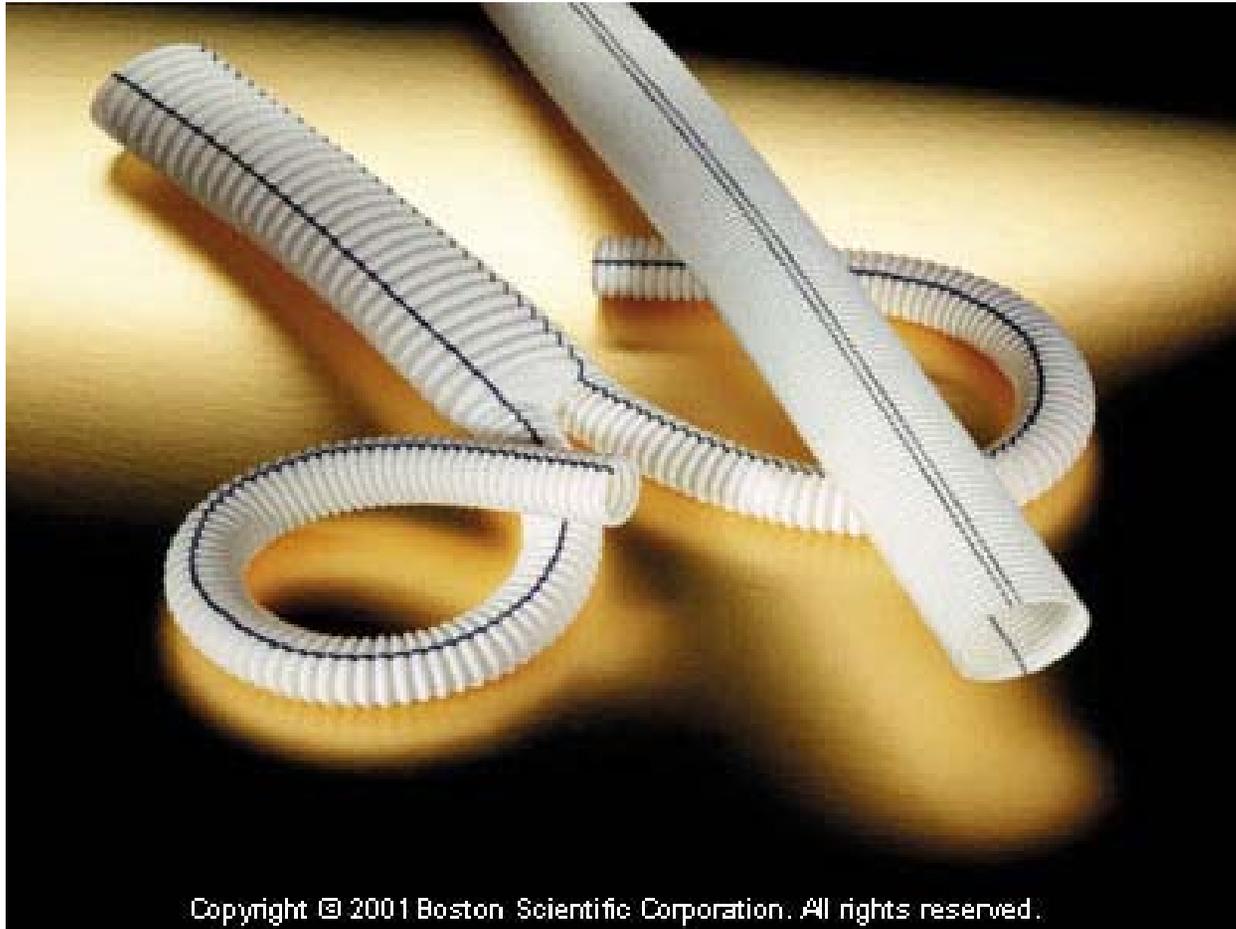
- Anesthesiology - tubing, check valves, gaskets, respirator masks and duck bills.
- Drug Delivery - Precision pump tubing, feeding tubes, cassette diaphragms|
- Ophthalmic Surgery - tubing, infusion sleeves, test chambers
- Surgical Products - wound drains, tubing, clamp covers, vein ties, loops, sterilization aids, balloons
- Cardiovascular - multi-lumen tubing, catheters , connectors
- Urology - incontinence products, catheters, tubing
- Gastroenterology - transfer pump tubing, balloons, feeding tubes

Biomaterial Applications in Cardiology



- Vascular Grafts
- Vascular Access Devices (VADS)
- Cardiac repair
- Electrophysiological control

Vascular Grafts



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Graft-background

- When natural blood vessels fail, vascular grafts are used to continue critical natural function of the vessels.
- first choice for replacement is typically the autologous vessel usually saphenous vein (ASV);
- when unavailable, artificial grafts are used;
- large diameter vessel applications;
- recent efforts directed towards finding suitable methods for medium and small diameter vessel repair;
- Artificial grafts include: treated natural tissue, laboratory-engineered tissue, and synthetic polymer fabrics.
- Dacron and Teflon are the most commonly used of the synthetic grafts.

When A Native Fistula Is Not A Viable Option, artificial grafts are used



-minimizes fistula
needle site bleeding
and leakage thereby
restoring hemostasis



Vascular Graft -Properties

- Achieve and maintain Hemostasis
- Porous
- Good suture retention
- Adequate burst strength
- High fatigue resistance
- Low thromobgenecity
- Good handlability
- Biostable

Common complications of vascular grafts are:

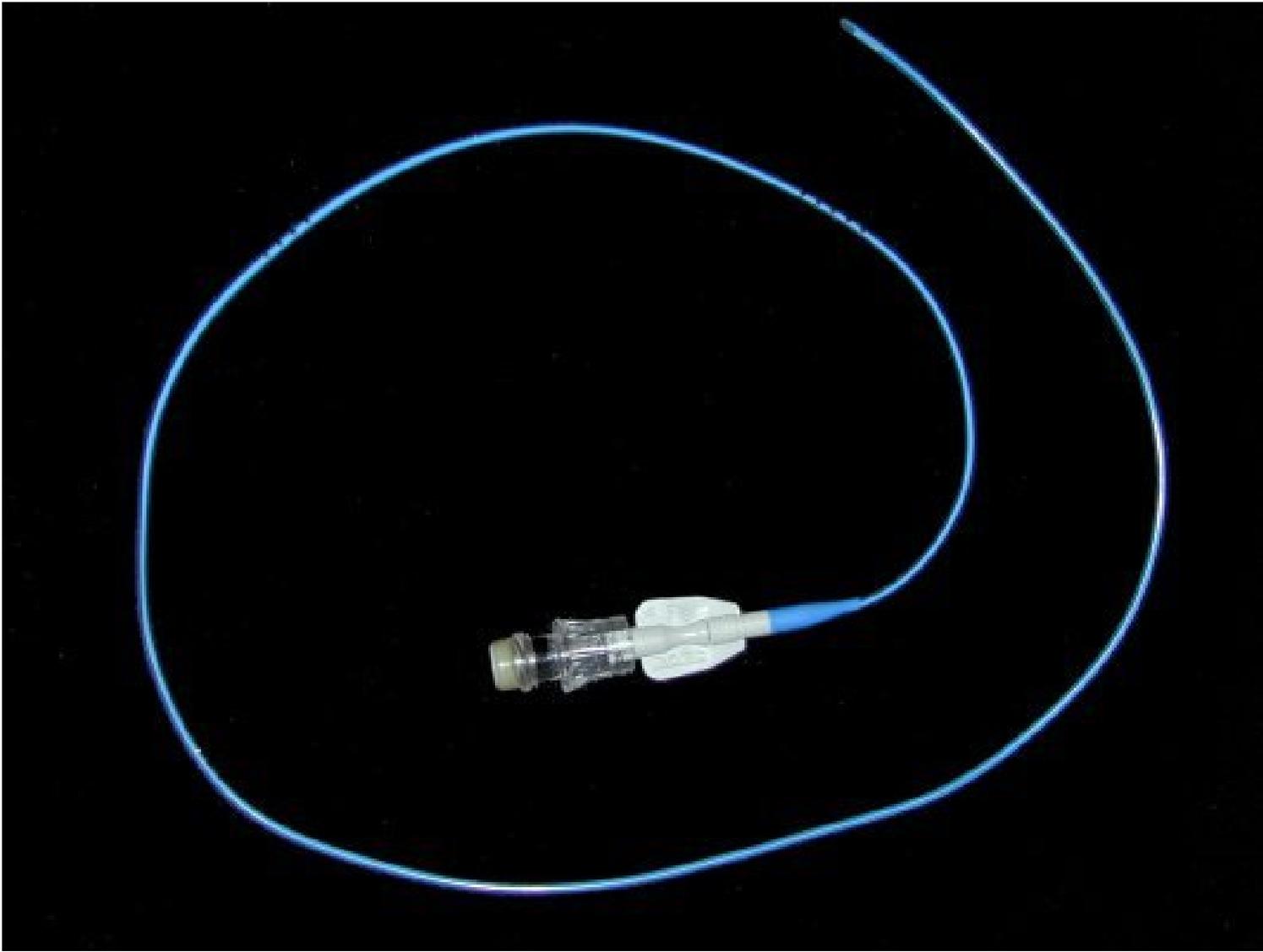


- Graft occlusion
- Graft infection
- Aneurysms at the site of anastomosis
- Distal embolisation

Vascular Access Devices (VADS)



- Used for administration of antibiotics, chemotherapy, hydration, TPN, or long-term blood sampling.





VADS or Catheters

- **Peripheral Venous Access**
- **Midline Peripheral Catheters**
- **Peripherally Inserted Central Catheters (PICCs)**
- **Central Catheters, Tunnelled**



Peripheral Venous Access

- typical "hospital IV" line put in your hand or forearm ;
- short catheter, usually 3/4 to 1 inch long, inserted into a small peripheral vein and designed to be temporary;
- need to be changed every three days;
- a plastic dressing kept over the catheter, which has to be kept clean and dry at all time;
- work well in the hospital, where there are nurses to monitor and change them frequently, but are impractical for extended home use because of the potential for dislodging the small catheter from the vein;
- Blood cannot be drawn for lab tests from a peripheral catheter.



Midline Peripheral Catheters

- inserted into your arm near the inside of the elbow and threaded up inside your vein to a length of 6 inches;
- typically last about six weeks -- a perfect catheter for a short course of antibiotics, but not really practical for long-term intravenous therapy;
- Because the catheter is so soft and the end is well inside the vein, the chances of it dislodging are much less than with a peripheral IV;
- Needs to be flushed with saline and heparin after each use or at least once daily if not in use;
- Blood may not be drawn for lab tests with this catheter.

Peripherally Inserted Central Catheters (PICCs)

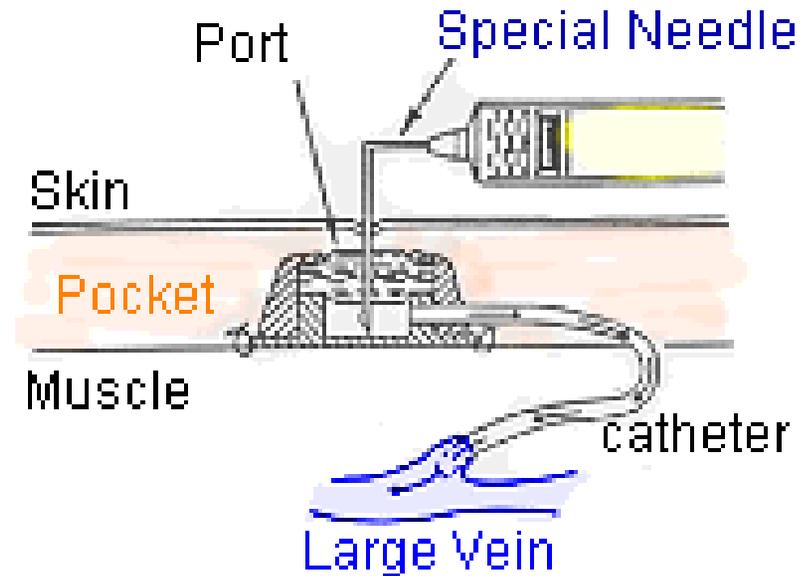


- centrally placed, meaning the tip ends up in the Superior Vena Cava
- "Peripherally inserted" means it goes into your body at your elbow and the tip is threaded up into your vein;
- have a valve at the tip, preventing blood from backing up into the catheter, so heparin is not necessary.
- After the catheter is inserted, a chest X-ray is required to make sure the tip is in the right location above the heart.
- With this type of catheter, you can do most normal activities, except swimming or other extreme movements of the arm;
- Blood can be drawn;

Central Catheters, Tunnelled and Implanted ports



Subcutaneous Vascular Access Device (SVAD)



Catheters



- Approximate duration of catheter placement, in the absence of complications:
 - CVC - 30 days
 - SICCC - 180 days
 - PICCC - 360 days
 - SVAD - Indefinitely.
(These are intended only as guidelines, based on clinical judgement and catheter function.)



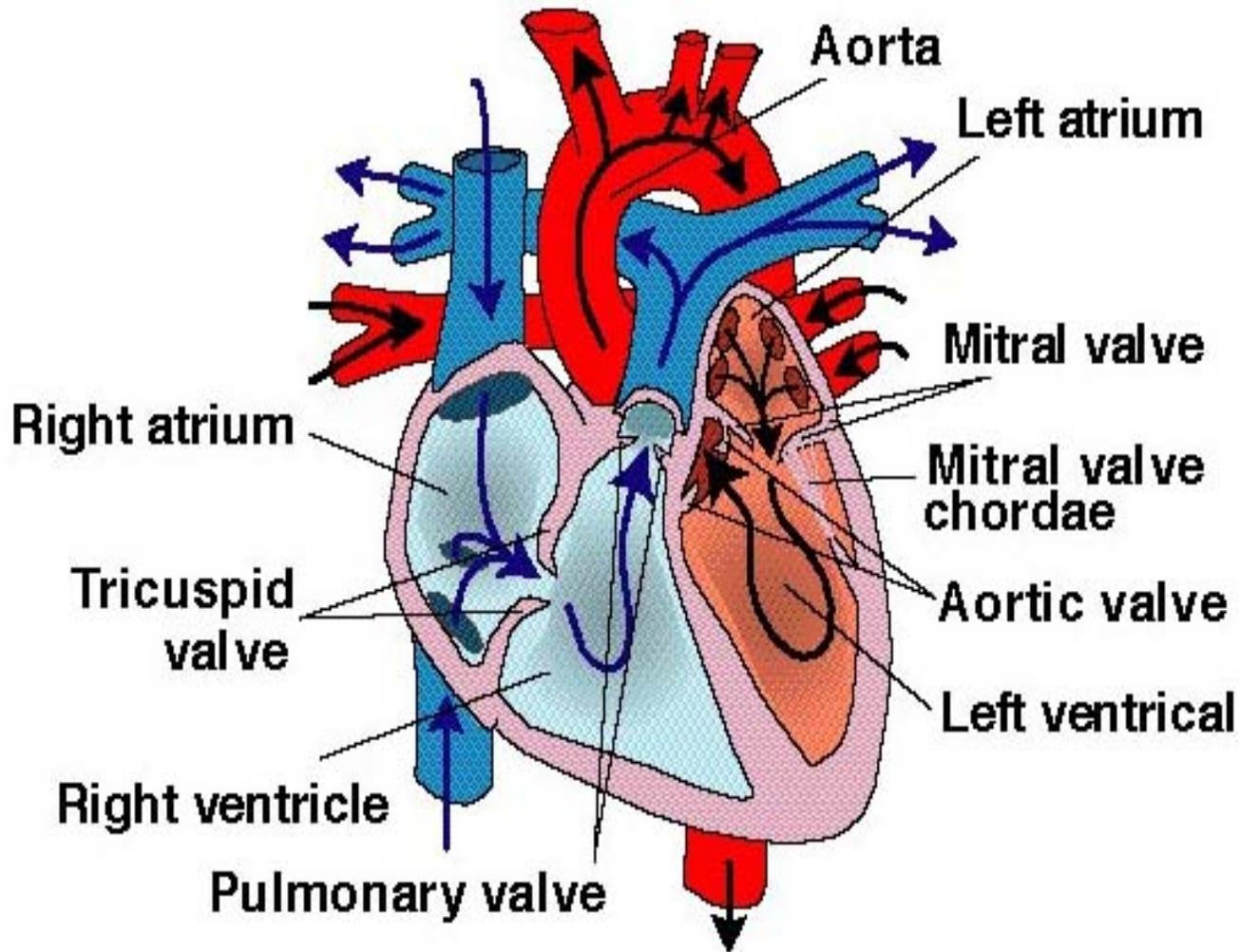
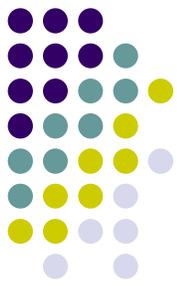
Catheters

- Two most common materials silicone and polyurethane;
- Two most common complications are infection and thrombosis (embolism)

Applications in Cardiology

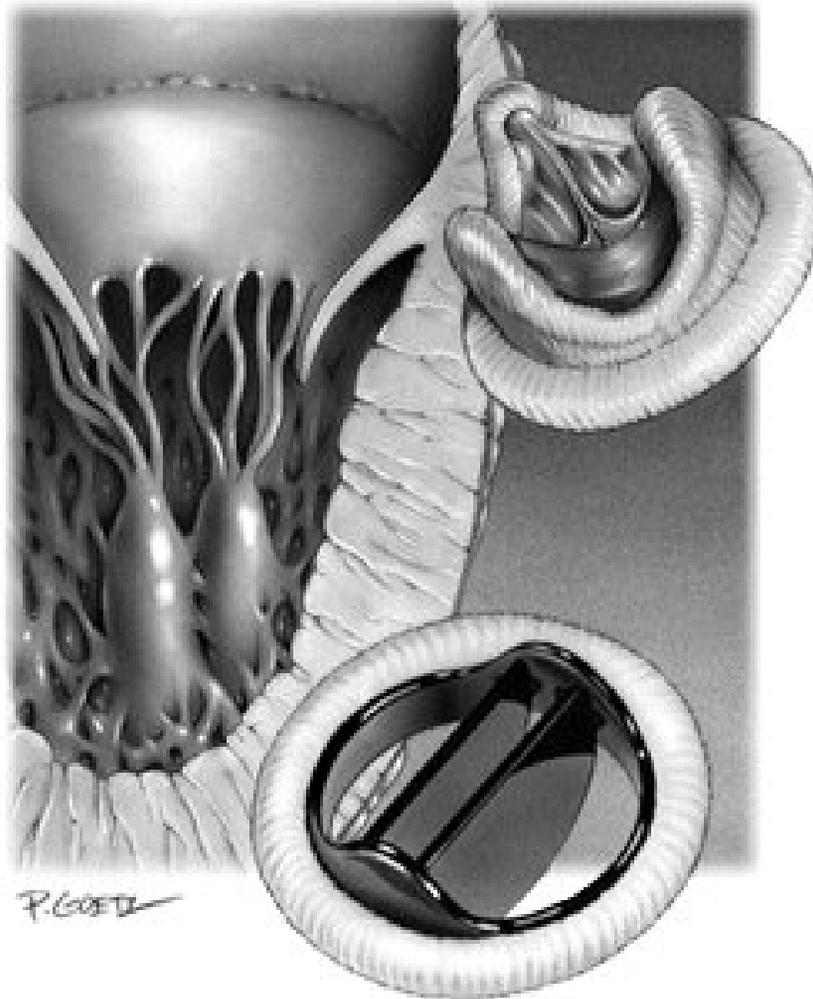


- Cardiac repair
 - Valves-mechanical and Tissue
 - Coronary artery bypass connectors
 - Assist devices
 - Patches
- Electrophysiological control
 - Pacemakers and accessories



HEART and VALVES

Prosthetic Heart Valves





How Heart Valves Fail

- Stenosis
- Mitral Valve Prolapse
- Regurgitation
- Congenital defects

Common Bioprosthetic Valve Problems



- Infection
- Thrombosis
- Calcification