Medical Device Polymers

- **Polyolefins**
  - Polyethylene (PE)
  - Polypropylene (PP)
  - Polylefins (PA)
  - Polyethylene terephthalate (PET)

- **Cyclic Olefin Copolymers (COCs)**

- **Fluoropolymers**
  - Polytetrafluoroethylene (PTFE)

- **Elastomeric Synthetic Polymers**
  - Polyethylene (PE)
  - Polypropylene (PP)
  - Polyurethane (PU)

- **High-Temperature Thermoplastics**
  - Polyetheretherketone (PEEK)

- **Biopolymers**
  - Polylactic Acid (PLA)

- **Others**
  - PANI, PPy, PVAC, PEG

FDA Medical Device Categories

<table>
<thead>
<tr>
<th>FDA Category</th>
<th>Common Devices</th>
<th>Synthetic Polymer Material Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arterial</td>
<td>Cultural collars</td>
<td>Polyethylene; Polypropylene; Polyurethane</td>
</tr>
<tr>
<td>Central Nervous System</td>
<td>Implantable</td>
<td>Polyethylene; Polypropylene; Polyurethane</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>Arthroplasty</td>
<td>Polyethylene; Polypropylene; Polyurethane</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Left Ventricular Assist Device</td>
<td>Polyethylene; Polypropylene; Polyurethane</td>
</tr>
<tr>
<td>Dental</td>
<td>Dentures</td>
<td>Polyethylene; Polypropylene; Polyurethane</td>
</tr>
<tr>
<td>Endovascular</td>
<td>Balloon catheter</td>
<td>Polyethylene; Polypropylene</td>
</tr>
<tr>
<td>Bone, joint, and tendon</td>
<td>Osteointegrated implants</td>
<td>Polyethylene; Polypropylene</td>
</tr>
<tr>
<td>Soft Tissue</td>
<td>Tissue expander</td>
<td>Polyethylene; Polypropylene</td>
</tr>
</tbody>
</table>

Teo, AJT. Polymeric Biomaterials for Medical Implants and Devices. ACS Biomaterials Sci. Eng. 2016, 2, 684-693
Anesthesiology…

- Epidural catheters

Cardiovascular…

- Pacemaker

Cardiovascular…

- Mitral valve annuloplasty vs. prosthesis for stenosis.
Abdominal aortic aneurysm graft.

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.

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

\[
\begin{align*}
\text{HO} & \quad \text{PA} & \quad \text{O} & \quad \text{C} & \quad \text{O} & \quad \text{PE} & \quad \text{O} & \quad \text{H} \\
\text{Nylon 12} & \quad \text{Variable} & \quad n
\end{align*}
\]
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).

**Cardiovascular…**

**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.

- **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.
**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).

- **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.

**Parker's disposable silicone laryngeal mask device.**
- 100% medical-grade silicone device enables easy insertion and is designed to produce an effective seal.
Polymethylsiloxane and Trimethylsiloxy end-blocked polydimethylsiloxanes. 
- Silicones have excellent biocompatibility and biodurability.
- Flexible with lower tensile strength or tear resistance compared to polyurethanes.
- Degradate 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.

\[
\text{CH}_3 \quad \text{Si} \quad \text{O} \quad \text{Si} \quad \text{CH}_3 \quad \text{CH}_3 \quad \text{Si} \quad \text{O} \quad \text{Si} \quad \text{CH}_3 \quad \text{CH}_3 \\
\text{(n = 0, 1, ...)}
\]

Silicones have excellent biocompatibility and biodurability. Flexible with lower tensile strength or tear resistance compared to polyurethanes. Degradate 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.

---

**Ear, Nose and Throat…**

- **Ototronix Maxum implant in situ on ossicular chain.**

---

**Gastroenterology and surgery:**
- Penile implants
- Neurostimulation or sacral nerve stimulation
- F odbycaser
- Artificial urinary sphincter implants
- Hernia or vaginal mesh

**General and plastic surgery:**
- Synthetic blood vessels
- Breast implants
- Obese, cosmetic skin implants
- Lip implants
- Trauma surgical implants
- Hip implant

**Hematology and pathology:**
- Central venous access device
- Port/AV fistula/Arm/Arm Central

---

Teo, AJT. Polymeric Biomaterials for Medical Implants and Devices. ACS Biomaterials Sci. Eng. 2016, 2, 464-472
Urology...

- Indwelling Foley catheter.

Hematology...

- Pulmonary artery catheter

---

**Oncologic and gynecologic**
- Intravenous Devices (IV)
- Intravaginal Rings
- Cone Conization (LLETZ)
- Urology and Gynecology Devices
- Urology Surgical Flash Implants
- First Responder Kits

**Orthopedic**
- Ceramic implants
- Polyethylene
- Polyurethane
- Polyethylene terephthalate
- Polypropylene

---

Teo, AJT. Polymeric Biomaterials for Medical Implants and Devices. ACS Biomater Soc. Eng. 2016, 2, 684–693
**Obstetrics and Gynecology**

- Intrauterine device for contraception.

![Intrauterine Device](Left: Wikimedia Commons. Right: Bioceptive IUD inserter.)

---

**Orthopedic**

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

![Taylor Spatial Frame](From Wikimedia Commons.)

---

**Orthopedic**

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

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.

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

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