Introductory Medical Device Prototyping

Biomaterials Part 2 – Polymers

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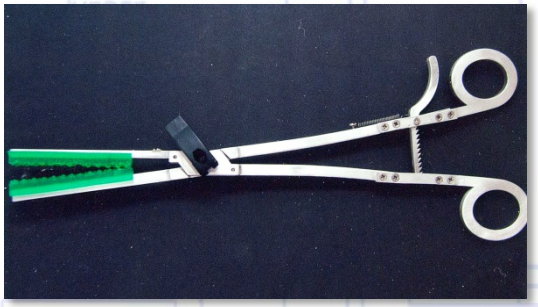
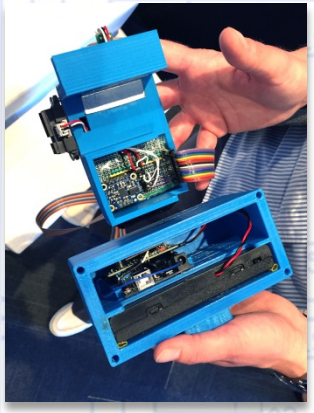
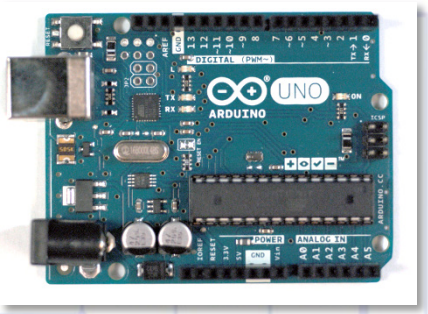
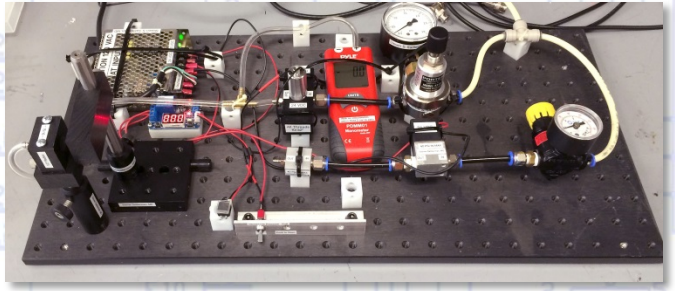
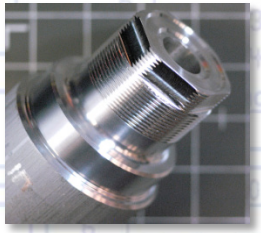










Definition of a Biomaterial

- "A *biomaterial* is a substance that has been engineered to take a form which, alone or as part of a complex system, is used to direct, by control of interactions with components of *living systems*, the course of any *therapeutic* or *diagnostic* procedure."*
- Materials are part of a *medical device* and subject to the ISO 10993 requirements for medical devices, including *biocompatibility*.
- The FDA regulates medical devices in the United States, and divides devices into *Classes.*

*Elsevier Biomaterials Journal

FDA Medical Device Classes

Class I devices	Tongue depressors
	Bandages
	Gloves
	Bedpans
	Simple surgical devices
Class II devices	Wheelchairs
	X-ray machines
	MRI machines
	Surgical needles
	Catheters
	Diagnostic equipment
Class III devices	Heart valves
	Stents
	Implanted pacemakers
	Silicone implants
	Hip and bone implants

McKeen, L.W. in *Handbook of Polymer Applications in Medicine and Medical Devices*, 1st ed., Elsevier, William Andrew (2014).

Some Common Concerns…

- Physical, mechanical, thermal and electrical properties.
- Machinability and moldability.
- Joining and welding.
- Porosity and pore morphology.
- Permeability.
- Degradation and degradation products.
- Biocompatibility (in vivo and in vitro).
- Sterilization

Medical Device Polymers

- **Polyolefins**
  - Polyethylene (PE)
  - Polypropylene (PP)
  - Cyclic Olefin Copolymers (COCs)
  - Polyvinyl Chloride (PVC)
- **Polystyrene/styrenics**
  - Polystyrene
  - Poly(acrylonitrile-co-butadiene-co-styrene) (ABS)
  - Polyacrylate (Acrylic, PMMA)
  - Polycarbonate (PC)
  - Polyurethanes
  - Polyformaldehyde (POM) (Delrin or Acetal)
- **Polyamides**
  - Polyamide (Nylon 6)
  - Poly(hexamethylene adipamide) (Nylon 66)
  - Polyether Block Amide (PEBA)
- **Polyesters**
  - Poly(butylene terephthalate) (PBT)
  - Poly(ethylene terephthalate) (PET, PETG)
- **High-Temp Thermoplastics**
  - Polysulfone (PSF)
  - Polyimide (PI) (Kapton)
  - Poly(ether ether-ketone) (PEEK)
- **Fluoropolymers**
  - Poly(tetrafluoroethylene) (PTFE) (Teflon), PVDF, FEP, ePTFE
- **Elastomers**
  - Silicones
  - Thermoplastic elastomers (TPE): TPA (polyamide TPE), TPC (copolyester TPA), TPO (olefinic TPE), TPS (styrenic TPE), TPU (urethane TPE), and TPV (vulcanized TPE).
- **Poly-p-xylylene (Parylene)**
- **Biopolymers**
  - Polylactic Acid (PLA)
  - Polyglycolic Acid (PGA)
- **Others** – PANI, PPy, PVAC, PEG

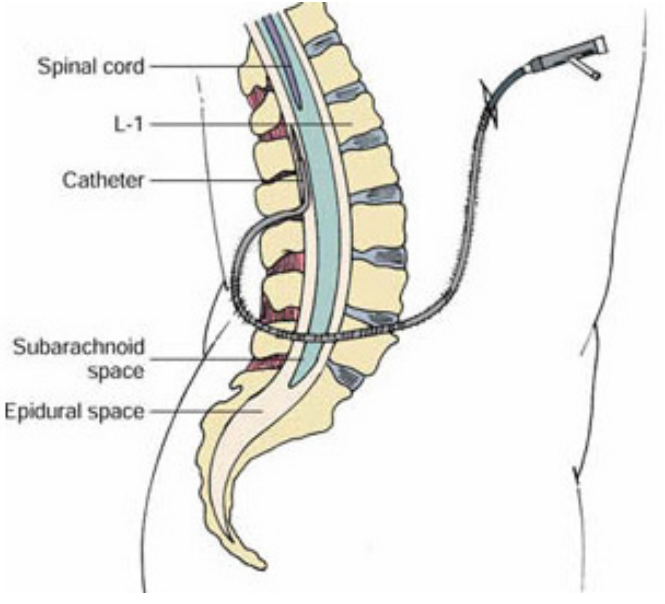
FDA Medical Device Categories

FDA Category	Common Devices	Synthetic Polymer Material Used
Anesthesiology	• Epidural catheters	• Polyethylene • Polytetrafluoroethylene • Polyamide
Cardiovascular	• Pacemaker • Implantable cardioverter/defibrillator • Left Ventricular Assist Device • Mechanical heart valves • Artificial blood vessels • Catheters	• Polypropylene • Polyethylene • Polytetrafluoroethylene • Polyamide • Polyethyleneterephthalate • Polydimethylsiloxane • Polyhydroxyalkanoates
Dental	• Dentures • Dental Implants	• Polymethylmethacrylate
Ear, nose, and throat	• Cochlear implants • Stapes implants • Nasal implants for nose reconstruction	• Polydimethylsiloxane • Liquid crystal polymer • Silicone • Parylene • Polyethylene

Teo, AJT. Polymeric Biomaterials for Medical Implants and Devices. ACS Biomaterials Sci. Eng. 2016, 2, 454−472

Anesthesiology…

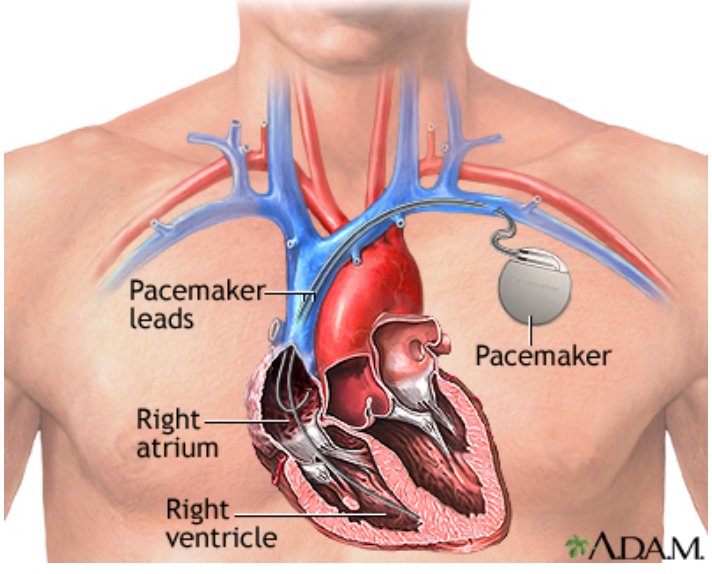
- Epidural catheters



(Left) Image Courtesy of Rush University Pain Centers.
(Right) Image courtesy of Texas Scientific Instruments.

Cardiovascular…

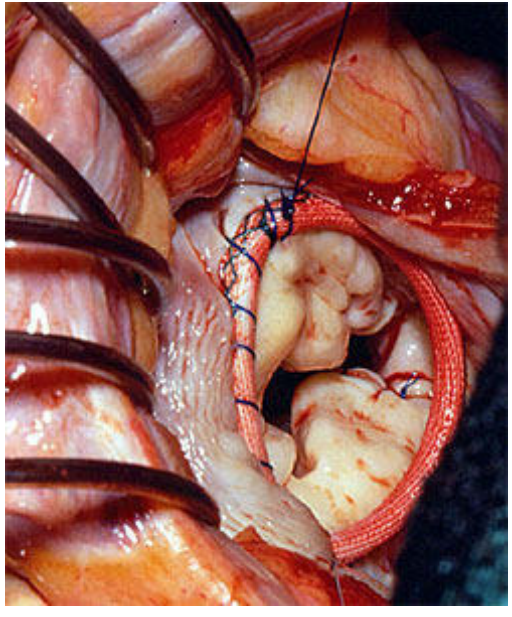
- Pacemaker

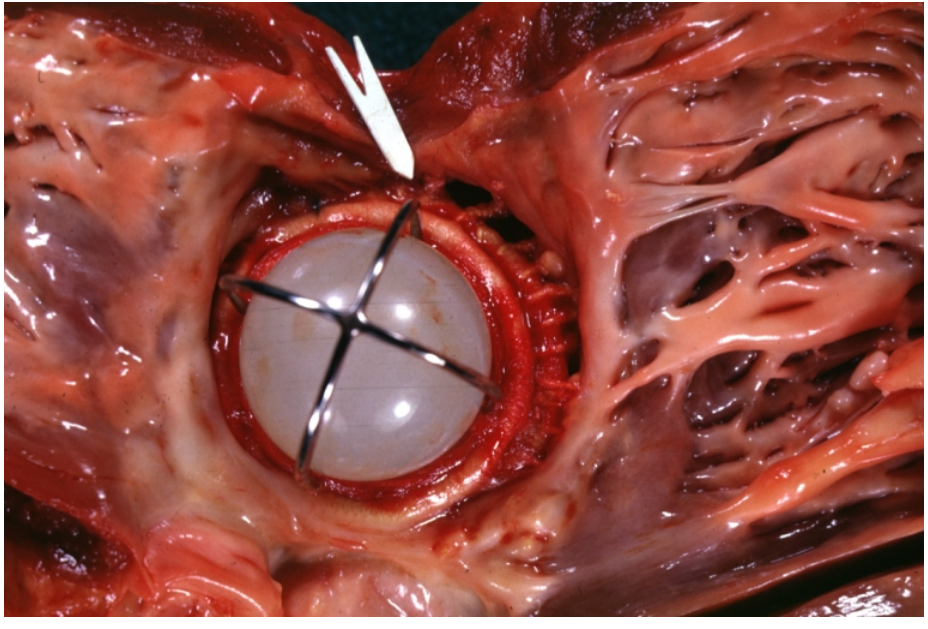


(Left) Image Courtesy of NIH Medline Plus.
(Right) Image courtesy of Medtronic.

Cardiovascular…

- Mitral valve annuloplasty vs. prosthesis for stenosis.

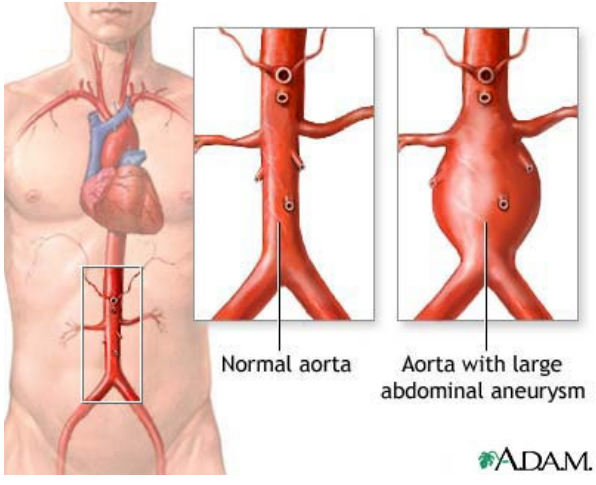


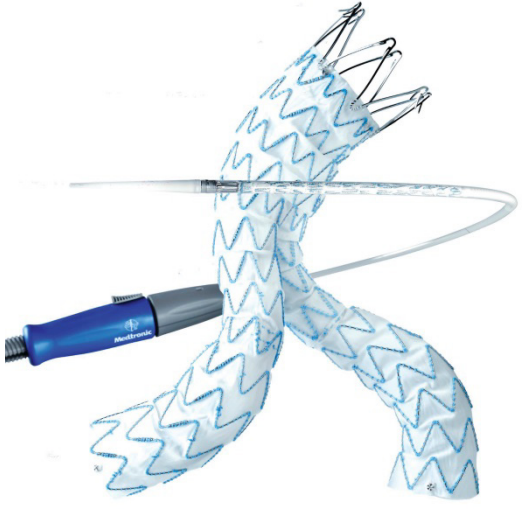


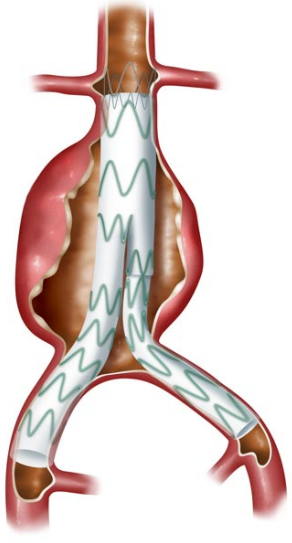
(Left) Image Courtesy of Adam Pick, Heart Valve Surgery.com.
(Right) Image courtesy of Prof. Peter Anderson.

Cardiovascular…

- Abdominal aortic aneurysm graft.







(Left) Image Courtesy of NIH Medline Plus
(Center & Right) Images courtesy of Medtronic

Cardiovascular…

- Catheters
  - Applications for Arkema Pebax® MED include catheters (angioplasty, stent-delivery, diagnostic, ablation…), balloons, tubes (peristaltic pumps, connecting tubes, colonoscopes, hearing aids…) and small-dimension molded parts.

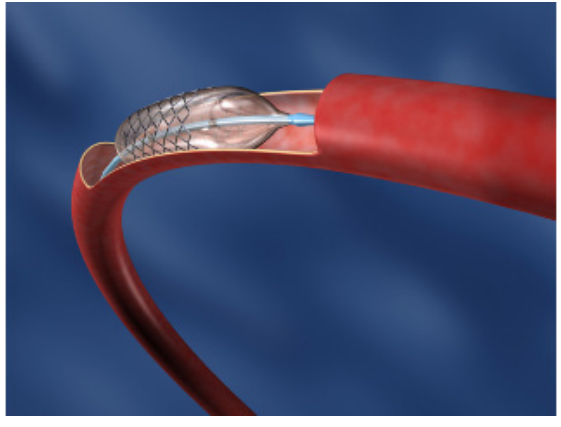


Image courtesy of Arkema

- Polyether Block Amide (PEBA)…
  - Copolymer of polyamide and polyethylene

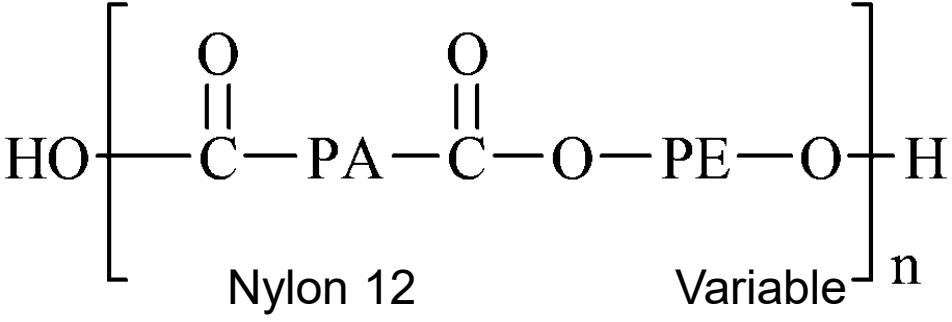
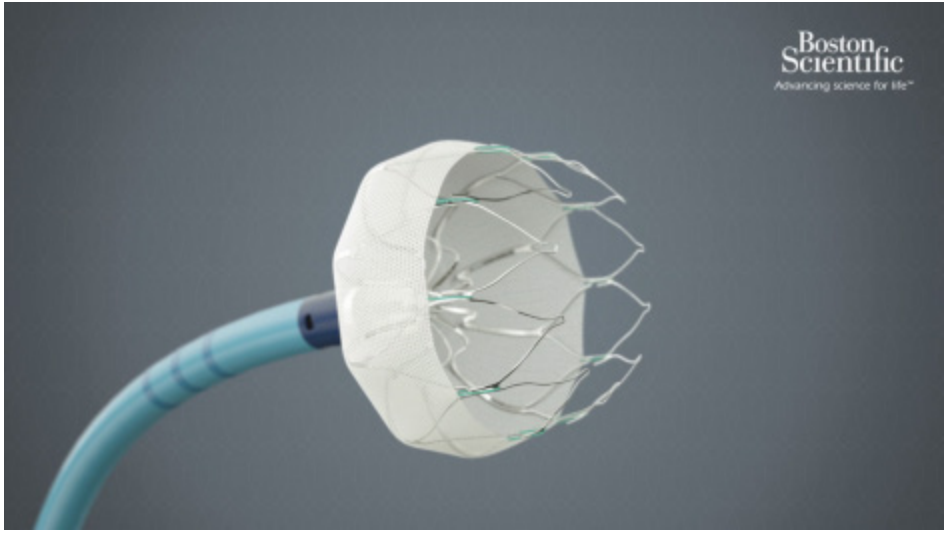
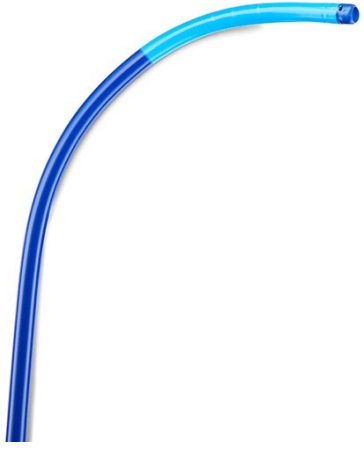


Image courtesy of RSC Advances

Cardiovascular…



The WATCHMAN® LAAC Device is a catheter-delivered heart implant designed to close the left atrial appendage (LAA). PET knit fabric mesh.

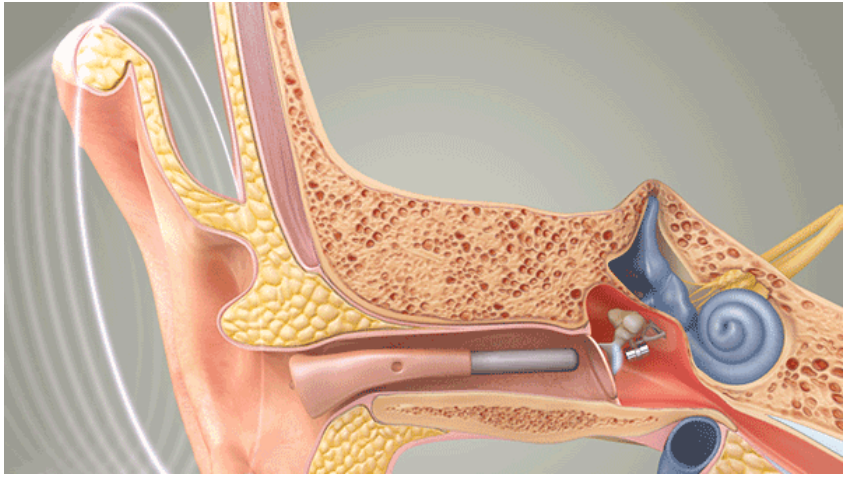


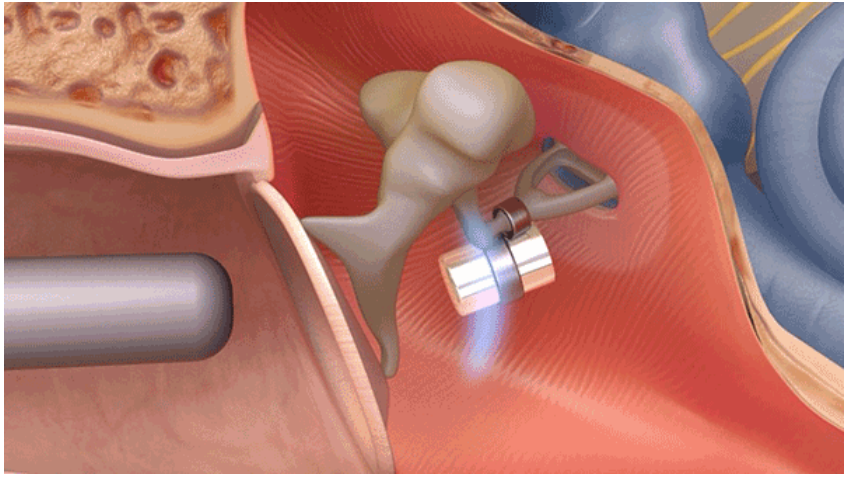
Access sheath is made from Polytetrafluoroethylene (PTFE) (Teflon)

Images courtesy Boston Scientific.

Ear, Nose and Throat…

- Ototronix Maxum implant in situ on ossicular chain.





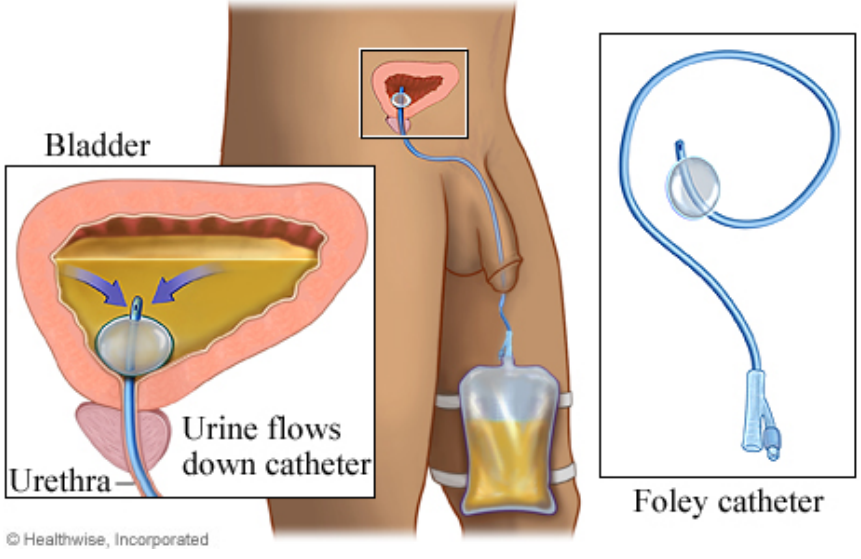
Images Courtesy of Ototronix, D. L. Beck and M. Glasscock

Gastroenterology and urology	• Penile implants • Neurostimulator in sacral nerve stimulation • Foley catheter • Artificial urinary sphincter implant • Hernia or vaginal mesh	• Polydimethylsiloxane • Polyethylene • Polytetrafluoroethylene • Polyamide • Polyhydroxyalkanoates • Silicone • Polypropylene
General and plastic surgery	• Synthetic blood vessels • Breast implants • Cheek, jaw and chin implants • Lip implant • Titanium surgical implants • Hip implant	• Polypropylene • Polyethyleneterephthalate • Polytetrafluoroethylene • Silicone • Polydimethylsiloxane
Hematology and pathology	• Central venous access device • Peripherally Inserted Central Catheter	• Polyethylene • Polytetrafluoroethylene • Polyamide

Teo, AJT. Polymeric Biomaterials for Medical Implants and Devices. ACS Biomaterials Sci. Eng. 2016, 2, 454−472

Urology…

- Indwelling Foley catheter.



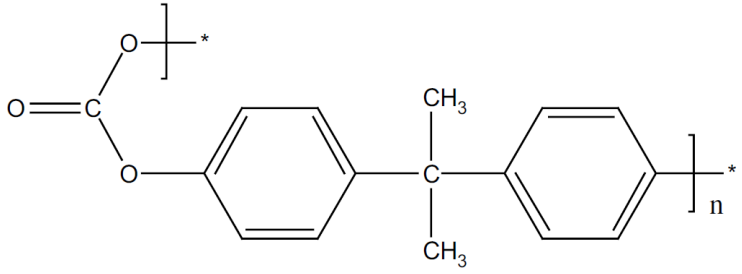
(Left) Image Courtesy of WebMD
(Right) Images courtesy of Poiesis Medical.

General and Plastic Surgery…

- Scalpel
  - LNP Lubricomp® is a 30% carbon fiber reinforced polycarbonate resin from SABIC for replacing metal in scalpels and other components.

Image courtesy of SABIC

- Poly(bisphenol A carbonate) (Polycarbonate)
  - Amorphous highly transparent thermoplastic with properties of high impact strength, low moisture adsorption, good heat resistance, good rigidity and electrical properties, and high creep.
  - PC is a good low frequency and high voltage insulator, making it suitable for electrical and electronic components.
  - PCs are graded by addition of various amounts of glass fibers. These increases tensile strength, stiffness, compressive strength, and lowers the thermal expansion coefficient.



General and Plastic Surgery…

- Craniofacial implants made from PEEK polymers with EOS' laser sintering process.
  - Implants with patient-specific size and shape can be manufactured, based on three-dimensional imaging techniques like computed tomography (CT) and magnetic resonance tomography (MRT).

Image Courtesy of SME.org

- Poly(ether ether-ketone) (PEEK)
  - Semi-crystalline thermoplastic with excellent chemical resistance, very low moisture absorption, and is unaffected by continuous hot steam or water
  - Graded based on its filler. Unfilled PEEK is light brown or black and is FDA approved for contact with food. Glass filled (30%) PEEK reduces expansion and increases the flexural modulus.

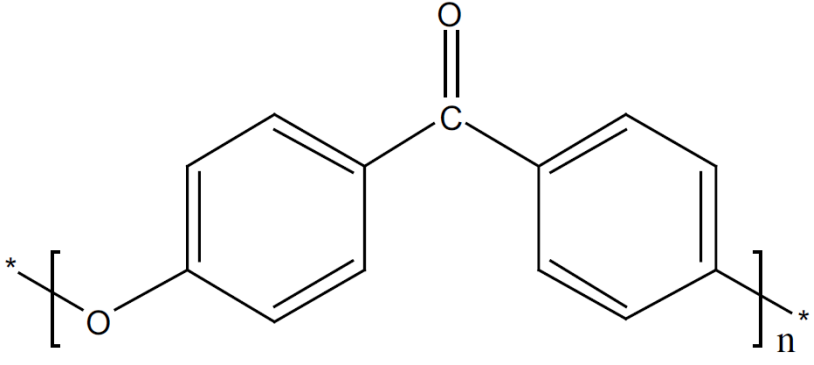


Image courtesy of Invibio.

General and Plastic Surgery…

- Parker's disposable silicone laryngeal mask device.
  - 100% medical-grade silicone device enables easy insertion and is designed to produce an effective seal.

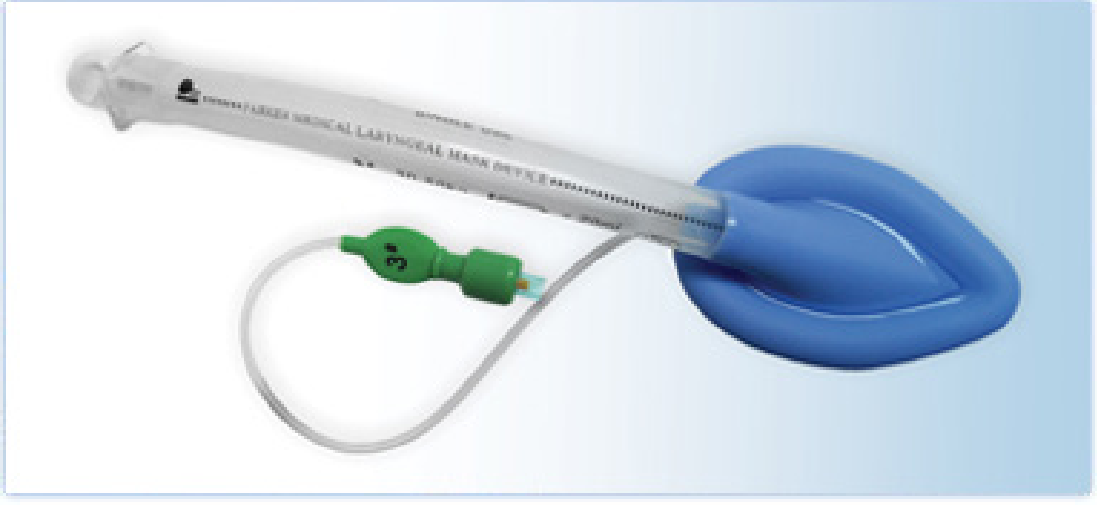
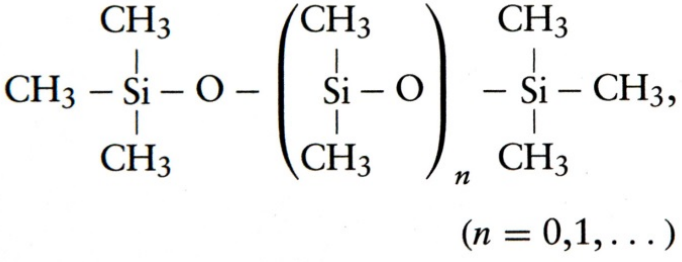
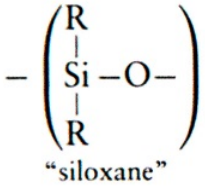


Image courtesy of Parker.

- Poly(dimethyl siloxane) and Trimethylsilyloxy end-blocked polydimethylsiloxanes.
  - Silicones have excellent biocompatibility and biodurability.
  - Flexible with lower tensile strength or tear resistance compared to polyurethanes.
  - Degrade in strongly acidic or basic environments.
  - Like all hydrophobic materials they become quickly coated with proteins when placed in tissue contact.
  - Silicone gels are used for breast, testicular and other soft tissue implants.
  - Silicone adhesives are used in bonding and soft skin adhesives to the skin.

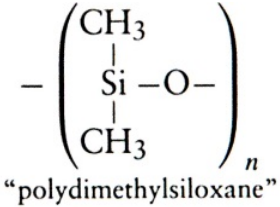


$(n = 0,1,\ldots)$



"siloxane"

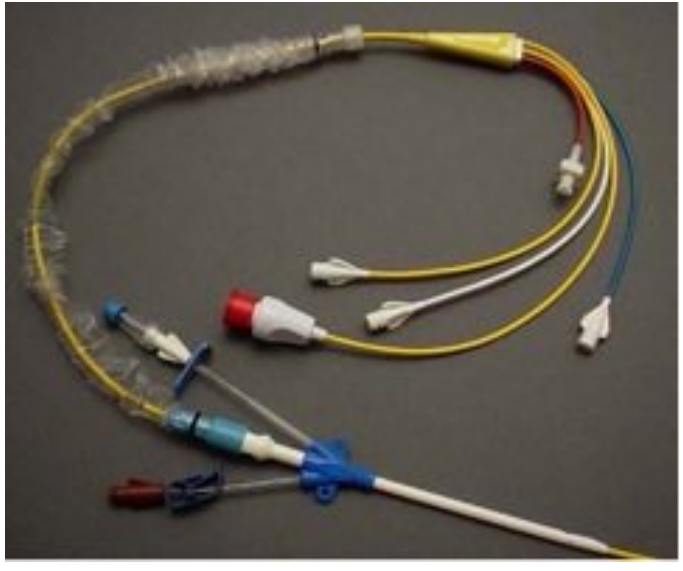
and if R is CH_3,



"polydimethylsiloxane"

Hematology…

- Pulmonary artery catheter



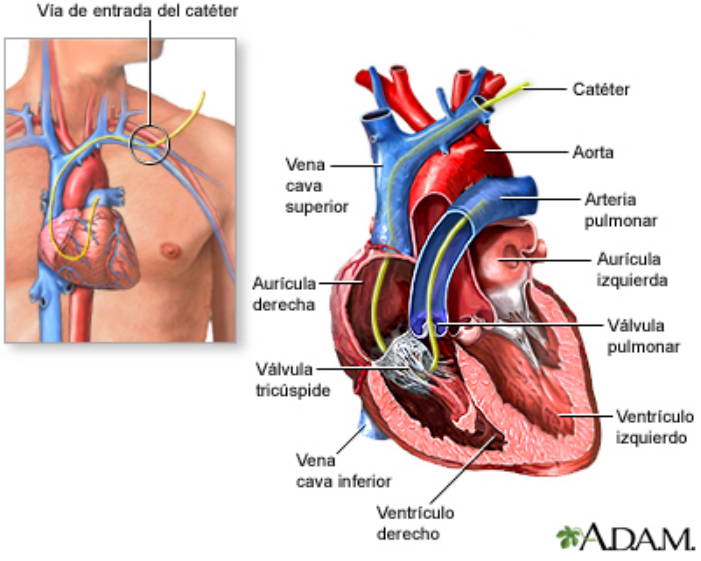


Image courtesy of Life in the Fast lane

Obstetric and gynecologic	• Intrauterine Device (IUD) • Intravaginal Rings • Etonogestrel-releasing Contraceptive Implant • Urogynecologic Surgical Mesh Implants • Fetal micro-pacemaker	• Silicone • Polyurethane • Polypropylene
Ophthalmic	• Dexamethasone Intravitreal Implant • Retinal Prothesis • Artificial Intraocular lens • Glaucoma valve • Fluocinolone Opthalmic Implant • Orbital Implant • Catheters	• Polymethylmetacrylate • Polyethylene • Polytetrafluoroethylene • Polyamide
Orthopedic	• Orthopedic implants	• Polyethylene • Polyether Ether Ketone • Polyhydroxyalkanoates

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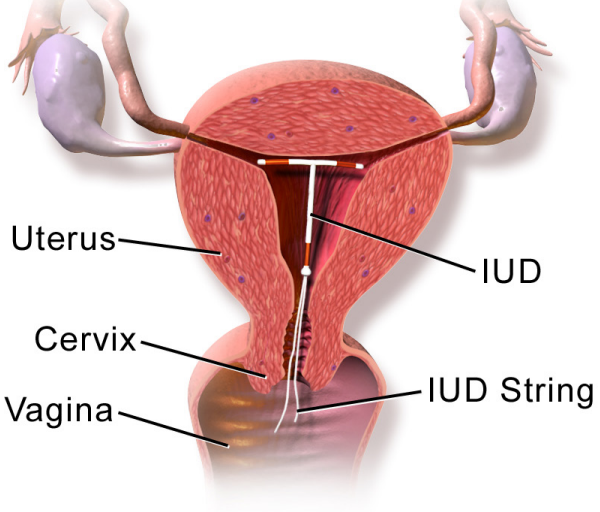
Obstetrics and Gynecology…

- Intrauterine device for contraception.



Intraunterine Device (IUD)

(Left) From Wikimedia Commons.
(Right) Bioceptive IUD inserter.

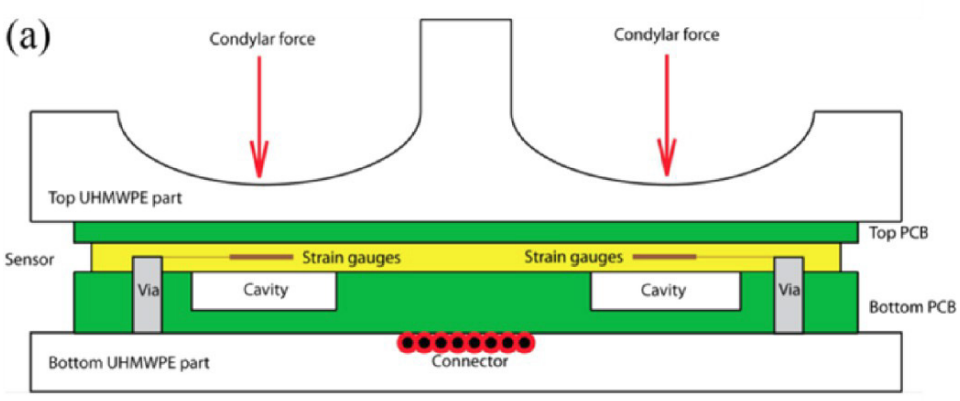
Orthopedic…

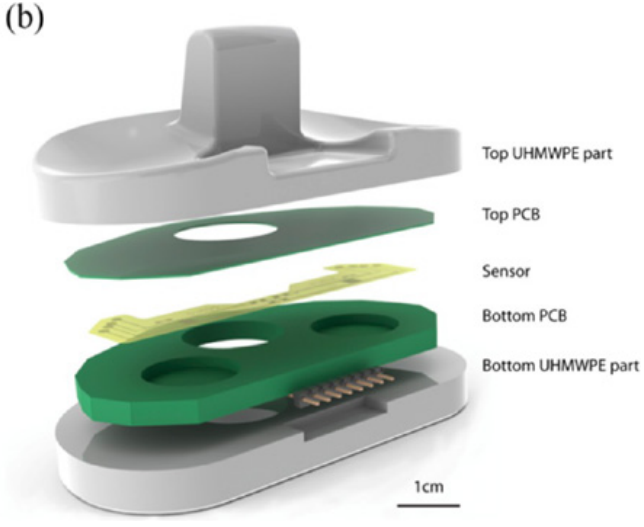
- The Taylor Spatial Frame is an external fixator used to treat complex fractures and bone deformities

From Wikimedia Commons

Orthopedic…

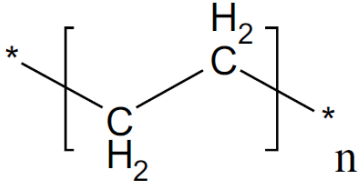
- Knee implant study device with stain gages made from UHMWPE.





Forchelet, D.; Simoncini, M.; Arami, A.; Bertsch, A.; Meurville, E.; Aminian, K.; Ryser, P.; Renaud, P. Enclosed Electronic System for Force Measurements in Knee Implants. Sensors 2014, 14 (8), 15009−15021.

- Polyethylene (PE)
  - Semi-crystalline material with good resistance to organic solvents, degreasing agents, and electrolytes.
  - It is resistance to wear, fatigue, and staining; and has low moisture absorption. PE is nontoxic and floats on water.
  - Graded as low density (LDPE), high density (HDPE) and ultra-high molecular weight (UHMWPE). The latter are self-lubricating, shatter resistance, machinable, and may be sterilized in steam



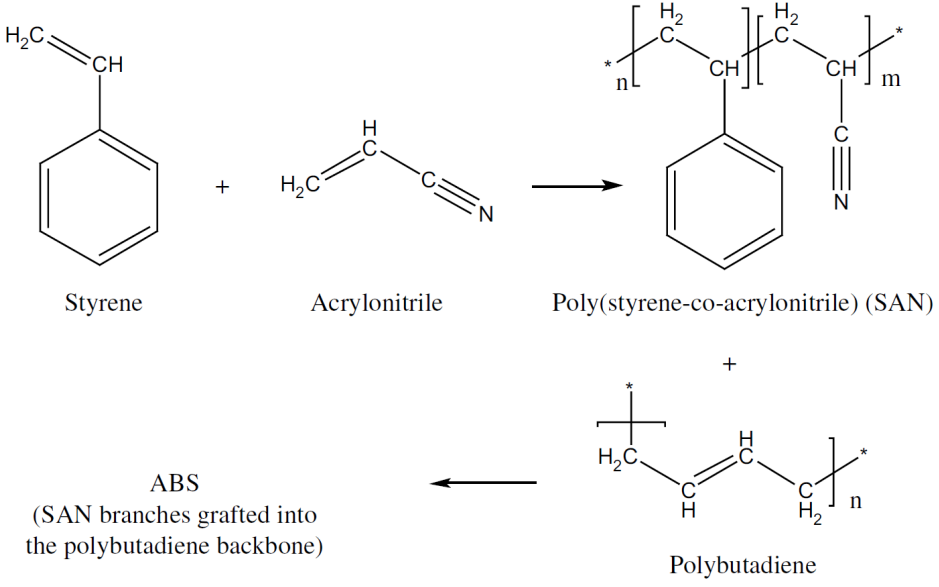
Boedeker Plastics Inc., 2004

Orthopedic…

- Intraoperative wrench tool
  - ABS-M30i works with 3D FDM Technology to build functional prototypes, tooling and production parts that can be gamma or EtO sterilized.

Image courtesy of Stratasys

- Poly(acrylonitrile-co-butadiene-co-styrene) (ABS)
  - ABD is strong & light weight.



Summary

- FDA Medical Device Categories
  - Anesthesiology
  - Cardiovascular
  - Dental
  - Ear, Nose & Throat
  - Gastroenterology & Urology
  - General and Plastic Surgery
  - Hematology & pathology
  - Obstetrics and Gynecology
  - Ophthalmology
  - Orthopedics