

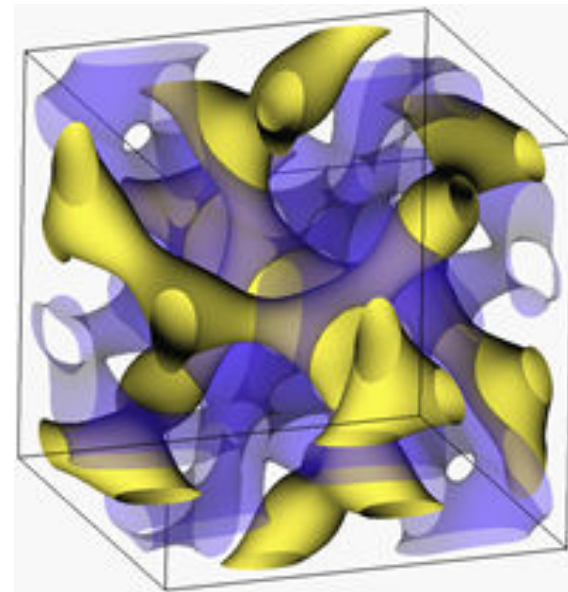
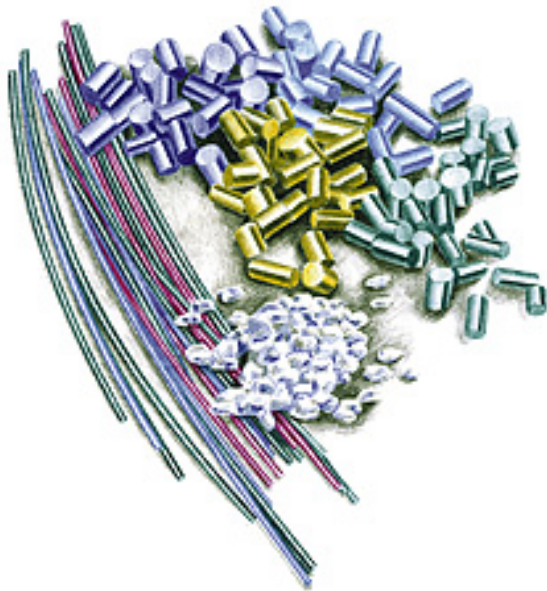


Introduction to Modern Biomaterials

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What is a biomaterial?

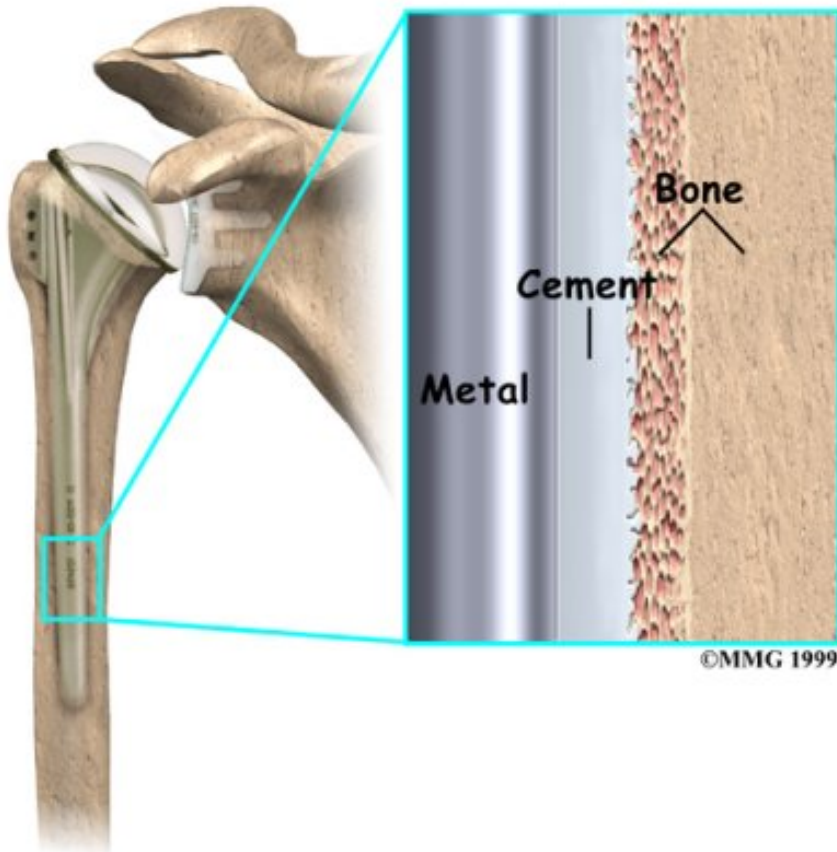




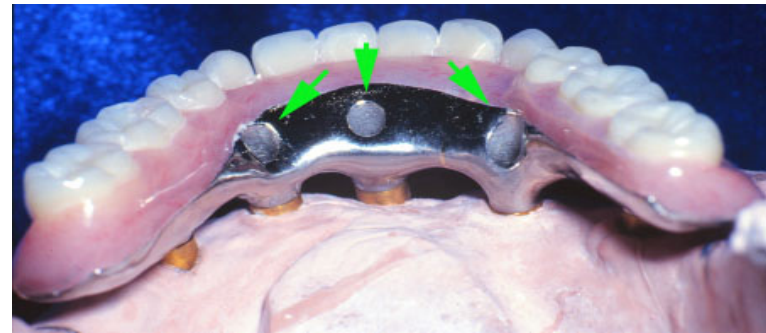
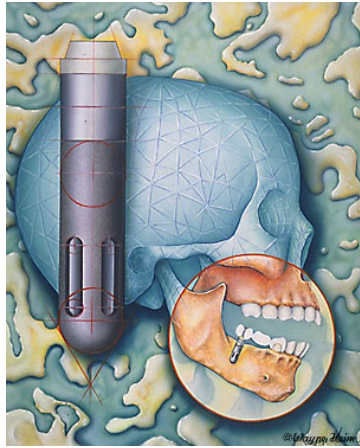
Definition: Biomaterial

Any material of natural or of synthetic origin that comes in contact with tissue, blood or biological fluids, and intended for use in prosthetic, diagnostic, therapeutic or storage applications without adversely affecting the living organism and its components.

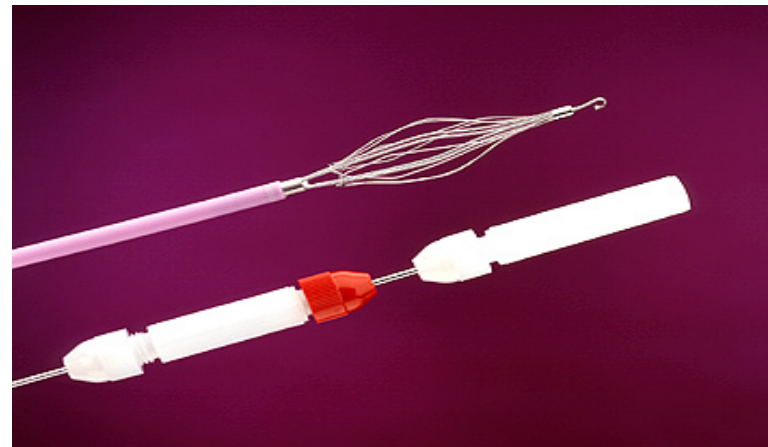
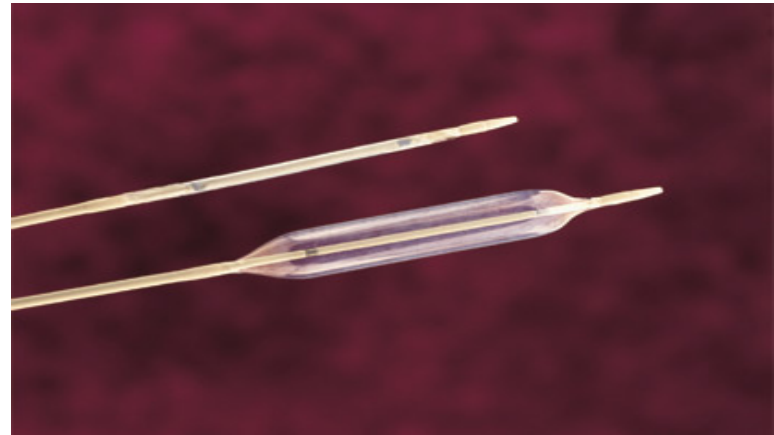
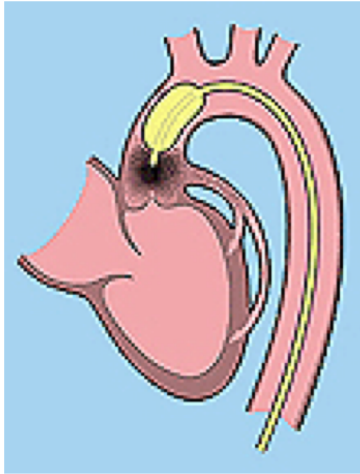
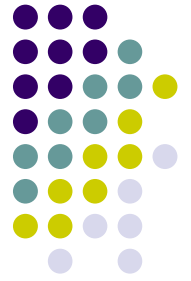
Therapeutic Devices in Orthopedics



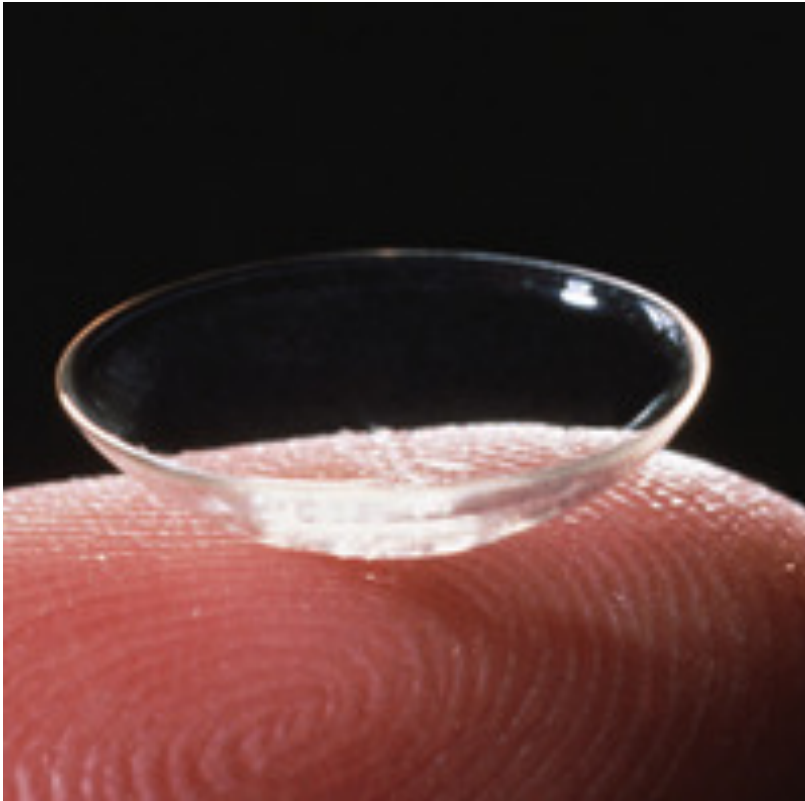
Applications in Dentistry



Catheters



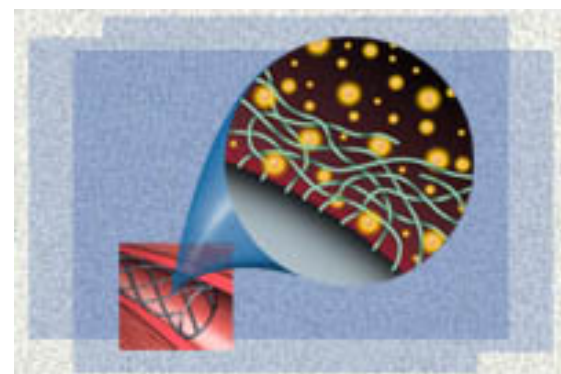
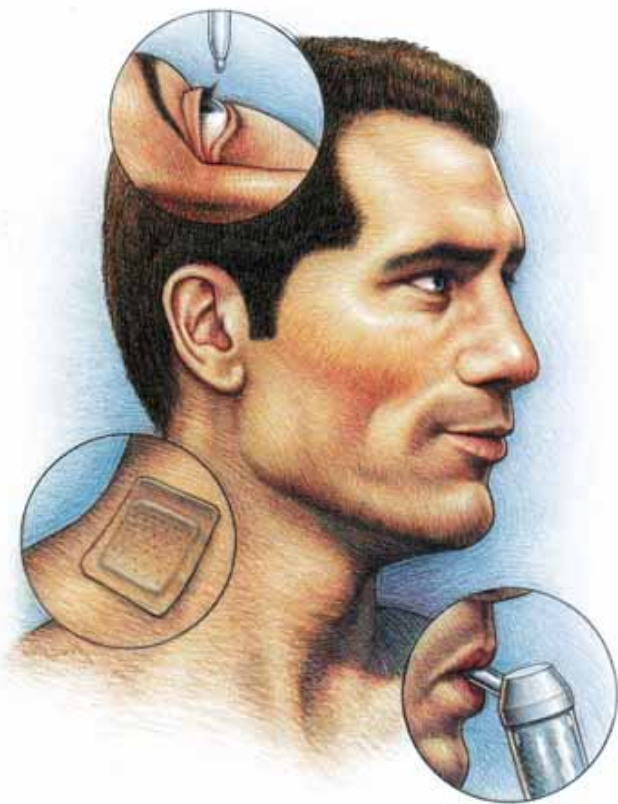
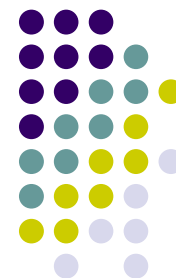
In Ophthalmology



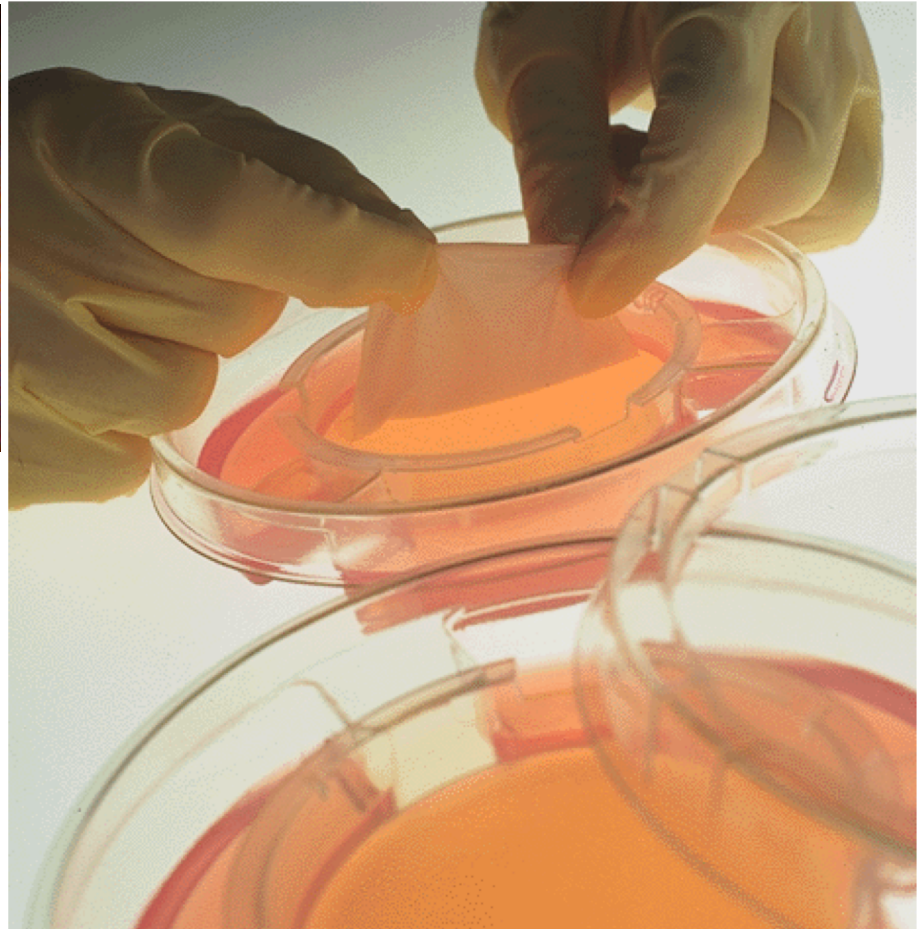
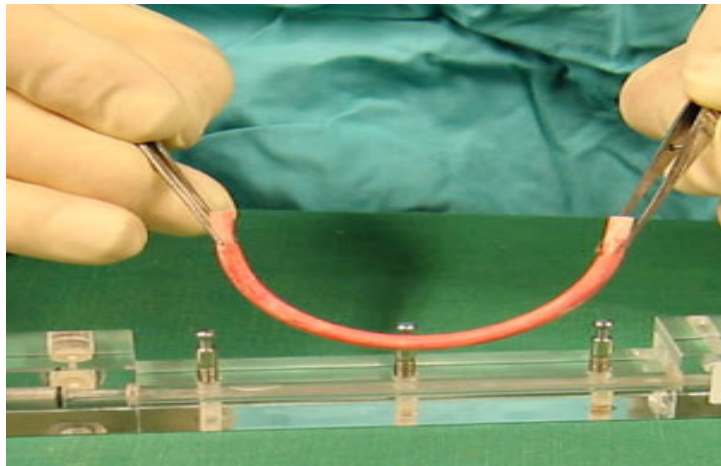
In Nephrology



In Drug Delivery



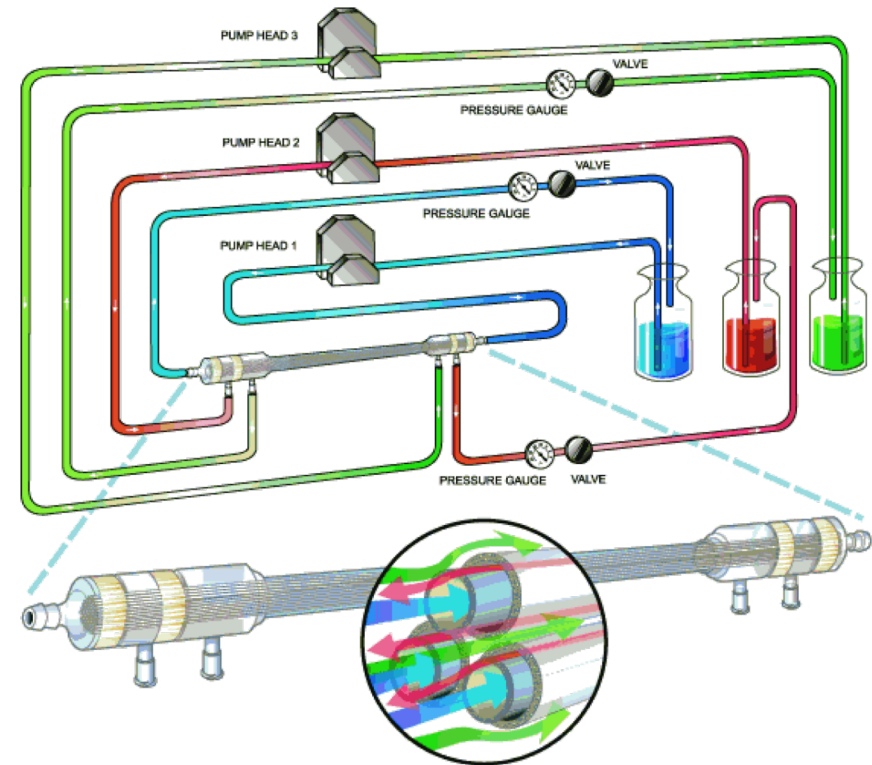
Future Applications- Tissue Replacement



Where are the biomaterials?



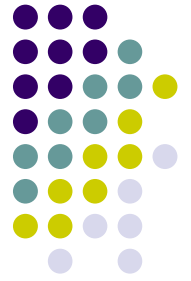
Would you have considered these items biomaterials?



Biomaterials Represent a Broad Range of Products



General Applications of Biomaterials



- Storage of fluids, tissues, and other biological products
- Diagnosis
- Monitoring
- Therapy



Definition: Biomaterial -FDA

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

The Food and Drug Administration



(www.fda.gov)

Regulates:

- Food-*Foodborne Illness, Nutrition, Dietary Supplements...*
- Drugs-*Prescription, Over-the-Counter, Generic....*
- Medical Devices -*Pacemakers, Contact Lenses, Hearing Aids...*
- Animal Feed and Drugs-*Livestock, Pets ...*
- Cosmetics-*Safety, Labeling.....*
- Radiation Emitting Products-*Cell Phones, Lasers, Microwaves.....*

CDRH- Center for Devices and Radiologic Health



(www.fda.gov/cdrh/)

- Responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.
- CDRH also regulates radiation emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Classification of Medical Devices



Based on the duration of the device use, invasiveness and risk to the user.

- **Class I devices:** crutches, bedpans, tongue depressors, adhesive bandages etc. –minimal invasiveness, does not contact the user internally.
- **Class II devices:** hearing aids, blood pumps, catheters, contact lens, electrodes etc. –higher degree of invasiveness and risk, but relatively short duration.
- **Class III devices:** cardiac pacemakers, intrauterine devices, intraocular lenses, heart valves, orthopedic implants, etc. -considerably more invasive and can pose immense risk to the user-implantables.

BIOMATERIAL OR MEDICAL DEVICE?



- It is important to know that the FDA neither approves materials nor maintains a list of approved materials
- Although FDA recognizes that many of the currently available biomaterials have vast utility in the fabrication of medical devices, the properties and safety of these materials must be carefully assessed with respect to the specific application in question and its degree of patient contact.
- An important principle in the safety assessment of medical devices is that a material that was found to be safe for one intended use in a device might not be safe in a device intended for a different use.
- Accurate characterization is an essential step in selecting a material for a medical device, but ultimately the final assessment must be performed on the finished product, under actual use conditions.

Biomaterials Research in Industry



- is dominated as much by the regulatory approval process and submission requirements as by the physical, mechanical, and chemical properties of the medical device.

Biological Response to Contact with Materials



A study of the molecular and cellular events that follow contact with biological fluids or tissues whether *in vitro* or *in vivo* from initial contact to the eventual culmination of the response.



Biocompatibility

A general term meaning that a biomaterial, device or construct can be brought into direct contact with living tissue without:

- causing a harmful tissue reaction (pain, swelling or necrosis) that could compromise function;
- causing a systemic toxic reaction; or
- having tumorigenic potential.

Manufacture of a Medical Device



- One of the first steps involves the selection of suitable biocompatible materials.
- This is an essential step because the types of tests required for evaluation of a device depend on the physical and chemical nature of its materials in addition to the nature of the device's exposure to the body.
- A specific material may appear suitable on the basis of its physical properties, cost, and availability, but might contain toxic chemical components.
- Therefore, it is advisable to screen the candidate materials at an early stage to eliminate those that are toxic, and select those that are sufficiently biocompatible or nontoxic for their intended use.
- Chemical constituents and potential extractables should be identified and quantitated for overall safety assessment of the device.



Biocompatibility Testing

- is performed to determine the potential toxicity resulting from contact of the device with the body.
- The device materials should not—either directly or through the release of their material constituents—produce adverse local or systemic effects, be carcinogenic, or produce adverse reproductive and developmental effects.
- Therefore, evaluation of any new device intended for human use requires data from systematic testing to ensure that the benefits provided by the final product will exceed any potential risks posed by device materials.

Biocompatibility testing include procedures designed to evaluate:



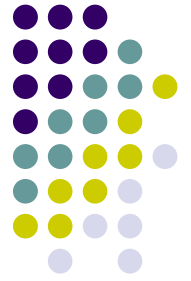
- cytotoxicity;
- acute, subchronic, and chronic toxicity;
- irritation to skin, eyes, and mucosal surfaces;
- sensitization;
- hemocompatibility;
- short-term implantation effects;
- genotoxicity;
- carcinogenicity; and effects on reproduction, including developmental effects.

Biomaterials Science is an Interdisciplinary Affair



Biomaterialists include physical scientists, engineers, dentists, biological scientists, surgeons, and veterinary practitioners in industry, government, clinical specialties, and academic settings.

Biomaterials Scientists



- study the interactions of natural and synthetic substances and implanted devices with living cells, their components, and complexes such as tissues and organs.

Biomaterials Engineers



- develop and characterize the materials used to measure, restore and improve physiologic function, and enhance survival and quality of life.

The Society For Biomaterials



A professional society which promotes advances in all phases of materials research and development by encouragement of cooperative educational programs, clinical applications, and professional standards in the biomaterials field. Internationally recognized leaders in the biomaterials field participate in the Society and sponsored events. (www.biomaterials.org)

Relevant Biomaterials Journals



Journal of Biomedical Materials Research
Biomaterials

Journal of Biomaterials Science. Polymer Edition

Journal of Biomaterials Applications

Journal of Materials Science: Materials in Medicine



Relevant Websites

- Biomaterials Network (www.biomat.net)
- Medical Device Information (www.devicelink.com)
- Medical Materials Engineering reference (www.engineeringreference.com)
- United States Patents and Trademarks Office (www.uspto.gov)
- General search-Google (www.google.com)
- MEDLINE-(www.ncbi.nih.gov/entrez/query.fcgi)

Where can I find information about medical devices?



- www.nlm.nih.gov/services/meddevice.html

Just a few of the sites are:

- - [Medical Device Link's Suppliers Page](http://www.devicelink.com/company/) at *http://www.devicelink.com/company/*
- - [MEDMarket Network's Internet Medical Products Guide](http://www.medmarket.com/index.cfm?id=product_guide) at *http://www.medmarket.com/index.cfm?id=product_guide*
- - [Yahoo! listing of Medical Equipment Companies](http://dir.yahoo.com/Business_and_Economy/Companies/Health/Medical_Equipment/) at *http://dir.yahoo.com/Business_and_Economy/Companies/Health/Medical_Equipment/*
- - [Yahoo! listing of Biomedical Device Manufacturers](http://dir.yahoo.com/Business_and_Economy/Companies/Biomedicine/Device_Manufacturers/) at *http://dir.yahoo.com/Business_and_Economy/Companies/Biomedicine/Device_Manufacturers/*