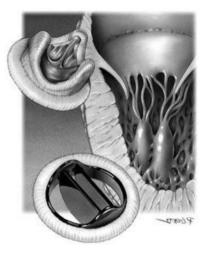
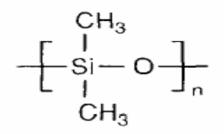
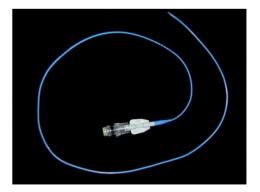


#### **Applications in Cardiology**



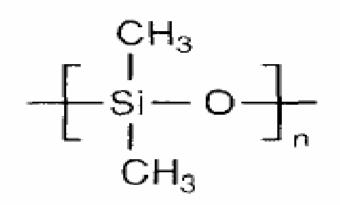








### Silicone (Silastic)



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



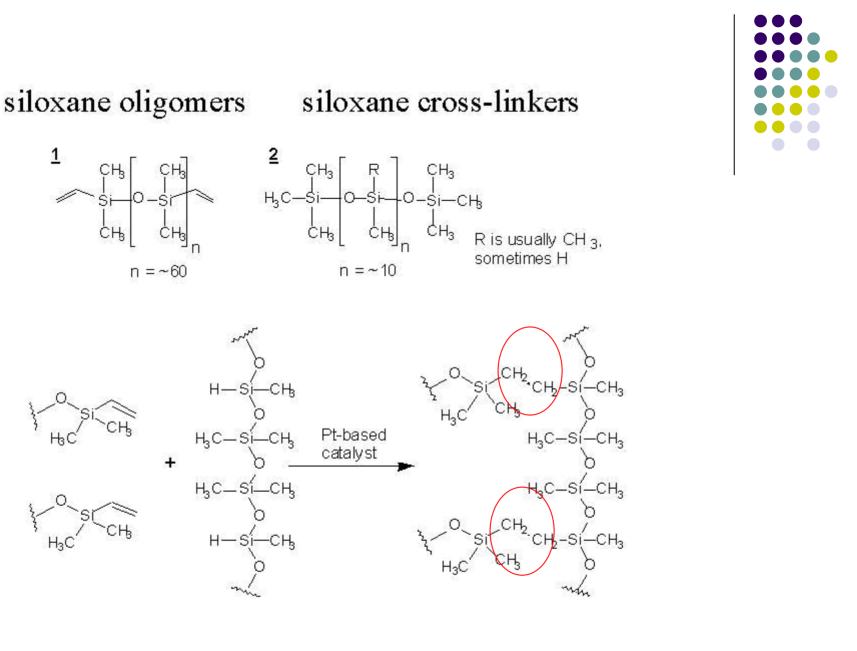
- One of the least attractive properties of conventional silicone elastomers in device manufacturing is that the materials require covalent cross-linking to develop useful properties;
- The precursors of silicones are homopolymers -viscous liquids or millable gums at room temperature used as lubricants;
- (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. 3

### Silicone

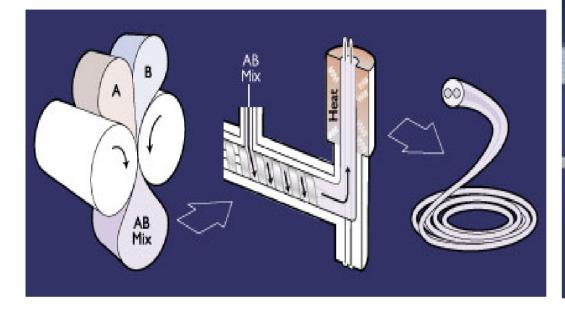
#### - cross-linking process



- 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.



#### **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 replacment
- 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 diaphrams





#### Pt-cured Silicone tubing

#### **Uses-continued**

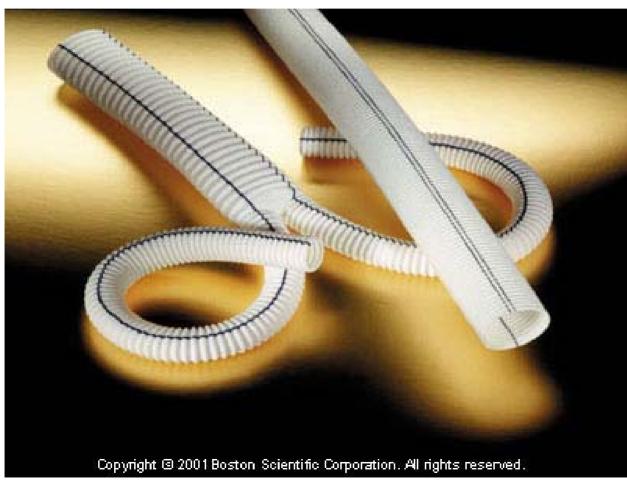


- Anesthesiology tubing, check valves, gaskets, respirator masks and duck bills.
- Drug Delivery Precision pump tubing, feeding tubes, cassette diaphragms|
- Opthalmic Surgery tubing, infusion sleeves, test chambers
- Surgical Products wound drains, tubing, clamp covers, vein ties, loops, sterilization 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**





### **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, laboratoryengineered tissue, and synthetic polymer fabrics.
- Dacron and Teflon are the most commonly used of the <sup>3/30/2</sup>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:

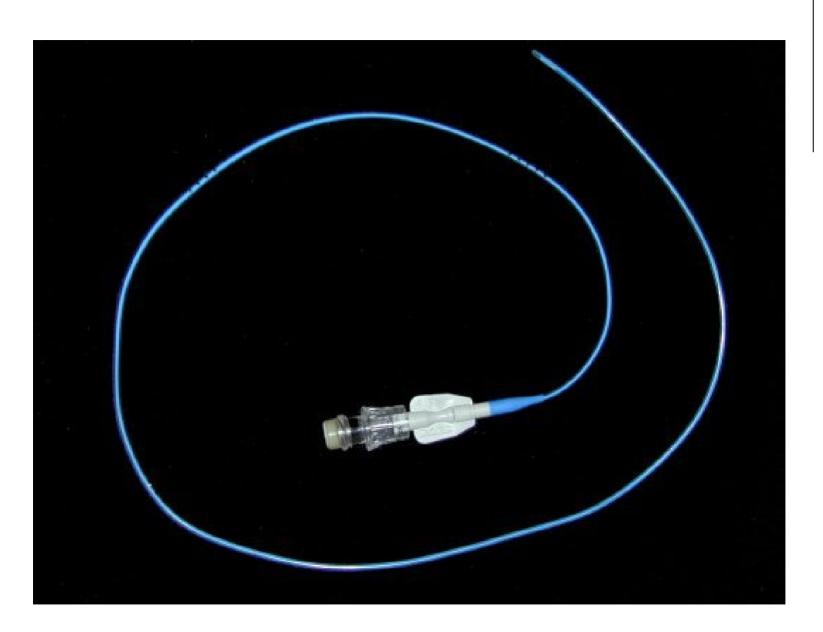
- Graft occlusion
- Graft infection
- Aneurysms at the site of anastomosis
- Distal embolisation



# 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 3/30/2006 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)



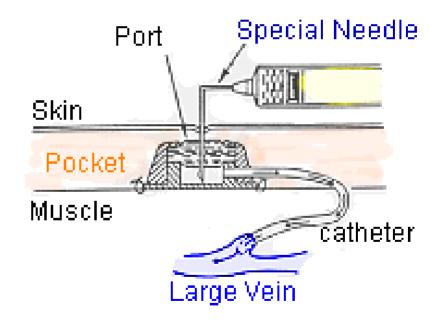
- centrally placed, meaning the tip ends up in the Superior Vena Cava
- "Peripherally inserted" means it goes into your body at your elbow and the tip is threaded up into your vein;
- have a value at the tip, preventing blood from backing up into the catheter, so heparin is not necessary.
- After the 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;

●0/2 Bolood 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
  - SICC 180 days
  - PICC 360 days
  - SVAD Indefinitely.

(These are intended only as guidelines, based on clinical judgement and catheter function.)

#### Catheters

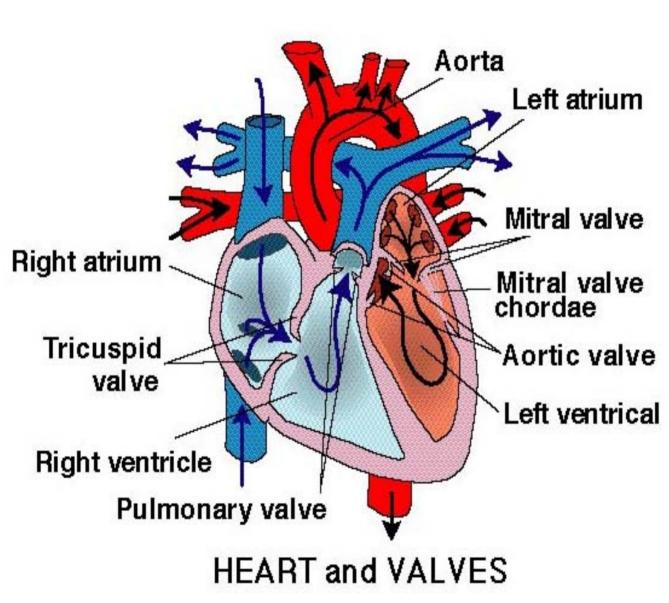


- Two most common materials silicone and polyurethane;
- Two most common complications are infection and thrombosis (embolism)

### **Cardiac repair**



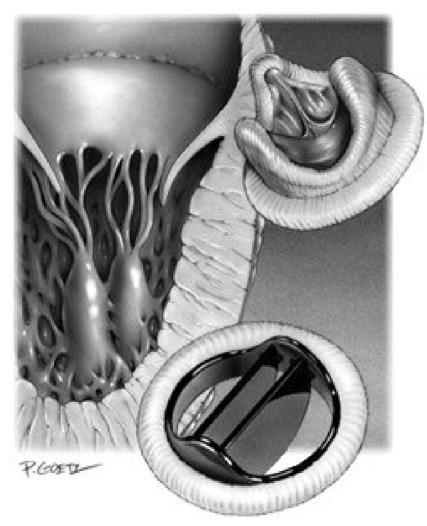
- Valves-mechanical and Tissue
- Coronary artery bypass connectors
- Assist devices
- Patches
- Electrophysiological control
  - Pacemakers and accessories







#### **Prosthetic Heart Valves**





#### **How Heart Valves Fail**

- Stenosis
- Mitral Valve Prolapse
- Regurgitation
- Congenital defects

#### Common Bioprosthetic Valve Problems

- Infection
- Thrombosis
- Calification

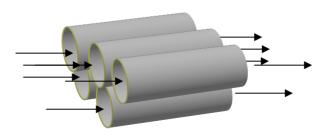
Hollow Fiber Membranes: Immunoisolation BS: 728-734

Applications in Nephrology: Extracorporeal Artificial Organs BS:514-526

#### **Hollow Fiber Membranes**



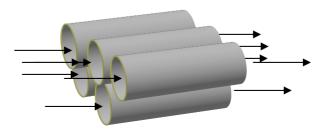
- Definition- materials capable of conducting flow in an axial direction or providing a conduit to guide the regeneration of tissue,
- semipermeable



#### **Hollow Fiber Membranes**



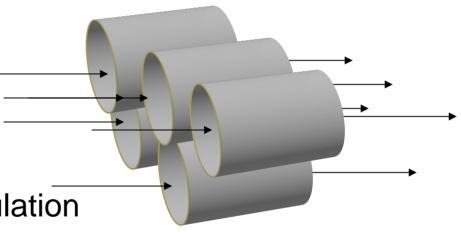
- Definition- materials capable of conducting flow in an axial direction or providing a conduit to guide the regeneration of tissue,
- semipermeable -capable of separating soluble molecules on the basis of size, and in certain specialized cases on the basis of charge, in some applications the separation is not molecular but cellular.



### **Applications**

- Liquid sterilization
- Kidney assist- Dialysis
- Blood oxygenators
- Plasmapheresis
- Liver assist
- Drug delivery-cell encapsulation
- Implantable Biosensors
- In vitro bioreactors
- Vascular grafts
- Nerve repair



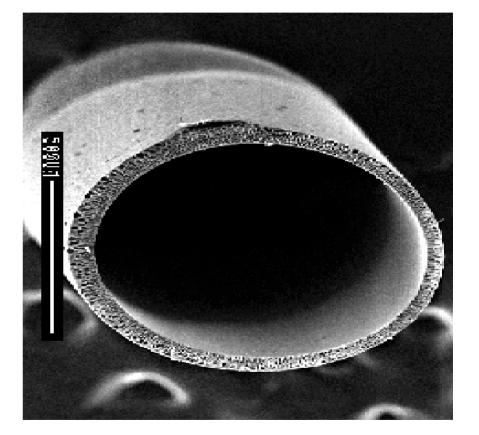


#### **Filtration**

- Hollow Fiber Membranes (HFM);
- Selective Separation;

#### **Materials**

- Thermoplastics-PS, PAN, PAN-PVC, CA, CN
- Polyurethane

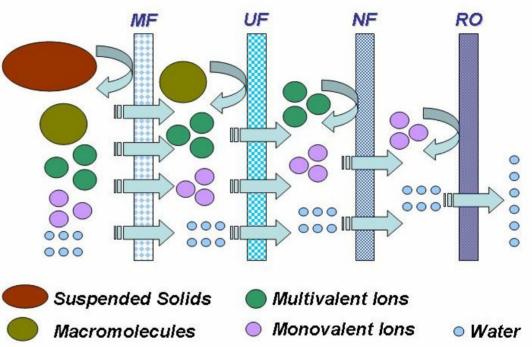




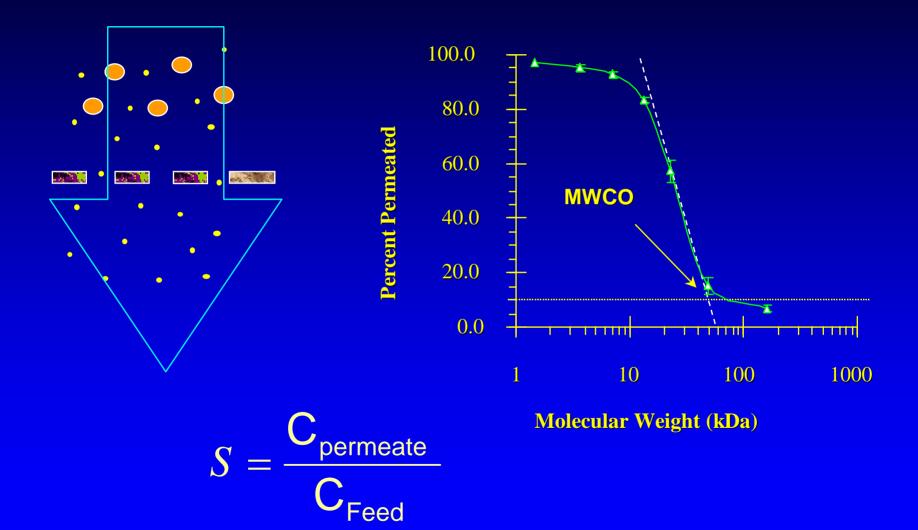
#### **Selectively Permeable**

Macroporous-cell permeable Ultrafiltration-rejection of molecules >100kD Nanofiltration-Multivalent lons

Reverse osmosis-Ion selective

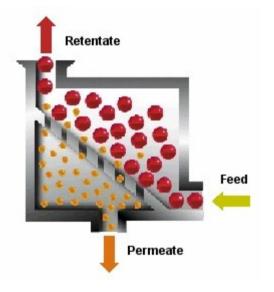


### **Sieving Characteristics**



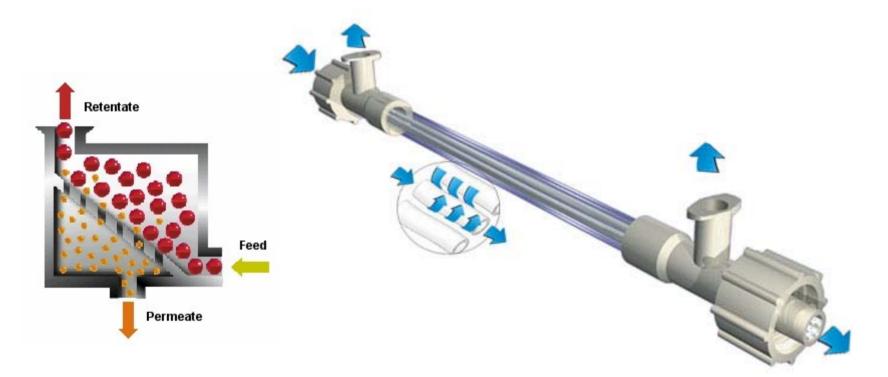


### **Filtration Modules**

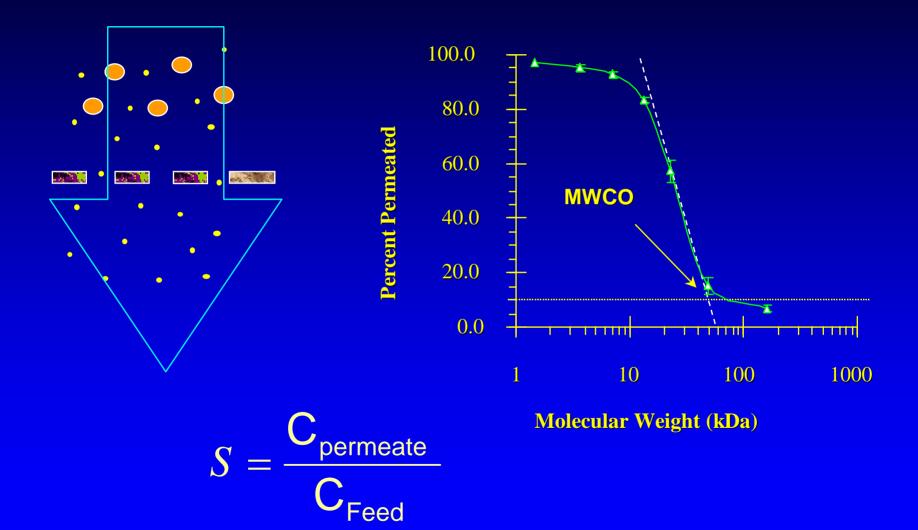


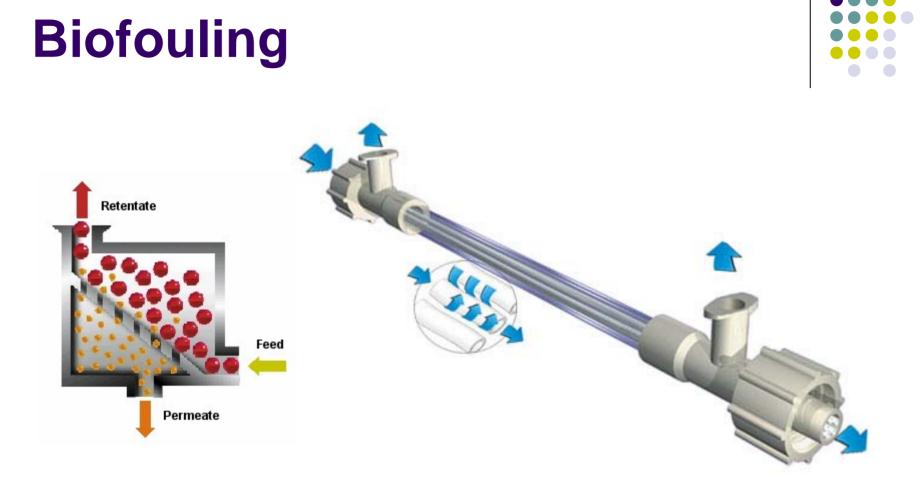
### **Filtration Modules**





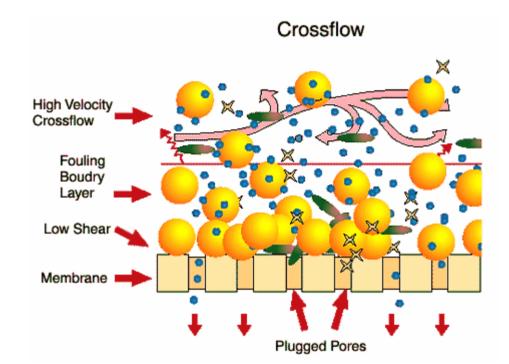
### **Sieving Characteristics**





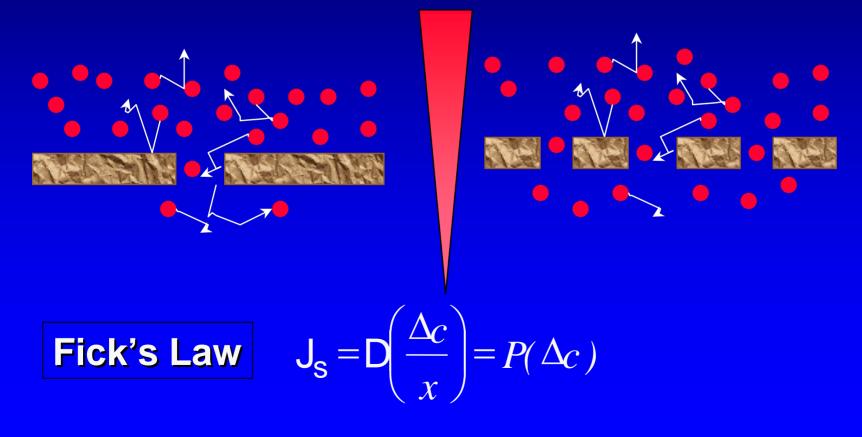
### **Cross-Flow**

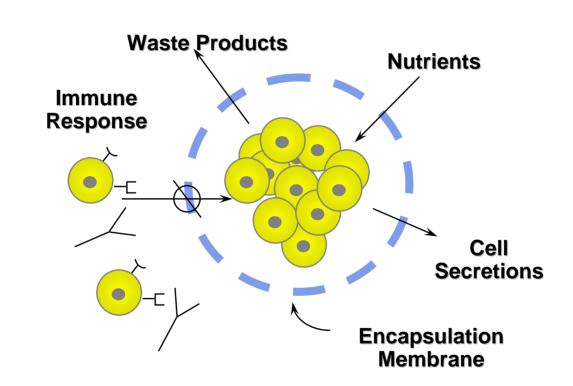




### **Increased Number of Pores**

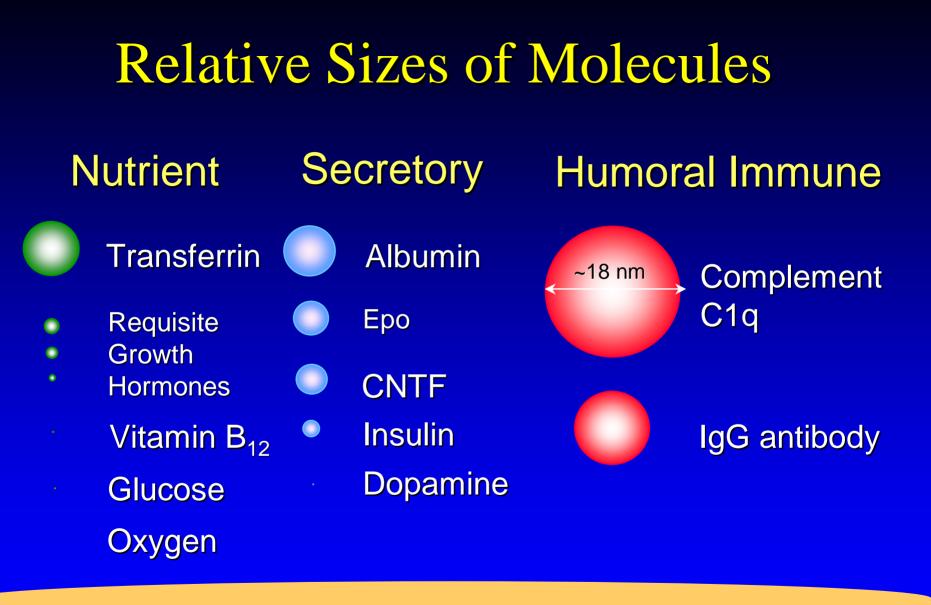
Concentration Gradient





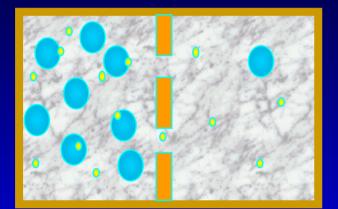




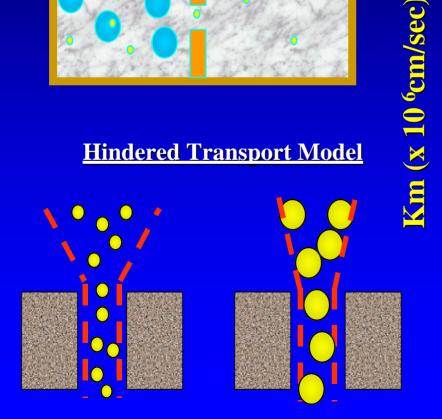


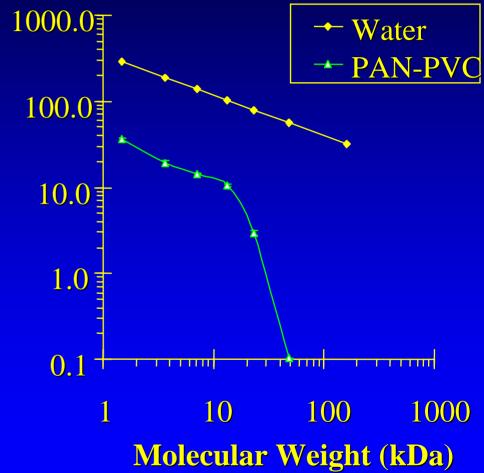
Lymphocyte Cell (7-14µm)

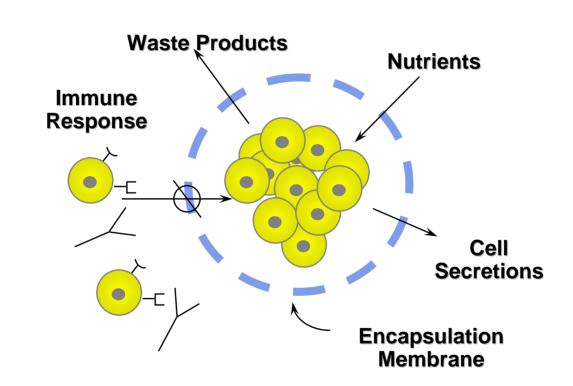
### **Diffusive Transport Characteristics**



#### **Hindered Transport Model**





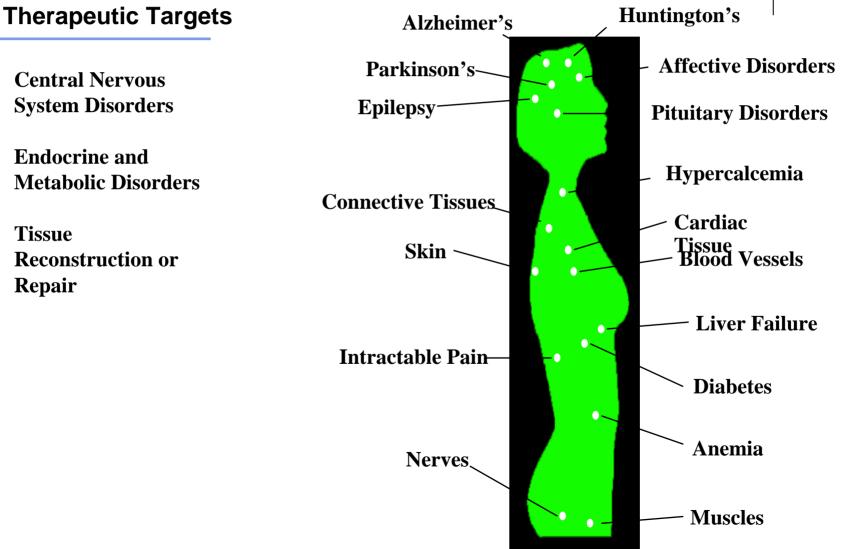






# **Cell Replacement Therapy**

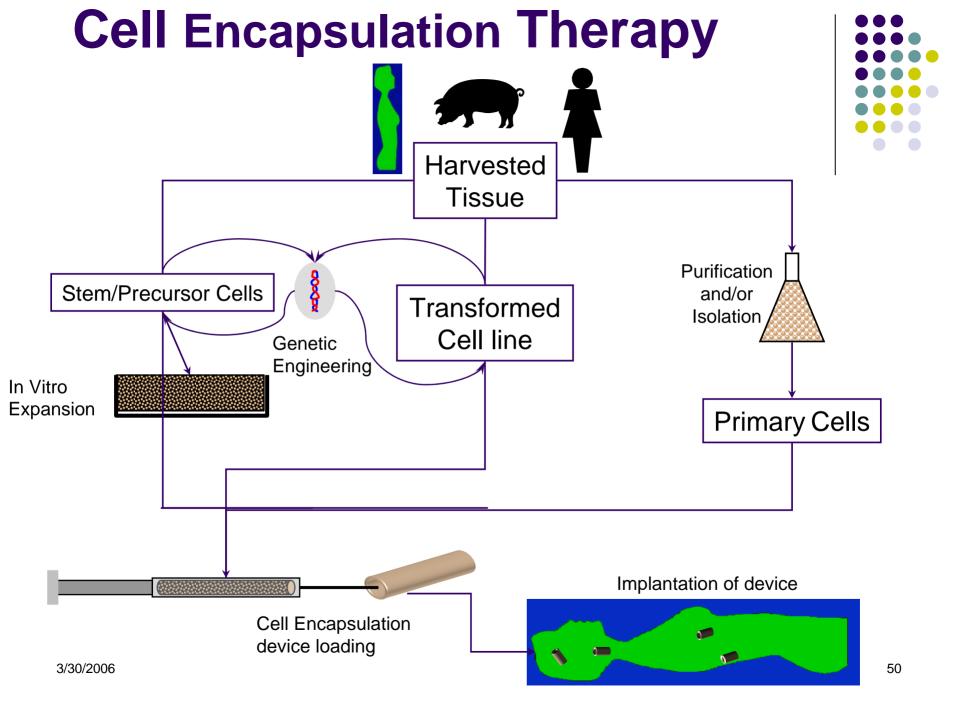


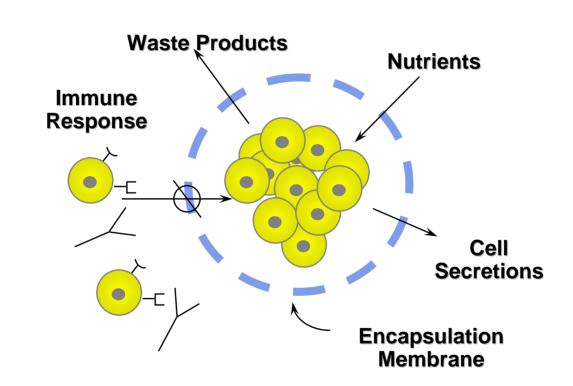


# **Problems with Conventional Cell Replacement Therapies**

- Immune rejection
- Shortage of donor cells
- Pathogenicity
- Tumor formation
- Non-reversible treatment



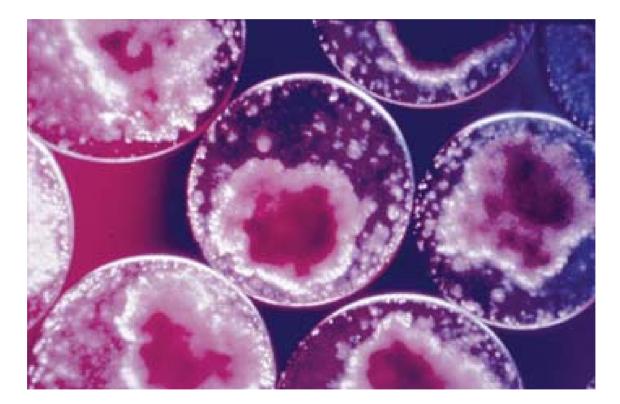






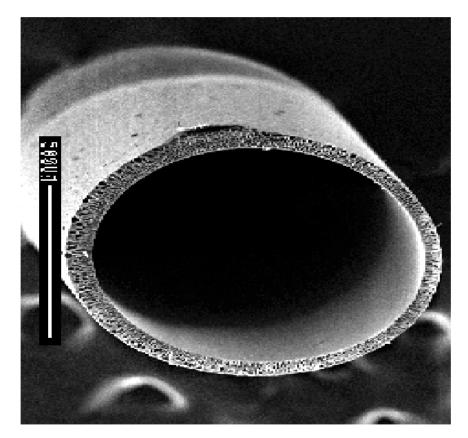


### **Cell Encapsulation**





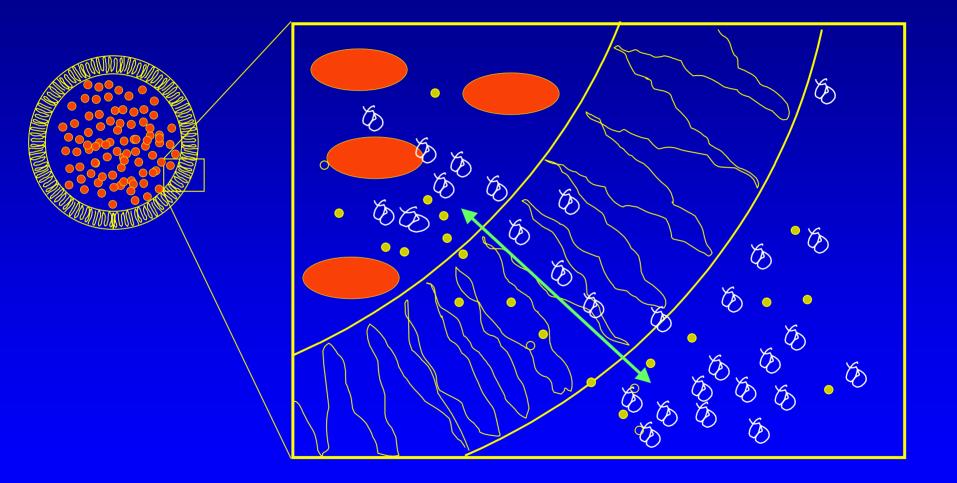
### **Cell Encapsulation**

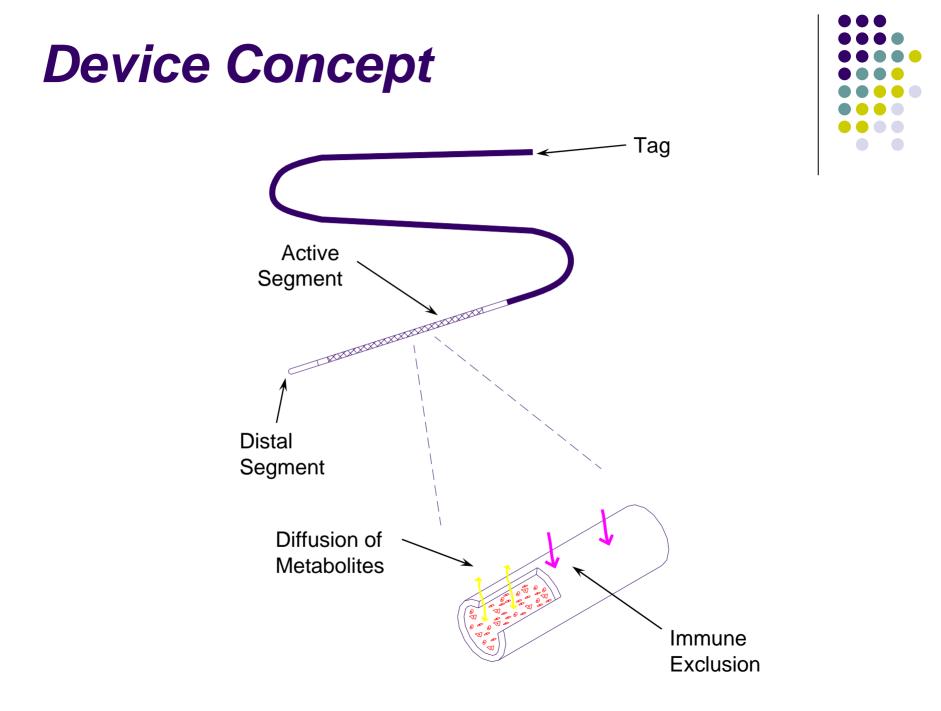




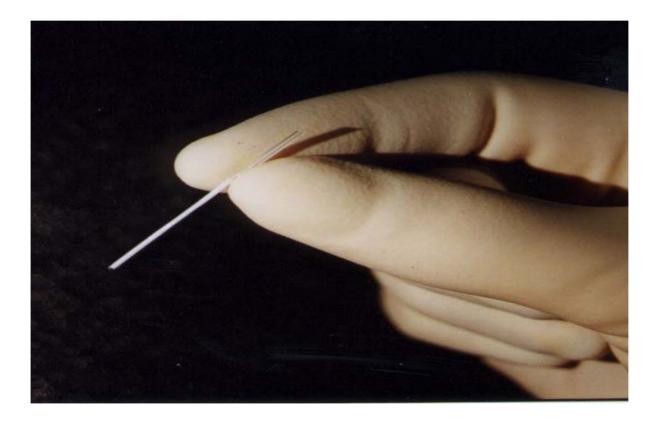


### **Separation Based on Size Exclusion**





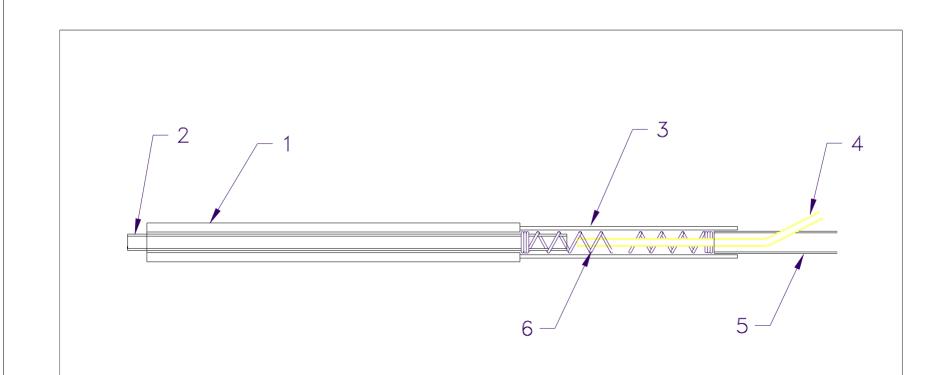




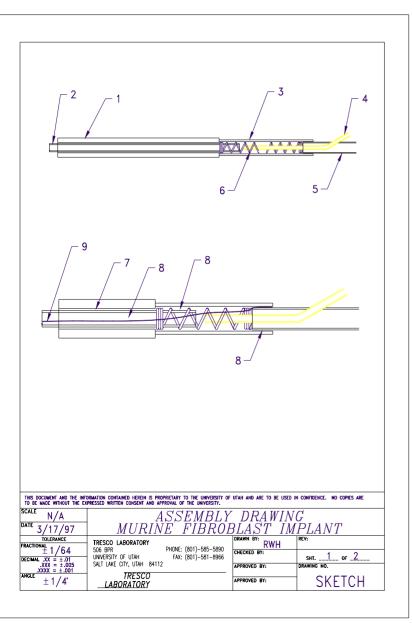


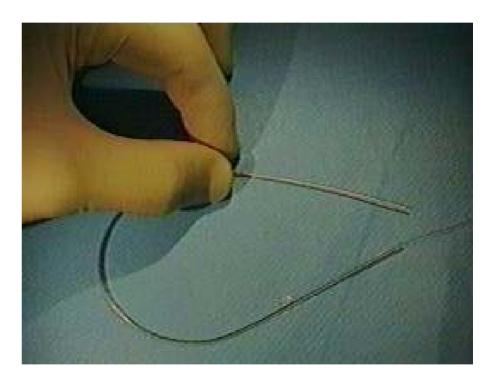


# **Cell Delivery Catheter**



### **Retrievable Cell Delivery**







## Lumbar Intrathecal Access

